INTERNATIONAL IP INDEX

RECOVERY THROUGH INGENUITY | 2021 NINTH EDITION

U.S. CHAMBER OF COMMERCE INTERNATIONAL IP INDEX

GIPC GLOBAL INNOVATION POLICY CENTER

U.S. Chamber of Commerce

The U.S. Chamber of Commerce's Global Innovation Policy Center (www.theglobalipcenter.com) is working around the world to champion intellectual property rights as vital to creating jobs, saving lives, advancing global economic growth, and generating breakthrough solutions to global challenges.

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Innovation | Technology Transfer | Intellectual Property | Market Access

This report was conducted by Pugatch Consilium, (www.pugatch-consilium.com) a boutique consultancy that provides evidence-based research, analysis, and intelligence on the fastest growing sectors of the knowledge economy. Authors of this report are Meir Pugatch and David Torstensson.

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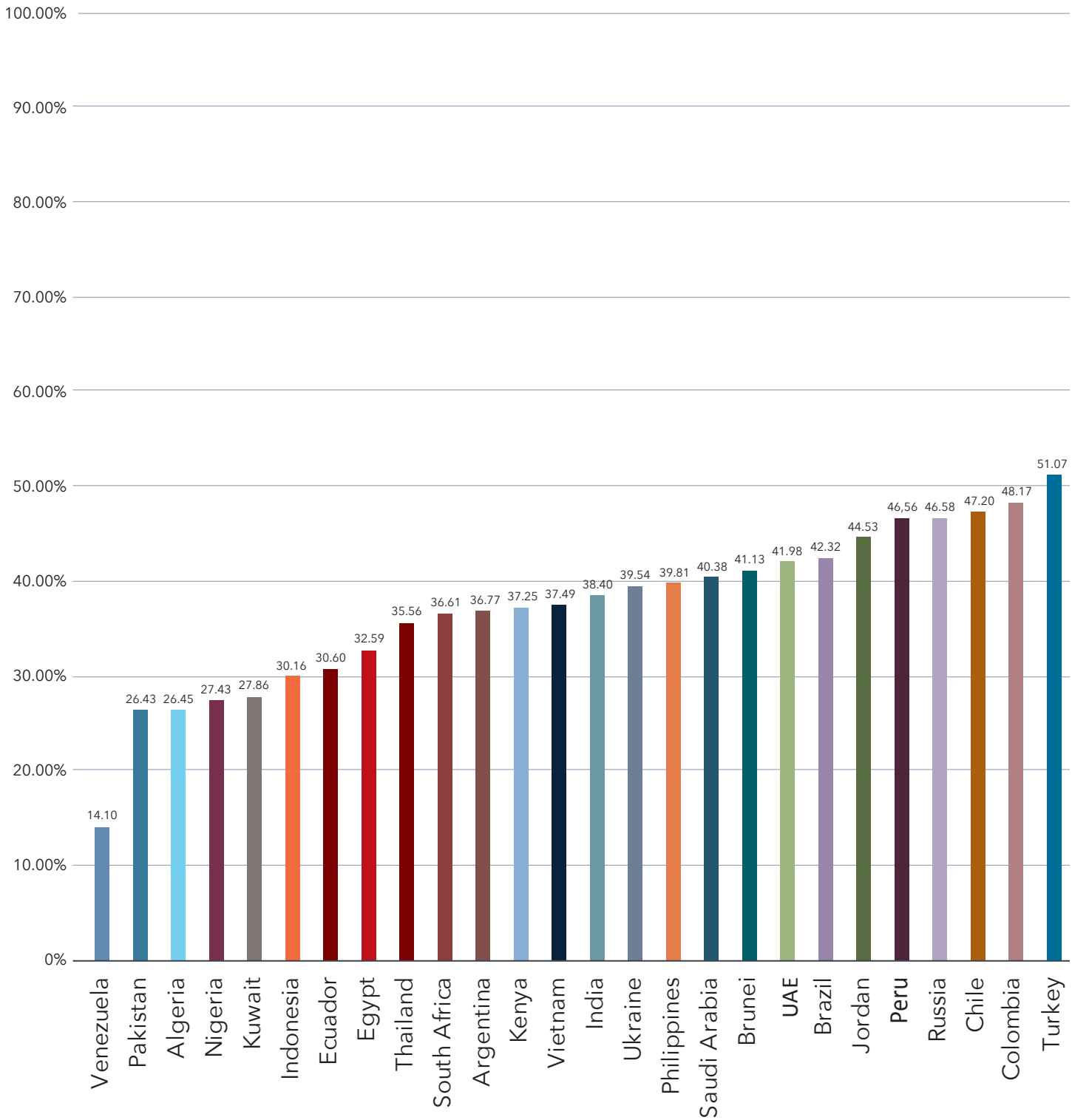
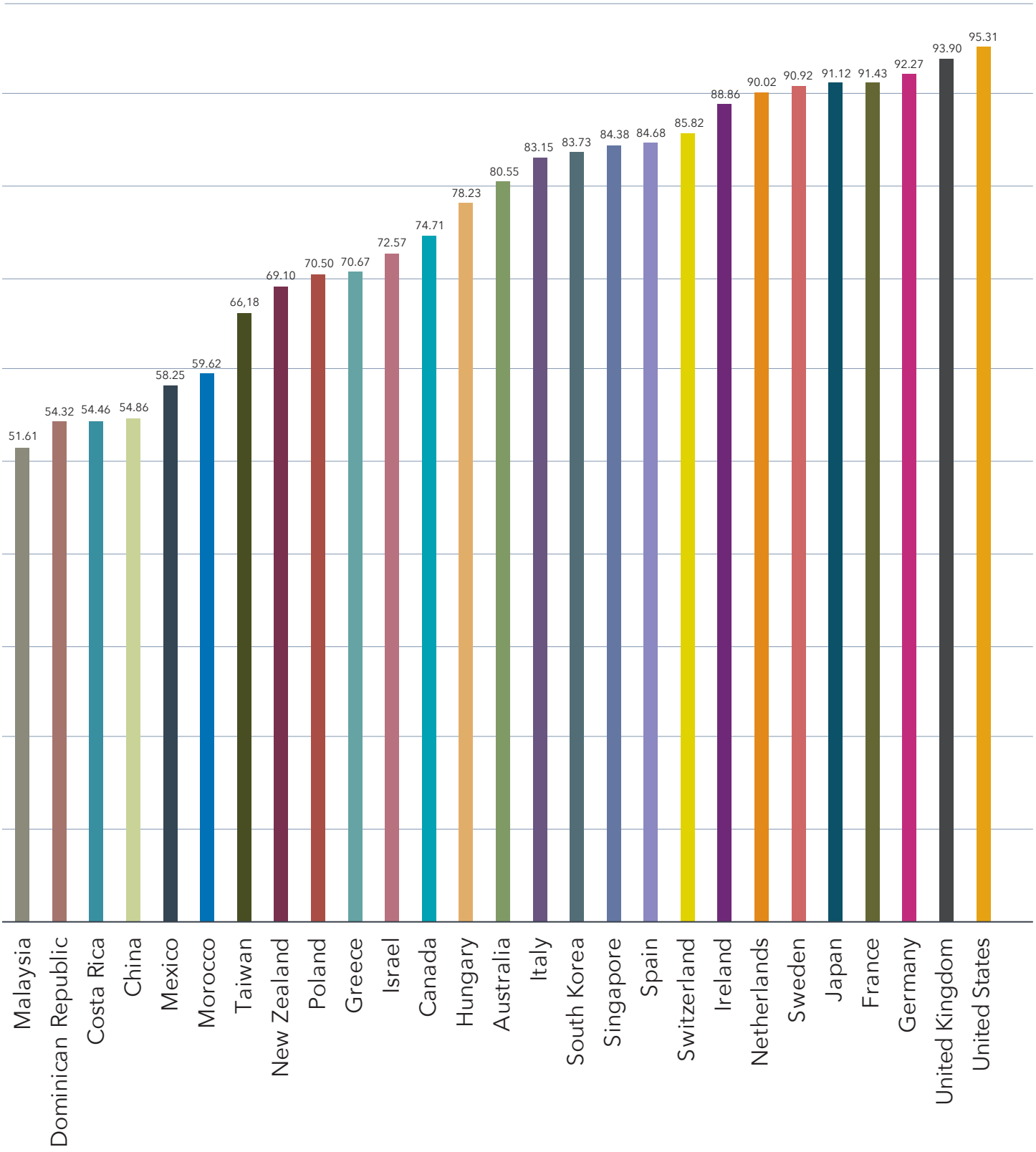
2021 OVERALL SCORES




51.61
54.32
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59.62
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93.90
95.31
Malaysia
Dominican Republic
Costa Rica
China
Mexico
Morocco
Taiwan
New Zealand
Poland
Greece
Israel
Canada
Hungary
Australia
Italy
South Korea
Singapore
Spain
Switzerland
Ireland
Netherlands
Sweden
Japan
France
Germany
United Kingdom
United States

1 FOREWORD

Every day, innovators and creators wake up ready to deliver the next big thing; They go to bed thinking about what challenge they're going to tackle next. They channel their passion and their talent in a million different ways – all so we can live healthier, more productive, more fulfilling lives.

Last year, COVID-19 effectively condensed every avenue for innovation into one: Defeat the COVID-19 pandemic. Innovators didn't panic, they pivoted, and poured every resource into our global emergency response.

The innovative scientific communities developed effective diagnostic tests, therapeutics, and vaccines: all the tools our doctors and nurses need to serve patients and their families. The wireless technology community fast tracked implementation of 5G to keep us connected and protected as we learned to work and learn from home. The entertainment, publishing, and arts community produced new content to enrich our lives as we adjusted to our new normal.

None of it was easy – all of it was important. The human impact of intellectual property-intensive industries is truly immeasurable. That doesn't mean it's not tangible. Through our global intellectual property (IP) system we value innovators' contributions to society and assure them that their investments are worthy of the risk required to make them.

The Index describes this function of the global IP system and identifies opportunities to strengthen the innovation ecosystem even further. The Index recognizes that with a robust global IP system in place, we can harness innovation for good to control COVID-19 and restore our world to health.

Recovery through ingenuity is within our grasp if we just enable innovators and creators to keep reaching.

– DAVID HIRSCHMANN

2 EXECUTIVE SUMMARY

The COVID-19 pandemic upended life as we knew it. As global citizens adjusted to living through a global pandemic, intellectual property played an essential—if oftentimes underappreciated—role in the creation and development of technological and creative solutions.

Treatments and vaccines for coronavirus were developed in record time as a result of the scientific community's ability to make high-risk, high-capital investments in R&D. As we adjusted to the way we work, teach, and connect with others, IP-enabled digital technologies allowed us to remain connected to one another, even if in isolation. And while many of us spent much of the year in quarantine, the development of new streaming services and creative content provided both a welcome escape and brought us together. Throughout the pandemic, transparent and predictable IP rights have also provided the legal and economic basis for an unprecedented level of highly successful collaborations between government, industry, academia, and non-governmental organizations.

In this context, being able to measure how equipped economies are to generate and safeguard innovation and creativity is more important than ever before. Now in its ninth edition, the International IP Index benchmarks the IP framework in 53 global economies across 50 unique indicators. An effective IP system, as outlined by the criteria evaluated in the Index, will be critical to rebuilding healthy communities, getting citizens back to work, and reinvigorating the global economy.

GEOGRAPHIC COVERAGE

Algeria	Indonesia	Russia
Argentina	Ireland	Saudi Arabia
Australia	Israel	Singapore
Brazil	Italy	South Africa
Brunei	Japan	South Korea
Canada	Jordan	Spain
Chile	Kenya	Sweden
China	Kuwait	Switzerland
Colombia	Malaysia	Taiwan
Costa Rica	Mexico	Thailand
Dominican Republic	Morocco	Turkey
Ecuador	Netherlands	United States
Egypt	New Zealand	UAE
France	Nigeria	United Kingdom
Germany	Pakistan	Ukraine
Greece	Peru	Venezuela
Hungary	Philippines	Vietnam
India	Poland	

KEY FINDINGS

Over recent years, the international IP environment has continued to strengthen, despite some negative developments resulting from certain governments' responses to COVID-19.

- In the 2021 report, 32 of the 53 economies benchmarked had positive improvements in their scores.
- Since the second edition of the Index in 2014, the aggregated score of the economies benchmarked has improved 6.24%.
- Of the BRICS economies included since the inaugural edition of the Index in 2012, China and India have improved the framework for IP-driven innovation and creativity. In that time, China's score has increased 18.34% while India's improved 13.44%. However, despite this positive progress, significant challenges remain for IP rightsholders in both markets.

Trade agreements continue to substantively improve national IP frameworks.

- In the 2021 edition, China achieved the largest overall increases in score – at 3.9% – as a result of legislative improvements resulting from the January 2020 U.S.-China Trade and Economic Agreement. These changes, if implemented effectively, should improve China's domestic IP framework. However, ongoing market access barriers, uneven enforcement, measures requiring forced technology transfer, and serious deficiencies in the rule of law continue to make the business environment in China highly challenging for rightsholders.
- As a result of the implementation of some commitments in the U.S.-Mexico-Canada Agreement (USMCA), Mexico had the second largest overall increase in score – at 3.87% – due to legislative changes to improve copyright and trademark protection and the commercialization of IP assets. However, Mexico forfeited more substantive gains for life sciences IP protection when critical protections were removed from the final agreement.

IP enabled the development of a pipeline of therapeutics solutions to combat COVID-19.

- While the vaccines currently authorized for use against COVID-19 use novel technologies, they are the result of decades of scientific research – made possible by effective IP – that has now been successfully applied during the pandemic.
- Of the over 1,600 active COVID-19 clinical trials, almost two-thirds tested existing medicines registered for a different indication, illustrating the ways IP enables follow-on innovation.
- Vaccines and therapeutics were developed at unprecedented speed because of the unprecedented scale of public-private partnership. As governments pivot their focus to the distribution of the vaccine, IP will be critical to facilitating licensing and technology transfer while also expediting the manufacturing and delivery of vaccines and therapeutics.

While IP was critical to the global response to COVID-19, economies took steps to undermine the framework that successfully enabled coronavirus-related innovation.

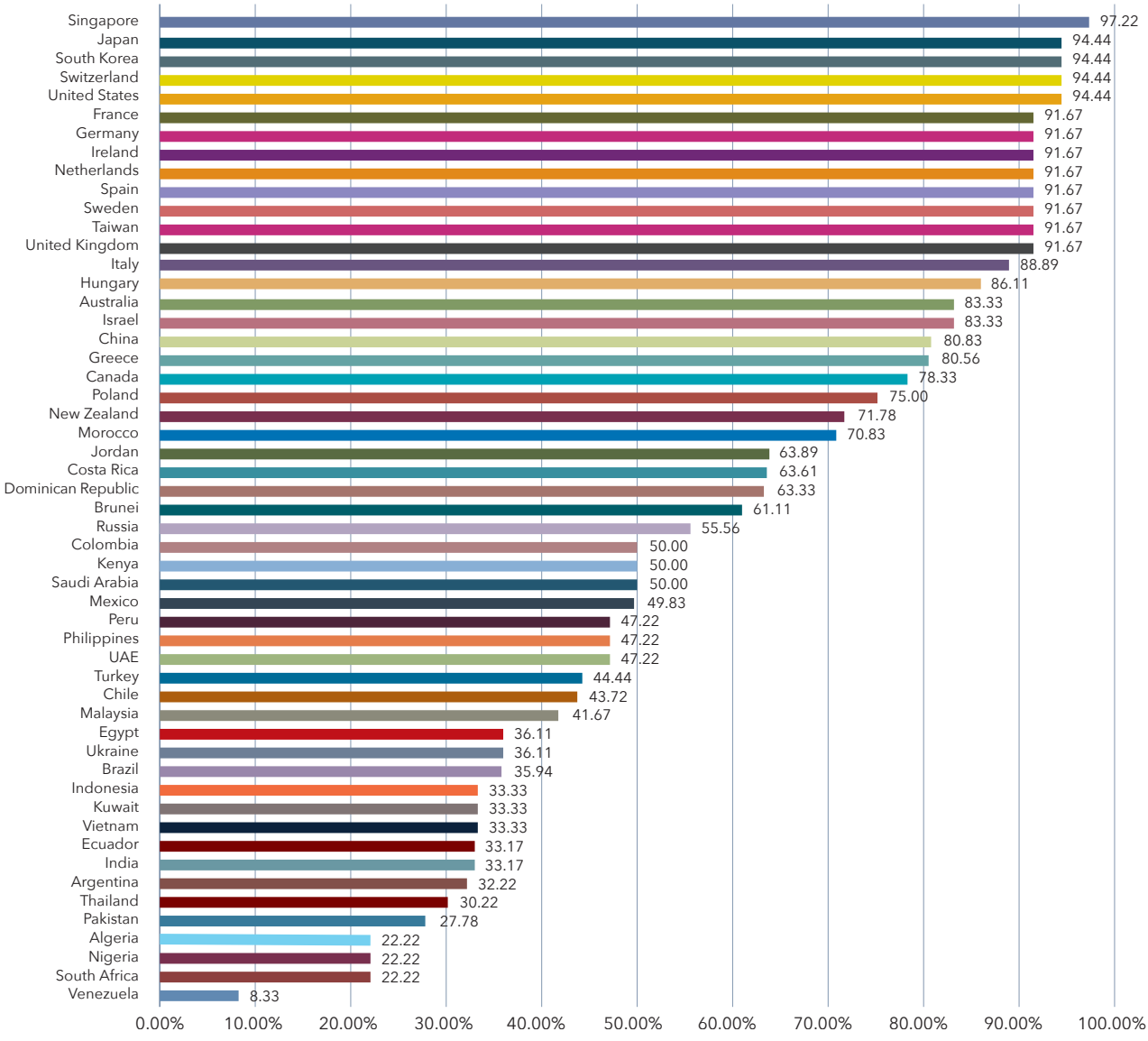
- In Israel, Hungary, and Russia, governments issued compulsory licenses for COVID-19 therapeutics.
- Other economies, including Chile, Colombia, and Indonesia called for or enacted new laws that expand the criteria for compulsory licensing.
- At the World Trade Organization (WTO), India and South Africa issued a proposal to waive IP rights on all COVID-19 related medicines, devices, and technologies through the TRIPS Council waiver

CATEGORY-BY-CATEGORY RESULTS

Patents, Related Rights, and Limitations

Twenty-one economies achieve a score of 70% or more of the available score and 31 economies in total achieve a score of over 50%.

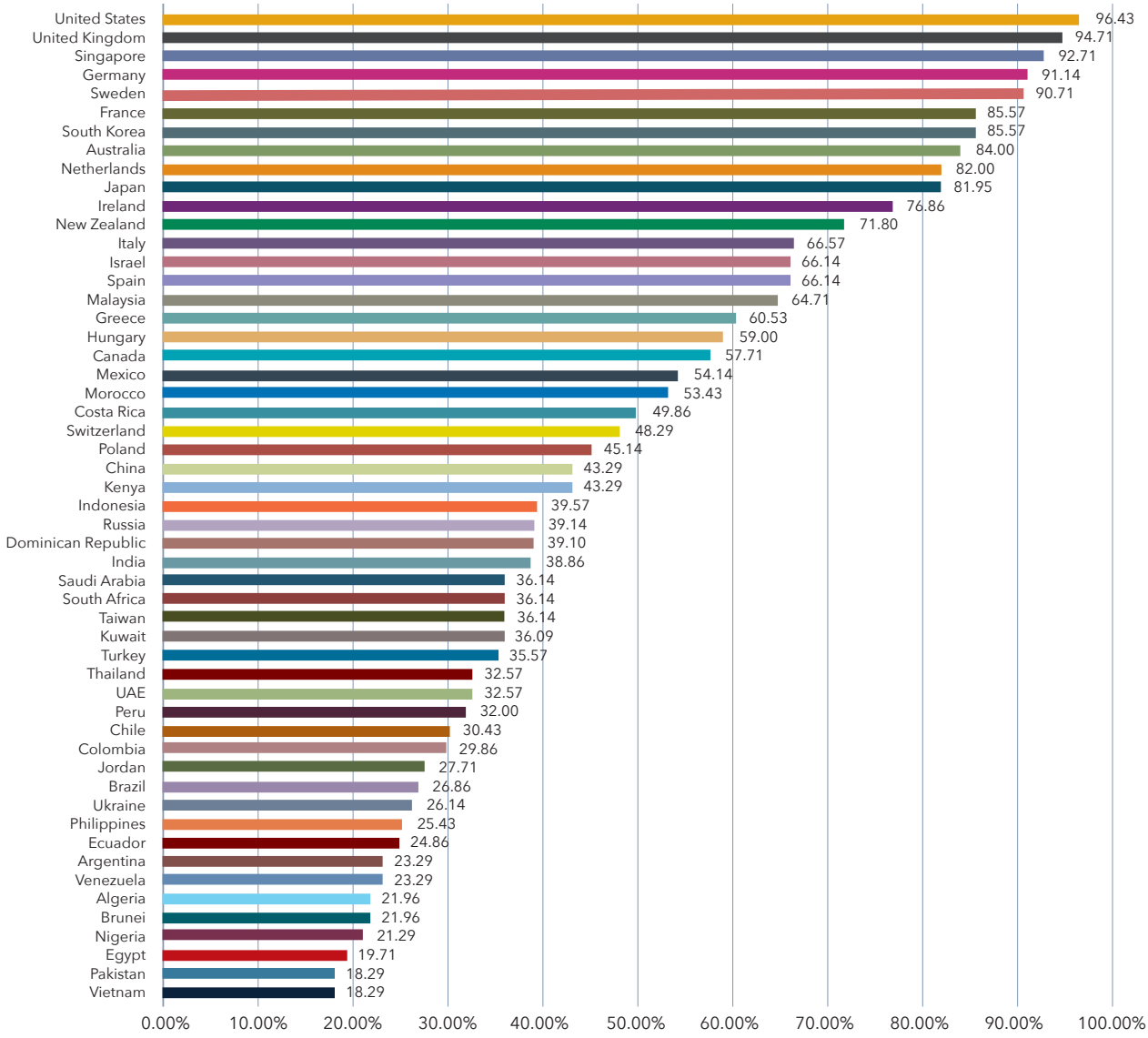
- In the United States, the U.S. Patent and Trademark Office (USTPO) guidance on patent eligible subject matter led to a statistically significant decrease in the first office rejections for *Alice*-related technologies. Additionally, USPTO proposed changes to the *inter partes review* process on patent validity challenges.
- In China, the government passed amendments to the Patent Law which outline China's new patent linkage regime and introduce patent term restoration for biopharmaceuticals.
- In Australia, the government announced their intention to create an early patent notification framework to create an opportunity for resolution of patent disputes before a generic is listed on the Pharmaceutical Benefits Scheme.
- In India, the government streamlined reporting requirements for patent holders under the Form 27 scheme.



Copyrights, Related Rights, and Limitations

The global environment for creators and copyright holders continues to be challenging, with 32 of the 53 economies failing to reach 50% of the total available score. However, there were a number of positive copyright reforms in Index economies over the last year.

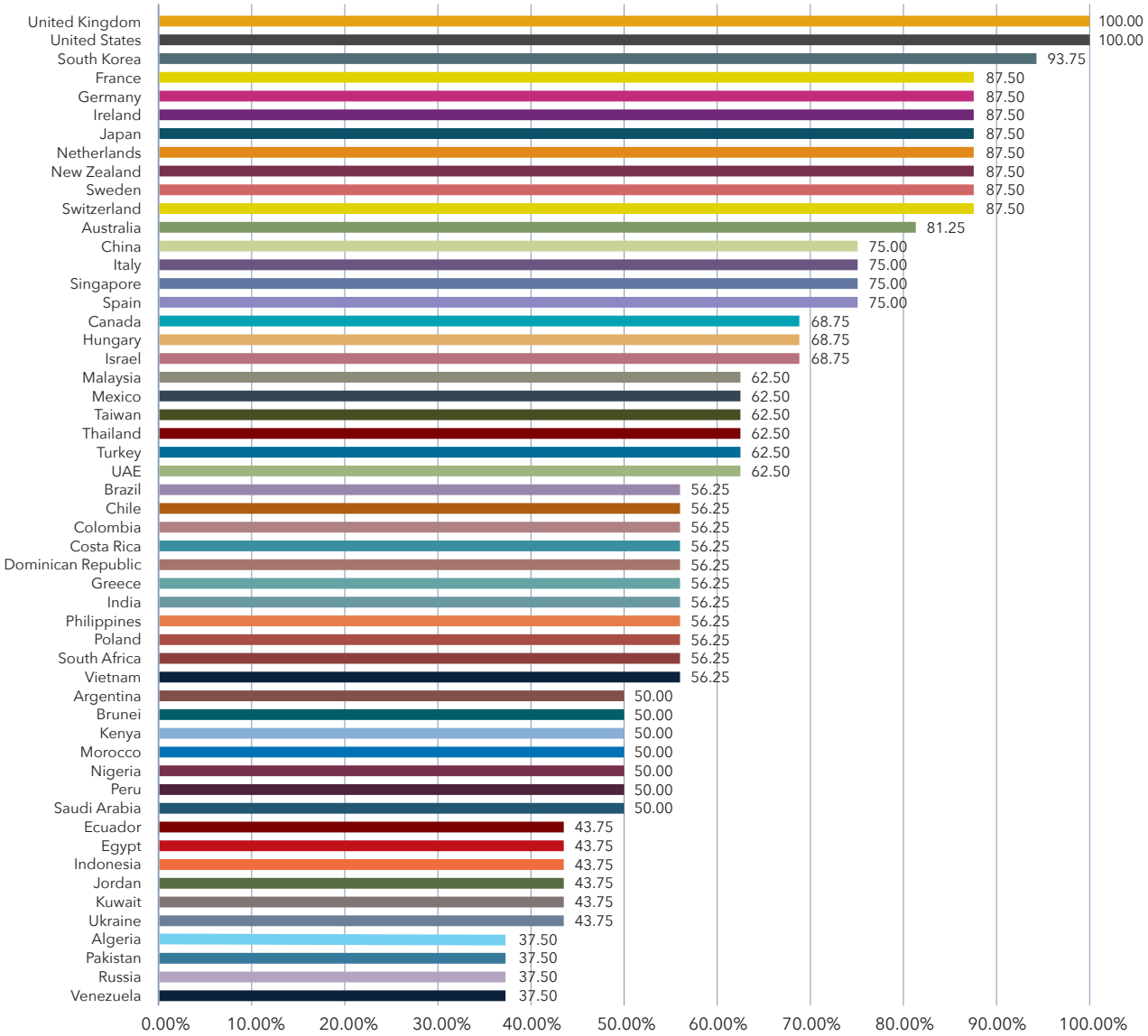
- As a result of the USMCA, both Mexico and Canada introduced copyright reforms. While the Canadian government extended the term of protection for some copyrighted works, the Mexican government introduced more substantive reforms to the Federal Law on Copyright.
- New amendments to the Chinese Copyright Law strengthened the legal framework for sound and broadcasting, improved provisions on technological protection measures (TPMs) and digital rights management (DRM) and increased statutory damages for copyright infringement.
- In Costa Rica, the government developed a new software asset management platform to ensure that all central government ministries use fully licensed software.



Trademarks, Related Rights, and Limitations

Online shopping increased dramatically during the COVID-19 pandemic, leading to a corresponding increase in the online sale of counterfeit goods. While many economies lack the appropriate resources to combat the increase sale of counterfeit goods online, there were a series of positive developments in 2020.

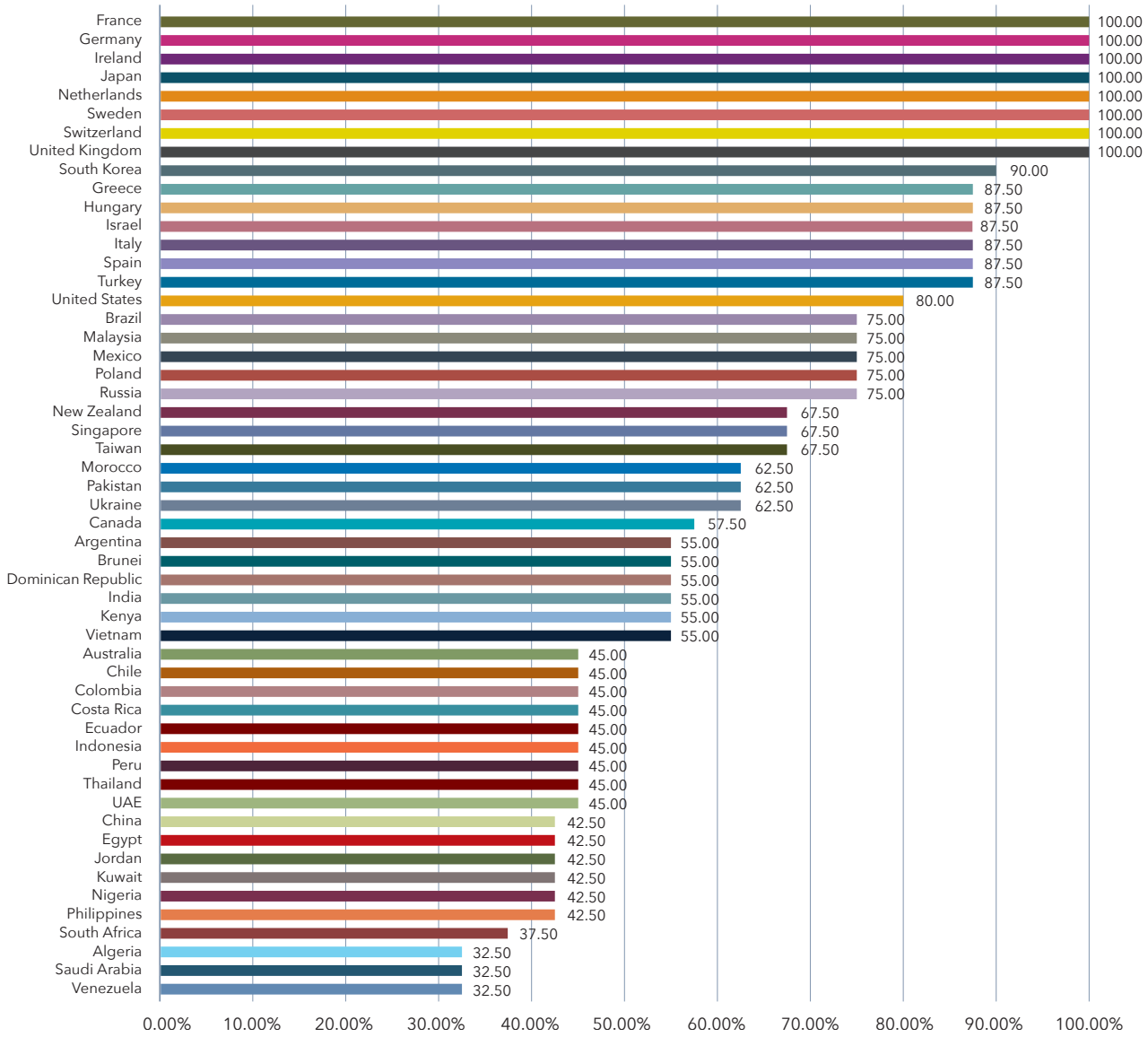
- In Thailand, the government applied an injunctive-style relief mechanism to disable access to websites with trademark-infringing content.
- In Mexico, the revised Industrial Property Law included a mechanism whereby injunctive-style relief can be obtained directly from the national IP office for online trademark violations.
- In Malaysia, the Parliament passed the Trademarks Act which expands the type of marks that can be registered, improves enforcement provisions against trademark-infringing goods, and makes Malaysia a contracting party to the Madrid Protocol.



Design Rights, Related Rights, and Limitations

Many of the Index economies have some form of design rights protection in place, with an average score of 64.95% in this category.

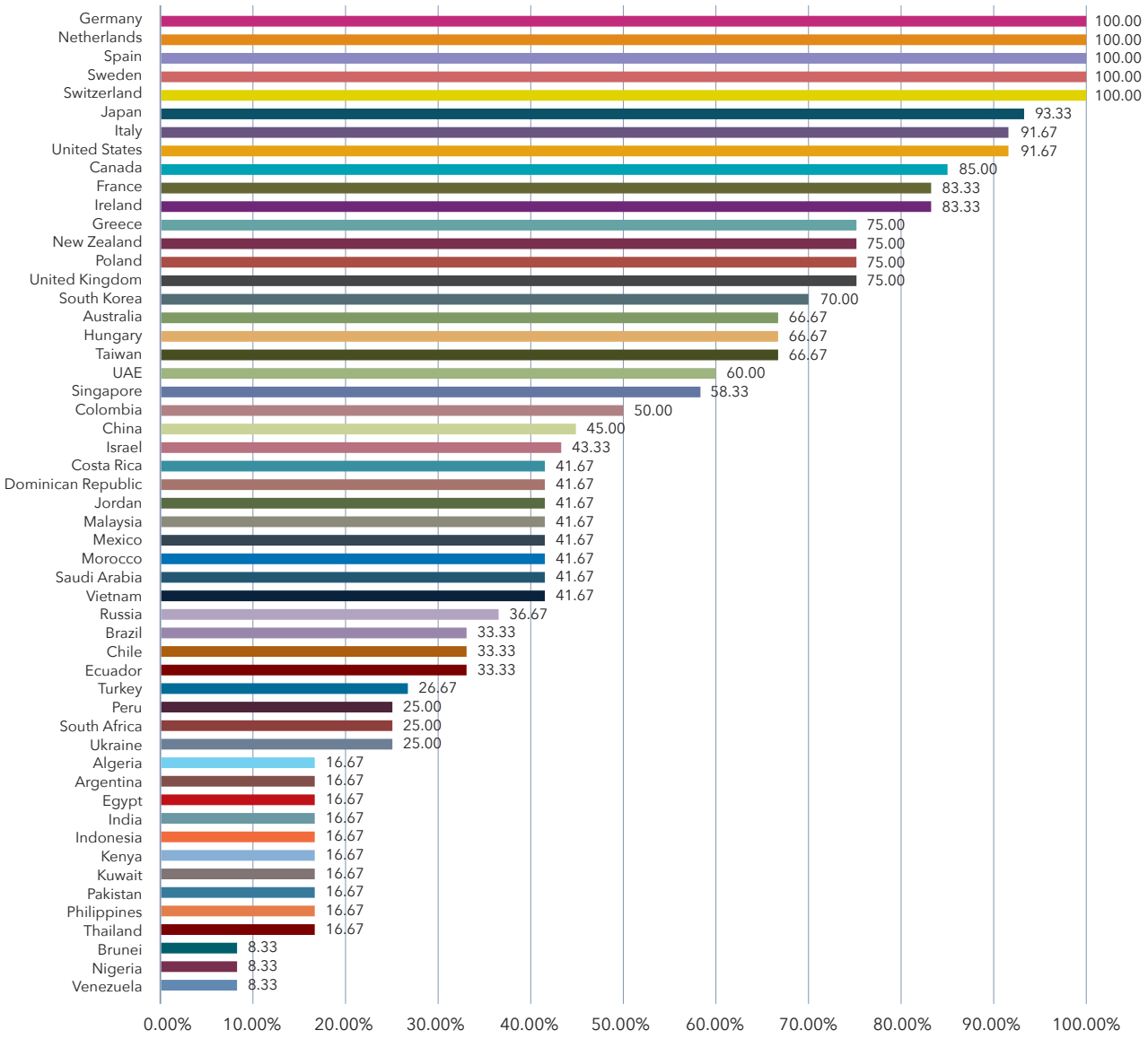
- In 2020, China, Japan and the Ukraine all increased the available term of protection for design rights.
- In the EU, design rights holders can file a request for customs action in individual Member States as well as all Member States specifying both registered and unregistered design rights be protected.



Trade Secrets, Related Rights, and Limitations

Many Index economies to do not have specific trade secrets legislation in place, with an average score of 49.40% in this category.

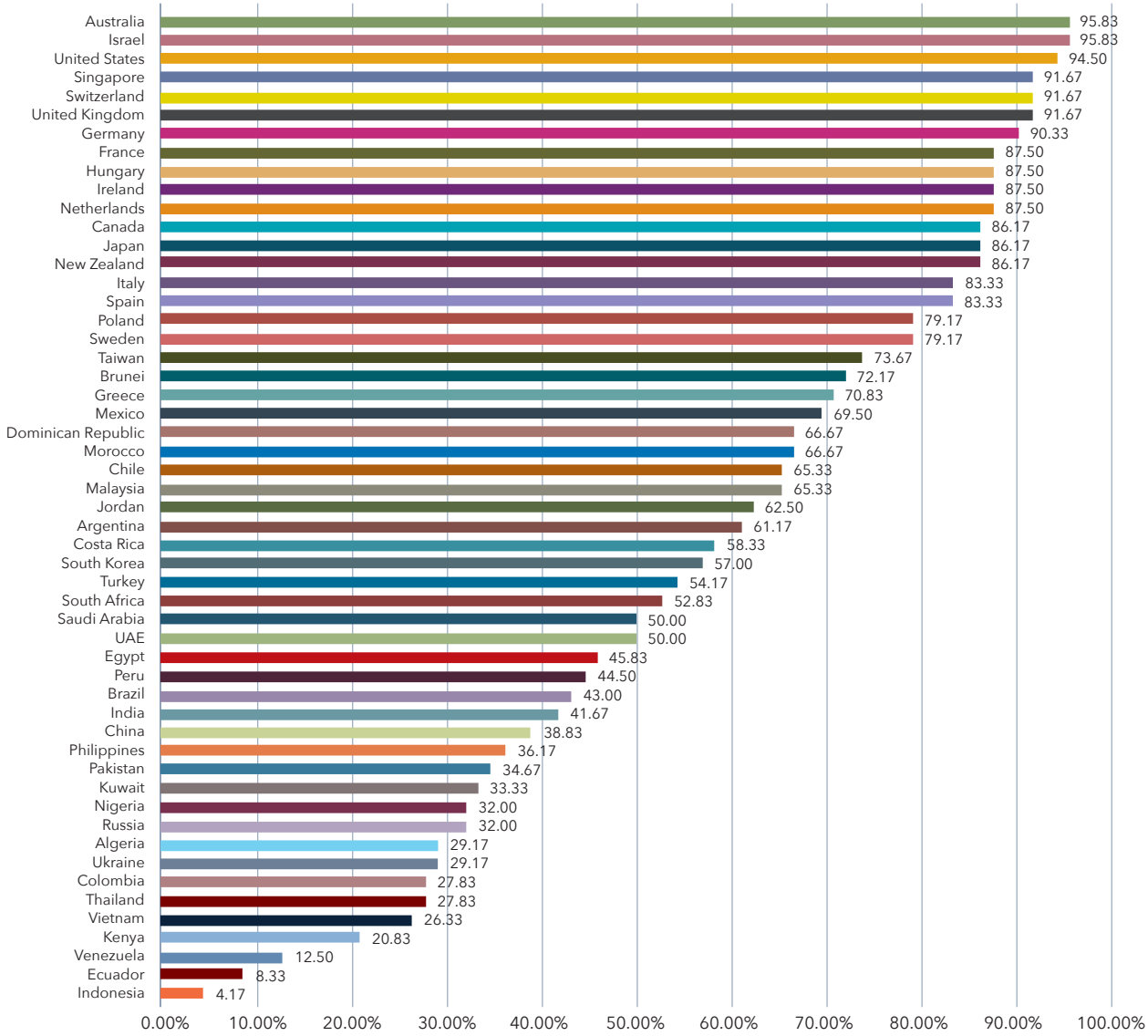
- In Canada, Parliament passed new criminal provisions, including a 14-year prison term, for the theft and misappropriation of trade secrets as part of its USMCA implementation.
- In Taiwan, the Legislative Yuan passed a new trade secrets law that provides stronger safeguards for foreign rights-holders and better protection for confidential information during criminal investigations.
- While the UAE introduced an 8-year term of regulatory data protection (RDP) for pre-clinical and clinical data, new draft implementing regulations in Saudi Arabia will limited the availability of RDP in the market.



Commercialization of IP Assets

Many of the economies benchmarked in the Index have introduced policies that limit market access or commercialization of IP assets, with an average score of 59.42% in this category.

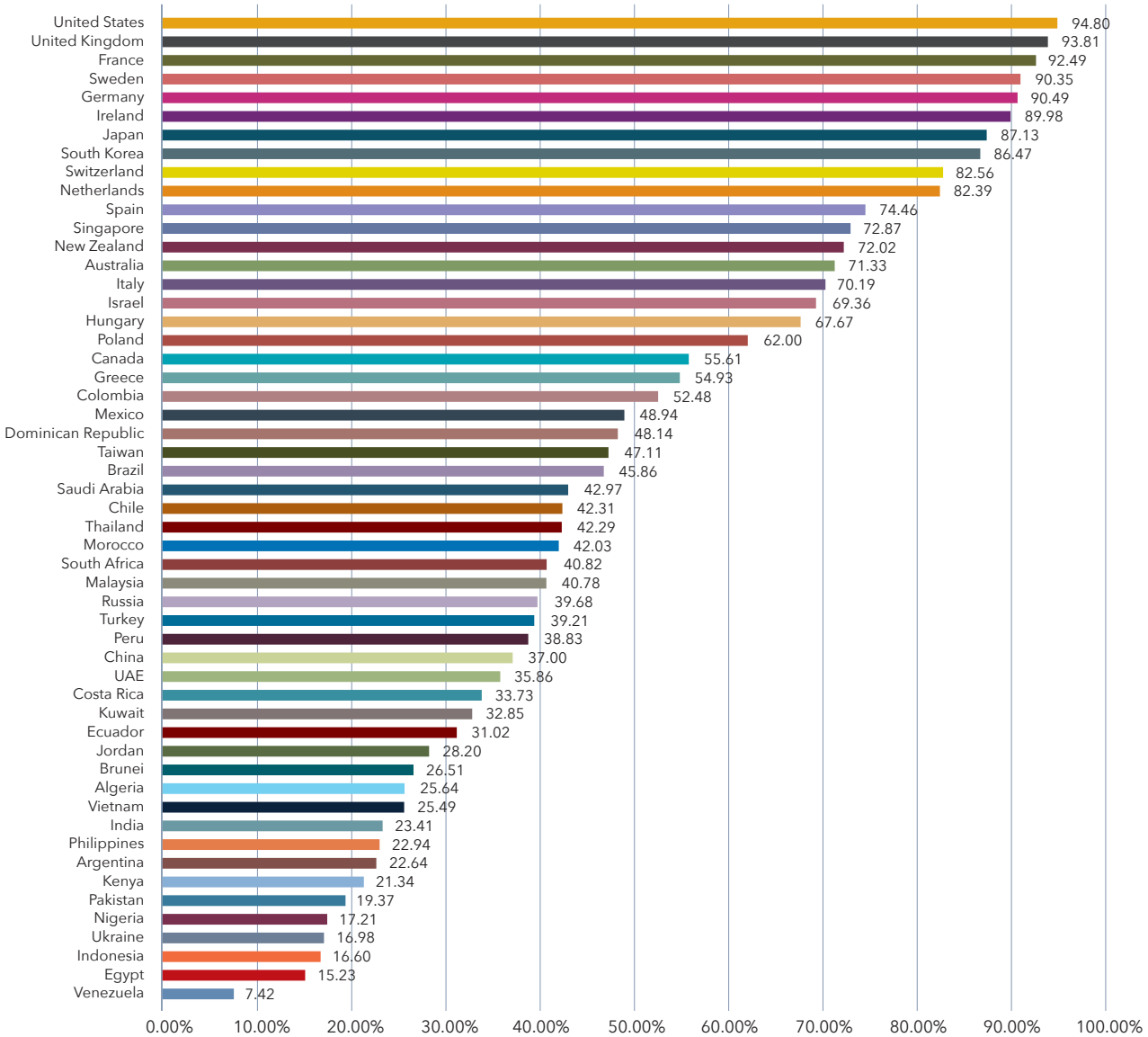
- While Algeria has historically had a poor environment for commercialization, the 2020 Finance Law removed the 51-49% ownership requirement for non-strategic industries.
- In Turkey, the Parliament passed amendments introducing new local data storage requirements for social media services.
- In Nigeria, the government introduced new guidelines and amendments that strengthen existing localization requirements for multinational software companies and the oil and gas industry.



Enforcement

Enforcement against IP theft continues to be a challenge for rights holders operating in global markets. Twenty-one economies (39.62%) achieve a score of 50% or more on this category, and only 10 economies achieve a score of 75% or more.

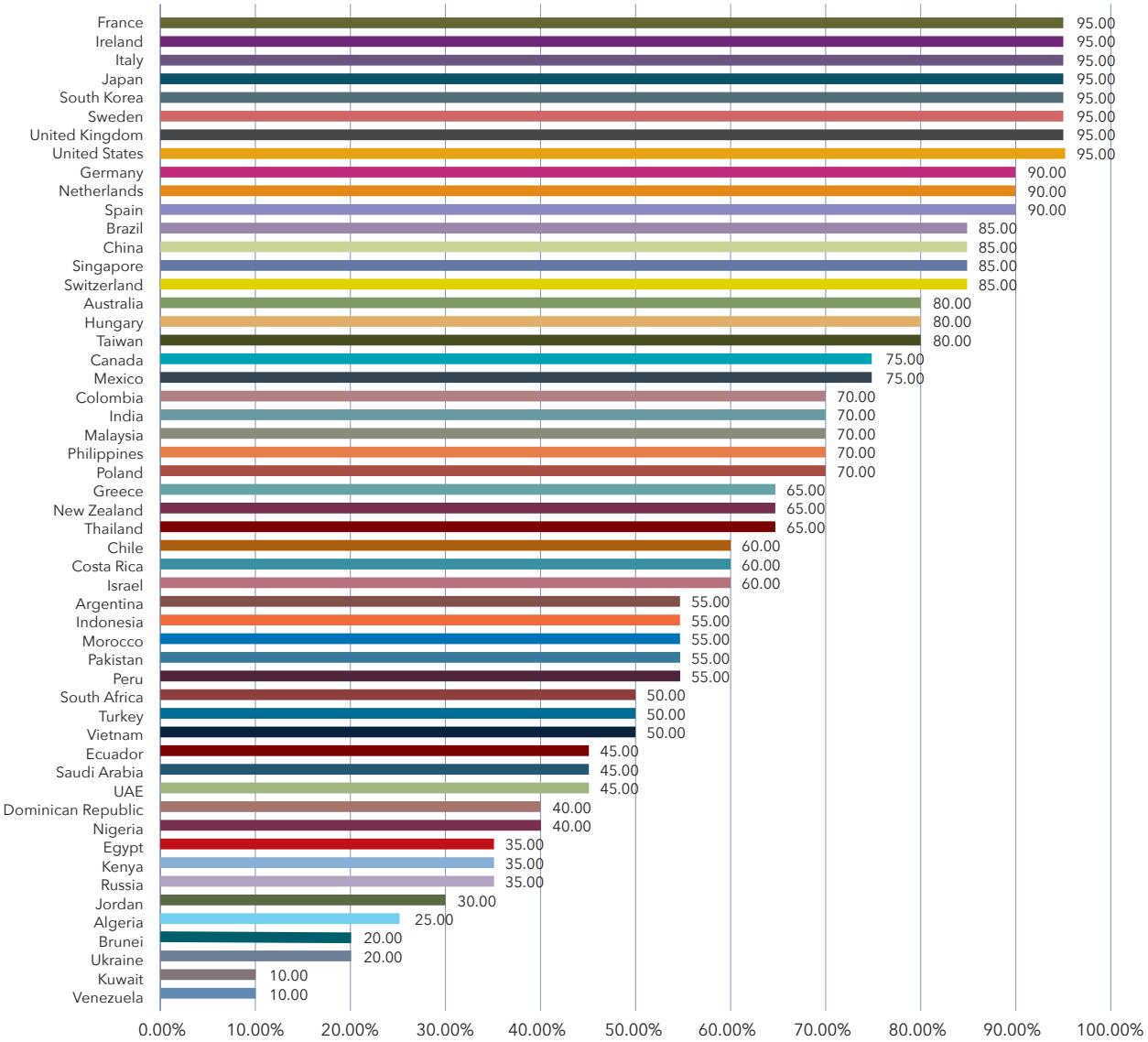
- Only 16 of the 53 economies sampled in the Index regularly publish data on customs actions taken against suspected counterfeit goods.
- However, in 2020, Algeria, Chile and South Korea issued new reports issued or transparency measures on counterfeit goods seizures.
- As part of its implementation of the USMCA in 2020, Canada passed new provisions providing *ex officio* authority to detain all suspected counterfeit goods, including those in-transit.



Systemic Efficiency

Many Index economies score well in the Systemic Efficiency indicators, with only 14 economies failing to achieve a score of 50% or above and an average category score of 63.11%.

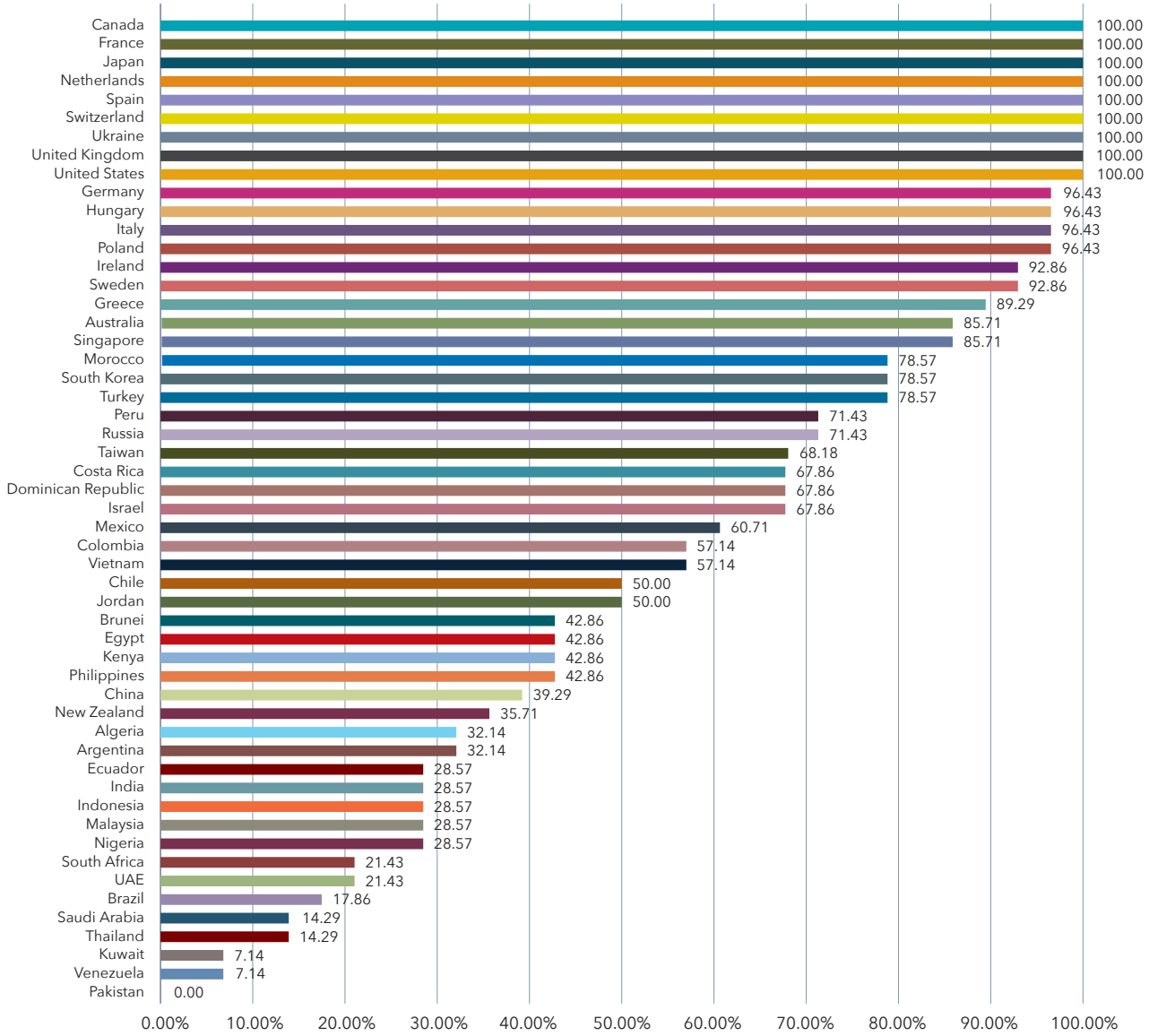
- In Costa Rica and Argentina, the national IP offices expanded existing public awareness campaigns.
- In Saudi Arabia and Ecuador, the national IP authorities launched new initiatives to help SMEs register and commercialize their IP assets.
- In Australia, the national IP offices issued a report that maps the contributions of IP-intensive industries to the Australian economy.
- Brazil concluded consultations for its first-ever National Intellectual Property Strategy—which will guide the country's IP policy for the next 10 years—and kicked off a National Innovation Strategy.



Membership and Ratification of International Treaties

While the numbers of treaties benchmarked in the Index has expanded over the nine editions of the report, many economies are not contracting parties to the majority of the treaties included. Twenty-one economies fail to achieve a score of 50% or more in this category.

- New trade agreements in China, Mexico, and Vietnam resulted in score increases for each of those three economies.
- In Egypt, the government acceded to the International Convention for the Protection of New Varieties of Plants, act of 1991.
- In Colombia, the government ratified the Convention on Cybercrime in March 2020, and the agreement is now in force.



ECONOMIES WITH
EFFECTIVE IP SYSTEMS

Are **38% MORE LIKELY** to attract venture capital and private equity

Have **2X MORE** innovation output

Have **OVER 550 MORE** high-value inventions patented per million population

Almost **5X MORE** knowledge output in scientific and technical journals

Host over **10X MORE** clinical trials

2X THE ACCESS to new music through legitimate and secure platforms

3 OVERVIEW OF THE NINTH EDITION

Now in its ninth edition, the U.S. Chamber of Commerce's International IP Index continues to provide an important industry perspective on the IP standards that influence both long- and short-term business and investment decisions. The Index is a unique and continuously evolving instrument. Not only does it assess the state of the international IP environment, it also provides a clear roadmap for any economy that wishes to be competitive in the 21st century knowledge-based global economy. Large or small, developing or developed, economies from around the world can utilize the insights about their own national IP environments as well as that of their neighbors and international competitors to improve their own performance and better compete at the highest levels for global investment, talent, and growth.

ECONOMIES INCLUDED

The Index today covers 53 economies that together represent both a geographical cross-section of the world and most of global economic output, together contributing over 90% of global GDP.

As Table 1 shows, the Index includes economies from all major regions of the world and is truly a global measure.[1]

Table 1: Ninth edition Index economies by World Bank region

ASIA	LATIN AMERICA & THE CARIBBEAN	AFRICA & MIDDLE EAST	EUROPE & CENTRAL ASIA	NORTH AMERICA
Australia	Argentina	Algeria	France	Canada
Brunei	Brazil	Egypt	Germany	United States
China	Chile	Israel	Greece	
India	Colombia	Jordan	Hungary	
Indonesia	Costa Rica	Kenya	Ireland	
Japan	Dominican Republic	Kuwait	Italy	
Malaysia	Ecuador	Morocco	Netherlands	
New Zealand	Mexico	Nigeria	Poland	
Pakistan	Peru	Saudi Arabia	Russia	
Philippines	Venezuela	South Africa	Spain	
Singapore		UAE	Sweden	
South Korea			Switzerland	
Taiwan			Turkey	
Thailand			United Kingdom	
Vietnam			Ukraine	

Source: World Bank (2020)

In addition to geographic diversity, the Index also includes economies from a broad spectrum of income groups as defined by the World Bank. Below, Table 2 provides an overview of all 53 economies sampled according to income group as defined by the World Bank.

Table 2: Ninth edition Index economies by World Bank income group

LOWER-MIDDLE-INCOME ECONOMIES	UPPER-MIDDLE-INCOME ECONOMIES	HIGH-INCOME ECONOMIES	HIGH-INCOME OECD MEMBERS
Algeria	Argentina	Brunei	Australia
Egypt	Brazil	Kuwait	Canada
India	China	Saudi Arabia	Chile
Kenya	Colombia	Singapore	France
Morocco	Costa Rica	Taiwan	Germany
Nigeria	Dominican Republic	UAE	Greece
Pakistan	Ecuador		Hungary
Philippines	Indonesia		Ireland
Ukraine	Jordan		Israel
Vietnam	Malaysia		Italy
	Mexico		Japan
	Peru		Netherlands
	Russia		New Zealand
	South Africa		Poland
	Thailand		South Korea
	Turkey		Spain
	Venezuela		Sweden
			Switzerland
			United Kingdom
			United States

Source: World Bank (2020)

REGIONAL RANKINGS

REGION	AVERAGE OVERALL % INDEX SCORE
North America	85.01%
Europe and Central Asia	77.18%
Asia	55.37%
Latin America	43.28%
Africa and Middle East	40.66%

NORTH AMERICA	OVERALL SCORE	REGIONAL RANKING
United States	95.31%	1
Canada	74.71%	2

EUROPE AND CENTRAL ASIA	OVERALL SCORE	REGIONAL RANKING
United Kingdom	93.90%	1
Germany	92.27%	2
France	91.43%	3
Sweden	90.92%	4
Netherlands	90.02%	5
Ireland	88.86%	6
Switzerland	85.82%	7
Spain	84.68%	8
Italy	83.15%	9
Hungary	78.23%	10
Greece	70.67%	11
Poland	70.50%	12
Turkey	51.07%	13
Russia	46.58%	14
Ukraine	39.54%	15

ASIA	OVERALL SCORE	REGIONAL RANKING
Japan	91.12%	1
Singapore	84.38%	2
South Korea	83.73%	3
Australia	80.55%	4
New Zealand	69.10%	5
Taiwan	66.18%	6

ASIA	OVERALL SCORE	REGIONAL RANKING
China	54.86%	7
Malaysia	51.61%	8
Brunei	41.13%	9
Philippines	39.81%	10
India	38.40%	11
Vietnam	37.49%	12
Thailand	35.56%	13
Indonesia	30.16%	14
Pakistan	26.43%	15

LATIN AMERICA	OVERALL SCORE	REGIONAL RANKING
Mexico	58.25%	1
Costa Rica	54.46%	2
Dominican Republic	54.32%	3
Colombia	48.17%	4
Chile	47.20%	5
Peru	46.56%	6
Brazil	42.32%	7
Argentina	36.77%	8
Ecuador	30.60%	9
Venezuela	14.10%	10

AFRICA AND MIDDLE EAST	OVERALL SCORE	REGIONAL RANKING
Israel	72.57%	1
Morocco	59.62%	2
Jordan	44.53%	3
UAE	41.98%	4
Saudi Arabia	40.38%	5
Kenya	37.25%	6
South Africa	36.61%	7
Egypt	32.59%	8
Kuwait	27.86%	9
Nigeria	27.43%	10
Algeria	26.45%	11

4 THE GLOBAL IP ENVIRONMENT IN 2020

THE BROADER CONTEXT: THE COVID-19 PANDEMIC

Over the past 15 months, the COVID-19 pandemic has dominated world affairs. At the time of research, over 100 million persons had tested positive for the virus globally and more than 2 million deaths were recorded.[2] While the outbreak was initially concentrated in China and high-income economies in Southeast Asia, Western Europe, and the United States, new cases are growing daily all over the world, including in lower-income emerging and developing world markets.

The pandemic is having a dramatic and deep impact on health systems and the global economy. Year-end estimates by the Organisation for Economic Co-operation and Development (OECD) in its December 2020 *Economic Outlook* found that real global gross domestic product (GDP) shrank by 4.2% in 2020.[3] The negative economic impact has been particularly pronounced in the United Kingdom, Latin America, the Eurozone, Russia, and the Middle East, with estimated national economic contractions of 5% or more. Global trade has also seen a sharp drop. The second quarter of 2020 saw a quarter-on-quarter decline of almost 15%, the highest on record.[4] World Trade Organization (WTO) estimates suggest that, while not as bad as the second quarter, the overall drop in merchandise trade volume is likely to be just under 10%, at 9.2%, in 2020. While economic activity is currently recovering in many economies, it is likely that there will be an extended period of time before the global economy will return to pre--pandemic levels.

INNOVATION AT THE SPEED OF LIGHT: COVID-19 AND THE BIOPHARMACEUTICAL INDUSTRY

While so many technology-based companies and IP-intensive industries have allowed consumers, businesses, and societies to keep functioning in the face of the unprecedented pressure of the COVID-19 pandemic, no other industry or sector can match the incredible accomplishments of the research-based biopharmaceutical industry. For the industry, the pandemic has been a cause for full-scale mobilization. Individual companies and industry associations are actively working with governments around the world to help alleviate the pressures on national health systems, develop new treatments and vaccines, and ensure manufacturing capacity can meet all demand. Since the onset of the pandemic, research-based companies have dedicated substantial scientific, financial, and medical resources to the fight against the virus. Specific examples include companies' pledges to donate millions of doses of potential medical treatments to affected economies; initiate new clinical trials and research for use of existing treatments in COVID-19 patients; create partnerships with other life sciences companies, the public sector, and nonprofits like the Gates Foundation on COVID-19 vaccine development; as well as direct financial donations to affected communities. According to data from the Biotechnology Innovation Organization (BIO), it took roughly three months from the publication of genetic sequencing data of COVID-19 until the first human studies for vaccine candidates began.[5] This compares to 20 months during the Severe Acute Respiratory Syndrome (SARS) outbreak in 2003. At the time of research, data published by the Pharmaceutical Research and Manufacturers of America (PhRMA) at the end of 2020 showed that almost 1,600 active clinical trials were taking place globally to test treatments and potential vaccines for COVID-19. Of these trials, almost two-thirds (994 trials) were testing existing medicines registered for a different indication. Almost 600 unique COVID-19 treatments were being tested, and a total of 145 vaccines were in clinical trials with a further 162 in preclinical testing. Most important, in December 2020,

two vaccines—discovered and developed by Pfizer-BioNTech and Moderna Therapeutics, respectively—were approved for emergency use in North America, Europe, and parts of Asia. At the time of research, millions of patients around the world had begun to receive the inoculations.

It is impossible to overstate the enormity of these accomplishments. The speed at which this research has taken place is unprecedented and shows the extensive scientific capacity developed by the biopharmaceutical industry and the biotech community and the ability to scale up quickly and decisively to understand and develop a treatment for a novel virus that was not prevalent in humans 18 months ago. At a scientific, manufacturing, distribution, and organizational level, the innovative scientific community's response to COVID-19 has been remarkable. As many politicians, policymakers, and scientists pointed out when the first vaccine was approved for emergency use by the U.S. Food and Drug Administration (FDA), this achievement truly amounts to a modern-day miracle.

Similarly, the innovation and creativity of other IP-intensive industries and sectors have been absolutely central to allowing societies, workplaces, and economies to function as the pandemic has raged across the world through remote working, the use of telehealth medical services, and online shopping. And while all these products and technologies existed before the pandemic struck, all areas of activity have, by and large, exploded in conjunction with the pandemic.

But what has enabled the creation and commercialization of these technologies?

The simple fact is that the innovation, science, and technological progress that has allowed societies to function during the COVID-19 pandemic did not emerge overnight.

Instead, these technologies and products are the fruit of a pre-existing innovation ecosystem that is centered on and built around IP rights and incentives. Without strong and clear IP rights it is unlikely that any of those products and technologies—or the underlying R&D—that have been so essential to keeping societies functioning and fighting the COVID-19 pandemic would exist.

As the Index and its accompanying *Statistical Annex* have shown over the past nine years, the link between IP rights, innovation, and the commercialization of new products and technologies is clear and statistically significant.

A SYMBIOTIC RELATIONSHIP: IP RIGHTS AND INNOVATION

The concept of innovation enjoys wide-ranging, if not universal, support. Both developed and developing economies alike recognize the importance and impact of innovation on their national economic performance, global competitiveness, and overall well-being. As part of their wider strategies for economic growth, they aim to put in place frameworks under which innovation can flourish. Innovation is, however, a complex concept that takes place in various shapes and forms. Peter Drucker, one of the gurus of innovation and entrepreneurship in the 20th century, considered innovation to be a social and economic phenomenon as much as it is a technological one. He found that innovation can be generated both from the supply side, via "the consistent manner of changing the yield (or maximizing the output) of existing resources," from the demand side, by "changing the value and satisfaction obtained from resources by the consumers," or through a combination of the two.[6] Other scholars have classified innovation not only according to its technological features (be it a product, a process, or a service) but also according to other characteristics, such as administrative or organizational structures (including the strategy, structure, system, and human capital of an organization), as well as the market itself (including pricing and marketing practices).[7] The bottom line is that innovation is highly complex, dynamic, and time sensitive. The composition, characteristics, pace, and direction of innovation—regardless

of the economic sector or industry—are influenced by a myriad of factors, external as well as internal, technological as well as social. Consequently, just as the manner in which innovation takes place is not subject to black or white patterns, neither can it be divided into good or bad categories. On the contrary, one can identify different forms of innovation—incremental, radical, modular, and architectural—all of which have a role to play in the overall life cycle of innovation and its interaction with society's progress.

Unfortunately, the complexity of and variety in how innovation takes place have shrouded one of its most fundamental driving principles: namely, that any attempt to dictate a certain direction of innovation (or when dealing with absolutes such as which innovations are desirable and which are not) using special "top-down instruments" will most likely end in failure. Rather, it is the dynamic relationship between firms, markets, the public, and the environment as a whole that directs the manner in which innovation and the creation and commercialization of new products and technologies is conducted, as well as the nature and direction it takes. Within this context, the existence of clear and strong IP rights is crucial both in theory and in practice.

FROM THE PROBLEM OF FREE-RIDING TO THE REAL WORLD OF INNOVATING, R&D AND CREATING NEW PRODUCTS AND TECHNOLOGIES: HOW IP RIGHTS ENABLE INNOVATION

> *"He who has no hope that he shall reap will not take the trouble to sow."*
>
> – Jeremy Bentham, 1800[8]

In the process of exploring ways of efficiently allocating scarce resources to unlimited wants, economists have come to find that private property rights are an efficient way of dealing with the problem of scarcity. Knowledge and other forms of intellectual creation, however, are a unique resource, given that they are not inherently scarce (at least not in the way economists understand the word). Theoretically speaking, the potential use of existing knowledge or any other form of intellectual creation is unlimited and may be diminished only when they become obsolete or irrelevant to society. In fact, the use of any intellectual creation or knowledge-based product by one individual does not reduce its accessibility to others but is more likely to increase it. Economically speaking, innovative products that are based on knowledge and other expressions of artistic and intellectual creations (be they a new piece of software, a medical technology, a pharmaceutical drug, or an innovative telecommunications product, to name just a few modern examples) have the characteristics of a "public good." They are "non-rival," in the sense that the use of such a product by one individual does not reduce its quantity or availability for others (i.e., there is not less of that creation to use). They are also "non excludable," in that the use of that creation by one individual does not prevent other people from using it at the same time.[9] For example, consider a case in which an author has introduced a brilliant masterpiece or the case of an innovator who was able to come up with a revolutionary invention in the medical field. Once these creations are introduced to the market, there is no physical limitation on the ability of others to freely use these creations to their own benefit. This is what makes knowledge-based products so special—the fact that they are not inherently scarce.

However, this is what also makes such products so vulnerable. In the absence of necessary protection mechanisms, there is an intrinsic temptation to use these products at the expense of the efforts and investment of their creators. The development of knowledge-based products is a very expensive, risky, and time-consuming endeavor. Yet, compared with the difficulties of creating a knowledge product, the cost of copying or downloading this product is negligible. As such, knowledge-based products are highly susceptible to the

so-called free-rider problem—a philosophical and economic dilemma referring to the act of using or deriving benefit from a social or economic outcome or activity without paying or contributing toward the cost or effort required to create it. Thus, economic theory suggests that, in the absence of any institutional provisions that establish property rights in knowledge-based products, the tendency to free-ride will increase. Consequently, the incentive to create these products will significantly decrease. This problem was recognized and noted in the 1800s by British philosopher Jeremy Bentham, who argued that "without the assistance of the law, the inventor would almost always be driven out the market by his rival, who finding himself without any expense, in possession of a discovery which has cost the inventor much time and expense."[10]

In order to prevent the problem of free-riding, society has designed various systems of IP rights and incentives. This includes everything from general, cross-sectoral rights such as patents, copyrights, trademarks, and design rights to more sector-specific rights and incentives such as regulatory data protection for biopharmaceutical test data. IP rights may be thought of as social contracts between society and the individual innovator (be it a person or company) who develops the new knowledge product or intellectual creation. This contract stipulates that, in exchange for society's ability to enjoy and use this new product or creation (which is a result of the time, money, and efforts invested by the individual), the innovator will be granted ownership, albeit for a limited period of time, of that product or creation. In this sense, IP rights have two major functions with regard to knowledge creation (and its uses) and innovation:

- IP rights provide confidence and security to the overall process of knowledge creation and innovation.
- IP rights also provide for the commercial platform on which knowledge is created, exchanged, and used for the purpose of advancing technological innovation.

Critically, the empirical evidence on the effects of IP rights on rates of innovation, high-tech output, and R&D largely bears out our theoretical understanding of how IP rights work: economies with strong national IP environments tend also to see higher levels of innovation, high-tech output, R&D, and commercialization activities.

LAYING THE FOUNDATION FOR FIGHTING THE NEXT PANDEMIC: MEASURING THE IMPACT OF IP RIGHTS ON INNOVATION AND ECONOMIC ACTIVITY

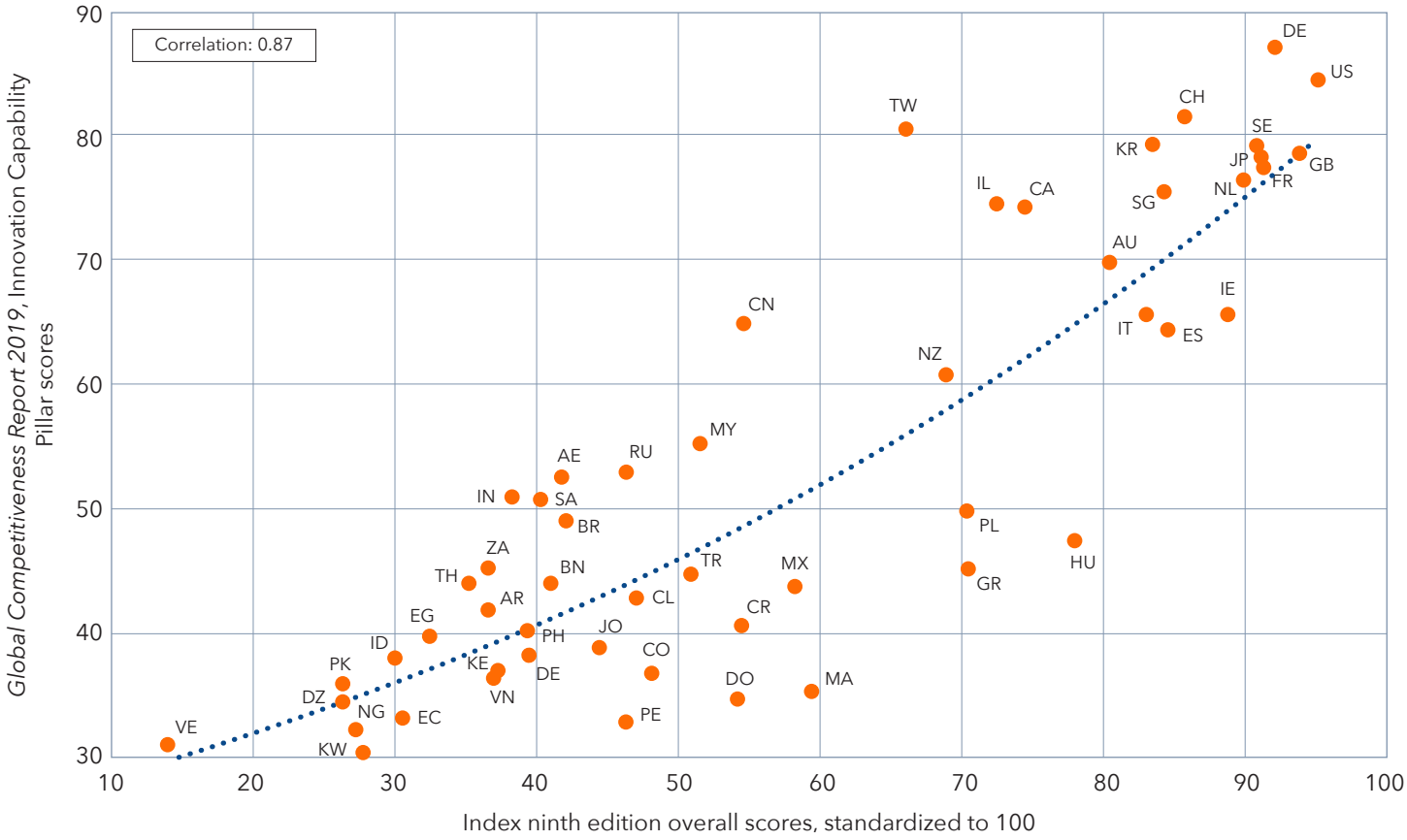
Since 2015, the Index has included a *Statistical Annex* that investigates the relationship between the strength of economies' national IP environments and different types of economic activity, including rates of R&D spending, innovation, technology creation, and creativity. The most up-to-date data on the benefits of IP protection reveal that IP rights are, in fact, a critical instrument for economies seeking to enhance access to innovation, grow domestic innovative output, and enjoy the dynamic growth benefits of an innovative economy. Conversely, weak IP protection stymies long-term strategic aspirations related to innovation and development.

This year's *Annex* has been updated with new data to reflect the expansion of the Index over the past two years from 50 to 53 economies. The evidence from these statistical correlations shows, again, the strong, direct, and statistically significant relationship between IP protection and innovation—ranging from attractiveness to venture capital and R&D investments, to high-tech employment, to the magnitude of innovative activities, outputs, and early adoption of technologies.

Specifically, looking at various measures of innovation capacity and output, the empirical evidence is quite clear—economies with stronger national IP environments have higher levels of innovation capacity and produce more innovation in the form of new products and technologies.

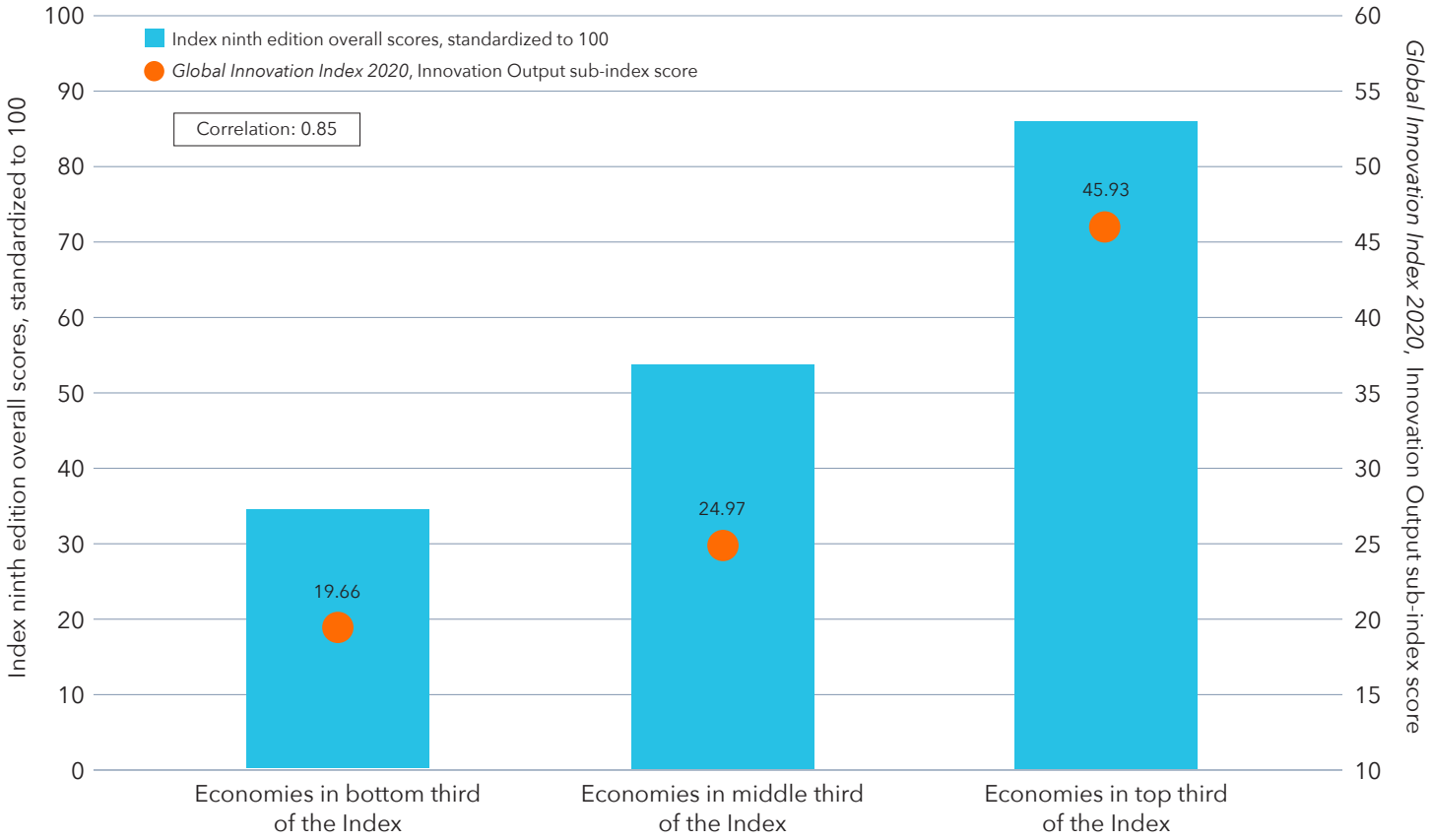
Below, Figures 1 and 2 show the relationship between "Innovation Capability" (as measured by the World Economic Forum in the *Global Competitiveness Report*), "Innovation Output" (as measured by WIPO and INSEAD in the *Global Innovation Index*), and strength of the national IP environment (as measured by the Index).

