By electronic submission:

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Washington, D.C.

2020 SPECIAL 301 SUBMISSION

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February 6, 2020

Jacob Ewerdt  
Director for Innovation and Intellectual Property  
Office of the U.S. Trade Representative  
600 17th Street NW  
Washington, DC 20508

Re: Federal Register Vol. 84, No. 246; Request for Comments and Notice of a Public Hearing Regarding the 2020 Special 301 Review, Office of the U.S. Trade Representative

Dear Mr. Ewerdt:

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 Regarding the 2020 Special 301 Review.

Intellectual property (IP) is critical to U.S. economic growth and competitiveness. IP-intensive industries directly employ over 45 million American workers and drive over $6 trillion in total U.S. gross domestic product (GDP). However, the benefits derived from IP-intensive industries are not limited by U.S. borders.

Yesterday, the Chamber released the eighth edition of its International IP Index (also known as The Index) titled “Art of the Possible,” which shows that economies of all sizes and levels of development have a stake in IP. And though the IP Index evaluates countries on the strength of their IP laws and enforcement, the data collected also helps us understand important correlations between IP and socioeconomic benefits—from access to venture capital and foreign direct investment to high-value job creation. As a companion to The Index, this year the Chamber launched the Innovation & Creativity Access Barometer, which measures the availability of life-saving medicines, popular movies and television shows, and advanced technology to consumers around the world. We are pleased to incorporate the findings of these signature research products into our attached comments.

The Chamber’s comments also discuss global trends and specific challenges in 16 markets and the European Union (EU). These countries were chosen due to market size, geopolitical significance, and severity of IP issues to U.S. industry and the global economy.

The Special 301 Report 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, U.S. Chamber’s Global Innovation Policy Center

Myron Brilliant  
Executive Vice President  
Head of International Affairs, U.S. Chamber of Commerce
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Executive Summary

The Cattedrale di Santa Maria del Fiore has become such a symbol of Florence, Italy, that it is simply known as il Duomo (the Dome). That iconic dome—the largest in the world made entirely of brick—was completed in 1436 by Filippo Brunelleschi, one of the finest architects of the Renaissance. Competition in the construction industry has always been fierce, and 13th century Italy was no exception. Powerful craft guilds dictated the who, when, and how work would be done. Brunelleschi chafed at the how part—especially considering the fact that he had a great idea: a boat to “bring in any merchandise and load on the river Arno etc for less money than usual, and with several other benefits.” Brunelleschi was so confident in his idea that in 1421, he petitioned the Council of Florence to allow him the exclusive right to operate his boat for the next three years. In a surprise move, the Council granted his petition, reasoning that “if he enjoyed some prerogative concerning this, he would open up what he is hiding and would disclose it to all.” And so, some months later, Brunelleschi’s paddle boat sailed down the River Arno with a load of Carrara marble. It sank.

Although Brunelleschi’s boat wasn’t quite as special as he claimed, his petition to the Council of Florence marked a turning point in human history. Whereas before the privileged few tightly controlled advances in technology, now any individual could create something new. More importantly, they would at least have the chance to try. Today, the protection of intellectual property (IP) continues to empower ordinary (and quite a few extraordinary) people to innovate in science, technology, and the creative arts; help deliver the latest and greatest products and services to consumers; and ultimately enrich humankind. But even Brunelleschi couldn’t do it alone—government played a critical role in making his idea a reality.¹ ²

More and more governments are understanding the importance of IP to power their economic and social development. To help them 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 (also called The IP Index or The Index). Every year, a new edition of The Index takes inspiration from some unique aspect of the innovators, creators, and businesses that have improved our lives. The Index—


its 8th edition—is titled “Art of the Possible” to honor the advances that have made modern life possible. Thanks to innovators that fought hard to make their ideas a reality, humans live healthier, richer lives.

*The Index* measures key indicators of strong intellectual property protections: patents, design patents, copyrights, trademarks, trade secrets, commercialization of IP assets, enforcement, systemic efficiency, and membership in and ratification of international treaties. This year, the Chamber notes that several emerging markets made steady progress in implementing pro-IP measures, with India and Brazil passing reforms and tackling administrative inefficiencies. We also congratulate Peru and Vietnam for gains in their *Index* rankings. Vietnam’s score increased in part from recent legislation to increase award damages for IP infringement and for its participation in international IP treaties like The Hague Agreement on Industrial Designs and the International Convention on for the Protection of New Plant Varieties. *The Index* began measuring treaties in detail this year because they are a first step in adopting global best practices for an effective intellectual property system.

*The Index* also touches on challenges that IP-intensive industries faced in 2019. The final United States-Mexico-Canada Agreement, for instance, represented a significant missed opportunity to elevate IP protections for innovators and creators in North America. While the original USMCA included many critical, high-standard IP protections, key life sciences IP protections were removed from the final deal struck in December 2019. Additionally, the July 2019 entry into force of the EU Supplementary Protection Certificate (SPC) to exempt the domestic manufacturing and export of generic pharmaceuticals may endanger the block’s ability to develop new cures and attract foreign investment. Worse still, some European countries are now considering disruptive compulsory licensing schemes to gain an advantage in pricing negotiations. Unfairly pulling the rug from under innovators undermines trust in institutions and the rule of law. Projects of this sort rarely comport with well-established norms for compulsory licenses in the TRIPS Agreement.

*The Index* acknowledges a step towards resolving the China trade dispute, as the U.S. and China signed the Phase I trade agreement on January 15, 2020. The agreement includes reforms to better protect against trade secrets theft, pharmaceutical-related IP and patent infringement, and bad faith trademarks. The agreement also includes provisions to strengthen the judicial enforcement of IP and commitments to combat counterfeiting and piracy. The Phase II agreement is expected to focus on IP reforms—many of which are noted in *The Index*. The Chamber is hopeful that this process will continue to improve IP protection globally.
All these subjects are raised in the Chamber’s comments to the Special 301 Report, which discuss the broader IP landscape as well as the IP system of 16 countries and the EU. This list includes developed markets: Australia, Canada, Chile, the EU, 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 severity 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.

The Chamber’s comments are also informed by the immense industry expertise of our members, who do business in all the markets mentioned above. It’s important to note that more than 96% of Chamber member companies have fewer than 100 employees. We are therefore cognizant not only of the challenges facing smaller businesses, but also those facing the business community at large.

The Chamber also wishes to thank every staff member in the U.S. government—including the person reading this report right now—for your hard work on these critical policy issues.
Section A: Measuring IP and Access

“Art of the Possible”, The 2020 Chamber International IP Index

Now in its 8th edition, the Chamber’s International IP Index creates a template for markets large and small to leverage IP protection to 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.

New Countries

This year, The Index added the Dominican Republic, Kuwait, and Greece to its list of countries measured.

New Indicators

This year, The Index includes five new indicators and two additions to existing indicators, including:

- Plant variety protection, term of protection (Indicator 4)
- IP-intensive industries, national economic impact analysis (Indicator 43)
- Membership in the Convention on Cybercrime, 2001 (Indicator 48)
- The Hague Agreement Concerning the International Registration of Industrial Designs (Hague Agreement and Geneva Act) (Indicator 49)
- Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (Added to Indicator 45)
- Patent Cooperation Treaty (Added to Indicator 46)
- A new category was created for Design Rights and Related Rights out of the existing Trademarks category (Creation of Category 4)
Key Findings

- **IP remained at the crux of the China trade dispute**
  - The United States and China signed a Phase I trade agreement on January 15, 2020. The agreement includes reforms to better protect against trade secrets theft, pharmaceutical-related IP and patent infringement, and bad faith trademarks. The agreement also includes provisions to strengthen the judicial enforcement of IP and commitments to combat counterfeiting and piracy. The Phase II agreement is expected to focus on IP reforms—many of which are noted in *The Index*—and will create an opportunity to improve global IP protection.

- **Several emerging markets made progress towards implementing a range of pro-IP measures to attract investment, but challenges remain**
  - In anticipation of the Phase I agreement, China introduced several IP reforms, including measures to strengthen the licensing and technology transfer environment, amendments to increase fines for bad faith trademark applications, and new legal protections for trade secrets.
  - India and Brazil passed a series of reforms and issued precedential rulings that strengthened IP enforcement, addressed administrative inefficiencies, and increased penalties for IP infringement.
  - Peru achieved the greatest overall score improvement of the Latin American economies. In Asia, Vietnam’s score a marked increase thanks to legislation to increase damages awarded for IP infringement and participation in several international IP treaties.

- **Undermining biopharmaceutical innovation reduces access to life-saving innovation and is the wrong approach to address health care costs**
  - In the EU, the Supplementary Protection Certificate (SPC) manufacturing and export exemption entered into force in July 2019. Designed to bolster the European generics industry, the export exemption will significantly undermine investment in R&D for new cures in the EU.
  - Economies of all levels of development—from the Netherlands to Greece to Chile—expanded their power to issue compulsory licenses. Utilizing compulsory licenses as a
tool for cost containment fundamentally undermines the legal certainty that effective IP systems need.

- Recent proposals by some U.S. policymakers to use compulsory licenses as a cost-containment tool risk killing the model of innovation that has cured patients and provided the world with advanced medical technologies since the mid-1980s. Alongside proposals for artificial price controls—such as HR 3—and the importation of price indexing and foreign-sourced medicines, these licenses pose an existential threat to the U.S.’ position as the undisputed global leader in biopharmaceutical innovation.

- **Government should use all bilateral and multilateral options to strengthen global IP standards, including free trade agreements (FTAs)**
  - The final United States-Mexico-Canada Agreement (USMCA) represented a significant missed opportunity to elevate IP protections for innovators and creators in North America. While the original USMCA included many critical, high-standard IP provisions, key protections for life sciences were removed from the final agreement in December 2019. The USMCA’s copyright provisions are also well behind contemporary thinking on the most important digital age issues.
  - Many FTAs passed in recent years—including the EU-Mercosur Association Agreement, the Indonesia Australia Comprehensive Economic Partnership Agreement, and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership—omit IP standards included in other 21st century, post-TRIPS FTAs.

- **While many economies omit IP commitments from FTAs, emerging markets are increasingly using international treaties and Patent Prosecution Highway (PPH) agreements to show that they are willing to abide by international IP standards**
  - Several major emerging economies—including Argentina, Brazil, India, and Peru—joined PPH agreements (we note, however, that some are sector-specific) to expedite patent examination and address backlogs.
  - Nearly all the economies in *The Index* are a contracting party to one or more of the treaties benchmarked. This strongly signals that economies of all levels of development want to participate in the global IP system.
Category-by-Category Results

Patents, Related Rights, and Limitations
- Though Singapore leads the global economy in patent protections, and 13 other high-performing economies receive over 90% of a perfect score. Still, challenges remain to securing effective protections in even the most developed economies.
  - In the U.S., Patent and Trademark Office Director Andrei Iancu sought to address long-standing uncertainty through new guidelines on patentable subject matter and reform of the *inter partes review* (IPR) process.
  - Canada’s Patented Medicine Prices Review Board (PMPRB) guidelines and the limited patent term restoration framework weaken the environment for biopharmaceutical innovators seeking to invest in R&D and limit access to the newest innovative medicines in Canada.

Copyrights, Related Rights, and Limitations
- Creators continue to struggle in securing effective copyright protection in global markets. Thirty-three economies failed to achieve 50% of the available score.
  - Many economies took steps to bolster protection for copyrighted content online. India, Greece and Ecuador utilized injunctive relief, anti-piracy legislation, or administrative orders to disable access to pirated content.
  - In Malaysia, the government used its authority to disable access to infringing-content provided through piracy devices, a growing trend in Asia for pirated content.

Trademarks, Related Rights, and Limitations
- While many of *The Index* economies have basic forms of trademark protection, the surge of counterfeit goods online creates challenges for rightsholders and puts consumers at risk. Courts and governments have stepped up to the plate to advance stronger trademark enforcement mechanisms online, but much work remains to be done.
  - In the EU, two European Court of Justice cases established an obligation for merchants to take down IP-infringing material sold in online auction houses.
  - In India, two Delhi High Court cases established a potential precedent that intermediaries and online marketplaces must remove patent, copyright, and trademark-infringing content upon notification from the rightsholder.
Design Rights, Related Rights, and Limitations

- The number of design applications has increased from less than 200,000 in 1995 to over 1 million in 2018. To show their growing importance to rightsholders, The Index created a new category for design rights (from the existing category for trademarks) this year.
- Many of the economies benchmarked in The Index have some protection for design rights, with an average score of 64.20%.

Trade Secrets and the Protection of Confidential Information

- Many economies do not have specific trade secret legislation in place. Instead, they rely on laws related to employment contracts and the disclosure of confidential information. However, several economies have recognized this gap and taken steps to better protect trade secrets.
  - In the EU, the Trade Secrets Directive sets minimum standards for trade secret protection and enforcement. But because the directive does not include criminal sanctions for trade secrets theft, it can be difficult for rightsholders to secure meaningful enforcement actions across member states.
  - In Asia, both Korea and China introduced measures to bolster trade secrets protection. In Korea, new legislation strengthened penalties for the theft of trade secrets theft while China the amendments to the Anti-Unfair Competition Law included a more comprehensive definition of trade secrets and increased the penalties for theft.

Commercialization of IP Assets and market access

- Technology transfer and licensing policies can help turn innovative ideas into consumer products. Our experience has shown that the most effective technology transfer systems are underpinned by IP frameworks, minimize barriers, and facilitate market-based partnerships.
  - China and the UAE introduced reforms to eliminate market entry barriers and facilitate voluntary technology transfer and licensing agreements.
  - Singapore and Switzerland introduced new R&D and IP-based tax incentives to facilitate investment in innovative goods and services.
  - Many governments—including Algeria, Indonesia, Nigeria, Russia, Thailand, and Turkey—continue to set licensing terms, which create barriers for foreign innovators and creators seeking to operate in the market.
Enforcement

- Enforcement of IP rights continues to be a challenge across global markets, with only 21% of the economies measured achieving a score of 50% or more. However, many markets took steps to strengthen IP enforcement in 2019.
  - The government of India strengthened civil enforcement measures and awarded substantive damages in two IP infringement cases.
  - In Korea, the government further strengthened its IP enforcement framework with amendments that increased the basis for which damages can be awarded for patent infringement and trade secrets theft.
  - The government of Brazil introduced a new criminal enforcement initiative. The Chamber notes, however, that the passage of Bill 333/1999—which would provide for equal criminal penalties for all types of IP infringement, including trademarks and design patents—would significantly improve Brazil’s enforcement framework.

Systemic Efficiency

- Many economies in The Index have committed to implementing a strong IP framework through enhancing their systemic efficiency.
  - In Saudi Arabia, the government introduced new IP awareness campaigns and held public consultations on IP policy. Similarly, in Brazil, the government created the Interministerial Group on Intellectual Property to coordinate the government’s IP policy and to conduct public consultations on the policy-making process.
  - While many of The Index’s developed economies quantify the economic impact of IP-intensive industries, several emerging markets—including Argentina, Malaysia, Mexico, Morocco, and Taiwan—also study the relationship between IP rights and economic activity.
Membership and Ratification of International Treaties

- Participation in international treaties reflects a market’s desire to join the global economy and embrace high-standard IP protections.
  - While many governments struggle to provide basic copyright protections, 77% of economies in The Index have signed and ratified the WIPO Internet Treaties. This suggests that incomplete implementation of the Treaties continues to hinder copyright-intensive industries operating in global markets.
  - Less than half of the economies measured in The Index have signed and ratified the Membership of the Convention on Cybercrime and the Hague Agreement Concerning the International Registration of Industrial Designs, two of the new treaties added to The Index in 2020.
“Fair Value for Innovation”, The 2019 Chamber Innovation & Creativity Access Barometer

The Chamber’s Value Ingenuity project tells the story of innovation while demonstrating how smart public policies can make a difference in the lives of future generations. One theme that we sought to highlight was how a country’s investment in the innovative and creative sectors—including through a strong intellectual property system—can be undone by negative market interventions. Indeed, we also explored what happened to investment when supported by positive interventions designed to support an innovation ecosystem.

The first research product produced as part of the Value Ingenuity project was the 2019 Chamber Innovation and Creativity Access Barometer (“The Barometer”). The Barometer is a new tool to measure commercial access to innovative and creative works in 20 leading economies (the G20 nations plus Algeria). It consists of 16 indicators in the following four categories:

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

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 today.3

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 classic protectionism favoring local producers (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. Behind the tariff line, market entry for

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 the access of their citizens to IP-intensive products, services, and technologies. Some key findings are explained in the following list:

- Scoring 93% across all four categories in *The Barometer*, the U.S. demonstrates the greatest openness to innovative and creative products, services, and technologies.
- Following at a notable 10% deficit, 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. Developing markets underperformed across the board on indicators that affect commercial access to innovative and creative goods and services.
Section B: Global Trends

The International IP Landscape Across Strategic Markets

Over the last year, the U.S. Chamber of Commerce has observed trends related to enforcement, compulsory licenses, online audiovisual content quotas, and others. To illustrate these issues, we have selected examples from global markets and explained what’s happening in detail. Where necessary, we reference similar happenings in other markets—paying special attention to issues raised in Sections C and E (Developed and Developing Market Profiles).

Enforcement

From Bangladeshi-made counterfeit pharmaceuticals popping up across Asia to design patent-infringing goods sold online, criminals continue to harness new technologies and legal loopholes to thrive. Take, for example, this trend’s well-known effect on the music industry. In 2007, an Institute for Policy Innovation study found that—thanks to some 20 billion songs illegally downloaded worldwide—the music industry lost $5.333 billion in revenues and a further $1.630 billion from physical piracy. Fast forward to 2019: 80% of the industry’s revenues depend on 61.6 million paid streaming subscriptions and ad sales on free platforms. The Chamber is troubled, however, that the pirates are reportedly running up a new sail: “stream ripping.” As of fall 2019, industry is tracking more than 200 of sites that convert tracks posted on video sharing websites into downloadable mp3 and mp4 files. Industry research also estimated that just two of such sites, Flyto and 2Conv, registered over 1.7 billion visits in the past year.

Advanced piracy methods are also affecting the audiovisual industry. As far back as 2017, the USTR helpfully highlighted the growing threat of how a benign set-top box, open source software, and apps offering infringing content can be assembled to create a new threat: illicit streaming/piracy devices.


These devices remain a growing threat, particularly in the Asia-Pacific, and we appreciate the U.S. government’s continued attention to this issue.

For major clothing and footwear brands, counterfeiters continue to leverage the internet to dupe customers intending to buy a legitimate product. Given the immense investments that legitimate businesses make in protecting consumers and meeting quality standards, the Chamber appreciates the U.S. government’s recognition of these threats in prior Special 301 and Notorious Markets reports. We encourage policymakers to consider our suggestions on anti-counterfeiting and enforcement highlighted in the section titled: “The International IP Landscape and Enforcement.”

Bangladesh

Bangladesh, along with Myanmar and Sri Lanka, have become important sources of counterfeit oncology drugs in Asia—affecting patients and legitimate commerce alike. The problem in India, for example, is two-fold: medicines allowed solely for production and consumption in Bangladesh (such as Afanix 40 or Crizoncent) are smuggled into India alongside infringing medicines manufactured solely for export (such as osimertinib, ibrutinib, and crizotinib). Even though unlicensed imports are illegal under India’s 1940 Drugs and Cosmetics Act, the lack of strict border controls or mandatory bar codes on medicine packs has ballooned the value of this “grey market” to Rs 300 crore, or $41 million. Reports also indicate that Bangladeshi counterfeiters heavily promote their fake products to patients and doctors in India through email and social media platforms like WhatsApp. 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. The Chamber is encouraged by news that India’s Border Security Force has improved its effectiveness through the Comprehensive Integrated Border Management System (CIBMS) and is


hopeful that this system could play a greater role in combatting this major regional public health risk. In addition, authorities should take greater action against websites selling illicit medicines and local distributors facilitating their spread.

**Taiwan**

Despite Taiwan’s position in the top half of The Index, copyright piracy on the island has worsened in the face of official inaction. Currently, Taiwan does not allow for no-fault injunctions to order ISPs to disable access to infringing sites, infringement of reading materials continues, and many copyright infringement-related actions—be it unauthorized camcording in a movie theater or internet piracy—are not considered “crimes.”

In fall 2019, industry reported that Dytt8.net and Dy2018.com, a pair of pirate websites with over 12,000 and 10,000 infringing titles, have become more popular—logging around 17.24 and 10.5 million visits per month. The Chamber also notes that these sites operated on servers in Taiwan. We also echo concerns from the publishing industry that the local .tw domain for Sci-Hub continues to ignore rightsholder requests to stop the unauthorized distribution of nearly 70 million journal articles and academic papers in the country. Given the Asia-Pacific region’s leadership in online enforcement, the Chamber is concerned that continued indifference could jeopardize anti-piracy efforts in this important region. We recommend greater engagement from the U.S. government on this growing piracy problem.

It should be noted that the picture for patents in Taiwan is much brighter. The Chamber was encouraged to see regulations issued on January 30, 2019 to implement patent linkage for both biologic and chemically synthesized medicines. In July 2019, the final patent linkage regulation was published and approved for implementation. It became effective on August 20, 2019. We commend this important step to improve Taiwan’s climate for biopharmaceutical research and development. At the same time, we have received reports from companies that certain valuable inventions covering the approved product—including certain dosage forms—are not able to be listed. These gaps undermine the effectiveness of the new system. The Chamber remains ready to ensure that implementation of this regulation fully meets its objectives.