Figure 1: Association between the Index scores and the Global Competitiveness Report 2019, Innovation Capability Pillar scores[11]



Source: World Economic Forum (2019); Global Innovation Policy Center, U.S. Chamber of Commerce (2021)

Figure 2: Association between Index scores and the Global Innovation Index 2018, Innovation Output subindex scores[12]



As Figure 1 shows, economies with fair to strong IP regimes are much more likely to maintain an environment capable of producing innovative outputs compared with weaker economies. There is a very strong relationship (a correlation of 0.87) between the Index scores and the *Global Competitiveness Report*'s "Innovation Capability" pillar scores. Similar results can be seen in Figure 2. The *Global Innovation Index*'s "Innovation Output" sub-index is an aggregate measure that looks at a wide variety of indicators reflecting knowledge creation and development, including intangible assets, research publications, and high-tech production. When compared with the Index, there is also a very strong correlation of 0.85 to the Index scores. Economies with robust IP regimes experience more knowledge-based, technological, and creative outputs than do economies whose IP regimes trail behind.

Finally, it is worth examining the evidence on biopharmaceutical innovation and strength of a national IP environment. As mentioned, the speed at which COVID-19 vaccines and treatments have been developed over the past year has been truly breathtaking. Yet the science and technological capacity that has allowed industry, public research organizations, and academic researchers to carry out this development are based on decades of R&D experience and innovation. Just as for other forms of technological innovation, it is highly unlikely that this biopharmaceutical R&D would have taken place without strong and clear IP incentives. Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratory, research facilities, and researchers are high. Compared with many other high-tech industries—for example, computer software—developing the next ground-breaking

treatment for cancer or Alzheimer's disease requires more than just a laptop and a great idea. As medicines become more targeted and technically sophisticated, the cost of development rises dramatically. In 1979, the total cost of developing and approving a new drug stood at USD138 million. Almost 25 years later, in 2003, this figure was estimated at USD802 million.[13] A 2012 estimate points to the total cost of drug development being approximately USD1.5 billion.[14] The latest, 2016, research from Tufts University suggests that it costs USD 2.6 billion, on average cost, to develop a new drug.[15] International experience and the basic economics of the biopharmaceutical industry show how critical IP rights are to incentivise and support this research and development of new medical technologies and products.[16] In particular, patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection (RDP) and special exclusivity incentives for the protection and production of orphan drugs, enable research-based companies to invest vast sums in R&D and the discovery of new drugs, products, and therapies. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market entrants who bore none of the costs of early-stage investment, R&D, and product commercialization. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws.

Indeed, the available evidence on clinical research and rates of innovative clinical trials bears this out. Clinical trials represent one of the most important activities carried out by biopharmaceutical companies in different countries. Clinical research is a cornerstone of the drug development process. Conducting clinical trials is part of an extensive process for determining which compounds out of hundreds under investigation may be further developed and eventually brought to market, and in what manner. The main purpose of clinical trials is to test and provide proof of the safety, quality, and efficacy of new drugs or new uses, forms, or dosages of existing drugs. Clinical trials are conducted within a highly controlled and studied environment where all aspects of a drug candidate are monitored, recorded, and subjected to high levels of scrutiny and evaluation. The clinical research process includes complying with a wide range of regulations governing international best practices related to the quality, safety, and efficacy of drugs, for instance, good laboratory practice guidelines on conducting toxicity studies, good manufacturing practice, and protecting the rights of patients through good clinical practice.[17] Without clinical trials, it would be exceedingly difficult to test the safety, quality, and efficacy of a proposed new medical technology. In this sense, while the nature of clinical research has changed over the past few decades with new development technologies emerging, clinical research is still a fundamental cornerstone of modern medical development. Clinical trials also provide patients with early access to innovative drugs, which may literally revolutionize existing treatments available domestically for prevalent diseases.[18] In fact, clinical trials enable advance access to treatments that may continue beyond the duration of the trial.[19] In this sense, the availability of a trial in a host country can be the difference between a patient gaining access to a given novel treatment in research or waiting for a number of years until the product has been fully developed and globally launched. For patients with rare and/or difficult and terminal diseases, the availability of local trials can be a question of life or death. Clinical trials also enable local physicians to participate in cutting-edge research as well as become members of multicenter research networks. Such experience helps build R&D expertise and prestige, and expands the ability of local researchers to publish their research and become key opinion leaders in their field. They often involve improvements to infrastructure—hospitals, clinics, and health technologies—in local communities.[20] Participation in multinational, cutting-edge research helps ensure that clinical trials and sites meet international standards of good clinical practice and expose clinicians to new techniques and treatment

strategies. In this sense, the growth and conduct of clinical trials improve the overall medical research infrastructure and experience in a given country and region. Finally, clinical research can have significant positive direct and indirect macroeconomic benefits, as it represents the largest portion of biopharmaceutical R&D spending. In 2019, global life sciences R&D spending was estimated by Deloitte to be around $177 billion. A substantial proportion of this expenditure comes from members of the PhRMA trade association. In its annual 2019 membership survey, PhRMA estimated that R&D expenditure by member companies in 2018 totaled over USD78 billion.

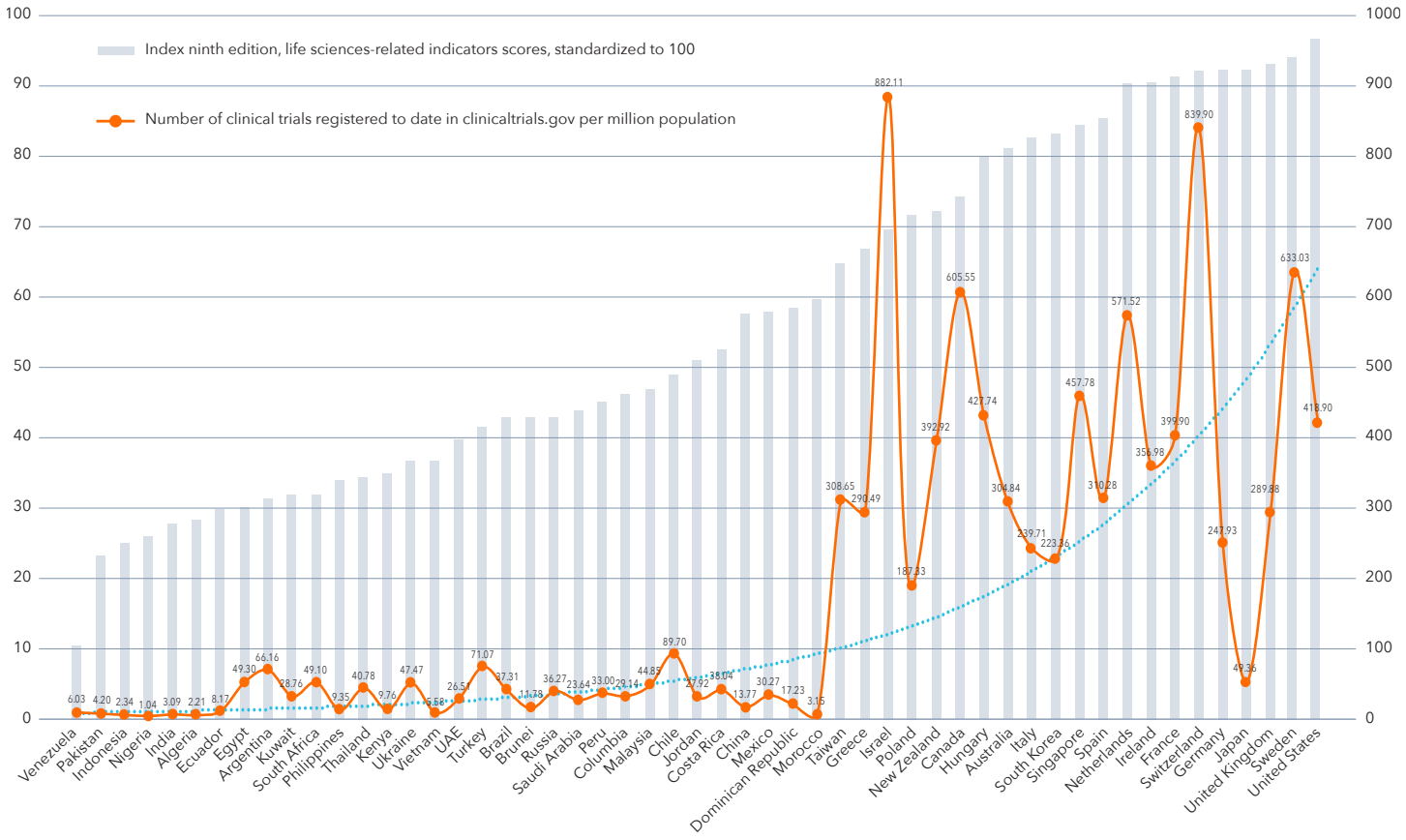
The level and complexity of clinical research and the number of active clinical trials is a good proxy for levels of biopharmaceutical innovation and R&D capacity. This is particularly true for the most complex and cutting-edge biopharmaceutical innovation represented by early-phase trials (phases I and II), and for trials involving large-molecule biologics and novel biotechnologies. The presence of high levels of per capita early phase trials suggests cutting-edge, innovative research is taking place, in the sense that these represent initial human testing of drug candidates' safety and efficacy, and therefore typically require very controlled environments and high-quality human resources and infrastructure that can ensure such an environment. Similarly, biologic and biotechnology-based medicines and technologies are increasingly being used in the treatment of some of the most difficult medical conditions today as well as in cutting-edge medical research. For example, the majority of the vaccines and therapeutics developed to be used against COVID-19 are based on new, complex biotech research. The vaccines developed by both Moderna and Pfizer-BioNTech are based on novel mRNA biotechnology. Unlike traditional vaccines, which inject a weakened or inactive pathogen, mRNA technology contains instructions on how the human body should make a specific piece of protein that elicits the desired immune system response.[21] Although scientists and biopharmaceutical researchers have been studying mRNA technologies for decades, the COVID-19 vaccines are the first that have been approved and used with this technology. Given the size, complexity, and inherent instability of a biologic, the R&D process requires a considerable level of stability and technical capacity. Testing of a biologic drug candidate's safety and efficacy within a clinical trial necessitates a highly controlled environment in which transportation and storage of the drug are controlled, the trial protocols are strictly adhered to, and patients are monitored carefully.

Looking at biopharmaceutical R&D and IP incentives, there is a strong and direct relationship between levels of clinical research and IP protection. Economies with higher levels of biopharmaceutical IP protection—that allow for the patenting of biopharmaceutical innovation, that provide RDP and full patent term restoration—tend also to host substantially higher levels of biopharmaceutical innovation as represented by clinical research. This year's *Statistical Annex* includes four relevant correlations relating to biopharmaceutical innovation:

1. Clinical trials
2. Early-phase clinical research
3. Development of biologic therapies
4. Biotechnological innovation

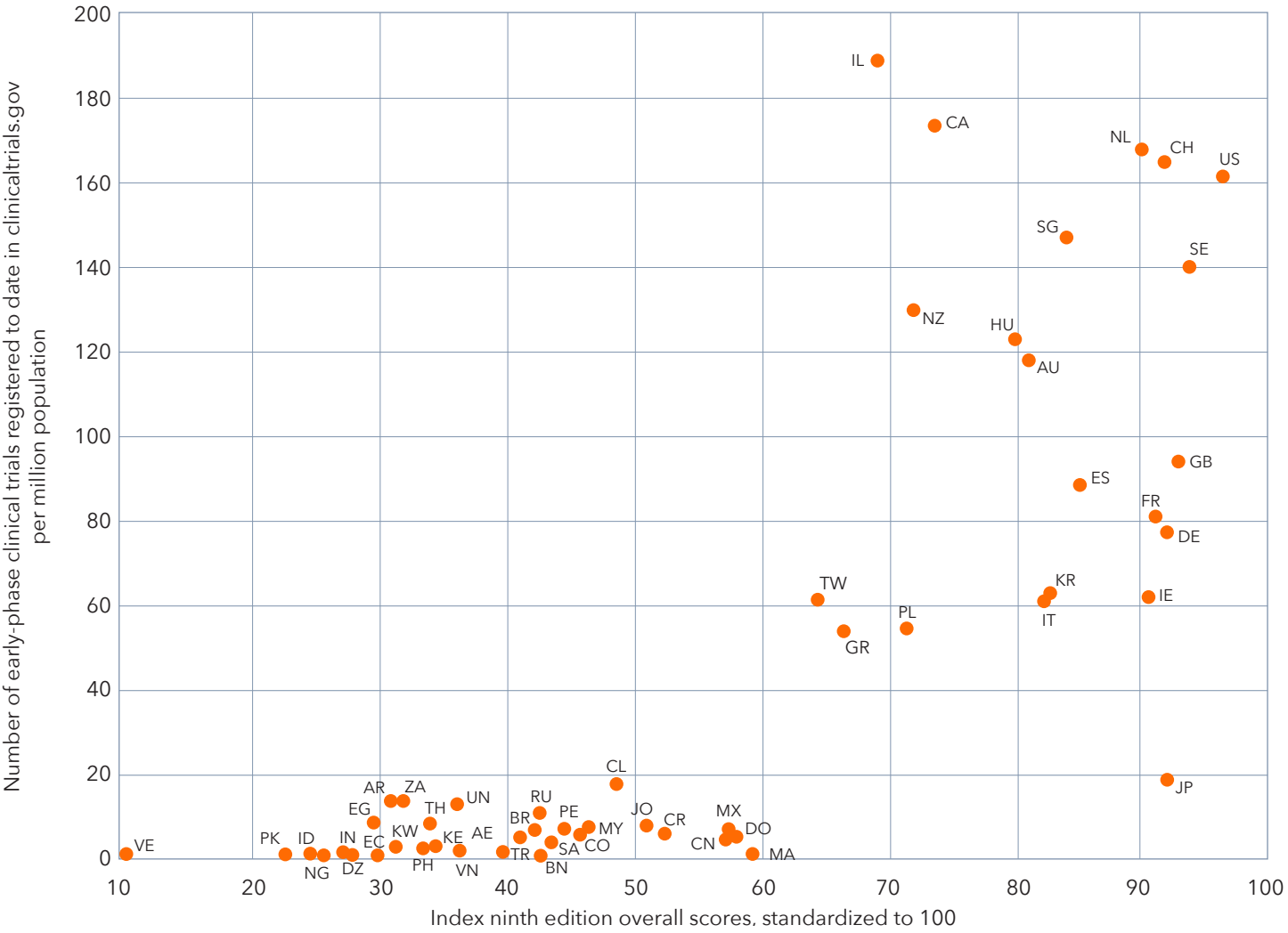
These correlations measure the relationship between IP rights specific to the biopharmaceutical sector and rates of the above-described indicators for biopharmaceutical innovation and R&D for the 53 economies include in the Index. Overall, the results are quite clear: There is a strong correlation between the availability of biopharmaceutical IP rights and levels of biopharmaceutical innovation as measured through levels of clinical research and by Scientific American's WorldView Scorecard. All correlations achieved a score of between 0.74 and 0.81, suggesting a strong relationship between the availability of relevant biopharmaceutical IP rights and the biopharmaceutical innovation variables measured.

Figure 3: Association between the Index life sciences-related indicators' scores and clinical trial activity[22]



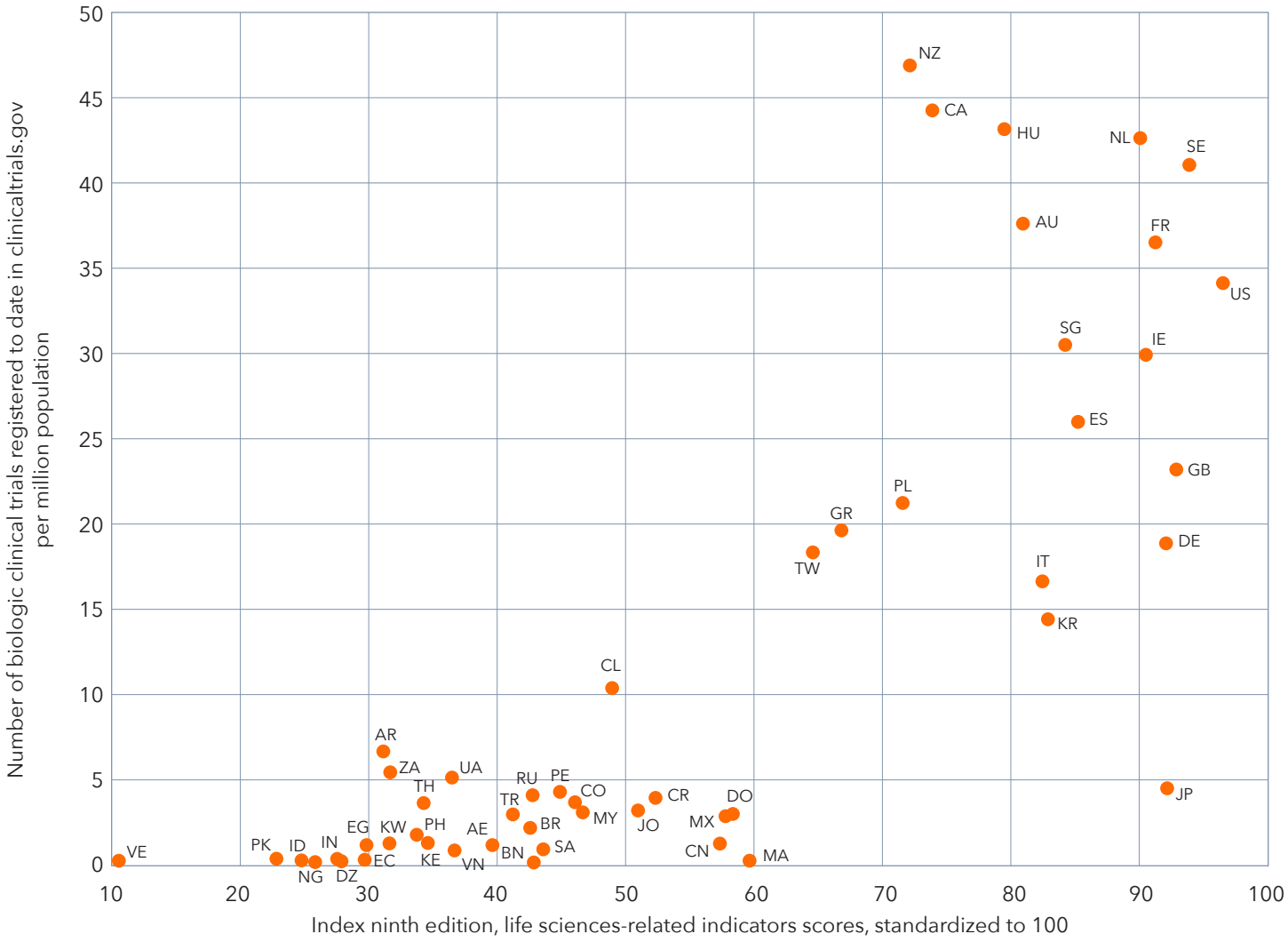
The availability of IP rights acts as a powerful incentive for attracting clinical research, which accounts for approximately 60% of biomedical foreign direct investment on R&D. On average, economies scoring in the upper half of the Index host as many as 15 times more clinical trials compared with economies in the lower half of the Index.

Figure 4: Association between the Index life sciences-related indicators' scores and early-phase clinical trial activity



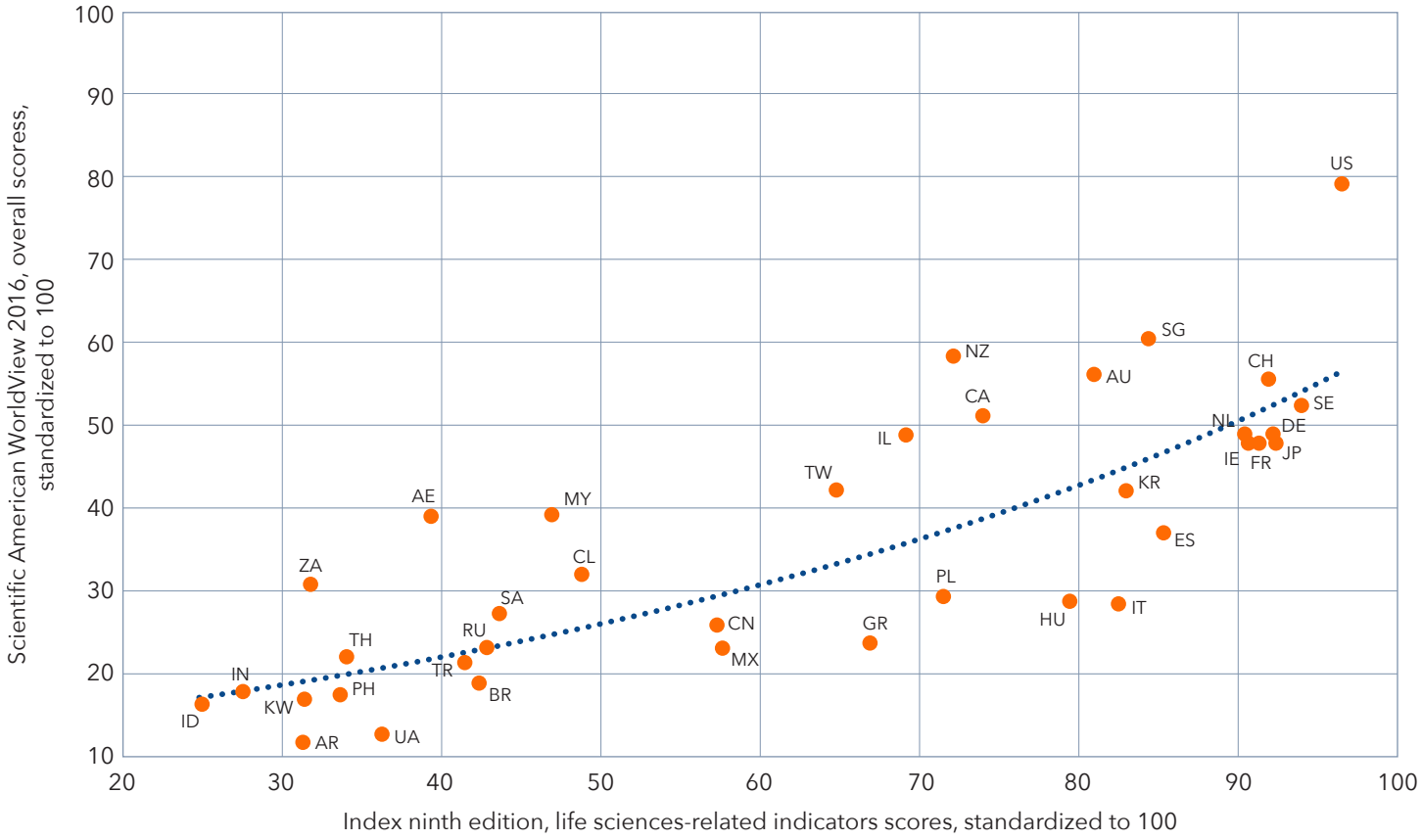
Economies that maintain robust IP environments tend to see more than 20 times more early-phase clinical trials on average compared with economies whose life sciences-related IP environments trail behind.

Figure 5: Association between the Index life sciences-related indicators' scores and biological clinical research intensity



Looking at clinical trials on biologics is a similar story. When looking just at life sciences-related protection, on average, economies within the upper half of the Index host substantially more clinical trials on innovative biologic drugs compared with economies falling within the lower half of the Index.

Figure 6: Association between the Index life sciences-related indicators' scores and the Scientific American WorldView scores[23]



Economies scoring in the top half of the Index are much more likely to provide environments that are conducive to biotech innovation than are economies scoring in the bottom half of the Index.

ACCENTUATING TRADITIONAL CHALLENGES FOR THE RESEARCH-BASED BIOPHARMACEUTICAL INDUSTRY: COVID-19, COMPULSORY LICENSING, AND LIMITATIONS ON IP RIGHTS

Despite the critical role that IP rights and incentives play in enabling biopharmaceutical innovation, in 2020, several economies restricted or overrode existing protections. Specifically, as a response to the COVID-19 pandemic, many policymakers and governments have called for or enacted new laws that expand relevant provisions relating to the use of compulsory licenses and the overriding of IP rights. In March 2020, the government of **Israel** authorized the issuing of a compulsory license for the antiviral drug lopinavir/ritonavir (AbbVie's Kaletra). The issuing of the license was based on existing emergency use powers under the Patent Law. Sections 104-105 grant the Israeli government broad powers, essentially allowing it to override any existing patent in the event of a national emergency or national security crisis. Under these provisions, a rights-holder has no ability to challenge the decision or access a recourse mechanism. Any royalties to be paid are ultimately set by a government-appointed body. While Article 31 of the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration are clear that compulsory licensing represents a "measure of last resort" intended primarily for public health and humanitarian emergencies such as the COVID-19 pandemic, it is regrettable that the Israeli government was unable to reach an alternative solution that did not involve the overriding of IP rights. Israel has made substantive progress over the past decade in strengthening its national IP environment for biopharmaceuticals and become a model for other economies seeking to build their research-based industries. It remains to be seen whether the use of compulsory licensing during the COVID-19 pandemic was a one-off or a new, negative policy departure.

On December 31, 2020, the **Russian** government issued a compulsory license under Order 3718. The order authorizes a local manufacturer to produce a generic version of remdesivir, an antiviral drug used in the treatment of COVID-19, and overrides the existing Eurasian patents for the drug. The order is based on Article 1360 of the Civil Code Part IV, which grants the government broad powers to act "in the interest of national security" and override any existing granted rights relating to patents, utility models, and industrial designs. News reports suggest that the order follows a request by the local manufacturer made to the government in November 2020. Article 1360 states that rights-holders shall be awarded "reasonable remuneration." The issuing of this license comes on the heels of two other licenses issued over the past three years. In 2018, the Moscow Arbitration Court granted a compulsory license to local manufacturer Nativa for Celgene's Revlimid. The compulsory license was for Celgene to license one of its granted patents for the production of a product in which a dependent patent was to be used by Nativa. Without a license, the use of this patent would constitute infringement of Celgene's patent. Critically, the lower cost of the product by Nativa was considered by the court as being economically advantageous and a deciding factor in granting the license. In 2019, another compulsory license was issued to Nativa on largely similar grounds. Finally, in November 2019, a bill was sent to the Duma that would amend existing laws on compulsory licensing (Article 1360 of Part IV of the Civil Code). The proposed amendments would provide a fairly broad ground for a compulsory license to be issued in the event of a national emergency and to protect the health and safety of the public. Compulsory licensing as an actively used tool in Russian industrial and health policy not only is outside international norms but is self-defeating. Over time it will hollow out Russia's national IP environment and incentives for future innovation, biopharmaceutical and otherwise. Critically, the negative effect will be the same on Russian as on foreign innovators.

While other economies have not issued involuntary licenses, many governments have called for or enacted new laws that expand relevant provisions relating to the use of compulsory licenses and the overriding of IP

rights. For example, in March 2020, again in response to the first wave of the COVID-19 global pandemic, the **Chilean** lower house, the Chamber of Deputies, passed a unanimous resolution endorsing the use of compulsory license for any and all products, diagnostics, medical devices, and other medical paraphernalia related to COVID-19. This was followed in June with a legislative proposal and set of amendments published by a group of senators. This proposal, Bulletin 13,572-11, would introduce sweeping changes to Chile's compulsory licensing regime, including an expedited and abbreviated process for the hearing and granting of compulsory licensing applications; the pre-fixing of applicable royalties to a maximum of 5% of the sales price of the licensed product; and a broad elimination of liability for manufacturers, individuals, and legal entities that violate existing IP rights (including patent rights and trade secrets) for the production or distribution of any medicines, vaccines, and other technologies related to the pandemic.

Similarly, in March 2020, an emergency law (Decree 476) was issued by the **Colombian** government in response to the COVID-19 pandemic. While the decree does not explicitly amend existing legislation relating to compulsory licensing, Article 1, sub-section 1.7 of the Decree grants the Minister of Health broad and full authority to make a Declaration of Public Interest relating to any and all "medicines, medical devices, vaccines and other health technologies that are used for the diagnosis, prevention and treatment of COVID19." While not legally a compulsory license, such declarations essentially nullify any existing IP protection and carry the same practical impact of eliminating a rights-holders' ability to freely use a granted exclusivity. On a parallel track, another group of legislators proposed a wide-reaching Senate Bill in December 2020 that would drastically modify Colombia's Pharmaceutical Policy. The Chamber's chief concern is the creation of so-called "automatic" compulsory licenses by the Colombian Commerce Ministry, Food & Drug regulatory agency, and Justice Ministry. The bill includes a troubling provision (Article 57, Paragraph 3) calling for the removal of governmental officials that do not grant a compulsory license with speed. Finally, the bill contains numerous unfortunate references to the belief that IP rights are a barrier to public access of IP-intensive goods. No doubt, these exceptional mechanisms may undermine bilateral norms for IP as established in the U.S.-Colombia FTA.

Outside of Latin America, there were similar developments in Asia. For example, in **Indonesia**, a new Presidential Regulation (No. 77 2020) on compulsory licensing was issued in July. The new regulation describes the circumstances under which government use of patented technologies is allowed. Specifically, it relates to government use of patented technologies and the overriding of any granted patent exclusivity in the event of a public emergency (including, but not limited to, a public health crisis) and for purposes of defense and national security. With respect to the government use and overriding of patents for medicines and biopharmaceutical products, the regulation states that this can be justified not only during a public health crisis, such as the current COVID-19 pandemic, but based on cost and specifically for "pharmaceutical products and /or biotechnology that are priced expensive[sic]." Under this regulation, the Indonesian government is considering government-use licensing for COVID-19 therapies already available locally under voluntary licensing, potentially reversing some of the recent positive steps taken by the Indonesian government to protect intellectual property.

More broadly, at the level of international institutions, there have also been efforts to undermine and weaken international standards of IP protection for COVID-19-related treatments and vaccines. Most notably, in October 2020, **India** and **South Africa** requested that the TRIPS Council and wider WTO General Council approve a TRIPS waiver for COVID-19-related products, including any approved vaccines.

As mentioned, the severe and sudden impact the COVID-19 pandemic is having on public health around the world means that, in effect, the conditions of the

potential issuing of a compulsory license are being met in many economies. However, it is squarely outside the scope of international law and applicable standards to define compulsory licensing as a potential catch-all mechanism that can be used to sanction the violation and overriding of granted property rights for any product, diagnostic, medical device, and other medical paraphernalia related to COVID-19. Unlike other pandemic-related emergency measures that have been introduced around the world, including, for example, in **Canada** and **Germany**, the proposed legislative amendments and changes introduced in Chile, Colombia, and Indonesia do not include any defined timeframe or suitable sunset clause.

TO SPC OR NOT TO SPC? EU INSTITUTIONS CONTINUE TO UNDERMINE BIOPHARMACEUTICAL IP INCENTIVES

As noted over the course of the Index, there continues to be a high degree of uncertainty regarding the availability of patent term restoration in the **EU** and the **United Kingdom**. 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening.

In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the **Ukraine** has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards.

Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union (CJEU) handed down a verdict in the case *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rulings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd*

v Comptroller-General of Patents—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization (MA) for the same active ingredient had already been granted. This decision has now, effectively, been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**." From a legal perspective, the court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and nonrevolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? That is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovation—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, Angiotensin-converting-enzyme (ACE) inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still, treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to

no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection.

More broadly, since 2018, the European Commission has been conducting a regulatory review of the Orphan Regulation and the Paediatric Regulation, which provide special incentives (including market exclusivity) for products developed for rare diseases and children. In November 2020, the commission published an "Inception Impact Assessment" with the view of proposing some legislative changes to both regulations. Orphan drugs are niche treatments for diseases with small patient populations and commercial markets. Since the 1980s, a series of financial and regulatory incentives in the United States (1983), Japan (1993), and the EU (2000) have managed to bring about a sea-change in R&D, clinical research, and the development of new products for rare diseases. For example, in the decade prior to the introduction of special incentives in the United States, 1973-83, only 10 products were approved for market—i.e., only one drug per year on average.[24] Since then, more than 575 drugs and biologic products have been developed and approved. A key driver of this success has been a clear and strong market exclusivity incentive. In the EU, the Orphan Regulation provides a 10-year term of marketing exclusivity (orphan status can be withdrawn after six years if designation criteria are no longer met, including if the drug is sufficiently profitable and, in addition, exclusivity may be extended by two years if a pediatric investigation plan has been completed when requesting approval.) On the back of these schemes, as well as key pharmaco-genomics discoveries that fueled interest in development of niche products,[25] the number of orphan drugs developed and authorized for rare diseases has increased exponentially. Since its introduction in 2000, the EU Orphan Regulation had, as of 2017, resulted in:

- nearly 2,000 orphan designations approved;
- over 150 orphan medicinal products approved by the EMA for over 90 rare diseases (up from only eight orphan products available in 2000);
- an increase of 85% in the number of rare diseases for which an orphan designation exists in the EU; and
- an increase of 88% in clinical research activity on rare diseases between 2006 and 2016, with the five largest EU countries experiencing an even bigger increase of 104% during that period.

It is critical that the Commission bear this positive impact in mind when reviewing how and what aspects of the regulation it proposes to change.

5 OVERALL RESULTS AND CATEGORY-BY-CATEGORY SCORES

Up or down? How have economies fared in this edition of the Index? And what do the results of the 2021 Index tell us about the state of the global IP environment? Below, Table 4 shows the overall results for the ninth edition of the Index and how it compares to last year's edition.

Table 4: Change in overall score, eighth edition versus ninth edition

COUNTRY	NINTH EDITION	EIGHTH EDITION	CHANGE IN OVERALL SCORE
United States	95.31%	95.28%	0.03%
United Kingdom	93.90%	93.92%	-0.02%
Germany	92.27%	91.08%	1.19%
France	91.43%	91.50%	-0.07%
Japan	91.12%	90.40%	0.72%
Sweden	90.92%	90.56%	0.36%
Netherlands	90.02%	89.64%	0.38%
Ireland	88.86%	88.98%	-0.12%
Switzerland	85.82%	85.34%	0.48%
Spain	84.68%	84.64%	0.04%
Singapore	84.38%	84.42%	-0.04%
South Korea	83.73%	82.20%	1.53%
Italy	83.15%	83.18%	-0.03%
Australia	80.55%	79.62%	0.93%
Hungary	78.23%	78.38%	-0.15%
Canada	74.71%	72.86%	1.85%
Israel	72.57%	72.76%	-0.19%
Greece	70.67%	70.10%	0.57%
Poland	70.50%	70.56%	-0.06%
New Zealand	69.10%	68.64%	0.46%
Taiwan	66.18%	66.33%	-0.15%
Morocco	59.62%	59.66%	-0.04%
Mexico	58.25%	54.38%	3.87%
China	54.86%	50.96%	3.90%
Costa Rica	54.46%	52.60%	1.86%

COUNTRY	NINTH EDITION	EIGHTH EDITION	CHANGE IN OVERALL SCORE
Dominican Republic	54.32%	53.96%	0.36%
Malaysia	51.61%	51.24%	0.37%
Turkey	51.07%	51.58%	-0.51%
Colombia	48.17%	46.40%	1.77%
Chile	47.20%	45.64%	1.56%
Russia	46.58%	45.92%	0.66%
Peru	46.56%	46.12%	0.44%
Jordan	44.53%	44.16%	0.37%
Brazil	42.32%	42.52%	-0.20%
UAE	41.98%	40.44%	1.54%
Brunei	41.13%	41.12%	0.01%
Saudi Arabia	40.38%	39.44%	0.94%
Philippines	39.81%	39.94%	-0.13%
Ukraine	39.54%	39.66%	-0.12%
India	38.40%	38.46%	-0.06%
Vietnam	37.49%	36.62%	0.87%
Kenya	37.25%	36.82%	0.43%
Argentina	36.77%	35.74%	1.03%
South Africa	36.61%	36.62%	-0.01%
Thailand	35.56%	33.96%	1.60%
Egypt	32.59%	30.18%	2.41%
Ecuador	30.60%	30.18%	0.42%
Indonesia	30.16%	30.24%	-0.08%
Kuwait	27.86%	28.02%	-0.16%
Nigeria	27.43%	27.62%	-0.19%
Algeria	26.45%	24.06%	2.39%
Pakistan	26.43%	26.50%	-0.07%
Venezuela	14.10%	14.22%	-0.12%

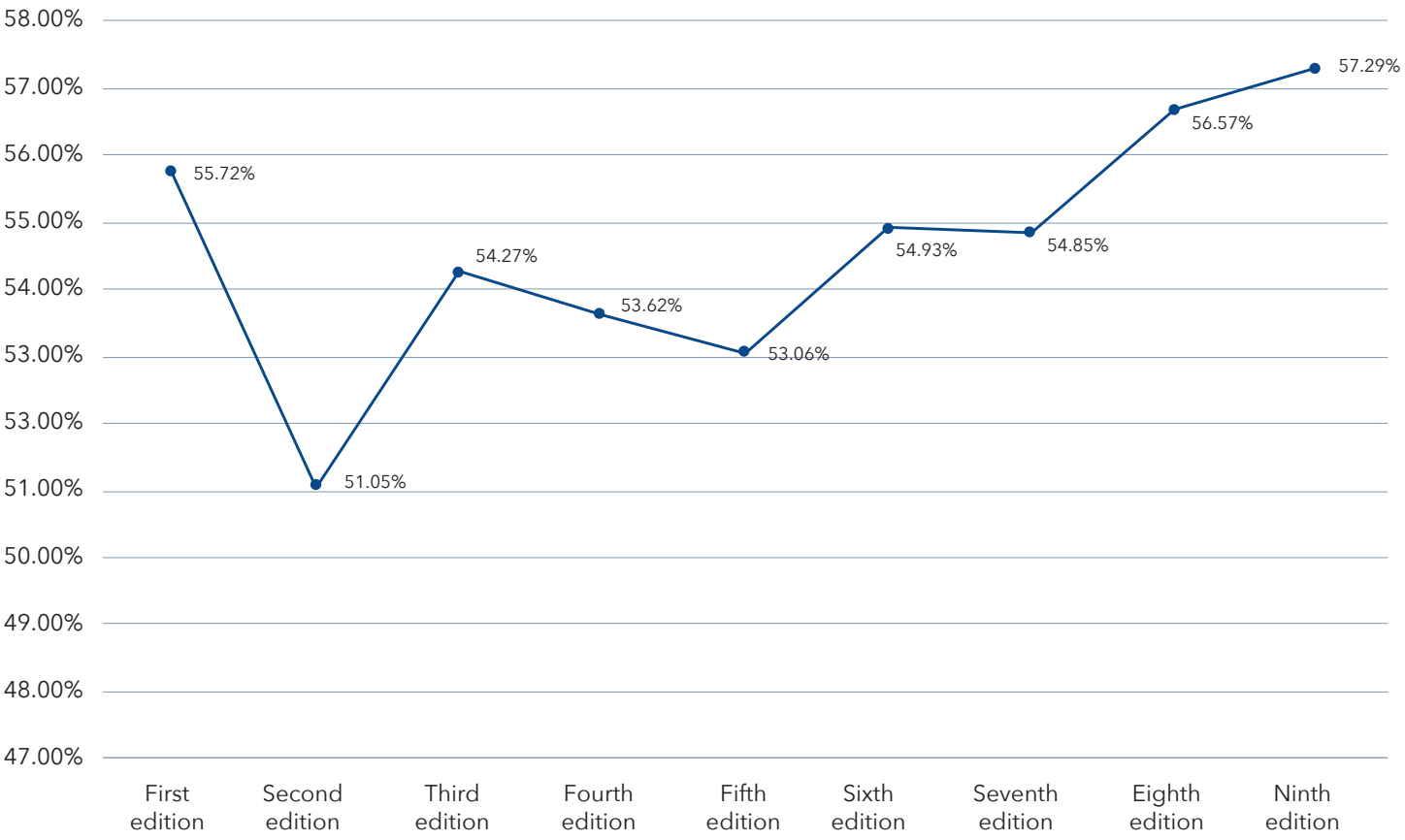
Overall, the vast majority of economies sampled in the Index have seen their IP environments improve in 2020. Out of the 53 economies included, 32 saw a positive increase. This compares with 21 economies that saw their scores drop. Furthermore, out of the 32 that saw an improvement to their national IP environments, almost two-thirds (19 economies) saw an increase of 0.5% or more. Two economies—**China** and **Mexico**—saw improvements of over 3%, at 3.90% and 3.87%, respectively. Out of the 21 economies that saw a score decrease, only one, Turkey, experienced a drop of more than 0.5%, at 0.51%.

To some extent, the improvement seen in 2020 builds on the preceding years, and in particular the last two editions of the Index. With Index scores now going back to 2012, there is a sufficient amount of data to analyze and spot trends over time. Indeed, looking at the movement of the aggregated scores of the Index historically allows us to get a sense of how the global IP policy environment has evolved over time and what underlying factors are shaping this movement, positive or negative.

MOVING AHEAD OR STANDING STILL? THE GLOBAL IP ENVIRONMENT OVER NINE EDITIONS OF THE INDEX

To start, we can calculate the overall total score of all sampled economies vis-à-vis the maximum available total score in the Index. Although not controlling for changes in the composition of the Index with respect to the number of economies sampled or the addition of new indicators, with these caveats in mind the total aggregated results provide a good starting point as a snapshot and point of comparison. Below, Figure 7 shows the composite score of the economies sampled as a percentage of the maximum score for each of the nine editions of the Index.

Figure 7: Overall total score, percentage available score, first to ninth edition of the Index



Comparing the starting point in 2012 with the latest edition, it is clear that there has been a positive movement of 1.57%. But the first edition of the Index contained only 11 economies. A more meaningful comparison with a bigger sample of economies is from the second edition of the Index, when the number of economies more than doubled to 25. Here we can see a substantial improvement of the aggregated score of 6.24%. This is a considerable difference and improvement over time. Looking at the past few years, we can see that this positive movement has been sustained between the seventh and ninth edition. Not coincidentally, this is the only time period for which there have been two or more consecutive positive increases over the life of the Index. So, on the face of it, the global IP environment today is quite a bit better than it was eight or nine years ago. Does this mean that every single economy in the Index today has a stronger national IP environment than it did in 2012? Not necessarily. Given that the Index now includes 53 economies, there is per definition a great deal of variation in how these different economies have performed over time. Some economies have improved, others have deteriorated, and many have simply stood still. Still, it is possible to see some mega-trends and the impact of international policy decisions, particularly international trade agreements.

STILL A FORCE FOR GOOD? INTERNATIONAL TRADE AGREEMENTS AND THE INTERNATIONAL IP ENVIRONMENT

Historically, trade agreements have been fundamental in setting international standards for the protection and enforcement of IP rights. TRIPS, the North American Free Trade Agreement, and numerous U.S.- and EU-led bilateral agreements have helped improve the global IP environment and set a floor for rights-holders around the world. It has been over a quarter of a century since the conclusion of the Uruguay Round. While the Doha Round had the potential to become a truly global trade agreement, it has effectively been shelved since 2015. Thus, it is new bi- and pluri-lateral agreements that have been the drivers in setting international IP standards.

Over the course of the Index, several international trade agreements have been concluded that contain substantial IP provisions. These include: the EU-Canada Comprehensive Economic and Trade Agreement (CETA); the Free Trade Agreement between the EU and Vietnam; the United States-Mexico-Canada Agreement (USMCA); the EU-Japan Economic Partnership Agreement; and the Economic and Trade Agreement between the Government of the United States and the Government of the People's Republic of China.[26] None of these agreements were perfect. In particular, the finalized USMCA was a significant missed opportunity to elevate IP standards through an FTA with the two largest U.S. trading partners. Despite some important gaps, overall, the IP standards in the original USMCA concluded in 2018 would have set a new, higher benchmark that would lead to more innovation, more job creation, and more economic growth across North America. Unfortunately, this original agreement was substantively revised. In December 2019, Speaker of the House Nancy Pelosi announced that a revised USMCA had been agreed on with the White House, Canada, and Mexico. The text of the final agreement revealed that important parts of the original USMCA had been either completely removed or fundamentally altered. This included critical provisions relating to biopharmaceutical IP protection and incentives. Nevertheless, these trade agreements have individually and cumulatively helped improve the global IP environment over the past decade. In fact, it is possible to see the direct positive impact these international treaties can have on individual economies' IP environment. This is particularly the case with the Agreement between the United States and China.

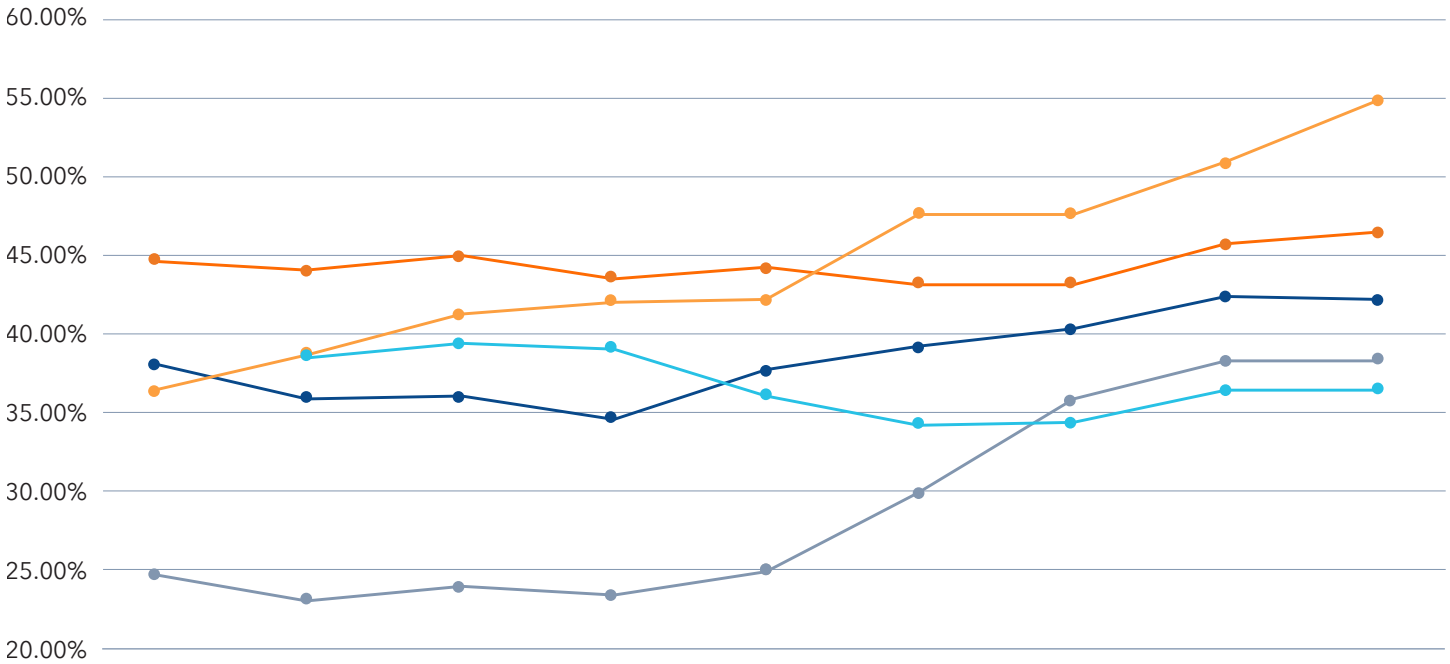
ZOOMING IN ON THE BRICS

To get a sense of what the score movement has looked like at an individual economy level and what some specific policy choices have driven this movement, it is instructive to isolate and contrast the Index score movements of some of the largest emerging markets included in the Index, namely the BRICS economies: Brazil, Russia, India, China, and South Africa.

For these five economies, we have almost a full decade's worth of data, with four of the five BRICS having been included in the Index from the beginning. Below, Figure 8 shows how the BRICS have performed over all editions of the Index.

Isolating the results of the BRICS reveals the stark differences in performance over the course of the Index. Of note are China and India. Both economies started from a relatively low base, at 36.52% and 24.96% of the available score, respectively, on the first edition of the Index in 2012. Yet, over time, there has been a remarkable improvement in their national IP environments as measured by the Index. China steadily improved its score over the first five editions. Then, over the past four editions—and especially the past two—this improvement has been extraordinary: over the past two editions of the Index, China has boosted its score by over 7%. Compared with 2012, China has improved its score by half—going from 36.52% of the total available score to 54.86% in this year's edition—a stunning growth of 18.34%. However, as has been detailed over the course

Figure 8: Overall scores, BRICS, first to ninth edition of the Index



	First edition	Second edition	Third edition	Fourth edition	Fifth edition	Sixth edition	Seventh edition	Eighth edition	Ninth edition
Brazil	38.28%	36.10%	36.20%	34.70%	37.80%	39.30%	40.56%	42.52%	42.32%
Russia	44.68%	44.27%	45.13%	43.53%	44.37%	43.23%	43.24%	45.92%	46.58%
India	24.96%	23.17%	24.10%	23.50%	25.00%	30.08%	36.04%	38.46%	38.40%
China	36.52%	38.73%	41.33%	42.13%	42.37%	47.70%	47.67%	50.96%	54.86%
South Africa		38.67%	39.53%	39.13%	36.29%	34.28%	34.56%	36.62%	36.61%

of the Index, it is important to note that, in China especially, while there have been improvements in terms of formal IP laws and regulations, the on-the-ground effects are harder to measure. The absence of predictable and transparent rule of law, and the use of industrial policies to favor domestic firms at the expense of multinational corporations, in addition to various other policies that affect the landscape for companies doing business in China, all tend to make it harder for IP-intensive businesses to operate and trade in the Chinese market.

Similarly, India has seen its score improve significantly in the past few years. Over the first five years of the Index, there was little movement in India's score, but between the fifth edition and today, India's score has surged by over 12%. Like China, India has over the life of the Index seen the strength of its national IP environment grow by half, rising from a score of 24.96% of the total available score in 2012 to 38.40% in this year's edition, an improvement of 13.44%.

Although not as strong as China and India, Brazil, too, has seen some improvement in its score. Over the course of the nine editions of the Index, Brazil's score improved by just over 4%. In contrast to Brazil's, China's, and India's level of improvement, Russia and South Africa have largely stood still. Russia's score today is just under 2% better than in 2012 but has hovered between 44% and 45% over the course of the Index. South Africa's score is actually worse today than in 2012, having dropped by just over 2%.

What explains these differences in performance?

While the number of indicators has grown substantially over the course of the Index—doubling from the original 25 in 2012 to 50 in today's Index—and has naturally had an impact on individual economies Index scores, it is also clear that individual governments' decisions and choices on IP policy have had a real and tangible impact on how different economies have performed on the Index. For example, China has over the past two years essentially revamped its national IP environment by amending and updating most major IP laws and regulations. As mentioned, this reflects the fact that China is implementing key parts of the negotiated trade agreement with the United States. Similarly, both the Brazilian and Indian governments have made concerted efforts to improve their IP environments. In Brazil, the national IP office has concentrated on institutional reforms, improving the licensing and technology transfer environment, and reducing a long-standing backlog of patent applications ranging from 10 to 13 years depending on the field of technology. Likewise, over the past few years, the government of India has made concerted efforts to join international IP initiatives and engage more fully in international IP fora. Most notably, India acceded to the WIPO Internet Treaties in September 2018, and in late 2018, Indian and Japanese authorities agreed to begin a Patent Prosecution Highway (PPH) program in the first quarter of 2019. The latter agreement is especially noteworthy, as up until this announcement, India did not have a functioning PPH with any major IP office. Does this mean that the IP environments in China, India, and Brazil are perfect? Of course not. While the improvements in all economies have been real, challenges remain in all three. Of the three, only China achieves a score of 50% or more. This is considerably less than the average score for the top-performing economies on the Index. And as described above, the on-the-ground realities for IP-intensive companies are more complicated than the Index score suggests. This year, on the ninth edition, the average score for economies in the top 10 was 90.43%. Still, these three economies' achievements are real and are the result of conscious efforts and policy choices made by their respective governments.

In contrast to the generally positive reforms in China, India, and Brazil, in Russia the IP environment continues to be shaped by the wider policy landscape and its focus on localization. As has been detailed over the course of the Index, Russian industrial and economic policy over the past decade has increasingly been driven by an effort to localize industrial production and R&D. While there have been pockets of improvement

and IP reform– including the copyright space where Russia's score on the Index has almost doubled over the nine editions–these positive efforts have largely been canceled out by these broader negative developments.

Over the eight editions of the Index in which South Africa has been included, there have been few substantive IP reforms attempted, let alone passed. And while the other BRICS have engaged more fully in international IP fora or through participation in PPHs, South Africa has remined on the outside of these efforts. Out of the nine international IP treaties included in the Index, South Africa is only a full contracting party to one, the Patent Cooperation Treaty. It has signed, but not ratified or acceded to, the WIPO Internet Treaties or the Convention on Cybercrime. Although South Africa has drafted legislation to accede to the WIPO Internet Treaties, questions remain about whether the Copyright Act Bill would include accession. The bill, for instance, does not clearly define key terms and introduces sweeping exceptions and limitations to current law. Additionally, South Africa is not a member of either the Global Patent Prosecution Highway, the IP5 PPH, or any other bi- or multilateral PPH. In 2018, the South African government released the long-awaited document *Intellectual Property Policy of the Republic of South Africa Phase I* (the *IP Policy*). As recognized at the time, it was a positive step that the government of South Africa recognized the need to reform its national IP environment and the value of consulting all stakeholders in that process. However, the *IP Policy* (as preceding draft policies and related documents) focuses primarily on ways in which South Africa could better access existing and developed forms of IP, rather than on the manner in which IP can be created, be commercialized, and become an industrial asset in South Africa. For all economies–emerging and developed alike–what drives innovation, technological advances, and, ultimately, economic development and growth is the creation of new forms of intangible assets and IP. Yet both the *IP Policy* and South African IP policymaking over the past decade have largely been silent on this. Efforts to introduced substantive examination for patents, pass a new Copyright Act, and modernize South Africa's national IP environment remain unfulfilled.

The direct link between policy choices and results on the Index is even clearer when examining the individual category-by-category scores, for both the BRICS and other economies.

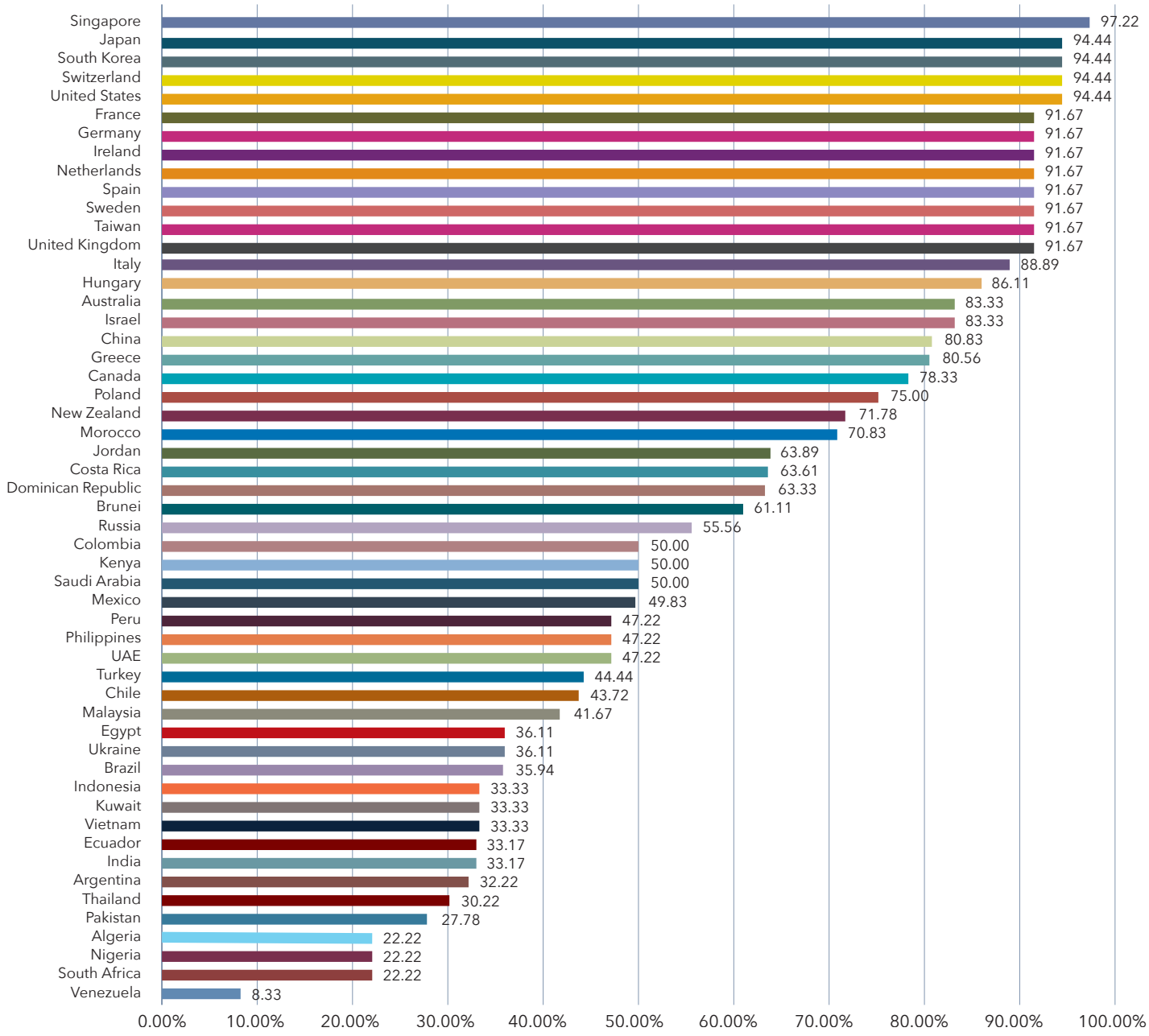
CATEGORY 1: PATENTS, RELATED RIGHTS, AND LIMITATIONS

Figure 9 summarizes the total scores for Category 1. This category measures the strength of an economy's environment for patents, related rights, and limitations. The category consists of nine indicators with a maximum possible score of 9.

As in past editions, the overall results for Category 1 are one of the strongest of all the categories included in the Index. Twenty-one economies achieve a score of 70% or more of the available score and 31 economies in total achieve a score of over 50%. The average score on the category is 60.87%, which is the second-highest-scoring category on the Index. As in years past, **Singapore** is ranked number one, comfortably ahead of **Japan, South Korea, Switzerland**, and the **United States.**

As noted in previous editions, the patenting environment in the **United States** continues to be held back by uncertainty over what constitutes patentable subject matter and patent nullity proceedings through the *inter partes review* (IPR), which occurs before the specialized Patent Trial and Appeals Board (PTAB) within the USPTO. Since the Supreme Court decisions in the *Bilski, Myriad, Mayo*, and *Alice* cases, there has been a high and sustained level of uncertainty as to which inventions are patentable in the United States. Since 2014, the USPTO has issued and updated patent examination guidelines almost on an annual basis. Lower and circuit court decisions in patent infringement proceedings have not always been consistent. The net result is that rights-holders are left without a clear sense of how decisions on patent eligibility will be made and,

Figure 9: Category 1: Patents, Related Rights, and Limitations, percentage available score



when granted patents are subsequently challenged or reviewed either through the courts or through the *inter partes* proceedings within the USPTO, which patent claims will be upheld.

Under the leadership of former USPTO Director Andrei Iancu, the USPTO has recognized this dilemma and over the past three years sought to re-formulate its position and the approach to be taken by its examiners. In January 2019, the office released new draft guidance covering section 101 patentability and section 112 claims relating to computer inventions, the "2019 Revised Patent Subject Matter Eligibility Guidance" and "Examining Computer-Implemented Functional Claim Limitations for Compliance with 35 U.S.C. 112." With respect to section 101 patentability, the new guidance provides more of

a principle-based analysis of how patentability will be judged and describes the stepwise approach examiners should follow to understand and apply the Supreme Court's *Alice/Mayo* test. As the guidance rightly points out, the key challenge for USPTO examiners and courts has been to "consistently distinguish between patent-eligible subject matter and subject matter falling within a judicial exception." The new guidance recognizes this and seeks, to the extent that is possible without further statutory changes, to clear this up with a revised procedure and process for examiners to follow.

In April 2020, the USPTO's Office of the Chief Economist published *Adjusting to Alice USPTO Patent Examination Outcomes after Alice Corp. v CLS Bank International*. This report examines the effect of the 2019 guidance on rates of first office rejections for *Alice*-related technologies—that is, technologies and applications that the USPTO and the U.S. Patent Classifications has defined as containing "abstract ideas." The report finds that, overall, since the introduction of the guidance, there has been a measurable and statistically significant decrease in the number of first office rejections for *Alice*-related technologies. Specifically, the likelihood of receiving a first office rejection decreased by 25% in the 12 months following the introduction of the guidance. As the USPTO rightly notes, this is positive news. The Index commends the USPTO for taking this action and working together with all stakeholders to improve what is a challenging situation for rights-holders, applicants, and examiners alike.

Similarly, over the past two years, the U.S. government (chiefly through the USPTO) has recognized the unintended effects of the PTAB system and publicly pledged to work with all stakeholders to address and remedy them. To begin with, the USPTO introduced several important changes in 2018 and 2019. In 2018, former USPTO Director Iancu stated that the reform of IPR proceedings was one of the agency's "highest priorities," and that the agency was considering "how and when we institute proceedings, the standards we employ during the proceedings, and how we conduct the overall proceedings. The goal, with whatever action we take, is to increase predictability of appropriately-scoped claims." Following these remarks, important reforms were announced during the year, which included: (1) changing the patent claim construction standard used, moving away from the broadest reasonable interpretation (BRI) standard to the so-called *Phillips* standard, the latter of which is the claim construction standard used in the judiciary since the mid-2000s; (2) a new Trial Practice Guide; and (3) Standard Operating Procedure (SOP) changes. Using the *Phillips* standard has aligned IPR proceedings with the same claim construction standards that are used in patent infringement proceedings at U.S. district courts. The revised Trial Practice Guide provides greater clarity on the grounds on which a review may be initiated. The changes to both SOP 1 and SOP 2 sought to streamline how judges are assigned, the composition of panels, and the way precedent-setting opinions are set. Specifically, SOP 2 set up a Precedential Opinion Panel (POP), headed by the director. Since its introduction, the POP has been active in shaping how the IPRs operate, with several of the panel's decisions having been of high procedural importance addressing issues relating to the USPTO director's decisions to institute IPR proceedings (see, for example, *Valve Corp. v Electronic Scripting Products Inc.*) and procedural rules including the declaration of interested parties (*ProppantExpress Investments LLC v Oren Techs. LLC*).

These efforts continued in 2020. Several new POP decisions were issued and the USPTO proposed important potential changes to the IPR process. In May, the agency published a "Notice of Proposed Rulemaking" in the *Federal Register*. The notice includes proposed procedural changes incorporating the Supreme Court ruling in *SAS Institute Inc. v Iancu* on how patent validity challenges should be accepted and whether proceedings should be initiated on a select number of claims or all claims. The changes also included a question on whether the presumption in favor of a petitioner should be maintained or eliminated in pre-trial proceedings. Further changes were proposed in October, when the agency published a "Request for Comments on Discre-

tion to Institute Trials before the Patent Trial and Appeal Board" in the *Federal Register*. The proposed changes focus on how the PTAB should deal with serial and parallel petitions. These are instances when the same patent and patent claims are petitioned to be challenged before the board in different petitions.

In addition to the USPTO's actions, the Supreme Court was also active in 2020. In April, the Court held in *Thryv Inc. v Click-to-Call Technologies LP, et al*. that the timeline for submitting an IPR petition is not subject to judicial review and rests solely with the PTAB. The decision reverses an earlier judgment by the U.S. Court of Appeals for the Federal Circuit, which held that the decision to hold an IPR proceeding in the case was an error. In October, the Supreme Court also accepted petitions to hear specific aspects relating to the case *Arthrex Inc. v Smith & Nephew Inc.* and whether PTAB judges have been unconstitutionally appointed. While the key issue at hand concerns administrative law and the technical categorization of judges serving on the PTAB, legal analysis suggests that the ramifications of the court's judgment could be significant. A substantial number of PTAB cases were vacated by the Federal Circuit's earlier decision and have been held in abeyance. Overall, the high level of administrative and judicial activity illustrates how U.S. rights-holders continue to face great uncertainty over how patent disputes will be adjudicated and how decisions will be made and upheld within different fora. Uncertainty over what constitutes patentable subject matter has crept into all facets of the patent system—from initial application and examination to standards of review and invalidity proceedings, whether administratively through the PTAB or through the judiciary.

In other economies, rights-holders continued to face uncertainty and a challenging environment.

As detailed in the preceding section, there continues to be a high degree of uncertainty regarding the availability of patent term restoration in the **EU** and the **United Kingdom**. Regulation 2019/933 remains in force and the SPC export exemption is, for all intents and purposes, legal and operational in all EU Member States. In July, the CJEU reversed earlier precedent from 2012 by disallowing the issuing of an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rulings, the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. The court's verdict sets an unfortunate precedent and will likely further limit the availability of European incentives for biopharmaceutical innovation. It also stands in contrast to thinking in other economies. Indeed, in other jurisdictions, authorities have found that equivalent mechanisms for term restoration *should* be made available to rights-holders for new innovations relating to approved biopharmaceutical products and treatments. For example, in **South Korea** an important decision was issued in 2020 by the Korean Intellectual Property Trial and Appeal Board (IPTAB). The IPTAB is a quasi-judicial body housed within Korea's IP Office, KIPO, and is the court of first instance in most IP disputes, including with regards to patent rights. In July, the IPTAB issued what could become a precedent-setting ruling that any term restoration granted should cover all uses under the existing patent and not be limited to just one primary or single use. This ruling clears up what has been a gray area for rights-holders in Korea and ensures that any term restoration granted provides a similar level of protection for any and all uses as that of the original patent.

With respect to the **United Kingdom**, although Brexit is technically in effect and the United Kingdom is no longer a member of the EU, under the terms of the *Withdrawal Agreement*, CJEU decisions made during the transition period will also apply in the United Kingdom. More broadly, while the U.K. government has the sovereignty and power to effectively shelve Regulation 2019/933, it has instead chosen to maintain the SPC exemption. In 2020, the U.K. Intellectual Property Office (UKIPO) held a public consultation on a draft Statutory Instrument that would amend the existing exemption, making it more compatible with U.K. statute. Unfortunately, de-

spite rights-holders calling for the U.K. government to reconsider its decision to retain the exemption, in its public response to the consultation, the government reiterated its position that the SPC exemption would be retained and be operable going forward.

The situation in the EU and United Kingdom can be contrasted with the positive actions taken in **China** to strengthen its biopharmaceutical IP environment. As noted in previous editions of the Index, since 2017, Chinese regulatory authorities have committed to introducing a patent linkage mechanism for biopharmaceuticals. In October 2017, the central government issued State Council Opinions on Deepening Regulatory Reforms to Encourage Drug and Medical Device Innovation, which confirmed the strengthening of the existing patent linkage mechanism in China (based on the existing Drug Registration Regulations) proposed earlier in 2017. However, the commitment to introduce a linkage regime was not implemented in 2018 and 2019. In early 2020, China again committed in the Agreement with the United States (Article 1.11) to adopt a form of patent linkage. In October 2020, a new set of patent amendments was passed into law and will take effect in June 2021. Article 76 of the updated Patent Law outlines China's new linkage regime, which will be based on both a potential judicial route of enforcement and administrative enforcement through the State Council. With regards to potential administrative enforcement, the amended law is not clear on what this would look like, simply stating that "specific measures for the connection of patent dispute resolution at the stage of drug marketing license approval and drug marketing license application" would be "formulated" by the authorities. Prior to the passing of the patent amendments, China's National Medical Products Administration, together with the China National IP Administration, published draft implementing regulations, the "Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial) (Draft for Comment)." These draft measures set out in some detail how the linkage regime and administrative enforcement would operate and provide rights-holders with potential avenues of redress prior to the marketing approval of a follow-on product. However, there are several important areas where the proposed measures are unclear. For example, the draft measures do not require that rights-holder be directly notified when a potential infringing follow-on application is submitted to the Chinese drug regulatory authorities. Instead, Article 7 presumes that rights-holders will proactively monitor the publication of the follow-on marketing authorization and, within 45 days, file a formal objection. If no objection is filed within the prescribed period, the relevant drug registration authorities have the discretion to decide on whether to approve the follow-on product. More broadly, the suggested stay period is only nine months. This is shorter than both previous draft proposals—which had a period of 24 months—and equivalent timelines in the United States and Singapore, where the period is 30 months. The linking of the approval of follow-on biopharmaceutical products to the exclusivity status of a reference product is an effective way of achieving a balance between the protection of pharmaceutical exclusivity (usually, but not always, through patent protection) and stimulating early market entry of follow-on generic products. Linkage ensures that any disputes are resolved prior to the marketing of a follow-on product. This grants innovators a fair opportunity to secure a return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity. It also limits potential damages for generic manufacturers, as no potentially infringing product is ever launched or approved for market. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit. In sum, a well-balanced linkage system recognizes the crucial role of patent protection in promoting innovation, and the role of generic entry in providing patients access to lower-cost biopharmaceuticals. Having in place a functioning linkage regime that provides rights-holders with a meaningful and real ability to stop follow-on products from being launched when a granted term of exclusivity is in place would be a substantial improvement to the biopharmaceutical IP environment in China. It is a positive step

that the Patent Law now includes such a statutory right. However, it is critical that the final system, as defined through implementing regulations, effectively ensures that any disputes are resolved prior to the marketing of a follow-on product in a fair and transparent manner for all parties.

Additionally, the amendments to the Patent Law also introduced a term of patent restoration for biopharmaceuticals. Article 42 of the amendments states that a period of term restoration of up to five years for biopharmaceutical products may be made available by relevant Chinese authorities. At the time of research, no implementing regulations or further details had been provided as to the specific circumstances that would be recognized or requirements needed to be met for any restoration to be granted, including, for example, the types of delays that would be recognized. As with the newly introduced linkage regime, it is vital that term restoration be provided in a fair and transparent manner recognizing the unique circumstances and long delays that the biopharmaceutical regulatory approval process entails. Still, the introduction of a five-year period of patent term restoration is a substantial improvement to China's biopharmaceutical IP environment. China's positive reform efforts can be contrasted with other emerging markets, which, instead of pro-innovation policies, are embracing greater restrictions on biopharmaceutical patentability and the overriding of patent rights through the use of compulsory licensing.

For example, in a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the **Ukraine** has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Specifically, these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter with second-use claims and follow-on products now defined, under an expanded Article 7, as ineligible patent matter. New procedural barriers to obtaining patent term restoration, as well as an export and stockpiling exemption, have also been introduced. The latter exemption appears to be modeled on the carve-out introduced by the European Commission through Regulation 2019/933, which has been operational in the EU since 2019. As the Index pointed out when the idea of an export exemption was first broached by the European Commission, the most obvious side effect of the overriding of IP rights in the EU would be that the policy would be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards.

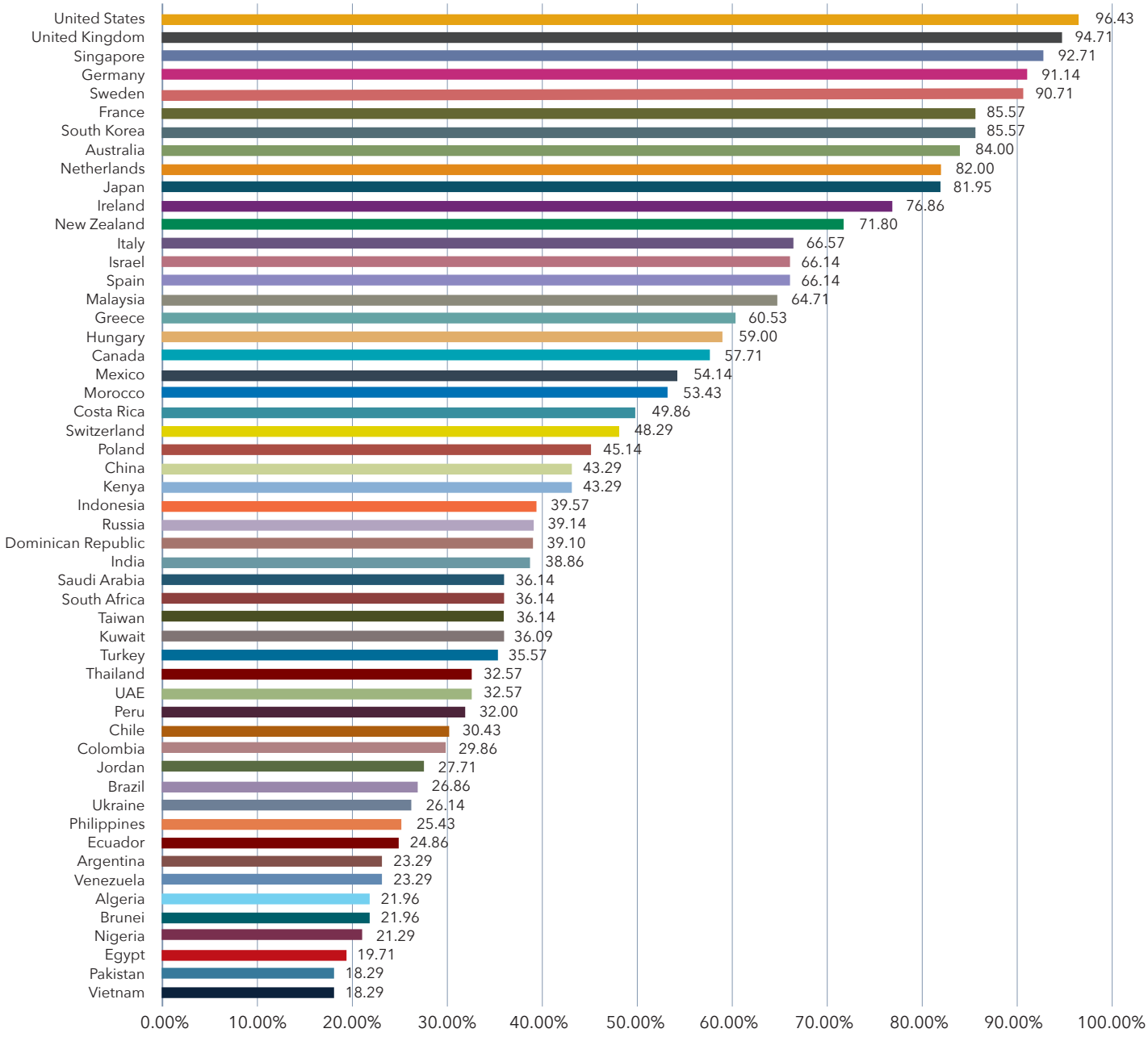
As detailed in the preceding section, as a response to the COVID-19 pandemic, many policymakers and governments have called for or enacted new laws that expand relevant provisions relating to the use of compulsory licenses and the overriding of IP rights. These include **Israel, Russia, Chile, Colombia**, and **Indonesia**. The severe and sudden impact the COVID-19 pandemic is having on public health around the world means that, in effect, the conditions of the potential issuing of a compulsory license are being met in many economies. However, it is squarely outside the scope of international law and applicable standards to define compulsory licensing as a potential catchall mechanism that can be used to sanction the violation and overriding of granted property rights for any product, diagnostic, medical device, or other medical paraphernalia related to the COVID-19 global pandemic. Unlike other emergency measures that have been introduced around the world, including, for example, in **Canada** and **Germany**, the proposed legislative amendments and changes introduced in Chile, Colombia, and Indonesia do not include any defined timeframe or suitable sunset clause. More broadly, compulsory licensing is not a cost-containment tool; cost is not a relevant justification or basis for compulsory licensing under the TRIPS Agreement.

CATEGORY 2: COPYRIGHTS, RELATED RIGHTS, AND LIMITATIONS

Figure 10 summarizes the total scores for Category 2. This category measures the strength of an economy's environment for copyrights, related rights, and limitations. The category consists of seven indicators, with a maximum possible score of 7.

As in years past, the results for Category 2 show how challenging the environment is for creators and copyright holders in the majority of sampled economies. Thirty-two of the 53 economies sampled failed to reach 50% of the available score. Many economies have only the most basic forms of protection in place and enforcement remains wholly inadequate. Critically, this is not a problem confined to lower-income economies.

Figure 10: Category 2: Copyrights, Related Rights, and Limitations, percentage available score



As noted in previous editions of the Index, online piracy in **Switzerland** is a long-standing issue and a departure from Switzerland's otherwise gold-standard IP regime. The broad precedent established in the landmark 2010 Federal Supreme Court's decision *Federal Data Protection and Information Commissioner v Logistep AG*—in which IP addresses were viewed as constituting "personal data"—has severely limited the ability to identify and build cases against infringing users. This development has discouraged Swiss prosecutors from taking on such cases. Without a legal tool for targeting infringing users or the platforms on which they operate, digital and online piracy has remained widespread, and Switzerland has become a hub for sites hosting infringing content. For example, the Office of the U.S. Trade Representative's (USTR) annual "Notorious Markets Report" has included sites hosted in or through Swiss entities. The Swiss government has long recognized this broader problem and in 2014 announced an ambitious reform plan following the recommendations by the Swiss Working Group on Copyright. In late 2017, the Swiss Federal Department of Justice and Police published new draft amendments and announced that copyright reforms would finally go ahead. These amendments were approved by the Swiss Federal Council (*Bundesrat*) in November 2017 and the Federal Assembly (*Schweizer Parlament*) in 2019. They then became law in April 2020. The Swiss government should be commended for finally taking legislative action and attempting to address a long-standing weakness in its national IP environment. However, the final amendments do introduce new measures to fight copyright piracy. The amendments require Internet Service Providers (ISPs) to both remove and keep infringing content off their servers. A new Article 39d of the Copyright Act inserts a legal obligation on the part of internet hosting services to act against infringing content upon notification. The law states clearly that a "provider of an internet hosting service which stores information entered by users is required to prevent a work or other protected subject matter from being unlawfully remade available to third parties through the use of its services." The national IP Office—the Swiss Federal Institute of Intellectual Property—has publicly stated that this amounts to a requirement for a "stay down" mechanism whereby hosting services must ensure that infringing content is not made accessible again after a notification of infringement has been made and acted on. The new law also attempts to address challenges processing of personal data when filing criminal complaints. Article 77i clarifies that rightsholders filing a criminal complaint may access and use personal data for this purpose. Critically, this does not apply to civil proceedings, which, under the new law, can be filed only once criminal proceedings have commenced. Still, overall, the reforms are a missed opportunity. While addressing some of the shortcomings in the existing legal framework, the amendments do not fundamentally change the dynamics of copyright enforcement and online piracy in Switzerland. The amendments do not include any requirement or option to disable access to illegal content through the judiciary or an administrative mechanism. The past half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to disable access to infringing content effectively. Today, EU Member States, the United Kingdom, India, Singapore, Russia, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Furthermore, the Swiss amendments do not change the existing dynamic with respect to defined personal and private use exceptions to copyright. Historically, Switzerland's private use exception has been interpreted broadly (and has been confirmed) by the Swiss government and existing case law to include the downloading and sharing of infringing content. Article 19 of the Copyright Act asserts that the downloading of content (other than software) for private use is not a copyright infringement (although distribution of such content that does not amount to private use, as well as any uploading of the content, represents an infringement). Such an expansive private use exception differs from other broad private copy exceptions—such as in Germany—in that, in Swiss law, there is no distinction made between whether or not the downloaded copy is itself a legal version. In other words, even if the ma-

terial has been made available in an illegal manner, the private use exception still applies in Switzerland. This remains unchanged. The Federal Institute of Intellectual Property currently states on its website that the changes to Swiss copyright law do not affect existing personal use exceptions: "Nothing changes for consumers of illegal content. They are allowed, for example, to continue downloading music which was published online without the permission of the rightsholder for private use." Finally, it is not clear what the legal consequences, if any, will be for internet hosts that fail to comply with the conditions of Article 39d or under what circumstances a refusal to comply with the law is acceptable.

Not all economies included in the Index are failing to effectively address the issue of copyright infringement. In fact, there were several positive developments in 2020 on both the legislative and enforcement fronts.

For instance, because of the USMCA, there were substantive copyright reforms in **Mexico** and smaller changes in **Canada**. In the latter, the term of protection for some copyrighted works was extended to 75 years through the Canada-United States-Mexico Agreement Implementation Act. In Mexico, more significant changes were made through amendments to the Federal Law on Copyright. These amendments incorporate many of the most important copyright provisions of the USMCA. Overall, the amendments strengthen the level of protection for copyrighted works in Mexico, extending this protection to the internet and the digital environment. Specific changes include (1) a new notification system whereby ISPs are obliged to act expeditiously and remove suspected content upon receiving a notification (Articles 114 and 232); (2) robust Digital Rights Management (DRM) and Technological Protection Measures (TPMs) provisions outlawing the use, manufacture, sale, importation, distribution, or otherwise offering to the public of circumvention devices and technologies (Article 232); and (3) making illegal the use, manufacture, import, or other form of distribution of satellite signal decoders (Article 145). These are positive developments and have resulted in score increases for Mexico. However, some parts of the amendments remain unclear. For example, with respect to potential ISP liability for infringing content, Article 114(8) is quite clear that ISPs will not be responsible for any damages caused by potential copyright infringement as long as they act expeditiously and in good faith to remove infringing content and take measures to prevent the same infringing content from reappearing. However, in the same article, sub-section V, the law states that the "inability of an Internet Service Provider to meet the requirements set forth in this article by itself does not generate liability for damages for violations of copyright and related rights protected by this Law." For any notification system to be effective in addressing online infringement, the responsibilities and legal expectations for each affected party must be clear. At the time of research, no implementing regulations or further guidance had been issued.

In other economies, too, there were positive developments as a result of international trade negotiations. As mentioned above, **China** has over the past two years reformed many important parts of its IP framework. This is in large measure a result of negotiations with the United States and the conclusion of the deal. In 2020, new amendments to the Chinese Copyright Law were finally passed. These include important changes and a strengthening of the legal framework, including in relation to sound and broadcasting. A revised Article 3 provides new definitions of copyrightable material, including for "audiovisual works" and a broad "other intellectual achievements that meet the characteristics of the work." Rights relating to performance rights, sound recording, and broadcasting have also been more clearly defined. Provisions relating to TPM and DRM have been strengthened through Articles 49, 51, and 53, which now provide a broader definition of infringement, including for the manufacturing, importation, and offering of circumvention devices to the public. Statutory damages for copyright infringement have also been substantially increased following similar changes to the Patent Law and Trademark Law. These are positive changes that could, in aggregate, amount

to a significant improvement of the copyright environment in China. Over the next few years, the Index will monitor how these legislative changes are applied in practice and the extent to which they improve the ability of rightsholders to enforce their copyrights.

In the Middle East, **Saudi Arabia's** Authority for Intellectual Property (SAIP) continues to tackle the long-standing challenge of copyright infringement with stronger enforcement actions. Since its inception in 2017-18, the SAIP has worked on improving the copyright environment and the ability of rightsholders to enforce their rights more effectively. In 2019, the authority announced that over 160 cases of alleged copyright infringement had been referred to the relevant Saudi enforcement authorities and fines and penalties had been imposed. The SAIP has also made the disabling of access to infringing content part of its enforcement remit. The authority offers a portal through which rightsholders can directly communicate any suspected online infringement to the SAIP, which will then take enforcement action. In June 2020, the SAIP announced that it had disabled access to 231 websites that had been disseminating infringing content. The next step would be to institutionalize SAIP's administrative enforcement through the issuing of more detailed guidelines or a process note. Nevertheless, this is another positive step taken to offer rightsholders a more effective and practical route of copyright enforcement in Saudi Arabia. Additionally, Saudi Arabia could further strengthen its copyright enforcement environment through greater action against piracy devices and corresponding services, which are still easily available in Saudi Arabia.

With regards to more industry specific copyright indicators, there were more mixed results.

Meanwhile, **Ukraine** continues to struggle with public sector use of unlicensed software. This long-standing problem—in where the Ukrainian government and public sector entities use unlicensed software--has been noted since Ukraine was first included in the Index in 2013. Rightsholders and the U.S. government have, for many years, pointed to the need for fundamental reform and the effective application of requirements that software used by government agencies be properly licensed. A 2003 Ukrainian Cabinet regulation banned the use of unlicensed software by government agencies and established procedures for legal access to software. Still, as USTR noted in 2020, "widespread use of unlicensed software by Ukrainian government agencies" Continues. Given the lack of effective action by the Ukrainian government on this issue for the past eight years, the score on this indicator has been reduced to 0.

In contrast to the Ukraine, other economies included in the Index have been able to take more forceful and effective action against unlicensed software.

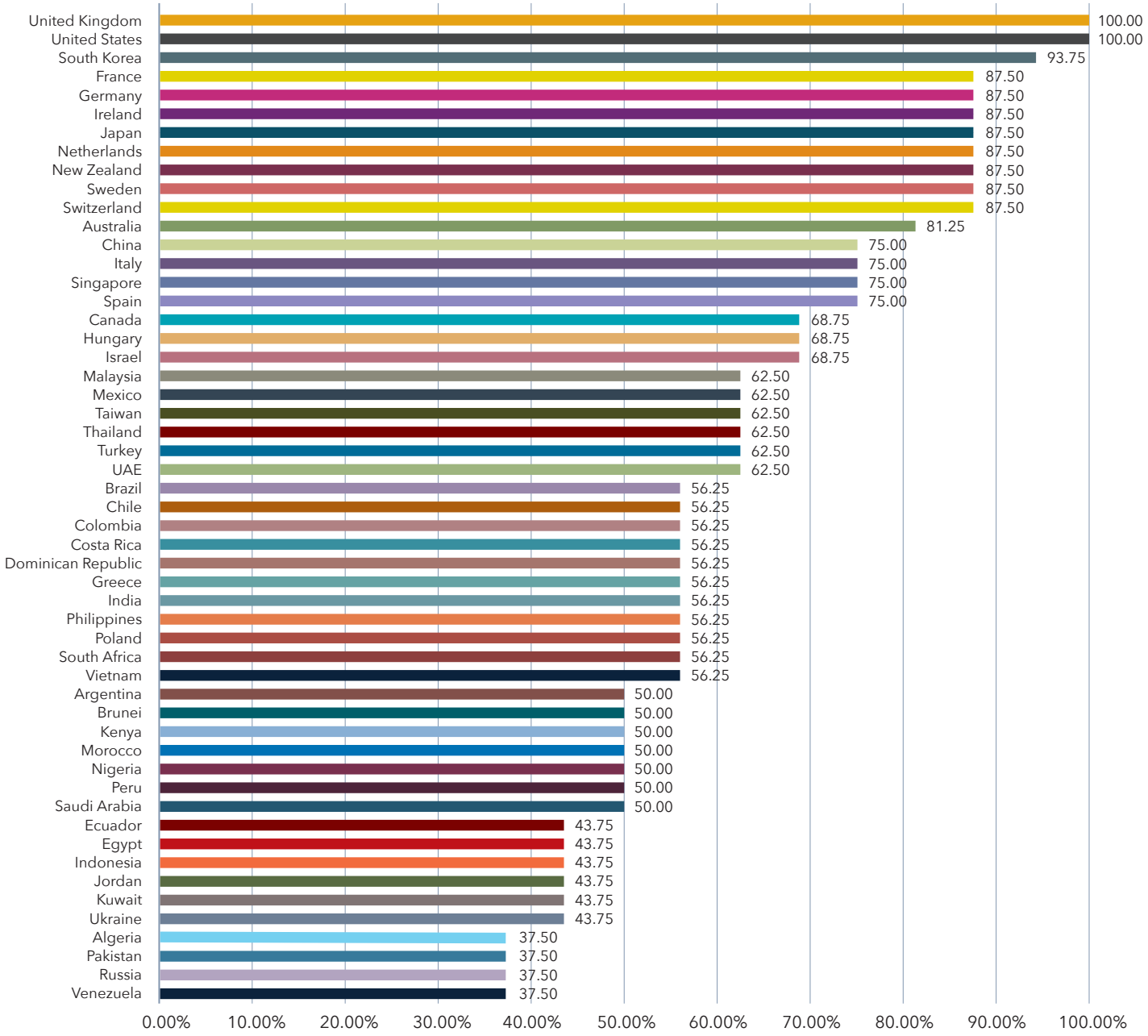
For example, **Costa Rica** has since 2012 had in place relevant rules and regulations that all central government ministries and agencies have an obligation to ensure that all software, whether proprietary or open source, used on public Information Communications Technology (ICT) systems should be fully licensed. Up until now, there has been only partial evidence that relevant government institutions were effectively monitoring the application of these requirements. Over the past two years, a new automated registration, compliance, and software asset management platform, "El sistema de legalización de software", has been built. This web portal will allow all ministries and relevant government agencies to electronically file annual software audits, inventories, and proof of licensing compliance and provide the national IP office (National Registry) with a centralized platform to store and process data and information. The creation and use of this tool should allow the National Registry and relevant staff operating it to monitor compliance with Executive Decree No. 37549-JP more effectively. At the time of research, the platform was operational and available on the National Registry's website. As result of these positive actions, the score on this indicator has increased.

CATEGORY 3: TRADEMARKS, RELATED RIGHTS, AND LIMITATIONS

Figure 11 summarizes the total scores for Category 3. This category measures the strength of an economy's environment for trademarks, related rights, and limitations. The category consists of four indicators with a maximum possible score of 4. The average score on this category was 62.97%.

Most economies sampled in the Index offer basic forms of trademark protection. As discussed over the years in the Index, however, rightsholders face a growing challenge: shifting sales of counterfeit goods from physical to online markets. Especially during the COVID-19 pandemic, online marketplaces—including third-party intermediaries—are essential to moving goods from manufacturers and suppliers to end users. Unfortunately,

Figure 11: Category 3: Trademarks, Related Rights, and Limitations, percentage available score



criminals are misappropriating online marketplaces to traffic counterfeit products. The shift to online shopping has naturally accelerated as a result of the COVID-19 pandemic. This has been most pronounced in high-income OECD economies. Both the second and third quarters of 2020 saw increases of 44.4% and 37.1%, respectively, with online sales estimated to make up roughly 20% of total retail sales in the United States for the year. Less than a decade ago, in 2011, total e-commerce sales were less than 7% of total retail sales. Unfortunately, as online shopping becomes more popular and widespread, so too does the proliferation and sale of counterfeit goods. Certain online third-party marketplaces are working with brand owners and rightsholders to adopt swift takedown procedures, pursue joint criminal actions, and encourage information sharing, among other efforts. Such practices offer improvements to a complex environment and work best as a collaborative effort involving brand owners, online marketplaces, and policymakers—as well as consumers. However, few economies have appropriate resources, technology, or effective mechanisms to combat the increased sale of counterfeit goods online. There are some examples in where relevant legislation or case law has established an obligation for online merchants to take down IP-infringing material upon notification by a rights-holder. However, overall, the mechanisms in place are outweighed by the sheer quantity of counterfeit goods available online. Still, just as in the past two years, there were some new positive developments in 2020.

In **Thailand**, a precedent-setting application of an injunctive-style relief mechanism originally pioneered for copyright infringement could pave the way for a more structured application within the sphere of online trademark enforcement. Under the 2016 Computer Crime Act, the Ministry of Digital Economy and Society (MDES) may file a motion for a permanent injunction to disable access to websites with IP-infringing content (defined as computer data that are a criminal offense against IP). MDES is notified by IP owners (or their representatives) of infringing content and then sends a request for injunctive relief to a court. If an injunction is granted, MDES orders the ISP to disable access to the site. Local legal analysis suggests that over 90 of these injunctive-style relief requests had been sent to MDES, with access disabled to over 1,400 websites and portals. But as of 2020, the mechanism had exclusively been used by copyright holders. In early 2020, however, both the MDES and a relevant court approved an order disabling access to several websites on the basis of infringement of trademark rights. The decision marks a new and pivotal avenue whereby rightsholders can more effectively enforce their trademarks online in Thailand.

Like in many other economies, online shopping and retail is increasing in **Mexico** as more people obtain broadband and mobile telephone connectivity. But until 2020, there was no regulatory or administrative framework for rightsholders to effectively address the sale of counterfeit goods and infringement of trademark rights online. Only some online merchants, including eBay and Mercado Libre, have had in place specific notice-and-takedown mechanisms giving rightsholders the ability to directly alert the platforms of potential infringements. Mexico's revised Industrial Property Law (implementing the USMCA) introduces a new mechanism whereby injunctive-style relief can be obtained directly from the national IP office, the Instituto Mexicano de la Propiedad Industrial (IMPI), for online violations. Specifically, Article 344 sub-sections VII and VIII give the IMPI the power to "order the alleged offender or third parties to suspend, block, remove content or cease acts that constitute a violation of this Law through any virtual, digital or electronic means, known or to be known."

The past year also saw important improvements to **Malaysia's** trademarks law. In December 2019, the Malaysian Parliament finalized and passed a new Trademarks Act. The new legislation is the culmination of a long legislative process that saw Malaysia become a contracting party to the Madrid Protocol. The new act modernizes the legal framework and contains several changes to how trademarks are registered and protected. It expands the types of marks that can be registered, including sound, scent, shape, color, and other so-called

non-traditional marks. The new act also contains significant changes to trademark enforcement. Specifically, trademark infringement can now be prosecuted on the basis of a mark appearing on "similar" goods or services as opposed to "identical." Under the old regime, rightsholders often had to rely on the 2011 Trade Descriptions Act, which provided criminal remedies for "false trade description in relation to trademark," including minimum fines and potential imprisonment. This has now changed, with most of the enforcement provisions of the Trade Descriptions Act now being moved into the Trademarks Act. Local legal analysis suggests that this will improve the operational aspects of enforcement as rightsholders will no longer need to obtain a specific trade description order to begin infringement proceedings against the use of non-identical marks. Potential penalties, including damages, have also been strengthened.

CATEGORY 4: DESIGN RIGHTS, RELATED RIGHTS, AND LIMITATIONS

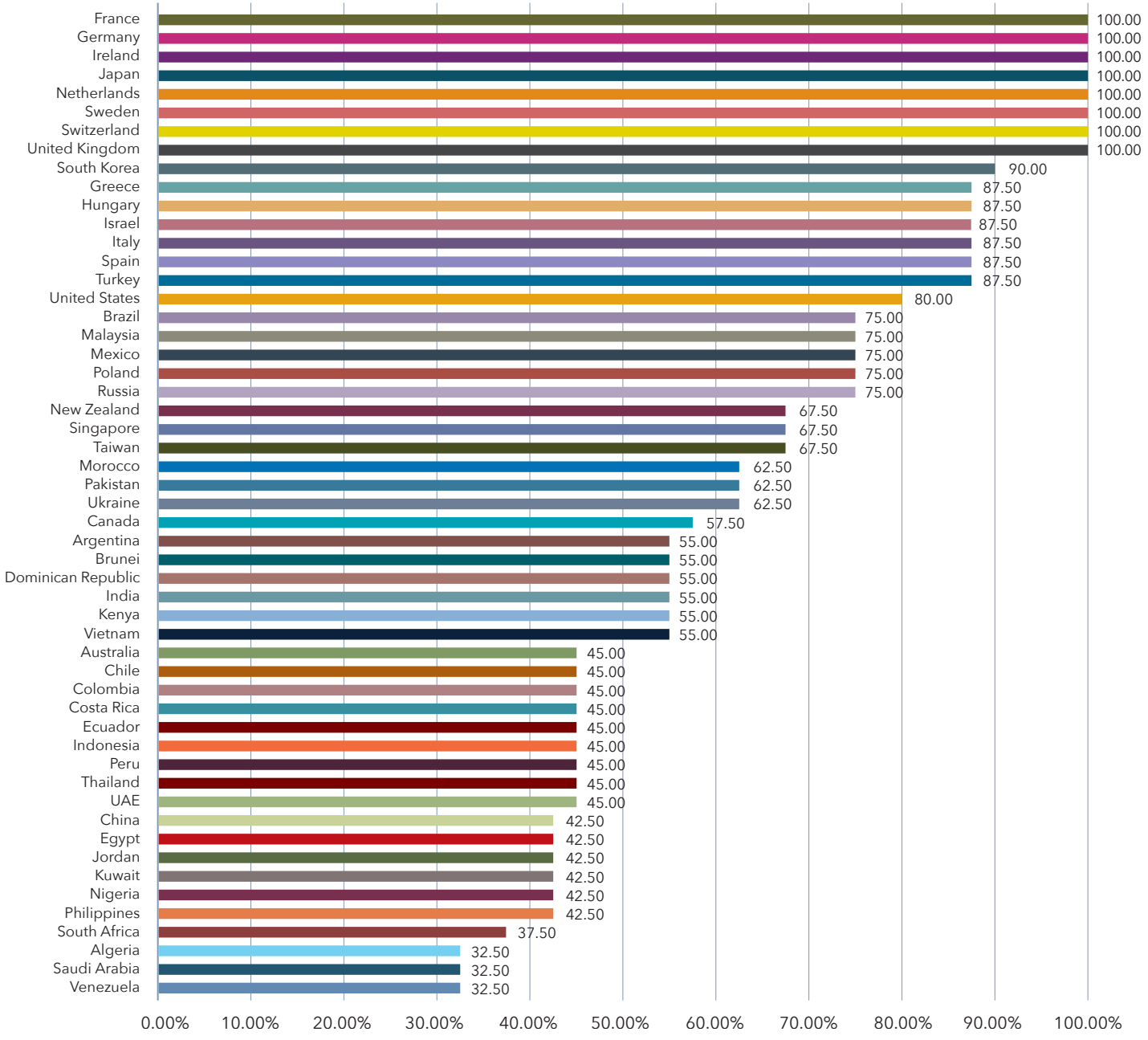
Figure 12 summarizes the total scores for Category 4. This category measures the strength of the environment for design rights. The category consists of two indicators with a maximum possible score of 2. These indicators measure the maximum term of protection being offered (including renewable periods) for design rights and the extent to which economies have in place and apply laws and procedures that provide necessary exclusive rights. The average score on this category was 64.95%

Most economies included in the Index have in place some form of design law and defined term of protection for registered design rights. As noted in past editions, design rights and IP rights for industrial designs are becoming increasingly important to rightsholders across the world. Statistics from WIPO on total design applications (direct and via the Hague System) between the mid-1990s and today show the number of applications globally growing from less than 200,000 in 1995 to over 1 million in 2018. In the United States, the number of design patent applications has shown similar growth, increasing from just over 15,000 applications in 1995 to over 45,000 in 2018. In 2020, there were some important developments for both the provision of statutory design rights and their enforcement.

In 2020, several economies included in the Index—**China**, **Japan**, and the **Ukraine**—all increased the available term of protection for design rights. As part of the 2020 amendments to the Patent Law, the term of protection for design patents in China was extended from 10 to 15 years. In both Japan and Ukraine, the term of protection for design rights was extended to 25 years. This matches the benchmark used by the Index and has resulted in a score increase to 1 for both economies on this indicator.

In 2016, the OECD estimated that the international trade in counterfeit and pirated goods represented about 2.5% of global trade. In the latest available update to this estimate released in the 2019 *Trends in Trade in Counterfeit and Pirated Goods*, the OECD and EU Intellectual Property Office (EUIPO) now find that the value of the international trade in counterfeit and pirated goods has risen to an estimated 3.3% of global trade, over $500 billion. Customs and enforcement data from around the world reveals that a large portion of counterfeit goods are designed goods. This includes different types of clothing and apparel, watches, sunglasses, handbags, and similar accessories. While most customs authorities have experience dealing with traditional trademark and copyright enforcement—and many economies offer rightsholders the ability to record their rights with national customs authorities—this option is not always available for design rights. The EU is one of the few jurisdictions where it is possible to file a request for customs action in individual Member States as well as all Member States specifying both registered and unregistered design rights as a right to be protected. This is currently not possible in the **United States**. As has been noted by a growing number of rights-holders, counterfeiters are increasingly becoming more sophisticated, often bypassing trademark infringement when importing infringing products into the United States. In an effort to address this gap in current legislation,

Figure 12: Category 4: Design Rights, Related Rights, and Limitations, percentage available score

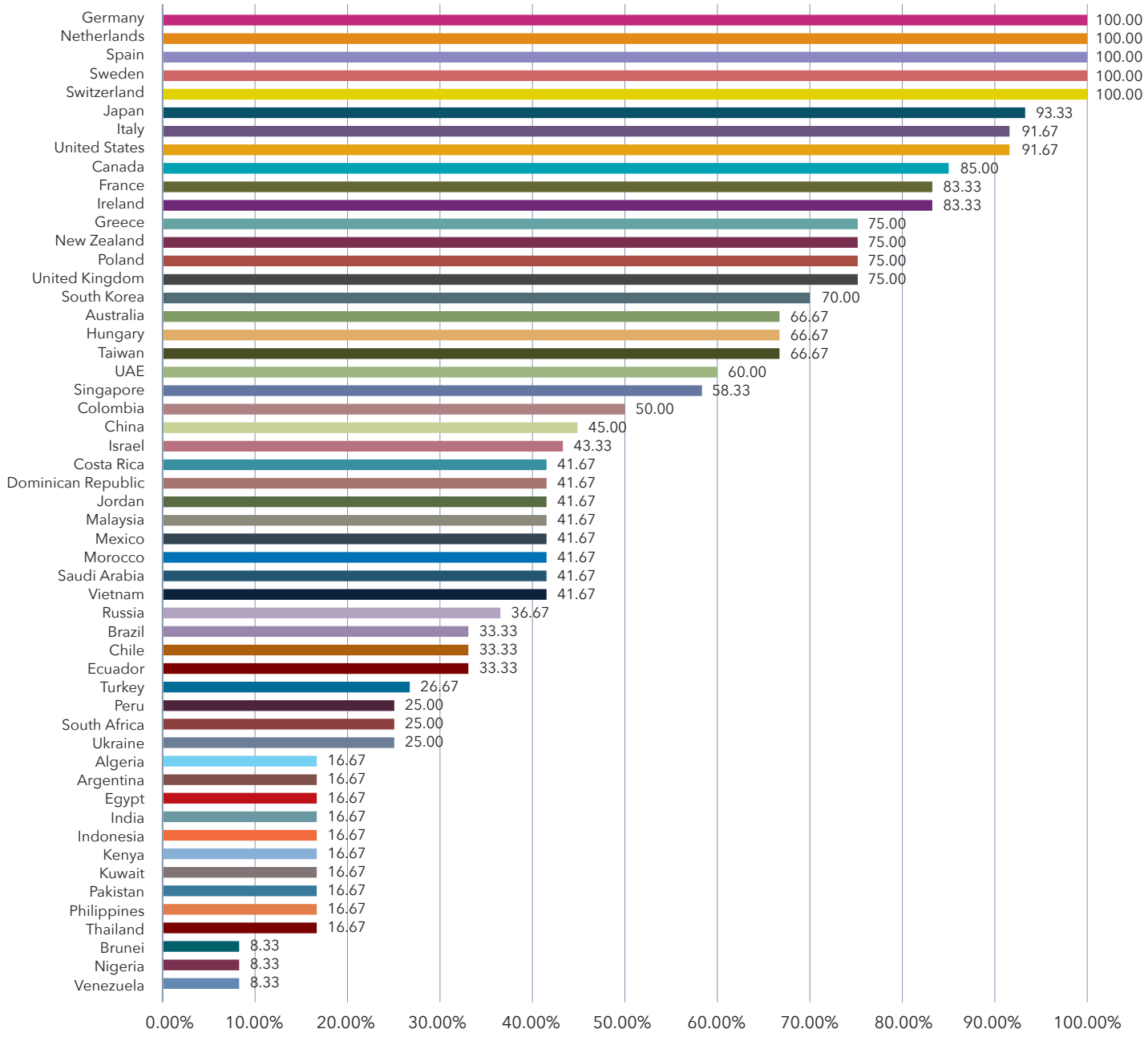


a group of U.S. senators introduced the "Counterfeit Goods Seizure Act of 2019" in December of that year. The proposed bill would give U.S. Customs and Border Protection the authority to act against goods suspected of infringing design patents just as they are authorized to do for suspected trademark and copyright-infringing goods. U.S. Customs and Border Protection has long served as a global leader for the enforcement of IP rights and the fight against counterfeiting. Adding this capacity to the existing border enforcement framework would be a positive step and give border agents an additional tool in the fight against counterfeiting. At the time of research, no legislative action had been taken on the bill and it was unclear how the proposed legislation would fare in a new Congress.

CATEGORY 5: TRADE SECRETS AND THE PROTECTION OF CONFIDENTIAL INFORMATION

Figure 13 summarizes the total scores for Category 5. This category measures the strength of the environment for trade secrets and confidential information. For trade secrets, the category includes two indicators measuring the availability of civil remedies and criminal sanctions, respectively, in relation to the misappropriation or improper acquisition, use, or disclosure of trade secrets or confidential business information, and the application of this legislation and effective access to these remedies. In addition to the protection of trade secrets, this category also measures the existence of an RDP term for biopharmaceuticals. In total, the category consists of three indicators with a maximum possible score of 3. The average score on this category was one of the weakest on the Index, at 49.40%.

Figure 13: Category 5: Trade Secrets and the Protection of Confidential Information, percentage available score



As noted in past editions of the Index, many economies do not have specific trade secret legislation in place. Instead, they rely on laws for employment contracts and the disclosure of confidential information. Consequently, there are sizable gaps in protection in many economies. "Trade secrets" are often not explicitly defined in relevant laws and regulations, and courts have limited experience ruling on cases involving the misappropriation or improper acquisition, use, or disclosure of trade secrets or confidential business information. This gap is especially pronounced with respect to criminal sanctions. Many economies—including developed OECD members—do not have statutory criminal sanctions in place for the theft and misappropriation of trade secrets. On a positive note, in 2020, there were some important developments, with several economies introducing changes to their legislative frameworks.

Historically, for instance, **Canadian** law has not provided a statutory definition or criminal sanctions for the theft or misappropriation of trade secrets. Any potential criminal prosecution, then, must rely on other parts of the legal code. As part of its implementation of the USMCA, the Canadian Parliament passed new criminal provisions for the theft and misappropriation of trade secrets through the Canada-United States-Mexico Agreement Implementation Act. Section 391 of the Criminal Code now contains a maximum 14-year prison term for anyone who "by deceit, falsehood or other fraudulent means, knowingly obtains a trade secret or communicates or makes available a trade secret." As a result, Canada's score on this indicator has increased.

There were also positive changes to **Taiwan's** legal framework for trade secrets and confidential information. In December 2019, the Taiwanese Legislative Yuan passed a new trade secrets law. The new law replaces the 2013 Trade Secrets Protection Act and provides several important updates to what was, already, a comprehensive legislative framework. The new law updates the original act by providing stronger protection for foreign rightsholders and better protection for confidential information during criminal investigations. Article 13-5 now provides foreign entities and persons with the right of filing criminal and civil complaints. Up until now, this had been possible only if a bilateral agreement existed between the country of residency of the foreign entity or person and Taiwan. Now, all foreign entities and persons have this right of protection regardless of treaty status. Articles 14-1 to 14-4 introduce so-called confidentiality protective orders (CPOs). These CPOs are meant to provide prosecutors and investigators an additional tool to ensure that any confidential information that is examined, discussed, or otherwise shared during the course of a criminal investigation is not disseminated.

With respect to RDP of submitted biopharmaceutical test data during regulatory review, there were more mixed developments.

The protection of biopharmaceutical innovation in the **UAE** has historically been defined by Ministerial Decree 404 (2000), which tied the exclusivity status of a product in the UAE to the term of patent protection in the country of origin. The period of protection for applications submitted for marketing approval after January 1, 2000, has been for the remaining term of the patent or patents protecting the drug in its country of origin. As such, there is no period of RDP defined or recognized in UAE law. In 2020, however, this changed with the Ministry of Health and Prevention's issuance of Ministerial Resolution 321. The resolution provides a defined eight-year period of RDP for submitted pre-clinical and clinical data submitted by an original reference applicant. Article 2 of the resolution explicitly states that it is "not permissible" for a follow-on applicant to "obtain the marketing approval for a similar drug product" by relying on a previously submitted dossier. There is, however, some uncertainty over the whether the full eight-year RDP term will be available. Specifically, Article 3 allows follow-on applicants to register their products in the last two years of the granted RDP in what amounts to a so-called "Bolar exemption." Bolar exemptions are established to allow follow-on manufacturers to conduct research and necessary scientific studies to meet regulatory safety and quality requirements in preparation

for market approval. Due to the long timelines involved in the drug approval process, the primary goal of these types of exemptions is to ensure that there is no undue delay for the launch of a generic follow-on product once the reference product's exclusivity has expired. In the case of the UAE, Article 3 of the resolution does not specify or outline what type of activities follow-on manufacturers may engage in, and there is no assurance that the reference product's full eight-year period of data exclusivity will be maintained. Nevertheless, the introduction of a defined term of RDP is a positive step and an improvement in the biopharmaceutical IP environment in the UAE.

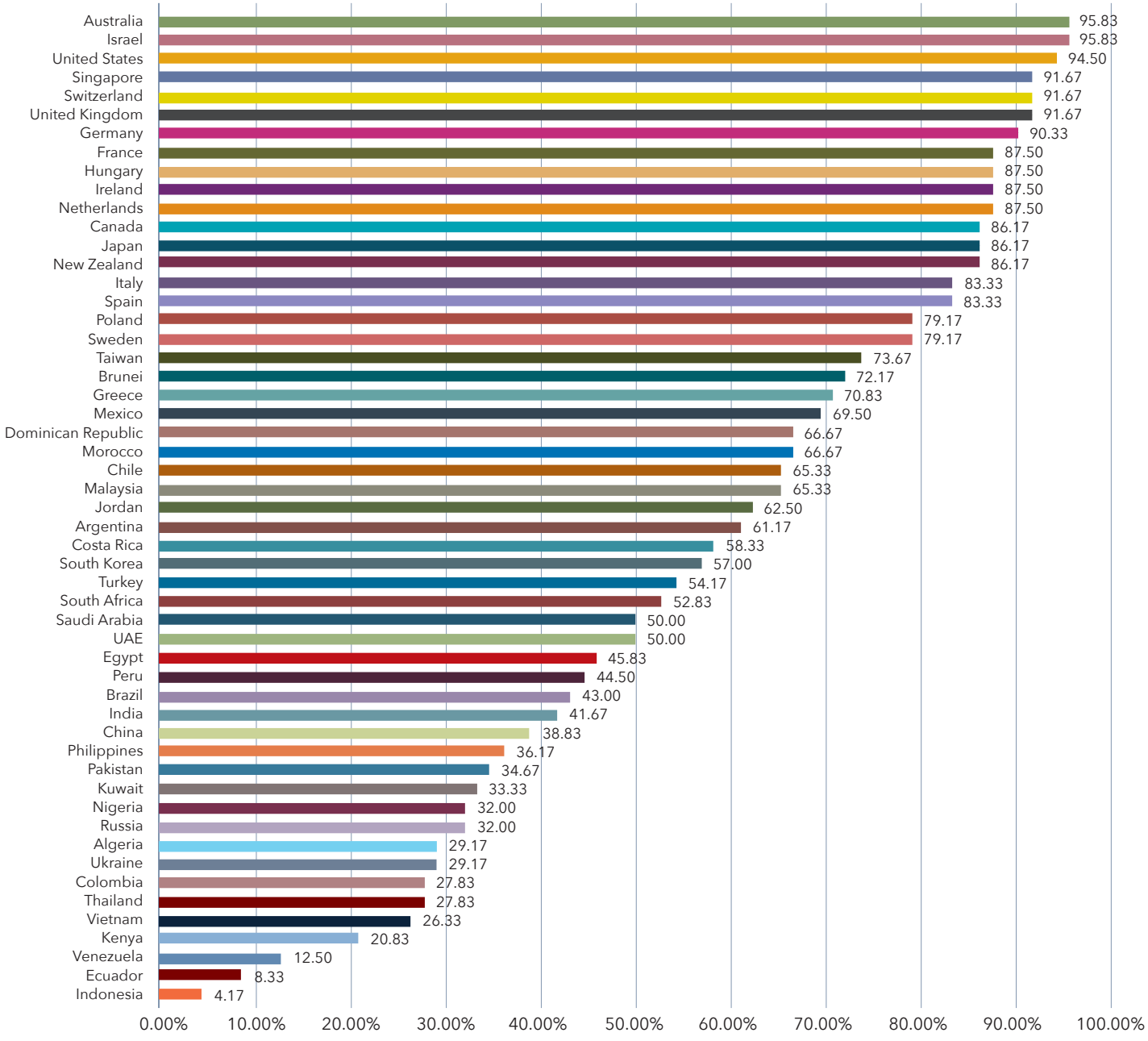
In contrast to the positive developments in the UAE, proposed changes to the RDP regime in **Saudi Arabia** were less positive. The 2005 Minister of Commerce and Industry's Decision No. 3218, "Regulations for the Protection of Confidential Commercial Information," provides specific protection for submitted clinical research data as part of a biopharmaceutical market registration application. Article 5 of the regulations provides a clear and unambiguous protection term of five years from the date of approval. It also states that relevant Saudi authorities "shall undertake to protect such information against unfair commercial use, for a minimum period of five years from the date of obtaining the approval." The existence of this RDP is a positive feature of Saudi Arabia's national IP environment. However, as noted over the course of the Index, uncertainty exists over the actual availability of this protection. Industry reports have suggested that follow-on products have been approved through the use of "indirect reliance" on submitted clinical research data. International standards and best practices for RDP, however, are quite clear on this subject: neither direct nor indirect reliance on submitted clinical test data should be used to approve follow-on products within any specified and granted term of exclusivity. In 2020, the SAIP released new draft implementing regulations on how confidential commercial information will be protected in Saudi Arabia. While the SAIP should be applauded for publishing these draft regulations, holding a public consultation, and inviting stakeholder feedback on the matter, the regulations themselves are deeply flawed and stand outside established international standards of RDP. Specifically, Article 4(1) of the regulations states that any term of protection offered in Saudi Arabia would begin "the date of the first registration of the preparation **in another country**." If implemented, this would dramatically re-write existing regulations and significantly curtail rights-holders' effective RDP term. The introduction of such a definition and the linking of the exclusivity period in Saudi Arabia to a product's first global launch would severely limit the availability of RDP in Saudi Arabia and undermine the incentives for innovation and investment such exclusivity provides. Moreover, the draft regulations do not allow a period of RDP for new indications. The implementation of this regulation and application of the existing provisions in relation to RDP would result in a reduction of the score to 0 for this indicator.

CATEGORY 6: COMMERCIALIZATION OF IP ASSETS

Figure 14 summarizes the total scores for Category 6. This category consists of six indicators with a maximum possible score of 6. These indicators measure the presence of barriers and incentives in place for the commercialization and licensing of IP assets. This ranges from barriers to technology transfer, to registration and disclosure requirements of licensing agreements, to direct government intervention in setting licensing terms, to the existence of tax incentives for the creation and commercialization of IP assets. The average score on this category was 59.42%

New technologies can contribute to economic activity only if they are successfully commercialized in the marketplace. Technology transfer and licensing are critical mechanisms for commercializing and transferring research from public and governmental bodies to private entities and private-to-private entities for the purpose of developing usable products and commercially available technologies. They also provide a

Figure 14: Category 6: Commercialization of IP Assets, percentage available score



significant and distinct contribution to the economic strength and well-being of the economies in which they take place. For less developed economies, international licensing of technology can provide the basis for local technological development and building a more sophisticated absorptive capacity. Global technology flows and the commercialization of IP assets are, thus, crucial drivers of innovation. However, licensing and technology transfer rely on a supportive and efficient environment that minimize red tape, facilitate market-based partnerships, and uphold the integrity of partnerships. Yet, in many respects, economies are failing to provide the necessary regulatory and IP-specific infrastructure to help incentivize and better facilitate domestic and cross-border licensing and technology transfer. One of the most significant barriers that affects licensing and

technology transfer—domestic and cross-border—is direct government intervention and setting of licensing terms. As has been noted in previous editions of the Index, many of the economies benchmarked in the Index are introducing policies that make it more difficult to access their respective markets or commercialize IP assets. This continued in 2020, with several negative developments. However, there were also some surprisingly positive changes.

In late 2019 and 2020, **Algeria** embarked on a series of ambitious reforms to fundamentally alter its relationship to foreign direct investment. The Algerian government has historically imposed localization rules for how foreign firms may participate in the market and has actively pursued an import substitution policy. The stated objective of these rules has been to reduce imports, encourage domestic production, and maximize technology transfer. These policies also span various sectors and have included national public procurement rules. Specifically, access to tenders for foreign bidders has been greatly limited by Decree 10-36 (2010), which gives a 25% price preference to national producers. Foreign bidders have been able to qualify as local if they have partnered with national companies that are majority-owned by Algerian residents. The most onerous requirement is the strict ownership limitations. On the basis of a pre-existing measure in the oil and gas sector, the 2009 Complementary Finance Law had limited foreign investment to a minority stake (49% or below) in any industrial sector. As a result of the profound political changes taking place in Algeria, the past 12 months have seen what potentially could amount to a sea-change in Algeria's openness to and relationship with foreign investment. Specifically, through the 2020 Finance Law, the government removed the 51-49% local ownership requirement for non-strategic industries. The Finance Law did not specify how the elimination of the local ownership requirement would be implemented or which industries would be considered non-strategic or strategic. In June 2020, a Supplemental Finance Law was enacted and published in the official gazette. Article 50 of the law outlines which industries and sectors of the economy are to be considered as strategic and still subject to the 51-49% local ownership requirement. These include mining, hydrocarbons, industries relating to national defense, physical infrastructure (railways, ports, and airports), and the pharmaceutical industry. With regards to the pharmaceutical industry, the law appears to provide an exception to the local ownership requirement for this capital and research-intensive industry. However, this exception is not entirely clear and appears to be contingent on fulfilling several conditions. At the time of research, no implementing regulations had been drafted or issued outlining the specific conditions and requirements to qualify for the exception. The removal of the local ownership requirements is a positive development for Algeria affecting most indicators included under Category 6.

Unfortunately, not all economies have re-thought their economic models. In recent years, there were negative developments in **Turkey** and **Nigeria**, both of which have long-standing mandatory localization requirements that target IP-intensive, high-tech sectors. Turkish industrial and economic policy over the past two decades has increasingly been driven by an effort to localize industrial production and R&D. A major part of these efforts has been localization and import substitution policies that actively discriminate against foreign entities and favor domestic Turkish companies. The biopharmaceutical and ICT sectors have been heavily targeted by these policies. In 2016, the Turkish Medicines and Medical Devices Agency began implementing an import substitution plan whereby drugs that have at least one local generic or therapeutic equivalent are required to localize their production by 2018 or be excluded from public reimbursement. Industry reports suggest that close to 200 products were delisted in 2018, of which 71 medicines were identified and delisted from reimbursement in early 2018 by the Turkish Social Security Institution. In 2019, the European Union filed a complaint before the WTO alleging that Turkey's localization policies were in violation of fundamental provisions of the General Agreement on Tariffs and

Trade (GATT), Agreement on Trade-Related Investment Measures (TRIMS), TRIPS, and Agreement on Subsidies and Countervailing Measures (SCM). In September 2020, the WTO announced that, due to the COVID-19 pandemic, no final report would be issued on this dispute until the second half of 2021. More broadly, the Turkish government actively uses public procurement policies as a form of incentivizing localization and discriminating against foreign bidders. Since 2002, under Article 63 of the Procurement Law, domestically manufactured products are afforded a 15% price advantage . In addition, since 2015, all government ministries have the possibility to apply "Industrial Cooperation" (civil offset) clauses for public procurement contracts. And in the ICT sector, Turkish laws place onerous requirements (including local data storage) on ICT companies and digital service providers. Sector-specific data storage requirements are in place on payment service providers and banking and financial services institutions. As with other localization measures, the requirements for data providers intensified in 2020. In August, the Turkish Parliament passed amendments to Law No. 5651 (the Regulation of Internet Broadcasts and Prevention of Crimes Committed through Such Broadcasts). These amendments require social media service providers with over 1 million visits per day to store any user data locally in Turkey, appoint a legal representative in Turkey, and report regularly on their activities and requirements under these amendments. Non-compliance is potentially subject to substantial fines. Cross-border transfers are permitted; however, such transfers can take place only after explicit consent has been obtained from the data subject or the country to which data is being transferred to provides an equivalent level of protection as in Turkey.

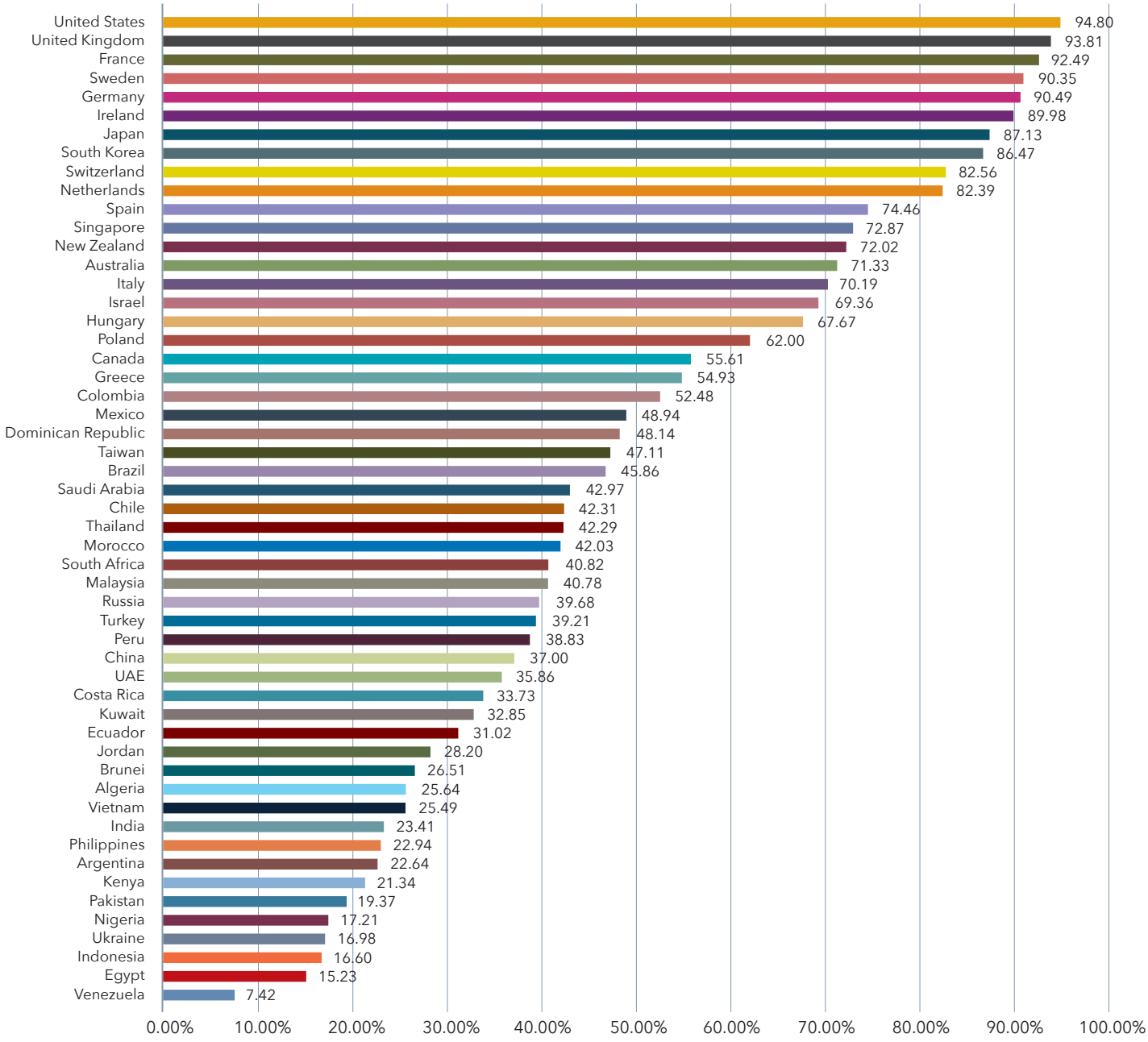
Like Turkey, Nigeria has had several localization policies and local content requirements in place since 2010. These policies have targeted specific sectors of the economy, including energy and ICT. The 2010 Nigerian Oil and Gas Industry Content Development Act is the legislative basis for most of these policies. The law and accompanying regulatory guidance provide a detailed list of requirements ranging from employment of local staff to mandatory local procurement and levels of technology transfer. Over the past few years, these regulations have intensified for oil rigs and related technologies. Similar requirements are in place for the ICT sector through the *Guidelines for Nigerian Content Development in Information and Communication Technology* developed and enforced by the Office for Nigerian Content Development in Information & Communication Technology (NITDA). These guidelines impose substantial localization requirements, including the hosting of government data within Nigeria. Foreign entities are required to put in place plans for the development of local content and support initiatives and all Nigerian public sector entities are required to procure ICT equipment and software locally. More broadly, local content requirements and preferencing are in place for all government procurement through Executive Order No. 5 from 2018. In 2019 and 2020, these localization requirements intensified. In late 2019, NITDA updated its guidelines and re-stated its commitment to the full implementation of its localization initiative. This included retaining some of its most onerous and restrictive requirements with respect to multinational software companies. Under section 10.3 of the guidelines, multinationals are required to continue to "provide verifiable information and sign affidavits about the origin, safety, and workings of software being sold and deployed within the country in order to ascertain the full security of the product and protect National security." More broadly, in May 2020, the upper chamber of the National Assembly announced that it was working on new amendments to the Nigerian Oil and Gas Industry Content Development Act. The stated purpose of these changes would be to not only strengthen existing localization requirements for the oil and gas industry, but also extend these requirements to other sectors.

CATEGORY 7: ENFORCEMENT

Figure 15 summarizes the total scores for Category 7. This category measures the prevalence of IP rights infringement, the criminal and civil legal procedures available to rights-holders, and the authority of customs officials to carry out border controls and inspections. The category consists of seven indicators, with a maximum possible score of 7.

As in years past, a clear majority of the sampled economies in the Index struggle in this category. Only 21 economies (39.62% of the sample) achieve a score of 50% or more on this category. And only 10 economies achieve a score of 75% or more. As with Category 2, the average score on this category is one of the weakest on the Index, at 49.67%. Still, despite the overall poor performance on this category, there were some positive

Figure 15: Category 7: Enforcement, percentage available score



economy-level developments in 2020. In particular, several economies improved their score on indicator 38. This indicator measures the extent to which customs authorities in a given economy publish statistics and data on trade-related IP infringement. A surprisingly large number of economies do not publish any statistics on actions taken by customs with regards to suspected IP-infringing goods. Only 16 of the 53 economies sampled in the Index regularly publish data on customs actions taken against suspected counterfeit goods, and twenty-three economies publish some information. However, this may be on an ad hoc basis or not always include relevant descriptive information such as countries of origin or volume and estimated value of the seized goods. And 14 economies do not publish any relevant information. In 2020, **Algeria**, **Chile**, and **South Korea** all improved their scores on this indicator.

The Algerian Customs Authority (*Direction Générale des Douanes*) does not publish systematic or annualized data on seizures relating to IP-infringing goods. There are no annual reports published or official data and statistics on the authority's seizure activities against counterfeit and IP rights-infringing goods. This remains the case today. However, in 2019, the authority began briefing the local media on its annual anti-counterfeiting activities. In an article published in April 2019 with the *Algeria Press Service* (the largest domestic news agency), the authority detailed its activities for 2018, including the number of counterfeit items seized and country of origin. In total, over 455,000 counterfeit items had been seized, of which more than 70% came from China. The largest categories of goods seized related to sports and textiles, which together accounted for close to 85% of all goods seized. In January 2020, a similar report was issued for the Port of Algiers (one of the largest ports in Algeria), with an estimated DZD1 billion worth of goods seized and 31 cases of enforcement activity against suspected counterfeit goods taken.

Similarly, although the Chilean Customs Authority (*Servicio Nacional de Aduanas de Chile*) does not publish an annual compendium or review on its enforcement activities against trade-related IP infringement, over the past few years the agency has notably increased its level of transparency and publicly-available data on its activities. For example, the agency actively publishes press releases on seizure activity, including information on the number of counterfeit items seized, estimated value, and country of origin. At the time of research in 2020, close to 30 such notices had been released, averaging close to four per month. As noted in past editions of the Index, there have also been examples in the past whereby the agency has released aggregated data on seizure activity in a given year. However, this data has not always included full information about the number of items seized, types of items, estimated value, or countries of origin.

As a next step, the Index would urge the customs authorities in both Algeria and Chile to consider publishing a stand-alone, annual review dedicated to providing the public with a full and comprehensive overview of the agency's enforcement activities against trade-related IP infringement.

In South Korea, statistics on anti-counterfeiting and seizure activity by the Korea Customs Service (KCS) have historically not been available on a systematic and regular basis. This changed in 2015 with the publication of the KCS' *Annual Report on Intellectual Property Rights Seizures*. This report provides a detailed breakdown of the KCS' anti-counterfeiting activities and investigations of suspected IP violations. It includes the number of seizures, categories of goods seized, and primary countries of origin. The latest report, published in 2019, shows that there were almost 53,000 seizures carried out over the course of 2018, a 360% increase compared with 2017. This rise in the number of seizures was a result of greater cooperation between the KCS, private rights-holders, and the postal service at Incheon airport and a notable increase in seizures of small parcel shipments. Of note is that nine out of 10 IP-infringing goods (92.9%) came from China. At the time of research, no report had been made publicly available in 2020. The KCS should be congratulated

for making this information available to the public in a dedicated, regularly recurring report.

There were also economy-level improvements in 2020 with regards to the ability of border officials to take effective action against suspected counterfeit goods.

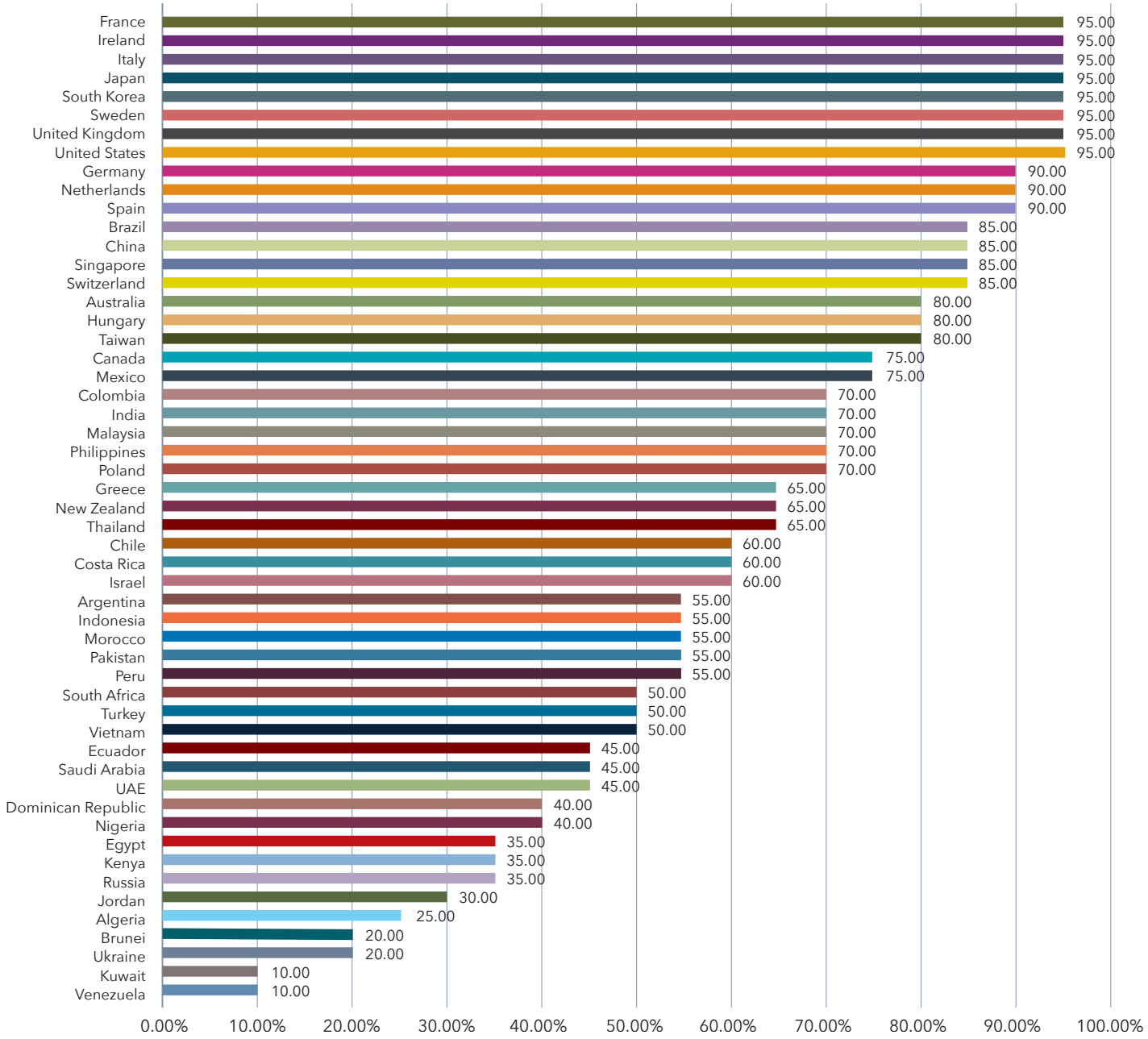
Border officials in **Canada** have historically not had *ex officio* powers to search and seize goods suspected of infringing on IP rights, and a court order has been required for seizure and detaining of suspected goods by customs officials under both the Copyright Act and the Trade-Marks Act. Bill C-8, passed in 2014, introduced more robust border measures, including new civil and criminal options as well as expanded powers for customs officials by, for example, enabling the detention of goods suspected of copyright or trademark infringement. However, while customs officers were given a right of detention, at the time of enactment, it was not clear whether in practice this right extended to goods for which rights-holders had not made a specified "request for assistance." During the 10th review of the trade policies and practices of Canada through the WTO in June 2015, the Canadian government clarified this point. In its official written responses to questions from other WTO Member States, the Canadian government stated that the newly enacted and in force legislation did, in fact, provide *ex officio* authority to customs officers. Unfortunately, the new legislation did not extend to counterfeit goods in transit, which--provided they were not destined for the domestic Canadian market--could continue to pass through Canadian customs largely unimpeded. Canada is a contracting party to the USMCA. Chapter 20 of the USMCA includes a clear requirement that border agents be granted *ex officio* authority to detain any and all suspected counterfeit goods, including goods in transit. As part of its implementation of the USMCA in 2020, Canadian Parliament passed new provisions relating to goods in transit through the Canada-United States-Mexico Agreement Implementation Act. Section 51.03 of the Trademarks Act now includes reference to transshipped goods and goods in transit. At the time of research, there was no corresponding legislative change to the Copyright Act or the Combating Counterfeit Products Act.

Finally, there has been further movement for many economies' score for indicator 32. The score for each economy on this indicator is derived from a proprietary estimate of levels of counterfeiting, the *Global Measure of Physical Counterfeiting*. This measure was developed by the U.S. Chamber of Commerce and Pugatch Consilium in 2016 to provide a new global measure of physical trade-related counterfeiting. The measure provides a total and per economy estimate for each of the 53 economies included in the Index of rates of physical trade-related counterfeiting. The methodology of the Global Measure of Physical Counterfeiting builds on that developed by the OECD and the EUIPO in their series of reports on global levels of trade-related counterfeiting, the latest being *Trends in Trade in Counterfeit and Pirated Goods* published in 2019. To obtain a unique estimate for each of the 53 economies included, the Global Measure of Physical Counterfeiting applies three weighted factors to provide a holistic take on the propensity for counterfeiting in the selected economies. The first factor is a subset of the scores for the indicators within Category 7 of the Index. The second factor incorporates the most recent updates to the OECD's *General Trade-Related Index of Counterfeiting* (or GTRIC-e) benchmark. The third factor used is the rate of perceived corruption within an economy, as measured by Transparency International's *Corruption Perceptions Index*. In 2019-020, there were new editions and data released by both the OECD and Transparency International. The changes in economies' underlying scores on these measures has, consequently, affected their scores on the Index. A full description of the Global Measure of Physical Counterfeiting and sources used is available at the end of the Index in the appendix.

CATEGORY 8: SYSTEMIC EFFICIENCY

Figure 16 summarizes the total scores for Category 8. Indicators included in this category seek to measure national efforts at coordinating IP rights enforcement; the existence of stakeholder consultation mechanisms during IP law and regulation-making processes; existence of awareness-raising and educational activities on the importance of IP rights and incentives; targeted incentives for small and medium-sized enterprises (SMEs) for the creation, registration, and use of IP assets; and the extent to which the relevant authorities in a given economy seek to map and measure the economic impact and importance of IP-intensive industries to their national economies. This category consists of five indicators, with a maximum possible score of 5.

Figure 16: Category 8: Systemic Efficiency, percentage available score



As in previous editions, the majority of sampled economies in the Index do quite well on this category, with only 14 economies failing to achieve a score of 50% or above. Indeed, many economies perform better on this category than in other parts of the Index, with an average category score of 63.11%. In 2020, these positive efforts continued.

In **Costa Rica** and **Argentina**, there were notable efforts to expand and institutionalize existing public awareness campaigns. In Costa Rica, the national IP office, The National Registry, has run several initiatives, the most notable being the National Intellectual Property Communication Strategy (*Estrategia Nacional de Comunicación de Propiedad Intelectual*) in partnership with WIPO. The purpose of the strategy is to promote IP awareness and respect for IP rights and creators and innovators. The program targets young people and school children. One key educational component is the "*Mis Creaciones Valen*" (My Creations Are Worthy) campaign, which includes training and educational activities for elementary and high school students. The program was first launched in 2016 and has, in aggregate, reached over 1 million people and close to 100,000 school children and teachers. The National Registry has announced that the initiative has been renewed for a new four-year period running to 2023 and will now target both private and public institutions. Similarly, in Argentina, there were positive efforts to institutionalize existing educational and coordination efforts. Following through on a commitment made in 2017 to the Argentine Chamber of Medium-Sized Enterprises (*Confederación Argentina de la Mediana Empresa*) and the Argentine Anti-Piracy Association (*Asociación Civil Antipiratería Argentina*), in December 2019 the national IP office, Ministry of Justice, and Ministry of Security announced the formation of a new national anti-counterfeiting and IP enforcement mechanism, the "Federal Committee to Combat Contraband and the Falsification of Trademarks and Designations" (*Comité Federal de Lucha Contra el Contrabando y la Falsificación de Marcas y Designaciones*). One of the committee's key tasks is awareness-raising public educational activities on the dangers of counterfeiting.

In **Saudi Arabia** and **Ecuador**, new initiatives were launched to help SMEs register and commercialize their IP assets. Working together with WIPO and the World Economic Forum (WEF), the Ecuadorian national IP office, *Servicio Nacional de Derechos Intelectuales*, has launched a dedicated program to help individual inventors and small businesses through the "Inventor Assistance Program." Launched globally in 2016, the program seeks to match inventors with legal practitioners who provide pro-bono legal advice on the technical evaluation and registration process for the IP created. At the time of research, the program was fully operational, with the first patent applications having been filed in Ecuador. Similarly, the Saudi National IP Authority, SAIP, announced several new initiatives targeting SMEs in 2020. In June, the "Intellectual Property Advisory Clinics Program" was launched. The program seeks to help SMEs develop, register, and commercialize IP assets. The SAIP also released an "Intellectual Property Policies Manual" to help and guide SMEs, academic institutions, and individual inventors. Finally, the authority, in partnership with WIPO, opened 21 support centers as part of a national network of IP centers.

In **Australia**, the national IP office, IP Australia, mapped and measured the impact of IP-intensive industries on the Australian economy. As noted in past editions of the Index, various parts of the Australian government actively measure and seek to understand the economic contribution and value of IP-intensive industries to the Australian economy. For example, IP Australia has since 2012 had in place an Office of the Chief Economist, which published and commissioned various sector- and IP right-specific research studies. These include the 2015 *Economic Impact of Innovation Patents*, the 2013 *Economic Impact of Human Gene Patents*, and other stand-alone research papers on topics including design rights, the mining industry, and trademarks. In addition, based on WIPO's methodology and study guidelines, Australian public entities have conducted or supported several research reports on the economic contribution of the copyright-based industries to the Australian economy. The latest of these, released in 2017, *The*

Economic Contribution of Australia's Copyright Industries 2002-2016, was prepared by the consultancy PwC for the Australian Copyright Commission. In April 2020, IP Australia released its eighth report on the national IP environment, *Australian Intellectual Property Report 2020*. The report provides a considerable amount of data and insight on registration trends and how Australian inventors and businesses are using the national IP system. A new component of the report is a focus on IP-related economic activity. Using 2019 data collated by the Australian Bureau of Statistics, Chapter 7 of the report provides a dedicated section to understanding the link between economic activity and the use of IP rights by Australian businesses. The chapter makes several important findings on the use and positive economic impact IP rights have had on the Australian economy. For example, it finds that—when looking at average profits per employee—firms making use of IP rights tend to have higher average profit levels than those firms not owning any IP rights. This was estimated at AUD48,368 for IP rights-owning firms compared with AUD23,404 for non-IP rights owning firms. Firms owning registered IP rights--particularly multiple IP rights--had higher average profits as a percentage of invested capital than did non-IP rights owning firms.

CATEGORY 9: MEMBERSHIP AND RATIFICATION OF INTERNATIONAL TREATIES

Figure 17 summarizes the total scores for Category 9. This category measures whether an economy is (1) a signatory of and (2) has ratified/acceded to international treaties on the protection of IP. The category consists of seven indicators with a maximum possible score of 7.

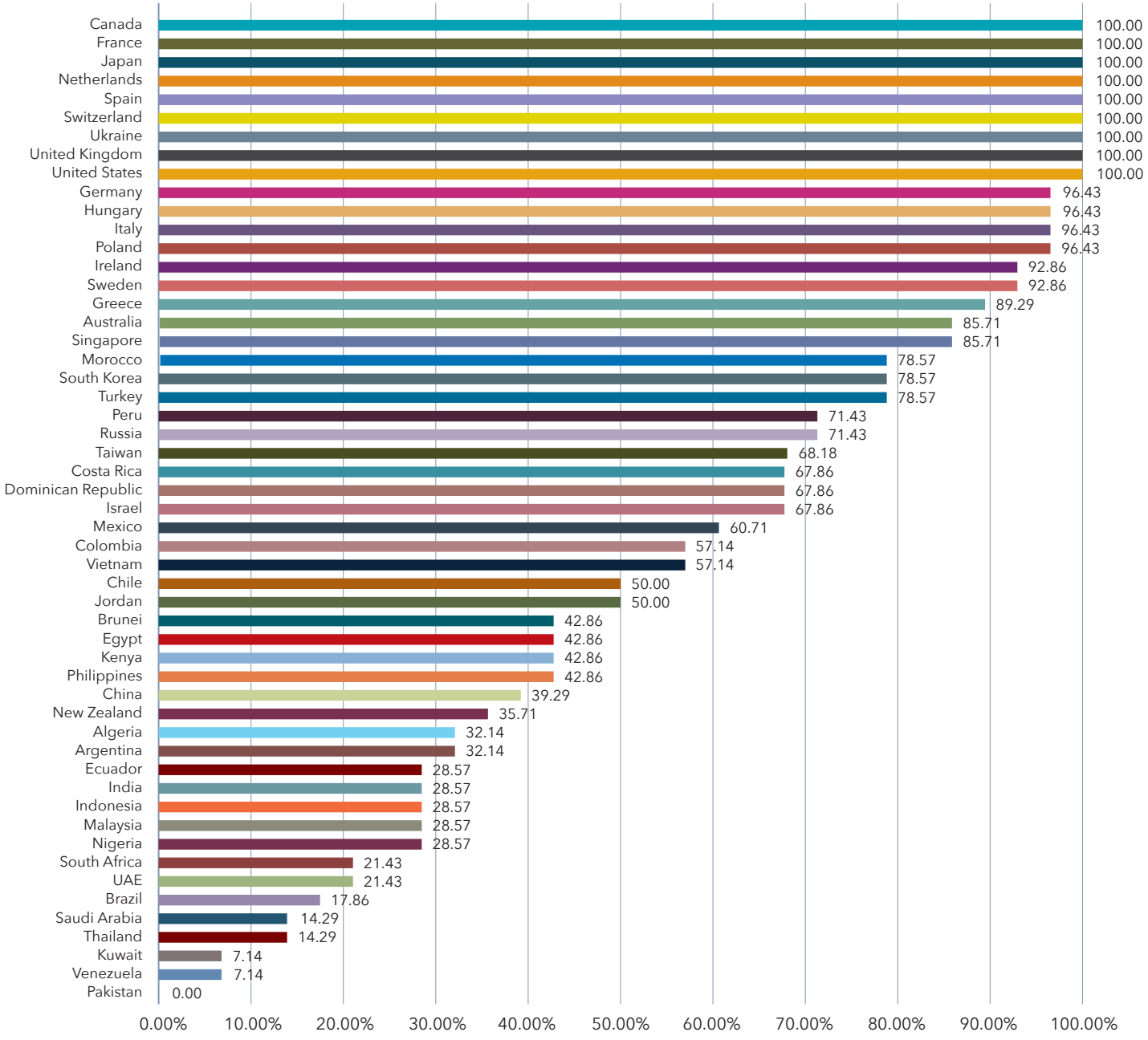
Over the course of the Index, the number of treaties included in this category has expanded substantially, and today nine are included. Yet a surprisingly high number of economies benchmarked in the Index are not contracting parties to most of the international IP treaties included in this category. This year, 21 economies failed to achieve a score of 50% or more on this category. In 2020, there were positive developments, with several emerging markets improving their score on this category.

This past year, three separate trade agreements were ratified and came into effect: the Free Trade Agreement between the EU and Vietnam, the USMCA, and the 2020 U.S.-China Trade and Economic Agreement. As a result, **China**, **Mexico**, and **Vietnam** all increased their scores.

Egypt's score also rose, as it acceded to the International Convention for the Protection of New Varieties of Plants, Act (UPOV) of 1991. In July 2019, the Egyptian Parliament passed amendments to relevant sections of Law 82 with the view of making the law and administering authority compliant with the 1991 UPOV treaty. In December 2019, Egypt formally acceded to the 1991 act and became a member of UPOV.

Similarly, **Colombia's** score increased, too. In March 2020, the Convention on Cybercrime was formally ratified and is now in force.

Figure 17: Category 9: Membership and Ratification of International Treaties, percentage available score



6 ECONOMY OVERVIEWS

INTRODUCTION

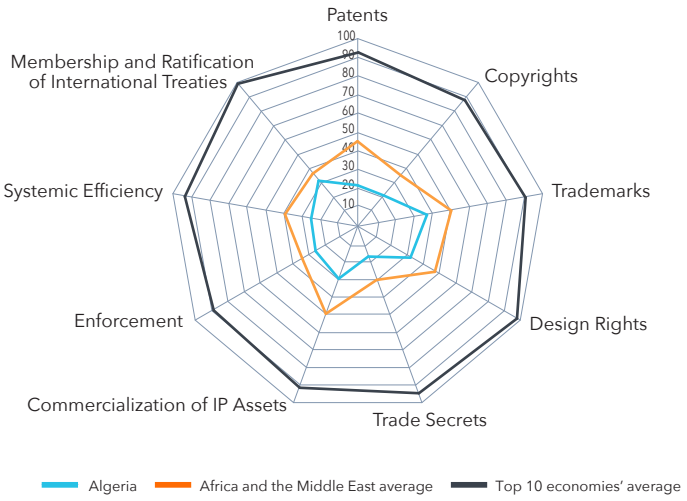
This section provides an overview and analysis of each individual economy's score on all 50 indicators.

In addition to the total score and overall rank vis-a-vis the other economies included in the Index, each economy overview includes two figures. The first figure displays each economy's performance relative to the top 10 performers in each category of the Index as well as the regional average for that particular economy. The second figure displays each economy's overall score compared with the regional average for that particular economy and top- and bottom-performing economies. Specific challenges, debates, and issues relating to the most important recent developments under each category are discussed in more detail in a separate sub-section titled "Spotlight on the National IP Environment."

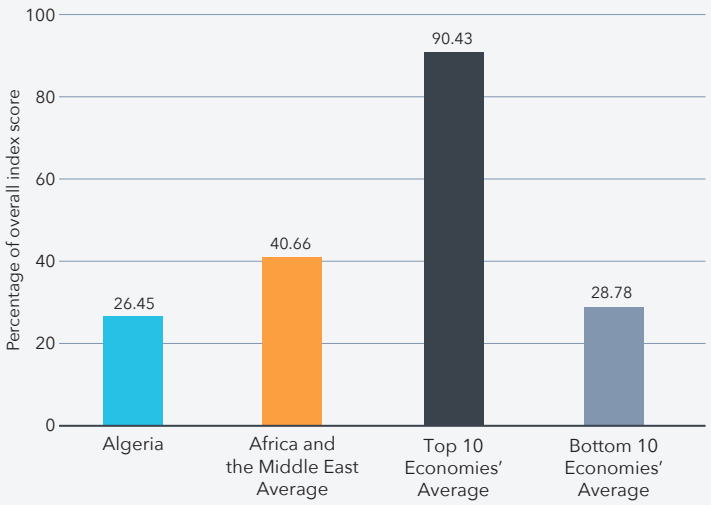
ALGERIA

RANK
51/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ The 2019/2020 reforms and removal of 51-49% local ownership rule could amount to a sea-change in Algeria's openness to and relationship with foreign investment
- ✓ Basic framework for IP protection in place
- ✓ Contracting party to WIPO Internet Treaties, Patent Cooperation Treaty, Patent Law Treaty, and Madrid Protocol
- ✓ Plant variety protection in place

KEY AREAS OF WEAKNESS

- × Historically, a difficult localization policy environment with import substitution, bans, and local ownership requirements
- × Weak patenting environment with basic rights missing
- × Major holes in copyright framework—limited coverage and applicability of existing framework to online environment
- × High rates of piracy
- × Not a WTO member or TRIPS signatory

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**2.00**
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.53**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.00
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**1.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.00
Category 4: Design Rights, Related Rights, and Limitations	**0.65**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**1.75**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.25
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**1.80**
32. Physical counterfeiting rates	0.37
33. Software piracy rates	0.18
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**1.25**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.00
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.00
Category 9: Membership and Ratification of International Treaties	**2.25**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 13.23

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Score

Algeria's overall score has increased from 24.06% (12.03 out of 50) in the eighth edition of the Index to 26.45% (13.23 out of 50) in the ninth edition. This reflects score increases on indicators 26, 27, 28, 29, and 38.

Commercialization of IP Assets and Market Access

26. Barriers to market access: The Algerian government has historically imposed localization rules for how foreign firms may participate in the market and has actively pursued an import substitution policy. The stated objective of these rules has been to reduce imports, encourage domestic production, and maximize technology transfer. These policies have run across various sectors. Key measures have included quantitative restrictions on imports when local production exists (for instance, on second-hand equipment for all sectors); a registration tax levied only on new imported vehicles as well as a requirement for car dealers to set up a domestic activity of an industrial nature in addition to the dealership, such as production of car parts, in order to keep their import license; and local content requirements in procurement of office equipment of up to 15% of tenders. Additional cross-sectoral policies in support of local sectors have included national public procurement rules. Specifically, access to tenders for foreign bidders has been greatly limited by Decree 10-36 (2010), which gives a 25% price preference to national producers. Foreign bidders have been able to qualify as local if they have partnered with national companies that are majority owned by Algerian residents, but qualifying national companies are limited and determined by a government-generated list and/or (under the 2011 Decree 11-98) have provided an investment plan cleared by the National Investment Development Agency. Moreover, some tenders have been statutorily restricted to domestic bidders with foreign firms invited to bid only if the contract is not awarded to a local producer. Most onerously of all have been strict ownership limitations. On the basis of a pre-existing measure in the oil and gas sector, the 2009 Complementary Finance Law has limited foreign investment to a minority stake (49% or below) in any industrial sector. The 2014 Financial Law extended 2009 rules to companies only engaged in importation (and not domestic manufacturing activities), of which foreigners were previously allowed to own a 70% share. The rule was removed from the new Investment Law in August 2016 but was later reintroduced in the 2017 Finance Law. As a result of the profound political changes taking place in Algeria, the past 12 months have seen what potentially could amount to a seachange in Algeria's openness to and relationship with foreign investment. Specifically, through the 2020 Finance Law, the government in December 2019 removed the 51-49% ownership requirement for non-strategic industries. The Finance Law did not specify how the elimination of the local ownership requirement would be implemented or which industries would be considered non-strategic or strategic. In June 2020, a Supplemental Finance Law was enacted and published in the official Gazette. Article 50 of the law outlines which industries and sectors of the economy are to be considered as strategic and still subject to the 51-49% local ownership requirement. These include mining, hydrocarbons, industries relating to national defense, physical infrastructure (railways, ports, and airports) and the pharmaceutical industry. Most economies around the world have in place foreign investment and ownership restrictions on strategic parts of the national economy related to defense and critical infrastructure. This includes industries and entities directly related to national security, defense suppliers and contractors, infrastructure including ports, railways, telecommunications, utilities, and the like. With regards to the pharmaceutical industry, the

law appears to provide an exception to the local ownership requirement for the research-based industry. However, this exception is not entirely clear and appears to be contingent on fulfilling several conditions. At the time of research, no implementing regulations had been drafted or issued outlining the specific conditions and requirements that would need to be met to qualify for the exception. The Index will continue to monitor these developments in 2021. As a result of this positive action, the score on this indicator has increased by 0.25.