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Ukraine

From the threat of compulsory licensing for innovative pharmaceuticals to disorganized guidelines for collective management organizations, the legal framework in Ukraine for intellectual property remains marked by uncertainty. The country has also found itself an attractive home base for patent and copyright-infringing criminals. In 2019, the Ukrainian State Border Guard Service and police authorities uncovered a pharmaceutical counterfeit operation in Kyiv. An ongoing investigation has since discovered that a group of Ukrainian citizens were importing trademark-infringing counterfeit medicines to sell within the country and abroad. Its likely unprecedented size and scope has spurred concerns among even domestic manufacturers of Ukraine’s ability to effectively deter this type of IP crime.

Ukraine is also a destination of choice in Europe for hosting servers distributing pirated content. In fall 2019, industry reported that Fmovies.is/to (with 67.76 million visitors per month—one of the most popular in the world) and Tamilrockers.ws (which, according to SimilarWeb, ranks in the top 200 most popular websites in 12 countries) were hosted on Ukrainian servers. Given its multi-sector IP challenges, the Chamber urges the U.S. government to engage with the government of Ukraine to strengthen its legislative and enforcement capabilities.

United Arab Emirates (UAE)

The enforcement landscape in the United Arab Emirates is also troubling—particularly as it relates to patent protection. Under the Ministry of Health Decree 404, the Ministry of Health (MOH) denies marketing approval for copy products that infringe on a patent existing either in the UAE or in the Gulf Cooperation Council (GCC). The UAE government has confirmed that both UAE national and GCC regional patents are recognized and enforced in the UAE, clarifying certain questions that arose in 2017-2018 concerning GCC regional patents. The Ministry has also observed a long-standing practice offering market exclusivity to innovative medicines by prohibiting reliance on the pre-clinical and clinical data of the original product until the expiration of the patent in the country of origin (COO), the market from which the product has been imported. However, in 2017, the UAE government approved a generic version of a pharmaceutical product that remains patent-protected in the country of origin and which therefore should prohibit reliance on the data necessary for licensing in the UAE. This development undermined the life sciences IP environment in the UAE, since pharmaceutical patents are not truly protected in the country but based on market exclusivity and the protection of data linked to the patent’s expiration in the COO. While the UAE has engaged in constructive discussions to resolve industry’s concerns and enhance its competitiveness in the sector, the Chamber notes that there is not yet a workable solution to this issue. The Chamber encourages the U.S. government to continue to highlight the importance of respecting existing patents in bilateral dialogues with UAE government officials.

Compulsory Licenses & Price Controls

Compulsory license or government-use mechanisms—where governments override patent protections to allow the generic, local manufacture of a medicine—create a harmful precedent. Innovator firms seeking to expand access in markets require legal and regulatory certainty that their products will be protected. Revoking a previously-granted IP right to unilaterally reduce prices in undermines the confidence necessary for research, development, and access to products.

While compulsory licenses have been seen for many years in Argentina, Colombia, and Indonesia, the Chamber notes that now even European countries are considering compulsory licenses to gain an advantage in pricing negotiations. Unfairly pulling the rug from under innovators damages trust in institutions and the rule of law. More importantly, they rarely comport with well-established norms for
compulsory licenses in the TRIPS Agreement, which state that compulsory licenses may only be used as a last resort or in the gravest public health emergencies (like pandemics).

The Chamber also observes many governments—both developed and emerging—are considering or have enacted new price controls limiting the ability for innovative medicines to be reimbursed for the value that they bring to society and patients. The negative free riding effect of these prices controls is further compounded by countries adopting reference pricing regimes.

**Malaysia**

Malaysia has been a user of compulsory licenses since 2004, when the government ordered the importation of generic antiretroviral medicines. On September 20, 2017, **Malaysia** again issued a government-use license (a public form of a compulsory license) for *sofosbuvir*, a breakthrough medicine to treat Hepatitis C. In an accompanying statement, the Ministry of Health explained that the decision was driven primarily by the medicine’s cost—even though the U.S. manufacturer had agreed to include Malaysia in its voluntary license territory. In contrast, TRIPS Article 31 and the Doha Declaration suggest that compulsory licensing—or in this case, government-use licensing—is intended primarily for public health and humanitarian emergencies (such as pandemics) and should be used only after all other options for negotiating pricing and supply have been exhausted.

Although Malaysia has publicly stated its ambition to expand access to advanced treatments while developing its high-tech, biopharmaceutical, and innovative industries. It is unlikely, however, that the issuing of a government-use license will help the government reach its goal. On the contrary, industry experience has shown that public-private access partnerships can boost both biopharmaceutical innovation and access.\(^\text{12}\) It is important to note, however, that voluntary licensing is not a one-size-fits-all solution, but determined by a number of factors, such as: a country’s ability to pay, the burden of a disease and scale of unmet need. We also note that if a voluntary license is forced, it effectively becomes a compulsory or government-use license all over again—ultimately undermining access to medicines.

\(^\text{12}\) Such policies, including voluntary licensing, treated over 15,000 patients in 2018 in Vietnam; however, Malaysia’s government use license reportedly treated 1,501 patients over the same period.
Audiovisual Content Quotas Online

For years, governments have sought to promote their domestic audiovisual industry or “national culture” through film and television programming quotas. The most extensive can be found in the European Union, whose Audiovisual Media Services (AVMS) Directive has established quotas based on language and “European-ness” as far back as the VHS era: 1989. Around the same time, Canada sought to protect its cultural industries in the Canada-U.S. Free Trade Agreement by establishing a discriminatory “cultural carve-out” regime.

As the sector digitized, however, experts predicted that it was only a matter of time before this old framework would cease to exist. But despite the internet’s effectively unlimited storage capacity and consumer demand for international content, the reach of government content quotas has only grown. In 2018, for instance, an updated AVMS Directive—expanded to regulate services on the internet and on-demand—entered into force, with Member States expected to fully implement it as part of their national laws by fall 2020. Since then, other governments have followed the EU’s lead: Colombia included language in its 2019 National Development Plan to establish a prominence requirement for locally produced content on OTT platforms, Mexico and Indonesia reportedly began studying stricter domestic quotas for OTT platforms, and legislative proposals in Brazil called for the expansion of that country’s Pay-TV law (including strict local content quotas and a higher tax burden) to digital platforms. Even today, the USMCA maintains Canada’s 80’s-era cultural carve-out—a notion that should clearly have no place in future trade agreements and should never be invoked. The Chamber notes that such domestic content quotas, especially as governments push them further online, unfairly limit consumer choice and could inadvertently fuel piracy. We urge the U.S. government to engage with governments on this serious and growing market access issue.

Vietnam

Of all the governments mandating content quotas in the digital space, none is more concerning than that of Vietnam—a strategic and growing regional market for rightsholders. For background, the country has long maintained burdensome screen (20% for national films) and broadcast quotas (50% limit on foreign content during all broadcast time, with a blanket ban during prime time). The resulting lack of choice for content lovers in Vietnam likely fuels the country’s long-time piracy problem.

The Chamber is concerned, then, that the government of Vietnam is considering greater restrictions on the sector. 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 6. Worse still, the amendments established a licensing scheme that would require a local presence for foreign companies through 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. Though U.S. industry has continued to engage with Vietnamese officials, and the amendments have not yet been approved, the Chamber notes that Decree 6-like measures may only grow in the coming years. We urge the U.S. government to aid industry in retooling the amendments.

**Forced Localization**

As economies industrialize, some governments have resorted to distortionary policies to encourage local research, innovation, and manufacturing. Such localization barriers are particularly felt in the biopharmaceutical sector, which has reported longstanding issues in markets as varied as Argentina, China, Egypt, and Russia. Indonesia is also known for—in exchange for market access—forcing U.S. pharmaceutical companies to partner with a local company, allow that company to access its intellectual property, and assent to its manufacture of the same products within five years. The Chamber notes that these policies can have adverse effects on developing economies, such as reduced investment, low rates of knowledge-based employment, and greater isolation from the global economy.

**Turkey**

Turkey is notable for the scope of its worsening localization requirements for the pharmaceutical sector. In a public move to promote local industry, the government has threatened the loss of exclusivity for foreign medicines from the country’s reimbursement list unless manufacturing occurred in Turkey. From winter 2017 to summer 2018, some 119 products were delisted under this policy—forcing the European Union to file a WTO dispute in April 2019 regarding Turkey’s TRIPS and national treatment obligations. Larger problems remain with the reimbursement program itself—particularly in the way the country’s Health Ministry has adjusted fixed Euro/Turkish Lira exchange rates to artificially secure discounts on innovative medicines. By means of example, under the country’s Pricing Decree, the exchange rate for pharmaceuticals is normally set at 60% (note that this is the only type of product subject to this policy). In 2018, the fixed rate was not met and in 2019 the rate was again changed from 70 to 60%—further reducing business certainty for U.S. companies in Turkey. To top it off, industry reports
that the broader reimbursement process lacks transparency. The Chamber asks the U.S. government to engage in constructive consultations to quickly resolve the many issues brewing in this strategic market.

**Use of Competition Law to Curtail IP rights**

The use of competition laws to curtail IP rights has been particularly rampant in Asia. **China** has an established record of selective enforcement of the Anti-Monopoly Law (“AML”) against foreign companies to enhance the competitive position of Chinese companies seeking to license foreign technology.\(^{13}\) Such actions often employ intimidating and non-transparent procedural mechanisms to pressure U.S. rightsholders to license technology to Chinese parties at below-market rates. This deprives U.S. companies of the fees they would otherwise be able to charge—fees that appropriately reflect the value of U.S. technology. China’s discriminatory enforcement of antitrust laws to advance its ambitions to overtake the U.S.’ leadership in critical technology is integral to China’s industrial development model. It has been employed the telecommunications, medical devices, auto parts, and other sectors.

**Republic of Korea**

Competition authorities in other countries have followed China’s example. In **Korea**, the Korea Fair Trade Committee (“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 U.S. companies to procedurally defective competition proceedings and imposed 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 full access to information in its case file, undermining the ability of U.S. companies to defend themselves. As the USTR recognized in the 2019 National Trade Estimate report, Korea’s proposed amendments to the Monopoly Regulation and Fair Trade Act (“MRFTA”) do not meaningfully address U.S. concerns.\(^{14}\) Having robust procedural protections in place would 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.15 16

Resource Challenges in the U.S.

As one of the world’s most innovative economies, jobs in the U.S. depend on consistent IP standards enforced worldwide. Nevertheless, improvements to this critical framework have tapered off since the WTO TRIPS Agreement entered into force in 1995. This year, as the TRIPS Agreement celebrates its 25th anniversary, the Chamber notes that countries continue to struggle with implementing the Agreement’s most basic principles. In this environment, U.S. government leadership and the partnership of like-minded nations have been critical in holding the line on TRIPS standards and promoting a data-driven dialogue in multilateral organizations about the importance of IP.

Globally, the U.S. Patent & Trademark Office’s IP attachés compliment the U.S. government’s work by engaging local governments and other stakeholders. Unfortunately, the Chamber understands that in some cases the IP Attachés’ lower diplomatic rank limits their ability to engage senior officials in foreign governments. We urge USTR, the Department of State, and other relevant agencies to adjust the attachés’ diplomatic status—ensuring that the U.S. government is as effective as possible in supporting strong IP protections around the world.


The International IP Landscape through Trade and Multilateral Organizations

USMCA

The final United States-Mexico-Canada Agreement (USMCA) represented a significant missed opportunity to elevate IP standards with two of the U.S.’ largest trading partners. Chapter 20 of the USMCA also had the potential to set new, 21st century IP standards as explained in the list below:

- Stronger pharmaceutical-related IP protection, including regulatory data protection terms of 5 years for new chemical entities (NCEs) and 10 years for biologics.
- More effective trade secret protection including criminal sanctions.
- Ex officio border enforcement against all suspected counterfeit goods including goods in-transit.
- Strengthened copyright provisions, including a full term of protection, digital rights management (DRM)/technological protection measures (TPM), and exceptions and limitations governed by the long-standing, internationally accepted three-step test.

The draft USMCA signed in 2018 was a significant improvement over NAFTA, TRIPS and the original TPP agreement. However, the agreement was not perfect and lacked many provisions relating to a 21st century copyright regime. Then in December 2019, the text of Chapter 20 was significantly revised and important components of the original USMCA had either been removed completely or fundamentally altered in the following ways:

- Removed provisions relating to a 10-year term of regulatory data protection for biologic medicines.
- Weakened patentability standards by not allowing second and additional use claims.
- Weakened administrative mechanisms that link the registration and market approval of a follow-on product to the exclusivity status of a reference product.
• Weakened provisions relating to term restoration for biopharmaceutical products.\textsuperscript{17, 18}

The Chamber was disappointed by the removal of these critical IP provisions, as it was based on the false assumption that these protections would raise U.S. drug prices. In fact, the original biologics provision would have resulted in more funding for innovative medical research at no additional cost to U.S. consumers. Now, the only beneficiaries will be foreign governments and consumers who will continue to free-ride on the benefits of American research into new cures without contributing to their development. The Chamber urges the U.S. government to ensure that the USMCA will not be used as a template for future agreements, as the provisions no longer represent 21st century IP protections.

U.S. FTAs with the United Kingdom, European Union, and Japan

Amid the initial steps to resolve IP challenges in China with the Phase I Agreement and failure of USMCA to address pressing IP issues, opportunities remain to set the bar higher through the next generation of FTAs with the United Kingdom (U.K.), European Union (EU) and Japan. The Chamber also notes that the U.S. government may initiate talks with many other economies this year, including: India, Brazil, South Africa, and Vietnam.


United Kingdom

The U.S. business community recognizes the importance of U.S.-U.K. trade. Considering the very strong IP regimes in both countries, the Chamber sees FTA negotiations as a real opportunity to set the highest global standards for IP-led creativity and innovation. Creative works, inventions, and brands are a significant competitive advantage for both the U.S. and the U.K. in the global economy. This is clearly illustrated by the fact that the two economies sit atop The Index as global leaders in IP protection and enforcement. By ensuring that patents, copyrights, trademarks, and trade secrets are uniformly well protected between the two biggest Atlantic economies, U.S.-U.K. negotiations have the potential to do the following things:

• Increase—U.S.-U.K. trade flows.
• Incentivize—businesses to make long-term, high-risk, capital-intensive investments in innovative and creative industries.
• Enhance—the global standing of both countries as leading innovative and creative economies.
• Exemplify—to the rest of the world of what a high-ambition, pro-IP FTA looks like.

There are also opportunities for the U.S. and U.K. to learn from each other. The U.K., for instance, provides a strong model for rightsholders seeking redress for online infringement. And though both countries have versions of secondary liability for copyright infringement, in various respects the U.K.’s copyright protection regime for online enforcement is stronger than that of the U.S. By contrast, intellectual property standards for the biopharmaceutical sector are a relative advantage for the U.S., and these negotiations represent an opportunity to enhance British competitiveness in innovative medicines.

To achieve this, any agreement should include provisions that recognize and seek alignment to the high standards available in the U.S. and U.K., including an adequate patent term extension mechanism to compensate for patent term lost to marketing approval delays; a mechanism to permit innovators to prevent generic launch during the patent term; and adequate levels of regulatory data protection (including 12 years of regulatory data protection for biologics) to ensure that investment incentives in clinical trials in both the U.S. and U.K. are enhanced. Both countries should also avail themselves of the opportunity to advance a model approach to sustainable access to innovation and creativity through respect for property rights and a return of fair value for innovation.
Japan and European Union

The U.S.-Japan and U.S.-EU trade negotiations also present opportunities to set high standards for IP-led creativity and innovation. These economies have relatively strong intellectual property rights regimes and the negotiations should prioritize advancing a model approach to sustainable access to innovation and creativity through comprehensive trade agreements that encourage respect for property rights and a return of fair value for innovation. We urge USTR to negotiate robust IP protection and enforcement commitments in both FTAs, including appropriate patentability standards, patent term restoration and adjustment, patent term linkage, and 12 years of regulatory data protection for biologics.

African Continental Free Trade Agreement

The Chamber remains hopeful that Phase II negotiations on the African Continental Free Trade Agreement will bear fruit, given Phase I’s successful entry into force in spring 2019. This initiative will encourage social development and economic integration. As signatory countries begin discussing IP, competition, and investment-related chapters in Phase II, the Chamber supports IP-related capacity building in the African Union to ensure that high-standard rules are set from the start.

The Chamber notes with concern that the stakes in this growing region could not be higher as anti-IP proposals gain traction—such as a pair of bills undermining international copyright and contracting norms under consideration by the President of South Africa. To that end, the Chamber hopes that the U.S. government will use these negotiations as an opportunity to share best practices and encourage a fact-based dialogue around a successful IP framework.
Norm-Setting Multilateral Environment

Overview

Specialized agencies in the United Nations (U.N.) framework continue to play an important role in the administration of global IP rights. As the subject-matter expert, the World Intellectual Property Organization (WIPO)—guided by the World Trade Organization’s (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement—provides the necessary technical expertise in this system. However, special interest groups, certain countries, and other U.N. agencies continue to advance negative exceptions and limitations to benchmarks established by the TRIPS Agreement.

Despite WIPO’s role as a technical advisor, there is a continued push in the organization to further the “development agenda” and cross-border uses through greater exceptions and limitations to copyright. 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.19

The Chamber has also observed that there is a similar effort in multilateral organizations to weaken biomedical innovation in cell and gene therapy (C&GT), with several countries pushing for a standalone treaty on genetic resources. C&GT products are providing new hope for patients with blood cancer, blindness, and other devastating conditions. Undermining the IP incentives for development of C&GT would have a devasting effect on the U.S. innovation ecosystem that produced these products, as well as on the patients who need them.

We also note that many WIPO member states staunchly oppose efforts to streamline the 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 benefit most from this type of capacity building.20 In the Chamber’s view, such work-sharing could be a way to raise global IP standards while meeting countries’ socio-economic goals.


20. “WIPO Match is an online tool to match seekers of specific intellectual property (IP)-related development needs with potential providers offering resources.” https://www.wipo.int/wipo-match/en/
We also have concerns regarding the Organization for Economic Cooperation and Development’s Directorate for Science, Technology and Innovation which, despite its lack of technical expertise, continues to assert that copyright is an impediment to digital commerce. This opinion persists despite the copyright-driven success of the American and European creative industries—not to mention findings in The Index that show how legal protections for copyright have a positive correlation with a robust digital sector.\textsuperscript{21} The Chamber is also concerned that the many countries seeking OECD membership seem unwilling to satisfy the high standards of OECD member states—particularly with respect to IP. Allowing accession on substandard terms weakens the entire organization, and the Chamber hopes that the U.S. government will continue to stress the importance of high-standard policy frameworks in this critical organization.

Some years after a change in U.N. leadership and the publication of the patently anti-IP recommendations of the U.N. High-Level Panel on Access to Medicines (UNHLP), activists and supportive countries continue to use their contents to fuel a broader anti-IP campaign in Geneva and multilateral organizations. At the WHO, some countries—and even WHO staff—have proposed weakening intellectual property rights to lower the cost of medicines. This is 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 like hospitalization. We urge the U.S. government to continue its holistic approach in acknowledging the complex factors that affect access to medicines; reject all attempts to incorporate deleterious anti-IP language into official agendas and resolutions, including at the WHO Executive Board and the World Health Assembly meetings; and to work with other member states to reassert their leadership and not allow secretariats a free pass to shape the agenda.

Most recently the Chamber has observed activists and governments seeking to use the WHO’s Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) as a vehicle to weaken the IP rights that are so vital to improving global health. WHO Executive Board members should insist that the WHO promote polices that will raise the level of IP protections in all countries. The WHO should also act strictly within its mandate and not advise countries to adopt policies that are not endorsed by its member states.

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, the U.N., WHO, WTO, and OECD will only find success

\textsuperscript{21. Ibid.}
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. In this vein, the Chamber applauds the U.S. government for resolving its outstanding payments to WIPO and encourages further collaboration between U.S. government agencies to engage in the U.N. architecture.

**International Treaties and Patent Prosecution Highways (PPHs)**

Becoming a contracting party to an IP treaty is a strong signal of a country’s desire to participate in the international IP system. This year, *The Index* expanded the suite of treaties measured—like the Madrid Agreement on Marks, Patent Cooperation Treaty, Convention for the Protection of New Varieties of Plants, Convention on Cybercrime, and Hague Agreement on Industrial Designs—to further understand the strength of that country’s overall IP system. The findings showed that, despite adoption by most of the world’s countries, outliers remain. The Patent Cooperation Treaty (PCT), for instance, remains unsigned by **Pakistan** and **Venezuela**. **Argentina**, despite signing on in 1970, has still not ratified PCT provisions into domestic law—the only major economy in the world to do so.

A patent office’s collaboration with its international counterparts through Patent Prosecution Highways (PPHs) is also helpful in assessing the overall strength of a market’s IP system. Since the mid-2000s, PPH programs have leveraged the sharing of information to lower costs, improve the quality of examinations, and harmonize the granting of patents in multiple markets. Since 2017, countries like **Argentina**, **Brazil**, and **India** have entered into PPHs of varying scope with agencies such as the USPTO and Japanese Patent Office. We would also like to specially recognize **Peru’s INDECOPI** which, by joining a GPPH Pilot Program in January 2019, continues a positive trend of that office’s thoughtful adoption of global IP best practices. The Chamber hopes that the trend toward technology and sector-neutral collaboration continues—noting that the government of Argentina initially limited PPH participation with the USPTO to petrochemical-related innovations and JPO to ICT-related innovations (later expanded in 2019 to include chemistry). Given Argentina’s challenging patent environment and substantial application backlog, its scope should be expanded to include more sectors and should not be treated as a model for future PPH participation schemes.
Misuse of Competition Law in Multilateral Fora

The Chamber notes increasing 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. 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. They have also called for greater capacity building in how competition law, IP rights, and technology transfer interface in developing countries.

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

Overview

The global scope of physical counterfeiting is the largest it has ever been—measured at $509 billion dollars by the Organization for Economic Cooperation and Development in its 2019 report, *Trends in Trade in Counterfeit and Pirated Goods.* 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. IP theft undercuts a relationship built on years—if not generations—of trust that helps consumers know that the products they use are authentic, safe, and effective. When that system is undermined, so is consumer confidence. Criminals often go to painstaking lengths to replicate the look and feel of branded websites and products, from displaying the logos of unaffiliated payment processors to (ironically enough) seals from consumer protection groups. Some sites go as far as to blatantly copy images, advertisements, and pictures of company presidents directly from legitimate websites to maintain the illusion. No wonder, then, that consumers are often confused.

Although physical markets such as *Rua 25 de Março* in São Paulo, Beijing’s *Silk Market,* or Paraguay’s *Ciudad del Este* continue to be significant contributors to physical piracy, fighting illicit actors online has become just as important. Criminal IP theft is a plague on safety and freedom on the internet. It profits from the hard work of America’s creative industries and the millions of people they employ. Worse still, the United Nations Office on Drugs and Crime (UNODC) found that the illegal trafficking of counterfeit goods and cross-border organized crime is a multibillion-dollar industry. And according to Europol and the EUIPO, sophisticated criminal networks have begun playing a larger part—trafficking counterfeit goods alongside illegal drugs and firearms.


The USTR has recognized the problem of illegal websites, business-to-consumer and business-to-business transactions through its Special 301 Out-of-Cycle Reviews of Notorious Markets. We urge the USTR to factor its Notorious Markets findings into the annual Special 301 review and encourage foreign governments to address any notorious markets in their jurisdiction. When examining preventive measures, we encourage the USTR to use objective factors, including current and future best practices for platforms.

IP-intensive industries support more than 45 million U.S. jobs in 81 sectors. As one of the pillars of the U.S. economy, IP accounts for more than half of all U.S. exports: $842 billion, or almost 40% of U.S. GDP. But the U.S. is not the only country vulnerable to the impacts of IP theft. All nations can protect their domestic innovative and creative industries by being vigilant against counterfeiting and piracy. Below, the Chamber has outlined major challenges that countries face when enforcing IP as well as potential remedies for policymakers to consider.

Global Enforcement Trends

Transshipment and Small Parcels

Overseas criminals and sellers may remotely 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, inspected and assessed for duties by U.S. Customs and Border Protection (CBP), and are 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. And depending on the size of the order, many websites will break up shipments into several small packages—including a package with a fraudulent label or trademark tag—to avoid seizure. Remote sellers may even offer refunds for seized products to attract U.S. consumers. 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.\textsuperscript{33}

This issue of counterfeits in express and mail shipments has continued to grow, as noted by the CBP, the World Customs Organization\textsuperscript{34}, and the U.S. IP Enforcement Coordinator.\textsuperscript{35} 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.\textsuperscript{36} 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 Chamber is encouraged, however, by the success of Operation Mega Flex, an effort to enhance the inspection and monitoring of high-risk international mail coming into the U.S. The three actions, which took place between July and September 2019, yielded 1,061 shipments of counterfeit products, 2,890 discrepancies, and 174 controlled or prohibited substances.\textsuperscript{37} As these actions continue, we are hopeful that rightsholders and CBP strengthen processes for information sharing to help track the real importer, increase enforcement actions, and reduce repeat counterfeit sellers and shippers.

\textbf{Counterfeit Goods Online}

As the online ecosystem continues to expand and evolve, combating IP theft has become increasingly challenging. 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 and chemical safety standards, to name a few. As a result, it has become extremely difficult for consumers to differentiate between legal,


authentic, safe, and trustworthy products and from fake products 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—has long been used as a resource by law enforcement and IP rightsholders to help identify and combat the criminals operating in the online environment. Recently, registrars and registries have shut down public access to this information because of their overly broad interpretation of the EU’s General Data Protection Regulation (GDPR). While public access to WHOIS information is critical, the information needs to be accurate, and it often contains fictitious information. The Internet Corporation for Assigned Names and Numbers (ICANN) and the registries and registrars that are accredited by ICANN can do more to help address this unfortunate situation. Sadly, even in the cases where criminals can be identified accurately, they may be located 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 unclear or inadequate laws, while others might impose impractical standards, such as numerical thresholds, that stifle enforcement efforts. Also, some counties simply lack the will to bring cases to court, sometimes for political or even more questionable motivations.

Weak links in the chain of international laws and enforcement efforts serves to aid the criminal enterprises behind online counterfeiting and piracy to pick and choose a forum where they can evade the law without significant consequences. Further, the continued operation of these criminals undermines domestic enforcement efforts by providing international alternatives to the illicit operations targeted here in the U.S. This harm has given rise to the widespread recognition of the need for legal tools to disrupt access to and operations of illegal foreign websites, and to implement strategies to take the money out of online piracy through better and more transparent policies related to ad placement and the provision of financial services. This ensures legitimate enterprises are not unwittingly providing funding to, or otherwise contributing to the operation of, pirate sites.

Industry has made significant investments to combat online crime, with rights-holders spending hundreds of millions of dollars annually on these efforts. The U.S. government has achieved some victories, such as “Operation In Our Sites.” Since 2010, nearly 26 countries have worked together to bring about the seizure of over 2.2 million URL links distributing dangerous and illicit goods. In 2018, IOS
brought about the criminal seizure of over 22,000 domain name registrations and the civil seizure of over 1.2 million domain name registrations. In one of the highlights of Operation In Our Sites, cooperation with certain foreign governments resulted in action against criminals selling dangerous counterfeit medicine online. Operation In Our Sites shows that international cooperation on IP enforcement is possible and, when it occurs, can be highly effective. Unfortunately, to date, such cooperation remains the exception rather than the rule.\textsuperscript{38}

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. A good 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, OECD instituted a task force on countering 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.

**Illegal Diversion of Drugs**

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 alternatives to 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. 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**

Piracy devices (also known as Illicit Streaming Devices, or ISDs) are devices that allow users to locate and stream or download unauthorized content from the internet. These devices include media boxes, set-top boxes, or other devices that perform similar functions. Piracy devices and enabling apps can take many forms but have common features, and they have become a common means through which pirated content is made available to consumers throughout the world. Since piracy devices allow both live television and unauthorized on-demand content to be sent directly to the user’s television, they have become increasingly popular. The vast majority of these devices are manufactured in China, and they are distributed to the Chinese domestic market and exported to other markets worldwide. This proliferation of piracy devices has created a global threat to content creators and rights-holders.

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. These devices use apps to facilitate identification and access to online sources of unauthorized entertainment content including motion pictures and television programming (including encrypted content), but also music, music videos, video games, published materials, and even karaoke. Piracy devices are available either pre-installed with apps that facilitate infringement (these are installed prior to shipment, by vendors prior to sale, or as an after-sale service), or users may install the apps required to access the infringing content themselves. These apps allow the users to connect to a supporting online infrastructure that provides them with instant access to infringing audiovisual content. Many of these piracy apps cross over multiple platforms, including set-top boxes, mobile phones, and computers.

These piracy devices and apps are part of an online ecosystem that facilitates access to pirated content through an integrated and sophisticated network, making enforcement against piracy devices especially challenging. Because piracy devices are also capable of other uses, retailers and distributors can only be held liable under certain fact patterns—not an easy task. Enforcement often requires that the app developer responsible for facilitating online infringement can be identified and located; and action may also be taken against illegal distribution sites. But unless coordinated and aggressive government actions are taken against the criminals who have invaded the online ecosystem, the threat of piracy devices on the legitimate market for digital delivery of copyrighted content will become ever more severe.
Global Enforcement Priorities

Enforcing Baseline Protections

At the core of any functioning IP framework are the accepted standards for protection and enforcement in physical markers and online. Many of these standards have been accepted globally as part of major trade and IP agreements and treaties. Some of the leading instruments include the TRIPS Agreement of the WTO, and the WIPO Copyright Treaty and Performances and Phonograms Treaty (commonly known as the WIPO Internet Treaties). Other examples reflect widespread and/or regional standards, such as the provisions of the IP chapters of the U.S.’s free trade agreements (FTAs). These standards have been accepted on five continents and have been a model for IP protection and enforcement to FTA partners and non-FTA partners alike. As we enter negotiations for new and updated FTAs, we must insist on the most up-to-date standards for effective action against IP theft.

In order to promote the enforcement of existing international obligations, it is important that the U.S. government continue to work with foreign governments. In many cases, there have been significant improvements—such as provisions that ensure greater transparency between rights-holders and law enforcement and/or provide ex officio authority to law enforcement and customs officers to seize counterfeit or pirated goods—but in other cases, we have seen considerable setbacks. Additionally, the Chamber is particularly concerned about the transshipment of illicit goods, including counterfeit products, and the process by which these goods are destroyed once seized.

Full and complete implementation of these baseline standards is essential to begin to address the forum shopping and flight from jurisdiction to jurisdiction that we have seen repeatedly in the fight against criminals engaged in online IP theft. We urge the USTR to continue to make this a top priority and that where our trading partners fail to meet these standards, they be held accountable through all the tools at USTR’s disposal.

Increased Enforcement

As customs organizations worldwide battle this very issue, the U.S. can study their successes to make progress in the fight. For example, Her Majesty’s Revenue and Customs (HRMC) in the U.K. has made significant progress against express and mail shipments by deploying tactical “Anti-Ilicit Trade Teams” to strategic postal depots. Working closely with commercial stakeholders, HMRC staff increased
the X-ray examination of parcels, enabling them to target high-risk locations and significantly improve seizure rates. In the years since this program began, it continues to show sustained success.39

The Chamber believes that, through targeted technological solutions, we can standardize CBP’s existing—and time-consuming—seizure and notification process. The Chamber urges the U.S. government to work with its trading partners to ensure their customs agents have the authority to confiscate, seize, and destroy goods that are determined to be illicit. Other countries, for instance, already empower their customs agencies to seize products based on design registrations, including the European Union, China, Mexico, and Japan, among others. CBP should also be able to seize infringing goods based on existing design patents. Furthermore, there shouldn’t be undue requirements placed on rightsholders to prove that the seized goods are counterfeit, and that all seized counterfeit goods, materials, and related manufacturing equipment pieces are swiftly destroyed. Effective destruction procedures are essential to prevent both counterfeit goods from returning to legitimate trade channels and manufacturing equipment from returning to illicit factories. In addition, CBP should develop standard notifications and enhanced information-sharing with industry to help identify the underlying sources and distributors of counterfeit products. If we are going to be credible in our requests for our trading partners to employ best practices for the enforcement of IP, we must set the right example. The Chamber welcomes the passage of specific provisions of the STOP Act (2018) by the U.S. Congress, which requires advanced electronic data to be shared with CBP, which should assist their inspection and targeting efforts.40 The Chamber also works collaboratively with CBP and USPS to improve real-time information sharing and enhance efficiencies at international mail facilities. We ask USTR to urge our trading partners to do their part.

Voluntary Agreements

Combating criminal activity in the online ecosystem requires more than simply enforcing laws and IP provisions in free trade agreements (FTAs); education about the potential risks to consumers and companies conducting e-commerce, use of best practices, and adherence to voluntary agreements between companies and organizations operating in the online environment are effective deterrents that should be considered as complementarily strategies to help limit online infringement.

39. HM Revenue and Customs. www.hmrc.gov.uk

40. Synthetics Trafficking and Overdose Prevention Act. (“STOP Act”; P.L. 115-271; Title VIII, Subtitle A)
Governments, businesses, and all relevant stakeholders should support strategies that promote an environment of accountability and the benefits of reasonable steps across industry sectors to restrict the use of their services by criminals operating in the online environment. Voluntary agreements—such as the EU’s 2016 MoU between platforms and rightsholders or Brazil’s Guide to Best Practices to Combat Counterfeits Online, published in December 2019—can play a role in reducing IP theft online, support legitimate commerce, and protect consumers.\footnote{European Commission. “Memorandum of Understanding on the sale of counterfeit goods via the internet.” (May 2011). \url{https://ec.europa.eu/growth/industry/intellectual-property/enforcement/memorandum-understanding-sale-counterfeit-goods-internet_en}}\footnote{Government of Brazil. “Boas práticas e orientações para a implementação de medidas de combate à pirataria nas plataformas de comércio online.” (December 2019). \url{https://www.mattosfilho.com.br/Documents/Guia%20pirataria%20come%CC%81rcio%20eletro%CC%82nico%20%20-%20v.%203.pdf}} Numerous factors affect effective enforcement efforts in the online environment, but stakeholders can still voluntarily adopt best practices to help fight counterfeit goods, including by:

- **Requiring**—upfront screening and authentication of potential vendors, screening for high-risk profiles, and banning repeat offenders.
- **Empowering**—consumers with clear labels and accurate information about a product—including whether it’s authenticated—and its seller.
- **Thinking**—about the role of shipping, distribution, and fulfillment in the spread of counterfeit goods and associated responsibilities.
- **Sharing**—information with rightsholders.

Already, payment processors and advertisers have collaborated and entered into various voluntary agreements with rights-holders to address threats from online IP crime while respecting the need to maintain a free, open, and safe internet. Some e-commerce platforms and search engines have taken steps to address the problems as well. The Chamber supports the continued progress of these partnerships.
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. While Australia has taken steps to strengthen its IP framework, 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.

IP Index

Australia’s overall score has decreased from 80.13% (36.06 out of 45) of the total possible score in the seventh edition of the Index to 79.62% (39.81 out of 50) in the eighth edition. This was a reflection of Australia’s overall mixed performance on the new indicators added to the Index.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, Australia scores 6th out of the 20 economies benchmarked, receiving 71.36% of the overall score (with a score of 11.42 out of 16.00). While Australia scores among the top economies overall in the Barometer, several sector-specific regulations, enumerated below, limit the availability of the newest innovative and creative goods.
Patents and related rights

Patent Linkage and Market-Sized Damages

The Australian patent linkage system is derived from Article 17.10.4 of the 2004 U.S.-Australia Free-Trade Agreement (AUSFTA). However, several elements of the Australian system could be strengthened in order to effectively protect life sciences innovators in Australia. 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).

Additionally, 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). Instead, a certification option is available, which does not require notification to the patentee. In turn, patent holders are informed only after the follow-on products have been approved. As noted above, the most effective patent linkage mechanisms include a window of notice prior to the generic’s entry into the market. To ensure that the linkage framework in Australia balances the protection for life sciences innovators with the entry of generic medicines, the Australian government could introduce a sufficient period of notice to enable the innovator to defend its patent prior to generic entry. However, in spring of 2019, the Australian government conducted a transparency consultation on reforms to the generic medicine market authorization process. Specifically, the government solicited feedback on whether to create a notification period prior to generic entry into the marketplace. While the results of the consultation have not yet been released, the Chamber believes the creation of a notification mechanism will increase transparency, improve legal certainty for innovators and generics alike, and reduce the need for infringement litigation.
In addition to the absence of an effective notice procedure, the uneven penalty structure, and the lack of automatic stay, commercial pressures further undermine legal certainty. Specifically, because Australia’s Pharmaceutical Benefit Scheme (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 policy sends a troubling signal that IP protection can be undermined in an effort to drive down pharmaceutical prices. This weakens Australia’s attractiveness for biomedical foreign direct investment.

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. In January 2005, the Australian government amended the TGA to bring the law into compliance with the terms of the AUSFTA. However, amendments to the TGA under sections 26B(1)(a), 26C, and 26D allowed the government to seek these market-size damages to reimburse the PBS when a company pursues unsuccessful patent enforcement. In a letter from then-U.S. Trade Representative Robert Zoellick to Australian Trade Minister Mark Vaile in 2004, Zoellick states that the “U.S. reserves its rights to challenge the consistency of these amendments with such obligations.” Given that these amendments appear to be inconsistent with the letter of the AUSFTA, the Chamber requests that the Office of the U.S. Trade Representative (USTR) utilize its rights under the AUSFTA to challenge the legitimacy of the amendments and work with the Australian government to identify a legislative fix that will prohibit the government from pursuing these damages. At a minimum, the Chamber believes the introduction of a 12-month notification period as an amendment to the TGA would bring Australia into compliance with its AUSFTA obligations and reduce the need for legal action over patents. The Chamber

encourages USTR to prioritize the market-size damages policy and the need for an appropriate notification period to ensure a fair and predictable market for biopharmaceutical investors in Australia.

Of further concern in the litigation arena is that there appears to be a recent shift in the Australian courts negatively impacting patent holders as to injunctions. In a recent decision, *Sanofi-Aventis v. Deutschland GmbH v. Alphapharm Pty Ltd (No 3)(2019) FCAFC 28*, the Full Court upheld a decision denying a preliminary injunction in part on the basis that it is more difficult to calculate the patentees losses than the accused infringers losses. A major shift, injunctions are now less likely to be granted due to the perception that it is more difficult to calculate potential losses for a challenger than to calculate patentee’s losses. The Chamber encourages injunctive relief assessments which are based on the facts of each specific case and not adopt the default position that is would be more difficult to calculate patentee’s potential losses.

Finally, Australia’s system lacks a patent register analogous to the Orange Book in the U.S. In a framework in which there is neither actual nor constructive notice of the existence of patents relevant to the reference product, the risk of experiencing a patent dispute is even higher. Australia’s mechanisms would be strengthened through the creation of a patent register, which could reduce the likelihood of patent infringement proceedings and contribute to a more effective linkage system. The Chamber encourages USTR to continue to work with their Australian government counterparts to create a more robust and effective linkage system in Australia, which will help bolster Australia’s innovative industry, attract greater biopharmaceutical foreign direct investment, and support Australia’s economic and global competitiveness.

**Intellectual Property Laws Amendment Bill**

In July 2019, the Australian Senate introduced the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Bill 2019. The Bill contains provisions that are of concern to IP-intensive industries operating in Australia. The Bill currently proposes replacing 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

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44 Ibid; https://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/1216_ems_2d30b94a-4f04-46e8-bbe4-4be1c39bad05/upload_pdf/712877em.pdf;fileType=application%2Fpdf
“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.

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. For these reasons, the Chamber encourages the U.S. government to work with their Australian government counterpart 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.

https://parlinfo.aph.gov.au/parlInfo/download/legislation/ems/s1216_em_2d30b94a-4f04-46e8-bbe4-4be4e39bad05/upload_pdf/712877em.pdf;fileType=application%2Fpdf
Yet there is still room for improvement. Evidence submitted by the Australian Film and TV Bodies earlier this year 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 would like to suggest 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.

**Commercialization of IP Assets and Market Access**

**Reimbursement and Listing Uncertainty**

Innovative industries operating in Australia continue to face a number of market access barriers, such as difficulty and uncertainty in listing new medicines on the PBS. For new medicines, navigating the regulatory framework of market authorization and reimbursement remains complex. This is compounded by the unofficial “offset” policy that every dollar spent on new medicines must be counterbalanced by an equivalent offset saving, determined in advance, from within the health budget. The pricing and
reimbursement system’s strong focus on cost containment comes at the expense of access to the newest 21st century medicines. For example, Australian patients had access to only 42% of the 55 global oncology products available within two years of global launch, compared to 84% in the United States and 75% in Germany. Additionally, between 2012 and 2017, 46% of all drugs registered in Australia were reimbursed, but reimbursement took an average of 426 days, compared to 89 in Japan and 117 in Germany. The Chamber recommends that the U.S. government encourage the Australian government to streamline the process for listing new medicines on the PBS 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. The Chamber recommends that the Australian government limit the use of local content requirements for creative works from around the world be more readily, legally available in Australia.

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. The United States-Mexico-Canada Agreement (USMCA) IP chapter created an opportunity to harmonize and strengthen IP protection across the region in many areas. However, the final agreement removed or omitted many IP provisions that would have strengthened the environment for innovators and creators in Canada. Notably, the 10-year term of regulatory data protection for biologics was removed and obligations on secondary liability were noticeably absent from the agreement altogether. And under Article 32.6 of the agreement, Canada’s cultural industries receive an exception—a template that should never be invoked nor replicated in future trade agreements. Any cultural exception threatens to significantly limit the availability of U.S. copyrighted content in the Canadian marketplace.

Given the missed opportunity the USMCA created to raise the bar for IP protection in Canada, the Chamber believe it is even more important that the U.S. government work closely with its Canadian government counterparts to address the remaining challenges outlined below.