27. Barriers to technology transfer; 28. Registration and disclosure requirements of licensing deals; and 29. Direct government intervention in setting licensing terms: While there are no direct restrictions on licensing or technology transfer to Algeria, the ownership restrictions limiting foreign investment to a minority stake (49% or below) have *de facto* restricted the ability for rights-holders to transfer technology and IP into Algeria given that no fully owned subsidiary has been allowed to be established. More broadly, licensing agreements must be registered with the relevant Algerian authorities, although this process is not overly burdensome. These authorities also reserve the right to, for some sectors and industries, intervene and stipulate contractual terms. There is also a direct and indirect review mechanism of all business dealings between Algerian and foreign entities through domiciliation requirements and contractual review by the National Investment Development Agency (*Agence Nationale de Développement de l'Investissement*). At the time of research, there had been no changes to these requirements. The removal of the local ownership requirements described under indicator 26 is a positive development for Algeria affecting most indicators included under Category 6: Commercialization of IP Assets and Market Access. As a result, there has been a score increase of 0.25 on indicators 27, 28, and 29.

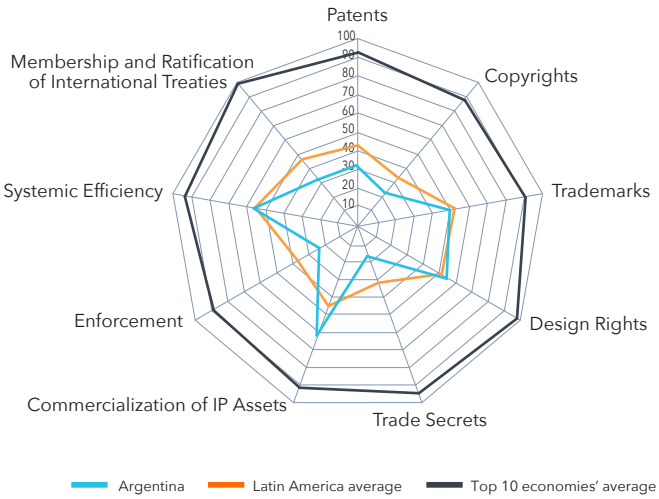
Enforcement

38. Transparency and public reporting by customs authorities of trade-related IP infringement: As noted in previous editions of the Index, the Algerian Customs Authority (*Direction Générale des Douanes*) does not publish systematic or annualized data on seizures relating to IP rights-infringing goods. There are no annual reports published or official data and statistics on the authority's seizure activities against counterfeit and IP rights infringing goods. This remains the case today. However, beginning in 2019, the authority has begun briefing the local media on its annual anti-counterfeiting activities. In an article published in April 2019 with the *Algeria Press Service* (the largest domestic news agency), the authority detailed its activities for 2018, including the number of counterfeit items seized and country of origin. In total over 455,000 counterfeit items had been seized, of which more than 70% came from China. The largest categories of goods seized related to sports and textiles, which together accounted for close to 85% of all goods seized. In January 2020, a similar report was issued for the Port of Algiers, one of the largest ports in Algeria, with an estimated DZD1 billion worth of goods seized. As a result of this increased public reporting and transparency, the score on this indicator has increased by 0.25. The Index will continue to monitor these developments in 2021. We encourage the Algerian government and Algerian Customs Authority to more systematically brief rights-holders and the public on their anti-counterfeiting activities with a standardized and annual report.

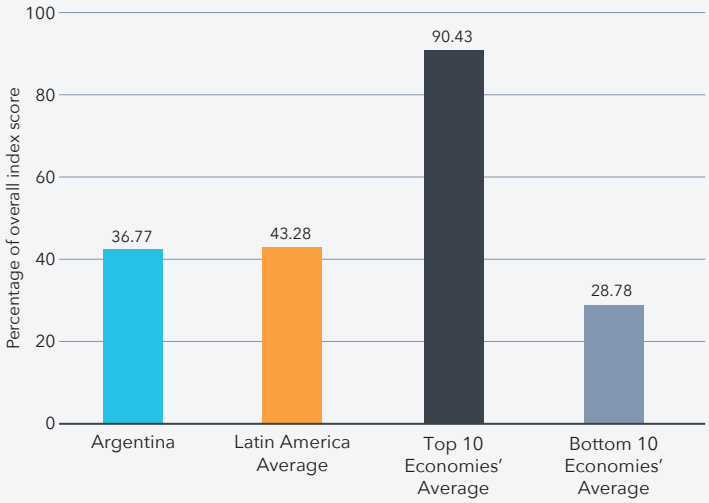
ARGENTINA

RANK
43/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Basic framework for IP protection
- ✓ Pronounced efforts over past few years to strengthen international cooperation on IP, including through PPHs and increased technical cooperation with the European Patent Office
- ✓ Ongoing streamlining of administrative and enforcement bodies
- ✓ Draft Penal Code (2019) would strengthen criminal sanctions relating to IP infringement

KEY AREAS OF WEAKNESS

- × Key life sciences IP rights missing
- × Biopharmaceutical patentability standards remain outside international standards
- × Gaps in legal framework for enforcing copyright online, though some important instances of judicial action exist
- × Persistently high rates of piracy, including physical counterfeiting
- × Limited participant in international treaties—has not acceded to the Patent Cooperation Treaty

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**2.90**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	0.90
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.63**
10. Term of protection	0.63
11. Exclusive rights	0.25
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.00
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.67**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**1.58**
32. Physical counterfeiting rates	0.25
33. Software piracy rates	0.33
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**2.25**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.25
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 18.38

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Score

Argentina's overall score has increased from 35.74% (17.87 out of 50) in the eighth edition of the Index to 36.77% (18.38 out of 50) in the ninth edition. This reflects score increases on indicators 39 and 41.

Systemic Efficiency

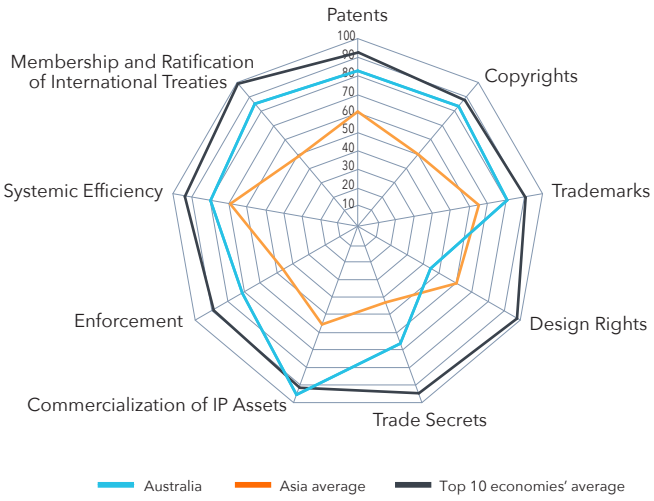
39. Coordination of IP rights enforcement: Historically, there has been no systematic coordination and cooperation between different parts of the Argentinean government on IP enforcement. There have been some examples of cooperation between public and private sector entities, but, as has been noted by the U.S. government, there has been no comprehensive strategy outlined, implemented, or supported by the Argentinean government. Following through on a commitment made in 2017 to the Argentine Chamber of Medium-Sized Enterprises (*Confederación Argentina de la Mediana Empresa*) and the Argentine Anti-Piracy Association (*Asociación Civil Antipiratería Argentina*), in December 2019 the National Institute of Industrial Property (INPI), Ministry of Justice, and Ministry of Security announced the formation of a new national anti-counterfeiting and IP enforcement mechanism, the Federal Committee to Combat Contraband and the Falsification of Trademarks and Designations (*Comité Federal de Lucha Contra el Contrabando y la Falsificación de Marcas y Designaciones*). This new committee is defined by Joint Resolution 9/2019 (*Resolución Conjunta* 9/2019) issued in December 2019. The resolution outlines an ambitious program including anti-counterfeiting enforcement (with a focus on trademarks and hard goods piracy); consumer awareness raising; public educational activities on the dangers of counterfeiting; anti-counterfeiting training programs for all relevant public sector staff; coordination and encouragement of cross-agency coordination, training, and improved information-sharing; and a national strategic plan. Establishing this new committee and initiative is a positive development and has resulted in a score increase of 0.25 on this indicator.

41. Educational campaigns and awareness raising: As noted in previous editions of the Index, there have been examples of public awareness and educational campaigns in Argentina on the benefits of IP rights and the socio-economic harm of counterfeiting and piracy. This includes ad hoc campaigns such as the 2012 "For an Original Look" campaign by the Argentinian movie industry association, the 2007 essay competition titled "Innovating Minds for Development," and some institutionalized efforts such as educational programs run by WIPO, INPI, and some local universities. Between 2014 and 2019, seven such programs supported by WIPO were carried out across Argentina. However, there has been limited involvement by the public sector and relevant government agencies in supporting more systematic and comprehensive efforts. For example, at the time of research, the IP in Practice database hosted by WIPO did not list any public sector-specific or -sponsored campaigns in Argentina. As discussed above under indicator 39, both public awareness-raising and educational activities are core mandates under the new Joint Resolution 9/2019 and the Federal Committee to Combat Contraband and the Falsification of Trademarks and Designations. Article 5 of the resolution states that the committee should promote both public awareness campaigns on "the harmful effect that the consumption of pirated or counterfeit goods causes" and "education programs dedicated to highlighting the value of legal trade for society, as well as the economic and social damage caused by illegal trade." Establishing this new committee and initiative is a positive development and has resulted in a score increase of 0.25 on this indicator.

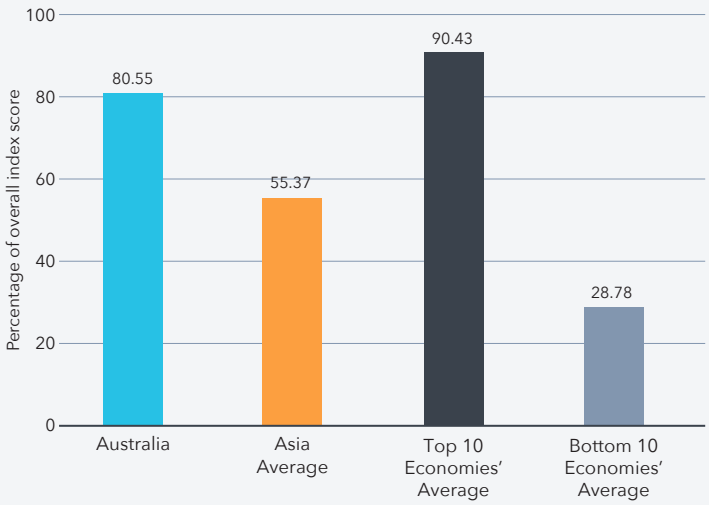
AUSTRALIA

RANK
14/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Global leader on copyright enforcement in the online space
- ✓ Established system of injunctive relief permitting the disabling of foreign-hosted infringing websites
- ✓ National Security Legislation Amendment (Espionage and Foreign Interference) 2018 introduces stiff penalties for industrial espionage on behalf of a foreign state entity
- ✓ No administrative or regulatory burdens in place hindering licensing activity
- ✓ New case law clarified grounds for patentability of biotechnology inventions

KEY AREAS OF WEAKNESS

- × Pre-grant patent opposition system causes significant delays to patent grants
- × Not a contracting party to the Hague Agreement

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**7.50**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**5.88**
10. Term of protection	0.63
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.25**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**2.00**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**4.99**
32. Physical counterfeiting rates	0.67
33. Software piracy rates	0.82
34. Civil and procedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**4.00**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

TOTAL: 40.27

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Score

Australia's overall score has increased from 79.62% (39.81 out of 50) in the eighth edition of the Index to 80.55% (40.27 out of 50) in the ninth edition. This reflects score increases on indicators 2 and 43.

Patents, Related Rights, and Limitations

2. Patentability requirements: Australian patentability standards are generally in line with international best practices. For a patent to be valid in Australia, it must be new, involve an inventive step, and have industrial applicability. Section 18 of the Patent Act defines a patentable invention. Patents have historically been granted for most types of inventions. Since the publication of the first edition of the IP Index, there have been some important developments with regards to the patentability with respect to both statutory law and relevant case law. In the 2012 IP Laws Amendment (Raising the Bar) Act, the statutory definition of patentability was changed with the inventive step being assessed against the common general knowledge, considered either alone or together with additional prior art. More recent amendments to the Patent Act include the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020. This follows the work of the Productivity Commission and the government's response to the commission's recommendations. As in other jurisdictions, including the United States, a key area of debate in Australia has been the patentability of biotechnology-based or -derived inventions and what constitutes patentable subject matter. Overall, there has been a level of uncertainty and unpredictability on the patentability of biotechnology innovation with conflicting case law and rulings on the matter. On the one hand, in a landmark judgment in 2014, the Australian Federal Court confirmed the patentability of isolated genetic material in *D'Arcy v Myriad Genetics*. In the decision, the court found that claims containing isolated genes were acceptable if the claimed structure or potential function does not exist in the gene's natural state. The court ruled that isolated gene sequences that result in non-natural structures and/or uses with economic significance should be considered patentable subject matter. The Australian Federal Court's ruling came in the face of an opposite ruling by the United States Supreme Court in 2013, in which the court invalidated Myriad's claims on isolated genes. However, in 2015, the Australian High Court reversed this ruling. In the decision, the High Court found that the isolation of genetic material did not constitute an inventive step since it considered that the protected substance—the genetic material—was essentially the same information as in its natural form. This decision weakened the patentability of biotechnology and diagnostic-related inventions in a manner similar to what has taken place in the United States since the mid-2010s. Following a period of uncertainty, the past few years have seen several important decisions taken through both new case law as well as administrative rulings by IP Australia on what constitutes patentable subject matter for biotechnology. Most notably, *Cargill Incorporated v Dow AgroSciences LLC and Arrowhead Research Corporation* (2016) confirmed that isolated nucleic acids are patentable as long as they have been modified. Equally important are two decisions rendered by the Australia Federal Court in the past two years. The first case, *Meat & Livestock Australia Limited v Cargill Inc.* (2018), involved a determination as to the patentability, not of isolated naturally occurring gene sequences, but of their actual practical application and use in a given invention. The second case, *Sequenom Inc. v Ariosa Diagnostics Inc.* (2019), involved a similar claim as to whether the disputed patent involved an inventive step and, specifically, a "human action" with economic utility as opposed to simply being a naturally occurring phenomenon. In both cases,

Justice Beach ruled in favor of the patent holder and clarified the grounds for patentability of biotechnology innovations. Following these rulings, IP Australia's *Patent Manual of Practice & Procedure*, section 2.9.2.6 Nucleic Acids and Genetic Information, was updated in June 2020 to now also include reference to this new body of case law. As a result of this new body of case law and its incorporation into existing examination practices, the score on this indicator has increased by 0.25.

5. Pharmaceutical-related patent enforcement and resolution mechanism: As noted in previous editions of the Index, Australia's pharmaceutical linkage mechanism has several notable deficiencies. The system lacks an automatic stay (as provided by, for example, Hatch-Waxman in the United States) and instead gives patent holders interlocutory injunction relief through a court of competent jurisdiction. 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, penalties for providing false or misleading information are disproportionately higher for a 26C Certificate (patent holder) than for a 26B Certificate (generic producer). Historically, patent holders have not been 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). Rather than notifying patent holders, generic manufacturers have summarily certified their belief that their products do not infringe enforceable patents. In turn, patent holders were informed only after the follow-on products have been approved. There have also been strong commercial incentives for generic manufacturers to launch at risk due to the structure of the Australian health care system. 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 has been a strong incentive for generic companies to launch at risk and innovator companies must pursue preliminary injunctions in order to resolve patent disputes. This negative dynamic may now be changing. In October 2020, the TGA concluded an 18-month consultation on prescription medicines transparency measures. As a result of the consultation, the government announced its plan to introduce legislation to create an earlier patent notification framework. The legislation will require that applicants for the first generic and biosimilar form of an originator product notify the patent holder when his or her application is accepted for evaluation by the TGA. The change was designed to create an opportunity for earlier negotiation and resolution of disputes on potential patent infringements before the generic is listed in the PBS. Additionally, beginning in January 2021, the TGA will publish a description of major innovative medicines applications that it is evaluating. The Index applauds these changes to the Australian system, which could increase transparency, reduce the need for costly litigation, and improve the regulatory framework for innovative companies operating in Australia. Finally, since 2012, Australia's Department of Health has pursued market-sized damages (on top of those sought by the generic company) aimed at compensating the PBS for any higher price paid for a patented medicine during the period of a provisional enforcement measure, but there is no corresponding mechanism to compensate innovators for the above-mentioned losses if an infringing product is launched prematurely. In 2020, the court ruled in the long-running case *Commonwealth of Australia v Sanofi (No. 5) FCA 543*, which has the potential to set a new precedent for the imposition of market-sized damages moving forward. The case revolves around the actual ability of the Australian government to claim damages

and is the first time a court has made a judgment as opposed to the relevant parties reaching an agreement through a private settlement. In the April 2020 verdict, the court ruled against the government, dismissing its claims for damages. Local legal analysis suggests that the judgment sets a high bar for future claims as although the court recognized the legitimacy of the claim, a successful claim will have to prove a direct link between the granted preliminary injunction and listing on the PBS. The Index will continue to follow this case and a potential appeal in 2021.

Systemic Efficiency

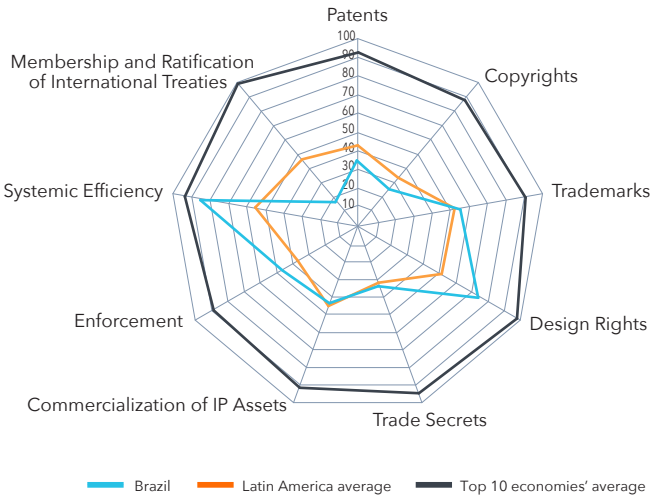
43. IP-intensive industries, national economic impact analysis: As noted in past editions of the Index, various parts of the Australian government actively measure and seek to understand the economic contribution and value of IP-intensive industries to the Australian economy. For example, since 2012, IP Australia has had in place an Office of the Chief Economist. The Chief Economist's role is described by the agency as to "understand the role intellectual property (IP) plays in our economy." Since 2013, the office has published and commissioned various sector- and IP right-specific research studies. These include the 2015 *Economic Impact of Innovation Patents*, the 2013 *Economic Impact of Human Gene Patents*, and other stand-alone research papers on topics including design rights, the mining industry, and trademarks. In addition, based on WIPO's methodology and study guidelines, Australian public entities have conducted or supported several research reports on the economic contribution of the copyright-based industries to the Australian economy. The latest of these, released in 2017, *The Economic Contribution of Australia's Copyright Industries 2002-2016*, was prepared by the consultancy PwC for the Australian Copyright Commission. In April 2020, IP Australia released its eighth report on the national IP environment, *Australian Intellectual Property Report 2020*. The report provides a considerable amount of data and insight on registration trends and how Australian inventors and businesses are using the national IP system. A new component of the report is a focus on IP-related economic activity. Using 2019 data collated by the Australian Bureau of Statistics, chapter 7 of the report provides a dedicated section to understanding the link between economic activity and the use of IP rights by Australian businesses. As the report rightly points out, "one of the key purposes of the IP system is to promote economic development by creating an innovation-friendly and fair competition environment." The chapter makes several important findings on the use and positive economic impact IP rights have had on the Australian economy. For example, it finds that, when looking at average profits per employee, firms making use of IP rights tend, on average, to have higher profit levels than those firms not owning any IP rights; this was estimated at AUD48,368 for IP rights-owning firms compared with AUD23,404 for non-IP rights owning firms. Of the IP rights examined (registered patents, trademarks, and design rights), firms with the highest profit levels were those with registered patent rights at AUD61,394 per employee and combined registered patent rights and trademarks at AUD101,278 per employee. Although not as consistent as average profit per employee, the report also finds that there is a reasonably strong relationship between average profits measured as a percentage of invested capital. Firms owning registered IP rights, and particularly multiple IP rights, had higher average profits as a percentage of invested capital than non-IP rights owning firms. In addition, IP Australia's Office of the Chief Economist continued to provide valuable research and data on Australia's national IP environment. In 2019, the office supported the publication of reports on IP activity in machine learning, patent protection, and mining technologies, as well as making more of IP Australia's historical IP data available for public research. IP Australia should be congratulated for its efforts and for placing a greater emphasis and

concomitant resources in investigating the economic impact IP rights have on innovation, economic development, and firm-level business activity in Australia. As a result, the score on this indicator has increased by 0.25.

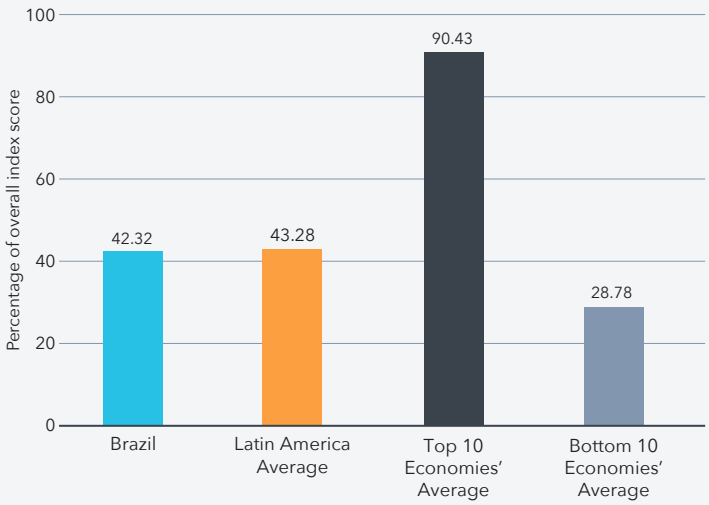
BRAZIL

RANK
34/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ INPI's 2019 patent backlog plan, "*Plano de Combate ao Backlog de Patentes*," seeks to eliminate long-standing registration backlogs. It is supported by a 10-year minimum term of patent protection in place for administrative delays
- ✓ Stronger criminal enforcement on copyright through "Operation 404" in 2020 and "Operation Copyright" in 2019
- ✓ In 2019, Decree 9,931 established a new Inter-ministerial Group on Intellectual Property to coordinate and oversee all issues relating to IP policy in Brazil. This group spearheaded the public consultation on the National IP strategy released in late 2020.

KEY AREAS OF WEAKNESS

- × Key life sciences IP rights missing and challenging patentability environment
- × Patentability barriers still in place through Brazilian Health Regulatory Agency (ANVISA) review of biopharmaceutical patent applications
- × Limited participant in international IP efforts—only a full contracting party to two out of nine treaties included in the Index

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**3.24**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	0.74
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**1.88**
10. Term of protection	0.63
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.25
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.00**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**2.58**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.33
Category 7: Enforcement	**3.21**
32. Physical counterfeiting rates	0.43
33. Software piracy rates	0.53
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**4.25**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**1.25**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 21.16

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Brazil's overall score has decreased from 42.52% (21.26 out of 50) in the eighth edition to 42.32% (21.16 out of 50) in the ninth edition. This reflects a small score decrease on indicator 32.

Area of Note

In 2020, the government of Brazil launched two new important initiatives—a National Innovation Policy and a National Intellectual Property Strategy. In August 2020, the government released for public consultation a draft National Intellectual Property Strategy. This document outlines the strategic direction and policy goals of the Brazilian government with respect to the protection of IP for the foreseeable future. The goal of the strategy is to "achieve an effective and balanced National System of Intellectual Property (SNPI), which is widely used and encourages creativity, investments in innovation and access to knowledge, aiming at increasing competitiveness and economic and sociocultural development of Brazil." Overall, it is an ambitious document touching on IP policies across the board. The strategy consists of what are termed seven "strategic axis" or policy areas. These range from the legal environment, to education and training, to governance and strengthening of national IP institutions, to the role of Brazil in international IP policymaking. Of note is Strategic Axis 4, "Modernization of Legal and Infralegal Landmarks," which outlines several important areas identified for potential changes to the legal and regulatory environment. These include copyright, biopharmaceutical IP rights, trade secrets, customs, and anti-counterfeiting. As has been noted over the nine editions of the Index, these are areas where current Brazilian laws and regulations could be reformed and better aligned with international best practices. The government of Brazil also highlighted further integrating itself into the global IP system, in Axis 7. As the Index has pointed out both generally and with respect to Brazil, full participation in the global IP system, PPH initiatives, and increased cooperation between IP offices are the most tangible ways the administration and functioning of the international IP system can be improved and harmonized to help inventors and rights-holders. Brazil has made noticeable strides on this in the past few years, joining the Madrid Protocol as well as initiating new PPHs. On October 28, 2020, Decree 10,534 was issued to launch the National Innovation Policy. The policy seeks to coordinate and further innovate policies at all levels of government and builds on long-standing efforts by the Ministry of Science, Technology and Innovation. The Brazilian government should be congratulated for taking such a holistic approach to reforming the entire innovation and IP policy ecosystem and from the outset inviting a broad range of stakeholders, including industry, to participate in this long-term structural reform process. Covering 50 indicators across nine separate categories the Index has for almost a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rights-holders need to be able to fully develop and commercialize their ideas and products. The Index will continue to monitor these developments in 2021.

Systemic Efficiency

41. Educational campaigns and awareness raising: As mentioned in preceding editions of the Index, 2019 saw the creation of a new coordinating body charged by the president to coordinate and oversee all issues relating to IP policy in Brazil. 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." Historically, anti-piracy and educational activities have been coordinated by the National Council to Combat Piracy and Crimes against Intellectual Property (*Conselho Nacional de Combate à Pirataria e Delitos contra a Propriedade Intelectual*), which was established in 2005. The council included representatives from both public and private sectors. The Brazilian government and private sector have supported several educational efforts and awareness-raising campaigns (past and current) highlighting the negative impact of piracy and counterfeiting and the positive socio-economic impact of IP rights. WIPO's "IP Outreach in Practice" database identifies 28 such campaigns sponsored by both public and private sector entities. Initiatives supported by the government include programs relating to training, enforcement, and general awareness raising, as well as those initiatives supported by the private sector. Of note is an industry-led online anti-piracy campaign called "click original," which was launched in 2013 by the Brazilian National Forum against Piracy and Illegality (*Fórum Nacional Contra a Pirataria e a Ilegalidade*), a coalition of some of the largest content and brand owners in Brazil and internationally. This initiative, on the one hand, provides rights-holders with the opportunity to submit information on potential infringement of their brand and, on the other, gives the public at large and consumers a source of evidence and statistics on the scale of online piracy in Brazil. In this respect the web portal serves as an effective source of information on both the scale of piracy and counterfeiting and danger it presents to Brazilian consumers.

Membership and Ratification of International Treaties

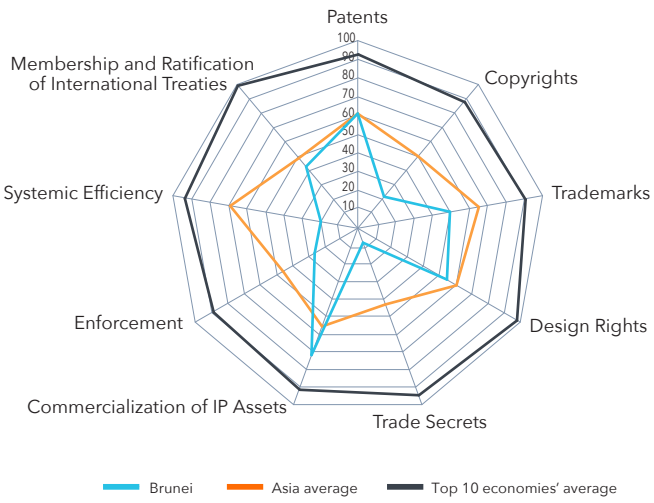
Brazil scores low in its participation in and ratification of international treaties. Brazil is not a contracting party to the WIPO Internet Treaties; the Singapore Treaty on the Law of Trademarks; the International Convention for the Protection of New Varieties of Plants, Act of 1991 (Brazil is a contracting party to the 1978 Convention); the Convention on Cybercrime, 2001; or the Hague Agreement Concerning the International Registration of Industrial Designs. Brazil was in 2019 invited by the Council of Europe to join the Convention on Cybercrime; the invitation is valid until 2024. Brazil is a contracting party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks (acceding in 2019) and the Patent Cooperation Treaty. Brazil is a signatory to the Patent Law Treaty but has not acceded to it. As part of the regional trade bloc Mercosur, in 2019 Brazil concluded negotiations with the EU on a free trade agreement between the two trading blocs. The agreement is now subject to final legal revisions and then will be subject to ratification by all parties. While technically a post-TRIPS FTA that does contain a separate IP chapter, overall, the IP provisions of the EU-Mercosur FTA are notably weaker compared with current international standards and other post-TRIPS agreements concluded by the EU. The treaty does not include any substantive provisions regarding patent rights. Copyright provisions are relatively limited. Similarly, border measures are weak, with parties largely exempt from taking effective border measures; the treaty does not require customs officials to be provided with *ex officio* authority to act against suspected goods. Moreover, in-transit goods are explicitly exempt from any action under Article X.58(2). There is clear language on civil and administrative enforcement (including the need for an established calculation for damages), but there are no corresponding provisions relating to crim-

inal enforcement. Looking at IP-intensive sectors specifically, there are no provisions relating to the biopharmaceutical sector. This stands out compared with previous EU post-TRIPS FTAs such as the EU-Andean Community FTA, which included a requirement for a five-year RDP term. Trade secret provisions are relatively strong and include clear language and definitions of trade secrets and infringement. Nevertheless, this agreement is notably weaker than are preceding EU FTAs, including recent agreements like the EU-Japan Economic Partnership Agreement, the EU-ANDEAN Community FTA, or the Canada-European Union Comprehensive Economic and Trade Agreement.

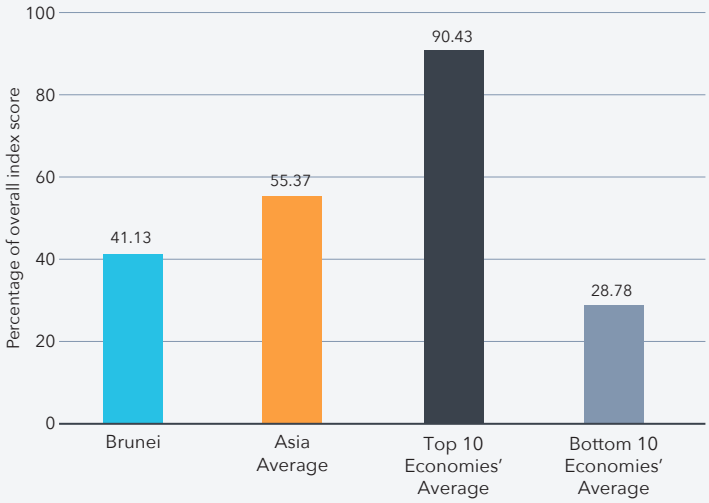
BRUNEI

RANK
36/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Acceded to WIPO Internet Treaties in 2017
- ✓ Major IP reforms over past decade, including establishing Brunei Intellectual Property Office (BruIPO)
- ✓ Removed from Special 301 Report
- ✓ PPH agreement in place with Japan
- ✓ No fundamental administrative or regulatory barriers in place for execution of licensing agreements

KEY AREAS OF WEAKNESS

- × Limited legal framework for protection of trade secrets and confidential information
- × Life sciences IP rights lacking
- × Regulatory data protection not available
- × Limited framework for addressing online piracy and circumvention devices
- × High software piracy rates–64% in latest estimates
- × Limited incentives in place for the creation and use of IP assets for SMEs

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**5.50**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	0.75
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**1.53**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.00
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.25**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.00
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**4.33**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.33
Category 7: Enforcement	**1.86**
32. Physical counterfeiting rates	0.50
33. Software piracy rates	0.36
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.00**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.00
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**3.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

TOTAL: 20.57

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Score

Brunei's overall score has increased slightly from 41.12% (20.56 out of 50) in the eighth edition to 41.13% (20.57 out of 50) in the ninth edition. This reflects a marginal increase on indicator 32.

Patents, Related Rights, and Limitations

3. Patentability of CIIs: The Patents Order 2011 defines the patentability criteria used and applied in Brunei. Under section 13, a patentable invention is defined as one that is new, involves an inventive step, and is capable of industrial application. Neither software nor CIIs are explicitly excluded and defined as non-patentable subject matter under the order or the implementing regulations, the Patents Rules 2012. Although not excluded by statutory law, looking at available statistics from WIPO and BruIPO suggests that, in practice, there have been relatively few computer-related applications filed in Brunei. Available information in the WIPO IP Statistics Data Center shows that, between 1999 and 2013 (the latest year for which data is available), computer technology applications were the smallest total number of applications, at 0.95% of all applications included in WIPO's "top fields of technology" for Brunei. This compares to the two top fields of technology, "Semiconductors," which composed 36.97% of all applications, and "Electrical machinery, apparatus, energy," which composed 33.65% of all applications during the same time period. Filing statistics housed by BruIPO paint a similar picture. Of the 1,411 applications listed in the office's publicly searchable database for patents, only 26 applications were retrieved using a key word search for "computer." This is the equivalent of 1.84% of the total.

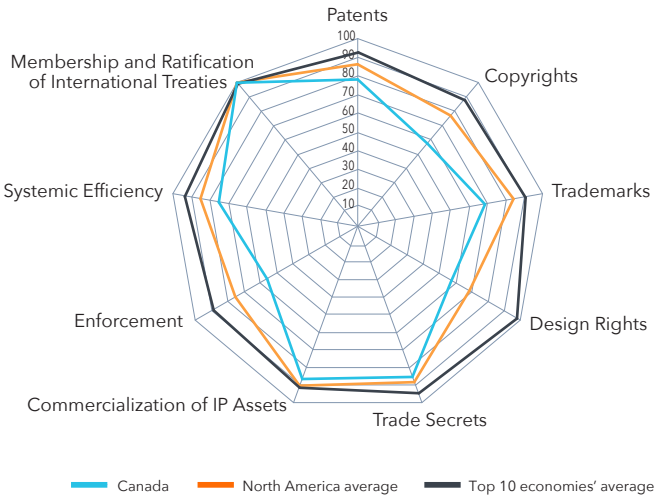
Commercialization of IP Assets and Market Access

26. Barriers to market access: Brunei is a relatively free and open economy with no direct limits on foreign direct investment or ownership. Brunei does limit access to its domestic market through some specific barriers (including import restrictions on non-certified Halal meat products) and some localization requirements. However, the divulging and sharing of IP and technology are not part of these barriers and/or local preferences. The most prominent local content requirement in place is through the directives on Local Business Development in Oil and Gas from 2011 and 2012, respectively. Directive 2 contains a local employment and local content requirement by which local workers and firms are to be prioritized in contracting and sub-contracting. The directive, however, contains several carve-outs, including for "highly specialized" contracts that are not subject to the requirements. The emphasis of the directives is primarily with regards to employment with no mention of technology transfer, local technology acquisition, or the sharing/divulging of IP assets as a policy goal.

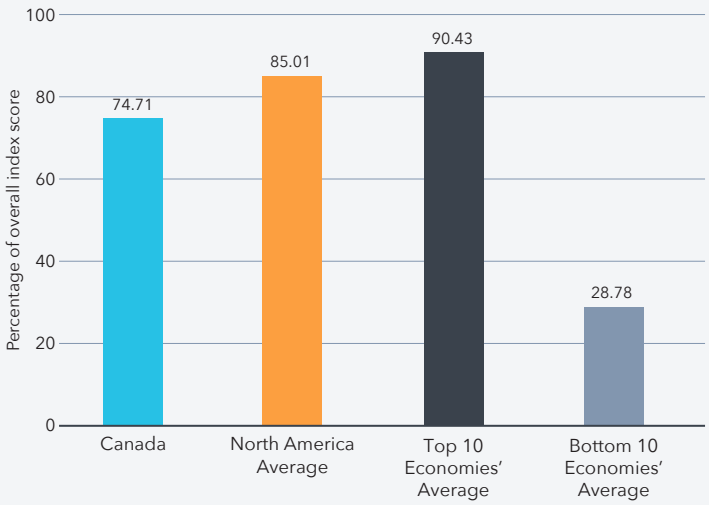
CANADA

RANK
16/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ USMCA took effect in 2020, resulting in longer copyright term, new criminal sanctions for theft and misappropriation of trade secrets, and *ex officio* authority for border action against in-transit goods
- ✓ The 2017 Supreme Court judgment on utility doctrine finally aligns Canada's patentability environment with international standards
- ✓ Implementing CETA legislation in place in several areas, including patent term restoration
- ✓ Significant damages awarded in precedent-setting 2017 Federal Court case with regards to Canada's DRM provisions

KEY AREAS OF WEAKNESS

- × Continued uncertainty over existing interpretation of educational exceptions to copyright
- × CETA amendments to Patent Act introducing patent term restoration includes restrictive eligibility requirements as well as an export claw-out, which effectively undermines biopharmaceutical exclusivity
- × Deficiencies with respect to pharmaceutical patent enforcement remain unaddressed in Patented Medicines Notice of Compliance (PMNOC) Regulations

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**7.05**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.30
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**4.04**
10. Term of protection	0.79
11. Exclusive rights	0.50
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**2.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.15**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.55**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.80

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.17**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**3.89**
32. Physical counterfeiting rates	0.61
33. Software piracy rates	0.78
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**3.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 37.35

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Score

Canada's overall score has increased from 72.86% (36.43 out of 50) in the eighth edition to 74.71% (37.35 out of 50) in the ninth edition. This reflects score increases on indicators 10, 24, and 37.

Area of Note

Biopharmaceutical rights-holders face growing challenges in Canada in exercising their IP rights and granted periods of exclusivity. Overall, there is a strong focus on cost control and minimizing overall biopharmaceutical spending within the Canadian health system. Over the past several years, Canadian authorities have been reforming how patented medicines are evaluated and priced through the Patented Medicine Prices Review Board's (PMPRB's) evaluation methodology. As has been noted in previous editions of the Index, these changes will substantially lower the overall price comparisons and thus the overall biopharmaceutical price level in Canada while adding additional layers of complexity to the pricing and reimbursement process. At the time of research, there was uncertainty as to when the changes to the PMPRB would come into effect. The outbreak of the COVID-19 pandemic had initially postponed these changes by 12 months, but subsequent announcements made in January 2021 by the Canadian government seem to have halved this postponement. The changes to Canada's biopharmaceutical pricing and reimbursement system will exacerbate what is already a challenging market access environment and make it less likely that Canadian patients can access new innovative biopharmaceutical treatments and products.

Copyrights, Related Rights, and Limitations

10. Copyright (and related rights) term of protection: The term of protection for most copyrighted works has been extended to 75 years as part of Canada's implementation of the USMCA through the Canada-United States-Mexico Agreement Implementation Act. Section 6.1 of the amended Copyright Act provides this extended term of protection to "every original literary, dramatic, musical and artistic work." As a result, the score on this indicator has increased.

12. Expeditious injunctive-style relief and disabling of infringing content online: The Copyright Act does not include provisions for an injunctive-style relief mechanism, nor does it define an administrative or judicial route whereby rights-holders can petition a court of law or administrative body for injunctive relief akin to similar mechanisms in place in many economies in Europe and Southeast Asia. In January 2018, a group of rights-holders requested that the Canadian Radio-Television and Communications Commission (CRTC) establish such a regime for disabling infringing content online. The CRTC subsequently held a public consultation ending in May 2018 on the matter, but no further action was taken on the proposal. In what could potentially become a landmark decision, in November 2019, a Canadian court ordered a group of ISPs to disable access to websites hosting alleged infringing content. The case, *Bell Media Inc. v GoldTV.Biz*, shows both the limitations and potential for this route of copyright enforcement in Canada. On the one hand, the granting of a permanent injunction shows that the possibility does exist under existing statute in Canada for rights-holders to access this type of relief. On the other hand, the injunction was granted only following initial complaints that went unheeded when preliminary injunctions were asked for and granted in the summer of 2019. Given the advanced nature of technology today and the scale and breadth of

copyright infringement through the internet, to be effective, modern-day copyright enforcement must be fast moving and responsive to, for example, the creation of mirror sites and/or the use of other technologies to evade initial attempts to disable access. More broadly, it is unclear whether the decision will provide a meaningful precedent for rights-holders as one of the ISPs compelled under the order, Teksavvy, filed an appeal following the November decision. At the time of research, this appeal was pending before the Federal Court of Appeal.

14. Limitations and exceptions: As has been noted in the Index, the 2012 amendments to the Copyright Act considerably broadened Canada's framework for exceptions to copyright, including expanding educational and personal-use exceptions. Canadian Supreme Court decisions of the same year also widened the scope for existing exceptions to the extent that continued compatibility with the Berne three-step test was highly questionable. The net effect has since been a contraction in the publishing sector with the Canadian publishing industry and individual rights-holders reporting publishing income decreasing substantially following 2012. In 2017, a statutory review of the Copyright Act was initiated by the Canadian Parliament with two different committee reports issued in 2019: one by the Standing Committee on Canadian Heritage (May 2019) and the other by the Standing Committee on Industry, Science and Technology (July 2019). The reports differed sharply in their recommendations on the issue of educational exceptions. The Standing Committee on Canadian Heritage in its list of recommendations to the Canadian government called for amending the Copyright Act to "clarify that fair dealing [exceptions] should not apply to educational institutions when the work is commercially available." The committee also recommended that the government "promote a return to licensing through collective societies." In contrast, the Standing Committee on Industry, Science and Technology in its list of recommendations did not ask for any substantive changes or legislative amendments. Instead, the committee simply recommended that the government "consider establishing facilitation between the educational sector and the copyright collectives to build consensus towards the future of educational fair dealing in Canada." It also recommended that the committee should itself "resume its review of the implementation of educational fair dealing in the Canadian educational sector within three years, based on new and authoritative information as well as new legal developments." In 2020, there were further developments on this issue. In April, the Federal Court of Appeal released its judgment in the long-running case *York University v The Canadian Copyright Licensing Agency* ("Access Copyright"). Having run on for nearly 10 years, the dispute centers on both the meaning of fair dealing within the context of educational institutions' use of copyrighted content, as well as the extent to which York University was bound by Access Copyright's licensing terms (as a collective body representing many rights-holders) and established royalty tariffs. A 2017 lower court decision had found that, first, York University's existing fair dealing guidelines and policy did not pass existing tests of fairness as defined and applied by the Canadian Supreme Court and, second, that the University was also bound to pay Access Copyright relevant licensing tariffs for the use of their work as defined and approved by the Canadian Copyright Board. In a departure from this decision, the Federal Court of Appeal held that York University was not bound by the existing tariff structure and Access Copyright's claims were dismissed with the Court, arguing that "tariffs do not bind non-licensees." On the other hand, the Canadian Supreme Court concurred with the lower court's finding that York University's copyright guidelines did "not ensure that copying which comes within their terms is fair dealing." The verdict leaves rights-holders in a highly precarious spot as, while both courts have clearly recognized that

copyright has been infringed by York University, to achieve redress, rights-holders must now pursue new legal action against the university seeking damages on the basis of copyright infringement. In June 2020, both York University and Access Copyright had filed appeals to the Supreme Court. The Index will continue to monitor this case in 2021.

Trade Secrets and the Protection of Confidential Information

24. Protection of trade secrets (criminal sanctions): Historically, Canadian law has not provided a statutory definition or criminal sanctions for the theft or misappropriation of trade secrets with any potential criminal prosecution needing to rely on other parts of the legal code. As part of its implementation of the USMCA, Canadian Parliament passed new criminal provisions for the theft and misappropriation of trade secrets through the Canada-United States-Mexico Agreement Implementation Act. Section 391 of the Criminal Code now contains a maximum 14-year prison term for anyone who "by deceit, falsehood or other fraudulent means, knowingly obtains a trade secret or communicates or makes available a trade secret." As a result, the score on this indicator has increased by 0.5.

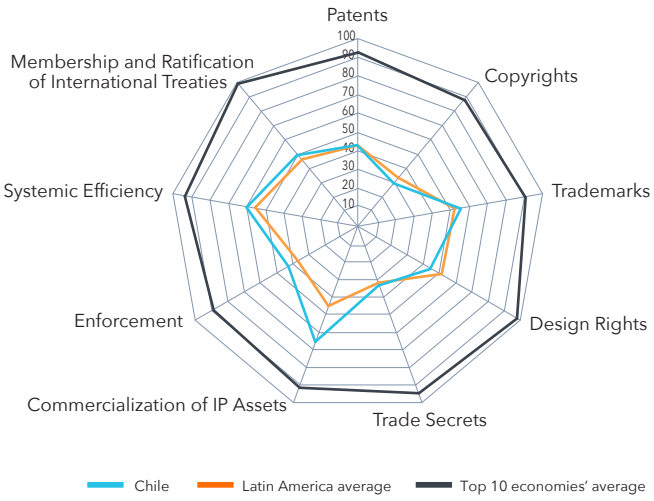
Enforcement

37. Effective border measures: Canadian border officials have historically not had *ex officio* powers to search and seize goods suspected of infringing on IP rights, and a court order has been required for seizure and detaining of suspected goods by customs officials under both the Copyright Act and the Trade-Marks Act. Bill C-8, passed in 2014, introduced more robust border measures, including new civil and criminal options as well as expanded powers for customs officials by, for example, enabling the detention of goods suspected of copyright or trademark infringement. However, while customs officers were given a right of detention, at the time of enactment it was not clear whether in practice this right extended to goods for which rights-holders had not made a specified "request for assistance." During the June 2015 10th review of the trade policies and practices of Canada through the WTO, the Canadian government clarified this point. In its official written responses to questions from other WTO Member States, the Canadian government stated that the newly enacted and in force legislation did, in fact, provide *ex officio* authority to customs officers. Unfortunately, the new legislation did not extend to counterfeit goods in transit, which, provided they were not destined for the Canadian market, could continue to pass through Canadian customs largely unimpeded. Canada is a contracting party to the USMCA. Chapter 20 of the USMCA includes a clear requirement that border agents be granted *ex officio* authority to detain any and all suspected counterfeit goods, including goods in transit. As part of its implementation of the USMCA in 2020, Canadian Parliament passed new provisions relating to goods in transit through the Canada-United States-Mexico Agreement Implementation Act. Section 51.03 of the Trademarks Act now includes reference to transshipped goods and goods in transit. The section states that such goods "while being shipped from one place outside Canada to another, are in customs transit control or customs transshipment control in Canada are considered to have been imported for the purpose of release." At the time of research there was no corresponding legislative change to the Copyright Act or the Combating Counterfeit Products Act. As a result of the amendments to the Trademarks Act, the score on this indicator has increased by 0.25.

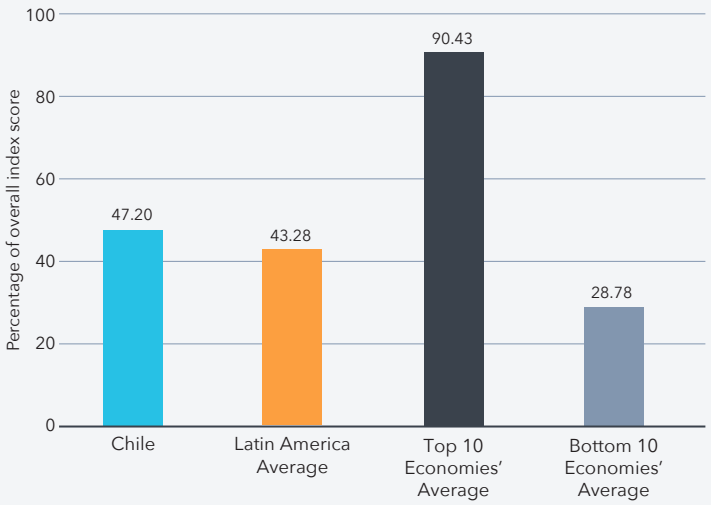
CHILE

RANK
30/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ New member of Global Patent Prosecution Highway (GPPH)—joined in July 2020
- ✓ Stronger efforts to increase transparency and public reporting of customs enforcement activities
- ✓ Commitment to improve IP environment through international trade agreements
- ✓ Efforts to streamline IP registration
- ✓ Promotion of IP commercialization

KEY AREAS OF WEAKNESS

- × Threat of compulsory licensing based on cost considerations for COVID-19 and hepatitis C drugs persisted in 2020
- × Patchy patent protection for biopharmaceuticals, including obstacles to patentability and lack of effective patent enforcement
- × High levels of counterfeiting and piracy for an OECD economy—55% estimated software piracy
- × Lack of sufficient framework to tackle online piracy, though some success in disabling access to infringing websites

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**3.94**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.00
4. Plant variety protection	0.74
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.70
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.13**
10. Term of protection	0.63
11. Exclusive rights	0.25
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.00
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.00**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.92**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	0.75
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**2.96**
32. Physical counterfeiting rates	0.51
33. Software piracy rates	0.45
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**3.00**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**3.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

TOTAL: 23.60

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Chile's overall score has increased from 45.64% (22.82 out of 50) in the eighth edition to 47.20% (23.60 out of 50) in the ninth edition. This reflects score increases on indicators 8 and 38.

Patents, Related Rights, and Limitations

6. Legislative criteria and active use of compulsory licensing of patented products and technologies: The Chilean government has over the course of the Index shifted its policies on the use of compulsory licenses, embracing their potential use as a cost-containment policy. In 2017, the Chilean Chamber of Deputies passed a bill that directed the Ministries of Economy and Health to issue compulsory licenses for medicines based on broad grounds that go beyond international standards, including price considerations, and to import less-expensive generic versions of medicines. The government was reportedly at the time considering compulsory licenses for the prostate cancer drug Xtandi and hepatitis C drug Sovaldi. In 2018, these efforts for the issuing of a compulsory license on the grounds of cost were endorsed by the outgoing government. In January 2018, the Chamber of Deputies approved a resolution that requested the use of compulsory licenses for drugs formulated with sofosbuvir. Subsequently, in March 2018, in response to a request presented by some patient groups and parliamentarians, the Minister of Health issued Resolution 399, which discusses the public health justification for a compulsory license. A third resolution by the Chamber of Deputies with the same request was approved in June 2018. On August 28, 2018, the new Minister of Health issued Resolution 1165, rejecting the patentee's challenge to Resolution 399/2018. These pro-compulsory licensing efforts continued in 2019-20. In 2019, President Sebastian Pinera urged the Chilean Congress to approve the Drugs Act II (*Ley de Farmacos II*) as one of the measures of the National Drug Policy presented in October 2019 that seeks to improve the availability of drugs and reduce out-of-pocket costs. During the bill's long iteration through the Chilean Congress, new provisions were added that put IP rights at risk. Specifically, provisions of the act greatly extend the reach of nonvoluntary licenses, incorporating discretionary elements such as "economic inaccessibility" to products as a legitimate ground for issuing a license. The draft act also includes provisions effectively reducing a rights-holder's use of its trademarks in the course of trade. At the time of research, the legislation was still pending in the Chilean Congress. Members of congress also continued to pressure the government to use compulsory licenses as a cost-containment tool and have submitted new compulsory license proposals for hepatitis C products to the Ministry of Health. In March 2020, in response to the COVID-19 global pandemic, the Chamber of Deputies passed a unanimous resolution endorsing the use of compulsory licenses for any and all products, diagnostics, medical devices, and other medical paraphernalia related to the COVID-19 global pandemic. This was followed in June with a legislative proposal and set of amendments published by a group of senators. This proposal, Bulletin 13,572-11, would introduce sweeping changes to Chile's compulsory licensing regime, including an expedited and abbreviated process for the hearing and granting of compulsory licensing applications; the pre-fixing of applicable royalties to a maximum of 5% of the sales price of the licensed product; and a broad elimination of liability for manufacturers, individuals, and legal entities that violate existing IP rights (including patent rights and trade secrets) for the production or distribution of any "medicines, vaccines, and other technologies subject to patent rights, utility models, undisclosed information, intended to meet public health needs or other public interest within the national territory, in a context of health alert,

epidemic or pandemic decreed by the health authority, and that without knowledge of the existence of affected industrial property rights or acting in good faith, violate the provisions of law No. 19.039." The severe and sudden impact the COVID-19 pandemic is having on public health around the world means that, in effect, the conditions of the potential issuing of a compulsory license are being met in many economies. However, it is squarely outside the scope of international law and applicable standards to define compulsory licensing as a potential catch-all mechanism that can be used to sanction the violation and overriding of granted property rights for any product, diagnostic, medical device, and other medical paraphernalia related to the COVID-19 global pandemic. Unlike other emergency measures that have been introduced around the world, including, for example, in Canada, the proposed legislative amendments do not include any defined timeframe or suitable sunset clause. Compulsory licensing is not a cost-containment tool; cost is not a relevant justification or basis for compulsory licensing under the TRIPS Agreement. TRIPS Article 31, 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 be aimed solely at protecting public health. In addition, 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. This is currently not the case in Chile.

8. Membership of the Patent Prosecution Highway (PPH): In a positive move, the National Institute of Industrial Property (INAPI) in July 2020 joined the Global Patent Prosecution Highway. Chile is now the 27th member of this global PPH. This is a significant step to support innovators and inventors in Chile. PPH initiatives and increased cooperation between IP offices are among the most tangible ways the administration and functioning of the international IP system can be improved and harmonized to help inventors and rights-holders. Chile's membership in the GPPH builds on its membership in other international PPHs, including the South American PROSUR PPH initiative and bilateral agreements with the Japan Patent Office and the State Intellectual Property Office of the People's Republic of China. As a result, the score on this indicator has increased by 0.5.

Enforcement

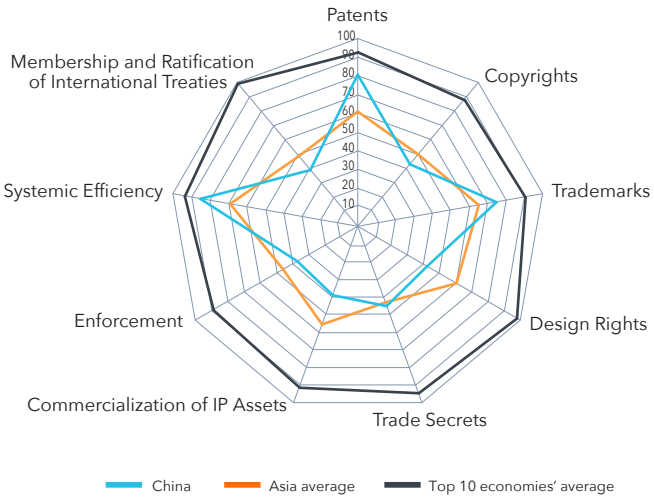
38. Transparency and public reporting by customs authorities of trade-related IP-infringement: Although the Chilean Customs Authority (*Servicio Nacional de Aduanas de Chile*) does not publish an annual compendium or review on its enforcement activities against trade-related IP infringement, over the past few years the agency has notably increased its level of transparency and the availability of data on its activities to the public. For example, the agency actively publishes press releases on seizure activity, often including data on the number of counterfeit items seized, estimated value, and country of origin. At the time of research in 2020, close to 30 such notices had been released. As noted in past editions of the Index, there have also been examples in the past whereby the agency has released aggregated data on seizure activity in a given year. However, this data has not always included full information about the number of items seized, types of items, estimated value, or countries of origin. Still, because of this increased activity and dedication to improving trans-

parency, the score on this indicator has increased by 0.25. As a next step, the Index would urge the agency to consider publishing a stand-alone annual review dedicated to providing the public with a full and comprehensive overview of the agency's enforcement activities against trade-related IP infringement.

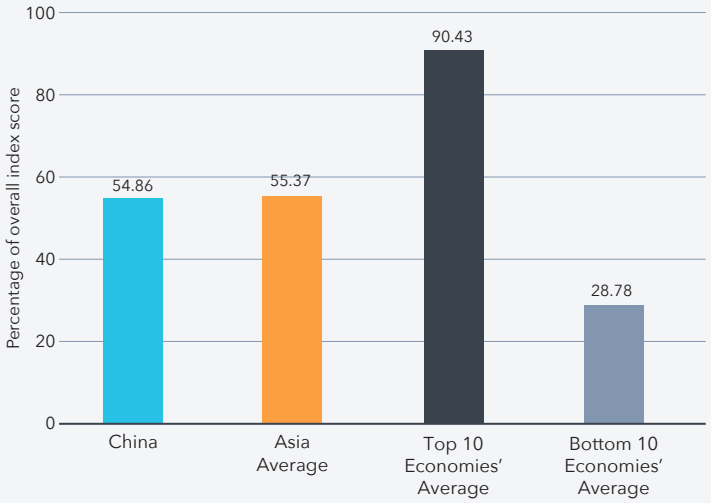
CHINA

RANK
24/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Continued reform of IP laws in 2020—follows trade agreement with United States
- ✓ Patent Law amendments of 2020 improve environment for biopharma and other patent-dependent industries and extends term of protection for design patents
- ✓ Copyright Law amendments of 2020 improve copyright environment
- ✓ Removal of some barriers and restrictions on technology transfer and licensing in 2019
- ✓ Trademark amendments of 2019 seek to address issue of bad faith filings
- ✓ Amendments to Anti-Unfair Competition Law of 2019 seek to strengthen protection of trade secrets
- ✓ Strong efforts to raise awareness and leveraging of value of IP rights in academic and private spheres

KEY AREAS OF WEAKNESS

- × Some uncertainty over implementing rules for biopharmaceutical linkage mechanism
- × Despite improved enforcement efforts, levels of IP infringement remains high
- × Interpretation of IP laws can be fragmented and out of sync with international standards
- × Broader industrial and investment policies continue to undermine the investment and operating environment

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**7.28**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	0.78
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**3.03**
10. Term of protection	0.53
11. Exclusive rights	0.75
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.25
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.75
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**1.35**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.60

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**2.33**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.33
Category 7: Enforcement	**2.59**
32. Physical counterfeiting rates	0.00
33. Software piracy rates	0.34
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.25**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**2.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.50

TOTAL: 27.43

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

China's overall score has increased from 49.96% (24.98 out of 50) in the eighth edition to 54.86% (27.43 out of 50) in the ninth edition. This reflects score increases on indicators 5, 7, 11, 15, and 21. China has over the past two years essentially revamped its national IP environment by amending and updating most major IP laws and regulations. As mentioned, this is in large measure a reflection of China's implementing various parts of its negotiations with the United States. Overall, the past two editions of the Index have seen China boost its score by 7.20%.

Area of Note

In January 2020, the United States and China signed the Economic and Trade Agreement between the Government of the United States and the Government of the People's Republic of China. The Agreement includes both a dedicated chapter on IP (chapter 1) and technology transfer and licensing (chapter 2). The IP chapter covers most major IP rights, sector-specific rights, and enforcement, and addresses many of the challenges raised in the Index over the past nine editions. As noted in last year's Index, Article 1.35 of the chapter states that, within 30 days of the entry into force of the deal, China will "promulgate an Action Plan to strengthen intellectual property protection aimed at promoting its high-quality growth." Following the signing of the agreement, several IP reform initiatives were announced, including the Opinions on Strengthening the Protection of Intellectual Property Promotion Plan (the "Plan"), which was released in April 2020. The Plan includes 133 action points and IP related reforms ranging from substantive structural reforms, such as legislative amendments and the issuing of new judicial interpretation guidelines, to grassroots surveys of users of the national IP system. In terms of major proposed statutory and regulatory changes, of note were proposed efforts to reform the Patent Law, Copyright Law, Trademark Law, Regulations on the Protection of New Varieties of Plants, Civil Code, Criminal Law, Anti-Unfair Competition Law, and E-Commerce Law. At the time of research, draft amendments had been published and made available for public comment for some, but not all, laws and some draft changes had even been passed into law, including a new Patent Law passed in October 2020 and amendments to the Copyright Law passed one month later, in November. Many of these changes were positive and broadly in line with the Agreement. For instance, the passed amendments to the Patent Law begin to address two long-standing weaknesses in China's national IP environment relating to biopharmaceuticals: the availability of a pre-market approval administrative patent enforcement mechanism for follow-on products (linkage system) and a term of patent restoration. (See indicators 5 and 7 below for a full discussion of both.) The Patent Law has also extended the term of protection for design patents, another positive step described below. Moreover, many of these laws include new and heightened statutory damages; in the amendments to the Copyright Law, for example, statutory damages have been increased substantially. There have also been several new draft interpretations issued by the Supreme People's Court on the application of civil and criminal law in IP proceedings, especially relating to trade secrets and the protection of confidential information. At the time of research, these interpretations were still subject to review and finalization.

Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism: As noted in previous editions of the Index, Chinese regulatory authorities have committed to introducing a patent linkage mechanism for biopharmaceuticals. In October

2017, the central government issued State Council Opinions on Deepening Regulatory Reforms to Encourage Drug and Medical Device Innovation, which confirmed the strengthening of the existing patent linkage mechanism in China (based on the existing Drug Registration Regulations) proposed earlier in 2017. Article 16 provided for the notification of patent holders of applications of relevant follow-on drugs (in comparison to the publishing of applications under the existing system) within a set period. It also specifically permitted the initiation of patent disputes once the patent holder was made aware of the application (instead of forcing patent holders to wait until the follow-on drug is marketed). Moreover, the measure indicated that the approval of the follow-on product would not take place if, "within a certain period of time," a patent dispute was not yet resolved. Following that period, the China Food and Drug Administration could approve the product for marketing. These actions were recognized in the sixth edition of the Index as positive and important steps in strengthening China's biopharmaceutical IP environment and, as a result, the score on this indicator was increased by 0.5. However, the commitment to introduce a linkage regime was not implemented in 2018 and 2019. In early 2020, China again committed in the Agreement (Article 1.11) to adopt a form of patent linkage. In October 2020, a new set of patent amendments was passed into law and will take effect in June 2021. Article 76 of the updated Patent Law outlines China's new linkage regime, which will be based on both a potential judicial route of enforcement and administrative enforcement through the State Council. With regard to potential administrative enforcement, the amended law is not clear on what this would look like, simply stating that "specific measures for the connection of patent dispute resolution at the stage of drug marketing license approval and drug marketing license application" would be "formulated" by the authorities. Prior to the passing of the patent amendments, China's National Medical Products Administration, together with the China National IP Administration, published draft implementing regulations, the Implementation Measures for the Early Resolution Mechanism for Drug Patent Disputes (Trial) (Draft for Comment). These draft measures set out in some detail how the linkage regime and administrative enforcement would operate and provide rights-holders with potential avenues of redress prior to the marketing approval of a follow-on product. However, there are several important areas where the proposed measures are unclear. For example, the draft measures do not require that rights-holders be directly notified when a potential infringing follow-on application is submitted to the Chinese drug regulatory authorities. Instead, Article 7 presumes that rights-holders will proactively monitor the publication of the follow-on marketing authorization and, within 45 days, file a formal objection. If no objection is filed within the prescribed period, the relevant drug registration authorities have the discretion to decide on whether to approve the follow-on product. More broadly, the suggested stay period is only nine months. This is shorter than both previous draft proposals—which had a period of 24 months—and equivalent timelines in the United States and Singapore, where the period is 30 months. The linking of the approval of follow-on biopharmaceutical products to the exclusivity status of a reference product is an effective way of achieving a balance between the protection of pharmaceutical exclusivity (usually but not always through patent protection) and stimulating early market entry of follow-on generic products. Linkage ensures that any disputes are resolved prior to the marketing of a follow-on product. This grants innovators a fair opportunity to secure return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity. It also limits potential damages for generic manufacturers, as no potentially infringing product is ever launched or approved for market. Indeed, linkage also provides both innovators and generic companies with an opportunity of lower-risk challenges of validity or non-infringement, by largely

taking the issue of damages out of the equation. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit. In sum, a well-balanced linkage system recognizes the crucial role of patent protection in promoting innovation, and the role of generic entry in providing patients access to lower-cost biopharmaceuticals. Having in place a functioning linkage regime that provides rights-holders with a meaningful and real ability to stop follow-on products from being launched when a granted term of exclusivity is in place would be a substantial improvement to the biopharmaceutical IP environment in China. It is a positive step that the Patent Law now includes such a statutory right, and on this basis the score on this indicator has increased by 0.25. However, it is critical that the final system as defined through implementing regulations effectively ensures that any disputes are resolved prior to the marketing of a follow-on product in a fair and transparent manner to all parties. The Index will continue to monitor these developments in 2021.

7. Patent term restoration for pharmaceutical products: As noted, in October 2020, new draft amendments to the Patent Law were passed. Article 42 of these amendments states that a period of term restoration of up to five years for biopharmaceutical products may be made available by relevant Chinese authorities. At the time of research, no implementing regulations or further details had been provided as to the specific circumstances that would be recognized or requirements needed to be met for restoration to be granted, including, for example, the types of delays that would be recognized as justifying such restoration. The introduction of a five-year period of patent term restoration is a substantial improvement to the biopharmaceutical IP environment in China and has resulted in a score increase on this indicator from 0 to 1. As with the newly introduced linkage regime, it is vital that term restoration be provided in a fair and transparent manner, recognizing the unique circumstances and long delays that the biopharmaceutical regulatory approval process entails. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations and Enforcement

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 15. Digital rights management legislation; and 35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement: As has been noted over the course of the Index, rights-holders have historically faced substantial challenges in China with respect to both the legal copyright framework and enforcement of their rights. Not all rights have been clearly defined in law. Particular areas of uncertainty have been in relation to sound, broadcasting, and the extent to which the broadcasting of live sporting events has been eligible for copyright protection. Concerns have also been raised over existing provisions relating to digital rights management and technological protection measures, which have banned only the act of circumvention (as long as it is intentional) and not the manufacture, importation, distribution, or sale of circumvention devices. Many enforcement mechanisms have also, in effect, not been available to rights-holders with a lack of functioning notification and takedown regimes and injunctive-style relief. More broadly, enforcement has historically been an area of real concern in China, with high levels of both physical hard goods piracy and online infringement. In particular, as internet penetration and broadband capacity has increased, the problem with the protection and enforcement of copyright online has only grown worse. Specific problem areas have included the illicit streaming of live sports (both domestically and for an international audience) as well as unconven-

tional and pervasive file-sharing techniques, such as deep-linking. As noted in previous editions of the Index, there have been efforts by the Chinese authorities over the past few years to improve the copyright enforcement environment. In 2015, the National Copyright Administration (NCAC) took concrete steps to enforce copyrights against online infringement through Operation Sword Net, including a deadline for online music service providers to remove infringing songs that resulted in over 2 million files being deleted from major music outlets in China. Similarly, a district court in Beijing endorsed the ability to copyright live sports broadcasts, raising the hope of stronger protection in this area. In 2018, at the request of the NCAC, 15 video-sharing online platforms stepped up their enforcement efforts and disabled access to over 570,000 infringing videos, some of which were hosted by overseas servers. Also, at the request of the China Audio-Video Copyright Association, karaoke owners reportedly banned over 6,000 copyright-infringing songs from their business. Additionally, Lego registered an important victory in a copyright court case against four domestic infringers and was awarded USD650,000 in damages. There have also been intermittent efforts since 2013 to strengthen the Copyright Law and address many of the legal gaps outlined above. In 2020, new amendments to the law were finally passed. These include important changes and a strengthening of the legal framework in relation to sound and broadcasting. A revised Article 3 provides new definitions of copyrightable material, including for "audiovisual works" and a broad "other intellectual achievements that meet the characteristics of the work." Rights relating to performance rights, sound recording, and broadcasting have also been more clearly defined. Provisions relating to TPM and DRM have been strengthened through Articles 49, 51, and 53, which now provide a broader definition of infringement, including for the manufacturing, importation, and offering of circumvention devices to the public. Statutory damages for copyright infringement have also been increased substantially following similar changes to the Patent Law and Trademark Law. These are positive changes that could, in aggregate, amount to a significant improvement of the copyright environment in China. The Index will over the next few years monitor how these legislative changes are applied in practice and the extent to which they improve the ability of rights-holders to enforce their copyrights in China. As a result of these changes, the scores on indicators 11 and 15 have increased.

Design Rights, Related Rights, and Limitations

21. Industrial design term of protection: As part of the 2020 amendments to the Patent Law described above, the term of protection for design patents was extended from 10 to 15 years. As a result, the score on this indicator has increased.

Commercialization of IP Assets and Market Access

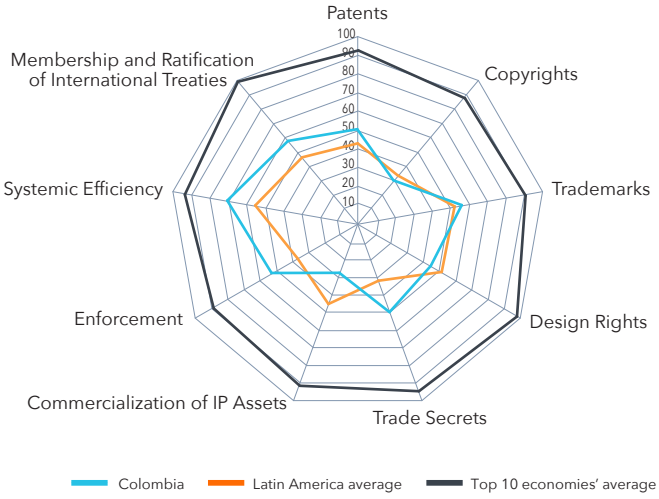
26. Barriers to market access; 27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: As noted in previous editions of the Index, rights-holders have over the years faced a growing number of regulatory, procedural barriers and inflexible terms to licensing in China that impede technology flows and R&D cooperation. China has imposed restrictions on the foreign IP rights-holders to freely negotiate market-based contractual terms in licensing and other technology-related contracts concerning the transfer of technology to China. The Technology Import/Export Regulations historically included discriminatory conditions for foreign licensors, including indemnification of Chinese licensees against third-party infringement and transfer of ownership of future improvements on a licensed technology to the licensee, which restrict the ability of foreign companies to negotiate licensing and technology contracts on market

terms and to fully commercialize their technology in China. Under the Joint Venture regime, licenses and tech transfer contracts could not last more than 10 years, after which the licensee retained the right to use the transferred technology, although this might still be under a term of exclusivity. Adopted in 2018, the Working Measures for Outbound Transfer of Intellectual Property Rights tightened the scrutiny on outbound transfer of technology and IP. More broadly, in the context of standards setting, there has also been a trend toward greater administrative involvement in determining patent licensing terms and the ability to secure relief from infringement. The National Security Law, Cybersecurity Law, Security Assessments for Network Products and Services, and other relevant standards all contain product reviews that require IP disclosure. These restrictions and the active discrimination against foreign entities have been at the heart of trade and market access related bi- and pluri-lateral discussions with China for several years. Both the United States and the EU have filed their own complaints with the WTO against China over its technology licensing practices and this has been a central point of contention and negotiation in the trade dispute between the United States and China. As detailed in last year's Index, 2019 saw significant positive changes to China's technology transfer and licensing environment. The Foreign Investment Law, the Technology Import and Export Regulations, and Regulations for the Implementation of the Law of the People's Republic of China on Chinese-Foreign Equity Joint Ventures were changed, with many of the most onerous provisions described above now removed. As part of China's commitments in the Agreement with the United States, these reforms continued in 2020. Of note is a new Civil Code passed into law in May 2020. Although this sprawling piece of legislation touches on all aspects of civil law, it also includes specific provisions relating to technology transfer and contract law in a dedicated chapter, chapter 20. Of note is that, in general, although providing a legal framework and reference point for technology transfer and licensing contracts, the articles of this chapter place an emphasis on contractual terms being market driven and at the discretion of the contracting parties. For example, on the issue of ownership and rights related to any improvement of an existing technology or IP right transferred or licensed, Article 875 makes clear that such benefits shall be agreed between the parties "in accordance with the principle of mutual benefit." Still, there are some notable areas where there is a lack of clarity, including, for instance, Article 847 and rights pertaining to technological improvements and inventions carried out by individuals, including employees. In terms of sector-specific developments, over the past few years the government of China has worked on and held several public consultations on a new Biosecurity Law. The proposed law was in 2020 fast-tracked for legislative approval and implementation and is, in part, a response to the COVID-19 pandemic. The finalized version of the law was published in October 2020. Chapter VI of the law contains several potential restrictions and requirements for research relating to biotechnological and biological material. This includes strict registration requirements, potential restrictions on both foreign entities to conduct genetic research in or outside of China, and the need to partner with a Chinese entity. As such, the law puts in place a potential *de facto* localization and local partnership requirement for entities involved in any type of biotechnology research. This includes entities within the health, food, industrial, and environmental space. The new Civil Code came into effect January 1, 2021, and the Biosecurity Law is slated to take effect later in 2021. The Index will monitor how both are interpreted and applied moving forward.

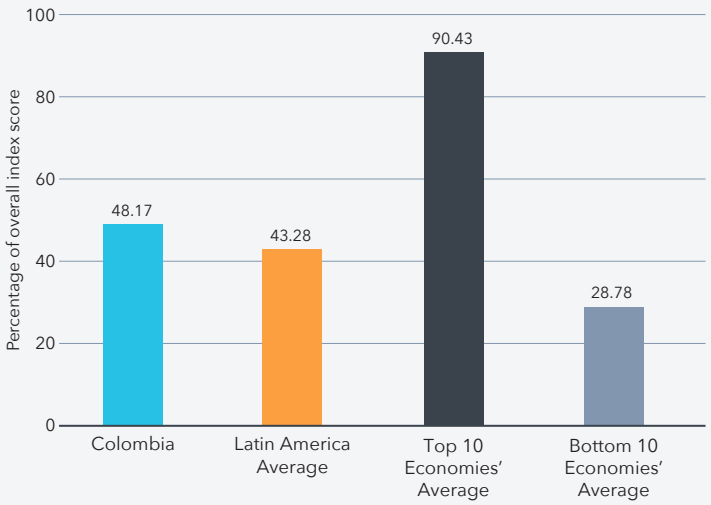
COLOMBIA

RANK
29/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Acceded to Convention on Cybercrime in 2020
- ✓ 2019 Colombian Constitutional Court issued a ruling (C-345-19) that recognizes the constitutionality of statutory damages for copyright infringement introduced by 2018 amendments to Copyright Law
- ✓ Targeted incentives in place for the creation and use of IP assets for SMEs—this includes reduced filing fees and technical assistance
- ✓ Efforts to coordinate inter-agency IP enforcement and raise public/stakeholder engagement on IP policymaking and education

KEY AREAS OF WEAKNESS

- × History of use of compulsory license regime to leverage price reduction for biopharmaceuticals—2020 emergency COVID-19 laws provide exceptional broad basis for use of public interest declarations without sunset clauses or similar limitations
- × Substantial barriers in place for licensing activities, including direct government intervention and review of technology transfer and licensing agreements
- × Key life sciences IP rights missing, including patent term restoration and mechanisms for early patent dispute resolution
- × Uncertainty over availability of RDP for biopharmaceuticals
- × Inadequate/delayed prosecution of and penalties for IP infringement

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**4.50**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.09**
10. Term of protection	0.84
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.50**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**1.67**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**3.67**
32. Physical counterfeiting rates	0.40
33. Software piracy rates	0.52
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**4.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

TOTAL: 24.08

SPOTLIGHT IN THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Colombia's overall score increased from 46.40% (23.20 out of 50) in the eighth edition to 48.17% (24.08 out of 50) in the ninth edition. This reflects a score increase on indicator 48 and a small decrease on indicator 32.