IP Index

Canada’s overall score has increased substantially from 66.4% (29.88 out of 45) in the seventh edition to 72.86% (36.43 out of 50) in the eighth edition. This reflects Canada’s overall strong performance on the new indicators added.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, Canada scores 8th out of the 20 economies benchmarked, receiving 67.65% of the overall score (with a score of 10.82 out of 16.00). While Canada scores in the top half of the Barometer, certain sector-specific regulations limit the availability of the newest innovative and creative goods.
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.47

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.48

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, 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 sets a timeline for the submission of CSP applications based on the regulatory status of a given product in a set of “prescribed economies.”

The net effect is that the availability of a CSP is made contingent on early market entry. Equally troublingly, the law also contains an 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. 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**

**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 335 and 1.2 billion 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 artists’ songs for just 0.15 and albums for $1.50 each) and audiovisual content streamer *B9good.com* (tailored for the Japanese market)
locate their servers or proxies in Canada. Fortunately, 2019 saw the shutting down of three major (and popular) infringers in Canada: Vader Streams, Openload.co, and Streamango. First came the August 2019 injunction by the Canadian Federal Court against Vader Streams, one of the world’s most prolific IPTV piracy networks. Using the open-source software Kodi used to support many piracy devices, Vader Streams offered unauthorized access to a library of nearly 2,400 movies, 350 television shows, and 1,300 live television channels. It was reported that the service provided pirated content to nearly 200 other providers and 8 million subscribers. Then, in October 2019, the Alliance for Creativity and Entertainment (ACE) announced a successful enforcement action against Openload.co, and Streamango, which agreed to cease operations. These two sites were, according to ACE, “providing content to 72% of the top 50 illegal video streaming and linking sites in the world.”

Although the Chamber welcomes these positive developments, pirate sites will continue to evolve if adequate deterrents are not established. The U.S. government should commit to greater engagement with the government of Canada to discourage copyright infringement, or support for their activities in other ways, on the internet.

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.

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,


   https://www.accesscopyright.ca/media/1106/access_copyright_report.pdf
and clarification of the educational fair dealing exception. The Chamber appreciates this second look at the 2012 Copyright Act amendments and hopes the Canadian government will continue the frank discussion about the environment for rightsholders in the country. 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.

**Trade secrets and related rights**

**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.”

The Chamber encourages the U.S. government to work the Canadian government to ensure that Canada is sufficiently respecting the rights of American IP owners through its domestic pricing policies.

CHILE

Overview

As a result of its OECD membership, “very high” human development index score (0.847 in 2019—the highest in Latin America), and stable economic growth, Chile has increasingly become an attractive destination in the region for investment. Despite its presence among the world’s richest countries, however, the country’s IP framework is marred by holes akin to those seen in developing countries. Worse still, many of these outstanding IP issues were addressed long ago in the country’s 2004 free trade agreement with the United States and remain unimplemented by the government. These outstanding obligations could undermine the country’s ability to attract long-term foreign-direct investment and hamper the growth of domestic innovation and creative industries. The Chamber encourages the U.S. government to work closely with the Chilean government to ensure that Chile implements its FTA commitments and address outstanding gaps in IP protection in order to align the IP framework with that of its OECD counterparts.

IP Index

Chile’s overall score has increased from 44.37% (19.97 out of 45) in the seventh edition to 45.64% (22.82 out of 50) in the eighth edition. This reflects a relatively strong performance on the new indicators added to the Index.

Patents and related rights

Compulsory Licensing

The Chilean government is currently considering multiple pieces of legislation to expand the basis for compulsory license applications, which would significantly undermine the environment for life sciences innovation in Chile. First, the Chilean Congress is considering Bill 12.135-03, which includes several troublesome 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, in October 2019, President Piñera urged the Chilean Congress to approve the pending 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 considerably limits the right to use a registered trademark in a way that is inconsistent with Chilean and international law.

Furthermore, Members of Congress have continued pressuring the government to use compulsory licenses as a cost-containment tool—unilaterally declaring Hepatitis C a “public emergency” in 2018/19 to allow for INAPI-issued compulsory licenses on Hepatitis C medicines. Although a formal compulsory license has not been issued, utilizing cost to support such a proposal is not a relevant justification for compulsory licensing under the TRIPS agreement. 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 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 solely be aimed at protecting public health. In addition, Article 31 and the Doha Declaration suggests 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.
The Chamber strongly encourages the U.S. government to work closely with the Chilean government to ensure that compulsory licenses are only used in extraordinary circumstances to respond to public health emergencies, rather than address budgeting short-falls.

**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.

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.\(^5\) 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-

\(^5\) Law 19.039 (Chile) art. 89; Supreme Decree No. 107/08, Dec. 1, 2010.
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.

**Copyrights and related rights**

**Online Piracy**

Despite its high level of economic development, copyright infringement remains a major challenge in Chile. By means of example, *Cinecalidad.to*, a regional piracy website linking to more than 2,000 movies and television series, is the 27th most popular website in the country by Alexa rank. It is worth noting that *Cinecalidad.to* clocked a higher Alexa ranking than the much larger—and now shut down, thanks to a high-profile INTERPOL investigation—*Pelispedia.tv/Pelisplus.tv* group of sites, which ranked at 82nd and 215th in 2018, respectively. It’s 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. The rate of unlicensed software use in 2017—55%, some $238 million worth—is also 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 Chile loses some $93 million from signal theft. 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.

56. Law 19,039 (Chile) art. 91; Supreme Decree No. 107/08, Dec. 1, 2010 (Chile)


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 create ineffective protection for the creative industry in Chile. 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 and civil ex parte inspections are often undermined by a requirement that investigation requests be submitted and publicly available on an online database. Despite the well-intentioned attempt at transparency, this type of disclosure can sabotage the authorities’ ability to perform an effective search.

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 vacuum continues 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. Because of this, industry reports that circumvention devices are widely available online and in brick-and-mortar marketplaces.

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 cause for concern. Because of this, the Chamber notes that the commercialization of Pay-
TV signals has continued in Chile—severely affecting the Pay-TV and content industries. We ask the U.S. government to engage constructively with the Chilean government to address this issue.

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**

In October 2019 Chile’s Chamber of Deputies gave its approval, in a first legislative stage, to a bill adding a chapter on screen quotas to law N° 19.981 on Audiovisual Promotion. This bill 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. This proposal, which remains active in the legislature, appears to contravene Chile’s bilateral FTA commitments.

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59. Bill 11867-24 (Chile), July 3, 2018 (Chile)  
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.”⁶⁰ The Chamber wishes to thank the U.S. and EU delegations for their hard work and supports continued—if not more frequent and continuous—bilateral engagement on IPR issues. 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 recent passage of an “export and stockpiling waiver” to Supplementary Protection Certificates (SPCs). These developments present enormous challenges for U.S. businesses.

IP Index

The lion’s share of European nations ranks toward the top of The Index, and even outranks the U.S. in some respects, but this positive momentum will halt or even backslide if certain IP-degrading initiatives are fully realized. While the EU (and its member states) generally maintain intellectual property (IP) protections that enable the research and development of innovative products, the Chamber is concerned by the potential future direction of an ongoing European Commission (EC) review of IP incentives for innovative biopharmaceuticals, which could result in weakening of IP rights in one of the world’s largest markets. Changes finalized during 2019 to the patent term extension mechanism (supplementary protection certificates (SPC)) sent a negative signal about the EU’s view of IP and pharmaceuticals and suggest there could be further negative policies under consideration as part of the broader EU incentives review taking place in the comings years.

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Barometer

In addition, as is made very clear by the Chamber’s *Innovation and Creativity Access Barometer*, European citizens’ ability to access the latest creative and innovative products is seriously hampered by government mandated content quotas for creative products as well as price controls for innovative medicines which prioritize short term costs cuttings over the appropriate valuing of innovation.

Patents and related rights

**EU Incentives Review and Orphan Medicinal Products**

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. However, the Chamber is concerned that this review could result in the weakening of existing incentive mechanisms for biopharmaceutical innovation and create an unlevel playing field for transatlantic medicines trade and investment.

In 2015, under the overarching initiative to reform and deepen the single market with the purpose of spurring economic growth in the EU, the European Commission announced its intentions to explore options for recalibrating certain elements of patent term restoration for biopharmaceuticals, so-called Supplementary Protection Certificates (SPCs). One option for change put forth by the Commission was to provide European manufacturers of generic drugs and biosimilars with an SPC manufacturing and export exemption (‘SPC exemption’). The overriding purpose of the proposal was to provide European manufacturers of generic drugs and biosimilars a competitive advantage by weakening IP protection for innovators. The underlying logic of the Commission’s proposal was highly dubious, and the claims of economic gains were subsequently questioned by several studies. Furthermore, economic modelling suggested that, in fact, the proposed policy was likely to have a negative impact on the research-based industry.

However, in 2019 the EU finalized changes to its legislation amending the EU’s patent term restoration mechanism, to introduce an SPC export and stockpiling waiver (in force as of 1 July 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 stockpiling 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.

More broadly, instead of allowing European generic manufacturers to gain a competitive advantage it is much more likely that over time other economies will emulate the EU and also introduce policies that undermine biopharmaceutical IP protection. In fact, the obvious response to the EU SPC exemption is other economies asking themselves: “If the European Union is weakening IP standards to benefit their domestic industries why shouldn’t we do the same?” Overall, instead of benefiting the European generics industry the SPC exemption is likely to hurt Europe’s research-based industry and lead to a global race towards the bottom in weakening global IP standards. Indeed, this has been recognized by several key EU Member States.

In addition to the SPC manufacturing waiver, the Chamber is also concerned with the pending review of the regulations concerning orphan and pediatric medicinal products and associated IP incentives. While regular reviews are important, changes to the existing incentives’ framework are unlikely to address any affordability or access issues in the healthcare system. Post-adoption in 2000, the EU Orphan Regulations have proven successful in driving investments and boosting research in the field of rare diseases, resulting in significant increases in approvals of orphan medicines in Europe. Any adverse reforms resulting in IP protections’ erosion would tip the current balance and further undermine the rationale for future private sector investment in innovative medicines in European markets. On the contrary, reforms should introduce targeted incentives to address unmet needs, such as in the areas of AMR and pediatric rare diseases.
Copyrights and related rights

General Data Protection Regulation (GDPR)

The EU’s GDPR, which went into effect in May 2018, significantly affects American companies of all sizes and sectors operating in the European market. American companies have spent the last two years coming into compliance with this new regulation, yet significant uncertainty in its implementation and enforcement remains. This regulation affects the WHOIS database maintained by ICANN by limiting the personal information that domain name registries and registrars can provide in order to be compliant with GDPR’s heightened level of privacy by default. This effectively requires them to change their delivery of public WHOIS or face stiff fines and possible litigation. The WHOIS database provides valuable information on registrants of most top-level domains and serves as an essential tool in investigating online violations and abuses. If registrars put this data behind a privacy firewall because of the GDPR, law enforcement, cybersecurity professionals, brand-protection representatives, and others could lose continued access to this key resource. Ensuring that legitimate players have continued access to this data in order to protect consumers and to protect against illegal activity online is critical.
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. 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, over the last three years, 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 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.

IP Index

Japan’s overall score has increased from 87.73% (39.48 out of 45) in the seventh edition to 90.40% (45.20 out of 50) in the eighth edition. This reflects a strong performance on the new indicators added to the Index and an increase in score on indicators 10 and 15.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, Japan scores 3rd out of the 20 economies benchmarked, receiving 82.19% of the overall score (with a score of 13.15 out of 16.00).
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 business’s 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. The Japanese government intends to move from the current biennial price revision system to an annual revision system. There have also been additional recent changes to the pricing rules, such as “optimal use guidelines,” which has been imposed suddenly and without meaningful stakeholder involvement by the Japanese government. Moreover, Japan must eliminate the *Tokurei Kakudai Saisantei* (special expansion re-pricing or huge-seller penalty), which cuts the price of a product purely on the ground that its sales have far exceeded the sales originally projected. This significantly penalizes and undervalues breakthrough therapies in an attempt to manage budget impact. Such actions 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 has 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 a poorly 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.
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 and the fact that they increasingly do not recognize a reasonable return of fair value for innovation. The Chamber encourages the U.S. government to engage its Japanese counterparts at the earliest opportunity -- including through the next stage of trade talks -- to bring about a greater appreciation by the government of Japan to play its part in supporting global R&D on innovative medicines and to ensure, at the very least, that U.S. business has an opportunity to contribute its views on any new policy reforms in this area.
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.

IP Index

The Republic of Korea’s overall score has increased from 80.13% (36.06 out of 45) in the seventh edition to 82.20% (41.10 out of 50) in the eighth edition. This reflects a relatively strong performance on the new indicators added to the Index and score increases on indicators 24 and 35.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, the Republic of Korea scores 10th out of the 20 economies benchmarked, receiving 49.26% of the overall score (with a score of 7.88 out of 16.00).
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 policy in an effort to obtain deep price cuts from U.S. patent holders that local firms were unable to achieve through commercial negotiations. For instance, a 2017 decision by the Korean Fair Trade Commission (KFTC) took an unprecedented and dangerous global approach 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.
SWITZERLAND

Overview

Despite Switzerland’s strong overall score on the The Index, the Chamber would like to call the U.S. government’s attention to the now well-established registered companies, computer servers, torrents, and cyberlockers based in Switzerland. From 2018 to 2019, industry reports that this concentration of sheltered, illegal activity has flourished: cyberlockers like Uploaded.net (owned by Swiss company Cyando AG) and Uptobox.com (owned by Swiss company Upworld Genius) continue to flagrantly profit from the sale of “subscriptions” and advertising to view copyright-infringing content; torrent site 1337x.to, despite blocking orders in eleven countries, received 52 million visits from 6.8 unique visitors in summer 2019; and hosting providers with servers in Switzerland, such as the familiar Private Layer and newcomer Network Dedicated SAS, continue to ignore infringement notices from rightsholders. By spurning a growing global best practice for Internet Service Providers to block access to infringing websites, the Swiss government will continue to drift further afield of its international intellectual property obligations explained in detail below.

IP Index

Switzerland’s overall score has increased from 82.77% of the total possible score (37.25 out of 45) in the seventh edition to 85.34% (42.67 out of 50) in the eighth edition. This was driven by a strong performance on the new indicators added to the Index and a score increase on Indicator 31.
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 we have not seen any substantive changes to Swiss policy toward copyright over the last year. Indeed, difficulties faced by U.S. (and other) rights-holders to exploit and protect their copyrighted works go back well before 2016. Swiss ratification of the 1996 WIPO Treaties did not take place until 2008. The implementing legislation is substandard in comparison to that of EU member states and other national laws in developed countries around the world. Leaving aside the enforcement problems faced by rights-holders, the Swiss approach to copyright law undervalues the sanctity of exclusive rights and contractual freedom, which is in marked contrast to Swiss policy on other mechanisms to protect IP, such as through patents and trademarks. The Swiss government’s failure to protect rights-holders includes broad exceptions which fail to pass the widely recognized Berne Convention’s three-step test. Some of the most glaring examples for the audiovisual sector are:

- A private copy exception which extends to copies made from illegal sources\(^{61}\)
- 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

Rather than address these issues, pending legislation in Switzerland introduced in Parliament in late 2017 will only exacerbate them and further usurp the exclusive rights and contractual freedoms of rights-holders. While certain aspects of the draft amendments provide positive and welcome changes, such as an increased term of protection to match that offered elsewhere, they also contain a number of troubling provisions. Moreover, the draft amendments omit important and much-needed protections. In particular, the government persists in its position that individual downloads from illegal sources are not

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\(^{61}\) This assertion is expressly supported by the European Court of Justice holding in *ACI Adam BV and Others v Stichting de Thuiskopie and Stichting Onderhandelingen Thuiskopie vergoeding*, Case C-435/12, ECLI:EU:C:2014:254
themselves actionable.\textsuperscript{62} And while the draft offers one isolated enforcement instrument (a stay-down duty for certain hosting providers), it leaves large parts of Switzerland’s enforcement deficit unresolved (including by not providing for an access-blocking mechanism or a legal basis for obtaining injunctions against intermediaries). It also introduces a troubling collective management remuneration right for video on demand (VoD) that will interfere with industry practice, including in the music industry, as well as a retransmission exception for hotels and similar entities that ignores Berne rules on remuneration.

The government’s dispatch and public comments on the draft appear to demonstrate an unwillingness to address either of these two key issues, siding with Internet Service Provider (ISP) preferences against enforcement needs. Moreover, 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.

The Chamber urges the U.S. government to work with Swiss authorities to increase their efforts to address online piracy, and to encourage the government of Switzerland to revise the proposed draft amendments to the Copyright Act to bring it in line with the TRIPS requirements, including by providing a site-blocking mechanism.

Section D: China

Overview

The U.S. Chamber of Commerce and its member companies have long been and remain committed to mutually beneficial U.S.-China economic and commercial relations. We continue to work closely with the government of China on a full suite of issues, including improving the protection and enforcement of intellectual property rights (IPR) across a broad range of IP policy concerns on behalf of our diverse membership.

Over the years, the Chinese government has acknowledged a need to bolster its protection of IPR, and has made efforts to implement reforms on institutional reorganization and proposed legislative reforms, although the net effect is yet to be seen. In November 2019, the General Office of the Communist Party of China (CPC) Central Committee and the State Council issued the new IP Policy Roadmap, which reads that strengthening IPR protection is the biggest incentive to boost China’s economic competitiveness. The IP Policy Roadmap reiterates strong intention to reform key areas of interest to our members, such as pharmaceutical IP protection, live sport broadcast, bad faith trademark, and anti-counterfeiting, although key measures and concrete actions are somewhat short of expectations.

In 2018, China carried out a significant government restructuring, including reorganizing and consolidating IP authorities and enforcement power. The State Intellectual Property Office (SIPO), State Administration of Industry and Commerce (SAIC) and Administration for Quality Supervision, Inspection and Quarantine (AQISQ) are combined into the State Administration for Market Regulation (SAMR), working as the unified national authority for the administration of trademarks, patents and geographical indications. In the end of 2019, China started to practice the new amended Trademark Law. Starting from the end of 2018, China began reviewing a new version of the patent law amendment and is expected to restart the copyright law amendment. Moreover, we recognize Chinese IP judges’ efforts to increase damage awards and implement various judiciary reforms, including setting up the IP Court of the Supreme People’s Court (SPC), establishing eighteen additional specialized IP tribunals since 2017, and creating Internet Courts in Beijing, Guangzhou and Hangzhou. China’s continued efforts aimed at accepting amicus-type submissions, developing a case database system, and curating its guiding case system are all positive signs for the judicial protection of IPR in China. However, counterfeiting and

piracy in China remain at epidemic levels, particularly in the online environment, as shown by the fact that the Office of the U.S. Trade Representative (USTR) has re-integrated Taobao.com on the Notorious Market List. Enforcement efforts have continued at a similar pace in the last few years, yet counterfeits sourced in China are increasing instead of decreasing. Physical counterfeiting accounts for the equivalent of 12.5% of China’s exports of goods and over 1.5% of its gross domestic product (GDP). Consequently, it is estimated that 72% of counterfeit goods in circulation in three of the world’s largest markets for such products, namely the EU, Japan, and the U.S., have been exported from China. New, popular online platforms in China are reportedly inundated with counterfeiting and piracy as well. No genuine efforts to restructure the counterfeit manufacturing sector in China have been offered. The benefits of such efforts would protect consumers and stimulate long-term economic growth in China and around the world.

At the same time, a lack of sufficient IP protection and difficulty prosecuting IP infringements are top IP challenges for foreign companies operating in China. According to the American Chamber of Commerce 2018 Business Climate Survey, over half of respondents continue to feel that IP leakage and information technology (IT) and data security threats are greater in China than in other regions where they operate.

In addition to the challenges posed by IP laws and enforcement, foreign companies must navigate an overall regulatory environment that is increasingly shaped by industrial policy priorities, deal with inconsistent regulation and enforcement and unfair treatment by government policies, and contend with enforcement relative to local companies, especially in strategic and technological sectors. These issues are long-standing, and the Chamber, in particular the Chamber’s China Center, has been forthright in expressing our serious concerns regarding a range of Chinese government policies and practices that restrict access to its market, condition participation in the market on technology transfer, and broadly seek to undermine the value of IP held by American companies.

The ongoing trade negotiations between the U.S. and China regarding long-standing concerns about IP protection and technology transfer provide an opportunity for our two countries to address and resolve systemic challenges that keep us from realizing the full potential of bilateral trade and commercial


65. Ibid.
relations. Despite some positive—albeit incremental—changes in China, we continue to advocate for bold reforms that will result in meaningful changes for foreign companies.

**IP Index**

China’s overall score increased from 47.67% (21.45 out of 45) in the seventh edition to 50.96% (25.48 out of 50) in the eighth edition. This reflects, on the one hand, a mixed performance on the new indicators added to the Index, a score decrease on Indicator 5, but, on the other hand, score increases on indicators 19, 23, 26, 27 and 29.

**Barometer**

In the Chamber’s 2019 *Innovation and Creativity Access Barometer*, China scores 19th out of the 20 economies benchmarked, receiving 6.70% of the overall score (with a score of 1.07 out of 16.00).

**Innovation and Industrial Policy**

**Overview**

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. In the proceeding sections, our submission highlights the laws, regulations, and standards with an IP nexus that are of particular concern to American industry in China.
Cybersecurity and National Security

China Cybersecurity Review Regimes

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.

Draft Measures for Data Security Management

On May 28, 2019, the Draft Measures for Data Security Management (the Draft Measures), formulated by the Cyberspace Administration of China (“CAC”) together with relevant departments, was issued for public comments. Applying to all network operators, the draft provides detailed implementing rules for data security, specifically calling for the protection of “personal information” and “important data,” vaguely defined terms which are used seemingly interchangeably in Chapters II and III of the text.
Critically, the Draft Measures broadly require all network operators to obtain regulatory approval (regardless of MLPS level) before transferring “important data” overseas.

If a network operator collects “important data” or “sensitive personal information” for the purpose of operation, the Draft Measures require that said operator register with the local cyberspace affairs department. The content of registration includes data collection and use rules, purpose, scale, mode, scope, type, and term of data collection and use. The definition of the term “purpose of operation” is not clearly defined in the draft. While network operators are not required to register data content itself, Article 36 broadly requires that network operators provide all data requested by the government for the purpose of “national security, social management, economic control, and other functions and duties.” In practice, these measures establish a wide-ranging scope for data regulation that will impose very high administrative burdens on both businesses and regulatory authorities. In addition, the Article 26 requirement to route “domestic user” data flows “in-country” when accessing the “domestic internet” is functionally unrealistic and threatens to render the use of VPNs illegal.

According to the Draft Measures, before releasing, sharing, trading or offering important data to a third party, network operators must evaluate the possible security risks and report to the competent regulatory authorities for approval. If companies are not sure about the industry regulator, they should go to the provincial cyberspace administration agency for approval.

**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).
Draft Measures for the Security Assessment of Cross-Border Personal Information Transfers

Released by the CAC for public comment on June 13, 2019, the Draft Measures require all network operators transferring personal information (PI) overseas to submit to pre-transfer security assessments and provincial CAC approval (Art. 2), a requirement inconsistent with the Cybersecurity Law, which provided that only “critical information infrastructure operators” (“CIIOs”) be subject to security assessments. The Draft Measures also contain a requirement to provide third-party beneficiary rights to individual PI subjects, which would enable individuals to bring direct claims against PI recipients (Art. 13). The procedural costs of complying with the Art. 2 requirement for pre-transfer security assessments and provincial CAC approval could overwhelm both businesses and regulators alike, forcing companies to either localize data processing operations in China or limit investment due to excessive compliance costs. The Art. 13 requirement to provide third-party beneficiary rights to PI subjects exceeds most international standards—including GDPR—and its requirement to provide provincial CAC authorities with copies of contracts signed with data recipients would risk disclosing proprietary details.

Cloud Computing Service Security Assessment Measures

Released on July 22 by the CAC, NDRC, MIIT, and MOF, the Assessment Measures establish security assessment procedures for cloud services suppliers to party/state agencies or to CIIOs, and create a new office within CAC to coordinate security assessments to be conducted by outside technical organizations. The Assessment Measures emphasize “security and controllability”—including the security of a cloud platform’s service supply chain (Art. 3)—which cloud service providers are expected to self-assess and provide in report form to CAC (Art. 6). CAC will conduct spot-checks and request reports in order to conduct “continuous supervision” of cloud platforms that have passed their initial assessment, with an emphasis on supervising issues such as “effectiveness, major changes, emergency response, and risk management of relevant security control measures.” (Art. 13). Despite the positive inclusion of a provision designed to protect IP (Art. 16), the fact that the Assessment Measures are grounded in the politicized concept of “security and controllability” threatens to punish companies that rely on complex global supply chains. Additionally, Art. 13 will increase compliance burdens on companies, as well as challenge the working capacity of regulatory authorities.
Industrial Policy and Patent Licensing

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 looks forward to engaging the Chinese government on these recently released revision, and intends to submit comments by the end of January 2020.

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.66

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.67 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 propose 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.

As part of our ongoing work to track China’s implementation of the AML and provide input to the Chinese government regarding U.S. practices in the field, the Chamber has provided detailed comments on a number of regulations, rules, and guidelines, including:

**IP Abuse Rules**

- In May 2013 and April 2014, respectively, on SAIC’s draft *Rules on the Prohibition of Abuses of Intellectual Property Rights for the Purposes of Eliminating or Restricting Competition* (draft rules). 68

**IP Abuse Guidelines**

- In December 2012 on SAIC’s unofficial draft of its *Intellectual Property Rights Enforcement Guidelines under the Anti-Monopoly Law* (draft guidelines).
- In September 2015, on the National Development Reform Commission’s questionnaire on the proposed *Antitrust Guidelines against Abuse of Intellectual Property*.
- In February 2016 on the National Development Reform Commission draft *Antitrust Guidelines against Abuse of Intellectual Property*.
- In February 2016 on SAIC’s draft *Antitrust Guidelines against Abuse of Intellectual Property*.

68. The U.S. Chamber of Commerce submitted comments to SAIC on the draft Guidelines on Anti-Monopoly Law Enforcement of IPR. [http://image.uschamber.com/lib/feed13797d6c06/m/1/Chamber+Comments+on+SAIC+AML+IP+Abuse+Nov++2012.CH+EN.pdf](http://image.uschamber.com/lib/feed13797d6c06/m/1/Chamber+Comments+on+SAIC+AML+IP+Abuse+Nov++2012.CH+EN.pdf)

The multiple editions of the drafts, many of which were made public to the local and global legal community, attracted rounds of discussions and submissions among professional groups and government agencies. The most recent draft guidelines continued to raise serious concern among industry regarding provisions that would impose anti-monopoly sanctions on refusal to license and excessive pricing, as well as provisions that provide for an expansive “essential facilities doctrine.”

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 is 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.

**Technology Transfer and The U.S.-China Phase I Trade Agreement**

The U.S.-China Phase I Trade Agreement contains many 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.
The fact that these commitments have been explicitly codified in the Phase I Agreement is promising, and demonstrates China’s eagerness to demonstrate progress on this issue. 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 I 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 begins to implement its Phase I 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. 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.

http://www.mofcom.gov.cn/article/b/g/201904/20190402855130.shtml

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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, which 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 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, may 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. 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. 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 draft Export Control Law—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.  

**The Standardization Law**

The latest revision to the Standardization Law expands on a public disclosure requirement that is both unique to China and potentially damaging to all market participants, and would add unnecessary costs and risks for all enterprises in China. Furthermore, a newly added and deeply concerning article stipulates state endorsement of incorporating indigenously innovated technology into industry and social standards. Combined with other implementation documents and public statements that allow social standards to be transposed to become national and industry standards, the inclusion by the state of a preference for indigenous innovation (i.e., domestic Chinese IP) seems to create a trade barrier that would conflict with the WTO Technical Barriers to Trade.

**Other Policies and Trends that Impact IP and Innovation**

**2019 IP Policy Roadmap**

In this roadmap document, the Chinese government continues to emphasize the importance of a well-functioning IP system in six aspects, including strengthening IPR protections, compliance measures, improving enforcement coordination, facilitating the international cooperation/communication, and reinforcing capacity building.

The Roadmap calls for strengthening IPR protection through the criminal justice system, and emphasizes the protection of trade secrets, confidential business information, and source code. By

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73. The U.S. Chamber of Commerce and the American Chamber of Commerce in China. “Joint Comments to the National People’s Congress on the Draft Revisions on the Standardization Law.” (September 2017)


http://www.npc.gov.cn/npc/flcazqyj/2017-09/04/content_2028318.htm
improving the revision of criminal laws and judicial interpretations, China will further strengthen criminal IP enforcement, lower the standard of proof to secure a criminal conviction, increase sentencing, and improve the procedure for disposing of seized/confiscated goods. The legislature will discuss the necessity and feasibility of fundamental IP legislation, and further improve the Patent Law, Trademark Law, Copyright Law and laws related to geographical indications. The Roadmap also calls for speeding up the introduction of a punitive compensation system for infringements of patents and copyrights. Additionally, the Roadmap refers to exploring the establishment of a patent linkage and patent term restoration system. Finally the Roadmap states that China will research the enhancement of protection of live sports broadcasting and promote the application of an electronic notarization mechanism. All these three specific reforms are squeezed into a paragraph that lacks details about which agency will be responsible for implementation.

The Roadmap encourages the introduction of a technical investigator system into IP administrative enforcement cases and judicial activities, which could assist administrative and judicial departments in effectively evaluating technical facts. The document also calls for the improvement of courts’ infringement appraisal and damage assessment capacity, as well as advancing the professionalism of appraisal institutions.

Finally, the Roadmap stipulates a compliance system to ensure local governments take serious efforts to strengthen IP enforcement. IPR enforcement will become a performance measure for reviewing local party committee and government effectiveness, as well as reviewing the business environment evaluation system.

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 Competiveness, that, among other things, aim to strengthen indigenous innovation, IP, and brands.
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 slated to come online. 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 an algorithmic scoring system based on government-determined criteria. 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”\(^\text{75}\);

• **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.

Of particular concern, all data will be processed using basic infrastructure provided by Huawei, algorithms controlled by Huawei and Alibaba, and databases established and managed by Alibaba, Tencent, and Taiji Computer. Additionally, video surveillance data collected by VisionVera will be integrated into the system. 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.

**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.\(^\text{76}\) 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

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\(^{75}\) 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.

\(^{76}\) 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).
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.

**Patenting in Strategic Technologies**

In addition to the difficulties of protecting and enforcing legal claims on IP in China, U.S. companies have been hindered in even obtaining patents—potentially for discriminatory reasons. New research finds that foreign patent applicants in technical fields that are of strategic importance to China are less likely to be approved than local applicants. This finding indicates that Chinese industrial policies permeate the decision-making processes throughout China’s regulatory system and suggests a potential violation of national treatment principles.

**Remuneration**

China’s position on service invention remuneration is unclear. The latest draft patent 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.

**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 restrictions.


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. The Chamber urges China to address concerns that have been raised.

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 from all walks of life in recent years. The Regulations on the Management of Human Genetic Resources were officially announced and 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 shall be jointly

Rule of Law

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 U.S.-China Phase I 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 I Agreement, in 2019 the CCP began rolling out a number of provisions similar to commitments made in Phase I when it released the Implementation Opinions on Strengthening the Reform and Innovation of Intellectual Property Trials,80 aiming to further improve Beijing’s IP judicial protection system. 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 citing precedents from the 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.” 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. 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).

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.

In 2019, the SPC’s IP Court opened its first circuit trial at the SPC's Third Circuit Court in Nanjing, eastern China's Jiangsu Province. Circuit trials, designed to make judicial decisions more expedient and accessible, are also expected to gradually strengthen and standardize overall judicial expertise.

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. 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.

**Partial judgments**

In February 2019, the Shanghai Intellectual Property Court (SIPC) rendered a so-called partial or interlocutory judgment during a patent infringement lawsuit filed by the French automotive parts manufacturer Valeo against three Chinese defendants. It’s said that this is the first time the SIPC has made such a partial judgment for an IP case. A partial judgment can be a good thing to try for applicable cases where IP ownership or infringement may be easily concluded based on the available facts and evidence, particularly if the plaintiff seeks quick deterrents as well as the leverage to negotiate a satisfactory settlement. It can be a viable approach to save time, efforts and costs for both the parties and the courts.

**Electronic Evidence**

In 2019, the Jiangsu High Court issued a guidance for recognition of evidence collected or preserved by timestamp, blockchain, and other devices, or obtained with remote login control realized with Telnet commands. For further context on evidence collection issues, civil court proceedings before Chinese courts have generally allowed very limited evidence disclosure. The litigants usually have to do their own investigation and evidence preservation before filing the case. Chinese courts impose strict requirements on acceptable forms of evidence. Normally, any digital evidence needs to be notarized by a Chinese public notary in order to be allowed as evidence. In this regard, notarization provides verification of the integrity of digital evidence. However, in most instances notarization has proven to be disproportionately costly, especially for cases where the amount of damages is relatively small. Nevertheless, the recently concluded Phase I Agreement provides that, in civil judicial procedures, formalities such as obtaining a consular official’s seal or chop shall not be required in order to authenticate evidence. According to Article 1.30: “For evidence that cannot be introduced or authenticated through stipulation, or witness testimony under penalty of perjury, China shall streamline notarization and authentication procedures.” It is our hope that these commitments do much to ease the process of evidence authentication and disclosure for foreign litigants in Chinese courts.

The 2019 guidelines issued by the Jiangsu High Court would likely extend the use of blockchain evidence, previously only considered acceptable for use by specialized internet courts. In practice, all
courts in Jiangsu province would follow the guidelines when hearing IP cases. The recognition of blockchain forensics may speed up evidence collection and lower costs for foreign companies.

**Patents and related rights**

**Patent Protection and Enforcement**

The latest version of the draft of the Patent Law amendment was released for public comments on January 4, 2019 and a February 3, 2019 deadline for the Chinese legislature to accept public comments. Compared to the earlier version, the draft has eliminated some provisions that generated intense discussions, e.g., rules related to administrative enforcement on repeated infringement matters, some special rules on service invention, and secondary infringement etc. As mentioned above, the draft has introduced a new provision on patent term extension for innovative pharmaceutical drugs, among other notable points. Highlights of the changes are as follows:

- Article 6 of the Draft relates to service invention. The new rules seem to intend to give more freedom to employers to handle employees’ service inventions. It is made clear that the employer is entitled to deal with the right to file a patent and the subsequent patent rights (if granted) for any service invention under law.

- Article 20 of the Draft adds a new broad rule against patent abuse, which stipulates that “The applying of a patent and exercising of patent rights shall abide by the principle of good faith. Abuse of patents shall not be allowed to harm public interests and others’ lawful rights and interests or to exclude or restrict competition.”

- Article 43 extends the patent term of design patent to 15 years. The Article also stipulates patent term extension for pharmaceutical inventions.

- Article 50-51 stipulates a system of “open license” for patents. Under this system, a patent owner may publish the licensing royalty rates and a potential licensee can take on the license based on such terms by written notice.

- Article 70 of the Draft provides the patent enforcement powers by the CNIPA and its local patent offices.

- Article 72 of the Draft provides one to five times punitive damages for willful infringement. But the issue of willful infringement is not addressed.
One of the primary concerns in the latest proposed amendment to the Patent Law pertains to the expansion of the remedial powers of local administrative agencies. Local intellectual property offices may be empowered to impose injunctive relief, damages, fines, and penalties for patent infringement, powers previously limited to the more experienced judicial authorities. We believe the courts—and not the patent administration agencies—are the best vehicle for the efficient and effective adjudication of patent disputes. The Chamber urges continued close monitoring by USTR in this regard. This proposed dual system of enforcement will increase litigation and costs and will produce conflicts with judicial actions. In addition, there is potential for increased assertion of low- or no-quality patents by domestic entities to disrupt foreign-owned patent holders and options for such entities to forum-shop for the most attractive venue. This will greatly increase the potential for abuse by patent holders that seek not just appropriate compensation, but to harass and burden competitors and impede their competitiveness and innovation capabilities in China.

China’s current Patent Law was implemented in 1985, and was revised three times in 1992, 2000 and 2008. Given the fact that the last round of Patent Law amendments happened about 11 years ago, the Chamber hopes that the revisions may include more meaningful changes to the Chinese patent system.

New Policies for Innovative Drugs

In April 2018, the State Council adopted a series of measures to enhance IP protection of innovative drugs, involving the exemption of cancer drugs from customs duties; the expedition and optimization of the process for authorization on the commercialization of imported innovative drugs; and enhancement of IP protection, such as a six-year maximum data exclusivity period for innovative drugs and a maximum of five years’ compensation of patent term that will be offered for innovative new drugs applied for commercialization on domestic and overseas markets simultaneously. In January 2019, the latest version of the draft of the patent law amendment released for public comments. The proposed rule in the draft also states that “The State Council may make a decision to extend the duration of the innovative pharmaceutical patents that are synchronously applied for market launch in China and abroad, to make up the time used for drug approval”. The draft language seems to require lots of clarifications, but in general it should be beneficial to innovative pharmaceutical companies.

Protection of the Graphical User Interfaces (GUI)

In November 2019, the Guidelines for Patent Examination were revised. The revisions of the Guidelines amendments incorporate the product name, view submission, and brief description of content
in the product design review specification of the GUI into the new section of the Guidelines. The requirements for submitting views are also further simplified.

**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.

**New Policy of Patent Invalidation Proceedings**

The Guidelines for Patent Examination revised in November 2019 introduced a new policy of patent invalidation proceedings. If the requester submits multiple prior art documents and indicates two or more ways of prior art combination, one major combination shall be indicated for examination by the panel. If such a major combination is not indicated, the first combination of prior art will be considered as the main combination.

**Patent Linkage**

In 2017, the Chamber applauded China, namely the China Food and Drug Administration (CFDA), for its recent major breakthrough in calling for the adoption of a patent linkage system. The Chamber has been making substantial efforts to promote the economic benefits of a patent linkage system in the past few years, and we are pleased that China is moving toward establishment of such a regime via the May 2017 CFDA circulars and the October 2017 joint State Council/CPC opinion. On Oct. 8, 2017, the General Office of the CPC Central Committee and the General Office of the State Council jointly proposed exploring the patent linkage system, carrying out a pilot program for patent term extension and improving the regulatory data protection system. In May 2017, the CFDA published Policies On Encouraging The Innovation Of Drug Medical Devices To Protect Innovators’ Rights (Circular No. 55), proposing the establishment of a patent linkage system. According to the Circular, a drug applicant should disclose relevant patent information that the applicant knows or should know about when filing an application for drug registration, and the applicant should notify the patentee within 20 days if the drug applicant is going to challenge the innovative drug’s patents. If the patentee believes that its patent is
infringed, it should file a patent infringement lawsuit within 20 days from receiving the notice, and the CFDA may set a stay period of up to 24 months to stay the drug approval. Once the settlement is reached or an effective decision is made by the court within the stay period, the CFDA may approve or disapprove the drug registration. Otherwise, the CFDA may approve the drug registration once the stay period expires. We are supportive of the intensifying efforts of the CFDA and various other ministries in setting up the patent linkage system. It will be in the best interest of China and U.S. industries if China closely consults with the innovative pharmaceutical industries and experts with sufficient expertise in formulating the rules.

Despite those efforts, patent linkage was not referenced in the draft of the Patent Law amendment cleared by the State Council in December 2018, which was submitted to the NPC Standing Committee for review and was released for public comments in January 2019. An earlier State Council notice in August 2018 on deepening reform in China’s medical sector also omitted any reference to patent linkage. Though the latest version of the draft of Patent Law amendment fails to introduce rules to enable the patent linkage system, the General Office of the Central Committee of the CPC and the General Office of the State Council printed and issued the Opinions on Strengthening Intellectual Property Protection in November 2019, which again indicated that China will explore the establishment of patent linkage system. The Chamber looks forward to the implementation of an effective patent linkage system in China and encourages the U.S. government to push China to add patent linkage language to the draft amendment of the Patent Law.

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 (now CNIPA) 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 U.S.-China Phase I 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.” 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 SIPO (now 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 (now CNIPA) officially permitted patent examiners to conduct patent searches to examine novelty of utility model application and design patent applications. The change of practice reportedly has led to numerous rejections issued by SIPO (now CNIPA) 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. 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


83. 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)
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.\(^{84}\) 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.

**Acceleration of the Review of Patent Applications**

The State Council’s executive meeting decided on July 19, 2019 that China will shorten the time required for reviewing applications of high-value patents and for trademark registrations as part of its effort to strengthen the protection of intellectual property rights and improve the business climate. The goal is to shorten the time needed for reviewing applications of high-value patents to within 17.5 months, and the average review period for trademark registration to within five months, by year's end. Smart systems of patent examination and trademark registration will be developed at a faster pace. As the Chinese government works to accelerate the pace of patent application reviews, however, it is imperative that the professional quality of patent examinations and reviews is not compromised in the process.

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Copyrights and related rights

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.\(^8\) 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

\(^8\) 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-ifynnsc4222799.shtml
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.