Patent Rights, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: Up until the mid-2010s, the imposition and discussion of compulsory licensing for biopharmaceuticals had not been a recurring issue in Colombia. Article 70 of the 2014-18 National Development Plan widened the basis for the issuing of compulsory licenses in a manner that goes beyond the TRIPS Agreement, Article 31 and the 2001 Doha Ministerial Declaration, and subsequent General Council decision concerning paragraph 6. The provision allows Colombian authorities to define public health emergencies broadly and to actively seek out compulsory licenses, allowing for grounds outside extreme circumstances, including industrial or commercial objectives, to play a role in the issuing of compulsory licenses. In 2016, the Ministry of Health and the Colombian government actively considered issuing a compulsory license on the oncology drug Glivec on the grounds of high prices. Subsequently, the Colombian government issued a "Declaration of Public Interest" via Resolution 2475 and committed to unilaterally reducing the price of 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 traditional 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. Shortly after the issuance of Circular No. 3, in December 2016, the National Pricing Commission issued Circular No. 4 of 2016, which sets the price of Glivec at about 44% of its former price. 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. Subsequent to these developments, a new application for a public interest declaration was made and accepted for review for medicines related to the treatment of hepatitis C by the Ministry of Health in December 2017 through Resolution 5246. Unlike previous applications, this application did not identify a specific patent or set of patents to which the declaration should pertain, instead identifying the whole class of hepatitis C products. Local legal analysis suggests that there has been no further action taken by the authorities. Still, at the time of research, the situation remained unresolved. As such, it imposes yet another layer of uncertainty on rights-holders' ability to make use of their granted exclusive rights fairly and effectively in Colombia. In March 2020, Decree 476 was issued by the Colombian government in response to the COVID-19 pandemic. While the decree does not explicitly amend existing legislation relating to patent protection and compulsory licensing, Article 1, sub-section 1.7 of the decree grants the Minister of Health broad and full authority to make a Declaration of Public Interest relating to any and all "medicines, medical devices, vaccines and oth-

er health technologies that are used for the diagnosis, prevention and treatment of COVID19." As mentioned, while not legally a compulsory license, such declarations essentially nullify any existing IP protection and carry the same practical impact of eliminating a rights-holders' ability to freely use a granted exclusivity. On a parallel track, another group of legislators proposed a wide-reaching Senate Bill in December 2020 that would drastically modify Colombia's Pharmaceutical Policy. Industry's chief concern is the creation of so-called "automatic" compulsory licenses by the Colombian Commerce Ministry, Food & Drug regulatory agency, and Justice Ministry. The Chamber also notes a troubling provision (Article 57, paragraph 3) calling for the removal of governmental officials that do not grant a compulsory license with speed. Finally, the bill contains numerous unfortunate references to the belief that IP rights are a barrier to public access of IP-intensive goods. The severe and sudden impact the COVID-19 pandemic is having on public health around the world means that, in effect, the conditions of the potential issuing of a compulsory license are being met in many economies. However, it is squarely outside the scope of international law and applicable standards to define a declaration of public interest as a potential catch-all mechanism that can be used to sanction the violation and overriding of granted property rights for any product, diagnostic, or medical device, and other medical paraphernalia related to the COVID-19 global pandemic. Furthermore, unlike other emergency measures that have been introduced around the world, including, for example, in Canada, the proposed legislative amendments do not include any defined timeframe or suitable sunset clause. Instead, Articles 1 and 2 simply state that the provisions of the decree will be in effect until the national emergency caused by the pandemic has been lifted. But compulsory licensing and the over-riding of property rights is not a cost-containment tool; cost is not a relevant justification or basis for compulsory licensing or equivalent declarations under the TRIPS Agreement. TRIPS Article 31, 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 be aimed solely at protecting public health. In addition, 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. This is currently not the case in Colombia. The Index will continue to monitor these developments in 2021.

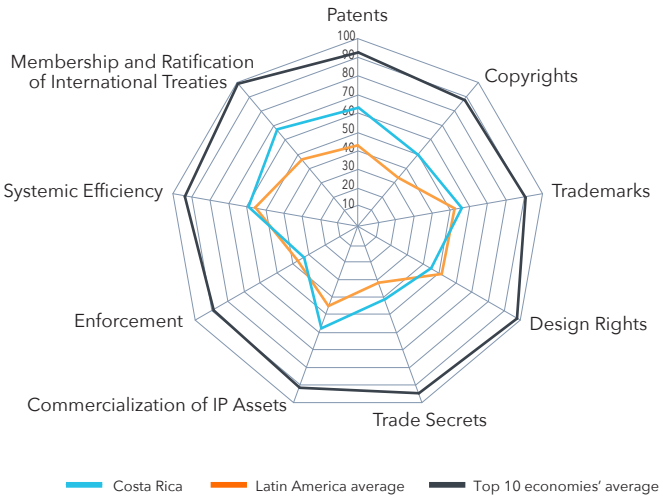
Membership and Ratification of International Treaties

48. Membership of the Convention on Cybercrime, 2001: As noted in last year's Index, Colombia has over the past few years been taking the last steps to accede to the Convention. Law 1928 of 2018, through which the Convention was approved, was passed by the Colombian Congress and declared constitutional by the Constitutional Court in May 2019. The Convention was formally ratified in March 2020 and has been in force since July 2020. As a result, the score on this indicator has increased to 1.

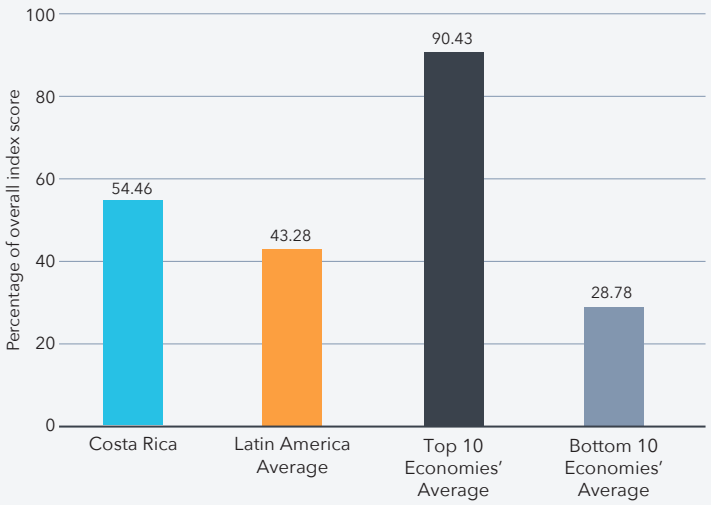
COSTA RICA

RANK
25/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Implementation of new software management tools for public sector in 2019-20
- ✓ Expanded support for awareness raising and IP rights educational activities in 2020
- ✓ Member of the regional PROSUR PPH initiative
- ✓ Patent framework in line with international standards, with some exceptions
- ✓ Some elements of an advanced online copyright regime in law
- ✓ Customs authorities empowered to address various types of infringing goods *ex officio*

KEY AREAS OF WEAKNESS

- × No significant R&D- or IP-based tax incentives in place
- × Delays and significant lack of implementation of online copyright regime
- × Gaps in effectiveness of life sciences IP rights
- × System of enforcement of IP rights slow and lacks effectiveness
- × Inadequate penalties for IP infringement

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**5.73**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.75
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.48
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**3.49**
10. Term of protection	0.74
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.50**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**2.36**
32. Physical counterfeiting rates	0.44
33. Software piracy rates	0.42
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.50
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**3.00**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**4.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

TOTAL: 27.23

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Costa Rica's overall score increased from 52.60% (26.30 out of 50) in the eighth edition to 54.46% (27.23 out of 50) in the ninth edition. This reflects a score increase on indicators 16, 41, and 42.

Copyrights, Related Rights, and Limitations

16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software: The 2012 Executive Decree No. 37549-JP states clearly that all central government ministries and agencies have an obligation to ensure that all software, whether proprietary or open source, used on public ICT systems should be fully licensed. Article 2 establishes that each relevant ministry should "establish systems and controls to guarantee the use in their computers, solely and exclusively, of those computer programs that comply with the corresponding copyright," audit this system regularly, and record the "results of the inventory of equipment and licenses acquired." Up until now, there has been only partial evidence that relevant government institutions were effectively monitoring the application of these requirements. For example, the U.S. government has noted a lack of dedicated resources as standing in the way of the effective application of this decree. Over the past few years, more information has become available suggesting that software auditing and asset management is taking place regularly. This includes a 2017 internal audit of the Ministry of Health's Institute for Research and Education in Nutrition and Health, a 2019 similar internal audit of the Ministry of Justice, and the results of the same type of software audit for the Ministry of Housing being published in 2020. In its 2019-20 annual report, *Informe de Labores 2019-2020*, the National Registry Office outlined the basis for a new automated registration, compliance, and software asset management platform, *El sistema de legalización de software*. This web portal will allow all ministries and relevant government agencies to file annual software audits, inventories, and proof of licensing compliance electronically and provide the National Registry with a centralized platform to store and process all data and information. The creation and use of this tool should allow the National Registry and relevant staff operating it to monitor compliance with Executive Decree No. 37549-JP more effectively. At the time of research, the platform was operational and available on the National Registry's website. As a result of these positive actions, the score on this indicator has increased by 0.5. The Index will continue to monitor this in 2021.

Systemic Efficiency

41. Educational campaigns and awareness raising: Relevant Costa Rican public and private bodies support educational and awareness-raising programs on the benefits of IP rights and negative impact of counterfeiting and physical and online piracy. The National Registry has run several initiatives, the most notable being the National Intellectual Property Communication Strategy (*Estrategia Nacional de Comunicación de Propiedad Intelectual*) in partnership with WIPO. The purpose of the strategy is to promote IP awareness and respect for IP rights and creators and innovators. The program targets young people and school children in particular. One key educational component is the "*Mis Creaciones Valen*" (My Creations Are Worthy) campaign, which includes training and educational activities targeting elementary and high school students. The program was first launched in 2016. Since 2017, there has been a strong focus of this campaign on social media. The 2017 annual report published by the National Registry stated that the campaign had reached almost 20,000 social media users. As reported in the National Registry's 2019-20 annual report, the campaign continued in

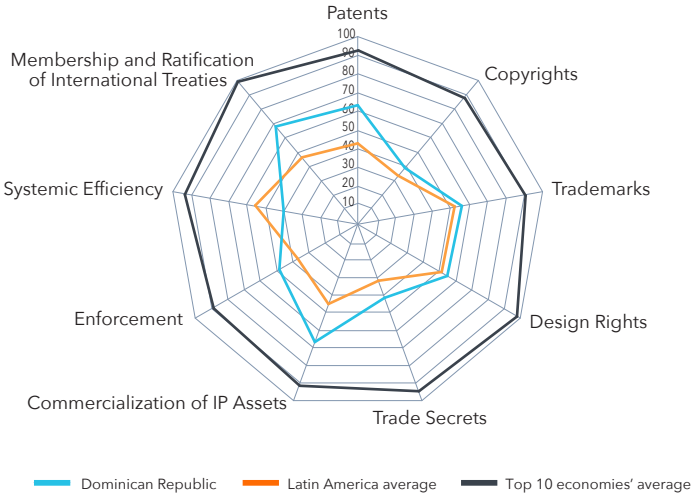
2018-19, reaching over 20,000 school children and close to 500 teachers. In aggregate, the program has since 2016 reached over 1 million people and close to 100,000 school children and teachers. The National Registry has announced that the initiative has been renewed for a new four-year period running to 2023 and will now target both private and public institutions. The National Registry and Costa Rican government should be congratulated for its focus and emphasis on this initiative. As a result of this positive commitment to continuing this educational activity and outreach to young people, the score on this indicator has increased to 1.

42. Targeted incentives for the creation and use of IP assets for SMEs: There is a growing recognition in Costa Rica of the importance of SMEs to the creation, dissemination, and commercialization of IP assets. Article 33 of Law 6867 (*Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad*) provides reduced registration fees for patent applications submitted by individual inventors, universities and public research institutes, and micro and small enterprises. However, there is no targeted technical assistance or education programs for the creation and commercialization of IP assets for SMEs by the National Registry or other major Costa Rican public institutions. The PROINNOVA office within the University of Costa Rica provides technical advice, expertise, and help with the evaluation and registration of IP assets for members of the university and functions as the University's technology transfer office but it is not directed or focused on SMEs or the business community outside the university. Similarly, the *InnovaciónCR* initiative, supported by the Ministry of Science, Technology and Telecommunications, provides grants and targeted assistance to SMEs, but this is not within the context of incentivizing the creation of IP assets but more broadly in supporting small business and enterprise. Although not specific to SMEs, the National Registry does support the registration and commercialization of IP assets by academic researchers, research institutes, and SMEs, through its *Centro de Apoyo a la Tecnología y la Innovación* (CATI) network of support centers. The CATI concept was developed by WIPO through its Technology and Innovation Support Centers (TISC) in 2009-10 and, as of 2019, over 80 economies (including Costa Rica) had established or were seeking to establish local TISC offices. In Costa Rica, these support centers offer researchers and institutions technical support and expertise on the registration and commercialization of IP. The number of centers and their activity levels have increased substantially over the past few years and, as of 2020, there were six such centers across the country. Costa Rica is now considered a regional leader on this front. These centers not only provide guidance and technical assistance but are also producing technical reports specific to the region and Costa Rica. As a result of this positive activity, the score on this indicator has increased by 0.25.

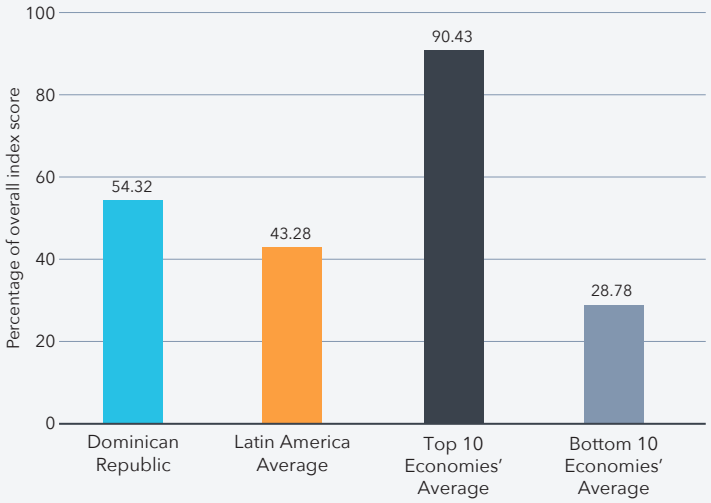
DOMINICAN REPUBLIC

RANK
26/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Central American Free Trade Agreement (CAFTA) membership fundamentally improved national IP environment
- ✓ Member of PROSUR regional PPH
- ✓ Plant variety protection in place
- ✓ No evidence of active government intervention in technology transfer or licensing
- ✓ Fairly strong legal requirements and administrative practices on public consultations

KEY AREAS OF WEAKNESS

- × Patentability standards outside international norms—no second-use claims for biopharmaceuticals and virtually no patent protection for CIIs
- × RDP term not being granted although required by law
- × Enforcement of copyright is highly challenging and is one of the main reasons the Dominican Republic has remained on the USTR's 301 Watch List for years
- × Infringement of copyright through signal piracy, online, and web-based streaming is highly pervasive and constitutes a major source of illegal content—not effectively addressed by Dominican government
- × Reports suggest customs authorities are not taking effective action against suspected infringing goods
- × Persistently high levels of piracy—estimated 75% software piracy rate

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**5.70**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.70
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**2.74**
10. Term of protection	0.74
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**4.00**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**3.37**
32. Physical counterfeiting rates	0.37
33. Software piracy rates	0.25
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**2.00**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**4.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

TOTAL: 27.16

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

The Dominican Republic's overall score has increased from 53.96% (26.98 out of 50) in the eighth edition to 54.32% (27.16 out of 50) in the ninth edition. This reflects a score increase on indicator 45.

Patents, Related Rights, and Limitations

8. Membership of the Patent Prosecution Highway (PPH): The Dominican Republic is not a member of the Global PPH or the IP5. However, the National Office of Industrial Property (*Oficina Nacional de la Propiedad Industrial*) is an active participant in an operational PPH program through the Latin American Regional Cooperation System on Industrial Property, PROSUR. PPH initiatives and increased cooperation between IP offices are one of the most tangible ways in which the administration and functioning of the international IP system can be improved and harmonized, helping inventors and rights-holders around the world.

Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy: Articles 19-20 of Law 65-00 2000 (as amended by Law 424-06 2006) outline rights-holders' exclusive economic rights, which include the right of distribution, reproduction, transmission, communication to the public, and other necessary related rights. There is no direct mention or reference to the online environment, including streaming, caching, or web linking. The law does not offer an injunctive-style relief mechanism for the disabling of infringing content. Copyright enforcement can take place both through the courts and administratively through the National Copyright Office of the Dominican Republic (ONDA). However, in practice, the enforcement of copyright is highly challenging and is one of the main reasons the Dominican Republic has remained on the USTR's Watch List for years. The infringement of copyright through signal piracy, online, and web-based streaming is highly pervasive and constitutes a major source of illegal content in the Dominican Republic. Specifically, signal piracy has been brought up numerous times by international rights-holders and the U.S. government. Authorities in the Dominican Republic have repeatedly made a commitment to better enforce copyright and address this issue but have thus far failed to do so. Such a commitment was, for example, made in a side letter between the United States and the Dominican Republic in 2004 during the conclusion of the CAFTA. This remained unchanged in 2020. The USTR, again noted in the 2020 *Special 301 Report* the lack of action on this issue, stating that "signal piracy by unauthorized cable operators and retransmission piracy by hotels are long-standing issues that remain unaddressed." The Dominican Republic also remains an international source for infringing material. For example, in November 2019, a Spanish court ordered the disabling of access to three notorious sources of infringing content, including the website Lomusical.org, which operates out of the Dominican Republic.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection term: Article 181 of Law 20-00 2000 (as amended by Law 424-06 2006) provides a clear and unambiguous requirement that market authorization authorities provide a five-year term of market exclusivity for submitted clinical test data for a new biopharmaceutical and that this data cannot be relied on by follow-on man-

ufacturers for the duration of the stated term of exclusivity. Rights-holders have in the past raised concerns that this term of exclusivity has not been provided or has been provided only under certain circumstances not specified in the existing regulatory framework. The availability of a defined RDP term of protection is a positive feature of the Dominican Republic's biopharmaceutical IP environment and an important mechanism for protecting innovation. The Index will continue to monitor this in 2021.

Systemic Efficiency

40. Consultation with stakeholders during IP policy formation: Through various laws and administrative actions, the government of the Dominican Republic has shown its commitment to public transparency and the principle of public consultations during the legislative process (IP rights included). For example, Article 31 of Law 107-13 on Public Administration has a requirement that the general public be involved and participate in the regulatory and rule-making process. Furthermore, the Dominican Republic has since 2012 been part of the international Open Government Partnership, which seeks to further government transparency and public participation in government. The website "*Gobierno Abierto*" provides a dedicated portal to government information and an overview of the various initiatives and actions the government is taking to improve transparency and public participation. Increased transparency and public participation are also parts of the National Development Plan.

Membership and Ratification of International Treaties

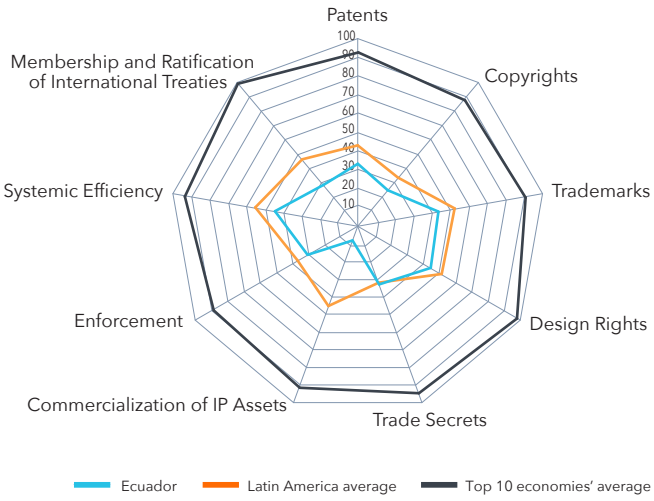
The Dominican Republic achieves a score of 67.86% for its participation in and ratification of international treaties, which is higher than many high-income economies including, New Zealand, the UAE, and Chile. It has signed and ratified the WIPO Internet Treaties; the Patent Cooperation Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; and the Convention on Cybercrime, 2001; and is a contracting party to the CAFTA. The Dominican Republic has signed, but not acceded to, the Singapore Treaty on the Law of Trademarks. It is not a contracting party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, the Patent Law Treaty, or the Hague Agreement Concerning the International Registration of Industrial Designs.

CORRECTION OF ERROR, 45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks: The Dominican Republic has not acceded to either the Singapore Treaty on the Law of Trademarks or the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. The Dominican Republic is, however, a signatory to the Singapore Treaty on the Law of Trademarks. Unfortunately, this was not recognized by the Index last year. This error has now been rectified, and the Dominican Republic's score on this indicator has been increased from 0 to 0.25. The Chamber apologizes for this error.

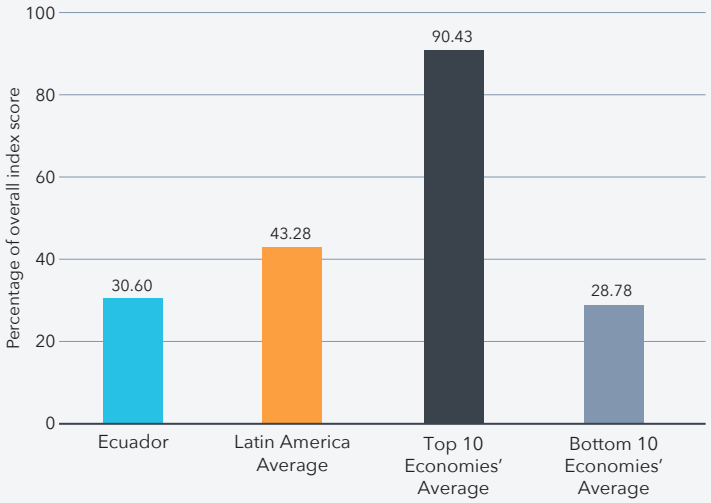
ECUADOR

RANK
47/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Strengthening of support for SMEs through WIPO-WEF Inventor Assistance Program in 2020
- ✓ National IP authority SENADI in 2019 ordered local ISPs to disable access to several websites hosting infringing and unlicensed content
- ✓ FIve-year term of RDP defined in 2016 law *Código Ingenios*
- ✓ Limited re-criminalization of IP rights through 2016 criminal law amendments
- ✓ Member of PPH

KEY AREAS OF WEAKNESS

- × Plant variety protection term shorter than internationally accepted term
- × Substantial barriers in place for licensing activities, including direct government intervention and review of technology transfer and licensing agreements
- × Key life sciences IP rights missing, including patent term restoration and mechanisms for early patent dispute resolution
- × Use of compulsory license regime for biopharmaceuticals as basis for cost-containment and industrial policy
- × *Código Ingenios* imposes additional limits on patentability and number of non-patentable subject matter
- × Persistently high levels of piracy—estimated 68% software piracy rate
- × Low score for participation in and ratification of international treaties

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**2.99**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.00
4. Plant variety protection	0.74
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**1.74**
10. Term of protection	0.74
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.00**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**0.50**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.25
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**2.17**
32. Physical counterfeiting rates	0.35
33. Software piracy rates	0.32
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**2.25**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.50

TOTAL: 15.30

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Ecuador's overall score increased from 30.18% (15.09 out of 50) in the eighth edition to 30.60% (15.30 out of 50) in the ninth edition. This reflects a score increase on indicator 42.

Area of Note

In February 2020, the Ecuadorean National Assembly approved the *Ley Orgánica de Emprendimento e Innovación*, a new legislative package aimed to promote and build entrepreneurship, innovation, and economic development. It includes provisions relating to starting a new business, accessing early-stage financing (including crowdfunding and venture capital), education and the development of human capital, corporate bankruptcy and restructuring proceedings, and a host of other legislative changes. Article 2 states that the purpose of the law is ultimately to create an environment "that encourages and fosters entrepreneurship, innovation and technological development." With regards to policymaking, Article 6 creates a new Council for Entrepreneurship and Innovation. This is to be a cross-governmental body formed to "promote and encourage entrepreneurship, innovation and systemic competitiveness of the country, through inter-institutional coordination, public-private alliance and academia." The governing body of the council is made up of representatives from across the public sector, academia, and local entities. Showing the importance placed on this body in Ecuadorean industrial and economic policy, the council will be chaired by a representative from the Office of the President. In addition, Article 10 of the law establishes a Consultative Council of Entrepreneurship and Innovation, which is to advise the Council for Entrepreneurship and Innovation. This body will consist of representatives from the private sector including industry associations and chambers of commerce. Of note is that the national IP office (*Servicio Nacional de Derechos Intelectuales*, SENADI) has not been included and IP policy does not seem to be part of the remit of either the council or, more broadly, of the new legislation. As the economic data and analysis in this Index's accompanying *Statistical Annex* and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for innovation and advanced economic development to take place. For all economies—emerging and developed alike—what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP. Yet, as noted again this year and over the course of the Index, Ecuador's national IP environment lacks many fundamental rights and incentives. Patentability standards continue to be outside of international norms (especially for biopharmaceuticals and CIIs); the protection of copyright remains under-developed and ill suited to the challenges of the internet era; and levels of physical and online counterfeit goods remain high, but relevant enforcement mechanisms are weak and non-deterrent. Rights-holders also face basic challenges with respect to technology transfer, licensing the use of IP assets, and the commercialization of IP assets. While the *Ley Orgánica de Emprendimento e Innovación* is a necessary recognition of the importance of innovation and entrepreneurship to Ecuador's future economic development, to be effective and achieve the stated objectives, these reforms should be complemented by strengthening the national IP environment.

Systemic Efficiency

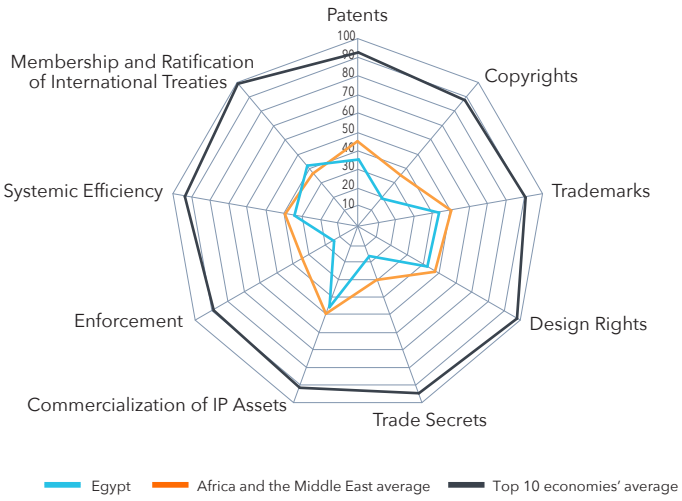
42. Targeted incentives for the creation and use of IP assets for SMEs: As noted in past editions, the Ecuadorian IP office, SENADI, and its precursor, the Ecuadorian Intellectual Property Institute, have been outspoken and frequently stated that assisting small business and SMEs is one of the office's core

objectives. For example, while there is currently no special priority or fast-track review of IP registration for SMEs, the agency does provides reduced filing fees to SMEs, universities, and individuals. Working together with WIPO and the World Economic Forum, the agency has launched a dedicated program to help individual inventors and small businesses through the Inventor Assistance Program. Developed by WIPO and the WEF and launched globally in 2016, the program seeks to match inventors with legal practitioners who provide pro-bono legal advice on the technical evaluation and registration process for the IP created. At the time of research, the program was fully operational, with the first patent applications having been filed in Ecuador. As a result of this positive activity, the score on this indicator has increased by 0.25.

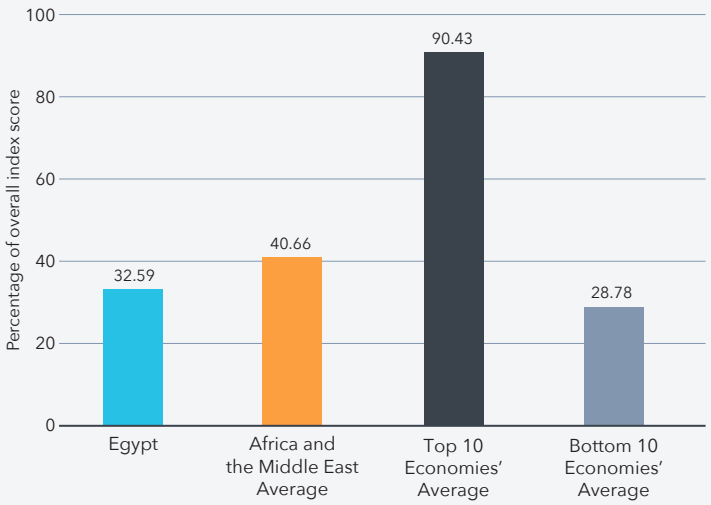
EGYPT

RANK
46/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Joined the UPOV, 1991 agreement in 2020
- ✓ Since 2015, a PPH has been in place with the Japan Patent Office (JPO)
- ✓ Relative freedom to patent CIIs and support from government agencies
- ✓ Relatively strong push from government to raise awareness of counterfeit products, particularly medicines

KEY AREAS OF WEAKNESS

- × Data protection law of 2020 will potentially impose new localization requirements
- × Limited framework for the protection of life sciences IP rights
- × Gaps in copyright law and framework, particularly with regards to protection of content online
- × High levels of piracy–BSA estimated 59% software piracy rate
- × Challenging enforcement environment and lack of border measures

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**3.25**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.38**
10. Term of protection	0.38
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.25
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**2.75**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**1.07**
32. Physical counterfeiting rates	0.16
33. Software piracy rates	0.41
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**3.00**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

TOTAL: 16.30

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Egypt's overall score increased from 30.18% (15.09 out of 50) in the eighth edition to 32.59% (16.30 out of 50) in the ninth edition. This reflects score increases on indicators 39 and 47.

Commercialization of IP Assets and Market Access

26. Barriers to market access: The Egyptian economy is generally free, non-discriminatory, and open to foreign investment. There are no general restrictions on foreign ownership or localization and local content requirements. Under Decree 184/2013, customs tariffs can be reduced based on the degree to which local content is used, but more broadly the sharing or divulging of IP and transfer of proprietary technology in exchange for market access are not part of the general policy environment or required by Egyptian law. With respect to data localization, there have been instances reported whereby the authorities have requested that data be kept locally in Egypt. However, there has not been a general data protection or localization policy in place. This may now be changing. In August 2020, the Egyptian president signed into law the Law on the Protection of Personal Data (Resolution No. 151 of 2020). The law imposes several new requirements, including the potential localization and local storage of data. Specifically, the law disallows the transfer of any data from Egypt to another legal jurisdiction unless, (1) the level of data protection is at least equivalent in the host jurisdiction as under the Egyptian law and, (2) the transfer has been approved by a new Egyptian regulatory authority, the Data Protection Authority. The law does not apply to any sector or area of economic activity supervised by the Egyptian Central Bank. It is unclear how these transfer requirements will be implemented. At the time of research, the Data Protection Authority had not yet been established and implementing regulations were not due to be published until the first quarter of 2021. For rights-holders across many different industries and sectors, these barriers to digital trade raise serious questions and concerns. The ICT and internet revolutions have fundamentally changed how people interact socially and economically. In virtually all industries, businesses and economic interaction are today being shaped by the collection of data and digital technologies. These technologies are allowing companies across all business sectors and public and private research organizations to collect and use greater levels of data and information than ever before in so-called "big data." Combined with increased computing capacity and the application of new technologies (such as artificial intelligence and machine learning) that allow people to analyze and better understand data collected is the possibility to make significant discoveries and breakthroughs in virtually any area of research and human socio-economic activity. Cross-border flows of data are ingrained in countless services relied on by consumers, with numerous digital, automated, and virtual services relying on the seamless movement and storage of data in various locations. Public policies relating to national data management should recognize this reality and be formulated accordingly. Mandating the local storage and processing of data is likely to lead to fewer digital services being available in Egypt and less innovation in many critical sectors. In conjunction with the signing of the law, Minister of Communications and Information Technology Dr. Amr Talaat stated that part of the purpose of the new legislation was to localize the data center industry. The Index will monitor these developments and the extent to which this new legislation seeks to mandate the localization of data and act as a barrier to international data transfers.

Systemic Efficiency

39. Coordination of IP rights enforcement: Egypt does not have an institution in the form of an IP office or directorate that centralizes the administration of IP rights. Instead, IP policymaking and the registration of IP rights is spread out over many different ministries and agencies that deal individually with different IP rights. Within this governing framework there is no designated body that is dedicated to the coordination of IP enforcement. Since 2014, an inter-ministerial committee (the National Committee on Intellectual Property Rights) has been in place. The purpose of this committee is to provide a central discussion point for IP policy across the government. In August 2020, Trade and Industry Minister Nevine Gamae announced that a Contact Point Organization (CPO) unit for IP rights within the ministry would be established and a stronger emphasis placed on cross-government coordination of IP policy. This body will be charged with sharing information with international counterparts and overseeing coordination and enforcement within Egypt as it relates to preventing the importation and exports of IP-infringing goods. The unit will include a dedicated staff toward research, training, information exchange, and arbitration. The CPO board will be charged to meet at least on a monthly basis, with representatives from several key ministries expected to participate. This is a positive step for Egypt in improving the ability of the government to oversee and coordinate IP policy more generally, as well as with respect to enforcement. As a result, the score on this indicator has increased by 0.25. The Index will continue to monitor the activities of the CPO unit in 2021.

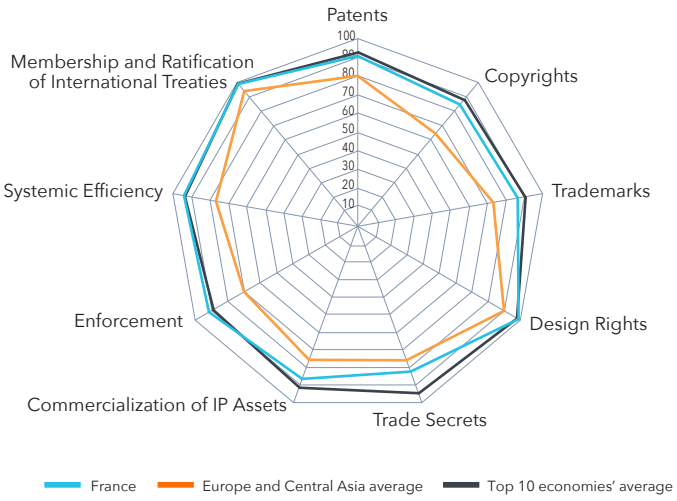
Membership and Ratification of International Treaties

Egypt's overall score on this category continues to improve, with Egypt in 2020 acceding to the International Convention for the Protection of New Varieties of Plants, Act of 1991. In July 2019, the Egyptian Parliament passed amendments to relevant sections of Law 82 with the view of making the law, and administering authority, compliant with the 1991 UPOV treaty. In December 2019, Egypt formally acceded to the 1991 Act and became a member of UPOV. As a result, the score on this category has increased by 1. Egypt is now a contacting party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Patent Cooperation Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; and the Hague Agreement Concerning the International Registration of Industrial Designs. Egypt is not a contracting party to the WIPO Internet Treaties, the Singapore Treaty on the Law on Trademarks, the Patent Law Treaty, or the Convention on Cybercrime. Finally, Egypt is a contracting party to the African Continental Free Trade Area, signed by 44 African countries in March 2018. The agreement holds the potential to fundamentally revolutionize economic activity in Africa by reducing barriers to trade and economic interaction across the entire continent. Parts of the Free Trade Area (Phase I) came into force in June 2019. In June 2020, as a result of the COVID-19 pandemic, the official launch and implementation of the agreed parts of the FTA were postponed until 2021. There was no official guidance or announcement regarding potential progress made on outstanding issues to be negotiated as Phase II of the agreement, including a Protocol on Intellectual Property.

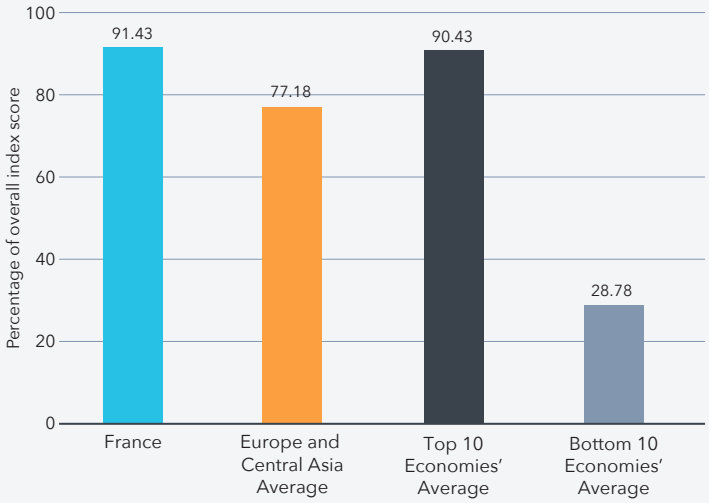
FRANCE

RANK 4/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Generous R&D- and IP-specific tax incentives in place through an R&D tax credit and special patent box tax rate (maximum of 17%) on income derived from qualifying licensing income and/or the sale of the patent or patentable technology
- ✓ Injunctive relief available and in use through court orders for the disabling of infringing content online
- ✓ Strong and sophisticated national IP environment

KEY AREAS OF WEAKNESS

- × Registration requirements for licensing agreements
- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to France's and EU's research- and IP-based biopharma industry

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**5.99**
10. Term of protection	0.74
11. Exclusive rights	0.75
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.50**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**6.47**
32. Physical counterfeiting rates	0.79
33. Software piracy rates	0.68
34. Civil and procedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 45.71

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

France's overall score has decreased slightly from 91.50% (45.75 out of 50) in the eighth edition to 91.43% (45.71 out of 50) in the ninth edition. This reflects a marginal decrease on indicator 32.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union handed down a verdict in the case *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rul-

ings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**." From a legal perspective, the court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers; ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still,

treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

France is in the process of implementing EU Directive 2019/790 on copyright and related rights in the Digital Single Market. At the time of research, only parts of the directive had been passed in Law 775, which amended the IP Code in 2019. This law established a neighboring right for press agencies and press publishers. Following the adoption of this law and a dispute between Google and press publishers in France, the French Competition Authority (*Autorité de la concurrence*) ordered Google to negotiate compensation for displaying content under its Google News application. Additional changes to the IP law (including transposing Article 17 of the law, the so-called "upload filter") are still pending. Originally part of a wider and separate legislative effort—the bill on Audiovisual Communication and Cultural Independence in the Digital Age—the transposition effort was, at the time of research, being proposed as individual decrees. The Index will continue to monitor these developments in 2021.

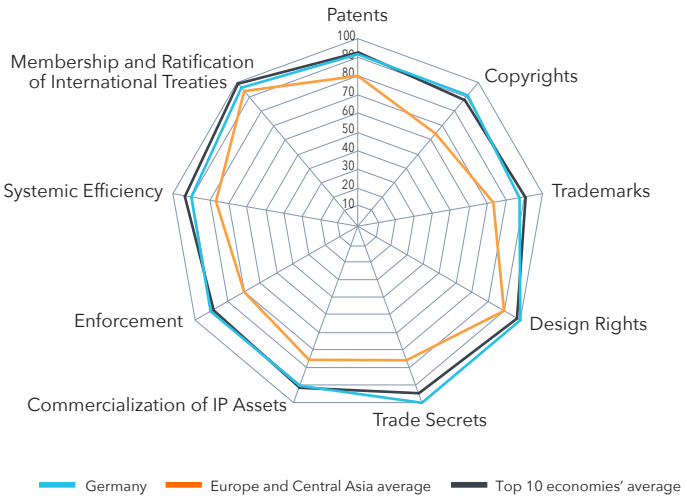
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking): The French government has since the late 2000s introduced several policies aimed at reducing online copyright infringement. In 2009, the government introduced a new set of anti-piracy laws and an enforcement agency, the *Haute Autorité pour la Diffusion des Oeuvres et la Protection des Droits sur Internet* (HADOPI). The HADOPI laws consisted of a graduated three-strikes response scheme that could lead to the disconnection of internet access for alleged copyright infringers. Academic research suggests that, subsequent to the introduction of these laws, music sales in France increased 20-25% relative to sales in other control-group countries. In July 2013, the French government announced significant alterations to the HADOPI laws. The threat of suspension of internet access for suspected repeat infringers was replaced by a graduated fining system. Since then, the agency has repeatedly been under attack. Dismantling HADOPI was first included in socialist presidential candidate Francois Hollande's electoral campaign agenda in 2012. An amendment to dismantle the HADOPI in 2015 was initially adopted by the French National Assembly but later removed by the French Senate. Most recently, the agency's powers had been questioned by several internet rights groups, including *La Quadrature du Net,* which argued that HADOPI's remit was unconstitutional and a violation of consumers' rights and privacy. In a May 2020 ruling, the French Constitutional Council found that HADOPI was allowed to continue its work, including to continue to obtain the identity of alleged copyright infringers. The council did find that some provisions of the IP Code defining the agency's powers did raise privacy concerns and should be repealed. The French government was given until the end of 2020 to amend or repeal these provisions. Despite these efforts to question the agency's remit and its legitimacy, the HADOPI has continued its work. Since 2011, the agency

has sent out a total of 12.7 million infringement notices. In 2019, almost 850,000 notices were sent out and close to 2,000 (1,748) cases were passed on to the prosecutor's office. While piracy levels in France remain relatively high, the agency found that the proportion of consumers accessing infringing forms of content declined in 2019 to 26%, while the proportion of consumers accessing lawfully obtained content increased from 44% in 2018 to 56% in 2019.

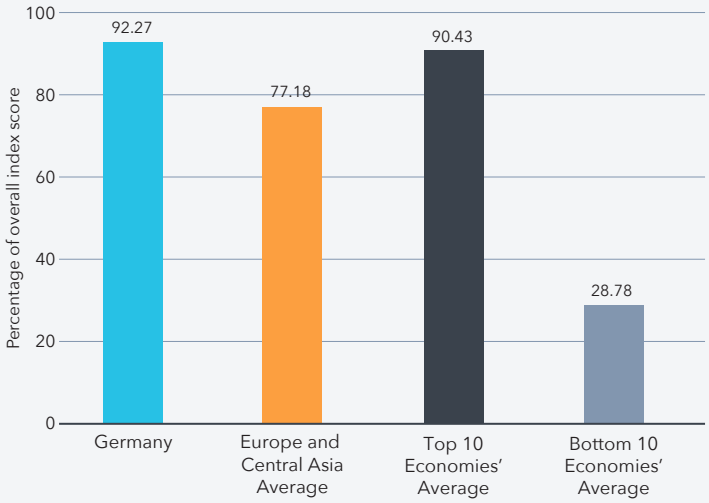
GERMANY

RANK
3/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ 2020 saw introduction of new R&D tax credits
- ✓ Advanced and sophisticated national IP environment
- ✓ Sector-specific IP rights in place
- ✓ Membership of all major international PPH tracks through the national patent office and EPO

KEY AREAS OF WEAKNESS

- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Germany's and EU's research- and IP-based biopharma industry
- × Patent Law Treaty signed but not ratified

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**6.38**
10. Term of protection	0.63
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.75
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.42**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**6.33**
32. Physical counterfeiting rates	0.78
33. Software piracy rates	0.80
34. Civil and procedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 46.13

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Germany's overall score has increased from 91.08% (45.54 out of 50) in the eighth edition to 92.27% (46.13 out of 50) in the ninth edition. This reflects a score increase on indicator 31.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union handed down a verdict in the case *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rul-

ings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**." From a legal perspective, the Court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still,

treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 13. Availability of frameworks that promote cooperative action against online piracy: As noted in the Index, the protection of online content in Germany is relatively strong. The Copyright Act provides authors with exclusive rights of reproduction, distribution, and exhibition. With regards to online infringement, Article 101 gives rights-holders the option of requesting an ISP to disclose the name and address of a subscriber suspected of infringing copyright. Although a court order is generally required for these details to be shared, German legal analysis suggests that most courts rule in favor of such requests. As in other EU Member States, German law has implemented the E-Commerce Regulations 2002 and applicable requirements of expeditious removal of any infringing material once an ISP has been notified or has received knowledge of any illegal activity. This is primarily through Articles 8-10 of the Telemedia Act. German case law has a long-established concept of *Stoererhaftung* (Breach of Duty of Care), which requires third parties (such as hosting providers) not only to expeditiously take down suspected content upon notification, but also to prevent the repetition of the specific infringement and other clearly recognizable infringements of the same form. While the case law is still evolving, several prominent cases have established these principles. They include, for instance, *Atari v Rapidshare*, 2012, for which the Federal Court of Justice ruled that Rapidshare (the host company) had a duty of care that extended to ensure that similar uploads of pirated files did not continue. Similarly, in a 2007 case involving eBay and the sale of counterfeit Rolex watches, the court ruled that the auction site had a duty of care not only for removing the infringing advertisements, but also to take measures to prevent future offers of infringement relating to Rolex. A long-running court case between music producer Frank Peterson and YouTube looks to set another important precedent. The dispute began almost 15 years ago with Peterson alleging that 36 music clips he had produced and claims to own the rights to have been uploaded and viewed on YouTube. The gist of the dispute is the extent to which YouTube, and by extension other internet intermediaries, can be held liable for the posting of infringing content on its platform. Peterson has argued that YouTube does have this responsibility and is liable for damages as it is indirectly profiting from the uploads through viewership, consequently depriving content creators and rights-holders, such as Peterson, from licensing income. The case has been running through the German lower courts over the past decade, with two judgments issued in 2010 and 2015, respectively, by the Hamburg District Court and Court of Appeal. In September 2018, the highest relevant court of law in Germany, the Federal Court of Justice (*Bundesgerichtshof*) was expected to issue a definitive ruling. Instead,

the court asked the European Court of Justice to examine the issue pertaining to EU law and specifically the meaning of three different EU directives: Directive 2001/29/EC On the Harmonization of Certain Aspects of Copyright and Related Rights in the Information Society; Directive 2000/31/EC On Electronic Commerce; and Directive 2004/48/EC On the Enforcement of Intellectual Property Rights. In July 2020, the CJEU's Advocate General, Henrik Saugmandsgaard Øe, issued a non-binding opinion on this case and the case *Elsevier Inc. v Cyando AG*. (The latter case touches on a similar set of legal principles—that is, the responsibilities and potential legal liabilities online service providers have for the content that is uploaded through and onto their platforms.) In a long discussion on the particulars of the cases and current EU and German law—the opinion made a point of **not** considering the new legal responsibilities under the pending transposition of the Digital Single Market (CDSM Directive), which is not due until June 2021—the opinion concluded that platforms could not be held directly liable for any potentially infringing content uploaded through their services. With regards to secondary liability, or any equivalent level of responsibility on part of the service providers, the Advocate General argued that this can be maintained only if the service provider has been served with "specific illegal information." The opinion also raised concerns over service providers becoming *de facto* judges over the legality of uploaded content and "over-removing" content. The Advocate General's opinion is not legally binding and does not represent the view of the full court. At the time of research, the CJEU's official opinion had not been published. Regardless of the ultimate outcome of these two cases, it is noteworthy that the rights-holders in question have been waiting for years to achieve redress for the alleged infringement: over a decade in the Peterson case and seven years in *Elsevier Inc. v Cyando AG*. The scale and speed of modern-day internet-based copyright infringement is such that new infringements take place by the hour. It is imperative that rights-holders can quickly and effectively achieve redress in cases in which their copyright is potentially being infringed. Today, most consumers in the EU own a smartphone and internet penetration is near universal. The growth and scale of online piracy since the early 2000s and advent of the internet—whether through downloading, streaming, or some other technology—has mirrored the growth in internet connectivity. This massive volume of online infringement has resulted in a growing strain on copyright holders. Rights-holders increasingly find themselves confronting a reality where there is limited practical recourse to take effective action against online infringement. Waiting for over a decade for a final court decision should not be viewed as acceptable. The Index will continue to monitor these developments in 2021.

Commercialization of IP Assets and Market Access

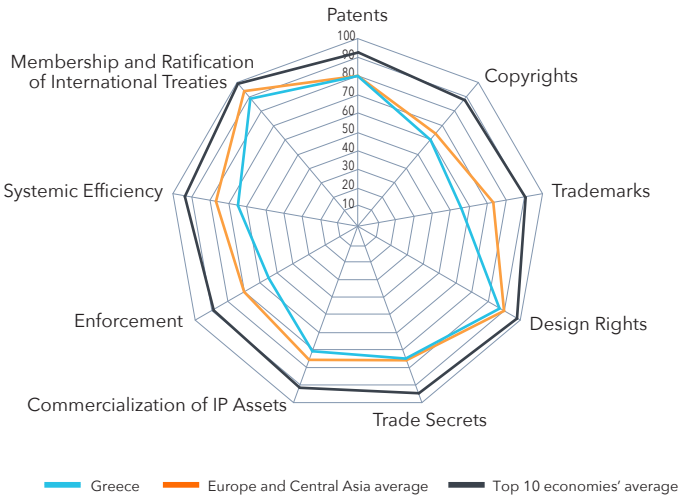
31. Tax incentives for the creation of IP assets: Historically, German tax law has not offered any R&D-based or IP-specific incentives. Instead, German R&D incentives have focused on non-repayable R&D grants. These grants normally make up 50% of a given project, with higher levels available for SMEs. Applications are made directly to the German federal government, which is now concentrating its R&D efforts and grants through the national innovation plan High Tech Strategy 2025 (*Hightech Strategie 2025*). Similar R&D grant schemes are available at the provincial and regional levels, with industry focus and eligibility requirements varying. In 2020, this changed with the coming into effect of a new R&D tax incentive law (*Gesetz zur steuerlichen Förderung von Forschung und Entwicklung*). The law was passed by the German Parliament in December 2019 and came into effect on January 1, 2020. The new law allows qualifying entities to be reimbursed a portion (up to 25%) of qualifying R&D expenditure. Initially, this incentive was

limited to a maximum of EUR500,000, but in June 2020 this was doubled as part of a fiscal stimulus package in response to the COVID-19 pandemic. Unlike in a growing number of economies around the world (including most recently Switzerland and Singapore), these legislative changes did not include any IP-asset specific innovation or patent box incentive. Still, this is a positive development and will strengthen Germany's already formidable innovation ecosystem. As a result of the introduction of this law, Germany's score on this indicator has increased by 0.67.

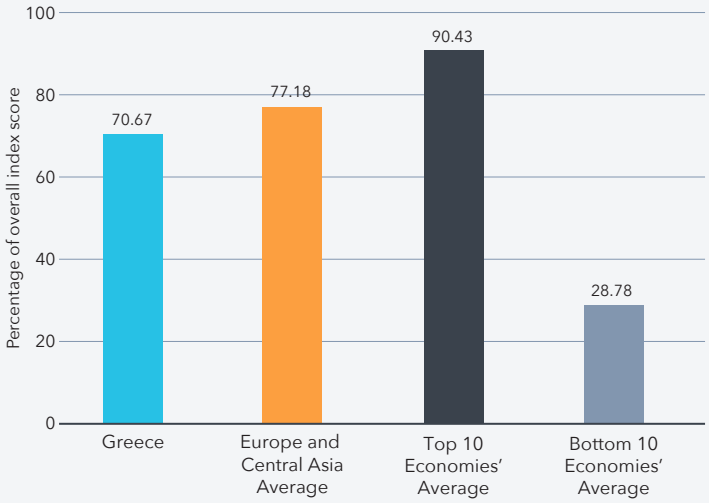
GREECE

RANK
18/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Continued strong efforts in 2020 on copyright enforcement through administrative relief and disabling of infringing websites, including introduction of dynamic injunctions
- ✓ Relatively strong national IP environment—Greece benefits from EU membership and being a contracting party to the European Patent Convention
- ✓ Many sector-specific IP rights in place
- ✓ Membership of all major international PPH tracks through the EPO

KEY AREAS OF WEAKNESS

- × Changes to compulsory licensing regime in 2019 out of line with international standards—introduce price considerations as a basis for issuing license
- × Historically, Greece has been home to high levels of online piracy
- × BSA estimated rates of the use of unlicensed software suggests that Greece has since 2011 had a remarkably high rate of software piracy for an EU and OECD Member State
- × Software piracy rate has consistently stayed between 61 and 63% (in 2018 it was an estimated 61%)—compares to an average estimated rate of 26% for the rest of Western Europe
- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Greece's and EU's research- and IP-based biopharma industry
- × Registration requirement for licensing deals in Greece

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**7.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**4.24**
10. Term of protection	0.74
11. Exclusive rights	0.50
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.75
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.25**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**4.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**3.84**
32. Physical counterfeiting rates	0.45
33. Software piracy rates	0.39
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**3.25**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.25**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 35.33

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Greece's overall score has increased from 70.10% (35.05 out of 50) in the eighth edition to 70.67% (35.33 out of 50) in the ninth edition. This reflects a score increase on indicator 12.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. In 2020 the Greek authorities, through Decision No. 33486, has instituted a formal procedure whereby prospective follow-on manufacturer's need to notify the OBI before the commencement of exempted manufacturing, export, and/or storage activity. Notification to the OBI is required three months ahead of manufacturing activity taking place and will be published by the OBI for public consumption through the agency's Special Bulletin of Industry Property. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over

the EU's SPC regime. In July, the Court of Justice of the European Union handed down a verdict in the case *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rulings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**". From a legal perspective, the Court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS an-

tiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still, treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

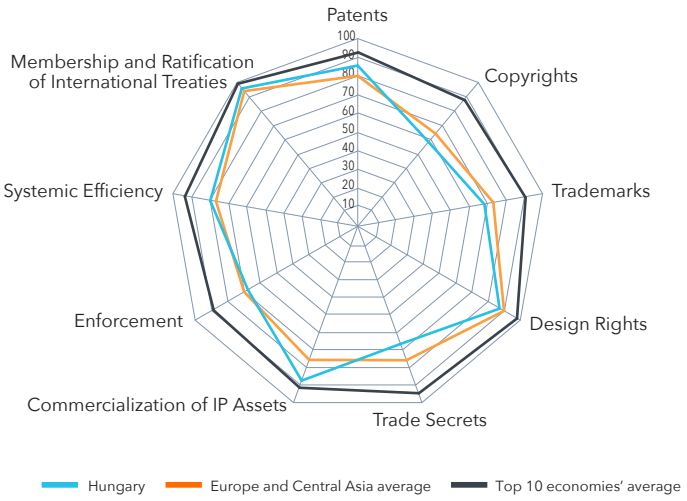
12. Expeditious injunctive-style relief and disabling of infringing content online: As noted in previous editions of the Index, rights-holders have long faced serious challenges defending and enforcing their copyrights in Greece. Historically, Greece has been home to high levels of online piracy, with limited to no practical remedial action available to rights-holders. For example, the BSA's estimated rates of the use of unlicensed software suggest that Greece has since 2011 had a remarkably high rate of software piracy for an EU and high-income OECD Member State. The rate has consistently stayed between 61 and 63% (in 2018 it was an estimated 61%). This compares to an average estimated rate of 26% for the rest of Western Europe. On unlicensed software, Greece is more comparable to economies outside of the EU in Asia, Latin America, and the Middle East and North Africa (MENA) region, where average rates of unlicensed software use are closer to 60%. Over the past few years, the Greek government has attempted to address some of these shortcomings with new legislation aimed specifically at combating online piracy. Article 52 of Law 4418/2017 set up what is essentially an administrative tribunal to review online copyright infringement cases, the "Committee for Online Copyright Infringement," which is housed under the Ministry of Culture and Sports. Under Article 52, the committee has the right to hear cases on alleged infringement and, where infringement is found, order the relevant parties and ISPs/internet mediators to remove and/or disable access to the infringing materials. Critically, the committee has the authority to order the disabling of access to infringing content within Greece even if the server/host is located outside of Greece. In November 2018, the committee issued its first substantive ruling, ordering the disabling of access to 38 websites enabling/hosting infringing content, including The Pirate Bay. These positive efforts continued in 2020 with both changes to existing legislation strengthening the powers of the committee and the continued disabling of infringing websites. At the time of research, the committee had made decisions and ordered that access to a total of 65 infringing websites be disabled. Unlike other economies where a similar injunctive-style relief mechanism has been established, in Greece there was no "dynamic" element to the disabling of access orders. In effect, infringing sites and hosts could simply change their domain names, forcing rights-holders to go through a similar process again. In July 2020, legislative amendments were passed addressing this deficiency. Under Article 25 of Law 4708/2020, the committee's powers have

now been expanded and include ensuring the prevention of "recurrence" of the infringing activity. In conjunction with the passage of the new amendments, the Ministry of Culture and Sports (the sponsoring entity of the new legislation) released a press release emphasizing the importance of this new dynamic capacity and powers granted to the committee. Minister Lina Mendoni said, "We have taken the necessary steps to ensure that the work of the artists is secured and that their copyrights are guaranteed. … The intellectual work of the creators is now being dynamically protected." The Greek government's actions are positive and should be applauded by rights-holders inside and outside Greece. As a result of these positive reforms and continued efforts by the committee, the score on this indicator has increased by 0.25.

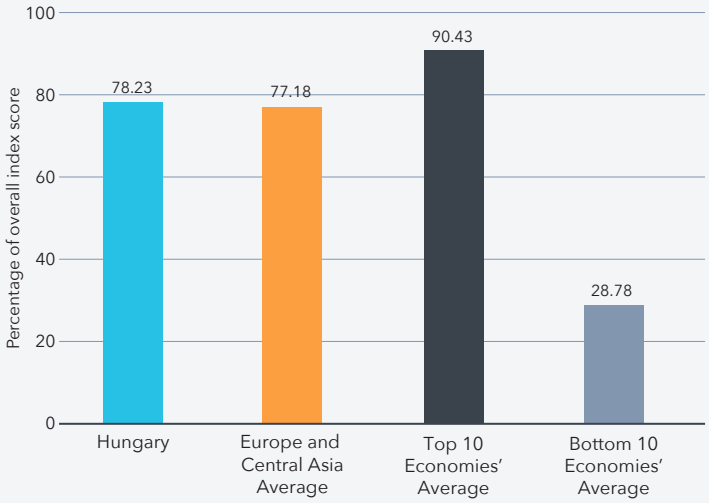
HUNGARY

RANK
15/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Transposed the EU Trade Secrets Directive into Hungarian Law in a new trade secrets law, Act LIV of 2018 on the Protection of Trade Secrets
- ✓ Generous R&D- and IP-specific tax incentives in place
- ✓ Fairly strong and sophisticated IP system conferred through EU membership
- ✓ Sector-specific IP rights in place
- ✓ Expanded emergency powers for compulsory licensing

KEY AREAS OF WEAKNESS

- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Hungary's and EU's research- and IP-based biopharma industry
- × Challenging enforcement environment—particularly with regards to online and digital content
- × Consultation mechanisms in place but time offered to make submissions relatively short

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**7.75**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	0.75
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**4.13**
10. Term of protection	0.63
11. Exclusive rights	0.50
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.75
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.00**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**4.74**
32. Physical counterfeiting rates	0.60
33. Software piracy rates	0.64
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.00**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 39.12

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Hungary's overall score has decreased slightly from 78.38% (39.19 out of 50) in the eighth edition to 78.23% (39.12 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In response to the COVID-19 pandemic, in May 2020 the Hungarian government issued Decree 212/2020, introducing an expedited compulsory licensing mechanism for biopharmaceuticals. This decree follows Act XII and the government's emergency powers to deal with the pandemic. The decree gives the Hungarian Intellectual Property Office (HIPO) the right to issue compulsory licenses to ensure the supply of any and all medical products (including biopharmaceuticals) needed to protect public health during the pandemic. The emergency nature of Decree 212 resulted in it effectively being repealed just over a month after it was issued on the basis that there was no longer a national emergency as the pandemic was viewed as being under control. However, the powers of granting a public health compulsory license as outlined in the decree were not eliminated. Unlike emergency powers granted in other economies (including France and Canada), these broad powers were not time limited. Instead, a new law, Act LVIII of 2020 on Transitional Rules Related to the Termination of State of Danger and on Epidemiological Preparedness, amended the Patent Act and, virtually verbatim, inserted the relevant compulsory license provisions of Decree 212 into the act. It is unclear why the Hungarian government felt the need to transpose these emergency powers into the Patent Act. In a separate development, a Hungarian manufacturer in October 2020 began producing a local version of the drug remdesivir for use in a local clinical trial. Registration data in the European Union Clinical Trials Register shows the trial is supported by the Hungarian government (the Ministry of Innovation and Technology through a consortium). It is unclear on what legal basis this research, manufacturing, and clinical trial is taking place. Industry sources suggests that a compulsory license was granted by the Hungarian authorities in November 2020. The basis of this license had, at the time of research, not been made public and it is not clear whether the Hungarian government had attempted to engage in any good faith negotiations on any alternative voluntary license with the rights-holder. Remdesivir is approved by the European Medicines Agency for emergency use in the EU through a conditional marketing authorization and is part of a Joint Procurement Agreement with the European Commission. As both TRIPS Article 31 and the Doha Declaration make clear, the issuing of a compulsory license represents a "measure of last resort." It is not clear that this is the situation in Hungary. Moreover, the European Commission recently re-validated its position via its Pharmaceutical Strategy and IP Action Plan, stating that CLs can only "be used as a means of last resort and a safety net, when all other efforts to make IP available have failed." The Index will continue to monitor these developments in 2021.

7. Patent term restoration for pharmaceutical products: 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 pro-

posal was to provide European manufacturers of generic drugs and biosimilars a competitive advantage by weakening IP protection for innovators. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union handed down a verdict in the case *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rulings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredi-**

ents as a medicinal product." From a legal perspective, the Court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins; zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still, treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

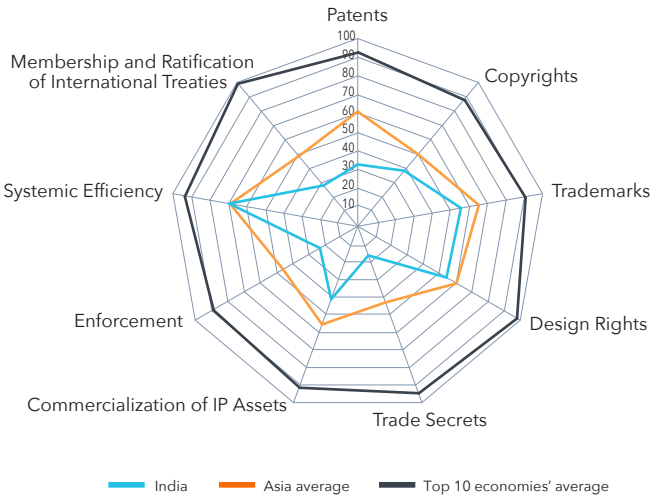
Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Digital rights management (DRM) legislation: Protecting copyrighted material—especially from online piracy—has long been a challenge for rights-holders in Hungary. Article 77 of the revised Criminal Code states that criminal material disclosed through an electronic communications network shall be rendered irreversibly inaccessible. Although this article does apply to cases of IP rights infringement, there is not much case law on the issue. The Hungarian E-Commerce Act provides a clear and timely notification and takedown procedure, whereby ISPs have 12 hours to remove the allegedly infringing content, as well as safe harbor mechanisms for ISPs. Although the original formulation refers mostly to copyright infringement, ISP liability has also been viewed from a broader societal perspective, including with respect to defamatory and hateful content. Injunctive relief against copyright-infringing content online is available under Law 78 (2013). Hungarian legal analysis suggests that national courts have the right to order the disabling of access to copyright-infringing content, but there is currently limited case law on the issue. The National Media and Infocommunications Authority maintains a "black list" of restricted content that is currently unavailable in Hungary. Yet it is unclear the extent to which copyright-infringing websites are being restricted, as mainly websites linking to inflammatory content (including Holocaust denial) and online gambling have been disabled. For example, in 2016, access to over 60 online gambling websites was disabled. More broadly, with respect to copyright enforcement, surveys and academic research suggest that Hungary has one of the highest rates of copyright infringement of all EU Member States. For example, even though the Copyright Act sanctions all major aspects of TPM circumvention and DRM alteration (Articles 95 and 96), academic research suggests that Hungary makes up a disproportionate share of global video game piracy. According to a study on bit torrent use conducted by academics from Aalborg University, the University of Waterloo, and Copenhagen Business School, Hungary was a top-5 country with the highest video game piracy user rate as a percentage of its population. Hungary is currently in the process of implementing EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive). Only parts of the CDSM Directive have so far been transposed into Hungarian law. Specifically, new exceptions relating to digital media usage in education were transposed through Copyright Act amendments passed in June 2020. At the time of research, the Ministry of Justice and HIPO had published a draft set of amendments transposing the remaining provisions and were holding a public consultation. The Index will continue to monitor these developments in 2021.

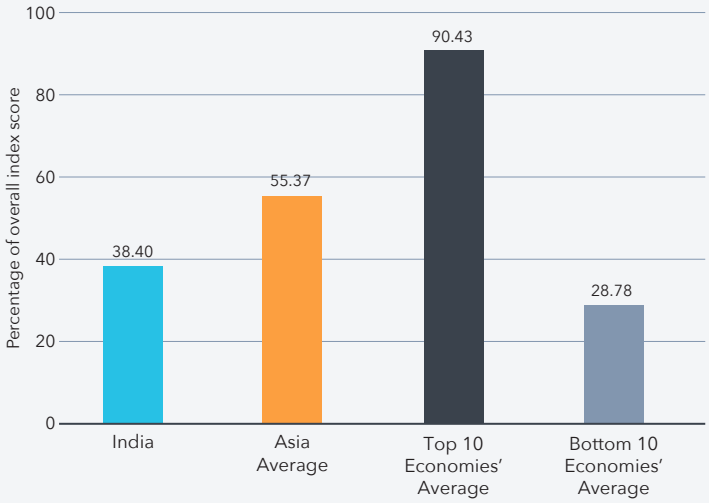
INDIA

RANK
40/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ New streamlined Form 27 in 2020
- ✓ Continued strong efforts on copyright piracy through 2019 issuing of "dynamic" injunction orders
- ✓ Precedent case law in 2019 on online trademark infringement and damages
- ✓ PPH program with the JPO is a positive step
- ✓ Generous R&D- and IP-based tax incentives
- ✓ Global leader on targeted administrative incentives for the creation and use of IP assets for SMEs
- ✓ Strong awareness-raising efforts on negative impact of piracy and counterfeiting

KEY AREAS OF WEAKNESS

- × Barriers to licensing and technology transfer including strict registration requirements
- × Limited framework for the protection of biopharmaceutical IP rights
- × Patentability requirements outside international standards
- × No RDP available or patent term restoration for biopharmaceuticals
- × Lengthy pre-grant opposition proceedings
- × Previously used compulsory licensing for commercial and non-emergency situations
- × Limited participation in international treaties

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**2.99**
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.75
4. Plant variety protection	0.74
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**2.72**
10. Term of protection	0.47
11. Exclusive rights	0.50
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.00
15. Digital rights management	0.25
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**2.50**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**1.64**
32. Physical counterfeiting rates	0.22
33. Software piracy rates	0.42
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 19.20

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

India's overall score has decreased slightly from 38.46% (19.23 out of 50) in the eighth edition to 38.40% (19.20 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Trade Secrets and the Protection of Confidential Information

23. Protection of trade secrets (civil remedies); and 24. Protection of trade secrets (criminal sanctions): As has been noted in previous editions of the Index, Indian statutory law does not provide specific protection for trade secrets or confidential information for civil or criminal infringement. The current applicable legal reference point is the 1872 Contract Act and existing case law. With respect to criminal infringement, the Information Technology Act 2000 provides limited potential recourse and only in relation to computer-related offences such as the unauthorized access to computer systems, accessing of data, and hacking. While common law does provide a measure of protection, and there is some judicial precedent, overall, rights-holder's ability to effectively enforce and protect their trade secrets in India is limited. This lack of adequate protection has been recognized by the Indian government. For example, the National Intellectual Property Rights Policy, released by the Ministry of Commerce and Industry and the Department of Industrial Policy and Promotion in May 2016, emphasized the need to introduce a legislative framework for the protection of trade secrets and confidential information. The negative impact of the lack of a statutory legal framework for trade secrets and confidential information came to the fore in early 2020. In the case *Prof Dr. Claudio De Simone & ANR v Actial Farmaceutica Srl*, the Delhi High Court held, in effect, that a trade secret, in itself, (1) is not an asset or form of property under Indian law and (2) cannot be held in conjunction with a granted patent right. In a complex case involving the licensing of a bacterial formulation used as a medical and dietary drug (for which a U.S. patent had been granted and subsequently expired) and claims of unfair competition, the judge stated that no right of action was available to the plaintiff as no defined property right existed under Indian law for trade secrets or confidential information: "The question which thus emerges is, whether an invention which does not qualify as patented product and has no property right therein, can acquire property rights by the third person entering into an agreement of exchange of Know-How and thus claiming confidentiality. In my opinion, no … confidential information and trade secrets are not equated to property in India." The judgment further argued that for any invention which a patent had been granted—in India or elsewhere—there could exist no separate know-how or trade secrets as, per definition, a patent application must include a full and detailed description of the invention including any, and all, proprietary know-how and trade secrets. Consequently, in the judgment's logic, once a patented invention's term of protection had expired, there could no longer exist any proprietary know-how or trade secrets as any trade secrets or know-how in relation to this patented invention must have been revealed in the corresponding patent application. Given that a patent for the disputed formulation had been granted in the United States and exclusivity had subsequently expired there was, in the court's view, no trade secret or confidential information to protect: "Since the plaintiffs have no subsisting patent protection in India, and since the patent based in US has expired, the innovation, as noted above, is in public domain. Hence, the claim for trade secret protection falls and the defendants cannot be restrained from manufacturing the product, in spite of the Know-How Agreement, as otherwise it would amount to judicial creation of an extra-statutory monopoly for perpetuity in the invention,

in contrast to the scheme of Patent Act, 1970 that seeks to bring an invention to public domain after the expiry of the term of the patent, and which is opposed to public interest as well as to judicial discipline." While even under existing Indian law the reasoning and logic of the judgment can be questioned, the bigger issue in India that this case illustrates is the lack of clear statutory law providing adequate levels of protection for trade secrets and confidential information.

Commercialization of IP Assets and Market Access

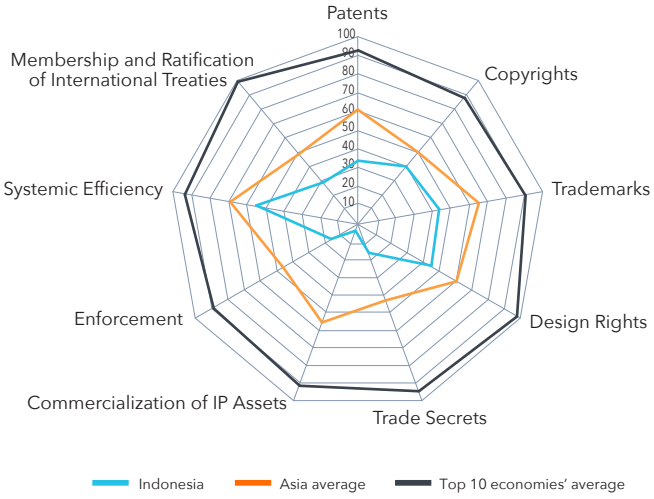
26. Barriers to market access: India has historically limited access to its domestic market through various barriers, localization requirements, and procurement preferences. More broadly, foreign investment is restricted with government approval and/or foreign ownership restrictions and partnership requirements in place for industries ranging from media and the audiovisual sector to insurance, banking, and food retail and trading. These barriers and requirements have intensified in the past few years as part of the "Make in India" campaign. Various government ministries and departments, including the Department of Industrial Policy & Promotion (DIPP), the Ministry of Electronics and Information Technology, and the Ministry of Chemicals and Fertilizers, have issued orders specifying the amount of local content required for public procurement. In May 2019, the DIPP issued a revised order, "Public Procurement (Preference to Make in India)," specifying the procedures and standards applied to all central government purchases that should provide preference to local suppliers and minimize the use of foreign vendors. The order reiterates that minimum content levels should be 50% with a margin of purchase preference for local suppliers of 20%. With regards to IP, these procurement and local content requirements are sometimes also used as a route to acquire proprietary technologies. For example, under the May DIPP Order, an exemption from the local content requirement will be provided on the basis of transferring proprietary technologies to a local partner. Specifically, Paragraph 13 states an exemption can be granted if there is an agreement to transfer technology and build and develop a local capacity. Similarly, the draft Personal Data Protection Bill, published in December 2019, contains several localization provisions mandating the local storage of data. For example, sections 33 and 24 of the bill mandate that "sensitive" and "critical personal" data shall both be stored geographically in India, and the latter, in addition, is only to be "processed" within India. There is no definition of what constitutes "critical personal data." In chapter 1 of the law, sensitive data is broadly defined and encompasses data pertaining to financial and health records to sexual orientation, religious beliefs, genetic data, and a host of other personal identifiers. Furthermore, section 15 allows the authorities to provide further definitions of sensitive personal data in future implementing regulations. With respect to "critical personal data," sub-section 33(2) simply leaves it at the discretion of the government to define what constitutes such data: "such personal data as may be notified by the Central Government to be the critical personal data." The draft bill imposes substantial sanctions on non-compliance. Specifically, non-complying entities that transfer or process data outside of India can, under section 57(2)(d), be fined up to 4% of their total global revenue. The bill echoes existing measures in place with respect to payments data. In April 2018, the Indian central bank, the Reserve Bank of India, issued the "Notification on Storage of Payment System Data (Data Storage Requirement)." The notice requires all payment service providers to store relevant Indian payment and transaction data locally in India. The Index will continue to monitor these developments in 2021.

28. Registration and disclosure requirements of licensing deals: Registration of patent licenses is mandatory under the Patent Act. Articles 68 and 69 outline the basis and requirements of registration. As part of these requirements, rights-holders must submit all details of a given licensing agreement, including the fully executed contract. Contract details and commercially sensitive information will be kept confidential only upon request from the registering parties. The failure to register a license may result in the agreement being 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...v 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." As noted in previous editions of the Index, there is also the issue of Form 27 for patents. This form requires that patent holders annually provide information on the extent to which a granted patent has been worked on by patentees and licensees. Part of the submission and documentation submitted pertains to the patent's value and commercial scale. There has historically been much uncertainty about what the relevant authorities will choose to disclose, as publication of Form 27 is at the authority's discretion; fines for non-compliance remain high. After a long-running court case in 2018, the Government of India (GOI) invited stakeholder feedback on potential changes to the form and submission process. In October 2020, a new Form 27 was finalized and published. This is, overall, a positive change. The new form removes questions pertaining to licenses, and it is now possible to file one form for several patents pertaining to the same invention. Still, the form does retain questions relating to the approximate value as either manufactured or imported into India. On this basis, while it is indeed a positive step that this administrative requirement has now been better streamlined and potentially slimmed down, it still imposes an unnecessary burden and additional bureaucracy on rights-holders.

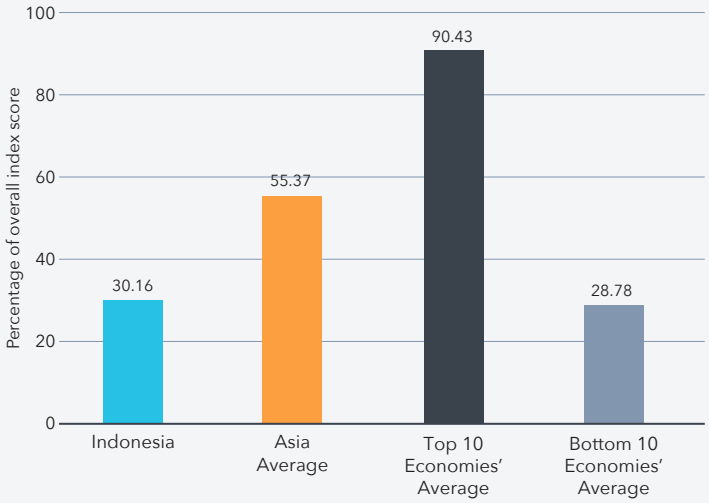
INDONESIA

RANK
48/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Omnibus Job Creation Bill 2020 draft eliminates general technology transfer and localization requirement of 2016 Patent Act
- ✓ PPH in place with JPO
- ✓ Administrative relief available for copyright infringement online
- ✓ Good cabinet-level coordination and coordinating framework for IP enforcement

KEY AREAS OF WEAKNESS

- × Significant barriers in place for licensing and commercialization of IP assets, including technology transfer
- × Biopharmaceutical patentability standards outside international norms
- × History of using compulsory licensing for commercial and non-emergency situations—2018/19 Regulations go far beyond the stated goals and circumstances for the issuing of compulsory licenses under the TRIPS Agreement
- × Presidential Regulation No. 77, of 2020 expands compulsory licensing and emergency use provisions further
- × Challenging copyright environment with high levels of piracy, as administrative measures do not address mirror and linking sites
- × Limited participation in international IP treaties

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**3.00**
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.77**
10. Term of protection	0.52
11. Exclusive rights	0.25
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**0.25**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.00
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.25
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**1.16**
32. Physical counterfeiting rates	0.24
33. Software piracy rates	0.17
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 15.08

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Indonesia's overall score has decreased slightly from 30.24% (15.12 out of 50) in the eighth edition to 30.16% (15.08 out of 50) in the ninth edition. This reflects a marginal decrease on indicator 32.

Patents, Related Rights, and Limitations

2. Patentability requirements: Indonesia's patenting environment has been marred by deep uncertainty and several negative legislative developments over the past half-decade. In 2016, the Indonesian Parliament passed a new wide-ranging patent law (Law 13 2016). While aiming 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. Article 4 inserted a new heightened efficacy requirement targeting biopharmaceutical products and outlawed second-use claims. Article 167 allowed the parallel importation of follow-on products under patent protection in Indonesia but approved for consumption in other markets. Finally, Article 20 of the 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. Sub-section (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. In July 2018, long-awaited Patent Regulations were published aiming to provide clarity on what Article 20 meant in practice. The regulations affirmed the meaning and intent of the original act that the "making" of a patent was 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. On a more positive note, the regulations did provide the possibility of indefinitely postponing these requirements. In 2019, the government announced that it would be issuing new regulations. However, instead of revised regulations the Indonesian government in February 2020 proposed fresh amendments to the Patent Act. In a reversal from its previous stance, the proposed amendments—as part of a sprawling legislative package, the Omnibus Job Creation Bill (*Undang-Undang (RUU) Omnibus Cipta Kerja*)—simply delete Article 20 of the 2016 Patent Act. Although unexpected, the removal of this article would be a positive step and help alleviate some of the uncertainty with respect to Indonesia's patenting environment. The Index will continue to monitor these developments in 2021.

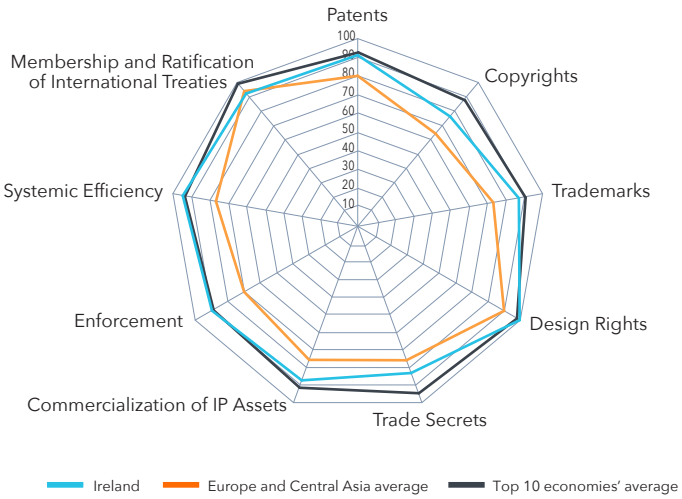
6. Legislative criteria and use of compulsory licensing of patented products and technologies: The Indonesian government has since the mid-2000s issued nine "government use" compulsory licenses overriding existing biopharmaceutical patents, primarily for hepatitis and HIV drugs. These licenses allowed the government to exploit existing patent-protected products in the event of threats to national security or an urgent public need. As noted in past editions, both the manner in which these licenses were issued and their justification were in contradiction of Article 31 of the TRIPS Agreement. The 2016 amendments to the Patent Act (see above discussion under Indicator 2) included changes with respect to compulsory licensing, expanding a regime that was already outside international standards and highly permissive. In December 2018, new Implementing Regulations (Regulation 38/2018) were released outlining the process and circumstances under which compulsory licensing could take place. These regulations go far beyond the stated goals and circumstances for the issuing

of compulsory licenses under the TRIPS Agreement. Specifically, the regulations allow the relevant authorities broad sway to issue a compulsory license when a patent has not been manufactured in Indonesia within a period of three years of grant or if the patent has been used in a manner that is viewed as detrimental to the public interest. It appears not only that these regulations insert a local manufacturing requirement as a prerequisite for **not** issuing a compulsory license, but also that there is no indication of what is meant by actions detrimental to the public interest. In 2020, there were further developments with the issuing of a new Presidential Regulation, Number 77 2020, on July 7 (*PERATURAN PRESIDEN REPUBLIK INDONESIA NOMOR 77 TAHUN 2O2O TENTANG TATA CARA PELAKSANAAN PATEN OLEH PEMERINTAH*). The new regulation describes the circumstances and process under which government use of patented technologies is allowed. Specifically, it relates to use of patented technologies and the overriding of any granted patent exclusivity in the event of a public emergency (including, but not limited to, a public health crisis) and for purposes of defense and national security. Article 13 and sub-sections (a), (b), (c), and (d) outline the non-national security/military emergencies that would allow the government to use the powers granted under the law. These include medicines and biotechnology products to be used in the event of public health emergencies, veterinary and agricultural biomedical/biotechnology products, and a rather broad condition relating to any "processes/products to overcome natural disasters and/or environmental disasters." The latter seems to encompass any and all patented products and processes that would be used in any type of natural or environmental disaster. With respect to the government use and overriding of patents for medicines and biopharmaceutical products, sub-section (a) explicitly states that this can be justified not only during a public health crisis, such as the current COVID-19 pandemic, but based on cost and specifically for "pharmaceutical products and/or biotechnology that are priced expensive" [sic]. The Presidential Regulations do not provide affected rights-holders the ability to appeal government-use decisions made. Unlike similar emergency measures that have been introduced around the world in response to the COVID-19 pandemic (including, for example, in Canada and Germany), the regulation does not include any defined timeframe or suitable sunset clause as the pandemic subsides. Instead, the broad nature and scope of the regulation suggest it will become a permanent feature of Indonesian law. The new regulation also poses an immediate threat to current treatments and vaccines in development to address COVID-19. This entails serious opportunity costs for future industry collaboration and investment. Before issuing government-use licenses, the Indonesian government should first engage with rights-holders to discuss available access strategies, including voluntary licensing, already underway in the country. The Index will monitor the application and use of these new powers in 2021 and beyond.

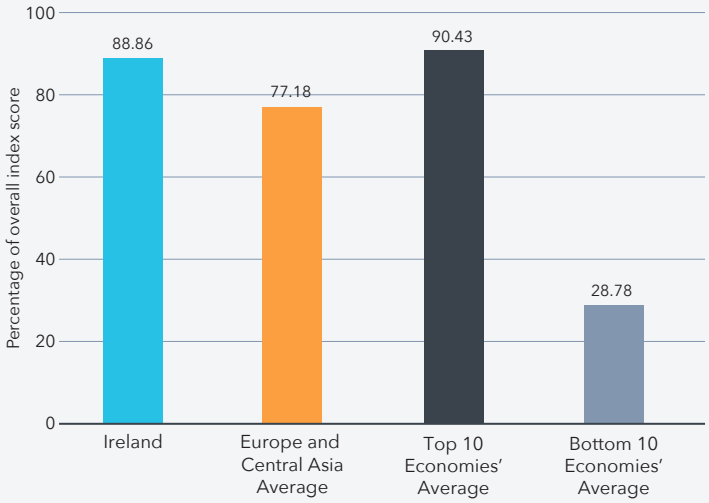
IRELAND

RANK
8/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Transposition in 2018 of EU Trade Secrets Directive through EU (Protection of Trade Secrets) Regulations 2018 (No. 188 of 2018)
- ✓ Generous R&D- and IP-specific tax incentives
- ✓ Strong and advanced IP system with robust protection of all major IP rights, including sector-specific protection
- ✓ Judicial mechanism for notifying online copyright infringers and disabling access to infringing content online

KEY AREAS OF WEAKNESS

- × Licensing registration requirements
- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Ireland's and EU's research- and IP-based biopharma industry

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**5.38**
10. Term of protection	0.63
11. Exclusive rights	0.75
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	0.75
15. Digital rights management	0.75
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.50**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**6.30**
32. Physical counterfeiting rates	0.84
33. Software piracy rates	0.71
34. Civil and procedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 44.43

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Ireland's overall score has decreased slightly from 88.98% (44.49 out of 50) in the eighth edition to 88.86% (44.43 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union handed down a verdict in the case *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rul-

ings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**." From a legal perspective, the Court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still,

treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

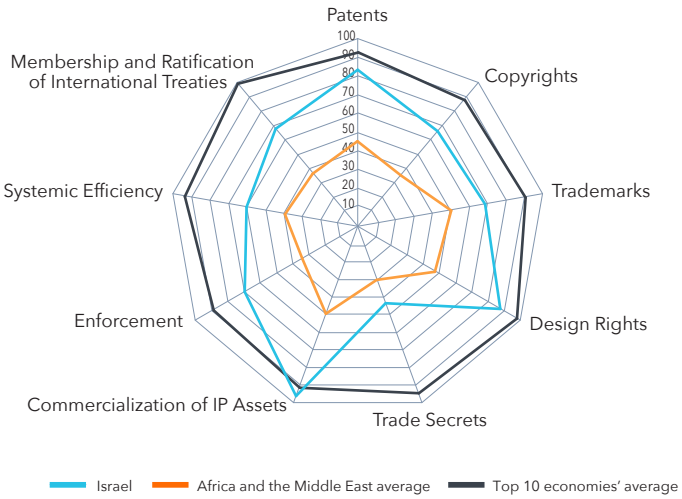
Commercialization of IP Assets and Market Access

27. Barriers to technology transfer: Ireland places a high value on the transfer of technologies and the commercialization of IP assets with a strategic policy environment in place focusing on providing generous incentives for public-private collaboration. The National IP Protocol (first drafted in 2012) was updated in 2016 following a consultation process led by Enterprise Ireland and Knowledge Transfer Ireland. The protocol provides a framework for companies and Research Performing Organizations on norms for research-related IP agreements. The protocol clearly spells out IP arrangements for research projects funded publicly, privately, or jointly by private and public entities. The national technology transfer system is well developed with many support programs in place, including Innovation Vouchers, the Technology Gateway Program, and the Technology Transfer Strengthening Initiative (TTSI). The TTSI was introduced in the mid-2000s and sought to professionalize the technology transfer system in higher education. It has been highly successful, with rates of licensing, start-up activity, business partnerships, and income for higher education institutions all up significantly since its launch. Knowledge Transfer Ireland's annual survey of universities and higher education institutions found that, in 2019, over 2,000 new contracts and research collaborations were concluded, over 200 licensing agreements were signed, almost EUR3 million in licensing income to Irish institutions; and 123 spin-off companies were actively employing around 1,000 people. A mere generation ago, few would have pointed to Ireland as a future high-tech powerhouse. Ireland was a middle-income economy with a per capita income 30-50% less than in developed OECD economies like the United States and Switzerland and lower than the United Kingdom's. Today, Ireland has a per capita income that is one of the highest in the world and almost double that of the United Kingdom. The Irish government has through concerted efforts successfully built an R&D-based, export-driven economy. Looking at concrete economic outputs in high-tech enterprises, Ireland has over the past three decades become a global leader and model of how to build high-tech manufacturing and R&D capacity, particularly in the most R&D-intensive sectors such as ICT and biopharmaceuticals. In 2019, the ICT sector in Ireland employed close to 40,000 people and generated EUR35 billion in exports. Similarly, the biopharmaceutical industry makes a huge contribution to the Irish economy, employing 25,000 people directly and an additional 25,000 indirectly. Ireland is the second biggest net exporter of drugs in the EU after Germany, and biopharmaceuticals account for about 25% of national exports.

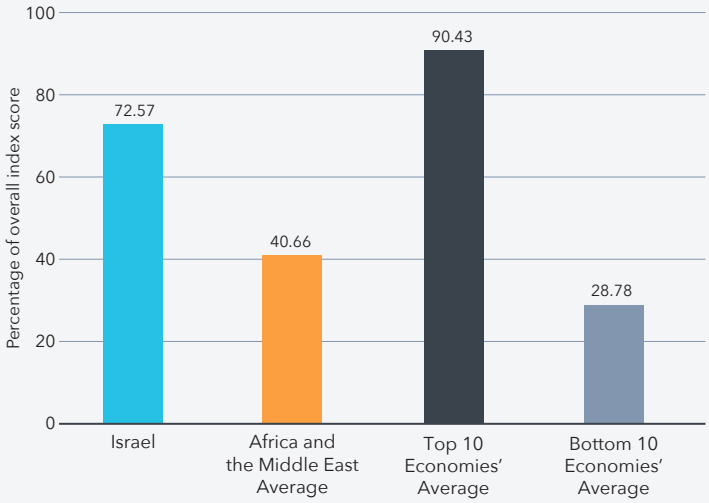
ISRAEL

RANK
17/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Copyright amendments of 2019 strengthen enforcement against online infringement—introduce possibility of injunctive-style relief
- ✓ Global leader in technology transfer and international licensing activity—no administrative or regulatory barriers in place
- ✓ Generous R&D- and IP-specific tax incentives in place
- ✓ Israeli Patent Office active participant in all major PPH tracks
- ✓ Life sciences IP rights reform efforts have considerably strengthened Israel's IP environment
- ✓ New industrial design law passed in 2017
- ✓ Joined Hague Agreement in 2019

KEY AREAS OF WEAKNESS

- × Issuing of compulsory license in 2020 in response to COVID-19 pandemic
- × Current pre-grant patent opposition proceedings are characterized by long delays to patent prosecution
- × Unclear the extent to which current RDP applies to large-molecule products

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**7.50**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**4.63**
10. Term of protection	0.63
11. Exclusive rights	0.75
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	1.00
15. Digital rights management	0.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**2.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**1.30**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.00
25. Regulatory data protection term	0.30

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**4.86**
32. Physical counterfeiting rates	0.63
33. Software piracy rates	0.73
34. Civil and procedural remedies	0.75
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.00**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**4.75**
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

TOTAL: 36.29

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Israel's overall score has decreased slightly from 72.76% (36.38 out of 50) in the eighth edition to 72.57% (36.29 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Patents, Related Rights, and Limitations

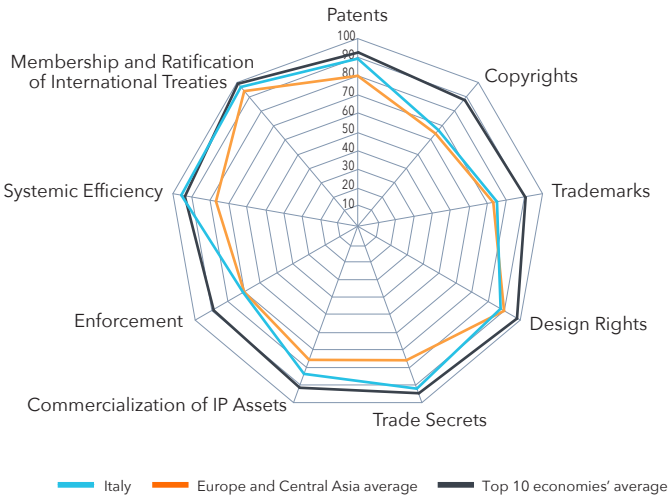
6. Legislative criteria and use of compulsory licensing of patented products and technologies: Biopharmaceutical rights-holders have historically faced a challenging IP environment in Israel. Developing a strong, self-sufficient generics industry to meet security and public health needs was for decades a key component of Israeli economic and industrial strategy, with IP protection viewed as a secondary priority. In the 1960s, Israel modified its Patent Law (5727-1967) to permit the domestic manufacturing of generic versions of patent-protected pharmaceutical products that were not marketed in Israel. In the 1990s, additional amendments to the Patent Law explicitly allowed for the use of innovators' confidential test data for commercial purposes. In 2005, another patent amendment added burdensome conditions that rendered the option of receiving a period of patent term restoration for biopharmaceuticals nearly impossible. Similarly, a change to the Pharmacist's Ordinance allowed the Israeli Ministry of Health to rely on innovative companies' confidential test data in approving follow-on products for domestic registration and export. More broadly, the regulatory environment for biopharmaceuticals—with respect to both patent prosecution and sanitary registration—was highly challenging. A shortage of qualified personnel and excessive bureaucracy led to long backlogs: the prosecution of pharmaceutical patents took four years on average and market registration for new products also took years. These challenges were compounded by an active compulsory licensing regime. During the early to mid-1990s, compulsory licenses were frequently granted by Israeli courts. This began to change after 1995, and no compulsory license had been granted in Israel since it acceded to the TRIPS Agreement. Under the current Patent Law, compulsory licenses can, generally, be granted only in cases in which there is an abuse of monopoly. Under sections 117-128 of the Law, the Patent Registrar has the authority to grant a compulsory license when "the exercise of a monopoly conferred by a patent shall be deemed abusive." The law specifies that such an abuse exists when the invention or related product or process is not meeting existing demand in Israel or being supplied or licensed in a fair and reasonable way. Sections 122-127 outline the process of the granting of a license and existing remedies available to the rights-holder, including the ability to challenge a decision in court. Although this is the primary route for the issuing of compulsory licenses, the Patent Law also provides emergency use powers under sections 104 and 105. In contrast to the provisions under sections 117-128, the powers granted under sections 104 and 105 are broad and essentially allow the government to override any existing patent in the event of a national emergency or national security crisis: "The Minister may permit the exploitation of an invention by Government departments or by an enterprise or agency of the State, whether a patent for it has or has not already been granted or has or has not already been applied for, if he finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services." Under these provisions, a rights-holder has no ability to challenge the decision or access to a recourse mechanism and any royalties to be paid are ultimately set by a government-appointed body. Up until 2020, these powers had never been used. In March 2020, during the height of the COVID-19 pandemic, the Israeli government authorized the issuing of a compulsory license for the antiviral drug lopinavir/ritonavir. In accordance

with sections 104 and 105, a license was issued to import generic product from India when no exclusivity for the drug is in place. The basis for the decision was that, first, the Israeli Ministry of Health viewed the drug as a potential treatment against COVID-19, and, second, that the manufacturer was viewed as not being able to meet potential domestic demand. The severe and sudden impact the COVID-19 pandemic is having on public health around the world means that, in effect, the conditions of the potential issuing of a compulsory license are being met in many economies, including Israel. The pandemic poses a clear and present danger to public health all over the world. However, unlike past experiences with compulsory licenses or public health emergencies, there was no globally recognized treatment or vaccine for the condition in question at the time the license was issued. When the license was issued, there was limited clinical evidence that lopinavir/ritonavir would be an effective treatment against COVID-19 and justify the use of such an extreme measure. Subsequent to the issuing of the license and importation of generic product from India, there is also no publicly available information that suggests that the generic product was ever used by the Israeli authorities or distributed to COVID-19 patients. While TRIPS Article 31 and the Doha Declaration are clear that compulsory licensing represents a "measure of last resort" intended primarily for public health and humanitarian emergencies such as the COVID-19 pandemic, it is regrettable that the Israeli government was unable to reach an alternative solution that did not involve the overriding of IP rights. Israel has made substantive progress over the past decade in strengthening its national IP environment for biopharmaceuticals and has become a model for other economies seeking to build their research-based industries. Following a 2010 Memorandum of Understanding with the United States, Israel carried out significant improvements in key areas of biopharmaceutical IP protection, including in relation to regulatory data protection, patent term restoration, and legal remedies for infringement. Specific improvements included changes to the Patent Law and the provision of RDP through amendments to the Pharmacist's Ordinance. As a result, Israel has become a global leader in biopharmaceutical R&D. Twenty years ago, the innovative research-based biopharmaceutical sector consisted mainly of research organizations and early-stage companies focused on licensing out technologies, with little development and commercialization of biopharmaceuticals and biomedical technologies in Israel. Since the IP policy reform efforts, biopharmaceutical foreign direct investment into Israel has surged, growing over 250% between 2010 and 2014. It is important to note that the IP reforms have not had a negative impact on the domestic generics industry. Contrary to common perceptions and perceived wisdom, providing a supportive environment for innovative activities in the life sciences (including a robust IP regime) has not hurt Israel's generic drugs industry, including its national champion, Teva. Israel has fought hard to strengthen its national IP environment over the past 10 years. It remains to be seen whether the use of compulsory licensing during the COVID-19 pandemic was a one-off or a new, negative policy departure. The Index will continue to monitor these developments in 2021.

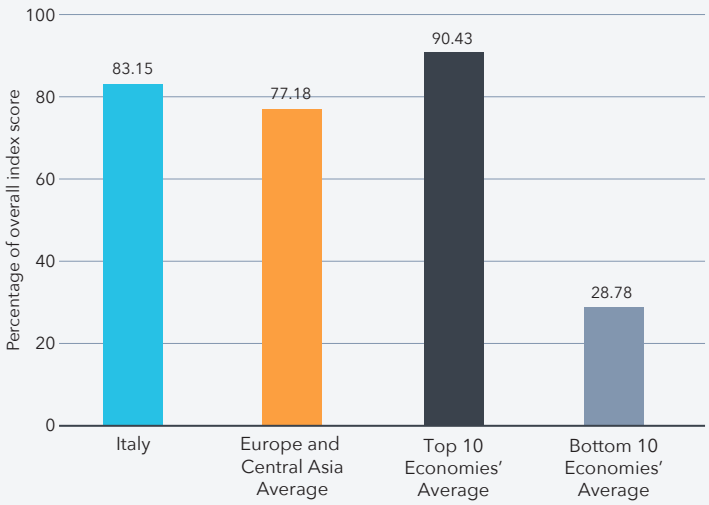
ITALY

RANK
13/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Generous R&D- and IP-specific tax incentives in place
- ✓ Fairly advanced national IP framework
- ✓ Major life sciences IP rights in place
- ✓ Administrative and judicial mechanisms for addressing online copyright infringement
- ✓ Public consultation during policy formation and efforts to raise awareness of IP importance present

KEY AREAS OF WEAKNESS

- × Registration requirements for licensing agreements
- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Italy's and EU's research- and IP-based biopharma industry

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.00**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**4.66**
10. Term of protection	0.66
11. Exclusive rights	0.50
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.75**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.00**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**4.91**
32. Physical counterfeiting rates	0.59
33. Software piracy rates	0.57
34. Civil and procedural remedies	0.75
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 41.57

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Italy's overall score has decreased slightly from 83.18% (41.59 out of 50) in the eighth edition to 83.15% (41.57 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union handed down a verdict in the case *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rul-

ings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product.**" From a legal perspective, the Court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still,

treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

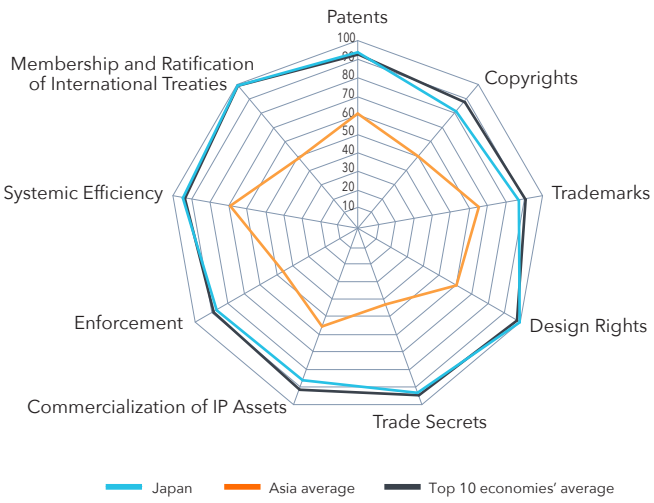
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking): Like many other EU Member States, Italy is currently in the process of transposing Directive 2019/790 on copyright and related rights in the Digital Single Market. In the fall of 2020, the Italian Senate (European Affairs Chamber) had in the fall of 2020 approved a draft version of the law and transmitted it back to the government with comments. The draft law pointed to several areas in need of better definition and clarification and how they would function in practice. This includes Articles 15 and 17, which relate to a neighboring right for press agencies and press publishers and the so-called "upload filter," respectively. The European Commission is currently assisting Member States in their national transposition processes through the Copyright Contact Committee and was set to issue specific guidance on implementation of some of the more complex aspects of the legislation, including Article 17. Member States have until June 2021 to transpose the Copyright Directive into their national laws.

12. Expeditious injunctive-style relief and disabling of infringing content online: As noted in previous editions of the Index, Italian Communications Regulatory Authority (AGCOM) has over recent years strengthened its power to fight online copyright infringement. This includes the power to ask ISPs to implement notice and stay-down measures, issue preliminary injunctions to disable access to infringing websites within three days upon receiving notification from a rights-holder, and issue "dynamic injunctions" to address alias sites (rule 490/13/CONS). Article 195 of Decree Law 34 of May 2020 (*Decreto Rilancio*) expands AGCOM's powers to protect copyrighted works through social platforms and telephone or instant messaging platforms—violations that up until now had escaped the authority's jurisdiction. In the event of non-compliance with AGCOM's orders, an administrative fine can be issued worth from EUR10,000 up to 2% of the turnover achieved in the financial year closed prior to notification of the dispute.

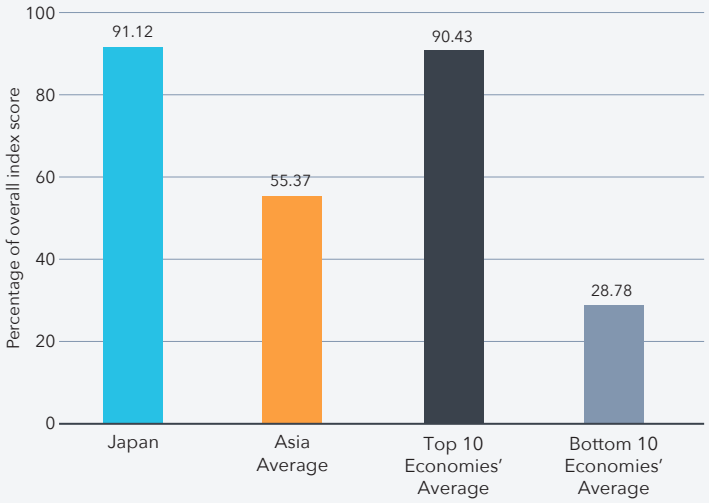
JAPAN

RANK
5/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Copyright Act 2020 amendments continue to strengthen copyright environment
- ✓ Design Act amendments came into effect in 2020–increase term of protection
- ✓ Copyright amendments of 2019 strengthen TPM laws and increase term of protection
- ✓ Global leader with respect to targeted administrative incentives for the creation and use of IP assets for SMEs
- ✓ Economic Partnership Agreement with EU–agreement includes a substantial IP chapter
- ✓ Licensing guidelines published by JPO provide balanced approach to licensing terms and conditions for SEPs
- ✓ Has signed and acceded to all international IP treaties included in the Inde
- ✓ Strong, sophisticated national IP environment in place with relevant IP rights and protection available for all major IP rights categories

KEY AREAS OF WEAKNESS

- × Uncertainty over the protection of biopharmaceutical patent rights following approval of several follow-on drugs in 2020 by the Japanese drug regulatory authority
- × No IP-specific tax incentives, such as a patent box regime, in place
- × Remedies against online copyright infringement remain under-developed compared with other OECD economies

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.50**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**5.74**
10. Term of protection	0.74
11. Exclusive rights	1.00
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.80**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	0.80

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.17**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**6.10**
32. Physical counterfeiting rates	0.76
33. Software piracy rates	0.84
34. Civil and procedural remedies	0.75
35. Pre-established damages	0.75
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 45.56

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Japan's overall score has increased from 90.40% (45.20 out of 50) in the eighth edition to 91.12% (45.56 out of 50) in the ninth edition. This reflects a score increase on indicators 14 and 21.

Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism: As noted over the course of the past nine editions, Japan has historically been one of the top-performing economies benchmarked and sampled in the Index. The Japanese national IP environment is highly sophisticated with particular strengths in Category 1: Patents, Related Rights, and Limitations: Japan has never ranked outside the top 10 on this category or scored lower than 90% on the category as a whole. This may now be changing. Following the conclusion of a patent invalidation action lodged in 2019 with the Japan Patent Office, in August 2020 the Japanese Ministry of Health, Labour and Welfare (MHLW) approved several generic follow-on products for the drug pregabalin. The MHLW's decision was surprising given that the JPO had upheld several of the innovator's claims and rights in the patent invalidation action. Following the approval, the rights-holder in question initiated patent infringement proceedings against the approved generic products. However, at the time of research, no injunctive or preliminary relief had been granted. Mid-December 2020 news reports suggested that these products had been added to the Japanese National Health Insurance price list and that at least one product had been introduced into the marketplace. The net result is that not only have several potentially patent-infringing generic follow-on products been introduced onto the Japanese pharmaceutical market and approved by Japan's drug regulatory authorities but, moreover, the rights-holder in question has been unable to achieve any effective preliminary relief in anticipation of a full patent infringement trial. There is a potential high cost to any national IP system that is unable to effectively resolve any biopharmaceutical patent infringement dispute prior to the marketing of a product and provide effective interim relief. In this respect biopharmaceutical products are unique, as they involve not only the potential infringing party and the rights-holder, but also patients whose health and well-being depend on the products in question. Consequently, the introduction of a potentially infringing product onto the marketplace puts both patients and the follow-on manufacturers at risk. In short, this situation creates significant uncertainty for innovators and generic manufacturers alike and could result in products being prescribed to Japanese patients that ultimately have to be withdrawn from the market based on the outcome of the pending litigation. It is exactly this uncertainty that well-functioning and effective patent enforcement systems are designed to avoid. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12.Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights: As has been noted in previous editions of the Index, online piracy (in particular of manga and anime) is an area of growing concern in Japan. As part of a broad coalition of industry and content creators, the Japanese Ministry of Economy, Trade, and Industry (METI) announced in 2014 it would "monitor and remove illegally uploaded copies" of both anime

and manga content through the Manga-Anime Guardians Project (MAGP). Initial reports from METI suggested that a significant drop in pirated anime and manga materials had been achieved, with close to 1 million infringing copies and online files being removed and/or deleted, corresponding to an estimated 70% of all illegal anime and manga content online. Unfortunately, infringement has continued in the years since the program was launched. Facing this growing challenge, Japanese authorities have over the course of the past three years announced new legislative proposals and increased enforcement efforts. These efforts have targeted disabling access to so-called "leech" websites—that is, aggregation websites that provide hyperlinks to infringing materials and webpages. As noted in previous editions of the Index, Japan provides for a relatively limited notice and takedown mechanism with regards to copyright-infringing materials. Under the Law Concerning the Limits of Liability for Damages of Specified Telecommunications Service Providers and the Right to Request Disclosure of Identification Information of the Senders (Law No. 137), Japanese ISPs have an obligation to act on being notified of a possible infringement by a rights- holder. However, unlike many other economies' notice and takedown systems, under Law No. 137, ISPs must inform the alleged infringer of the allegation of infringement prior to any takedown of the infringing material. On notification, the alleged infringer then has a period of seven days to respond to the allegation, and only upon the expiration of the seven days, if no response from the alleged infringer has materialized, can the ISP take down the alleged material. Japan has historically also had a relatively broad personal-use exception in place for copyright. While 2010 amendments to the Copyright Act clarified that existing personal-use exceptions did not apply in cases in which audio or film content was downloaded from what was knowingly an infringing source, these amendments were not expanded to cover other copyrighted content and works. To strengthen available enforcement remedies and provide a stronger deterrent against continued infringement of copyright online, the Japanese Diet in 2020 passed several sets of amendments to the Copyright Act introducing two major changes. First, criminal penalties and sanctions were introduced targeting the hosting, operation, and linking of leech websites that link to infringing materials and webpages, particularly for manga and anime. Second, downloading all forms of copyright-infringing content, not just audio and film, is now an offense. The Japanese government should be commended for taking legislative action and strengthening the national copyright environment. In particular, the elimination of the uncertainty around the private use exception to copyright is positive and has resulted in a score rise of 0.25 on indicator 14. Still, it is noteworthy that these legislative amendments did not go further. For example, the amendments contain no requirement or reference to one of the most forward-looking and effective means of limiting access to infringing content: injunctive-style relief. First pioneered in Europe, injunctive-style relief allows rights-holders to get immediate and effective relief against online infringement. As has been detailed in the Index over the past few years, economies that have introduced some system of injunctive-style relief include a growing number of EU Member States, Australia, Singapore, Russia, and India. Illegal, often foreign-based, websites such as The Pirate Bay have been effectively disabled and piracy rates have decreased measurably in the economies that have introduced these measures. But in Japan such a mechanism is not available, with any action taken by individual ISPs being on a voluntary basis. Although discussed in 2019, the final 2020 amendments to the Copyright Act did not contain any such measures, and the U.S. Chamber believes this is a missed opportunity. Introducing a more effective system to disable access to illegal and copyright-infringing environments would be a big step forward in strengthening Japan's copyright

environment and protecting the rights of its many creators and artists, manga and otherwise.

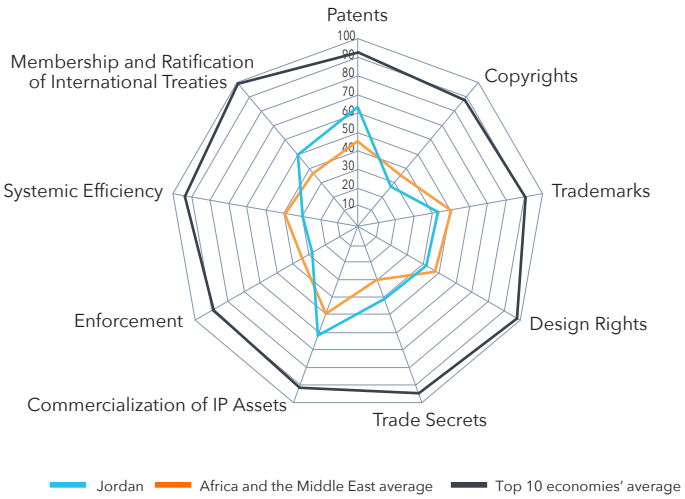
Design Rights, Related Rights, and Limitations

21. Industrial design term of protection: The Design Act 2019 amendments came into effect in early 2020. Changes included increasing the term of protection for registered design rights from 20 years to 25 years, matching the international benchmark used for this indicator. As a result, the score on this indicator has increased to 1.

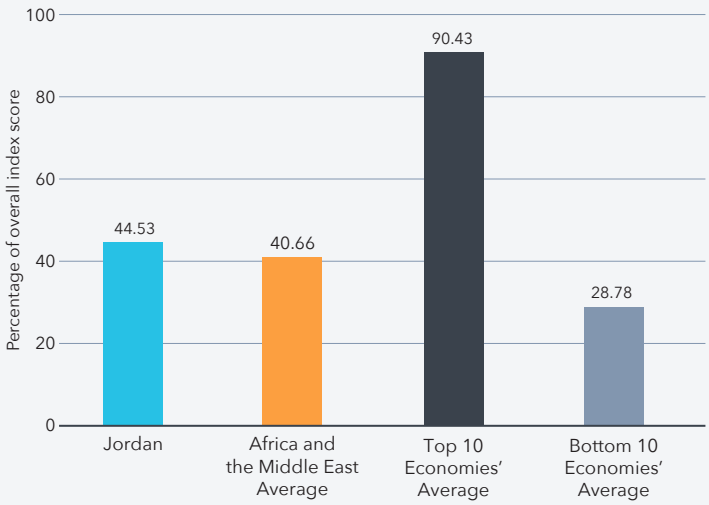
JORDAN

RANK
33/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Basic legal framework for major IP rights
- ✓ Sector-specific IP rights introduced as part of 2001 U.S. FTA

KEY AREAS OF WEAKNESS

- × No R&D- or IP-specific tax incentives in place
- × No targeted incentives for the creation and use of IP assets for SMEs
- × High levels of copyright infringement, particularly online
- × Uncertainty as to the actual availability of the full term of RDP protection—eligibility contingent on global launch and registration in Jordan within 18 months
- × Uncertainty over availability of patents for CIIs

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**5.75**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	1.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.94**
10. Term of protection	0.44
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.25
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**1.97**
32. Physical counterfeiting rates	0.27
33. Software piracy rates	0.45
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.50**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**3.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

TOTAL: 22.26

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Jordan's overall score has increased from 44.16% (22.08 out of 50) in the eighth edition to 44.53% (22.26 out of 50) in the ninth edition. This reflects a score increase on indicator 37.

Enforcement

37. Effective border measures: Under Law No. 20 of 1998, Jordanian customs officials have fairly clear *ex officio* powers to take action against suspected infringing goods. Under Article 41:6, sub-section D, the customs authorities "may suspend the procedures of clearance and the release of goods, if he is convinced, based on prima facie evidence, that there is an infringement occurrence in copyright/trademark related cases." Unfortunately, this clear right of action has historically had some considerable exceptions. To begin with, under the existing implementing regulations (Regulation No.7, "Border Measures for the Protection of Intellectual Property Rights"), the *ex officio* authority was exempted for goods in transit and goods in economic free zones. Although 2019 amendments to the law did not expand *ex officio* powers to also apply to goods in transit, Article 41:6, sub-section H, now states that *ex officio* authority extends to "Development Zones, Free Zones and Aqaba Special Economic Zone." This is a positive development and has resulted in a score increase of 0.25 on this indicator.

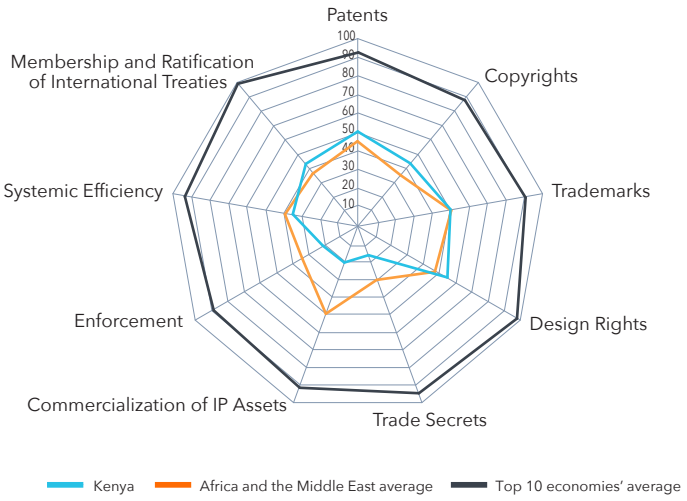
Systemic Efficiency

41. Educational campaigns and awareness raising: In Jordan, there are relatively few awareness-raising and public outreach campaigns on the importance of IP rights and socio-economic benefits IP industries bring. The Industrial Property Protection Directorate (IPPD) and other related institutions within the Jordanian government do not have dedicated programs in place. Looking at the IP Outreach in Practice database housed by WIPO, there are currently nine public outreach campaigns active in Jordan. None of these campaigns are sponsored or directly supported by the Jordanian government, and none of them are geographically specific to Jordan. Still, while not systematic, there have been some efforts by the Jordanian authorities to promote greater awareness of IP rights and the negative impact of counterfeiting and piracy. For example, the IPPD and other institutions have supported ad hoc programs and awareness sessions to explain the importance of IP registration and commercialization activities. Most notable of all has been the Jordanian FDA (JFDA) and Ministry of Health's efforts to combat counterfeit medicines. The pharmaceutical supply chain in Jordan has historically been affected by high rates of counterfeit and substandard medicines. A 2013 study of the incident of substandard medicines in a sample of Middle Eastern economies, including Jordan, found that half of antibiotics sampled were substandard. Similarly, a 2014 academic article surveying pharmacists' awareness of poor-quality medicines in the supply chain published in the *Journal of the Royal Medical Services* (the official journal for the Royal Medical Services, Jordan's armed service's health authority) found that 37% of pharmacists had come across counterfeit cases, with half of them having come across several cases. The JFDA and Ministry of Health have actively sought to combat this problem through multiple awareness-raising campaigns and enforcement action.

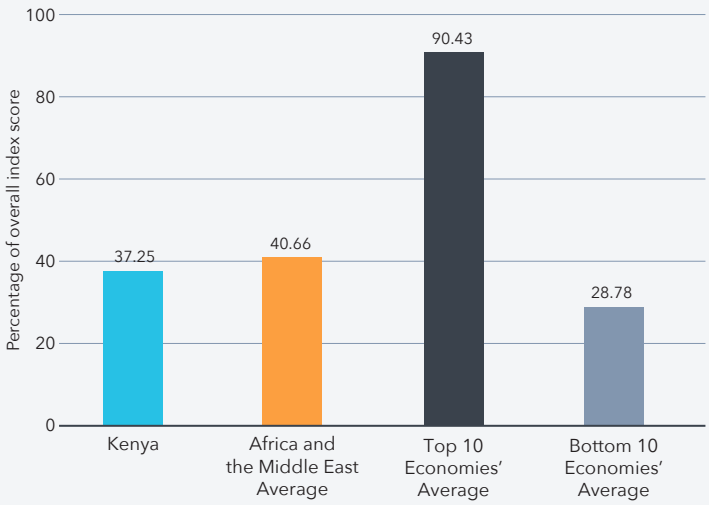
KENYA

RANK
42/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Anti-Counterfeit Act amendments of 2020 strengthen enforcement powers
- ✓ Copyright amendments of 2019 strengthen the protection of copyright in Kenya
- ✓ Basic IP framework in place, including several sector-specific rights
- ✓ Dedicated IP bodies and enforcement agencies
- ✓ Recent efforts to improve knowledge and frameworks for proper use and commercialization of IP assets

KEY AREAS OF WEAKNESS

- × Draft IP Bill in 2020 would combine IP authorities under one office; it is unclear whether each section would have enough resources and staff
- × Barriers in place for licensing and technology transfer
- × No R&D- or IP-specific tax incentives in place
- × No targeted incentives for the creation and use of IP assets for SMEs
- × Weak and backlogged judicial system with notable deficiencies in criminal enforcement
- × Important gaps in copyright protection and enforcement, particularly in the digital space
- × Legislative and resource barriers to border enforcement

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**4.50**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**3.03**
10. Term of protection	0.53
11. Exclusive rights	0.50
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**1.25**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**1.49**
32. Physical counterfeiting rates	0.23
33. Software piracy rates	0.26
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**1.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**3.00**
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 18.62

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Kenya's overall score has increased from 36.82% (18.41 out of 50) in the eighth edition to 37.25% (18.62 out of 50) in the ninth edition. This reflects a score increase on indicator 37.

Area of Note

The Kenya Industrial Property Institute (KIPI) in 2020 released a draft IP Bill. In terms of substantive changes, the primary stated purpose of the bill is to consolidate the administration of the current IP agencies into one body: an IP Office. It also consolidates all major IP-related legislation into one legislative act. The enacting of a new IP law provides Kenya a good opportunity to examine its national IP environment. As the Index has documented over the past five years, in several areas, legislative changes could strengthen Kenya's national IP environment and improve its economic competitiveness. At the time of research, the law was still in draft form.

Enforcement

37. Effective border measures: There are several layers of national and regional laws and enforcement organs that govern customs and anti-counterfeiting activities in Kenya. On the one hand, Kenya has its own national laws, regulations, and levels of application. On the other hand, anti-counterfeiting and customs activities are also governed by its regional commitments with Kenya being a party to the East African Community (EAC), a regional group consisting of six East African states. Since 2005, the EAC has had a Customs Union in place that is guided by the East African Community Customs Management Act. The end result has been a level of uncertainty and lack of clarity on how relevant statute (national and regional) and enforcement agencies interact. At the national level, the most relevant laws are the Customs and Excise Act and the Anti-Counterfeit Act, with the corresponding enforcement agencies being the Anti-Counterfeit Authority (ACA) and the Kenya Revenue Authority Customs Services Department. The ACA has broad authority over anti-counterfeiting enforcement activity throughout Kenya, including border enforcement. Section 23 of the Anti-Counterfeit Act gives designated inspectors broad and strong executive powers, including powers of seizure, inspection, and detainment of any suspected goods or activity pertaining to counterfeiting. Section 32 of the act outlines what constitutes an offence. Sub-section (f) states that it is an offence to "import into, transit through, tranship within, or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods." In contrast, the Customs and Excise Act does not grant as sweeping anti-counterfeiting powers as the ACA, with powers of seizure under section 199 reserved for goods that are defined as being "liable for forfeiture." In 2019, new amendments to the Anti-Counterfeit Act allow for the recordal of IP rights with the ACA. Rights-holders now have the ability to record any internationally registered IP rights. Although the amendments primarily refer to trademarks, sub-section 12 of section 34(B) clarifies that "the provisions of this Section shall apply to the recordation of copyrights, trade names, or any other form of intellectual property rights mutatis mutandis." Together with other legislative changes, the setting up of this recordal system has essentially transferred customs enforcement authority against suspected IP-infringing goods from the Kenyan Customs Service Department to the ACA. From an *ex officio* perspective, the 2019 amendments to the Anti-Counterfeit Act clarify the powers that inspectors will be able to exert within the context of border enforcement and importation. Specifically, section 23(5) of the amendments—Statute Law (Miscellaneous Amendments) 2018—states, "An inspector shall have the same

powers as are exercised by a customs officer with regard to importation of counterfeit goods under the East African Community Customs Management Act, 2005." The East African Community Customs Management Act provides clear *ex officio* seizure powers to border officials under section 213(1). Schedule 2, Part A—Prohibited Goods, sub-section 12, defines "counterfeit goods of all kind" as a prohibited good. However, with respect to goods in transit, the East African Community Customs Management Act explicitly exempts goods in transit and goods being transshipped from customs action through section 20 of the Act. This despite the fact that, as mentioned, Schedule 2, Part A—Prohibited Goods, sub-section 12, defines "counterfeit goods of all kind" as a prohibited good. Whether or not these legislative changes result in a stronger level of enforcement remains to be seen. In practice, both customs enforcement and anti-counterfeiting activity in Kenya has been lacking for some time. The Anti-Counterfeit Act and Agency have been criticized for a lack of action and effective implementation of its anti-counterfeiting mandate. The ACA was not operational in its first few years of existence, and local media reports suggest that, despite being in place for over a decade, there is a lack of inter-agency cooperation and clear understanding of the agency's authority and interaction with other enforcement bodies. A lack of staff also seems to be impeding effective application of the act. A 2018 report in the *Daily Nation* (Kenya's largest broadsheet newspaper) stated, "Rampant corruption, negligence, poor coordination among State agencies manning the country's borders and other systemic weaknesses give counterfeiters an easy time, making Kenya a free field for importing and dumping fakes." The report further noted that the Anti-Counterfeit Agency had a total of 24 inspectors nationally, making it physically impossible for the agency to carry out its core enforcement functions. There have also been several court cases involving ACA staff and inspectors accused of misconduct and potential corruption; see for example, the 2015 case *Hassan Elmi & 4 others v Anti-Counterfeit Agency*. In terms of the score on this indicator, the 2019 amendments to the Anti-Counterfeit Act have resulted in an increase of 0.25 for the institutionalization and clarification that inspectors under the ACA now have *de jure* the same powers as defined under the East African Community Customs Management Act.

Systemic Efficiency

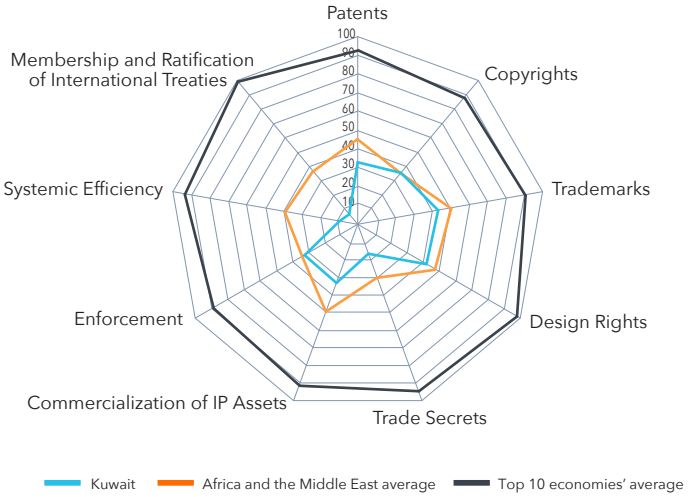
40. Consultation with stakeholders during IP policy formation: There is no formal or statutory requirement that Kenyan authorities offer public consultations on proposed legislative and regulatory changes. Articles 10, 69, and 118 of the 2010 Kenyan Constitution in broad terms encourage and stipulate the participation of the public in public policymaking with article 118 being the clearest, but this is in respect of the legislature, not the executive branch of government. Specifically, the article states that the Kenyan Parliament should "facilitate public participation and involvement in the legislative and other business of Parliament and its committees." For the executive branch, there is evidence of some public consultations taking place, but this is ad hoc and varies from government department to department, and the proceedings and timelines are not standardized or always laid out in such a manner as to ensure adequate notice and ability of stakeholders to participate. On a positive note, the KIPI is currently holding a public consultation on the draft Intellectual Property law. At the time of research, a Public Participation Bill was being debated in Kenyan Parliament. Various iterations of this legislation have been discussed since 2016. The bill would mandate the involvement of the public in official policymaking at all levels of government, including ensuring adequate timelines and notices of documents for public consultation. Adoption of this bill, or any equivalent piece of legislation, that formalizes the public participation process in law and regulatory rulemaking would be a positive de-

velopment. Regular consultations with all relevant stakeholders are a prerequisite for developing a world-class national IP environment in line with the highest international standards and practices.

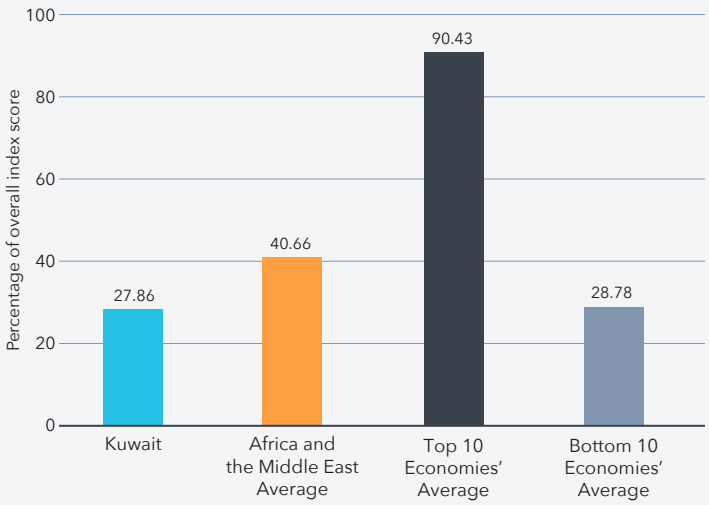
KUWAIT

RANK
49/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Basic IP framework in place
- ✓ Participant in regional patent and trademark harmonization efforts through GCC

KEY AREAS OF WEAKNESS

- × Most sector-specific rights missing
- × Barriers in place for licensing and technology transfer
- × No R&D- or IP-specific tax incentives in place
- × No targeted incentives for the creation and use of IP assets for SMEs
- × Limited participant in international treaties

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**3.00**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.25
4. Plant variety protection	0.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.53**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**2.00**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**2.30**
32. Physical counterfeiting rates	0.37
33. Software piracy rates	0.43
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**0.50**
39. Coordination of IP rights enforcement	0.00
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.00
Category 9: Membership and Ratification of International Treaties	**0.50**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 13.93

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Kuwait's overall score has decreased slightly from 28.02% (14.01 out of 50) to 27.86% (13.93 out of 50). This reflects a marginal score decrease on indicator 32.

Area of Note

On January 5, 2021, the Gulf Cooperation Council (GCC) Patent Office announced that, following the 41st Session of the Supreme Council and amendments to the Patent Regulation, the Patent Office would no longer be accepting patent applications. The announcement was unexpected, as the GCC patent application route had been operational for more than two decades. In 2016, the Kuwaiti Patent Office stopped accepting national patent applications. This follows the implementation of Law No. 71 2013 through implementing Regulation 115/2016. In effect, the two pieces of legislation repealed the old patent law and replaced it with the existing patent regime in place under the GCC. At the time of research, it was unclear what would happen to GCC applications filed prior to the announcement and how, or if, the Kuwait Patent Office would again start accepting patent applications. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy: As has been noted in previous editions of the Index, rights-holders face a challenging copyright environment in Kuwait. At the statutory level, the Copyright and Related Rights Law 2016 provided only basic exclusive rights. The law did not provide or define a notification system, safe harbor laws, or circumstances in which ISPs and internet mediators have responsibility for copyright infringement taking place via their operating systems. There is also no legally defined system of injunctive relief and the disabling of infringing content online—whether through a judicial or administrative authority. Since 2014-15, new laws relating to telecommunications and cybercrime have invested vast powers in a government regulator (the Communications and Information Technology Authority, CITRA) to oversee and regulate the online space. Under Law No. 37 of 2014 on the Establishment of Communication and Information Technology Regulatory Authority, CITRA has the power to suspend operating licenses and individual accounts. News reporting and published reports by the U.S. State Department suggest that the Kuwaiti authorities have disabled access to a variety of web content, including sites that link or provide access to copyright-infringing material. CITRA offers a dedicated web portal where online requests for the disabling of websites can be requested. However, this portal is not aimed at copyright-infringing content exclusively but is much more general and broadly defined. In 2019, a new copyright law, Law 75 on Copyright and Related Rights, was passed. Law 75 makes some potentially important changes to Kuwait's copyright regime. Article 36 provides potential new avenues for enforcement. Specifically, the article grants a broader type of administrative enforcement authority to designated officials compared with the provisions in the older Copyright Law. At the time of research, no implementing regulations had been issued and it was not clear how these enforcement powers would be administered and applied. Nevertheless, this is a positive development, and the Index will monitor the application of these new powers in 2021.

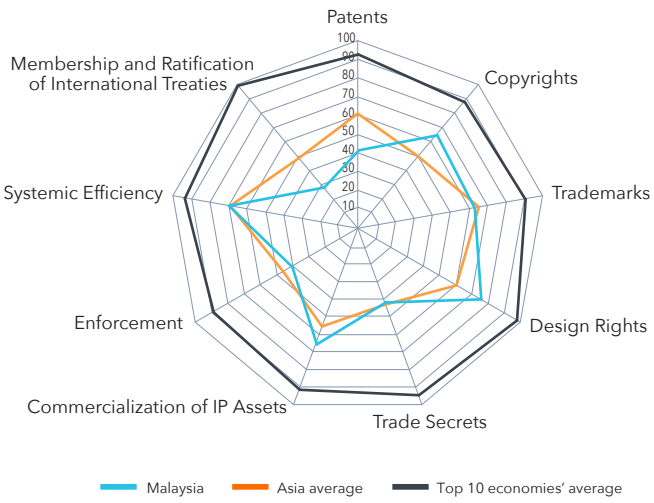
Membership and Ratification of International Treaties

Kuwait is a contracting party to only one of the nine treaties included in the IP Index, the Patent Cooperation Treaty. Kuwait is not a contracting party to the WIPO Internet Treaties; the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Singapore Treaty on the Law on Trademarks; the Patent Law Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; the Convention on Cybercrime; or the Hague Agreement Concerning the International Registration of Industrial Designs. Similarly, Kuwait has not concluded any post-TRIPS FTAs with substantive IP provisions. The GCC has concluded FTAs with Singapore and the European Free Trade Association (EFTA), but neither of these agreements include a dedicated or comprehensive IP chapter. Being a contracting party to key international IP treaties reflects a given economy's broader participation in the international IP community and embrace of the highest IP standards. Most economies benchmarked in the Index are members of two or more of the treaties included in the Index.

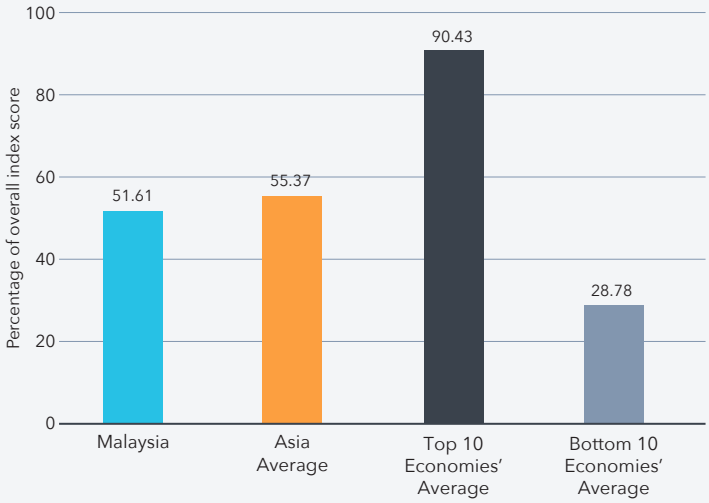
MALAYSIA

RANK
27/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Trademark Act amendments of 2020 strengthen enforcement environment
- ✓ Increased action against copyright infringement through set-top boxes in 2019
- ✓ Generous R&D- and IP-specific tax incentives in place
- ✓ Intellectual Property Corporation of Malaysia has PPH agreements in place with both the EPO and JPO
- ✓ Strong focus by Malaysian government on IP as a commercial asset and technology transfer

KEY AREAS OF WEAKNESS

- × Government use license (the equivalent of a compulsory license) issued in 2017 for sofosbuvir, a new breakthrough medicine to treat hepatitis C
- × *De facto* RDP full-term of protection is not offered to new products
- × Patent term restoration not offered

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**3.75**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**4.53**
10. Term of protection	0.53
11. Exclusive rights	0.75
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	0.50
15. Digital rights management	0.75
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.92**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**2.85**
32. Physical counterfeiting rates	0.36
33. Software piracy rates	0.49
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 25.80

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Malaysia's overall score has increased from 51.24% (25.62 out of 50) in the eighth edition to 51.61% (25.80 out of 50) in the ninth edition. This reflects a score increase on indicator 19.

Patents, Related Rights, and Limitations

6. Legislative criteria and active use of compulsory licensing of patented products and technologies: As has been noted over the course of the Index, Malaysian law and practice on compulsory licensing is firmly outside international standards. On the basis of price considerations, the Malaysian government in 2004 first issued a compulsory license for the importation of generic antiretroviral medicines. Thirteen years later, in 2017, Malaysia issued a government use license (the equivalent of a compulsory license) for sofosbuvir, a breakthrough medicine to treat hepatitis C, despite the fact that the U.S. manufacturer had decided to include Malaysia in its voluntary licensing program. In a statement accompanying the decision, the Ministry of Health (MOH) made clear that the decision to issue a compulsory license was driven primarily by the cost of the medicine: "The decision to initiate the Rights of Government was made after the MOH efforts to be included in the Medicine Patent Pool (MPP) and price negotiations with patent holder were unsuccessful [sic]. Through the implementation of The Rights of Government, the cost of treatment will be lower and more patients can be treated." The 2017 compulsory license was not further renewed upon expiry in 2020, which is a step in a positive direction. However, discussions on embracing compulsory licensing as a health policy tool continued in 2020. In August, Health Minister Dr. Adham Baba was asked about the need for the issuing of new compulsory licenses for COVID-19 treatments due to the potential high cost of potential therapies. The minister responded that, while this was a matter for the full cabinet, this was a course of action the government should consider. However, cost is not a relevant justification or basis for compulsory licensing under the TRIPS Agreement. TRIPS Article 31, including the amendments introduced in the 2001 Doha Ministerial Declaration, and the subsequent General Council decision that allows 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, should be aimed solely at protecting public health. In addition, 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. The severe and sudden impact the COVID-19 pandemic is having on public health around the world means that, in effect, the conditions of the potential issuing of a compulsory license are being met in many economies, including in Malaysia. The pandemic poses a clear and present danger to public health all over the world. In March 2020, during the height of the COVID-19 pandemic, the Israeli government authorized the issuing of a compulsory license for the antiviral drug lopinavir/ritonavir. However, the rationale and justification for the license was not cost. Instead, the basis for the decision was that, first, the Israeli Ministry of Health viewed the drug as a potential treatment against COVID-19 and, second, that the manufacturer was viewed as not being able to meet potential domestic demand. But the adoption of compulsory licensing as a health policy tool—as opposed to an emergency measure—raises several critical questions about the development of the

Malaysian economy. Since the early 2000s, Malaysia has embarked on a series of forward-looking policy reforms aimed at climbing the economic value chain and increasing the proportion of economic output generated from innovation and high-tech industries. Successive national five-year plans, the launch of the New Economic Model in 2010, and a host of programs aimed at growing the biotechnology and biopharmaceutical sectors—most notably the Bioeconomy Transformation Programme—have helped grow the economy and improve the Malaysian economy's international competitiveness. As has been documented in the Index over the past nine years, Malaysia has also improved its national IP environment, particularly with respect to the protection of copyright. In large measure these policies have been successful. In 2000, Malaysia had a per capita income of just under USD13,000 on a purchasing power parity (PPP) basis, roughly comparable to Mexico and Argentina. In 2019, Malaysia's per capita GDP had more than doubled, growing to almost USD30,000 and was 50% higher than Mexico's and more than 25% higher than Argentina's. Over the same time period the value and volume of high-technology manufacturing and exports had grown substantially. Yet it is difficult to see how embracing the overriding of patent rights for biopharmaceuticals as public policy will help Malaysia continue to build and develop its economy. For all economies—emerging and developed alike—what drives innovation, technological advances, and—ultimately—economic development and growth is the creation of new forms of intangible assets and IP. Embracing compulsory licensing as a cost-containment tool and institutionalizing it as part and parcel of Malaysian health policy will not act as an incentive or make it easier to invest, innovate, and create new biopharmaceutical products and technologies in Malaysia. More broadly, the overriding of biopharmaceutical IP rights on the basis of cost and price negotiations sets a wholly negative precedent that may be applied to other industries and sectors. If the Malaysian government wishes to pay less, or nothing, for medicines using compulsory licenses, what is to say that this will not be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech products that the public sector purchases?

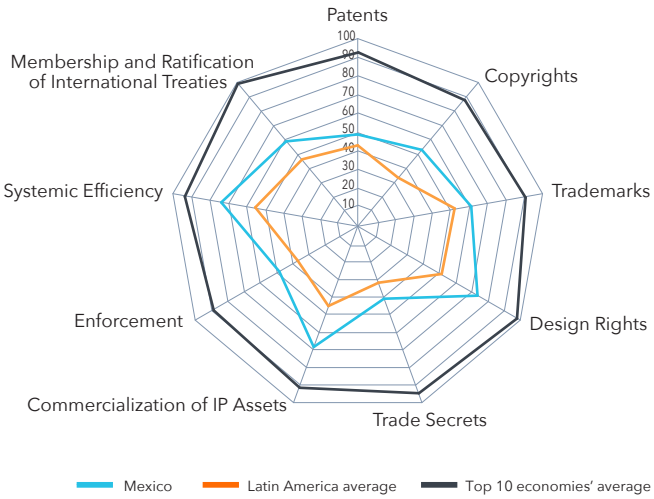
Trademarks, Related Rights, and Limitations

19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks: In December 2019, the Malaysian Parliament finalized and passed a new Trademarks Act. The new legislation is the culmination of a long legislative process that has seen Malaysia become a contracting party to the Madrid Protocol. The new Act modernizes the legal framework and contains several important changes to how trademarks are registered and protected. To begin with, the law expands the types of marks that can be registered, including sound, scent, shape, color, and other so-called non-traditional marks. The new act also contains significant changes to the enforcement environment. Specifically, trademark infringement can now be prosecuted on the basis of a mark appearing on "similar" goods or services as opposed to "identical." Under the old regime, rights-holders often had to rely on the 2011 Trade Descriptions Act, which provided criminal remedies in relation to "false trade description in relation to trademark," including minimum fines and potential imprisonment. This has now changed, with most of the enforcement provisions of the Trade Descriptions Act now moved into the Trademarks Act. Local legal analysis suggests that this will improve the operational aspects of enforcement, as rights-holders will no longer need to obtain a specific trade description order to begin infringement proceedings against the use of non-identical marks. More broadly, potential penalties, including damages, have been strengthened. As a result of these positive changes, the score on this indicator has increased by 0.25.

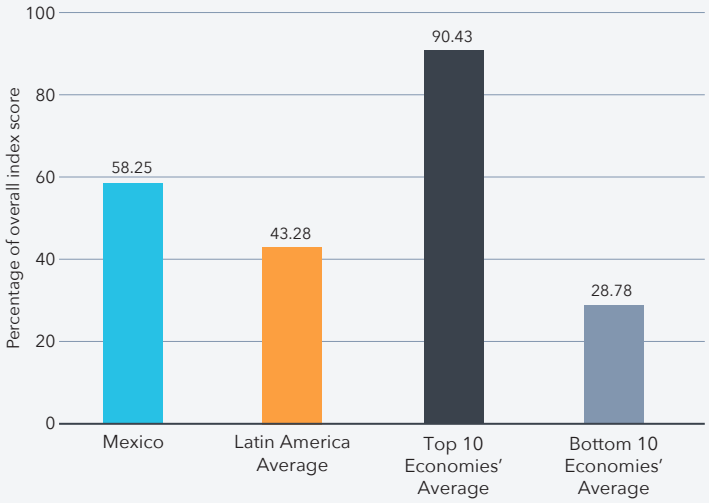
MEXICO

RANK
23/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Industrial Property Law 2020 amendments implement some provisions of USMCA
- ✓ Federal Law on Copyright 2020 amendments implement many provisions of USMCA
- ✓ Term of protection for industrial design rights extended to 25 years
- ✓ Efforts to ease ability to commercialize IP assets and develop public-private partnerships, particularly for public research organizations and universities
- ✓ Dedicated endeavor to streamline IP review process and criminal justice system and harmonize to international standards
- ✓ Efforts to increase awareness of importance of IP rights

KEY AREAS OF WEAKNESS

- × Partial and ambiguous protection for life sciences IP
- × Gaps in enforcement against online piracy
- × Significant gaps in application of remedies, such as severe delays and difficulty securing adequate damages
- × Inadequate border measures for trade-related infringement of IP rights

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**4.49**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.00
4. Plant variety protection	0.74
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**3.79**
10. Term of protection	0.79
11. Exclusive rights	0.50
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.25

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**4.17**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**3.43**
32. Physical counterfeiting rates	0.42
33. Software piracy rates	0.51
34. Civil and procedural remedies	0.50
35. Pre-established damages	1.00
36. Criminal standards	0.75
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**3.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**4.25**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 29.13

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Mexico's overall score has increased substantially from 54.38% (27.19 out of 50) in the eighth edition to 58.25% (29.13 out of 50) in the ninth edition. This reflects score increases on indicators 11, 13, 15, 20, 28, and 50.

Patent Rights, Related Rights, and Limitations

2. Patentability requirements; and 3. Patentability of computer-implemented inventions (CIIs): Historically, it has been difficult for rights-holders to obtain protection for computer programs, software, and CIIs in Mexico. Article 19, section 3.4 of the old Industrial Property Law excluded computer programs as patentable subject matter. Historically, there have been examples of patents being granted for CIIs in Mexico, but these are few and far between, and claims often needed to involve a hardware component. Legal practice and available patent statistics suggest that both the number of applications and patents granted for software and computer-related patents by the IMPI have been low. For example, looking at patent statistics housed by WIPO between 1980 and 2018, there were a total of 9,373 published patent applications (patent publications by technology) under the categories "Computer technology" and "IT methods for management." This compares to 299,582 total applications published during this period, or 3.13% of the total. Statistics for the number of patents granted, not only applied for, show an even lower proportion of computer-related applications granted patent protection. Looking again at statistics housed by WIPO on the number of patents granted by technology during the same time period shows a total of 1,456 patents granted under the categories "Computer technology" and "IT methods for management." This compares to a total number of 56,202 patents granted for all technologies, or 2.59% of the total number of patents granted. Local legal analysis suggests that, while the situation has evolved over the years, and the IMPI does not always reject CII applications; the success of a given application is largely dependent on showing how a given piece of software interacts and acts in concert with computer hardware. On July 1, 2020, the United States-Mexico-Canada Agreement (USMCA) formally took effect in all three countries. Relevant provisions of the USMCA are clear that patents should be granted for all inventions. Article 20.36 states that "each Party shall make patents available for any invention, whether a product or process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application." Neither computer programs nor software are excluded per se under sub-sections 2 and 3. However, Mexico's implementing law, the revised Industrial Property Law, does not offer the same level of clarity. Instead, like the old IP Law, Article 47(5) explicitly excludes "computer programs" as patentable subject matter. At the time of research, no implementing regulations or revised patent guidelines had been issued. The USMCA's language on patentable subject matter is quite clear. Full implementation and application of these requirements in Mexican law and practice will result in an increase in score on both indicators 2 and 3. The Index will continue to monitor these developments in 2021.

5. Pharmaceutical-related patent enforcement and resolution mechanism: While a 2003 Presidential Decree introduced a basic system for early adjudication of disputes relating to biopharmaceutical patent infringement and the marketing of a follow-on product, as noted over the course of the past nine editions of the Index, this has never represented an effective or transparent pathway because the patent holder receives no notification of infringing issues and is not formally involved in the adjudication process. Furthermore, the regulatory enforcement pathway has historically been

limited to substance and formulation patents only; use patents have not been included. In practice, resolution of patent disputes is delayed and often ineffective, whether through administrative or judicial routes. Industry sources suggest that, historically, where cases of infringement have been brought, substantial delays at both the administrative and judicial levels have hindered rights-holders' ability to secure damages effectively (reaching a total of about 10 years on average). Some reform proposals have been introduced over the course of the Index, but they have failed to sufficiently address the shortcomings of the existing system, with some instead compounding the existing deficiencies. For example, in 2019, modifications to the Health Law were proposed by the Mexican Senate. Under the proposed system, only one patent could be listed per each new chemical entity, and patents for biologics would not be considered. If adopted, this reform would further devalue the existing linkage regime and rights-holders' ability to enforce their patents. Mexico is bound through both the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and USMCA to introduce a more comprehensive and practical system of biopharmaceutical patent enforcement. Article 20.50 of the USMCA provides a clear requirement that the contracting parties provide "a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use … [and] adequate time and sufficient opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies." Mexico's revised Industrial Property Law, which implements the USMCA, does not contain any legal provisions relating to the existing linkage regime. Transitional paragraph (5) of the law simply states that the IMPI shall "participate" with the Mexican Federal Commission for Protection against Sanitary Risks (COFEPRIS) "in the establishment of the corresponding technical collaboration mechanism for inventions in the field of allopathic drugs." At the time of research, no new regulations or laws had been passed. A proposal for a revised linkage regime was put forth by the Chamber of Deputies in fall 2020. Unfortunately, this proposal does not incorporate the requirements of the USMCA and would not address the deficiencies in the current system. The USMCA's language on the requirements for an effective pharmaceutical-related patent enforcement and resolution mechanism is quite clear. Full implementation and application of these requirements in Mexican law and practice will result in a score increase on this indicator. The Index will continue to monitor these developments in 2021.

7. Patent term restoration for pharmaceutical products: Mexican law has historically not provided any restoration of patent term lost due to regulatory review periods for biopharmaceutical products. Article 20.46 of the USMCA requires that contracting parties make "available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process." The term of restoration is dependent on the type of mechanism used. Footnote 40 of the agreement describes that this can be a two-year additional *sui generis* protection or up to a five-year period of adjustment. Mexico's revised Industrial Property Law does not contain reference to a period of restoration or additional *sui generis* protection for delays caused by the drug registration and marketing approval process. Article 126 of the law provides the possibility of obtaining an adjustment to the term of protection only in the case of unreasonable delays at the IMPI as part of patent prosecution. Any adjustment period is available only if the processing of a patent application takes longer than five years and the delay is directly attributable to the IMPI. As with indicator 5 and the introduction of an effective

biopharmaceutical linkage system, the USMCA is clear on the requirement that contracting parties should make available a period of restoration due to delays caused by the market review process for biopharmaceuticals. Full implementation and application of these requirements in Mexican law and practice will result in a score increase on this indicator. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Digital rights management (DRM) legislation: As has been noted over the course of the Index, Mexico has historically had one of the more challenging copyright environments in the OECD, lacking in both substantive IP rights and enforcement against online and hard goods copyright piracy. The Federal Law on Copyright sets out standard exclusive rights of reproduction, public transmission, use, distribution, and sale, but has not included provisions or mechanisms that are more specific to addressing internet or online infringement. Up until now, proposed copyright reforms have not been successful. These include the Döring Act (2012), which sought to introduce a warning system for users and raise penalties to more deterrent levels. While amendments that would introduce a notice-and-takedown system and penalties for online infringement were shelved, some steps were taken in 2016 to enhance prosecution for online piracy. The USMCA contains several provisions that would strengthen standards of copyright protection in Mexico, including with regards to digital rights management and technological protection measures, cable and satellite piracy, and the introduction of a notice-and-takedown regime. On July 1, 2020, amendments to the Federal Law on Copyright were published, incorporating many of the most important copyright provisions of the USMCA. Overall, the amendments strengthen the level of protection for copyrighted works in Mexico, extending this protection to the internet and the digital environment. Specific changes include (1) a new notification system whereby ISPs are obliged to act expeditiously and remove suspected content upon receiving a notification (Articles 114 and 232); (2) robust DRM and TPM provisions outlawing the use, manufacture, sale, importation, distribution, or otherwise offering to the public of circumvention devices and technologies (Article 232); and (3) making illegal the use, manufacture, import, or other form of distribution of satellite signal decoders (Article 145). These are positive developments and have resulted in score increases on indicators 11, 13, and 15. However, some parts of the amendments remain unclear. For example, with respect to potential ISP liability for infringing content, Article 114(8) is quite clear that ISPs will not be responsible for any damages caused by potential copyright infringement as long as they act expeditiously and in good faith to remove infringing content and take measures to prevent the same infringing content from reappearing. However, in the same article, sub-section V, the law states that the "inability of an Internet Service Provider to meet the requirements set forth in this article by itself does not generate liability for damages for violations of copyright and related rights protected by this Law." For any notification system to be effective in addressing online infringement, the responsibilities and legal expectations for each affected party must be clear. At the time of research, no implementing regulations or further guidance had been issued. The Index will continue to monitor these developments in 2021.

Trademarks, Related Rights, and Limitations

20. Availability of frameworks that promote cooperative private action against online sale of counterfeit goods: Like in many other economies, online shopping and retail is increasing in Mexico in line with the spread of broadband and mobile telephone connectivity. Up until 2020, there was no regulatory or administrative framework for rights-holders to effectively address the sale of counterfeit goods and infringement of trademark rights online. Only some online merchants, including eBay and Mercado Libre, have had in place specific notice-and-takedown mechanisms giving rights-holders the ability to alert them directly of potential infringements. Mexico's revised Industrial Property Law contains a new mechanism whereby injunctive-style relief can be obtained directly from the IMPI in respect of online violations. Specifically, Article 344 sub-sections VII and VIII give the IMPI the power to "order the alleged offender or third parties to suspend, block, remove content or cease acts that constitute a violation of this Law through any virtual, digital or electronic means, known or to be known." As a result of the introduction of these new powers in the online space, the score on this indicator has increased by 0.25.

Trade Secrets and the Protection of Confidential Information

23. Protection of trade secrets (civil remedies); and 24. Protection of trade secrets (criminal sanctions): Unlike many emerging markets included in the Index, Mexico has had a statutory definition and both civil and criminal remedies in place for the protection of trade secrets and confidential information for decades. Specifically, trade secrets and the protection of confidential information are governed under three Mexican laws: the Industrial Property Law in relation to trade secrets in general and the remedies against a breach thereof; the Civil Law when considering a breach of a contractual relationship and a claim for damages; and the Federal Criminal Code when considering the disclosure of trade secrets as criminal offences in connection with the Industrial Property Law. The USMCA contains clear provisions on the protection of trade secrets and confidential information. Section I defines the meaning of trade secrets and misappropriation and outlines the civil and criminal remedies that contracting parties should make available. The revised Industrial Property Law, which implements the USMCA, includes some positive changes that incorporate these provisions. For example, Articles 163 and 402 now incorporate fuller definitions of misappropriation and potential criminal conduct, respectively. These new provisions complement and improve the existing statute. As has been noted over the course of the Index, IP rights-holders have long faced a challenge in effectively enforcing their IP rights, trade secrets included, in Mexico. Although relevant IP laws provide for administrative and civil remedies, including provisional measures, damages, and seizure of goods, in practice, it is difficult to secure remedies for infringement. There is a multilayer system for IP enforcement, which usually begins with an administrative action by the IMPI and then moves to the courts. Altogether, the process is complex, costly, and lengthy for rights-holders and often does not result in effective enforcement. Local legal analysis suggests that administrative proceedings before IMPI usually take between 18 and 24 months but can take up to five years. For trade secrets specifically, the enforcement environment has been found to be difficult. For instance, in the OECD's Trade Secret Protection Index, Mexico scores substantially lower on categories pertaining to enforcement than to legal definitions and remedies available. The Index will continue to monitor the ability of rights-holders to effectively protect their trade secrets and confidential information in 2021.

Commercialization of IP Assets and Market Access

28. Registration and disclosure requirements of licensing deals: Historically, the registration of licenses with the IMPI was required for the license to have effect against third parties. Local legal analysis suggests that the registration process was not overly burdensome, and it was possible to submit a shorter version of the licensing contract with confidential information omitted. This was amended by Mexico's accession to the USMCA, and the requirement to register licenses for patents and trademarks is now entirely voluntary as per the revised Industrial Property Law. As a result, the score on this indicator has increased by 0.25.

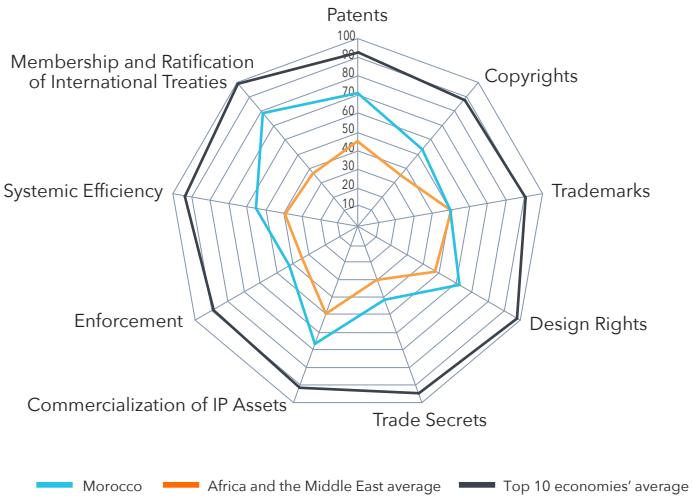
Membership and Ratification of International Treaties

50. Post-TRIPS FTA: On July 1, 2020, the USMCA formally took effect in the United States, Canada, and Mexico. Although weakened by the parties in December 2019, the agreement still contains many important post-TRIPS IP components. As a result of this agreement coming into effect in Mexico, the score on this indicator has increased by 0.5.