Copyright Law Amendments

China started a new round of comment collection for the amendments to its Copyright Law in 2018. The Chamber appreciated the work of the NCAC on earlier versions of these amendments and was pleased to have the opportunity to submit comments on those drafts. These amendments are an important opportunity for China to modernize and streamline its copyright system. Copyright law has been placed on tier one of the legislative agenda from 2018 to 2023. In 2019, a couple of Chinese officials have revealed that the amendments shall be approved soon in the coming year, according to the media. Given the importance of the legislation, the Chamber encourages China to expedite the legislative process. It is critically important that China’s copyright law move forward in solving the problems of administration and enforcement that have been identified by domestic and foreign rights-holders alike. This is especially true in the online environment, where China has made significant strides in recent years.
In particular, while the amendment process is pending, we urge China to use the SPC’s advisory opinions and official records of the legislature to document the consensus on some of the areas worthy of special attention, e.g., the copyrightability of live broadcasts of sports programming. China is now giving significant priority to sports industry development as part of its new round of economic reform. The government is deregulating the industry and is also trying to give more policy incentives to encourage more investment from the private sector. The lack of strong IP protection in this sector must be addressed urgently, especially considering the coming Beijing 2022 Winter Olympics. At present, the exact ways live broadcasts should be protected in China are unclear among policymakers, courts, and legal professionals. Some judges and scholars disapprove or doubt the copyrightability of live sports programming or believe it should be protected under the general legal principles of unfair competition law, while some scholars argue that live sports programming should be protected as “cinematographic works and works created by means similar to cinematography.” The highly regarded decision made by the Chaoyang District Court in Beijing—which recognized the copyrightability of live sports broadcasts in a ruling relating to the Chinese soccer league—has been overturned by the Beijing IP Court. Following that decision, Beijing First Intermediate People’s Court also ruled against the copyrightability of live sports broadcasts of NBA games, which obviously copied the reasoning of Beijing IP Court. The case has been appealed to Beijing Higher People’s Court, but the final decision has been pending for now. Hope is detectable in the Guideline for Trial of Copyright Infringement Cases issued by Beijing Higher People’s Court in April 2018, which expressly indicated that “sports broadcasts shall be protected by copyright law if it meets the requirement of works created by means similar to cinematography.” The issue of live sports broadcasting is briefly addressed in China’s recently released IP Policy Roadmap, which simply states that China will research the enhancement of protecting live sports broadcasting, without making any promises. It is suspected that this reference might have been included as a head nod to ongoing bilateral talks, with China wanting to send a positive signal on this issue.

Notably, the draft amendment of the Copyright Law proposes a new category of audiovisual works, which represents a potentially promising development. However, proposed legislative changes have had no immediate impact. The Chamber urges the U.S. government to closely engage China in addressing legal protection for live broadcasts through various channels.

Criminal Code Revision

The recent rounds of amendments to the criminal code led by the National People’s Congress Standing Committee in the last few years completely ignored IP issues. This is very disappointing. China must realize the importance of clarifying a number of issues in the current code, which include the use of
pirated business software that can be deemed a criminal offence; the “for-profit” requirement to pursue criminal liability against distributors of pirated works; reducing thresholds for criminal liability; and the application to online infringements, in which context the evidence needed to prove a certain threshold of violation is difficult, if not impossible, to obtain. Pre-installation of pirated software on personal computers has been a major reason for the rampant piracy of business software in China—where it is estimated that 66% of the software used is unlicensed. Chinese authorities are generally under the impression that the for-profit requirement is not met where software is installed for no additional cost. Pending amendment of the criminal code, the Chamber urges the SPC and Supreme People’s Procuratorate (SPP) to clarify that any pre-installation of pirated software by vendors of hardware may be deemed a criminal violation.

**Liability Thresholds**

The unclear schedule for work toward the IP amendment of the PRC Criminal Code’s provisions has frustrated the vast majority of police investigations into IP theft and functions as an enormous loophole, which is routinely exploited by infringers. A critical step in changing the IP environment in China is dependent upon amending the law to reduce liability thresholds for counterfeiting and piracy.

**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. 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. 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.

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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. 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, 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, and issuing penalties for sellers of counterfeit goods.

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 I 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 counterfeilers 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**

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. The Chamber hopes that USTR will encourage the Chinese legislature to approve such changes in the final text of the Patent Law.

**Trade secrets and related rights**

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 2019.

**Legislative Changes**

The General Rules of Civil Law (GRCL), adopted on March 15, 2017, includes trade secrets as the object of IP rights, and stipulates that rights-holders enjoy the proprietary right on trade secrets with civil rights and remedies. Following GRCL, the newly revised AUCL with respect to trade secret protection was issued and came into effect on April 23, 2019. The improved protection of trade secret through the new amendments to AUCL is quite encouraging.

The amendments expand the definition of trade secrets from “technical information and business information” to “commercial information such as technical information and business information”. The amendments recognize that trade secrets worthy legal protection are not limited to technical information (know-how in manufacturing process or formula etc.) and business information (customer list etc.). Some business information, e.g., stock option plan, have high commercial value to companies and should also be protected. The new amendments, while not listing out the specifics, leave some room for courts or administrative authorities to expand the coverage of trade secrets.

A significant change in the amendment is that more acts of trade secret infringement are now covered. Trade secret infringement acts under the current Anti-Unfair Competition Law includes the
following: (a) acquiring trade secrets through stealing, bribery, fraud or coercion or other illegal means; (b) disclosing, using or allowing others to use the trade secrets acquired in aforementioned paragraph; (c) disclosing, using or allowing others to use the trade secrets under a party’s control in violation of the agreements that this party is subject to or in violations of requirements of protection trade secrets imposed by the right holders. In addition to the above, the current law also holds a third party liable for acquiring, disclosing, using or allowing others to use trade secrets of the right holders when this third party knows or should have known the employees or ex-employees of the right holders or other entities or individuals have committed the illegal acts to infringe the trade secret under this law.

The amendments expand the scope of infringement acts in three ways. First, the amendment now provides that obtaining trade secret through electronic intrusion is also counted as trade secrets infringement. Second, clarify the agreements that may be violated by the infringers are duty of confidentiality. Third, China now recognizes secondary infringement, including inducement and contributory acts, in the context of breaching the duty of confidentiality or other requirements. All such new rules substantially expand the scope of what counts as stealing trade secrets.

To large extent the current law limits who may be liable for trade secret theft to competitors. Third parties are held liable only when they know or should have known the employees or ex-employees of the right holders or other entities or individuals have committed the illegal acts to infringe the trade secret. This means those third parties who may claim to “bona fide third party” may get away from legal liabilities. The new amendments get rid of this loophole. The amendments now explicitly provide that a party who are individuals, legal person or business organizations may all be held liable for trade secret infringement under this law.

The amendments introduce the concept of willful infringement into trade secret protection and impose punitive damages up to 5 times the actual loss of the rights owners or illegal profits gained by the infringers. The amendments also raise the cap of statutory damages to 5 million RMB from 3 million RMB. The administrative fine is raised up to 1 million RMB for normal infringement and up to 5 million RMB in serious cases. It is worth noting that the statutory cap for compensation and administrative fine had just been raised in the last amendment to Anti-Unfair Competition Law, which took effect as of January 1, 2018. The continued increase of liabilities shows a firm standing towards trade secret protection and should have more deterrent effect.

The most promising part of the amendments is that they adopt the new rule of shifting the burden of proof in the context of trade secret litigation. First, regarding the proof of trade secrets, the
amendments allow that the trade secret rights holder to present prima facie evidence that it has taken confidential measures to protect the asserted trade secret and reasonably establishes that the trade secret has been infringed. Then the accused infringer must prove that the trade secret claimed by the right holder does not fall within the scope of trade secret under this law. It appears that the amendment no longer requires the plaintiff to take extra efforts to prove the commercial value and secrecy of a trade secret, which are among the legal tests of what counts as a trade secret under the current law. The defendant would have to provide evidence to rebut. Second, regarding the proof of trade secret infringement, the amendments provide that, if the trade secret rights holder provides prima facie evidence to prove that the asserted trade secret is infringed and proves one of the following: 1) There is evidence that the alleged infringer had access to or had opportunity to obtain the trade secret and that the information used by the alleged infringer is substantially the same as the asserted trade secret, or 2) There is evidence that the trade secret has been disclosed, used or there is a risk of being disclosed or used by the infringer; or 3) There is other evidence to prove that trade secrets have been infringed by the alleged infringer, then the defendant must prove that they did not conduct any trade secret infringement.

The ultimate use of the trade secret and the venue where relief is pursued affects the ability to recover. Even if a trade secret misappropriation is actionable, proving it is extremely difficult. There is no discovery available, and oral testimony carries little weight. Original written evidence is critical but difficult to obtain. Often, the best way to secure evidence is through criminal prosecution, though trade secret owners have little sway in the decision to pursue a criminal case. Before the implementation of new amendments to AUCL, many courts required the trade secret owner to prove that the trade secret was not in the public domain, which generally requires the use of external experts who must submit a written document detailing the trade secret. The new burden of proof provision of AUCL no longer requires the plaintiff to take extra efforts to prove that the trade secret is not in the public domain, provided that there is prima facie evidence that it has taken confidential measures to protect the asserted trade secrets and reasonably establishes that the trade secret has been infringed. This is a notable development. The Chamber looks forward to seeing breakthrough results in practice.

In criminal cases, theft is determined not by the conduct itself, but by the consequences of the loss. Article 219 of the Criminal Law and relevant judicial opinions, as well as economic crime prosecution guidelines, require a loss by the trade secret owner or illegal profit by the misappropriator
valuing at least 500,000 RMB (about $75,000).\textsuperscript{88} Providing the required proof to initiate a criminal investigation can be difficult, if not impossible. Even if an investigation is successful, the misappropriator is generally imprisoned for less than three years, a punishment which provides limited deterrence.\textsuperscript{89}

Unfortunately, China’s courts still lack effective measures to prevent the leakage of evidence presented during civil enforcement. Therefore, the act of seeking relief can actually exacerbate the damage, and plaintiffs are often forced to withdraw their civil cases.\textsuperscript{90} Even if it makes sense to pursue civil enforcement, the damage may continue until the case is finally adjudicated. Currently, the deployment of preliminary injunctions to bar the use of trade secrets, while available, is exceedingly rare. In part, the unwillingness of foreign companies to use preliminary injunctions for this purpose has been due to the tremendously high burden of proof discussed above. However, Article 1.6 (2) of the U.S.-China Phase I Agreement provides that 'China shall identify the use or attempted use of claimed trade secret information as an 'urgent situation' that provides its judicial authorities the authority to order the grant of a preliminary injunction based on the specific facts and circumstances of a case.' We urge the U.S. government to ensure that this commitment is fully enforced, thereby enabling trade secret owners to use preliminary injunctions to prevent the use of stolen trade secrets before they have lost their value.\textsuperscript{91}

In November 2016, the Asia-Pacific Economic Cooperation (APEC), whose membership includes China, endorsed a set of best practices aimed at strengthening enforcement against trade secrets misappropriation. The U.S. should hold China accountable to upgrade its trade secret regime in line with the identified best practices.

\textsuperscript{88} Bankruptcy by the trade secret owner is also sufficient.

\textsuperscript{89} Losses great than 2.5 million RMB (about $375,000) qualify for longer prison terms.

\textsuperscript{90} See discussion above considering service inventions where trade secret owners may be forced into court by employees seeking greater levels of compensation by their employers.

\textsuperscript{91} Less than 1% of all IP cases in China get a preliminary injunction. This is even more difficult to achieve in trade secret cases.
Regulatory Data Protection

Though, formally, China provides a six-year term of RDP for small-molecule medicines, the scope of RDP remains at once ambiguous and narrow. On the one hand, both the Drug Administration Law and the Drug Registration Regulation lack a clear definition of a new chemical ingredient and what constitutes unfair commercial use of clinical data. China’s recent steps announcing an intention to increase these standards in May 2017 (Circular 55) has provided positive momentum. For example, the Circular proposes longer terms of data protection, including six years of data protection for biologics, orphan drugs, and pediatric drugs. The draft of *Pharmaceutical Data Exclusivity Implementing Rules (provisional)* released in April 2018 for public comments. The draft proposed six-year data protection for innovative new drugs, and innovative therapeutic biologics are eligible for 12-year data protection, even longer than the 10 years in the Circular. While the Chamber applauds the Chinese government for these proposed improvements, it is critical that China move forward to implement this proposal. More importantly, it is critical that these proposals be implemented in a way that values innovation and does not discriminate against U.S. companies. Proposals to limit these new protections to products that are “new to the world” rather than “new to China” would discriminate against U.S. companies and dramatically limit the benefit of proposed IP protections. However, although the draft of *Pharmaceutical Data Exclusivity Implementing Rules (provisional)* has completed the process for public comments for more than one year, it is still not officially passed and issued.
**Enforcement**

**Restructuring the Counterfeit Economy in China**

U.S.-China Phase I 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, if properly enforced, will help turn the tide on the flood of counterfeits made in China and sent around the world. While we highly anticipate the upcoming release of China’s Phase I IPR Enforcement Plan (as promised in the text of the Phase I Agreement), we believe that China’s leadership could further reform this sector of its economy by calling for its restructuring in China’s next 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.

**Size of the Problem and the Next Phase of the OECD’s Counterfeiting Study**

Two studies were released in 2016 which make clear that counterfeiting is a global epidemic, and that China remains the largest source of such illicit products. In April 2016, OECD’s *Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact* revealed that counterfeiting levels have doubled since
2005, totaling $461 billion of global trade.\(^2\) For the study, OECD collected data from customs offices in the EU and U.S., and the research team is ready to continue to mine the data to map the cross-border flows. The U.S. government should support and provide funding for the next phase of OECD’s counterfeiting study. This additional analysis is integral to devising effective anti-counterfeiting enforcement programs in the U.S., China, and countries around the world.

Counterfeiting and piracy in China remain at epidemic levels, particularly in the online environment. In another study, *Measuring the Magnitude of Global Counterfeiting*, among the 38 economies studied, China and Hong Kong are responsible for 86% of the global supply of counterfeit goods, with the next largest supplier at less than 1%. China and Hong Kong produce an estimated $396.5 billion of counterfeit goods each year.

**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 China Food and Drug Administration (CFDA) 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

\(^2\) The OECD’s report, based on 2013 trade figures, estimates that international trade in counterfeit and pirated goods make up 2.5% of global trade, representing $461 billion. This represents a value over double the OECD’s previous estimate of $200 billion based on 2005 trade flows.
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”.

The revisions to the Drug Administration Law are promising, the Chamber looks forward to the practical effect of the newly revised law. 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. 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. 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). 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. 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 police officers in the IP crime unit. 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. The Chamber highly encourages USTR to underscore to China the need for more innovative measures to promote cooperation between

96. 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
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 I 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

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months of the Agreement taking effect. The Chamber highly anticipates China’s forthcoming quarterly updates on enforcement actions, as stipulated in the Phase I 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. 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.

Some of our members reported a decrease in self-initiated inspections conducted by customs in 2016. According to the white paper published by the General Administration of Customs, in 2017 there was a slight increase, but the number was still lower than in 2015. A noticeable change is the types of goods inspected by customs. In 2016, customs seized nearly 1.4 million drugs, a figure 37 times higher than that of 2015. However, that number in 2017 was 20,772, a 98.51% decrease. Furthermore, only limited customs cases are shared with the Public Security Bureau for criminal investigations. In 2016, customs only provided clues to around 200 cases to the Public Security Bureau among 19,500 cases.

99. Ibid. Similar data was not mentioned in the white paper of 2017. The white paper of 2018 is not available at the time of this writing.
Section E: Developing Market Profiles

ARGENTINA

Overview

Despite its advanced socio-economic development, highly-ranked universities, and skilled labor pool, gaps in Argentina’s IP framework have limited the ways the country can capitalize on these characteristics to power its economic growth and global competitiveness. Of the concerns raised in detail below, at its core are localization, reimbursement and local content policies. In addition, Argentina’s legal framework doesn’t adequately protect the interests of innovative industries and the inefficiencies of the system create uncertainty around legal property rights. And fueled by the reluctance of customs authorities and weak information sharing, large-scale infringements of IP continue to thrive. A recent report from the Cámara Argentina de Comercio, for instance, found that the number of street stalls selling counterfeit goods has increased by 114% since October 2019. 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 sustainable economic growth, business investment, and workforce development.

IP Index

Argentina’s overall score has increased from 33.24% (14.96 out of 45) in the seventh edition of the Index to 35.74% (17.87 out of 50) in the eighth edition. This reflects a mixed performance on the new indicators added.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, Argentina scores 14th out of the 20 economies benchmarked, receiving 35.00% of the overall score (with a score of 5.25 out of 16.00).

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 solace 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 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 sponsored by former Senate Provisional President Federico Pinedo (PRO) for the “Regulation of Internet Service Providers and Internet Content Search Engines,” that would have significantly restricted industry’s online enforcement capabilities.

Specifically, the bill provided an overly broad safe harbor for a non-exhaustive list of service providers and required a court order for a service provider to remove infringing content. The Chamber notes that a court order would invariably involve a lengthy judicial process—making it difficult to stop the infringement of live content, which requires immediate action to be effective. Case in point: it wouldn’t do much good to have a court order for removal some weeks or months after a 90-minute soccer match has ended. Additionally, the bill had no provision for ISPs to cooperate with rightsholders in combating now-widespread copyright infringement in Argentina.

Although bill S-942/16 lost parliamentary status, it is likely that similar initiatives will resurface in some form in 2020, 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.

Penal Code Reform

Since 1921, seventeen attempts have been made to reform Argentina’s Penal Code. In June 2019, the Minister of Justice and Human Rights sent a new Penal Code Bill (PE-52/19) to the Congress. The bill includes a provision to make the theft of IP equivalent to the theft of physical objects and to make the incorrect reporting of Pay-TV subscriber numbers a penalty under the law. The bill also specifically addresses aspects of audiovisual content piracy in the following ways:

- Penalizing the use of any physical or virtual support to “communicate, distribute, retransmit and make available to the public, in any way and by any mean, a broadcast.”
- Penalizing the action of making available, storing, hosting, reproducing or distributing such broadcastings.
• Penalizing the use of technological measures included in electronic devices or carrier signals, destined to restrict or avoid the reproduction, public communication, distribution, transmission or availability of such broadcastings.

• Penalizing internet service providers who, having effective knowledge of the lack of authorization for the above acts, continue allowing the use of its system for the commission of such conduct.

As the bill awaits debate at the Senate's Justice and Penal Affairs Committee, the Chamber notes that this effort would be a significant tool to combat piracy in Argentina.

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 (the National Film and Audiovisual Arts Institute) published Resolution 1050/2018—requiring that 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. And while that 30% content quota was in effect previously, under the prior regulatory regime the screen could be shared with another film. Under the current regulation, should the exhibitor share the screen with another movie, the local production must be shown for two weeks, or until the quota is fulfilled. Also in July 2018, ENACOM (Argentina’s National Communications Agency) announced via Resolution 4513 that a 30%
local content quota would be enforced on free-to-air TV in urban areas (10-15% for lesser populated markets). Content quotas are widely expected to remain an issue in 2020, the Chamber encourages the U.S. government to closely monitor this issue, as audiovisual content quotas could become a damaging trend.

**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. Furthermore, 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.
BRAZIL

Overview

Brazil, like many other developing economies, is beginning to understand the importance of an innovation-led growth model. As a corollary, there is also a growing recognition of the fundamental link between IP and innovation in recent years. The Chamber is encouraged by the work undertaken under the National Institute of Industrial Property (INPI) to improve Brazil’s IP system by addressing lengthy backlogs and instituting a spirit of apolitical technical evaluation, and its willingness to engage with industry to solve problems. We are encouraged by the adoption of a technology-neutral Patent Prosecution Highway in 2019 which is limited in numbers but does appear to be the next step toward a fulsome PPH. Similarly, in Brazil important changes were introduced to improve the institutional capacity of the national IP system. Brazil also adopted the Madrid Protocol, as announced by Brazil’s Minister of Industry, Foreign Trade and Services in 2019 and has showed interested in a series of additional IP-related treaties.

2019 also saw the creation of a new coordinating body charged by President Bolsonaro to coordinate and oversee all issues relating to IP policy. Decree 9,931 established the Interministerial Group on Intellectual Property, GIPI (Grupo Interministerial de Propriedade Intelectual). The group consists of representatives from all major agencies within the government, including the Ministry of Justice, and is chaired by the Ministry of Economy. The Decree states that the purpose of the GIPI is to “promote the cohesion of actions, programs, projects and initiatives of public bodies and entities with competences related to the intellectual property theme”. Article 1 (VI) gives the group the power to hold consultations with and include representatives from the private sector and civil society in the policy-making process. Given the stark challenges facing rights-holders in Brazil with respect to the enforcement environment, the creation of the GIPI should lead to a renewed focus on coordination of enforcement activities within the Brazilian government. Historically, anti-piracy activities have been coordinated by the National Council to Combat Piracy and Crimes against Intellectual Property (CNCP), established in 2005. The council included representatives from both public and private sector.

IP reform is still needed to help assure investors that their innovations will be adequately safeguarded in a market that presents a tremendous long-term investment opportunity. In order to further support efforts in Brazil to improve the IP regime and to further reiterate the importance of robust IP protections to the growing bilateral relationship.
IP Index

Brazil’s overall score has increased from 40.55% (18.25 out of 45) in the seventh edition to 42.52% (21.26 out of 50) in the eighth edition. This reflects a mixed performance on many of the new indicators added to the Index, but score increases on indicators 2, 36 and 39.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, Brazil scores 12th out of the 20 economies benchmarked, receiving 40.43% of the overall score (with a score of 6.47 out of 16.00).

Patents and related rights

Patentability and Dual Examination

Brazil has been long-known for having of standards of patentability well outside 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. In 2017, an Interagency Ordinance sought to correct this by limiting ANVISA’s role in patent examinations to situations of “severe risk to public health.” In fall 2018 INPI approved, over the objections of ANVISA, a patent for Hepatitis C drug sofosbuvir. But a few days later, a then-candidate in Brazil’s Presidential election filed a lawsuit with the Brazilian Federal Court, alleging that approval of the patent would raise costs for patients. As the Court reviewed the case, the patent was suspended. Although patent protection for sofosbuvir was eventually granted by the Court, the Chamber notes that Brazil’s Federal Prosecutor’s office has issued a formal challenge to the 2017 Ordinance and is pending review. The Chamber encourages 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.
Backlog and Review Delays

As noted in previous editions of the Index, the Brazilian Patent Office (INPI) has a long-standing backlog of patent applications ranging from 10-13 years depending on the field of technology—with applications in the biopharmaceutical and ICT fields traditionally being the most affected. The last few years have seen a growing level of commitment from INPI to address this backlog.