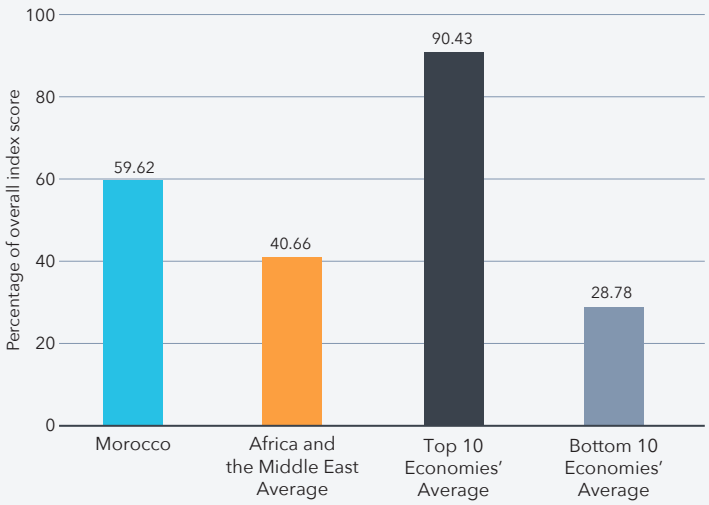
MOROCCO

RANK
22/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Fairly well-developed national IP system—highest-performing middle income economy in Index
- ✓ Strong protection for patents and related rights
- ✓ United States-Morocco FTA and agreements with EU have encouraged Morocco to strengthen IP environment and related standards
- ✓ PPH in place with Spain
- ✓ Moroccan IP Office (OMPIC) offers validation of all EPO-registered patents

KEY AREAS OF WEAKNESS

- × Challenging enforcement environment—high rates of physical counterfeiting and online piracy
- × BSA estimates a software piracy rate of 64%
- × Some uncertainty over practical availability of patents for CIIs

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**6.38**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	1.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.63
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**3.74**
10. Term of protection	0.74
11. Exclusive rights	0.50
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.25**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**4.00**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**2.94**
32. Physical counterfeiting rates	0.33
33. Software piracy rates	0.36
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.50
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**2.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**5.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.50
50. Post-TRIPS FTA	1.00

TOTAL: 29.81

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Morocco's overall score has decreased slightly from 59.66% (29.83 out of 50) in the eighth edition to 59.62% (29.81 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Area of Note

In 2020, the Intellectual Property Corporation of the Moroccan Office of Industrial and Commercial Property (OMPIC) released a new strategic visions document, *Vision stratégique OMPIC@2025*. This document outlines the guiding principles and areas of focus for national industrial property policy. The document touches on several important areas of the Moroccan national IP environment, including improving IP rights recourse mechanisms, stronger international partnerships, and a more holistic national innovation strategy. Above all, the visions document rightly recognizes how critical IP rights are to modern economic activity and the development of the Moroccan economy. For all economies —emerging and developed alike—what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP.

Copyrights, Related Rights, and Limitations

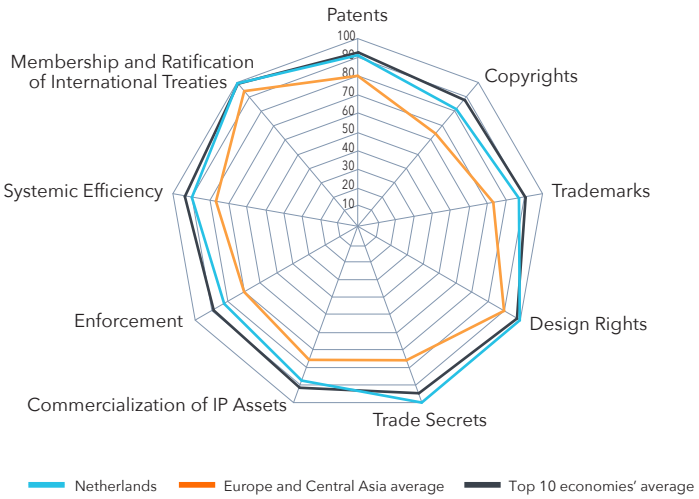
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Digital rights management (DRM) legislation: Morocco has a fairly strong statutory copyright framework in place. Article 10 of the Law on Copyright and Related Rights provides definitions of exclusive rights of exploitation, and standard civil remedies are available. Furthermore, Article 65.12 provides the possibility of seeking an injunction and a court order for the disabling of access to infringing content with respect to foreign hosts, and Law 34-2005 amended Article 60 and introduced a notice-and-takedown regime. Moroccan law also has in place robust provisions relating to digital rights management and technological protection measures. The 2005 copyright amendments made acts of circumvention and related activities (including manufacturing, sale, importation, offering for sale, and distribution to the public) infringements of copyright. The key challenge to rights-holders in Morocco has long been the lack of effective enforcement and application of the existing legal framework. Levels of copyright infringement remain high. For example, for over a decade, the estimated levels of software piracy in Morocco have been consistently high. The latest estimates from BSA put the overall level of software piracy at 64% in 2018. This is largely unchanged from 2009, when the level of unlicensed software used was 66%. This is substantially higher than the 56% average in the Middle East and Africa region. Furthermore, historically, rights-holders in North Africa and Morocco have faced significant problems with satellite decoding and broadcasting signal piracy. Decoders have been readily available and used across North Africa to illegally access copyrighted content. In 2011, the French satellite and content provider *Canal+* withdrew from the Moroccan and Algerian markets, citing widespread signal piracy as the main reason. The latest trend has seen a migration from physical decoders and satellite piracy to the use of set-top boxes and the accessing of infringing content over the internet through streaming. In February 2020, a copyright reform package was introduced in the Moroccan Parliament. The government-sponsored legislation would introduce some changes to the copyright statute and more extensively reorganize the Moroccan Copyright Office (*Bureau Marocain du*

Droit d'Auteur). The government's recognition of the need to modernize the copyright framework is commendable. The creative industries are an engine for economic growth and development, especially in emerging markets such as Morocco. With the right legal framework in place and the active enforcement of copyright laws, domestic creators and innovators can flourish. The Index will continue to monitor these developments in 2021.

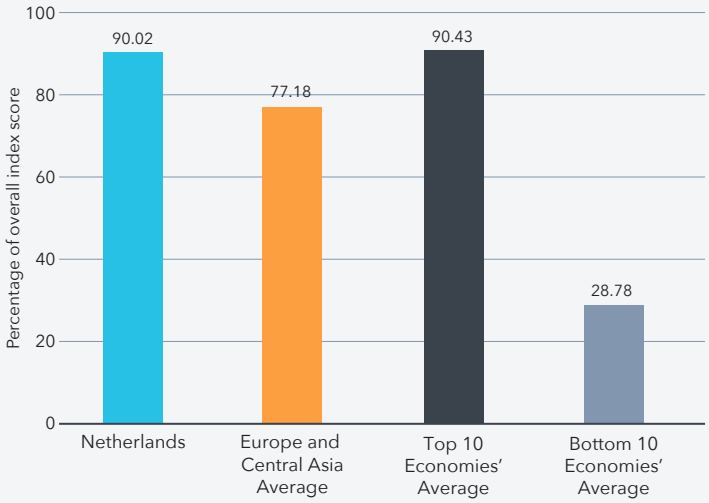
NETHERLANDS

RANK
7/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ EU Trade Secrets Directive 2018 transposition improves Dutch trade secret environment
- ✓ Generous R&D- and IP-specific tax incentives in place
- ✓ Advanced and sophisticated national IP environment
- ✓ Sector-specific IP rights in place
- ✓ Membership of all major international PPH tracks through EPO

KEY AREAS OF WEAKNESS

- × Registration requirements in place for licensing agreements
- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Netherlands' and EU's research- and IP-based biopharma industry
- × Proposals to explore the use of compulsory licensing for medicines whose price is deemed excessive is outside international norms

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**5.74**
10. Term of protection	0.74
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	0.75
15. Digital rights management	0.75
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**5.77**
32. Physical counterfeiting rates	0.74
33. Software piracy rates	0.78
34. Civil and procedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	0.50
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.50**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 45.01

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Netherlands' overall score has increased from 89.64% (44.82 out of 50) in the eighth edition to 90.02% (45.01 out of 50) in the ninth edition. This reflects a score increase on indicator 11.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union (CJEU) handed down a verdict in the case *Santen SAS v Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treat-

ments. In earlier rulings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**." From a legal perspective, the court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced

side effects. Still, treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

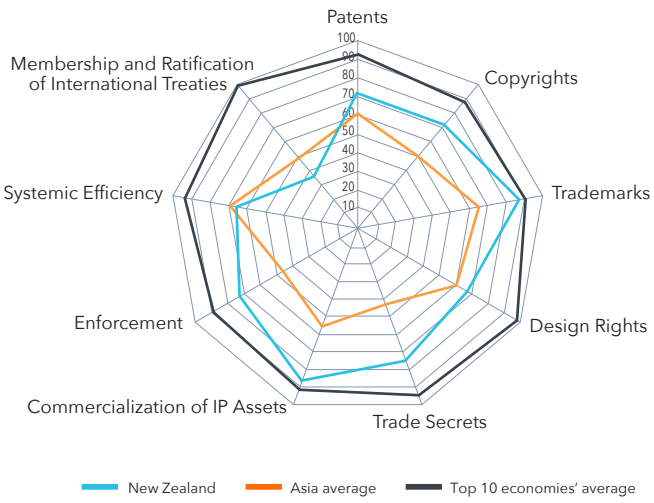
Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 12. Expeditious injunctive-style relief and disabling of infringing content online: As noted in previous editions of the Index, the EU's E-Commerce Directive (2000/31/EC), Articles 12-14, combined with the Copyright Directive (2001/29/EC), Article 8(3), enable a court or administrative authority to require ISPs to terminate or prevent copyright infringement by third parties using their services and lay the basis for injunctive-type relief against infringing websites in EU Member States (while still providing a safe harbor for ISPs). Recent case law from the CJEU suggests that this provision extends to disabling access to torrent websites, which are seen by the CJEU as falling under the umbrella of a "communication to the public" per EU copyright law. One of the key cases in question, C-610/15, BREIN/Ziggo, is a Dutch case. In 2012, the Dutch copyright foundation BREIN filed suit in the District Court of the Hague to order ISPs (Ziggo & XS4ALL) to disable access to the Pirate Bay's IP addresses. The court granted the order for these and other ISPs. During the course of 2014, the ISPs filed an appeal with the Court of Appeal in the Hague. The appeals court disagreed with the earlier ruling, judging that the Pirate Bay was not making infringing content "available to the public." The following year, BREIN appealed this judgment to the Dutch Supreme Court (*Hoge Raad*). The Supreme Court noted that it believed the Court of Appeal erred in its interpretation and stayed proceedings pending a prejudicial judgment from the CJEU. In September 2017, following a fresh lawsuit from BREIN, the District Court handed down a new judgment ordering the disabling of access to the Pirate Bay. In early 2018, the order to disable access to the Pirate Bay was expanded to include five more ISPs. And in June 2018, the Supreme Court decided to send the case back to the Amsterdam Court of Appeal for reconsideration. In June 2020, the Court of Appeal finally issued a final judgment in favor of BREIN. Specifically, the court ordered the continued disabling of relevant infringing websites through a dynamic injunction that also allows rights-holders to update the order when mirror sites emerge. The Appeal Court's decision marks the end of a long legal battle that began in 2010 and has shaped both Dutch and European jurisprudence on the enforcement of copyright online. Reports by BREIN suggests that, since the initial injunction disabling access was issued in 2018, web traffic and usage of the Pirate Bay in the Netherlands has fallen by 80-90%. As a result of this final verdict, the score on indicator 11 has increased by 0.25.

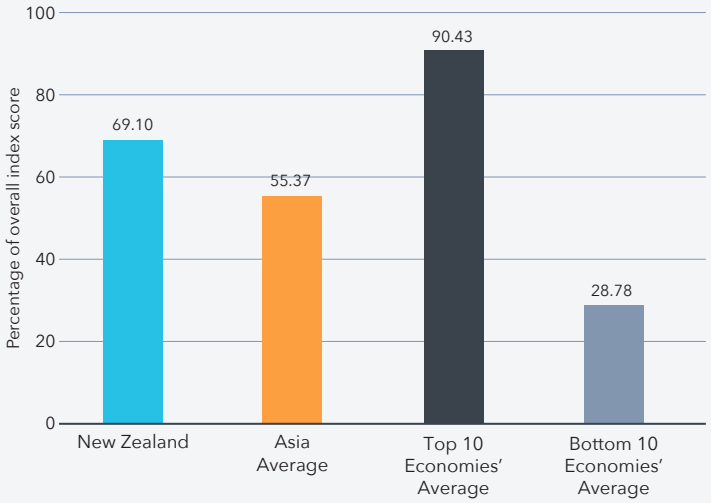
NEW ZEALAND

RANK
20/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ New R&D tax incentives passed in 2019
- ✓ Legislative amendments following ratification of the CPTPP provides border officials with clear *ex officio* authority
- ✓ Fairly sophisticated national IP environment with strengths across most categories of the Index
- ✓ No significant barriers or restrictions on licensing activity and technology transfer

KEY AREAS OF WEAKNESS

- × Practical application and net effect of Copyright (Infringing File Sharing) Amendment Act has been mixed at best, with few cases heard by Copyright Tribunal and most being dismissed on technicalities
- × No patent term restoration in place for biopharmaceuticals
- × Limited membership of international IP treaties

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**6.46**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	0.96
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**5.03**
10. Term of protection	0.53
11. Exclusive rights	0.75
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.35**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.25**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.17**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**5.04**
32. Physical counterfeiting rates	0.70
33. Software piracy rates	0.84
34. Civil and procedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.25**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**2.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 34.55

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

New Zealand's overall score has increased from 68.64% (34.32 out of 50) in the eighth edition to 69.10% (34.55 out of 50) in the ninth edition. This reflects a score increase on indicator 40.

Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy: In June 2017, New Zealand's Ministry of Business, Innovation and Employment (MBIE) announced that it would launch a review of the Copyright Act. This comes on the heels of MBIE's 2016 report *Copyright and the Creative Sector*. The purpose of the review is to, through a broad and lengthy consultation with the public and key stakeholders, identify how the act is meeting New Zealand's objectives and what potential areas are ripe for reform. In November 2018, MBIE released the document "Issues Paper Review of the Copyright Act 1994," a detailed overview of the review process and issues the MBIE has identified as the most pressing areas in need of potential reforms. Significantly, the paper includes an in-depth discussion about enforcement, the changing nature of copyright enforcement on the internet, and the challenges rights-holders face in New Zealand. In 2011, New Zealand introduced a graduated response scheme through the Copyright (Infringing File Sharing) Amendment Act, further outlined in the Copyright (Infringing File Sharing) Regulations. Specifically, this scheme amended the Copyright Act and introduced a mechanism whereby rights-holders can notify internet protocol address providers (IPAPs) about a suspected infringement; IPAPs are then obliged to pass on a "Detection Notice" directly to the account holder/suspected infringer. Under the terms of the regulations, continued suspected infringement can result in two further notices being issued and the rights-holder ultimately being able to apply to the Copyright Tribunal for compensation of up to NZ$15,000. The rights-holder can also apply for a court order for the alleged infringer's internet access to be suspended for a period of up to six months. While a positive step when it was introduced, today the overall effectiveness of the legislation is questionable. The number of cases filed before the tribunal has steadily decreased, and one major industry association, Recorded Music New Zealand, has reportedly reduced the number of notices sent out due to the high cost (there is a NZ$25 charge for each notification and an additional NZ$200 charge to file a complaint with the Copyright Tribunal for each case) and also stopped filing cases before the Tribunal. In total, there have been 23 decisions taken by the Copyright Tribunal since the introduction of the notification system. The latest decision taken by the tribunal is from February 2015 in the case *Recorded Music NZ Limited v Telecom NZ*. Emblematic of many of the previous decisions taken by the tribunal, this application was dismissed on a technicality; the notices sent to the accused account holder did not contain enough information about the relevant laws and legal process. While the tribunal noted that it "appreciates the difficulty that this [the basis of the decision] may cause for rights owners, who of course are not responsible for sending infringement notices, yet who bear the consequences of any errors in those notices that cause them to be invalidated," the bottom line for rights-holders is that there is no practical or effective remedy to what has become widespread copyright infringement in New Zealand through file sharing. Public opinion polls consistently show a high proportion of internet users in New Zealand engaging in copyright-infringing

activities online. A 2015 Colmar Brunton poll of young internet users shows close to 50% engaged in the illegal streaming of television programming. Similarly, in a 2016 survey by Ernest & Young on online consumer behavior in several economies in the Asia Pacific region, 58% of respondents in New Zealand admitted to illegal downloading and streaming. More recent research suggests that the situation remains largely unchanged. A 2018 survey by the satellite operator Sky TV New Zealand found that 8% of the respondents watched live pirated sporting events. The survey also found that half of the respondents had accessed pirated material in some form in the past. Like many other economies included in the Index, New Zealand has also seen a rise in the number of set-top-boxes sold—often branded as "Kodi boxes"—through which users can access copyright-infringing material online. The MBIE's "Issues Paper Review of the Copyright Act 1994" correctly identifies these challenges that rights-holders face in New Zealand. As the paper rightly notes, the Copyright Tribunal "is no longer being used by copyright owners." The paper recognizes the lack of effective enforcement mechanisms in New Zealand, plainly stating, "The use of pirate websites, which are usually hosted overseas and, therefore, beyond the jurisdiction of New Zealand's laws, and the development of new technologies for online infringement create new challenges for copyright owners in addressing online infringements. Traditional enforcement measures are becoming largely ineffective for addressing online infringements." In light of this statement, Paragraphs 507-511 of the paper bring up the possibility of considering additional enforcement measures, such as the disabling of access through an injunctive-style relief program. The past half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the United Kingdom, India, Singapore, Russia, India, and a host of other economies have introduced measures that allow rights-holders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called "dynamic" injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace. Of note is New Zealand's neighbor Australia, which has become a global leader in this area of copyright enforcement. Section 115a of the Copyright Amendment (Online Infringement) Act 2015, which allows courts to require ISPs to disable access to foreign-hosted sites (or "online locations") whose primary purpose is to infringe copyright, has set a global example for how copyright law can be shaped to directly aid rights-holders in enforcing their rights. At the time of research, the MBIE was still collecting stakeholder feedback, and no draft reform proposal had been published. The Index will continue to monitor these developments in 2021.

Systemic Efficiency

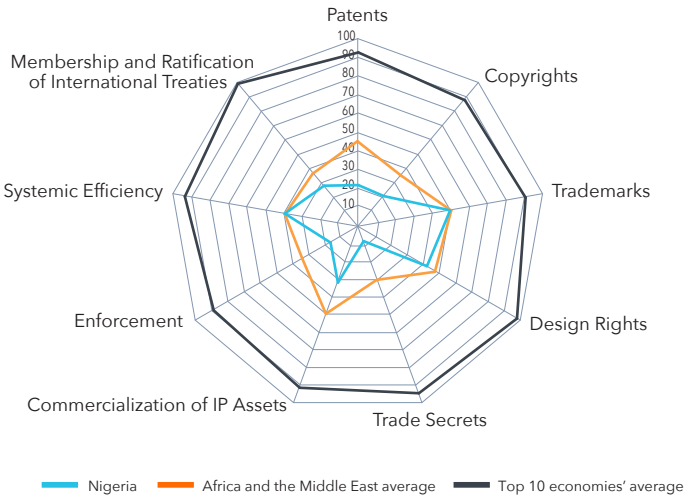
40. Consultation with stakeholders during IP policy formation: The government of New Zealand has historically included public consultation and stakeholder engagement as key features of its legislative and regulatory-making process. The Intellectual Property Office of New Zealand (IPONZ) and Ministry of Business, Innovation, and Employment regularly hold public consultations on prospective changes to IP laws and regulations. More broadly, draft bills in New Zealand Parliament undergo a consultation process, as do proposed changes to government regulations, which are statutorily required to be subject to a formalized regulatory impact analysis. For example, under the 2017 *Cabinet Office Circular CO(17)3 Impact Analysis Requirements* and the accompanying *Guide to Cabinet's Impact Analysis Requirements*, the requirement to carry out public consultations is

clearly defined. Section 10.3 of the guide states, "Agencies proposing new or changed regulation must demonstrate consultation with affected parties on the problem definition, the range of feasible options, and the impacts of the options." In 2019-20, these requirements were strengthened by the New Zealand Treasury, with a greater emphasis placed on public consultation as part of the regulatory-making process. An updated *Guidance Note Effective Consultation for Impact Analysis* was issued in December 2019. Similarly, in June 2020, a revised and updated *Cabinet Office Circular CO(20)2 Impact Analysis Requirements* and accompanying *Guide to Cabinet's Impact Analysis Requirements* were issued. In addition to the requirements outlined in the 2017 circular, government agencies are also now expected to "report on the results of consultation and your responses to the issues raised." As a result of these changes, the score on this indicator has increased by 0.25.

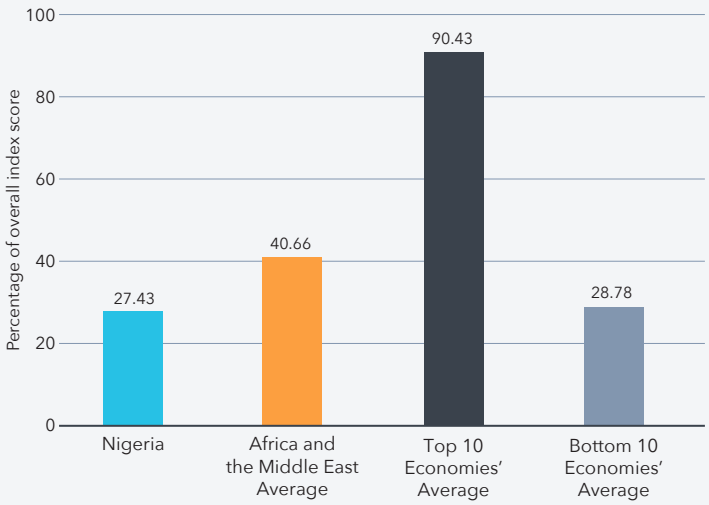
NIGERIA

RANK
50/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Ratified the WIPO Internet treaties in 2017
- ✓ Despite overall challenging environment, ongoing enforcement efforts by Nigerian Communications Commission (NCC) are encouraging

KEY AREAS OF WEAKNESS

- × Overall weak and limited legal and regulatory framework with major forms of IP rights not in place
- × Enforcement challenges persist—no national coordination, only ad hoc efforts
- × Persistently high rates of physical and growing online piracy
- × Software piracy estimated at 80% by BSA
- × Localization barriers and restrictions in place on technology transfer and licensing activities—intensified in 2020
- × National Office For Technology Acquisition and Promotion (NOTAP) oversees all technology transfer and licensing between Nigerian entities and foreign licensors and has the power to evaluate and approve or disapprove technology transfer agreements, including evaluating royalty amounts

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**2.00**
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.00
4. Plant variety protection	0.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.49**
10. Term of protection	0.74
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. Digital rights management	0.00
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.25**
23. Protection of trade secrets (civil remedies)	0.00
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**1.92**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.00
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**1.20**
32. Physical counterfeiting rates	0.25
33. Software piracy rates	0.20
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**2.00**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 13.71

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Nigeria's overall score has decreased from 27.60% (13.81 out of 50) in the eighth edition to 27.43% (13.71 out of 50) in the ninth edition. This is driven by an increase on indicator 20 but score decreases on indicators 26 and 32.

Trademarks, Related Rights, and Limitations

20. Availability of frameworks that promote cooperative private action against online sale of counterfeit goods: In 2019, total e-commerce sales worldwide were estimated to be USD3.46 trillion, up by 17.9% from 2018. E-merchants and online platforms such as eBay, Amazon, Alibaba, Mercado Libre, and others today account for a growing share of global retail sales. Unfortunately, as online shopping becomes more popular and widespread, so too does the proliferation and sale of counterfeit goods. Yet few economies offer effective mechanisms to combat the increased sale of counterfeit goods through these online auction houses and merchants. In this respect, Nigeria is no different from most other economies included in the Index. As rates of internet penetration increase—particularly through mobile phones—online shopping and e-commerce have grown exponentially. In 2018, the value of e-commerce in Nigeria was estimated at USD12-13 billion, or roughly 10% of the total retail market. There has historically been no comprehensive legal or regulatory framework akin to a notice-and-takedown regime for online shopping in Nigeria, and private initiatives have been lacking. Consequently, rights-holders have been limited in how they can combat the sale of counterfeit goods online. Today, the two largest online shopping sites in Nigeria, Jumia and Konga Online, have put in place more robust procedures and measures to help ensure the legality of goods on their respective websites. For example, Konga Online has an Authentic Items Policy program that actively monitors the authenticity of goods sold on its website. Under the policy, the company reserves the right to proactively remove IP-infringing and counterfeit goods, ban individual sellers, and give rights-holders the ability to contact them directly through a notification mechanism. Jumia offers a similar mechanism. As a result of these changes in local market conditions, the score for this indicator has increased by 0.25.

Commercialization of IP Assets and Market Access

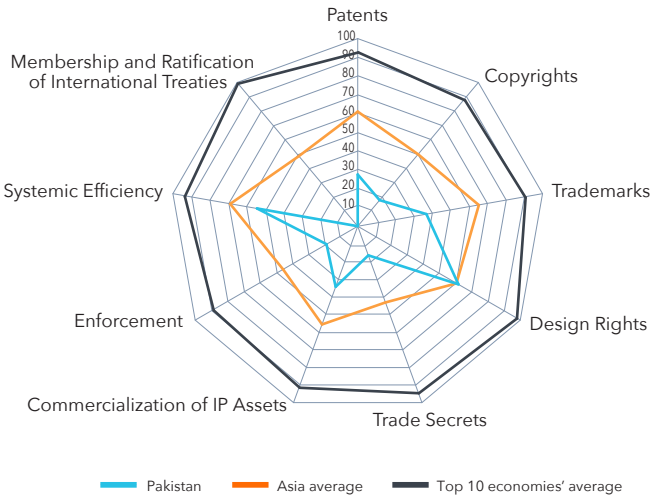
26. Barriers to market access: Nigeria has had several localization policies and local content requirements in place since 2010. These policies have targeted specific sectors of the economy, including energy and ICT. The 2010 Nigerian Oil and Gas Industry Content Development Act is the legislative basis for most of these policies. The law and accompanying regulatory guidance provide a detailed list of requirements ranging from the employment of local staff, mandatory local procurement, and technology transfer. Specifically, these requirements include that a minimum of 50% of oil or other petroleum products are reserved for trade and marketing for Nigerian-owned companies, and limits are in place for the filling of management positions for ex-patriots (at the time of research, this was a maximum of 5% of management staff). The law also requires foreign entities to actively engage in the transfer of technology to Nigerian entities. Specifically, Articles 43-46 of the act require affected entities to "carry out a programme … for the promotion of technology transfer to Nigeria in relation to its oil and gas activities." This includes taking part in joint ventures and partnering and licensing activities with local Nigerian companies. Over the past few years, these regulations have intensified with regard to oil rigs and related technologies. The U.S. State Department in its 2020 Investment Climate Statement stated that these

policies "may violate a company's intellectual property rights." Similar requirements are in place for the ICT sector through the *Guidelines for Nigerian Content Development in Information and Communication Technology* developed and enforced by the Office for Nigerian Content Development in Information & Communication Technology. These guidelines impose substantial localization requirements including the hosting of government data within Nigeria. Foreign entities are required to put in place plans for the development of local content and support initiatives, and all Nigerian public sector entities are required to procure ICT equipment and software locally. In 2019 and 2020, these localization requirements intensified. In late 2019, NITDA updated its guidelines and re-stated its commitment to the full implementation of its localization drive. This includes retaining some of the most onerous and restrictive requirements with respect to multinational software companies. Under section 10.3 of the guidelines, multinationals are required to continue to "provide verifiable information and sign affidavits about the origin, safety and workings of software being sold and deployed within the country in order to ascertain the full security of the product and protect National security." In May 2020, the upper chamber of the National Assembly announced that it was working on new amendments to the Nigerian Oil and Gas Industry Content Development Act. The stated purpose of these changes would be to not only strengthen existing localization requirements for the oil and gas industry, but also extend these requirements to other sectors of the economy. The conditioning of market access with the sharing of IP through direct technology transfer requirements or indirectly through local manufacturing, ownership, or production requirements is a significant barrier to trade and investment. Over the course of the Index, these requirements have not been rolled back in Nigeria but have, instead, intensified. As a result, the score on this indicator has decreased by 0.25. The imposition of additional requirements and the active implementation of existing requirements will further reduce the score on this indicator.

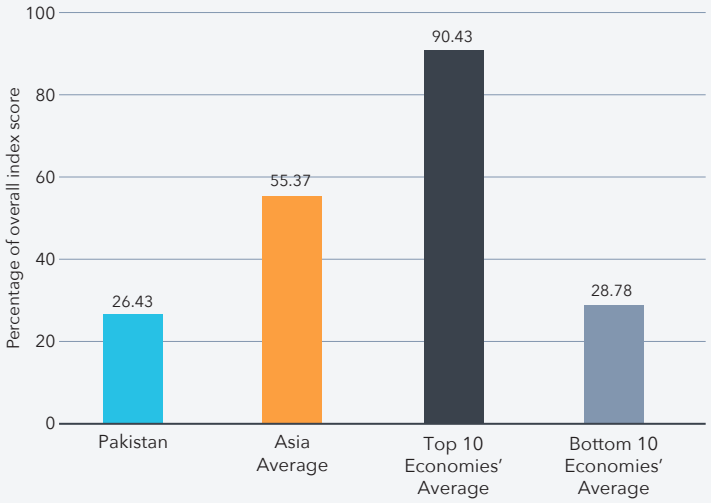
PAKISTAN

RANK
52/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Basic IP laws and legal framework in place
- ✓ Introduction of specialized IP courts and capacity building
- ✓ Greater efforts at public education, modernization of IP laws, and enhancing coordination among enforcement agencies

KEY AREAS OF WEAKNESS

- × Limited sector-specific IP protection available
- × Significant discrepancy between IP rights in law and level of practical enforcement
- × Enforcement often arbitrary and non-deterrent (though efforts to improve are underway)
- × High counterfeiting and piracy rates—latest BSA estimates put software piracy at 83%

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**2.50**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.28**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.00
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**1.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.00
Category 4: Design Rights, Related Rights, and Limitations	**1.25**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**2.08**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.33
Category 7: Enforcement	**1.36**
32. Physical counterfeiting rates	0.19
33. Software piracy rates	0.17
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.75**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**0.00**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 13.22

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Pakistan's overall score has decreased slightly from 26.50% (13.25 out of 50) in the eighth edition to 26.43% (13.22 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Design Rights, Related Rights, and Limitations

22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights: In 2020, the national IP office, IPO-Pakistan, issued for public consultation draft implementing regulations, "Registered Designs Rules," for the Registered Designs Ordinance of 2000. This is a positive step, as the 2020 legislation has, given the lack of implementing rules, yet to come fully into force. The draft rules provide registered design owners with exclusive right to make and sell, work articles bearing the design for commercial purposes. Remedies available to rights-holders are injunctions and damages, including the possibility to seek temporary injunctions against design infringement. A rights-holder can also initiate a criminal action against the infringer, who can be punished with up to two years in prison, a fine, or both. The Index will continue to monitor these developments in 2021.

Enforcement

34. Civil and procedural remedies and 36. Criminal standards including minimum imprisonment and minimum fines: As noted in previous editions of the Index, rights-holders in Pakistan face a challenging enforcement environment. While civil remedies are available for most major IP rights, there are considerable gaps in the legislation. Criminal penalties are inadequate and non-deterrent given the lack of minimum sentences. There are long delays in the judiciary. One report suggests that over 600,000 cases are pending in civil courts, with cases lasting up to five years, although many cases never reach trial. Some improvements to the enforcement system have taken place in recent years. For instance, certain provinces have raised penalties for IP infringement. In 2015, Punjab province increased penalties for the production and sale of counterfeit medicines to a minimum of five years (with a maximum of 10 years). Also in 2015, IPO-Pakistan introduced specialized IP courts, training for judges, and efforts to reduce red tape. Still, evidence on the ground suggests that the enforcement environment remains difficult, with counterfeit goods widely available domestically and Pakistan a source and supplier of counterfeit goods traded internationally. The OECD and EUIPO, in the 2017 *Mapping the Real Routes of Trade in Fake Goods*, listed Pakistan as the second largest source of counterfeit manufactured and non-manufactured foodstuffs globally. Customs data collected suggested that approximately 20% of global customs seizures of counterfeit food products originated in Pakistan, virtually tied with India, which was listed as the number one source. The report also found that Pakistan was a provenance economy for counterfeit perfumes and cosmetics and counterfeit clothing and textile fabrics.

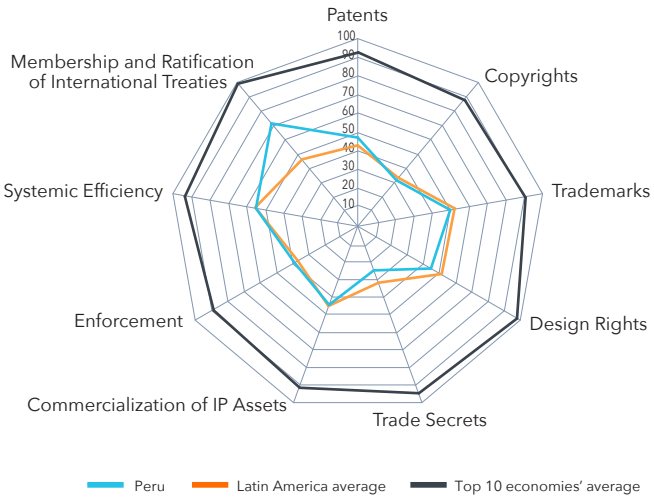
Membership and Ratification of International Treaties

As mentioned in previous editions of the Index, IPO-Pakistan has stated its plans to accede to various international IP treaties, including the Protocol Relating to the Madrid Agreement and the Patent Cooperation Treaty. In February 2021, WIPO announced that Pakistan acceded to the Treaty which would become operational and available to rights-holders later in the year. Pakistan's accession to the Madrid Protocol is a positive development and the Government of Pakistan should be congratulated. The accession to the treaty and resulting score increase for indicator 45 will be reflected in the next edition of the Index.

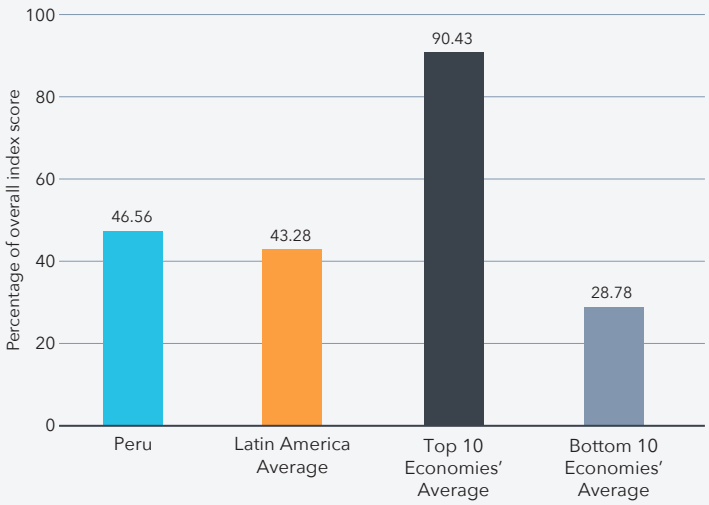
PERU

RANK
32/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Joined the Global Patent Prosecution Highway in 2019
- ✓ INDECOPI in 2019 continued suspending access to copyright-infringing websites
- ✓ Basic IP protections available
- ✓ Border measures provided for in legislation
- ✓ Efforts to coordinate IP rights enforcement across government agencies and to raise awareness about the importance of IP protection

KEY AREAS OF WEAKNESS

- × Compulsory license actively being considered for biopharmaceuticals based on cost
- × Administrative and regulatory barriers in place for licensing and technology transfer
- × Limited patentability and lack of effective IP protection for life sciences
- × Rudimentary digital copyright regime (with some exceptions)
- × High rates of counterfeiting and piracy
- × Gaps in IP enforcement on the ground

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**4.25**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**2.24**
10. Term of protection	0.74
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.75**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.25

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**2.67**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**2.72**
32. Physical counterfeiting rates	0.34
33. Software piracy rates	0.38
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**2.75**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**5.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

TOTAL: 23.28

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Peru's overall score has increased from 46.12% (23.06 out of 50) in the eighth edition to 46.56% (23.28 out of 50) in the ninth edition. This reflects a score increase on indicator 27.

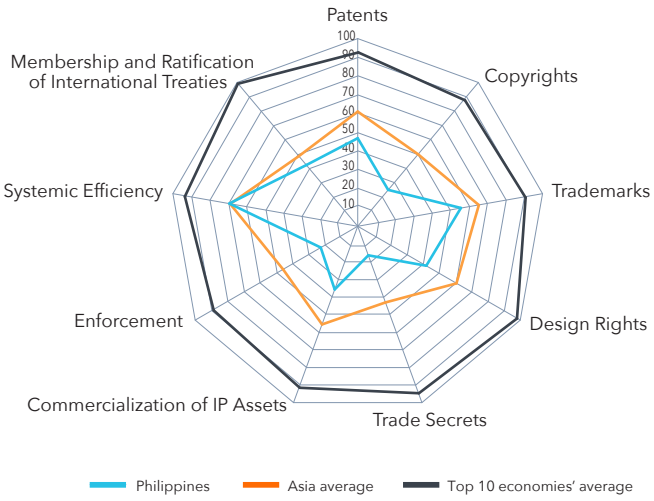
Commercialization of IP Assets and Market Access

27. Barriers to technology transfer: Like other members of the Andean Community trading bloc, Peru's IP laws are subject to decisions made by the Andean Community. Andean Decision 291 provides an overview of requirements for licensing technologies and technology transfer activities. Article 12 states that all licensing activity should be recorded and evaluated by the respective national authorities. Specifically, it states Andean Community members shall "evaluate the effective contribution of the imported technology by estimating the probable profits or the price of the goods that incorporate technology, or through other specific methods of quantifying the effect of the imported technology." One of the most significant barriers to all facets of licensing and technology transfer—domestic and cross-border—is direct government intervention and setting of licensing terms such as that captured in Decision 291. Such intervention consists of a centralized, top-down approach that seeks to mandate when and how licensing and technology transfer take place. Impeding licensing activity is not cost-free. Just like with other impediments to the protection of IP, the restriction of licensing hurts all parties, from licensors to licensees to the domestic economy in which the licensing is being restricted. Unfortunately, there is a risk that restrictions such as these neutralize other incentives for technology transfer and the registration and commercialization of IP assets. Like many economies, Peru is seeking to move up the economic value chain and transition its economy toward more innovation-based activities and to encourage the development of high-tech industries. The government –including the National Institute for the Defence of Competition and the Protection of Intellectual Property (INDECOPI)– has placed a special emphasis on promoting technology development and transfer. A special *Plan for Tech Transfer 2016-2021* was issued with the goal of enhancing industry's competitiveness and productivity through tech transfer and enhanced IP registration. Article 53 of the 2014 University Law No. 30,220 vests IP ownership with individual university institutions, which are also entitled to at least 20% of any royalties. Since 2014, several universities have developed IP policies along these lines. In 2020, INDECOPI introduced new measures aimed at accelerating the creation and transfer of technologies developed by universities. This includes a technical assistance program developed with the Ministry of Education and the National Council of Science, Technology and Technological Innovation. The program's primary objective is capacity building and to encourage and institutionalize the creation of IP assets and commercialization activities within individual institutions. In 2020, the initiative targeted 15 institutions in Lima and the surrounding region. As a result of these positive steps to improve the technology transfer environment in Peru, the score on this indicator has increased by 0.25.

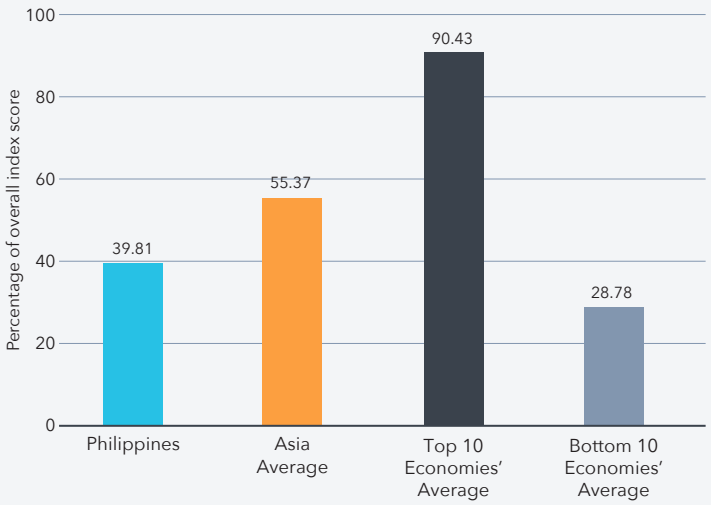
PHILIPPINES

RANK
38/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Draft amendments to IP Code would strengthen IP environment
- ✓ R&D tax incentives in place
- ✓ Most basic IP rights provided for in existing legislation
- ✓ Growing specialization and capacity building, such as in administrative IP courts

KEY AREAS OF WEAKNESS

- ✗ Barriers in place for licensing and technology transfer
- ✗ Significant gaps in life sciences and content-related IP rights
- ✗ Online piracy high, with digital protection largely unaddressed
- ✗ Software piracy estimated at 64% by BSA

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**4.25**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**1.78**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**2.17**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**1.61**
32. Physical counterfeiting rates	0.25
33. Software piracy rates	0.36
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**3.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 19.91

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

The Philippines' overall score has decreased slightly from 39.94% (19.97 out of 50) in the eighth edition to 39.81% (19.91 out of 50) in the ninth edition. This reflects a marginal score decrease on Indicator 32.

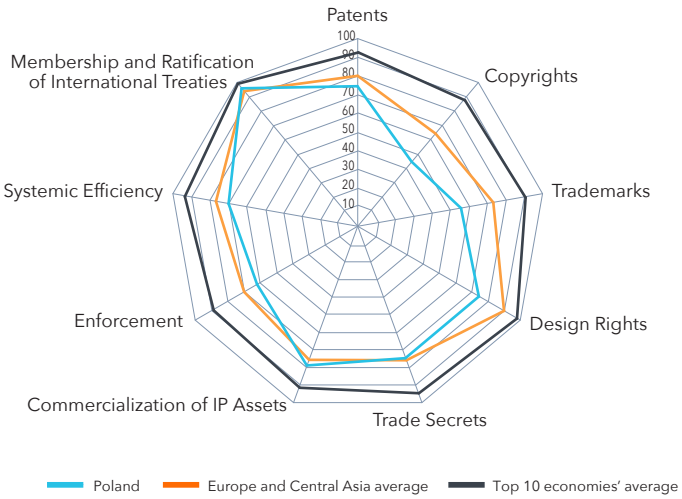
Copyrights, Related Rights, and Limitations; and Trademarks, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online; and 20. Availability of frameworks that promote cooperative private action against online sale of counterfeit goods: As noted in previous editions of the Index, the Philippines has intensified efforts in the fight against online infringement. In 2019, the national parliament, the Congress of the Philippines, moved closer to adopting substantive changes to its copyright environment that will provide rights-holders with more effective ways of combating online infringement. Specifically, two bills introducing a notification regime and injunctive-style relief are pending. House Bill 9148 would allow the Intellectual Property Office of the Philippines (IPOPHIL) to issue notice-and-takedown orders to address online piracy and counterfeiting. The bill would enable copyright owners to claim damages from infringing sites and grant them ownership of the domain name of the infringing site. The Philippines Online Infringing Act, which is being considered by the Philippine Senate (Senate Bill No. 497), would allow IPOPHIL to petition the National Telecommunication Commission to cancel an ISP's operating license should it fail to remove infringing content within 10 days from receiving a notification from IPOPHIL. At the time of research, these bills were still pending. With respect to online counterfeiting and trademark infringement, IPOPHIL has actively pursued expanded powers to address the growing presence of counterfeit and trademark-violating goods online. In 2019, IPOPHIL launched a focus group discussion with online platforms to address how to respond to violation notices more effectively and how to intervene preemptively to preclude online access to counterfeit goods. This continued in 2020 with proposed amendments to IPOPHIL's "Rules and Regulations in the Exercise of Enforcement Functions and Visitorial Power." Proposed revisions would expand the agency's powers to explicitly cover online IP-infringing activities. This would allow IPOPHIL to take stronger action based on rights-holders' complaints, including ordering the takedown of pages displaying infringing goods and, ultimately, the disabling of access to infringing sites. Citing the increased level of infringement and presence of counterfeit goods online during the COVID-19 pandemic, in November 2020, IPOPHIL's Director General pointed to the necessity of changing the agency's enforcement functions, saying this would "strengthen our enforcement mandate in the area of e-commerce, allowing us to request the take down and blocking of websites by rightful authorities." The introduction of such a mechanism allowing IPOPHIL to investigate and take effective action against illicit activity online would be a positive development. The Index will continue to monitor this in 2021.

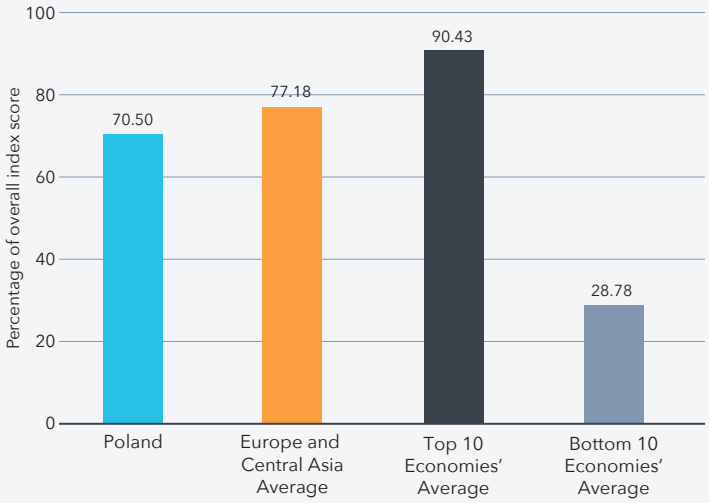
POLAND

RANK
19/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ R&D tax incentives in place
- ✓ Transposition of EU Trade Secrets Directive in 2018 harmonizes Polish trade secret law with EU standards
- ✓ Legal framework for IP protection largely aligned with EU standards

KEY AREAS OF WEAKNESS

- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Poland's and EU's research- and IP-based biopharma industry
- × Gaps in online copyright protection, including an effective notice-and-takedown system
- × Relatively high levels of online piracy in comparison with other high-income economies

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**6.75**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**3.16**
10. Term of protection	0.66
11. Exclusive rights	0.25
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**2.25**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**4.75**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**4.34**
32. Physical counterfeiting rates	0.55
33. Software piracy rates	0.54
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.25
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 35.25

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Poland's overall score has decreased slightly from 70.56% (35.28 out of 50) in the eighth edition to 70.50% (35.25 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force, and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union (CJEU) handed down a verdict in the case *Santen SAS v. Directeur général de l'Institut national de la propriété industrielle,* C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treat-

ments. In earlier rulings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now effectively been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**." From a legal perspective, the court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced

side effects. Still, treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence which, has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

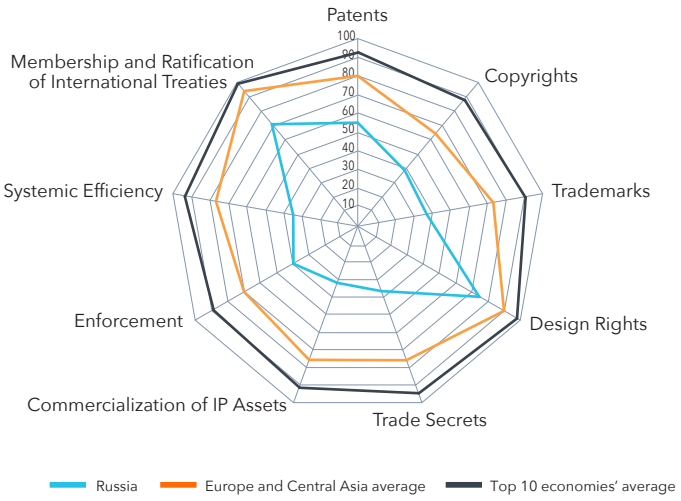
Enforcement

34. Civil and procedural remedies: Important changes to the civil enforcement of IP rights in Poland occurred in 2020. Specifically, amendments to the Code of Civil Procedure have introduced new specialized IP courts. Four courts of first instance have been created with another two courts acting as specialist centers for IP-related appeals. For complex and highly technical disputes—including relating to patent rights, CIIs, and trade secrets—the court in Warsaw will act as a national specialist court. Historically, enforcement through the judiciary has not always been smooth in Poland. As has been noted over the course of the Index, Polish IP jurisprudence has not always been in line with thinking in other major jurisdictions. See, for example, the 2016 Supreme Court judgment in case II CSK 282/15 on patent infringement and validity proceedings as well as a 2015 Constitutional Court ruling on copyright damages that effectively slashed the amount of damages available to rights-holders in infringement proceedings. These changes will hopefully improve the overall technical capacity, expertise, and quality of judicial enforcement.

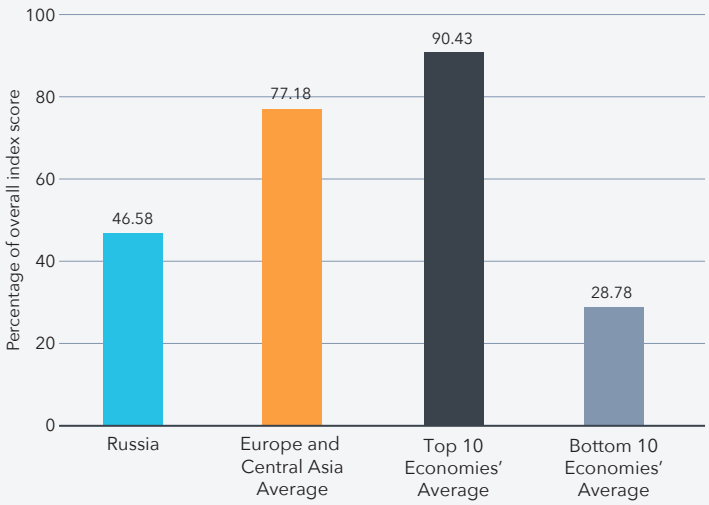
RUSSIA

RANK
31/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Past few years have seen new copyright laws passed—strengthens rights-holders ability to request the disabling of access to infringing material online
- ✓ ROSPATENT has in place numerous PPHs and is a full participant in the GPPH
- ✓ Full participant in international IP treaties

KEY AREAS OF WEAKNESS

- × Weakening of life sciences environment through new administrative barriers for patentability and term restoration
- × Use and threat of compulsory licenses and the overriding of IP rights as public health policy
- × Administrative and regulatory barriers in place for licensing activities—including direct government intervention
- × Increasingly punitive localization requirements targeting ICT and biopharmaceutical sectors
- × Data localization requirements for technology companies have been in place for a long time and have intensified over the past few years
- × For biopharmaceuticals, industrial localization policies have fused together with IP policy and broader health policy on the pricing and procurement of medicines
- × Lack of effective copyright criminal enforcement activity, primarily due to inadequate expertise and resources on the part of law enforcement and prosecutors

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**5.00**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**2.74**
10. Term of protection	0.74
11. Exclusive rights	0.50
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.00
15. Digital rights management	0.25
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**1.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.00
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.10**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.60

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**1.92**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.25
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**2.78**
32. Physical counterfeiting rates	0.40
33. Software piracy rates	0.38
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**1.75**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**5.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

TOTAL: 23.29

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Russia's overall score has increased from 45.92% (22.96 out of 50) in the eighth edition to 46.58% (23.29 out of 50) in the ninth edition. This reflects a score increase on indicator 36.

Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism: As noted in last year's Index, in September 2019, the Ministry of Health published draft legislative proposals for changes to Law No. 61-3, 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 IP exclusivity. Furthermore, Federal Service for Intellectual Property (ROSPATENT) is to house a register of the current exclusivity status of registered products. At the time of research, the draft law was still being debated and no final legislation had been passed or signed into law. Given the broader deterioration in Russia's biopharmaceutical IP environment, as noted in the Index over the past few years, the introduction of such a mechanism would be a positive step and result in a score increase on this indicator.

6. Legislative criteria and use of compulsory licensing of patented products and technologies; 26. Barriers to market access: As has been detailed in previous editions of the Index, Russian industrial and economic policy over the past decade has increasingly been driven by an effort to localize industrial production and R&D. Key policy initiatives include the Strategy for Innovative Development of the Russian Federation 2020; the State Coordination Program for the Development of Biotechnology; the Strategy of Development of the Pharmaceutical and Medical Industries; the New Digital Society Strategy 2017–30; and the National Economic Security Strategy, 2017. A major part of these efforts has been localization and import substitution policies that actively discriminate against foreign entities and favor domestic Russian companies. While covering most parts of the economy, high-tech sectors such as aerospace and nuclear energy, nanotechnology, medical technologies, ICT, and alternative fuels have been targeted. The requirements and intensity of these policies have varied from sector to sector, but both the ICT and biopharmaceutical sectors have been especially targeted. Data localization requirements for technology companies have been in place for a long time and have intensified over the past few years. For biopharmaceuticals, industrial localization policies have fused together with IP policy and broader health policy on the pricing and procurement of medicines. These policies intensified in 2019 and 2020. To begin with, amendments to the Code for Administrative Offences have increased potential fines and penalties for non-compliance with data localization requirements and could be as high as USD300,000. The rules require that all data processing of Russian nationals physically take place in Russia, with exceptions only provided for non-Russian nationals. Similarly, new restrictions and local production requirements have been put in place on the biopharmaceutical industry. In August 2020, the list of drugs classified as being of strategic interest and subject to local manufacturing requirements was increased from 57 to 215 ("Order of the Government of the Russian Federation of August 1, 2020 No. 2015-r On Amending the Order of the Government of the Russian Federation of July 6, 2010 No. 1141-r"). The result is a highly challenging environment that targets high-tech, innovation-based industries with requirements for local manufacturing, procurement preferences

for locally produced products, local clinical trials and R&D requirements, and the use and threat of compulsory licenses and the overriding of IP rights as public policy. Increasingly, Russian authorities, including members of the Russian Parliament (the Duma), the federal government, and judiciary, are viewing compulsory licensing for biopharmaceuticals as a legitimate policy tool for achieving industrial and public finance goals. The Russian Federal Antimonopoly Service (FAS) has been particularly active. In 2016, a compulsory license scheme as a method of reducing prices of certain high-cost specialty medicines was proposed by the agency. According to the proposed amendments to the Competition Act and the Civil Code, "threats to the individual and the rights of citizens to health protection and medical care" would justify the issuing of compulsory licenses. In 2017, the head of FAS, Igor Artemyev, stated it was only a matter of time before the government would formally begin to use this tool. In 2018, the first court-ordered biopharmaceutical compulsory license was issued. In July of that year, the Moscow Arbitration Court granted a compulsory license to local manufacturer Nativa for Celgene's Revlimid. The compulsory license was for Celgene to license one of its granted patents for the production of a product in which a dependent patent was to be used by Nativa. Without a license, the use of this patent would constitute infringement of Celgene's patent. Critically, the lower cost of the product by Nativa was considered by the court as being economically advantageous and a deciding factor in granting the license. In 2019, another compulsory license was issued to Nativa on largely similar grounds. In November 2019, a bill was sent to the Duma to amend existing laws on compulsory licensing (Article 1360 of Part IV of the Civil Code). The proposed amendments would provide a fairly broad ground for a compulsory license to be issued in the event of a national emergency and to protect the health and safety of the public. On December 31, 2020, the Russian government issued a compulsory license under Order 3718. The order authorizes a local manufacturer to produce a generic version of remdesivir, an antiviral drug used in the treatment of COVID-19, and the overriding of existing Eurasian patents for the drug. The order is based on Article 1360 of the Civil Code Part IV, which grants the government broad powers to act "in the interest of national security" and override any existing granted rights relating to patents, utility models, and industrial designs. News reports suggests that the order follows a request by the local manufacturer made to the government in November 2020. Compulsory licensing as an actively used tool in Russian industrial and health policy not only is outside international norms but is self-defeating. Over time it will hollow out Russia's national IP environment and incentives for future innovation, biopharmaceutical and otherwise. Critically, the negative effect will be the same on Russian as on foreign innovators.

Copyrights, Related Rights, and Limitations; and Enforcement

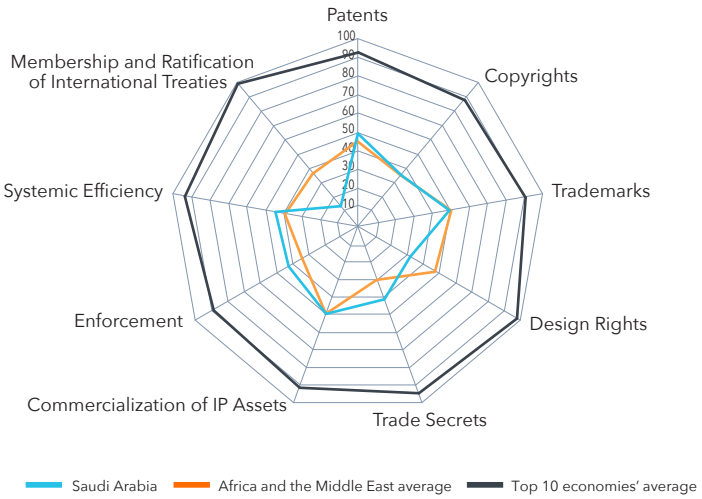
11. Exclusive rights; 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Cooperative action against online piracy; and 36. Criminal standards: Over the past decade, Russia has introduced and implemented a range of new laws and regulations to help combat the country's high level of online copyright infringement. Over the past nine editions, as a percentage of the available score, Russia's score on this category has almost doubled, rising from 20.67% on the first edition of the Index to 39.14% in this year's edition. This positive trend began in 2013, which saw the passing of several amendments to the Civil Code Part IV, including a notice-and-takedown provision with regard to the responsibilities of "information intermediaries," with an obligation to act on a notice of infringement from a rights-holder. These amendments also included the introduction of interim judicial measures, designating the Moscow City Court as the

first instance of such application and with the power of issuing temporary injunctions. Furthermore, a rights-holder could also apply to the Federal Service for Supervision in the Sphere of Telecom, Information Technologies, and Mass Communication (the ROSKOMNADZOR) for the enforcement of these provisions. Specifically, ROSKOMNADZOR was given the power to issue notices to the hosting service provider requiring (1) notification to the alleged infringer, and (2) if no action was taken, the restriction of access to the alleged infringing material. In 2017, further legislative changes were introduced to strengthen rights-holders' ability to request the disabling of access to infringing material online. Specifically, there were several important amendments to the "Law on Information, Information Technologies and Information Protection." These amendments included a ban on so-called mirror sites that infringe copyrighted content. These mirror websites are essentially replicas of sites that have been taken down or to which access has been disabled. Rights-holders now have the option of notifying the Ministry of Communications, which has two days to order the hosting provider to disable access to the site. Furthermore, internet mediators (including search engines) are obliged to remove links to sites that have been found to host illegal content. ROSKOMNADZOR actively monitors online infringement and has developed a database of infringing content. Finally, a "Counter-piracy Memorandum of Understanding" between creators and internet mediators was agreed and signed in late 2018. Although it still remains high, the aggregated result of these efforts has been a decrease in online infringement. For example, the Russian government has estimated that access has been disabled to almost 1,000 copyright-infringing websites since legislative changes were introduced. Similarly, statistics released by the cybersecurity firm Group-IB estimate that the Russian online market for copyright-infringing content in 2019 shrunk for the first time in five years. One area where there has long been a lack of consistent enforcement has been with respect to criminal sanctions for copyright infringement. Criminal standards are in place in the Criminal Code for most major IP rights, including copyright. However, as noted over the course of the Index, their application and enforcement have remained weak in relation to both physical and online piracy. The U.S. government has long pointed to criminal enforcement as an area in need of improvement. For example, the USTR in the 2020 *Special 301 Report* stated that "the United States is concerned about stakeholder reports that IP enforcement remains inadequate and that Russian authorities continue to lack sufficient staffing, expertise, and the political will to effectively combat IP violations and criminal enterprises." In what could be a precedent-setting case, in December 2019, a Russian court handed down a criminal conviction of the proprietor of a group of copyright-infringing websites providing access to pirated film and television. The conviction resulted in a two-year suspended prison sentence, with local legal analysis stating that this is the first criminal conviction of its kind in Russia. As a result of these stronger criminal enforcement efforts, the score for indicator 36 has increased by 0.25.

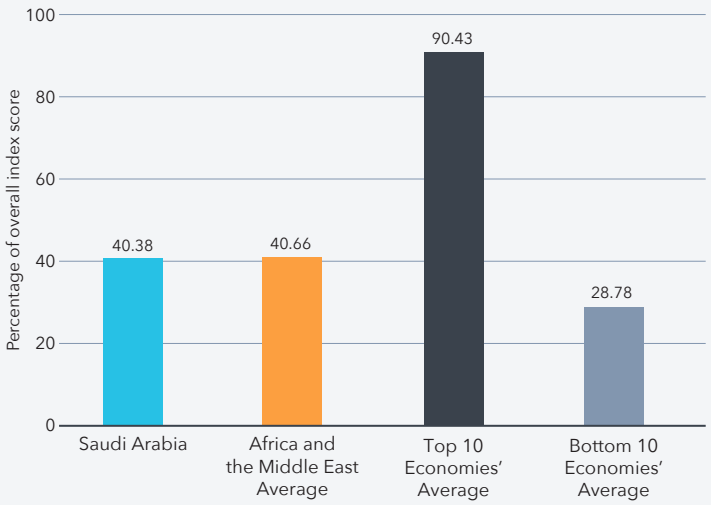
SAUDI ARABIA

RANK
37/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Saudi IP authority has put in place ambitious reform agenda—continued in 2020
- ✓ Joined multiple PPHs joined in 2019-20
- ✓ Increased consultation and awareness-raising activities in 2019
- ✓ Stronger copyright enforcement through Saudi IP Authority
- ✓ Strong and sustained focus by Saudi authorities and institutions to encourage IP commercialization and technology transfer
- ✓ *Ex officio* authority in place for customs officials

KEY AREAS OF WEAKNESS

- × Pharmaceutical patent protection and linkage mechanism in effect suspended through Saudi Food and Drug Authority (SFDA) actions in 2017
- × Significant gaps in copyright framework—chiefly relating to protection online
- × Increasing number of localization requirements
- × Industry reports of a lack of practical availability of RDP—indirect reliance has been allowed when reviewing follow-on products
- × Limited participation in international IP treaties

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**4.50**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.75
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**2.53**
10. Term of protection	0.53
11. Exclusive rights	0.50
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.25
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.65**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.00**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**3.01**
32. Physical counterfeiting rates	0.48
33. Software piracy rates	0.53
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.00
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**2.25**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**1.00**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 20.19

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Saudi Arabia's overall score has increased from 39.44% (19.72 out of 50) in the eighth edition to 40.38% (20.19 out of 50) in the ninth edition. This reflects score increases on indicators 12 and 42.

Area of Note

On January 5, 2021, the Gulf Cooperation Council Patent Office announced that, following the 41st Session of the Supreme Council and amendments to the Patent Regulation, the Patent Office would no longer be accepting patent applications. The announcement was unexpected, as the GCC patent application route had been operational for more than two decades. At the time of research, it was unclear what would happen to applications filed prior to the announcement. The Index will continue to monitor these developments in 2021.

Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism: Saudi Arabia introduced a patent linkage system in 2013. Under Circular Letter No. 7448, the Saudi FDA requires follow-on generic applicants to submit a letter from the Saudi Patent Office and/or the GCC Patent Office indicating that no registered patent exclusivity is or will be in place for the relevant reference product at the time of marketing approval. As discussed in previous editions of the Index, the Saudi FDA has effectively overridden Saudi Arabia's linkage regime by approving for market a follow-on product to daclatasvir, a medicine under a registered patent held by Bristol Myers Squibb (BMS). This is a highly negative development that undermines confidence in Saudi Arabia's national IP environment and the ability for innovators to maintain basic patent protection. More broadly, it runs counter to the goals and general principles of Saudi Arabia's economic policy as outlined in both the *Vision 2030* and *National Transformation Program 2020*. At the time of research, this issue had still not been rectified or effectively addressed by Saudi authorities.

6. Legislative criteria and use of compulsory licensing of patented products and technologies: There has historically been a degree of uncertainty regarding the use of compulsory licenses in Saudi Arabia. Article 24 of the Law of Patents, Layout Designs of Integrated Circuits, Plant Varieties, and Industrial Designs outlines the legal basis and process by which a compulsory license can be issued. Critically, the law provides a very broad public interest basis by which a government-based compulsory license can be issued, including on the basis of the development of the national economy. In 2020, the SAIP issued new implementing regulations ("The Executive Rules for the Compulsory Licensing of the Patent") outlining in more detail under what circumstances a biopharmaceutical rights-holder's exclusivity can be overridden. Unfortunately, these new regulations do not clarify the circumstances that the Law of Patents outlines but just reiterates them. 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 be aimed solely 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, not on the grounds of industrial or economic development.

8. Membership of a Patent Prosecution Highway (PPH): As noted in last year's Index, in a positive move the SAIP signed not one, but two, PPH agreements in 2019. The first agreement, signed in April 2019, is with the Korean Intellectual Property Office. The second agreement was signed with the USPTO in late 2019 at the sidelines of the 59th WIPO General Assembly held in Geneva. These efforts to integrate the Saudi Arabia more fully into the international IP framework continued in 2020. To begin with, another PPH came into effect with the Japan Patent Office. Furthermore, to boost the SAIP's ability to cooperate internationally, in July 2020, it was announced that the Saudi Council of Ministers had approved a standardized memorandum of international cooperation to be used. All of these are significant steps to support innovators and inventors in all affected economies. Until 2019, Saudi Arabia did not have a functioning PPH with any major IP office and its cooperation with other IP offices around the world was limited. PPH initiatives and increased cooperation between IP offices is one of the most tangible ways in which the administration and functioning of the international IP system can be improved and harmonized to help inventors and rights-holders.

Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online: As has been noted in previous editions of the Index, the protection of copyright in Saudi Arabia is highly challenging. Relevant laws and regulations are not well developed, and the illicit use of copyrighted material remains high. Current Saudi copyright law provides for only basic exclusive rights and protection of creative works. While Article 9 of the Copyright Law Royal Decree No. M/41 includes a reference to the exclusive right to communication of a given work to the public "via any possible means," no specific law or regulation is in place that provides a notification-and-takedown mechanism for infringing online content, nor is any similar legal framework in place to address the issue of online infringement more specifically. The Ministry of Culture and Information has sporadically disabled access to web content, including copyright-infringing content, but this has been on an ad hoc basis. Physical and online piracy remains high, with industry reports suggesting that, historically, as much as 90% of music and film content in Saudi Arabia has been pirated. The estimated rate of software piracy by the BSA for 2018 was 47%, only a small change from the 2009 estimated rate of 51%. Since its inception in 2017-18, the SAIP has worked on improving the copyright environment and the ability of rights-holders to enforce their rights more effectively. In 2019, the authority announced that over 160 cases of alleged copyright infringement had been referred to the relevant Saudi enforcement authorities, and fines and penalties had been imposed. The SAIP has also made the disabling of access to infringing content part of its enforcement remit. The authority offers a portal through which rights-holders can directly communicate any suspected online infringement to the SAIP, which will then investigate and take enforcement action. In June 2020, the SAIP announced that it had disabled access to 231 websites from which infringing content was being disseminated. The next step would be to institutionalize this route of administrative enforcement through the issuing of more detailed guidelines or a process note. Nevertheless, this is another positive step taken by the SAIP to offer rights-holders a more effective and practical route of copyright enforcement in Saudi Arabia. As a result, the score on this indicator has increased by 0.25.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection term: The 2005 Minister of Commerce and Industry's Decision No. 3218, "Regulations for the Protection of Confiden-

tial Commercial Information," provides specific protection for submitted clinical research data as part of a biopharmaceutical market registration application. Article 5 of the regulations provides a clear and unambiguous protection term of five years from the date of approval and states that relevant Saudi authorities "shall undertake to protect such information against unfair commercial use, for a minimum period of five years from the date of obtaining the approval." The existence of this RDP is a positive feature of Saudi Arabia's national IP environment. However, as noted over the course of the Index, a level of uncertainty exists over the actual availability of this protection. Industry reports have suggested that follow-on products have been approved using "indirect reliance" on submitted clinical research data. International standards and best practices for RDP are quite clear on this subject: neither direct nor indirect reliance on submitted clinical test data should be used to approve follow-on products within any specified and granted term of exclusivity. In 2020, the SAIP released new draft implementing regulations on how confidential commercial information will be protected in Saudi Arabia. While the SAIP should be applauded for publishing these draft regulations, holding a public consultation, and inviting stakeholder feedback on the matter, the regulations themselves are deeply flawed and stand outside established international standards of RDP. Specifically, Article 4(1) of the regulations states that any term of protection offered in Saudi Arabia would begin from "the date of the first registration of the preparation **in another country**." If implemented, this would dramatically re-write existing regulations and significantly curtail rights-holders' effective RDP term. The introduction of such a definition and the linking of the exclusivity period in Saudi Arabia to a product's first global launch would severely limit the availability of RDP in Saudi Arabia and undermine the incentives for innovation and investment such exclusivity provides. Moreover, the draft regulations do not allow a period of RDP for new indications. The implementation of this regulation and application of the existing provisions in relation to RDP would result in a reduction of the score to 0 for this indicator.

Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs: Historically, Saudi and GCC IP authorities have not offered any special incentives targeting SMEs. No reduced fees or an expedited approval process has been provided to SMEs, nor has there been a great deal of targeted technical assistance. The GCC Patent Office does offer wider support programs for IP practitioners and inventors, but these are not targeted at SMEs. Similarly, in Saudi Arabia, the King Abdullah University of Science and Technology and King Abdulaziz City for Science and Technology (KACST) sponsor several programs and provide direct support services for inventors, including SMEs. However, this support is not within the context of IP development, registration, and commercialization, but more broadly in terms of economic development, R&D, and encouraging innovation. This includes, for example, the "SMEs Support Initiative" run by KACST. This program "aims to provide a range of technical services starting from full technical upgrading of small and medium factories, in order to improve their level, qualify them to contribute to local content, and develop the quality and quantity of their products." This has now changed, with the SAIP recognizing support for SMEs as one of its key priorities. In 2020, the authority announced several new initiatives targeting SMEs. In June, the Intellectual Property Advisory Clinics Program was launched. The program seeks to help SMEs develop, register, and commercialize IP assets. The SAIP also released an "Intellectual Property Policies Manual" to help and guide SMEs, academic institutions, and individual inventors. Finally, the authority, in partnership with WIPO, opened 21 support centers as part of a national network of

IP centers. As a result of these positive efforts, the score on this indicator has increased by 0.25.

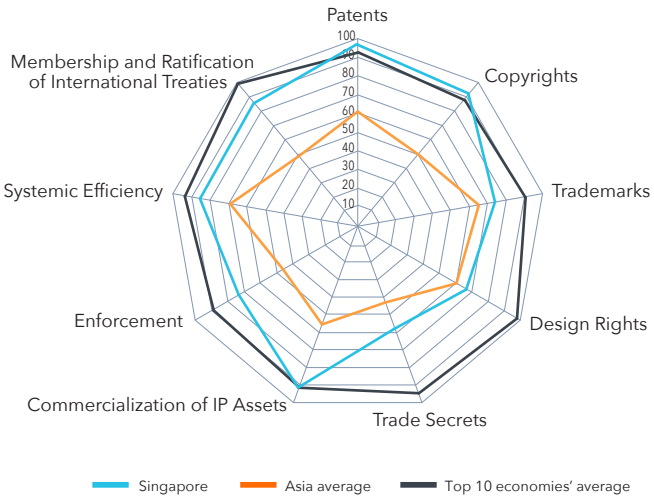
Membership and Ratification of International Treaties

Saudi Arabia scores low in its participation in and ratification of international treaties. Of the nine treaties included in the Index, Saudi Arabia is a contracting party to only two: the Patent Law Treaty and the Patent Cooperation Treaty. Saudi Arabia has not concluded a post-TRIPS FTA with substantive IP provisions. In a positive move, the SAIP in 2020 issued a call for comments and public feedback on the possibility of Saudi Arabia joining several international IP treaties. Among the many treaties proposed were two included in the Index: the Hague Agreement Concerning the International Registration of Industrial Designs and the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. Joining both these treaties would strengthen Saudi Arabia's national IP environment and lead to a score increase on this category of the Index. Furthermore, although not measured in the Index, the SAIP also announced in 2020 that Saudi Arabia had become a contracting party to the Locarno Agreement.

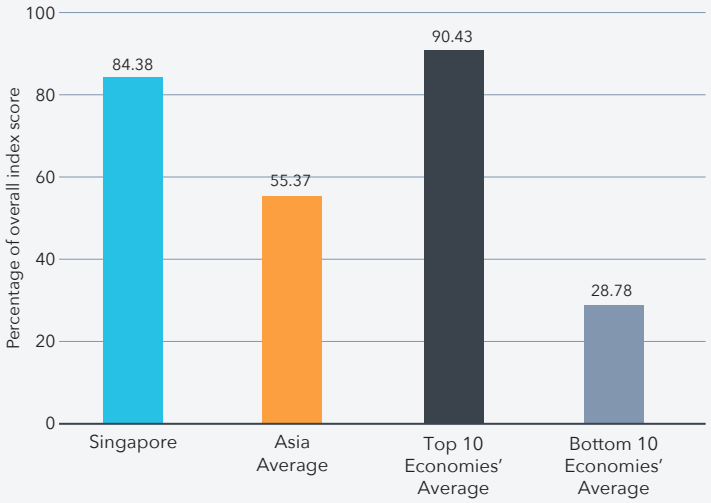
SINGAPORE

RANK
11/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Implementation of new R&D and IP tax incentives scheme in 2019
- ✓ Advanced national IP framework in place
- ✓ Global leader on online copyright enforcement: continued strong efforts in 2020
- ✓ Active participant in efforts to accelerate patent prosecution—IPOS has several PPHs in place and is a member of the GPPH

KEY AREAS OF WEAKNESS

- × Estimated software piracy has decreased from 35% in 2009 to 27% today—but still high for a developed high-income economy
- × Lack of transparency and data on customs seizures of IP-infringing goods

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.75**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	1.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**6.49**
10. Term of protection	0.74
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	1.00
15. Digital rights management	0.75
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.35**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**1.75**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.50**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**5.10**
32. Physical counterfeiting rates	0.62
33. Software piracy rates	0.73
34. Civil and procedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	0.75
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**4.25**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**6.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 42.19

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Singapore's overall score has decreased slightly from 84.42% (42.21 out of 50) in the eighth edition to 84.38% (42.19 out of 50) in the ninth edition. This reflects a marginal score decrease on Indicator 32.

Patents, Related Rights, and Limitations

9. Patent opposition: In 2013, the government of Singapore launched a strategic vision, the *IP Hub Master Plan*, to make Singapore one of the most competitive IP environments in the world. The plan focuses on three core areas: IP Transactions and Management, IP Filings, and IP Dispute Resolution. Over the past few years, the Ministry of Law and the Intellectual Property Office of Singapore (IPOS) have proposed several important changes to achieve these goals. To become a hub for IP dispute resolution, IPOS and the ministry have proposed to amend the way IP disputes are currently processed and resolved. An IP Dispute Resolution (IPDR) committee was set up in 2017, and an official review was carried out and published—*Final Report of the Review of Singapore's IP Dispute Resolution Framework*. In late 2018, a public consultation was held and in early May, draft legislation was released to the public. Passed over the summer, in November 2019, the Intellectual Property (Dispute Resolution) Act 2019 came into effect. The act makes substantial changes to the existing dispute resolution framework and amends several laws, including the Arbitration Act, the International Arbitration Act, and most major IP laws. Amendments to the Patents Act introduce two important changes in the way published patent applications and patents granted can be challenged. The first change relates to formalizing how pre-grant third-party observations can be submitted. Up until now, IPOS had operated a system whereby observations have informally been accepted and would, at IPOS' discretion, be forwarded to the relevant examiners. It has then been up to the relevant examiners to decide on the merits of the observations. Section 32 of the amended Patents Act now formalizes and defines this process. A formal route for the submission of third-party observations is available in most leading IP jurisdictions, and these changes mean that Singapore is now largely aligned with other major IP offices. The second change the Dispute Resolution Act introduces is in the way the validity of a granted patent can be challenged. Historically, Singapore has not had in place any type of patent opposition mechanism. Instead, the only way in which the validity of a granted patent could be challenged was through a formal revocation and patent nullity proceeding. Revocation procedures—outlined under section 80 of the Patents Act—are primarily administrative and usually proceed through the IPOS. However, not all revocation procedures take place before IPOS. Patent validity can also be brought before the judiciary (typically the procedure in patent infringement claims in which a counterclaim of invalidity is brought) and IPOS reserves the right to defer revocation applications to a court of law. Local legal analysis suggests that the revocation process can be both lengthy and expensive, involving a drawn-out process of evidentiary submissions, conferences, and hearings. Under the amended Dispute Resolution Act and Patents Act, a new section 38A introduces a post-grant patent re-examination route. The purpose of this re-examination route is to provide a more timely and cheaper option for resolving claims of patent invalidity. As such, these amendments amount to a potential improvement in Singapore's already world-leading patenting environment. All national IP systems should seek to ensure that granted patents are in line with well-established international standards of novelty, inventive step, and industrial applicability. When disputes over validity arise, resolution mechanisms should be readily available and provide all parties the means of being heard fairly and impartially in a quick and cost-efficient

manner. Unfortunately, in many jurisdictions, existing avenues of patent opposition and invalidity are frequently abused for commercial purposes to delay patent prosecution and limit competition. This is particularly the case for jurisdictions with pre-grant opposition procedures. In fact, many jurisdictions benchmarked in the Index in which a pre-grant opposition mechanism is in place have experienced systematic and severe delays to the patent prosecution process, with rights-holders negatively affected. For example, Australia has in place a pre-grant opposition system for patents. Under the system, third parties may file an objection between the publishing of the application and within three months after the application is accepted. The system extends the patent review process significantly, delaying the granting of patents and reducing the available term of protection afforded to patent holders. For example, a 2012 academic study published in the *University of New South Wales Law Journal* found that opposition filings typically delayed the granting of a patent by close to two years (the mean delay found was 2.4 years versus the median of 1.8 years). The same study found that the highest volume of oppositions were directed toward pharmaceutical patents, suggesting there is a clear commercial imperative behind these oppositions. Similarly, Israeli patent law provides for a pre-grant form of opposition to pending patent applications. Under the Israeli opposition system, the examination of a patent application can be extended by, at minimum, an additional 18 months, not including the process of re-examination and/or judicial hearings. Regardless of the merits of any opposition filing, these generous timelines add a significant burden and delay to the patent prosecution process in Israel and, just as in Australia, impose an undue burden on patent applicants. In the amendments to Singapore's Patents Act, safeguards have been put in place to ensure that the new re-examination system is not abused. Specifically, sub-section 38A(4) of the amendments gives IPOS the right to refuse any application for re-examination in cases in which the request is viewed as "frivolous, vexatious or an abuse of the process." The Index will monitor how the new re-examination system will work and its effect on rights-holders in Singapore in 2021 and beyond.