In 2019, for instance, a new INPI initiative was announced: the “Backlog Fight Plan” (Plano de Combate ao Backlog de Patentes). This initiative will be implemented through two new departmental administrative resolutions, INPI PR 240/2019 and INPI PR 241/2019. Both resolutions seek to accelerate the decision-making and patent prosecution process both for applications with existing prior art searches and documentation, and those without. Under two new “preliminary office actions” (Orders 6.21 and 6.22) the response time for preliminary action has been limited to 90 days. The INPI’s goal is to reduce the existing patent application backlog substantially by 2021; and reduce the average patent prosecution timeline to around two years. At the time of research these administrative changes had only begun to be implemented and it was not possible to assess their effectiveness. The Chamber supports the recent INPI initiatives and looks forward to collaborating with the U.S. government and INPI on further programs to address the patent backlog. We also note that Brazil’s July 2019 ratification of the Madrid Protocol on International Marks could help further reduce backlogs. The Madrid System entered into force in Brazil on October 2, 2019.101

More broadly, the new government led by President Jair Bolsonaro has taken substantive action in opening the Brazilian economy, improving public administration, and reducing bureaucracy. In 2019 the President signed into law the “Declaration of Rights of Economic Freedom” (Law No 13,874 2019) to elevate the right to free enterprise and economic activity as a guiding principle for the federal government. For example, article 3 of the Declaration inserts a requirement that any business or applicant requesting an action by a public entity—such as the issuing of a license to operate, permit or certification—should be immediately informed of the maximum time such an action will take. Failure of the public entity to act within the stated timeframe will automatically result in the approval of the applied for action. For IP rights-holders—both patents and for other registerable IP rights—this has the potential to provide a substantially higher level of clarity and certainty with how relevant Brazilian authorities will

deal with future applications and decision timelines. These actions, independently and in aggregate, have improved the overall environment for patent rights-holders in Brazil.

**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. As a specific example, on March 26, 2018, Brazil’s Ministry of Health (MoH) approved two administrative appeals for PDP proposals for lenalidomide filed by state-owned enterprises FUNED and TECPAR, along with Indian company Natco. It is important to note that INPI granted a patent to Celgene’s Revlimid drug in December 2017—the very first patent application for lenalidomide—that is valid until 2027. 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 Celgene’s 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 Reform**

In July 2019, the Ministry of Citizenship launched a public consultation to amend Brazil’s 1998 Copyright Law. The Chamber believes that this could be an opportunity for targeted changes to account for shifts in business and technology in 20 years. We also strongly support the continued reaffirmation of international norms for copyright, such as the Berne Convention and TRIPS Agreement, in any such consultation.

**Online Piracy and Enforcement**

The past year saw increased efforts by Brazilian law enforcement to tackle online copyright piracy. Historically, criminal enforcement against IP infringement had been lacking. Worse still, there are long backlogs in the Brazilian justice system and the majority of those arrested on suspicion of criminal IP infringement never face criminal charges or prosecution, with charges either dropped or suspended. In 2019 this changed with the launch of “Operation Copyright”, a new initiative by the Brazilian Federal Police to tackle copyright piracy. Reports suggest that the police took coordinated action in five Brazilian states, shutting down torrent sites and seizing equipment and suspected goods. In November 2019, CNCP and the Secretariat of Integrated Operations (Secretaría de Operações Integradas, SEOPI) coordinated Operation 404, which resulted in 30 search warrants in 12 different Brazilian States aimed at online piracy. This resulted in 210 infringing websites and 100 infringing apps taken down, the delisting and profile removals of the sites, and three people arrested in São Paulo. We encourage SEOPI to continue this type of operation, which would help Brazil reach a much higher standard in terms of IPR enforcement.

The Chamber also encourages 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. 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. 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 recommends that the U.S. government collaborate with Brazilian government colleagues to ensure that previously successful initiatives, like those of the CNCP, have the resources and local government support to more effectively combat all forms of copyright piracy throughout Brazil. We would like to draw attention, in particular, to the Ministry of Justice’s December 2019 best practices guide to fighting piracy online. Furthermore, we encourage Brazil to enact pending legislation authorizing court orders requiring internet service providers (ISPs) to block access to offshore websites dedicated to criminal activity, including criminal copyright infringement, and pending legislation to criminalize signal theft in the home entertainment sector. In addition, we encourage the Brazilian government to align its copyright standards with international best practices by acceding to the WIPO Internet Treaties.

**Unlicensed software use**

The rate of software piracy in Brazil has slowly decreased from 53% in 2011 to 46% in 2017—placing the use of unlicensed software in 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.

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https://www.mattosfilho.com.br/Documents/Guia%20pirataria%20come%CC%81rcio%20eletrC3%81%CC%82nico%20%20-%20v.%203.pdf
Trademarks and related rights

Trademark Registrations and Industrial Designs

The Chamber applauds INPI’s efforts to facilitate design patent and trademark registrations by hiring examiners and making IT investments. 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. 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. Brazil also adopted the Madrid Protocol, as announced by Brazil’s Minister of Industry, Foreign Trade and Services in 2019.

Trademark Enforcement

Most of the counterfeit footwear sold in Brazil is manufactured in the city of Nova Serrana, in the state of Minas Gerais. The city remains the biggest producer of counterfeited products and receives fiscal incentives from the Brazilian government. In fact, products originating in Nova Serrana are currently being exported abroad, and there were seizures of Brazilian products by Brazilian customs.

The Chamber also notes recent effort by the City Hall of São Paulo in coordination with Customs, Federal Revenue (DIREP), and State Police to better enforce against trademark enforcement in downtown São Paulo. Thanks to this effort, the taskforce has seized tons of counterfeit products and is pushing to close and maintain closed several centers of distribution of counterfeit products. To maintain the momentum, the Chamber recommends that the National Congress approve Bill 333/1999, which would bring criminal penalties and fines for trademark infringement in line with those already established for copyright infringement, for example. Bill 333/1999 also allows for the ex officio seizure and destruction of infringing goods—no doubt a major advancement in Brazil’s enforcement regime.
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 the audiovisual, music, and the information and communications technologies (ICT) sectors. Forced localization policies disrupt the existing supply chain, inhibit the growth of new technologies, and limit the legitimate content that Brazilian consumers can access—giving them no other choice but seek out the content they want by illegitimate means. 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 are examining the following questions:

- Should the 2011 Pay-TV Law should 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 should 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 by ANATEL 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. Final administrative decisions on both topics are expected in early 2020, while numerous related legislative proposals are under consideration, addressing both media cross-ownership and OTT distribution.

**VOD Regulatory Discussions**

For six 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, 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 to VOD through a 2012 normative ruling, which ANCINE intends to start enforcing. CONDECINE 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. A coalition of industry stakeholders has filed a request for annulment of the 2012 Normative Ruling.

**Screen Quotas**

For many years, Brazil has maintained restrictive quotas on theatrical exhibition, ranging from 28 to 800 days. A tie-in “supplementary quota” has also mandated that a single title not be shown on more than 30% of a theater’s screens. In January 2020, President Bolsonaro re-issued the screen quota decree (10.190/2019) though, importantly, did not include the supplementary screen quota. Though content quotas of any kind are detrimental to consumer choice and encourage piracy, the Chamber applauds the President’s decision not to renew the supplemental quota.

**Enforcement**

**Remedies**

IP holders face challenges utilizing the legal system to enforce against IP theft. For example, in the Judiciary of the State of São Paulo, IP owners report issues obtaining injunctions to seize counterfeit
products. The Chamber strongly encourages the U.S. government to engage with the government of Brazil to strengthen IP enforcement efforts and reduce legal barriers preventing IP rightsholders from utilizing the judicial system to protect their IP.

**Anti-Counterfeiting Operations**

Despite pervasive hard goods piracy in Brazil, the government—particularly through the National Council to Combat Piracy (CNCP)—continued to take helpful steps in 2018 and 2019 to fix the problem. Housed under the Ministry of Justice, the CNCP works with civil society and industry to develop anti-piracy strategies and methods. Since its reactivation in 2017, it has since spearheaded many impactful programs, including the “City Free of Piracy Initiative” to combat hard goods piracy, a new anti-piracy working group in 2019 between brands and platforms, and a best practices document outlining measures to fight piracy on e-commerce platforms.

The Chamber was also encouraged by the Latin American Anti-Contraband Alliance’s (ALAC) choice to meet for the first time in Brazil in 2018 to discuss public-private initiatives to combat counterfeit cigarettes, textiles, drinks, sporting goods, audiovisual content, and foodstuffs. Such collaboration could produce fiscal benefits too. Research from the Brazilian Institute of Competitive Ethics has shown that the state of Mato Grosso do Sul, for instance, loses nearly 130 million reais ($30 million) per year in revenue from taxes from the illegal sale of cigarettes.

**Camcording**

The unauthorized camcording of films in theaters continues to present a problem for copyright-intensive industries and further fuels online piracy in Brazil. In 2019, 19 illicit audio and/or video recordings of MPA member company films were traced to Brazilian theaters, down from 32 in 2018. Frequently, in-theater audio captures are merged with high-quality video camcorded somewhere else to create pirated content tailored to the Brazilian market. Because of this, it remains one of the largest sources of camcords in Latin America.

Fortunately, there are signs that legislative change may be afoot: The current Head of the Committee of Justice and Constitutional Affairs in the Lower House has released a helpful anti-camcording bill (No. 2714/2019) that removes the requirement to prove a profit motive when pursuing an anti-camcording case. The proposal has been unanimously approved at the Committee on Culture and now the bill sits at the Committee on Justice and Constitutional Affairs, where both the committee head
and the bill’s rapporteur have stated their intent to put the bill to a vote in Q1 2020. The Chamber notes that this measure would significantly improve Brazil’s ability to fight source piracy.

**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. Since 2006 the Brazilian government, through the INPI Academy, has sponsored research and offered accredited postgraduate courses in various fields of IP rights and innovation. Furthermore, the main socio-economic research arm of the Brazilian government, the Institute for Applied Economic Research (IPEA), has conducted several studies on the relationship between IP rights and economic activity, including the 2008 *Incentive Policies for Technological Innovation in Brazil* (Políticas de Incentivo à Inovação Tecnológica no Brasil), various technical notes (Nota Técnica), and sector-specific studies on the creative economy, such as the 2013 *Panorama of the Creative Economy in Brazil* (Panorama da Economia Criativa no Brasil). Still, there is no official program in place—as seen in other high-income, OECD member economies—to regularly measure the aggregate contributions of IP-intensive industries to national economic output and employment.
COLOMBIA

Overview

The Colombian government can capitalize on growing international investments by ensuring that domestic and international innovators and creators alike are better protected through more effective IP protection. To do so, the Colombian government must address several outstanding challenges which IP-intensive industries continue to face. Chief among these concerns are the recent declaration of public interest compulsory licenses, gaps in the implementation of copyright-related FTA commitments, and troublesome provisions in the recently passed 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.

IP Index

Colombia’s overall score increased from 43.77% in the seventh edition (with a score of 19.7 out of 45) to 46.40% in the eighth edition (with a score of 23.20 out of 50). This reflects a relatively strong performance on the new indicators added to the Index.
Patents and related rights

Patentability

Contrary to its TRIPS obligations, Colombia does not grant patents for second uses.

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

The Chamber remains deeply concerned by the Colombian government’s inappropriate use of compulsory licenses to achieve policy outcomes. 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 the innovative oncology medicine Glivec 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. Despite this development, 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.\(^\text{103}\) 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.

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. The Chamber welcomes this development and notes that the introduction of statutory damages for copyright in Colombia helped raise the country’s Index score.

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.

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. 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

https://www.repository.fedesarrollo.org.co/bitstream/handle/11445/3806/LIB_Agosto_2019_Yepes_y_Ramirez_English.pdf?sequence=2&isAllowed=y

105. Ibid.
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**

In May 2019, Colombia’s President signed the National Development Plan (NDP), which defines national goals and economic policies and reflects his administration’s interest in growing the “Orange Economy,” including the development of creative, digital and cultural initiatives. The NDP contains many reasonable and potentially useful provisions for the creative economy, including audiovisual production incentives. However, it also includes Article 154, which mandates, for SVOD platforms, “a section easily accessible to the user which includes audiovisual works of national origin.” This language runs counter to Colombia’s FTA commitments on interactive A/V services, thus requiring extensive stakeholder consultation to be undertaken by the Ministry of Trade in the coming months. The Chamber encourages the U.S. government to monitor this issue, as audiovisual prominence requirements in the digital space are a damaging trend and can 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.

**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.

**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 undergoing a dramatic transformation, underpinned by a strong government with a clear Parliamentary majority which, in turn, will likely remain in power for the full five-year term through 2024. The country’s economic transition includes broad-based reforms and a rapid expansion of the country’s infrastructure underpinned by massive and growing middle class of hundreds of millions of people. A key element of India’s reform efforts and focus on economic growth links directly to IP-intensive industries such as information technology, media and entertainment, pharmaceutical manufacturing, and other advanced technologies. The Chamber notes that in the pharmaceutical sector, for instance, companies on both sides need legal and regulatory certainty to operate. And while significant hurdles remain—such as patent workability, Issue 2 and issue 3—we acknowledge the consistent, incremental, steps taken by India’s Department for Promotion of Industry and Internal Trade (DPIIT) within the Ministry of Commerce and Industry to improve its national IP environment since the inception of its National IP Policy in 2016.

At the core of its improved IP environment, the National IP Policy led to critical changes to how the government of India (GOI) organizes, funds, manages, and supervises its IP agencies. The policy led to the centralization of most IP activities under DPIIT overseen by a single Joint Secretary. In short, the 2016 policy raised the profile and importance of IP within the Indian bureaucracy, centralized control over its implementation, and increased funding for staff, facilities, training, and anti-piracy and anti-counterfeit programs and consumer education. The consolidation of IP agencies also increased transparency, consistency and access to Indian officials responsible for various aspects of IP policy, regulation, and implementation. This dynamic continued into 2019 and positively impacted India’s standing in the 2020 Chamber International IP Index, where India continued its steady progress upward.

A major accomplishment during 2019 included the GOI’s initiative to gradually align India’s IP environment with the international IP system. Specific examples include India’s expected implementation of the WIPO Internet Treaties, the country’s very first pilot PPH with the Japanese Patent Office (JPO) in winter 2019, improved legal precedent for the awarding of damages in IP infringement cases, the introduction of geographic indicators regime, and continued momentum on the country’s online copyright enforcement regime. Anyone these represent important reforms, but when taken together change in India’s IP regime, and foretell continued improvements going forward.
The DPIIT also invested considerable energy to institute patent office efficiency, wherein the Indian Patent Office (IPO) demonstrated decreasing pendency rates for patent and trademark applications. The Office of the Controller General of Patents, Designs and Trademarks (CGPDTM) increased staff and resources invested into modernizing and improving its administrative capacities: The IPO currently has 618 patent examiners—up from 183 in 2015—and examinations went up by 407%, to 85,436, in 2018/2019 compared to 2015/2016 (16,853). Disposals increased by 135% in the same period. Of note, the government’s commitment to reducing patent application fees through an e-filing system (as well as a 10% discount) has contributed to its growth: now nearly 90% of patent applications in India are filed electronically. Most importantly, the government has continued to chip away at stubborn pendency times, which are now estimated at 18-24 months.

Following an initial set of reforms and improvements, India’s National IP Policy provides further opportunities to strengthen the generation of IPRs, guarantee their reliability, facilitate commercialization, nor provide deterrent-level enforcement. Moreover, despite the positive messaging at home in New Delhi, India continues to support unhelpful motions within multilateral organizations, for instance, by supporting a resolution originally put forward by South Africa and China to use competition law to circumvent IP policy to achieve public health outcomes. Serious work remains to be done to enforce patent terms, increase investment in R&D, institute a coherent vision on trade secrets protection, and establish a solid technology transfer mechanism.

The DPIIT initiated a stakeholder consultation period to revisit its arduous patent working requirements and proposed a quasi-streamlining of the SUGAM portal, but concrete and complete solutions remain elusive. Indian and foreign innovators alike would benefit greatly from a strong domestic ecosystem that can support the consolidation and commercialization from robust IP protection and enforcement. The Chamber encourages the GOI to keep consistent with its efforts towards stakeholder consultation as it undertakes a reassessment of various regulatory and administrative reforms to the IP system.

On February 1, 2020, the government of India unveiled its budget alongside new tariffs and fees on agricultural goods, medical devices, automobile parts, electronics and electric vehicles. Although the business community is still reviewing the Budget’s proposals, the Chamber has long maintained that tariffs raise prices for consumers and ultimately inhibit economic growth.
The Chamber and its members welcomed the frequency of engagement between the U.S. and Indian governments in 2019 but encourage both sides to come to the table as soon as possible to reconvene the U.S.-India Trade Policy Forum to keep the momentum of high-level bilateral engagement on the upswing and convene discussions under the IP workstream as soon as possible. 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 that has stalled some bilateral dialogues. We welcome discussions on an impending trade agreement between the two countries and look forward to a solutions-driven working relationship on IP.

As a complementary parallel track, 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, continued our successful dialogue around a solutions-driven approach to IP policy, innovation, and inclusive growth in October 2019. This Track 1.5 dialogue brought together leaders from the India’s Department of Industrial Policy and Promotion, Indian Patent Office, and the U.S. Patent and Trademark Office, along with leaders from the Indo-U.S. business community in New Delhi. The discussions included a focus on joint opportunities and challenges related to the full spectrum of IP, including patent filing, regulatory landscape, copyright and infringement, technology transfer, and enforcement. The Dialogue aims to identify solutions and share technical knowledge and expertise. The Chamber looks forward to working with both the GOI and USG on addressing certain issues together in the lead up to the 2020 iteration of this Dialogue in New Delhi or Washington, DC.

IP Index
India’s overall score has increased from 36.04% (16.22 out of 45) in the seventh edition to 38.46% (19.23 out of 50) in the eighth edition. This reflects a mixed performance on the new indicators added to the Index and but score increases on indicators 11, 12, 20 and 35.

Barometer
In the Chamber’s 2019 Innovation and Creativity Access Barometer, India scores 16th out of the 20 economies benchmarked, receiving 28.69% of the overall score (with a score of 4.59 out of 16.00).
**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 Gli
tvec 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.106 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 March 2019, it was reported that the GOI would integrate the WIPO Centralized Access to Search and Examination and Digital Access Service into IPO’s workflow—a welcome development alongside India’s new PPH partnerships. However, some outstanding issues remain unresolved, including the potential expansion of the “person interested” provision that would complicate the process (as in patent opposition issues), needless costs for translation and the requirement

that all communication be “in writing”, and the levying of harsh non-compliance penalties that are out of step with those seen in other countries. Instead of subjecting patent examiners to a wild-goose chase, the Chamber supports a practical way forward on notification procedures—one that can better focus the Indian government’s resources while providing better service to local and international innovators.

**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.

Compulsory Licensing and Price Controls

India continues to be a flashpoint for compulsory licensing for innovative biopharmaceuticals, both in capital and multilateral fora. While no additional compulsory licenses for biopharmaceuticals were issued by Indian authorities in 2019, Indian companies continued to seek compulsory licenses under Section 84 of India’s Patent Act and the GOI continues to consider compulsory licenses under Section 92. 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 weaponized to assist local manufacturers seeking compulsory licenses. Furthermore, the country’s 2017 Draft Pharmaceuticals Policy reserved the right to issue compulsory licenses. Compulsory licensing is short-termism at its worst. A blunt policy instrument, it fails to truly solve the pressing healthcare needs in developing countries, such as reliable infrastructure and financing mechanisms, or industrial policy goals—instead stifling investment in the very industries it hopes to encourage. We continue to urge the GOI to repudiate the use of compulsory license as a commercial tool and deepen engagement with innovators concerned to address public health challenges to arrive at win-win solutions.

Furthermore, pricing that does not properly value innovation undermines access to 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)**

In Q1 of 2019, a limited PPH program between Indian and Japanese authorities entered into force. 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. The Chamber notes, however, that several other BRICS economies (like Brazil) have or are looking to adopt technology-neutral PPH agreements. In time, the Chamber hopes that the IPO-JPO PPH can be expanded to include the biopharmaceutical industry and other sectors. The Chamber also encourages the start of a PPH between the IPO and USPTO.

**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. 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

Piracy

As broadband connectivity and mobile phone use has exploded in India, so has a marked increase in the availability of infringing content. Despite this shifting landscape, Indian law remains unclear about the availability and requirements of a notice and takedown system to combat online piracy. Studies have also shown that 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 in nothing short of an “epidemic.”107

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 107. 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
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.

Intermediary Liability

Many of the websites exposing Indians to pirated content are hosted outside of India; nevertheless, they are supported by online advertising originating in India and targeting Indian consumers. A concerted effort by the government to pressure the online advertising industry in India to stop funding piracy through online ads could significantly reduce revenue to these criminal enterprises. We urge the GOI to amend Article 69A of the IT Act to make copyright infringement a predicate offense and to cover linking and other sites that are central parts of the piracy ecosystem but do not themselves host content. This would provide an efficient administrative injunctive relief remedy against structurally infringing sites.

In 2018, India’s Ministry of Electronics and Information Technology (MeitY) introduced its Draft of Intermediary Guidelines. We would like to draw attention to Section 3(5) of the Guidelines: It is important that intermediaries are responsive to lawful orders in a timely manner. However, the insertion of “within 72 hours of communication” may be unreasonable in certain situations. We would recommend the Draft Guidelines direct responsiveness to lawful orders in an expeditious manner and perhaps indicate in response to copyright violations and emergency situations within 72 hours. In other cases, including copyright violations, where commercial-scale or other harms are likely to accrue within 72 hours, a more timely response is appropriate. With regard to Section 3(8), requests from the government to remove content that is a clear violation of the law, such as pirated content is not debatable, however in other contexts a government order to take down objectionable content may invoke legal and procedural challenges. We recommend the Draft Guidelines provide greater nuance to the extent to which notifications beyond court orders must result in an intermediary removing content or disabling access in 24 hours. We anticipate updated guidelines to be released shortly and hope for improvements within the IP space.

Copyright Board

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). The Chairman of IPAB has been appointed and has already taken charge, however, the process to appoint other members of the Board. The
process to engage with industry stakeholders is yet to fully take off. The Chamber encourages DPIIT to finalize the merger and announce the leadership of the Board. The Chamber encourage the USG to consider ways to provide technical assistance and training once the Board is fully operational.

**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 obligations, especially TRIPS, as it would be discriminatory and inconsistent with Article 3 and should be formally withdrawn.

**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.

**Standard Essential Patents**

We remain concerned that MeitY is working on a National Electronics Policy (NEP 2018) that includes potential government promotion of specific national standards, Indian-owned standard essential patents (SEPs), and Fair, Reasonable And Non-Discriminatory (FRAND) caps. In addition, the National Digital Communications Policy (NDCP) finalized in 2018 has provisions for “Providing financial incentives for the development of Standard Essential Patents (SEPs) in the field of digital communications technologies,” that would distort the standards-setting process by adding a preference for domestic technology, and eschewing best-in-class technology by adding preferential incentives for domestic players. The NDCP also calls for government intervention in setting FRAND rates by “Ensuring the availability of essential background IPR in FRAND terms required for promoting local manufacturing” which could interfere with a market-based approach and supersedes the judicial review of FRAND cases to adjudicate disputes. To date, the NEP has not been finalized.

**Government Access to Non-Personal Data**

With its surprise inclusion in the draft Personal Data Privacy Bill, India is charting new territory with provisions for government access, use, and community licensing of non-personal data. This topic is not well understood internationally, and might result in unforeseen problems around intellectual property rights, unfair trade practices, and could actually have an adverse effect on privacy – the core goal of the bill. Further, India inserted the language while MeitY has initiated the creation of a committee to look at non-personal data issues, and that committee has not finalized its report. The Chamber of Commerce encourages the GOI to remove these provisions since regulation of non-personal data is not well understood, adds complexity the difficult issue of creating privacy regulations, and creates uncertainty within the investment community for products and services that might require anonymization and delivery of data to the government.

**Telecommunications Network Security**

U.S. industry remains concerned about security testing requirements for ICT equipment. These requirements, notified by India's Department of Telecommunications (DoT), appear to deviate from global practices, and the government currently has 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.”

There is also the issue of "Form 27" for patents, which requires that patent holders annually provide information on the extent to which a granted patent has been used in India by patentees and licensees. Part of the submission and documentation submitted pertains to the value and commercial scale of the patent. There is much uncertainty as to what the Office will choose to disclose as publication of Form 27 is at the authority's discretion; fines for non-compliance remain high. In July 2019, the GOI invited stakeholder feedback and is currently considering potential reassessments to the procedure. Given that patent abuse is mitigated via other existing checks and balances, the Chamber recommends a complete reassessment of working requirements under Section 146 of the Patents Act and subsequent withdrawal of the outmoded Form 27 as its imposition undermines domestic innovation, undercuts existing and future innovative foreign investment, and their cross-collaboration. In the interim, we believe that simplifying Form 27 to address the issues outlined in this submission will constitute a step in the right direction. We look forward to a favorable conclusion of the reform process.

**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 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 rethink its dangerous proposal to expand the scope of Section 31D, instead looking to compliance with India’s international obligations.

**Publishing Registration Bill**

The Chamber welcomes the Ministry’s long overdue efforts to modernize the outdated Press and Registration of Books Act, 1867, but notes that the draft Registration of Press and Periodicals Bill, 2019—rather than modernize the registration process for press and publications—appears to install an opaque system which press and publication entities may find difficult to navigate. For instance, the bill does not clearly identify the grounds upon which decisions for registration will be taken, or the factors that would adjudge an applicant press or publication eligible for registration. 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 most recently updated FDI rules for the media sector in early 2018, furthering the trend toward liberalizing of the media, cable TV and satellite TV market. However, there remain several limits and structural contradictions impacting flow of investments, and skew playing field in favor of Indian-owned incumbents. While the GOI continues to liberalization of MandE sector incrementally, there remain several distant limits on international FDI into the sector, including:

- 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.

As an aside, we note that India’s largest private radio broadcaster, Radio Mirchi, started U.S. broadcasts in January 2019 via the purchase of multiple states in several East Coast markets. Despite 100% FDI in broadcast distribution platforms, specifically in the case of “Direct to Home” (DTH) and “Head-end in the Sky” (HITS), there remains a vertical integration restriction for foreign investors that does not impact domestic competitors. In case of both theses platforms the Permission Guidelines issued by the MIB limit the investments by broadcasting entities to 20%. This has remained to be the case since 2001 and these restrictions have continued despite the Consolidated FDI Policy 2016 as issued by DPIIT allowing 100% FDI in broadcast distribution platforms including DTH. It is also interesting to note that these restrictions exist only for DTH and HITS platforms and do not apply to Cable TV and “Internet Protocol Television” (IPTV) which essentially perform the same function i.e. carriage of TV channels to subscribers. It is because of this 20% ownership restriction that major U.S. broadcasters – who own broadcast TV channels in India – have not been able to meaningfully invest in DTH platforms, thereby limiting FDI in broadcasting services market. This seems in clear contradiction to government of India’s stated goal of increasing foreign investments in services sector. This has also disadvantaged US broadcasters in relation to their Indian counterparts who have successfully been able to circumvent these restrictions by using family-based ownership structures.

The broadcasting regulator, Telecom Regulatory Authority of India (TRAI) has asked for removal of these restrictions in its “Recommendations on new DTH licenses” dated July 23, 2014 and then re-iterated the same in its “Recommendations on media ownership” dated August 12, 2014. However, MIB has not yet actioned the same.
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.109

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. One area of concern has been the long pendency times in the Indian court system. The GOI has long recognized this challenge, 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 with Customs and to confirm that a shipment contains infringing products. Customs officers at all levels should be empowered and trained to combat infringing trade through authorization and use of risk-management targeting. Customs should be authorized to seize goods based on confirmation from the rights holders of the counterfeit status (currently, the rights holder must file a civil action to complete the seizure process if the importer does not voluntarily abandon the infringing goods).

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 writing, 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.

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, and compulsory licensing that can serve to either enhance or undermine legal certainty for investors in the innovative and creative investment community.

IP Index

Indonesia’s overall score has increased from 28.60% (12.87 out of 45) in the seventh edition to 30.24% (15.12 out of 50) in the eighth edition. This reflects a fairly strong performance on the new indicators added compared with Indonesia’s overall performance on the Index.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, Indonesia scores 20th out of the 20 economies benchmarked, receiving 6.67% of the overall score (with a score of 1.00 out of 16.00).
**Patents and related rights**

**Patent Law**

For background, the Indonesian government has since the mid-2000s issued nine “government use” compulsory licenses overriding existing biopharmaceutical patents primarily for hepatitis and HIV drugs. These licenses allow the government to exploit existing patent-protected products in the event of threats to national security or an urgent public need. The manner in which these licenses were issued and their justification were both in contradiction of Article 31 of the TRIPS Agreement. 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 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 solely be aimed at protecting public health. In addition, Article 31 and the Doha Declaration suggests 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.

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 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. On the one hand the Regulations affirmed the meaning and intent of the original act that the ‘making’ of a patent is an obligation on part of a given rights-holder to make products or use processes in Indonesia and that this must support technology transfer, investment and/or employment in Indonesia. Upholding the sweeping localization requirements of the original law is not only firmly outside international standards but is likely to do very little to encourage and incentivize the transfer of new technologies or foreign direct investment into Indonesia. On a more positive note the Regulations did provide the possibility of indefinitely postponing these requirements. Article 3 of the Regulations allowed patent holders to apply to “postpone” the production or use of the patent in Indonesia for up to five years. Article 6 also provided that this five-year postponement may be extended “with reasons”. All the same, the Regulations allowed 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. These Regulations went far beyond the stated goals and circumstances for the issuing of compulsory licenses under the TRIPS Agreement.

In early 2019 the government announced that it would be issuing new regulations describing the process for both the new compulsory licensing provisions and the broader localization and technology transfer requirement. New regulations (Regulation 30/2019) were released in December 2019. These regulations are an improvement on previous versions. With respect to compulsory licenses they provide a narrower definition of under what circumstances a compulsory license could be issued and the time period under which a patented invention must be worked. They also provide greater clarity on how to postpone the localization requirement and applicable process. Still, the new regulations do not change the sweeping localization requirements of the original patent law. It also remains to be seen how these regulations are implemented and the net effect on inventors in Indonesia.

Additionally, Article 4 of the patent law denied 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.

**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 in place a PPH. 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. While the scale of copyright piracy (both physical and online) remains an immense challenge to rights-holders in Indonesia, the Chamber is encouraged by these welcome steps. As policymakers continue to study initiatives to fight copyright infringement, the Chamber encourages the government of Indonesia to consider updating its system to allow for the dynamic blocking of “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.

Cooperative Frameworks to Prevent Piracy

Indonesia has made meaningful improvements over the past year, though significantly more needs to be done given the scale and scope of piracy in Indonesia’s market. The 2014 act provided new tools to combat online infringement and the circumvention of technological protection measures. Regulations implementing the law (Regulation Nos. 14 and 26) were enacted in July 2015, providing new administrative remedies in response to websites that facilitate infringement by disabling access to primarily infringing websites. Additionally, the Creative Economy Agency established an anti-piracy task force in the second half of the year. These new tools have already proven useful and suggest new dedication to anti-piracy efforts within Indonesia.

While recognizing these important developments, we also must note the significant challenges the creative community continues to confront in Indonesia. Piracy is persistent, and enforcement is wholly insufficient. Courts are mostly ineffective. Developments in 2015 were positive, but a significant and
continued investment of resources and training for enforcement entities and courts, and high-level political commitment, are needed.

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 are 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.
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.
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 Indonesia 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.
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 original U.S.-Mexico-Canada Agreement (USMCA) included many 21st century IP protections, the final agreement reached in December 2019 removed many of the key life sciences IP provisions that would have greatly strengthened the environment for biopharmaceutical IP in Mexico. Given the gaps in the USMCA chapter, it is all the more important that the U.S. government 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.

IP Index

Mexico’s overall score has increased from 53.20% (with a score of 23.94 out of 45) in the seventh edition to 54.38% (with a score of 27.19 out of 50) in the eighth edition. This is driven by a fairly strong performance on the new indicators added to the Index.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, Mexico scores 9th out of the 20 economies benchmarked, receiving 60.31% of the overall score (with a score of 9.65 out of 16.00). While Mexico scores in the top half of the Barometer, certain sector-specific regulations limit the availability of the newest innovative and creative goods.
Patents and related rights

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 Chamber recommends that the U.S. government work closely with its Mexican government counterparts to ensure that appropriate patent linkage obligations are adequately implemented and enforced in Mexico.

Compulsory Licensees

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.
Copyrights and related rights

Importance of USMCA Implementation

In summer 2019, the Mexican Congress used an existing copyright reform process as a starting point to study the implementation of USMCA’s copyright-related provisions into domestic law. In the new year, it is expected that the Mexican government will also discuss stronger anti-camcording laws without a “proof of profit” motive, border enforcement measures, and other issues. The Chamber also notes that Mexico still has not fully implemented the WIPO Internet Treaties—particularly measures against the circumvention of technological protection measures and protections for rights management information—some 18 years after ratification in 2002. Bearing this in mind, the Chamber asks that the U.S. government work with Mexico during its implementation of the USMCA to resolve these remaining issues.

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

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 do not give authorities ex officio powers to seize IP infringing goods. Instead, *every* shipment suspected of infringement must obtain a corresponding order from the Attorney General’s Office for inspection and detainment. To cope, industry has begun initiating administrative and criminal procedures, but these are expensive and time-consuming stop-gap measures. The Chamber urges the U.S. government to work with the Mexican government in improving its enforcement framework despite painful budget cuts. The Chamber also encourages Mexican legislators to introduce meaningful anti-counterfeiting legislation.
**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.

**IP Index**

Russia’s overall score has increased from 43.24% of the total possible score (19.46 out of 45) in the seventh edition to 45.92% (22.96 out of 50) in the eighth edition. This reflects a relatively strong performance on the new indicators added to the Index.

**Barometer**

In the Chamber’s 2019 *Innovation and Creativity Access Barometer*, Russia scores 17th out of the 20 economies benchmarked, receiving 26.82% of the overall score (with a score of 4.29 out of 16.00).
**Patents and related rights**

**ROSPATENT Amendments**

In late 2018, Order 527 amended the way Russia’s patent office (ROSPATENT) receives and processes applications, particularly regarding 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 additional new and 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**

In September 2019 the Ministry of Health published updated draft legislative proposals for changes to Law No. 61-Z On the Circulation of Medicines. The proposed changes include 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 includes a requirement that a follow-on applicant submit written documentation stating that the prospective registration does not violate any existing exclusivity. Furthermore, ROSPATENT is to house a register of the current exclusivity status of registered products. As of January 2020, the draft law was still being debated and no final legislation had been passed or signed into law. The introduction of such a mechanism would be a positive step and improvement to Russia’s national IP environment.

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.

**Compulsory Licensing**

After years of ever-louder calls for compulsory licensing from the Duma and the Russian Federal Antimonopoly Service (FAS), the Russian courts began 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.

http://kad.arbitr.ru/Card/322413fa-38a7-4085-9cc7-3c8ff9fd7d92
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. 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.

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. Despite this progress, industry reports that Russia’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: Rapidgator.net (a Russian-hosted cyberlocker logging some $3.7 million annual revenue from some 313 million visitors in 2019), 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

Overview

Despite some positive developments in the intellectual property regime in Saudi Arabia, we have detailed some instances in which there has been a lack of enforcement of IP protections, which seemingly disregard relevant laws in the kingdom. As such, we encourage the U.S. government to work with their counterparts in KSA to ensure that its IP laws are fully enforced. This should serve to protect inventors and creators and should encourage further investment by U.S. businesses in KSA in alignment with the objectives of Vision 2030.

IP Index

Saudi Arabia’s overall score has increased from 36.60% (16.47 out of 45) in the seventh edition to 39.44% (19.72 out of 50) in the eighth edition. This reflects a weak performance on the new indicators added to the Index but score increases on indicators 8, 11, 39, 40, and 41.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, Saudi Arabia scores 11th out of the 20 economies benchmarked, receiving 41.67% of the overall score (with a score of 6.25 out of 16.00).
Patents and related rights

Patent Linkage

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. This action runs counter to the country’s own goals and general principles to develop an innovation ecosystem as outlined in the Vision 2030 and National Transformation Program 2020. It also risks undermining the continued foreign investment needed to achieve these goals.

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, hosted the beoutQ signal. After years of international outcry, beoutQ was reportedly offline in fall 2019. But given widespread piracy in the MENA region and the chance that beoutQ may return, the Chamber asks the U.S. government to closely monitor this issue.112

Trade secrets and related rights

Regulatory Data Protection

Authority for Intellectual Property (SAIP) just issued for public comment draft Development of Regulations for the Protection of Confidential Business Information outlining the protection and enforcement of trade secrets and in particular a proposal to make the following changes to the regulatory data protection for certain agricultural and pharmaceutical products which shortens the term and reduces the number of products covered. Industry remains concerned that these changes do not go far enough—and in fact takes a step back from current obligations—to provide international best practices that create incentives for the development of innovative, life-saving treatments. To establish meaningful regulatory data protection in Saudi Arabia, authorities must establish a mechanism to ensure the following principles:

- That proprietary information submitted to obtain a license for product approval are confidentially maintained.
- That no person other than the person who submitted such data could, without the explicit consent of the person who submitted the data, rely on such data in support of an application for product approval.

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.
SOUTH AFRICA

Overview

As Africa’s largest and most-advanced economy, South Africa stands at a crossroads: the country could further its economic development by adopting a long-term, pro-innovation strategy, or it could continue to undermine itself—and foreign investment—by introducing uncertainty into its IP environment.

At the outset, we appreciate the South African government’s general attempt to engage more closely with industry. An improved stakeholder consultation process for its ongoing “IP Policy” process, for instance, has strengthened accountability and transparency. Drawing from South Africa’s IP Consultative Framework in 2016, the Intellectual Property Policy of The Republic of South Africa (“IP Policy”) is a series of policy documents addressing all major IP laws in the country. Phase I, focusing on patents (primarily for biopharmaceuticals) and related IP rights, was released in fall 2018. Throughout this process, the South African government has shown willingness to consult with stakeholders, and the collaboration has borne fruit: The Chamber was encouraged to see a section on “Rule of law, legal certainty and security of investments” included in the Phase I document.

Unfortunately, the IP Policy also represents a missed opportunity. Much like the 2016 framework, the IP Policy Phase I lacks incentives to create, commercialize, and capitalize on IP as part of a broader industrial strategy. For all economies—emerging and developed alike—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.

The Chamber also echoes rightsholders’ concerns on the Copyright Act Amendments and Performers Protection Amendment Bill that were swiftly passed by the South African parliament in 2019. We support the maintenance of international standards for copyright—such as the Berne Convention, three-step test, and TRIPS Agreement—along with the freedom for parties to enter into private contracts. By establishing exceptions to copyright and contracting standards outside of these norms, South Africa could run afoul of its international obligations and harm investment in its creative industries. We strongly recommend the U.S. government to engage with the government of South Africa in revisiting these bills.
In this vein, it is unlikely that any of these policies—individually or in aggregate—will help South Africa transition toward a knowledge economy and greater foreign investment, as their government seemingly intends.

IP Index

South Africa’s overall score has increased from 34.56% (15.55 out of 45) in the seventh edition to 36.62% (18.31 out of 50) in the eighth edition. This reflects an above average performance on the new indicators added to the Index.

Barometer

In the Chamber’s 2019 Innovation and Creativity Access Barometer, South Africa scores 13th out of the 20 economies benchmarked, receiving 36.67% of the overall score (with a score of 5.50 out of 16.00).

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. 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. 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 tool of last resort, such as public health emergencies. 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; 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. After this attempt was criticized for its ability to meet these obligations, the Department of Trade and Industry assembled a panel to lead public consultations on the issue. Despite South Africa’s past attempts to engage with industry the Chamber notes that this panel continued its work despite concerns that it did not have the necessary technical nor industry expertise. Nevertheless, in 2017 the Copyright Reform Act Bill and the Performers’ Protection Amendment Bill (PPAB, discussed below) as we know them today were drafted and released.

The Chamber echoes rightsholder concerns regarding the process in which these bills were drafted, their failure to appropriately define key terms, and support of provisions far afield from well-established norms for copyright—such as the TRIPS Agreement, Berne Convention, and three-step test. We also note that even South Africa’s High Court has affirmed copyright as a constitutionally-protected property right.

The Chamber is deeply concerned in how the Copyright Reform Act Bill’s introduces a hybrid fair use/fair dealing exception for copyrighted works in South Africa. Such an exception not only

113. South Africa signed the WIPO Internet Treaties in 1997.
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. To the added dismay of rightsholders, South Africa’s Council of Provinces and Parliament approved the bill in 2019 and it now awaits a signature from President Ramaphosa to become law. Helpfully, the President recently appointed a legal advisor and economist to examine the constitutionality of the bill. But given that this exercise began as an attempt to bring South Africa’s copyright framework in line with its international obligations, we note that these bills would do the exact opposite. As such, the flawed bill should be immediately returned to Parliament for a significant rewrite.

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 urges the South African government to return the bill to Parliament for a substantial rewrite.

Forced Localization
The South African government has for many years focused on developing its domestic economy through a range of general and sector-specific localization policies. For example, South Africa has longstanding local content requirements for certain sectors, including broadcasting. Within public procurement, significant local content requirements are in place since 2011 for a host of specially designated sectors ranging from automotive (buses), set-top boxes, clothing, and furniture. Local content requirements range from 10% to 100%, depending on the industry.

Specifically, the DTI is strengthening cross-governmental enforcement activities and ensuring greater compliance and application of these localization requirements. Furthermore, South Africa’s industrial policies place a heavy emphasis on the transfer of technologies from international rights-holders to local companies. Conditioning market access and access to opportunities for 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.