Copyrights, Related Rights, and Limitations

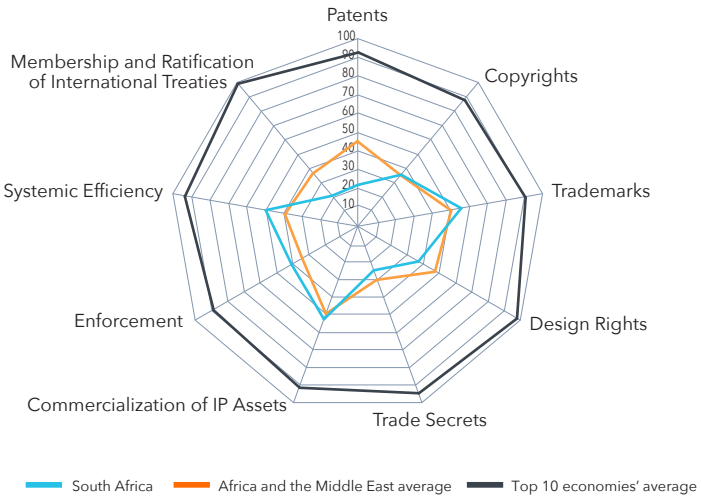
12. Expeditious injunctive-style relief and disabling of infringing content online; and 15. Digital rights management legislation: As noted in past editions of the Index, since 2014, Singapore has taken a real global leadership role with respect to copyright enforcement. That year, Singapore passed amendments to its Copyright Act, strengthening rights-holders' recourse mechanisms against online piracy. The amendments provide a more direct mechanism for rights-holders to take action against "flagrantly" infringing sites. These amendments provide rights-holders with an avenue to apply directly to the High Court for an injunction "requiring the network service provider to take reasonable steps to disable access to the flagrantly infringing online location." The legislation contains a non-exhaustive list of conditions and factors the High Court may consider when determining whether flagrant infringement is taking place. These factors include whether the main purpose of the "online location" is to infringe copyright, whether circumvention instructions are included on the site, or "whether the owner or operator of the online location demonstrates a disregard for copyright generally." In response to an application by the Motion Picture Association of America (MPAA), in 2016, the High Court issued its first order under these amendments, ordering all of Singapore's major ISPs to disable access to the piracy website Solarmovie.ph. In May 2018, the High Court ordered ISPs to disable access to another 53 websites after a new request from the MPAA. In October 2018, this order was followed up with the issuing of a so-called dynamic order

from the High Court whereby rights-holders can notify ISPs directly if counter-measures have been taken by the targeted infringing sites. This greatly reduces the administration of the system and improves the overall effectiveness of the orders. As in many other economies benchmarked in the Index, there has been an explosion in the growth and use of internet-based applications providing infringing content to set-top boxes in Asia, and Singapore in particular. A survey published in late 2018 commissioned by a local coalition of rights-holders—the Coalition Against Piracy—found that 15% of those surveyed used such a set-top box to access and stream illegal content. In response, rights-holders and policymakers have taken action in different fora. In another rights-holder led lawsuit, the High Court in November 2018 issued an order to disable access to internet-based applications providing infringing content to set-top boxes. In 2019, a local retailer was prosecuted for selling these set-top boxes. And in July 2020, another High Court order was issued. This time access to 60 different websites was ordered to be disabled, many of which provide illicit content to purchased set-top boxes. And as noted in last year's Index, on the legislative front the government has recognized the need for stronger action against piracy over set-top boxes. In the 2019 *Singapore Copyright Review Report*, the Ministry of Law and IPOS recognized the growing challenge of set-top box piracy and current legislative gaps. Conclusion 16 of the *Report* recommended passing new legislation that would introduce civil and criminal liability on any individuals who "willfully make, import for sale, commercially distribute or sell" such set-top boxes. At the time of research, no draft legislation had been introduced or passed into law. The Index will continue to monitor these developments in 2021.

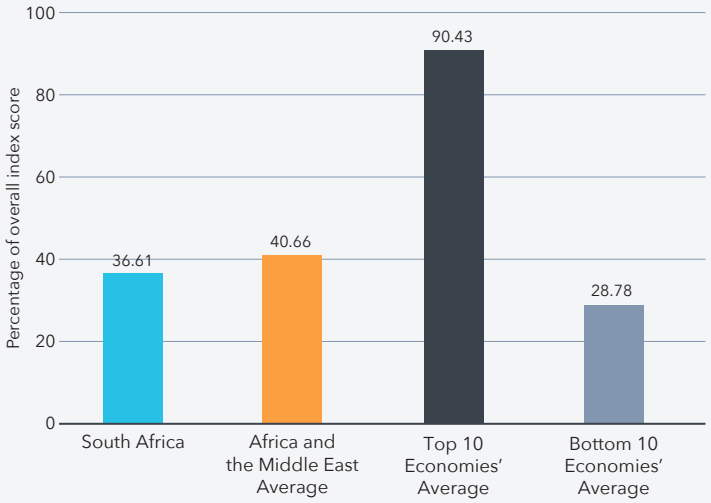
SOUTH AFRICA

RANK
44/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Basic IP framework in place
- ✓ Relatively low level of software piracy–32%–compared with other African economies

KEY AREAS OF WEAKNESS

- × Growing emphasis on localization and local content requirements in economic and industrial policy–intensified in 2020
- × Finalized *IP Policy Phase I* does not fundamentally address South Africa's gaps in IP protection–focus is not on innovation and development of new IP in South Africa but on use of existing developed IP through CLs, parallel imports, and restricting patentability of pharmaceuticals
- × Copyright amendments create uncertainty for rights-holders through expansive "fair use" definitions
- × Major gaps in laws and enforcement across all categories of the Index

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**2.00**
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**2.53**
10. Term of protection	0.53
11. Exclusive rights	0.50
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.25
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.75**
21. Industrial design term of protection	0.50
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.75**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.17**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**2.86**
32. Physical counterfeiting rates	0.43
33. Software piracy rates	0.68
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.50**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**1.50**
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 18.31

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

South Africa's overall score remains unchanged at 36.61% (18.31 out of 50).

Copyrights, Related Rights, and Limitations

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Scope of limitations and exceptions to copyrights and related rights; and 14. Digital rights management legislation: Over the past half-decade, South Africa has been engaged in reforming its copyright laws. Draft Copyright Act amendments were first published in 2015 and made open to public consultations. These amendments were then revised, and a new set of amendments were published in May 2017. Over the course of 2018 and the beginning of 2019, the draft bill went through several iterations and changes. In March 2019, a final bill was approved by both the National Assembly and the National Council of Provinces and sent to President Ramaphosa for his assent. At the time of research, the president had refused to sign the draft law, citing its potential unconstitutionality, and sent it back to the National Assembly for further review. As has been noted in previous editions of the Index, the proposed legislation suffers from several serious deficiencies. South African policymakers have correctly identified the need for modernizing the existing copyright laws. Just as for the rest of the world, the ICT and internet revolutions are fundamentally changing how South Africans interact socially and economically. In virtually all sectors and industries, businesses and economic interaction is today being shaped by digital and mobile technologies. Platforms and business models that did not exist a generation ago have been enabled by the advent of digital technologies. Having an effective, modern copyright regime that encourages innovation and creativity is critical to make the most of the socio-economic opportunities that these deep structural changes in human behavior offer. In 2010, the South Africa government together with WIPO examined the economic contribution of the copyright-based industries to the South African economy. The report found that these industries contributed 4.11% to GDP and 4.08% to national employment. While substantial, these contributions are smaller compared with in other economies with more modernized copyright frameworks, such as the United States and Korea, where the contribution was estimated by WIPO to be over 10%. Given the size and breadth of the creative sector in South Africa, with the right IP-based incentives in place, the creative industries could become an even more powerful source of economic growth and development. Unfortunately, the draft copyright amendments do not include or address the current shortcomings in South Africa's copyright regime. Instead, they add more uncertainty and potential difficulties for rights-holders. Provisions of the bill allow unlimited parallel importation of all copyright works. The amendments also introduce a system of "fair use" exceptions to copyright. For many years, there has been a lack of clarity in South Africa on what constitutes infringement of copyright and what is fair reproduction and use, with no relevant full definition in the current Copyright Act. Exceptions and limitations to copyright should be considered against the three-step test embodied in the Berne Convention and the WTO TRIPS Agreement. Yet it is unclear how the proposed new exceptions and system of fair use would work in practice without negating the exclusive rights of copyright owners and imperiling the legitimate markets for creative works. On the positive side, these amendments would strengthen and reinforce important aspects of South Africa's legal framework, including the protection for DRM and TPMs. There

is no current provision in the existing Copyright Act with regards to DRM or TPMs. The proposed amendments contain a fairly robust set of draft sections corresponding with those already contained in the Electronic Communications and Transactions Act (ECTA) law. Yet, apart from this, the proposed amendments do little in the way of strengthening rights-holders' ability to more effectively enforce their rights or address the growing issue of online piracy. The 2017 Cyber Crime bill—still pending parliamentary approval—would potentially improve the enforcement environment. Section 52 of the draft legislation includes a mandatory requirement that electronic service providers report any potential illicit behavior on or through their networks to the relevant authorities. Yet these provisions are not specific to copyright and equivalent requirements are not included in the draft Copyright Act. Of note is that the draft legislation did not consider additional enforcement measures, such as the disabling of access through an injunctive-style relief program. The past half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the United Kingdom, India, Singapore, Russia, and a host of other economies have introduced measures that allow rights-holders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called "dynamic" injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. The Index will continue to monitor these developments in 2021.

Commercialization of IP Assets and Market Access

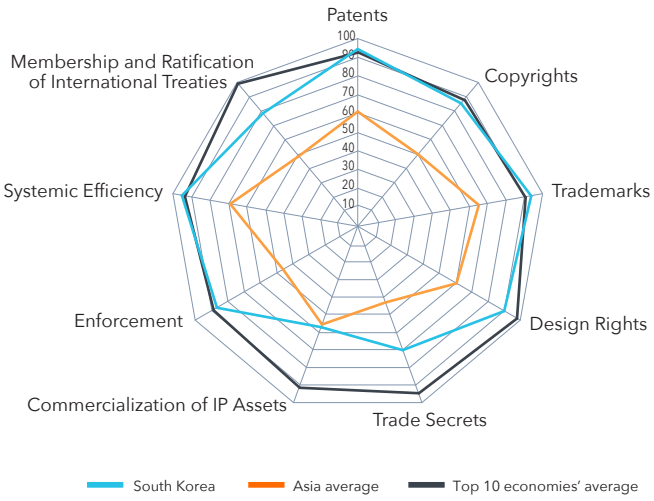
26. Barriers to market access: As noted in previous editions of the Index, South African industrial policy over the past decade has been characterized by a growing use of local content requirements and an increased focus on technology transfer through the localization of manufacturing and R&D activities. These policies are both general as well as industry and sector specific. For example, South Africa has long-standing local content requirements for certain sectors, including broadcasting. Within public procurement, significant local content requirements have been in place since 2011 for a host of specially designated sectors, ranging from automotive (buses) and set-top boxes to clothing and furniture. Local content requirements range from 10 to 100% depending on the industry and type of product. For example, for pharmaceuticals, the threshold is set at 70% of local content in terms of volume for Oral Solid Dosage tenders and 50% in terms of value for Family Planning Tender. More generally, the National Industrial Participation Programme (NIP) has been in place since the late 2000s. The NIP provides that foreign suppliers within a month of signing a contract with the procuring entity sign an obligation agreement in which they commit to local economic activities. The ultimate purpose of the NIP is to build domestic capacity and partnering between South African companies and international industry leaders. More broadly, South African industrial and economic policy is largely guided by central planning and targets through Industrial Policy Action Plans (IPAPs) designed by the Department of Trade and Industry (now the Department of Trade, Industry and Competition, DTIC). These IPAPs place a heavy emphasis on localization and increasing the amount of local content produced and procured in South Africa. Past IPAPs have confirmed the government's objective (first outlined in the 2014 five-year plan, Medium Term Strategic Framework) of achieving a level of 75% local procurement. The IPAPs, both more broadly and in the sectoral focus area discussions, place a heavy emphasis on the transfer of technologies from international rights-holders to local companies. There are also other sector-specific initiatives. For example, in 2014, the Department of Science and Technology

adopted a new bio-economy strategy document targeting the life sciences sector. A central part of this policy document was to strengthen local research, development, and innovation capabilities with a view of increasing local manufacturing of active pharmaceutical ingredients, vaccines, and biologics. The document set as a target that, within a decade, 25% of pharmaceuticals and 20% of vaccine imports should be replaced by local production. Foreign investment and market access are also affected by the Broad-Based Black Economic Empowerment (B-BBEE) program, an affirmative action program that scores firms according to their promotion of historically disadvantaged South Africans. B-BBEE requirements play an important role in public procurement, with the first round of tenders specifically dedicated to assessing compliance with them across a range of factors, and have been used to provide advantages to local bidders. These rules have been strengthened over the past few years, with a stronger emphasis placed on B-BBEE ownership. For example, in 2018, new B-BBEE rules and quotas were announced for the mining sector. Under these rules, mining rights-holders must increase the level of B-BBEE ownership to 30% from the then-current level of 26%. These localization requirements have only intensified in 2019 and 2020. In August 2020, Deputy Minister of Trade, Industry and Competition Fikile Majola stated that localization will be the "new focus" of the South African government and become more central to economic policymaking in the wake of the COVID-19 pandemic. As part of this focus, the DTIC is creating new industrial "master plans" for specific industries and sectors of the economy. These industrial plans, again, place an emphasis on local production and import substitution policies. For example, the Retail-Clothing, Textile, Footwear and Leather (R-CTFL) master plan, developed by the government with domestic stakeholders and finalized in November 2019, sets a target to increase local production of the market from 45% today to 65% by 2030. In an effort to improve the competitiveness of the local industry, under "Commitment 1: Grow the market for local CTFL producers," this target is to be achieved with the aid of government procurement and greater enforcement of a 100% local content requirement for all textile, clothing, leather, and footwear. In 2020, the DTIC re-emphasized its commitment to the plan and promised to intensify the localization drive, with DTIC Minister Ebrahim Patel stating that "the Covid-19 pandemic has made the argument for localisation even more urgent and important. The key issue for our economy now is the return of domestic demand. We need to stimulate the economy via deeper localisation efforts." One positive aspect of these efforts has been a recognition by the South African government that more needs to be done with regards to counterfeiting. A key component of the government's commitment in the R-CTFL is to increase anti-counterfeiting activity and the imports of illicit apparel and footwear. In a report to the Parliamentary Select Committee on Trade and Industry, Economic Development, Small Business Development, Tourism, Employment and Labour, the DTIC highlighted the increased customs enforcement and seizure activity in the period September 2019 to February 2020, with close to 1,000 seizures taking place.

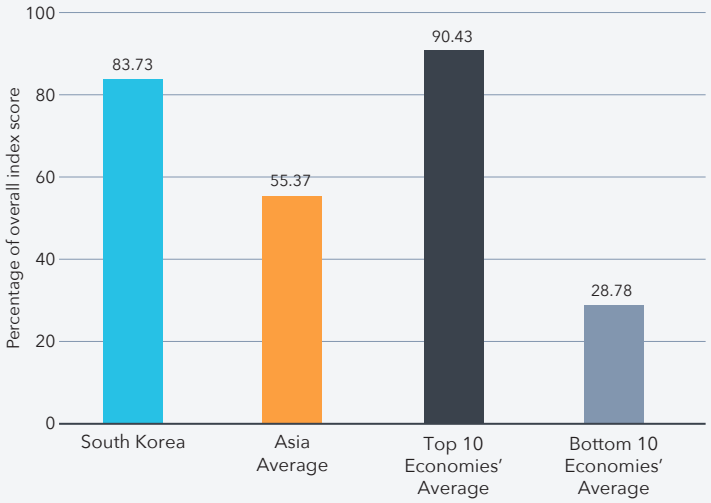
SOUTH KOREA

RANK
12/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Amendments to the Unfair Competition Prevention and Trade Secret Protection Act strengthen criminal sanctions for trade secret theft
- ✓ Amendments to Patent Act and Unfair Competition Prevention and Trade Secret Protection Act strengthened the basis for which damages can be awarded for patent and trade secret infringement
- ✓ Patenting standards generally in line with international best practices
- ✓ Generally strong online/digital copyright protection (with important exceptions, including software)
- ✓ Relatively robust legal framework for trademark and design protection
- ✓ Membership in Global PPH and IP5 and new post-grant patent opposition mechanism streamline patent office
- ✓ KIPO provides SMEs with a variety of educational and technical assistance programs as well as a right to reduced filing fees

KEY AREAS OF WEAKNESS

- × Not a contracting party to the Patent Law Treaty and the Convention on Cybercrime
- × Some barriers to market access that discriminate against foreign IP owners
- × Onerous licensing registration requirements

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.50**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**5.99**
10. Term of protection	0.74
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.75
15. Digital rights management	1.00
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**3.75**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	1.00
Category 4: Design Rights, Related Rights, and Limitations	**1.80**
21. Industrial design term of protection	0.80
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.10**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.60

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.42**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**6.05**
32. Physical counterfeiting rates	0.62
33. Software piracy rates	0.68
34. Civil and procedural remedies	0.75
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**5.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 41.86

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

South Korea's overall score has increased from 82.20% (41.10 out of 50) in the eighth edition to 83.73% (41.86 out of 50) in the ninth edition. This reflects a score increase on indicator 38.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: The Patent Act provides a clear five-year period of patent term restoration to compensate for the time lost during the regulatory review and product registration process for biopharmaceuticals. Concerns have been raised by industry in the past with regards to the effective availability of this restoration, including the extent to which additional uses of a patented invention are included under any restoration granted. In 2020, an important decision was issued by the Korean Intellectual Property Trial and Appeal Board (IPTAB). The IPTAB is a quasi-judicial body housed within Korea's IP Office, KIPO, and is the court of first instance in most IP disputes, including with regards to patent rights. In July 2020, the IPTAB issued what could become a precedent-setting ruling that any term restoration granted should cover all uses under the existing patent and not be limited to just one primary or single use. This ruling clears up what has been a gray area for rights-holders in Korea and ensures that any term restoration granted provides a similar level of protection for any and all uses as that of the original patent.

Enforcement

35. Preestablished damages and/or mechanisms for determining the amount of damages generated by infringement: South Korean laws provide a relatively strong framework for enforcing IP rights, both in terms of available civil remedies and criminal penalties for infringement. These include statutory damages and several mechanisms for determining adequate damages, although actual sums awarded in some cases can be relatively small—see, for instance, the 2012 case *Apple Inc. v Samsung Electronics Co Ltd*. As discussed in last year's Index, amendments to the Patent Act and Unfair Competition Prevention and Trade Secret Protection Act (passed at the end of 2018) came into force during 2019 and have strengthened the basis for which damages can be awarded for patent infringement and the theft or misappropriation of trade secrets and confidential information. These amendments provide for the possibility of awarding punitive damages and in 2020 they were extended to other forms of IP rights. In September 2020, the National Assembly passed the Intellectual Property Protection Act. This act amends the Trademark Act and Design Protection Act, introducing punitive damages and damage calculations similar to those passed last year for patents, trade secrets, and confidential information. This marks another positive step in strengthening the enforcement environment for rights-holders in Korea.

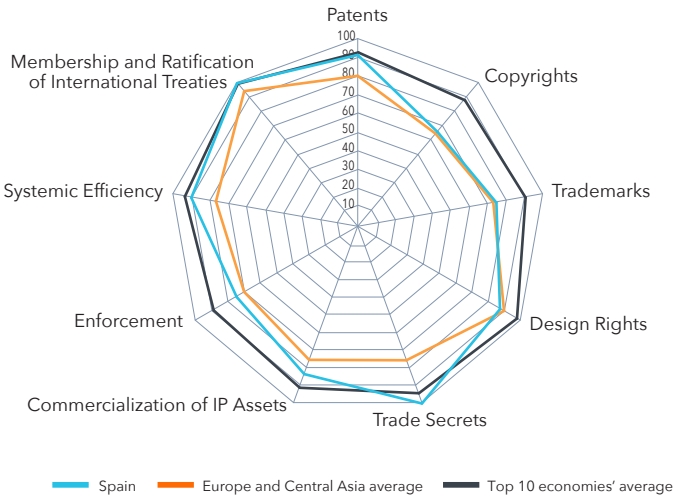
38. Transparency and public reporting by customs authorities of trade-related IP-infringement: Historically, statistics on anti-counterfeiting and seizure activity by the Korea Customs Service have not been available on a systematic and regular basis. This changed in 2015 with the publication of the KCS' *Annual Report on Intellectual Property Rights Seizures*. This report provides a detailed breakdown of the KCS' anti-counterfeiting activities and investigations of suspected IP violations. It includes the number of seizures, categories of goods seized, and primary countries of origin. The latest report, published in 2019, shows that there were almost 53,000 seizures carried out over the course of 2018, a 360% increase compared with 2017. This rise in the number of seizures was a result of greater cooperation between the KCS, private rights-holders, and the postal service at

Incheon airport, plus a notable increase in seizures of small parcel shipments. Of note is that nine out of 10 IP-infringing goods (92.9%) came from China. At the time of research, no report had been made publicly available in 2020. The KCS should be congratulated for making this information available to the public in a dedicated, regularly recurring report. As a result, the score on this indicator has increased to 1.

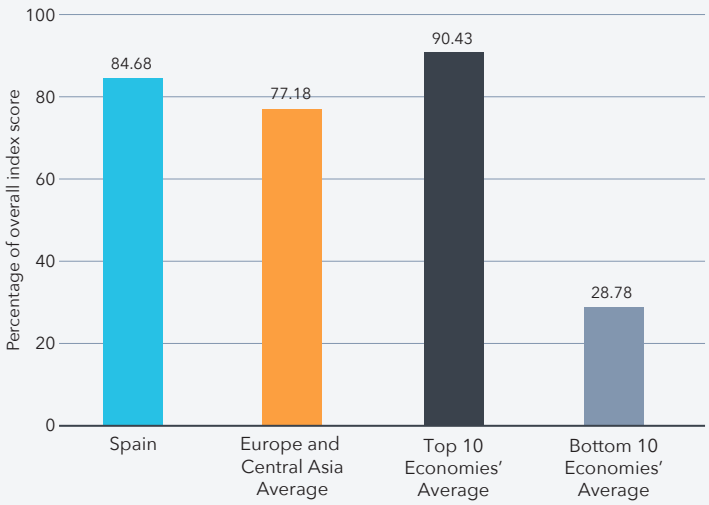
SPAIN

RANK
10/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Trade secret law operational as of 2019—Business Secrets Act entered into force in March 2019
- ✓ Stronger copyright enforcement measures in place through Royal Decree Law 2/2018—continued enforcement efforts through Ministry of Culture
- ✓ As an EU Member State, Spain has in place an advanced IP system
- ✓ Sector-specific rights in place and enforced
- ✓ Efforts to strengthen and modernize patent and copyright frameworks, including with respect to online copyright enforcement
- ✓ Civil and criminal reforms enhance remedies available for IP infringement
- ✓ Active public awareness campaigns and engagement efforts

KEY AREAS OF WEAKNESS

- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Spain's and EU's research- and IP-based biopharma industry
- × Counterfeiting and piracy levels remain high compared with other EU economies—software piracy estimated at 42%

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**4.63**
10. Term of protection	0.63
11. Exclusive rights	0.75
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.75
15. Digital rights management	0.75
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.00**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**5.21**
32. Physical counterfeiting rates	0.63
33. Software piracy rates	0.58
34. Civil and procedural remedies	0.75
35. Pre-established damages	0.50
36. Criminal standards	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 42.34

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Spain's overall score has increased slightly from 84.64% (42.32 out of 50) in the eighth edition to 84.68% (42.34 out of 50) in the ninth edition. This reflects a marginal score increase on indicator 32.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force, and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union (CJEU) handed down a verdict in the case *Santen SAS v. Directeur général de l'Institut national de la propriété industrielle,* C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treat-

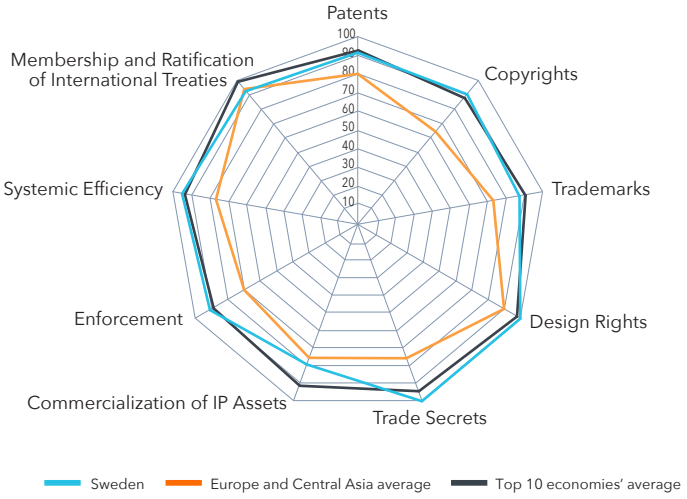
ments. In earlier rulings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now effectively been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**." From a legal perspective, the court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced

side effects. Still, treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

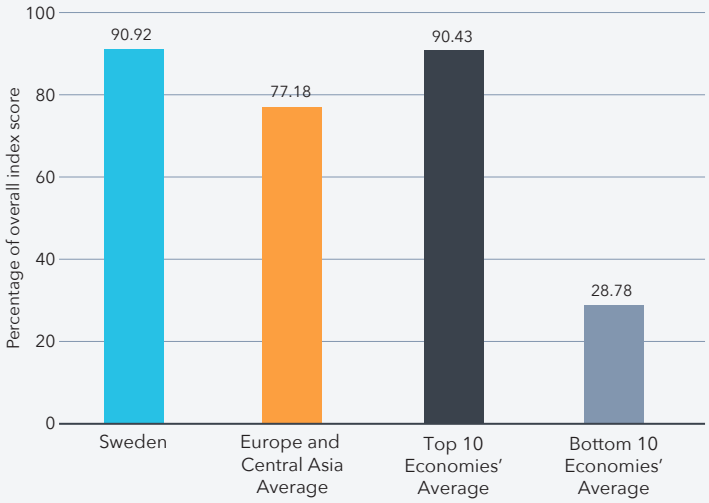
SWEDEN

RANK
6/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Strong and sophisticated national IP environment
- ✓ Online copyright enforcement improving over past few years, with stronger police enforcement and precedent-setting court decisions on ISP responsibility
- ✓ New case law in 2020 creates more certainty as to under what circumstances Swedish ISPs and internet mediators will be ordered to disable access to infringing content

KEY AREAS OF WEAKNESS

- × No R&D- or IP-specific tax incentives in place
- × Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Sweden's and EU's research- and IP-based biopharma industry

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**6.35**
10. Term of protection	0.60
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**4.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**6.36**
32. Physical counterfeiting rates	0.80
33. Software piracy rates	0.81
34. Civil and procedural remedies	0.75
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 45.46

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Sweden's overall score has increased from 90.56% (45.28 out of 50) in the eighth edition to 90.92% (45.46 out of 50) in the ninth edition. This reflects a score increase on indicator 11.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force, and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. As has been stated in previous editions of the Index, the decision to move ahead with the SPC exemption is a significant blow to biopharmaceutical rights-holders and weakens the IP environment across the EU. As a result of this action, the score on indicator 7 was reduced for all EU Member States included in the Index. Further developments in 2020 add to the uncertainty over the EU's SPC regime. In July, the Court of Justice of the European Union (CJEU) handed down a verdict in the case *Santen SAS v. Directeur général de l'Institut national de la propriété industrielle*, C-673/18. Originating in France and referred to the CJEU by the Paris Court of Appeal in 2018, the case is about the extent to which it is possible to obtain an SPC for new innovations relating to approved biopharmaceutical products and treat-

ments. In earlier rulings—see, for example, the 2012 *Neurim Pharmaceuticals (1991) Ltd v Comptroller-General of Patents*—the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now effectively been overturned. In its 2020 ruling, the CJEU emphatically stated "that an MA cannot be considered to be the first MA … where it covers a new therapeutic application of an active ingredient, or of a combination of active ingredients, and that active ingredient or combination has already been the subject of an MA for a different therapeutic application." The court argued that on this point the *Neurim* precedent had erred and not fully taken into account the intentions of the lawmakers when originally developing the underlying IP incentive and EU Regulation: "the EU legislature intended, in establishing the SPC regime, to protect not all pharmaceutical research giving rise to the grant of a patent and the marketing of a new medicinal product, **but to protect research leading to the first placing on the market of an active ingredient or a combination of active ingredients as a medicinal product**." From a legal perspective, the court's verdict may set an unfortunate precedent and further limit the availability of European incentives for biopharmaceutical innovation. More broadly, from a public policy perspective, the court's verdict is odd and fails to understand the basics of biopharmaceutical innovation. Technological innovation is frequently thought of as consisting of two distinguishable modes or models: radical innovation and incremental innovation. Radical innovation, as the name suggests, is the introduction of completely new or revolutionary ideas or products. Frequently, such innovations wholly alter the way an industry or even an economy functions, fundamentally changing economic and social behavior. In contrast to radical innovation, incremental innovation is a process of piecemeal improvement of existing technologies or techniques. Usually, incremental innovations follow on from revolutionary or radical innovations. Does this mean that radical innovation is the proverbial "good" form of innovation and non-revolutionary incremental innovation is "bad" and, from a societal perspective, largely useless? Because that is the underlying policy rationale behind the court's reasoning. In its verdict and assumptions about the intentions of European lawmakers, the court has implied that incremental biopharmaceutical innovations are less meaningful and therefore should not be eligible for the SPC incentive. But most biopharmaceutical innovation is in large part incremental. In fact, incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovations—and the IP incentives that drive investment and resources into developing them— the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, loss of sense of taste, skin problems, and painful nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced

side effects. Still, treatment centered on the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no major change in lifestyle. This allows patients to live socio-economically productive lives with what had once been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. It is hard to see how this type of innovation should not be eligible for IP incentives such as SPC protection. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 12. Expeditious injunctive-style relief and disabling of infringing content online: The protection of copyrighted material online has historically been a serious challenge for rights-holders in Sweden. In 2005, industry estimates suggested that half of all computer videogames were pirated. A 2015 report by Boston Consulting Group (*Svensk Filmnäring, Utveckling, utmaningar och möjligheter 2015*) for the Swedish content industry (*Film & TV-branschens samarbetskommitté*) found that an estimated 29–32% of the population accessed illegal television and/or film every month. The rate in neighboring Norway, Denmark, and Finland was significantly lower, at 19%, 12%, and 8%, respectively. Similarly, in 2017, Swedish media consulting firm *Mediavision* found that Sweden's rates of online piracy were about double the rates of neighboring Finland and Denmark, which have stronger enforcement measures in place. The study found that over two-thirds of Swedish young men ages 15-24 admitted to having accessed online pirated content over the surveyed period. Over the past two decades, Sweden has also become known as a host for websites providing access to illegal content. Most notably, the Pirate Bay was founded in Sweden in 2003 and originally hosted in Sweden. Over the past few years, the Swedish government and relevant authorities have begun taking more forceful action, and through new mechanisms of enforcement rights-holders have had a better chance of protecting their creations. The Pirate Bay founders have been arrested, successfully prosecuted, and sentenced. In 2015, the Swedish government took over ownership of all Swedish domain names related to the website. Enforcement action has also been taken against other Swedish pirate sites, including Swefilmer. Industry estimates suggested that, in the mid-2010s, Swefilmer had become the largest provider of pirated streaming services in Sweden. In July 2015, Swefilmer's premises were raided by the police and subsequently the site was shut down. The Swedish legal framework has also been strengthened. While Sweden has traditionally had in place a relatively sophisticated copyright regime with rights generally protected, this legal framework has now been complemented with online-specific legislation. In 2009, the Intellectual Property Rights Enforcement Directive (IPRED) was introduced. The law (which implements an EU directive) gave rights-holders the opportunity through a court to acquire the contact details of a suspected copyright infringer. Like the introduction of the HADOPI measures in France, research on the effects of the IPRED law in Sweden suggest that it had a positive and significant effect on short- to medium-term music sales. A study by Swedish economists shows that, overall, music sales increased by over 35% after the introduction of the law. Most importantly, over the past half-decade,

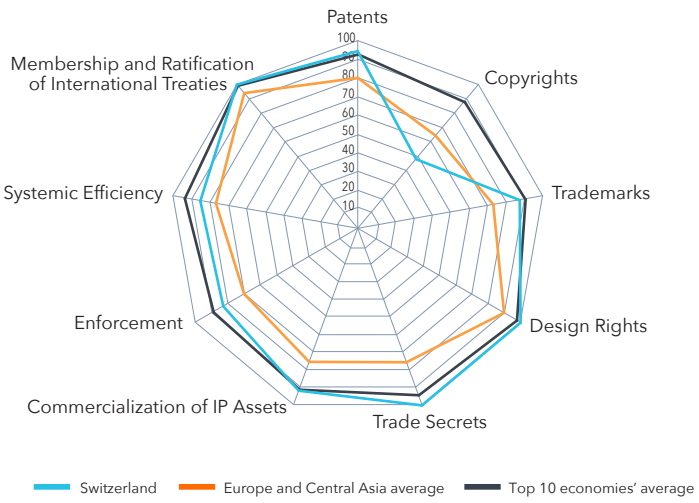
judicial precedents have been set with rights-holders being able to access redress through injunctive relief and the disabling of websites hosting copyright-infringing content. In 2014, a coalition of international and domestic Swedish content creators and providers (the group includes Universal Music, Sony Music, Warner Music, *Nordisk Film*, and *Svensk Filmindustri*) sought a court order to force one of the largest ISPs in Sweden, *Bredbandsbolaget*, to disable access and prevent its subscribers from accessing the Pirate Bay and Swefilmer streaming services. Initially, the lawsuit was rejected. The Stockholm District Court refused an injunction against *Bredbandsbolaget* to disable access to two torrent sites. In its public statements, *Bredbandsbolaget* said that ISPs should not be held responsible for the content distributed or transported over their network. The Stockholm District Court agreed and held that ISPs had no obligation to disable access to pirate websites unless they provide "direct assistance" to the primary infringers. The court's decision was based on an evaluation of Sweden's implementation of the EU's InfoSoc Directive (Article 8.3) and on the complicity concept within the Penal Code (Article 53b). By in effect removing virtually any responsibility from ISPs, this judgment severely restricted the means by which copyright holders could enforce their rights online. In February 2017, Sweden's new specialist IP appeals court, the Swedish Patent and Market Court of Appeal (*Patent- och marknadsöverdomstolen*), overturned this decision. The court ruled that *Bredbandsbolaget* should not only disable access to the torrent websites in question but also pay damages of SEK500,000 (about USD60,000). The ruling could not be appealed and has set an important precedent for Swedish rights-holders. Still, the situation has remained somewhat fluid and uncertain in the years since. There have been some key positive judgments following the precedent set by the *Bredbandsbolaget* case. For example, in October 2018, the specialist IP court of first instance, the Swedish Patent and Market Court (*Patent- och marknadsdomstolen*), ordered one of the largest ISPs in Sweden, Telia, to disable access to several websites enabling access to copyright-infringing content. A coalition of rights-holders had brought suit earlier in 2018, in part based on the precedent set by the *Bredbandsbolaget* case and developments in European jurisprudence. However, in February 2019, the appeals court, the Patent and Market Court of Appeal, overturned this order (case PMÖ 9945-18). Although the court stated that it was clear that copyright infringement had taken place as claimed by the plaintiffs, the court argued that it was a disproportionate response—in this specific case—to order the disabling of access to these websites as, in part, several were no longer operational or accessible. Given these circumstances, at that specific moment in time, the court stated that an order disabling access would not be a proportionate response. Given the long and difficult history rights-holders have faced in enforcing their copyright in Sweden, this decision raised the specter of undoing much of the positive momentum gained through the 2017 *Bredbandsbolaget* precedent. Yet, in October 2019, the same Court of Appeal appeared to veer in a different direction. In another appeals case involving a set of ISPs and rights-holders (*ComHem, Tele 2, Telia v Elsevier BV, Elsevier Ltd*, case PMÖ 7648-19), on the infringement and illegal access to scientific publications through the LibGen and Sci-Hub websites, the court upheld the lower court's judgment that the ISPs should disable access to these websites. In contrast to the Telia case, the court held that the disabling of access was, in this case and under these specific factual circumstances, a proportionate response. The combined effect of the Court of Appeal's judgments was to create a degree of uncertainty as to under what circumstances Swedish ISPs and internet mediators would be ordered to disable access to infringing content. When would the court rule that the disabling of access constitutes a "proportionate" response versus not? Some of these concerns have been alleviated in 2020 with another

precedent-setting verdict on online infringement handed down by the Court of Appeal. In June, the court upheld an initial ruling by the lower court that the ISP in question, Telia, was guilty of secondary infringement and was ordered to disable access to the infringing websites and portals in question. Crucially, the judgment included an order for the dynamic disabling of access, with the court recognizing that rights-holders should receive "effective protection against continued copyright infringement." On this basis, the court judged that a dynamic injunction was a proportionate response. Since 2016 and the first *Bredbandsbolaget* case, the body of case law on online copyright infringement in Sweden has evolved and is now fairly extensive. Rights-holders that for years struggled to effectively address the illegal accessing of their content online can now more effectively enforce their rights through the judiciary and established court-set precedents. The effect of these new enforcement tools can be seen in rates of online piracy. In November 2019, the Swedish Intellectual Property Office (PRV), commissioned an online survey of internet users and levels of copyright infringement. The survey found a notable decrease in the number of users engaging in piracy and accessing illegal content compared with the previous survey conducted in 2017. Overall, the number of respondents saying they accessed copyright-infringing content fell from 21 to 14%. Of note is the even steeper drop in the age category 16-29, for which the number of respondents saying they accessed copyright-infringing content fell from almost half (46%) of the respondents to 28%. As a result of the sustained progress Sweden has made on addressing online copyright infringement, the score on indicator 11 has increased by 0.25.

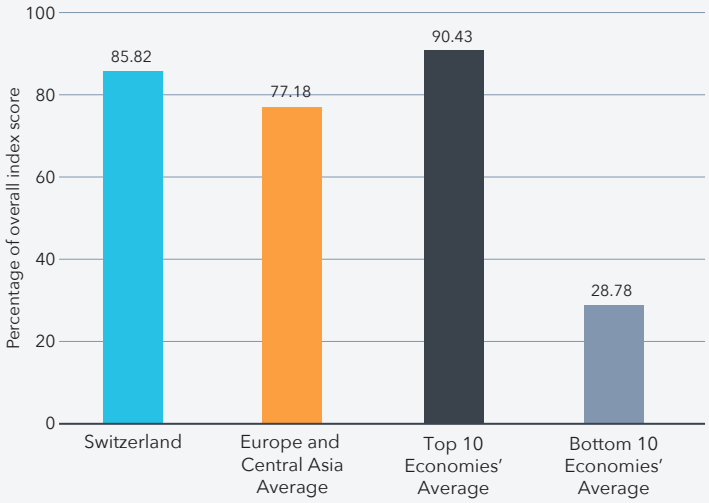
SWITZERLAND

RANK 9/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ R&D and IP tax incentives of 2019 in place
- ✓ Strong and sophisticated national IP environment
- ✓ Strong patent rights and enforcement environment
- ✓ Founding member of EPO and full participant in PPH initiatives

KEY AREAS OF WEAKNESS

- × Copyright law amendments of 2020 only partially address issue of online infringement–do not include option of disabling access to infringing content online or content hosted by foreign sites
- × Overly broad interpretation of limitations and exceptions for copyright–remains unchanged after 2020 amendments
- × Crucial gaps in enforcement and prosecution of online copyright infringement

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.50**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**3.38**
10. Term of protection	0.63
11. Exclusive rights	0.50
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.25
15. Digital rights management	0.50
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.50**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**5.78**
32. Physical counterfeiting rates	0.74
33. Software piracy rates	0.79
34. Civil and procedural remedies	0.75
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.25**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 42.91

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Switzerland's overall score has increased from 85.34% (42.67 out of 50) in the eighth edition to 85.82% (42.91 out of 50) in the ninth edition. This reflects a score increase on indicator 11.

Copyrights, Related Rights, and Limitations

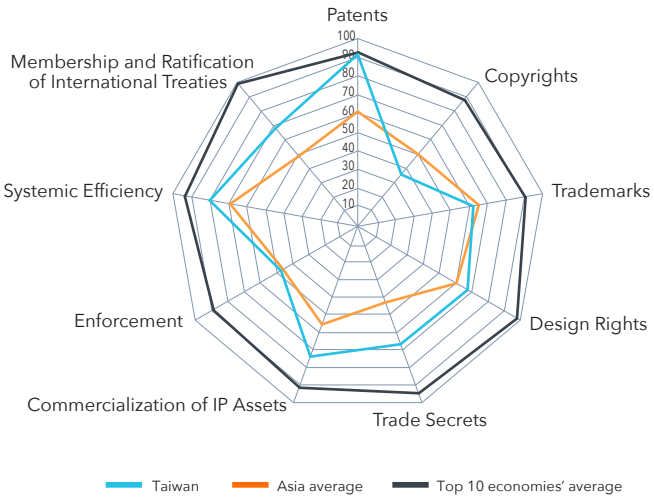
11. Legal measures that provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights: As noted in previous editions of the Index, online piracy in Switzerland is a long-standing issue and a departure from Switzerland's otherwise gold-standard IP regime. Broad precedent established in the landmark 2010 Federal Supreme Court decision *Federal Data Protection and Information Commissioner v Logistep AG*—in which IP addresses were viewed as constituting "personal data"—has severely limited the ability to identify and build cases against infringing users. This development has discouraged Swiss prosecutors from taking on such cases. While there are some examples of cases in which rights-holders have successfully been able to defend their copyrights, overall, the enforcement environment has been difficult. For example, while a 2014 judgment in the Zurich Canton High Court (*Obergericht Zürich*, case UE130087) on illegal file sharing did recommend the prosecution of the alleged infringing activity, the case also re-affirmed that the monitoring of the activity of the alleged infringer was a violation of the individual's privacy. Without a legal tool for targeting infringing users or the platforms on which they operate, digital and online piracy has remained widespread and Switzerland has become a hub for sites hosting infringing content. For example, the USTR's list of notorious marketplaces has included sites hosted in or through Swiss entities. The Swiss government has long recognized this broader problem and in 2014 announced an ambitious copyright reform plan following the recommendations by the Swiss Working Group on Copyright (AGUR12). A draft copyright law was presented for public discussion in December 2015 but, given the more than 1,200 contributions received, underwent further review by a new multi-stakeholder group (AGUR12 II). In late 2017, the Swiss Federal Department of Justice and Police (*Eidgenössische Justiz- und Polizeidepartement*) published new draft amendments and announced that copyright reforms would finally go ahead. These amendments were approved by the Swiss Federal Council (*Bundesrat*) in November 2017 and the Federal Assembly (*Schweizer Parlament*) in 2019, and became law in April 2020. The Swiss government should be commended for finally taking legislative action and attempting to address a long-standing weakness in its national IP environment. The final amendments introduce new measures to fight copyright piracy. The amendments require ISPs to both remove and keep infringing content off their servers. A new Article 39d of the Copyright Act inserts a legal obligation on the part of internet-hosting services to act against infringing content upon notification. The law states clearly that a "provider of an internet hosting service which stores information entered by users is required to prevent a work or other protected subject matter from being unlawfully remade available to third parties through the use of its services." The Swiss Federal Institute of Intellectual Property (*Eidgenössisches Institut für Geistiges Eigentum*) has publicly stated that this amounts to a requirement for a "stay down" mechanism whereby hosting services must ensure that infringing content is not made accessible again after a notification of infringement has been made and acted on. The

new law also attempts to address the issue of the processing of personal data when filing criminal complaints. Article 77i clarifies that rights-holders filing a criminal complaint may access and use personal data for this purpose; critically, this does not apply to civil proceedings, which, under the new law, can be filed only once criminal proceedings have commenced. Still, overall, the reforms are a missed opportunity. While addressing some of the shortcomings in the existing legal framework, the amendments do not fundamentally change the dynamics of copyright enforcement and online piracy in Switzerland. The amendments do not include any requirement or option for the disabling of access to illegal content, whether through the judiciary or an administrative mechanism. The past half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the United Kingdom, India, Singapore, Russia, and a host of other economies have introduced measures that allow rights-holders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called "dynamic" injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. Furthermore, the Swiss amendments do not change the existing dynamic with respect to defined personal and private use exceptions to copyright. Historically, Switzerland's private use exception has been interpreted broadly and has been confirmed by the Swiss government and existing case law to include the downloading and sharing of infringing content. Article 19 of the Copyright Act asserts that the downloading of content (other than software) for private use is not a copyright infringement (although distribution of such content that does not amount to private use, as well as any uploading of the content, represents an infringement). Such an expansive private use exception differs from other broad private copy exceptions—such as in Germany—in that, in Swiss law, there is no distinction made between whether or not the downloaded copy is itself a legal version. In other words, even if the material has been made available in an illegal manner, the private use exception still applies in Switzerland. This remains unchanged. The Federal Institute of Intellectual Property currently states on its website that the changes to Swiss copyright law do not affect existing personal use exceptions: "Nothing changes for consumers of illegal content. They are allowed, for example, to continue downloading music which was published online without the permission of the rights holder for private use." Finally, it is not clear what the legal consequences, if any, will be for internet hosts that fail to comply with the conditions of Article 39d or under what circumstances a refusal to comply with the law is acceptable. As a result of these deficiencies to the finalized copyright amendments, Switzerland's score on indicators 12, 13, and 14 remain unchanged, with only the score on indicator 11 rising by 0.25.

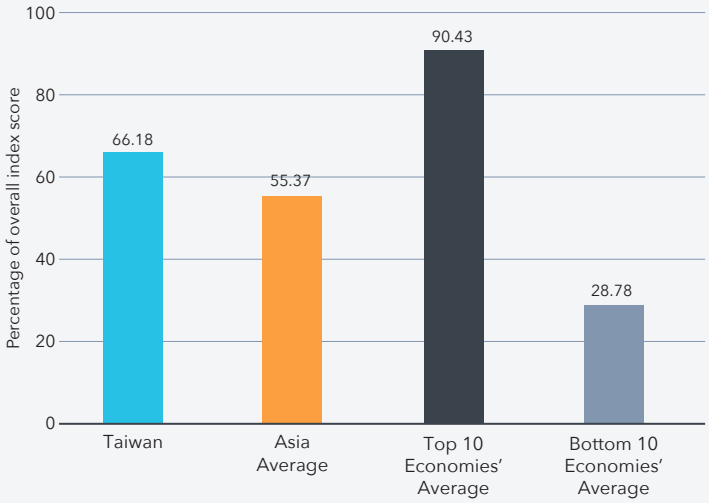
TAIWAN

RANK
21/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Amendments to trade secrets law improved IP environment in 2020
- ✓ Pharmaceutical linkage regime operational—strengthens protection and enforcement of biopharmaceutical IP rights
- ✓ Term of protection for industrial design rights extended from 12 to 15 years
- ✓ Patent framework in line with international standards
- ✓ Though facing political hurdles to becoming a contracting party, Taiwan has in many cases implemented the provisions of several international IP treaties

KEY AREAS OF WEAKNESS

- × Important gaps in digital copyright regime—draft copyright law amendments only partially address this
- × Relatively high rates of online piracy and physical counterfeiting

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	1.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**2.53**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.35**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.00**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**4.42**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**3.30**
32. Physical counterfeiting rates	0.39
33. Software piracy rates	0.66
34. Civil and procedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**4.00**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**3.75**
44. WIPO Internet Treaties	0.75
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.50
50. Post-TRIPS FTA	0.00

TOTAL: 32.10

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Taiwan's overall score has decreased from 66.33% (32.17 out of 48.5) in the eighth edition to 66.18% (32.10 out of 48.5) in the ninth edition. This reflects a score increase on indicator 23 but a score decrease on indicator 31.

Copyrights, Related Rights, and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights: As has been noted over the course of the Index, rights-holders face significant challenges in protecting their content in Taiwan. There are major gaps in the existing copyright legal framework, and enforcement remains inadequate. The Copyright Act provides for standard exclusive rights, including reproduction and performance. In 2009, amendments to the act introduced a notice-and-takedown mechanism including safe harbors for ISPs that remove access to infringing sites or forward notices from rights-holders to infringing users. However, there was a great deal of ambiguity regarding how the mechanism should be implemented. For instance, it was not clearly defined what infringements ISPs should act against, nor was it explained how ISPs should handle or respond to notices. In practice, although reports suggest that local ISPs frequently respond to rights-holder notices, the law does not provide a mechanism for addressing foreign content, which has become a major source of online piracy. There have been efforts on the ground to improve levels of enforcement, and relevant Taiwanese authorities have been fairly active. A special Intellectual Property Rights Police Force has been created and relevant Taiwanese IP authorities have recognized copyright infringement as a major challenge. The Taiwan Intellectual Property Office (TIPO) regularly publishes enforcement statistics on raids, arrests, and prosecutions. Still, digital and online piracy remain major problems in Taiwan. File sharing, streaming, and deep-linking sites, particularly from abroad, represent the top platforms for illegal content. For example, in 2020, the U.S. State Department noted the continued high levels of copyright infringement, including with respect to online piracy, academic book piracy, and illegal access to content through set-top boxes. Considering these challenges, amendments to the Copyright Act aimed at modernizing protection have been under review for the past half-decade. In 2014, draft amendments were proposed that introduced the concept of a right of distribution and public communication and revised the definition of public transmission and broadcast to include aspects applicable in the digital and online arenas. The amendments also sought to further clarify exceptions to copyright. In addition, the amendments expanded criminal liabilities beyond possession or distribution of physical goods specifically to works more broadly (which can thereby include digital works). The proposed revisions were never acted on by the Legislative Yuan and have remained dormant. In 2019, smaller reforms were passed by the Yuan. Amendments to Articles 87 and 93 of the Copyright Act strengthen existing DRM and TPM provisions by increasing criminal sanctions for manufacturers, importers, and distributors of pirated TV boxes with up to two years imprisonment and/or a fine. In 2020, this piecemeal reform effort continued, with TIPO releasing for public comment a new batch of draft amendments. The proposed changes include some aspects of the 2014 proposals, including an adjustment to the definition of public broadcasting and distribution, as well as changes to the existing framework on exceptions

and limitations. While some provisions strengthen the overall enforcement framework, including the introduction of statutory damages, overall, the proposed amendments do not fundamentally change the dynamics of copyright enforcement and online piracy in Taiwan. The amendments do not include any requirement or option for the disabling of access to illegal content, whether through the judiciary or an administrative mechanism. The past half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the United Kingdom, India, Singapore, Russia, and a host of other economies have introduced measures that allow rights-holders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called "dynamic" injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. The Index will continue to monitor Taiwan's efforts to improve its copyright environment in 2021.

Trade Secrets and the Protection of Confidential Information

23. Protection of trade secrets (civil remedies); and 24. Protection of trade secrets (criminal sanctions): In December 2019, the Taiwanese Legislative Yuan passed a new trade secrets law. The new law replaces the 2013 Trade Secrets Protection Act and provides several important updates to what was already a fairly comprehensive legislative framework. The 2013 Trade Secrets Protection Act introduced criminal penalties for trade secret violations. Since the law's entry into force, courts have applied criminal charges in several cases. The new law updates the original act by providing stronger protection for foreign rights-holders and better protection for confidential information during criminal investigation. Article 13-5 now provides foreign entities and persons with the right of filing criminal and civil complaints. Up until now, this had been possible only if a bilateral agreement existed between the country of residency of the foreign entity or person and Taiwan. Henceforth, all foreign entities and persons now have this right of protection regardless of treaty status. Articles 14-1 to 14-4 introduce so-called confidentiality protective orders. These CPOs are meant to provide prosecutors and investigators an additional tool to ensure that any confidential information that is examined, discussed, or otherwise shared during the course of a criminal investigation is not disseminated. As a result of these changes, the score on indicator 23 has increased by 0.25.

Commercialization of IP Assets and Market Access

31. Tax incentives for the creation of IP assets: Under the Statute for Industrial Innovation (SII), R&D credits are available for up to 15% of qualifying expenditures. In 2016, amendments to the SII introduced the possibility of a reduced rate of taxation on qualifying IP generated and licensed or transferred through either a 200% R&D deduction or tax credits. These amendments, however, expired at the end of 2019, and no equivalent amendments or changes to the tax law to extend these credits had been passed as of the time of research. As this tax incentive is no longer available, the score on this indicator has decreased by 0.33.

Membership and Ratification of International Treaties

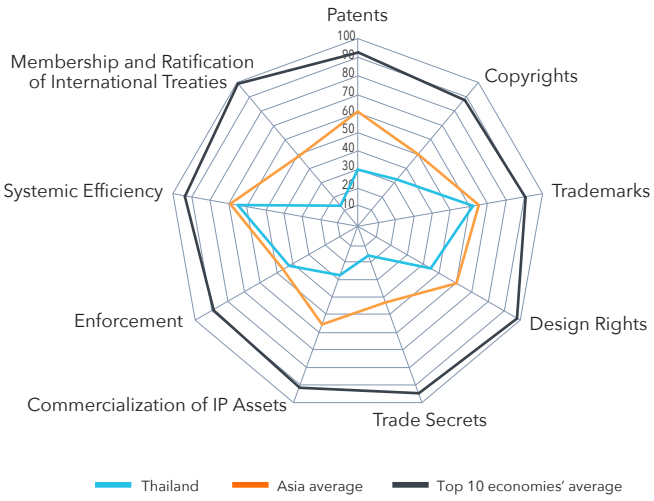
Taiwan is a full member of the WTO but is not eligible for membership in the United Nations (UN) or affiliated institutions, including WIPO. Taiwan is therefore unable to join and become a contracting party to any WIPO-administered treaty. Taking into consideration these political hurdles to Taiwan becoming a contracting party to many of the

treaties included in the Index, Taiwan has since the fifth edition of the Index not been scored on whether it is a signatory to and has acceded to these treaties. Instead, the Index has measured the extent to which core elements of the treaties included in the Index are present in equivalent Taiwanese domestic legislation. This is, however, not possible to do with all the treaties included in the Index. For example, those treaties whose primary goal is to establish and harmonize administrative and operational procedures for the international registration of IP rights cannot be wholly scored for Taiwan. Such treaties measured in the Index include the Patent Cooperation Treaty, Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, and parts of the Hague Agreement Concerning the International Registration of Industrial Designs. Consequently, the score for Taiwan on this category is 5.5 and not 7. Overall, Taiwan's maximum available score on the Index is therefore 48.5, not 50.

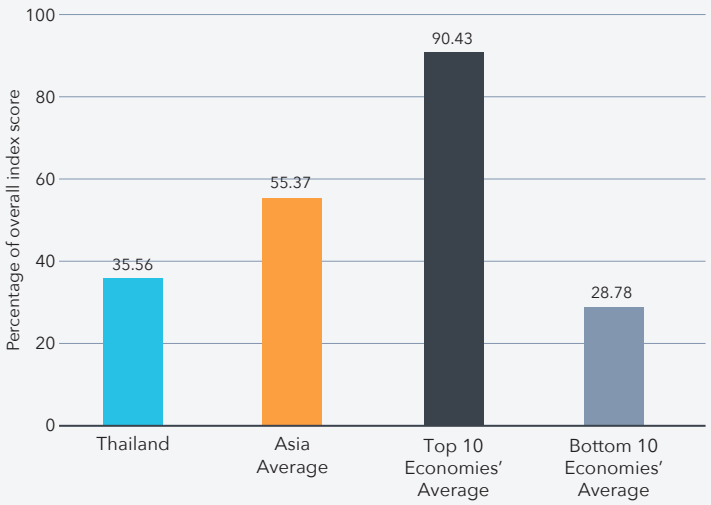
THAILAND

RANK
45/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Use in 2020 of injunctive-style relief mechanism under Computer Crime Act against trademark infringement—could prove to be a pivotal new tool against online sales of counterfeit goods
- ✓ Higher damages awarded in IP infringement proceedings in 2019-20
- ✓ Customs Act amendments of 2018-19 have resulted in greater anti-counterfeiting efforts against infringing goods in transit
- ✓ Proposed copyright amendments would address many of the existing deficiencies and weaknesses in Thai copyright law
- ✓ Moved from the Priority Watch List to the Watch List on USTR's Special 301 Out-of-Cycle Review—driven by stronger enforcement and coordination within Thai government
- ✓ Basic level of protection and registration system in place for copyrights, trademarks, and designs

KEY AREAS OF WEAKNESS

- × Inadequate patent protection, gaps in patentability, and severe patent backlogs
- × Life sciences IP rights inconsistent with TRIPS
- × Barriers to market access for patent holders
- × High physical counterfeiting and digital piracy rates—software piracy estimated at 64%
- × Limited participation in international treaties

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**2.72**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	0.72
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**2.28**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.75
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**1.67**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**2.96**
32. Physical counterfeiting rates	0.37
33. Software piracy rates	0.34
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**3.25**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**1.00**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 17.78

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Thailand's overall score has increased from 33.96% (16.98 out of 50) in the eighth edition to 35.56% (17.78 out of 50) in the ninth edition. This reflects score increases on indicators 19 and 20.

Trademarks, Related Rights, and Limitations

19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks; and 20. Availability of frameworks that promote action against online sale of counterfeit goods: As discussed in previous editions of the Index, rights-holders have long faced difficulties in protecting their trademarks in Thailand. The availability of physical counterfeit goods is high, and as e-commerce grows—JP Morgan in 2019 estimated that the Thai e-commerce market was worth just over USD26 billion—a growing proportion of the trade in counterfeits is moving online. The years 2019 and 2020 saw some major developments with respect to online enforcement against counterfeit goods. In 2019, the Thai government, through the Department of Intellectual Property (DIP), held consultations with some of the major e-commerce platforms aimed at discussing tools and procedures to tackle online infringement and the sale of counterfeit goods more effectively. The two largest online shopping platforms in Thailand, Lazada and Shopee, reported on existing or recently enhanced systems to tackle online piracy. Lazada—a subsidiary of Alibaba—has begun implementing Alibaba's IP Protection Platform system, which enables customers to file a complaint directly with the platform, either through the website or mobile application. Shopee reported on an online link and a call center line where rights-holders can submit their complaints. In July 2019, the DIP also organized a workshop bringing together rights-holders, internet platforms, and national and foreign enforcement agencies to discuss the platforms' role in tackling online piracy. The DIP has also created a dedicated unit for online violations tasked with furthering dialogue among relevant stakeholders, including online marketplaces. These positive developments continued in 2020, with what could perhaps be a precedent-setting application of an injunctive-style relief mechanism introduced in a set of legislative amendments to the 2016 Computer Crime Act. These amendments require ISPs to disable access to IP-infringing sites. Under the mechanism, the Ministry of Digital Economy and Society may file a motion for a permanent injunction for disabling access to websites with IP-infringing content. MDES is notified by IP owners (or their representation) of infringing content and then sends a request for injunctive relief to a court. If an injunction is granted by a court, MDES orders the ISP to disable access to the site. As of 2020, the mechanism had exclusively been used within a copyright context. Local legal analysis suggests that over 90 of these injunctive-style relief requests had been sent to MDES, with access disabled to over 1,400 websites and portals. In early 2020, this changed, with both the MDES and a relevant court approving and ordering the disabling of access to several websites on the basis of infringement of trademark rights. The decision marks a potential new and pivotal avenue whereby rights-holders can more effectively enforce their trademarks online. As a result of these positive developments, the score on indicators 19 and 20 have each increased by 0.25.

Enforcement

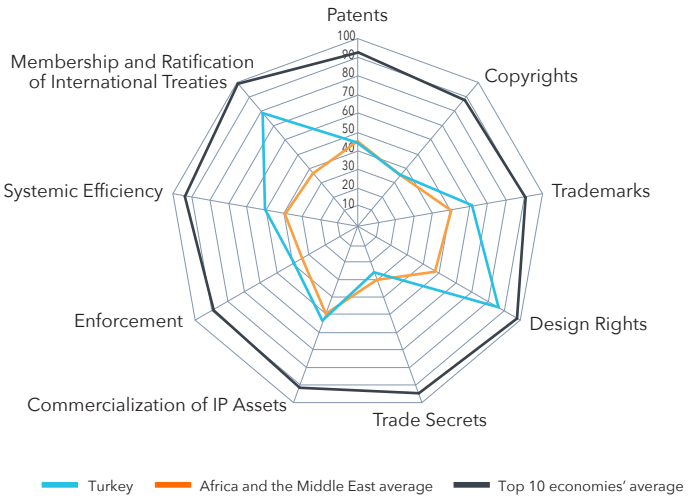
35. Preestablished damages and/or mechanisms for determining the amount of damages generated by infringement: Standard civil remedies, including mechanisms for calculating damages, are in place in Thailand for most major IP rights. However, these have historically been viewed as ineffective due to lengthy proceedings, uncertainty

about outcomes, and the fact that, generally, any damages awarded have been extremely low. In fact, local legal analysis suggests that damages awarded have often been lower than the costs associated with bringing a case. This may now be changing. In 2016, in an effort to reduce the existing case backlog and strengthen civil proceedings in lower courts, a new Specialized Appeals Court was established. Since 2018, there have been several high-profile cases involving different types of IP rights in which record damages have been awarded. This is a positive trend for Thailand's national IP environment and, as a result, the score on this indicator has increased by 0.25.

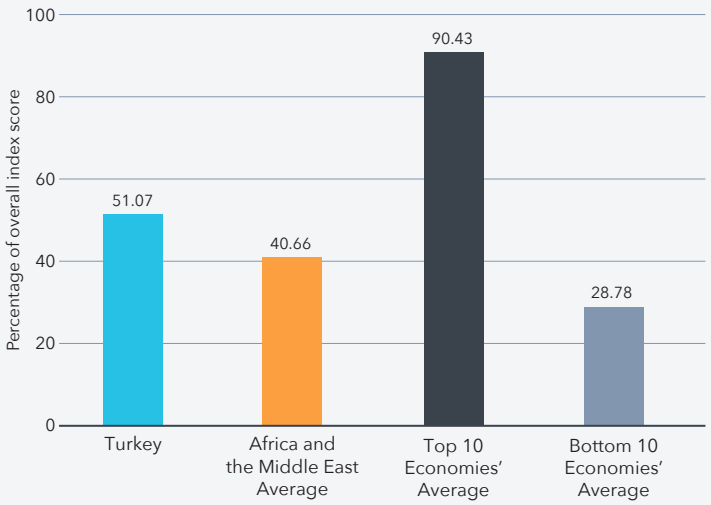
TURKEY

RANK
28/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Has over the years sought to align its national IP environment with EU standards
- ✓ Active promotion of importance of IP protection and use as an economic asset among the public and SMEs
- ✓ Generous R&D- and IP-specific tax incentives in place

KEY AREAS OF WEAKNESS

- × Localization policies becoming more prominent as part of industrial and economic policy targeting high-tech sectors—intensified in 2020
- × RDP not being granted to biologics
- × Key gaps persist in copyright environment and patent protection and enforcement
- × For biopharmaceuticals, industrial localization policies have fused together with IP policy and broader health policy on the pricing and procurement of medicines
- × High counterfeiting and software piracy rates—56% in latest BSA estimates

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**4.00**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**2.49**
10. Term of protection	0.74
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**0.80**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.30

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.25**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**2.74**
32. Physical counterfeiting rates	0.30
33. Software piracy rates	0.44
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**2.50**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**5.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

TOTAL: 25.53

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Turkey's overall score has decreased from 51.58% (25.79 out of 50) in the eighth edition to 51.07% (25.53 out of 50) in the ninth edition. This reflects a score decrease on indicator 26.

Commercialization of IP Assets and Market Access

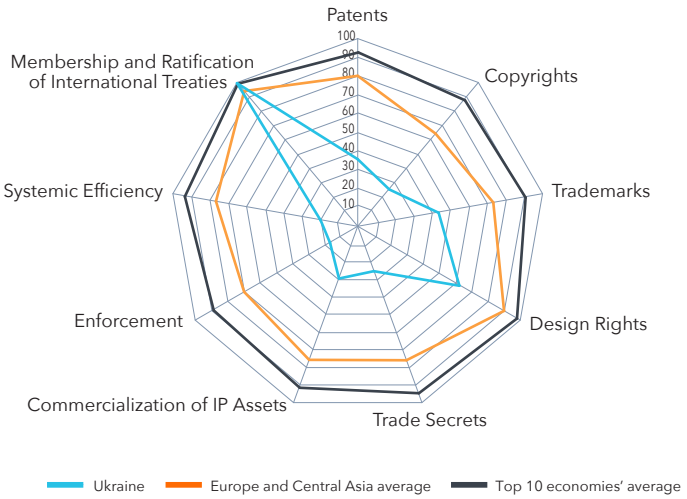
26. Barriers to market access: Turkish industrial and economic policy over the past two decades has increasingly been driven by an effort to localize industrial production and R&D. A major part of these efforts has been localization and import substitution policies that actively discriminate against foreign entities and favor domestic Turkish companies. The biopharmaceutical and ICT sectors have been heavily targeted by these policies. In November 2014, the Turkish prime minister presented the objectives of covering 60% of national demand for pharmaceuticals and 20% for medical devices with local production, as well as increasing clinical research by 25%. In 2016, the Turkish Medicines and Medical Devices Agency began implementing an import substitution plan whereby drugs that have at least one local generic or therapeutic equivalent are required to localize their production by 2018 or be excluded from public reimbursement. An Import and Transfer Commission was set up to manage the process and evaluate commitments by drug producers. Industry reports suggest that close to 200 products were delisted in 2018, of which 71 medicines were identified and delisted from reimbursement in early 2018 by the Turkish Social Security Institution. In 2019, the European Union filed a complaint before the WTO alleging that Turkey's localization policies were in violation of basic provisions of the GATT, TRIMS, TRIPS, and SCM. In September 2020, the WTO announced that, due to the COVID-19 pandemic, no final report would be issued on this dispute until the second half of 2021. More broadly, the Turkish government actively uses public procurement policies to incentivize localization and discriminate against foreign bidders. Since 2002, under Article 63 of the Procurement Law, domestically manufactured products are afforded a 15% price advantage in tenders. For several years, there was some uncertainty as to what constituted a "local" product. In 2014, the threshold for being considered a local product was explicitly defined and raised as part of Decree 2014/35. To obtain a "Domestic Goods Certificate" (and in so doing qualify for the price preference) all companies operating in Turkey, including foreign firms, must make domestic investments of at least 51% of the contract value. Moreover, this investment must include major parts of the production process and not just the final stages. Also, any applicants operating under a joint venture must have only domestic, Turkish partners. In addition, since 2015, all government ministries have the possibility to apply "Industrial Cooperation" (civil offset) clauses for public procurement contracts. With regards to the ICT sector, Turkish laws place onerous requirements (including local data storage) on ICT companies and digital service providers. Data storage requirements are in place on payment service providers and banking and financial services institutions. As with other localization measures, the requirements for data providers intensified in 2020. In August, the Turkish Parliament passed amendments to Law No. 5651 (the Regulation of Internet Broadcasts and Prevention of Crimes Committed through Such Broadcasts). These amendments require social media service providers with over 1 million visits per day to store any user data locally in Turkey, appoint a legal representative in Turkey, and report regularly on their activities and requirements under these amendments. Non-compliance is potentially subject to substantial fines. Cross-border transfers are allowed; however, such transfers can take place only after explicit consent has been obtained from the data subject or the country to which data is

being transferred to provide an equivalent level of protection as in Turkey. Given the deterioration of the localization environment in Turkey and the failure on part of the Turkish government to effectively address this, the score on this indicator has decreased by 0.25.

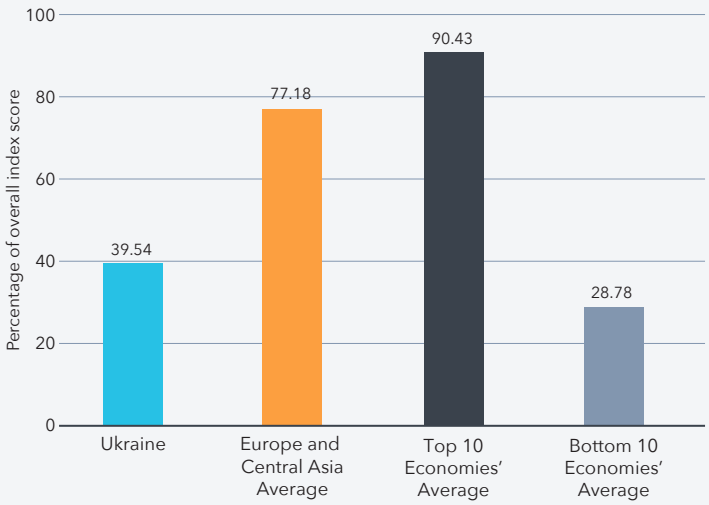
UKRAINE

RANK
39/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Amendments to law on design rights of 2020 extend term of protection to 25 years
- ✓ Growing body of case law on protection of trade secrets
- ✓ Amendments to Customs Code strengthen enforcement capacity
- ✓ Efforts to align IP legislation to EU standards and implement Deep and Comprehensive Free Trade Areas (DCFTA)
- ✓ New first instance Court for IP matters (the "High Court") set up in 2017—should help improve consistency and expertise within judiciary
- ✓ Contracting party to all international IP treaties included in the Index

KEY AREAS OF WEAKNESS

- × Amendments to Law on Protection of Rights to Inventions and Utility Models of 2020 weaken national IP environment—especially in relation to life sciences
- × Amendments of 2020 restrict patentability of biopharmaceutical inventions and introduce export exemption for products under patent term restoration (modeled on EU's Regulation 2019/933)
- × Major gaps across all categories of the Index—both a lack of relevant IP laws and weak enforcement
- × Latest BSA estimates of online piracy rate of 80%—continued lack of effective effort to reduce use of unlicensed software by public sector
- × High rates of physical counterfeiting—key transit point for counterfeit products entering the EU
- × Gaps in customs activities—notably lack of effective procedures for destruction of counterfeits

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**3.25**
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**1.83**
10. Term of protection	0.58
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.50
15. Digital rights management	0.25
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.00
Category 4: Design Rights, Related Rights, and Limitations	**1.25**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.75**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.00
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**1.75**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**1.19**
32. Physical counterfeiting rates	0.24
33. Software piracy rates	0.20
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.00**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 19.77

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Ukraine's overall score has decreased from 39.66% (19.83 out of 50) in the eighth edition to 39.54% (19.77 out of 50) in the ninth edition. This reflects a score increase on indicator 21, but score decreases on indicators 7 and 16.

Patents, Related Rights, and Limitations

2. Patentability requirements; and 3. Patentability of computer-implemented inventions: As noted over the course of the Index, the protection of patents in the Ukraine has long been problematic. Patentability standards have stood firmly outside international best practices, with restrictions in place on many innovation-based and high-tech industries. For example, the Law on Protection of Rights to Inventions and Utility Models has historically excluded computer programs from patentable subject matter. While there have been examples of patents granted for CIIs, these are a small minority of the total number of patents filed and granted. Looking, for example, at patent statistics housed by WIPO in the "IP Statistics Data Center" for Ukraine shows that a small number of patent applications (patent publications by technology) were under the categories "Computer technology" and "IT methods for management." Between 1980 and 2018, a total of 740 such applications were published. This compares to a total number of 58,845 total applications during this time, or 1.26% of the total number of applications published. In July 2020, new amendments to the law were passed by the Ukrainian Parliament. While these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. To begin with, the amendments do not address the existing deficiencies with respect to CIIs. Furthermore, these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter. Second-use claims and follow-on products are now defined, under an expanded Article 7, as ineligible patent matter. Ukraine is one of a growing number of economies seeking to develop high-tech industries and capacity for innovation-driven economic growth. Since being elected in 2019, President Zelensky has repeatedly emphasized the need to promote innovation and the digital transformation of the Ukrainian economy and public sector. Strengthening Ukraine's national IP environment and improving the ability of innovators and inventors to protect their innovations should be at the forefront of the government's policy platform. As the economic data and analysis in the Index, its accompanying sister publication the *Statistical Annex*, and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for innovation and developing high-tech industries. For all economies—emerging and developed alike—what drives innovation, technological advances, and, ultimately, economic development and growth is the creation of new forms of intangible assets and IP. Unfortunately, the changes introduced in the Ukraine's patent laws are unlikely to help it achieve its economic objectives and will, instead, make it more difficult to create, protect, and commercialize IP assets in high-tech industries.

7. Patent term restoration for pharmaceutical products: Under the Law on Protection of Rights to Inventions and Utility Models Term, restoration of up to five years for delays caused due to market authorization and regulatory approval for biopharmaceuticals has historically been made available to rights-holders. Although amendments passed in July 2020 to the law do not remove the possibility for rights-holders to apply for and receive a period of term restoration, these amendments have introduced new procedural barriers to obtaining the additional protection as well as export and stock-

piling exemption. The latter exemption appears to be modeled on a similar carve-out introduced in the EU through Regulation 2019/933, which has been operational since 2019. In the Ukrainian case, the exemption allows for the manufacture and export of a product for which a term of restoration has been granted. Manufacturing for the purposes of stockpiling is also allowed, beginning within a period of six months of any granted patent term restoration expiring. Beginning in last year's Index, the methodology used to calculate the score on this indicator has changed. This indicator now consists of two distinct variables: first, the existence of a term of patent restoration for pharmaceutical products due to the prolonged research, development, and regulatory approval periods for such products; and second, the existence of any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. Of the available score for this indicator, 0.75 is allocated to the existing term of protection compared with the current baseline rate of five years of term restoration used in the United States, EU, and Japan. The remaining 0.25 is allocated on the basis of a given economy providing any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. Given the introduction of a new export exemption in the Ukraine, the score on this indicator has been reduced from 1 to 0.75.

9. Patent opposition: The July 2020 amendments to the Law on Protection of Rights to Inventions and Utility Models also introduced a new patent opposition system in the Ukraine through both a pre- and post-grant opposition mechanism. Under the new changes, any party may challenge the validity of a patent application within six months of the official publication of the application. Traditionally, patents in the Ukraine could be challenged only in court-based patent nullity proceedings. As in many jurisdictions, challenging the validity of a patent in this manner can be a costly and lengthy process. Introducing an administrative opposition process offers the chance of a relatively quick and more cost-effective route for hearing and resolving patent validity challenges. Unfortunately, many patent opposition mechanisms around the world are neither cost-effective nor quick. This is especially the case for pre-grant opposition systems. In fact, many jurisdictions benchmarked in the Index in which a pre-grant opposition mechanism is in place have experienced systematic and severe delays to the patent prosecution process, with rights-holders negatively affected. For example, Australia has in place a pre-grant opposition system for patents. Under the system, third parties may file an objection between the publishing of the application and within three months after the application is accepted. The system extends the patent review process significantly, delaying the granting of patents and reducing the available term of protection afforded to patent holders. For example, a 2012 academic study published in the *University of New South Wales Law Journal* found that opposition filings typically delayed the granting of a patent by close to two years (the mean delay found was 2.4 years versus the median of 1.8 years). The same study found that the highest volume of oppositions were directed toward pharmaceutical patents, suggesting there is a clear commercial imperative behind these oppositions. Similarly, Israeli patent law provides for a pre-grant form of opposition to pending patent applications. Under the Israeli opposition system, the examination of a patent application can be extended by, at minimum, an additional 18 months, not including the process of re-examination and/or judicial hearings. Regardless of the merits of any opposition filing, these generous timelines add a significant burden and delay to the patent prosecution process in Israel and, just as in Australia, impose an undue burden on patent applicants. At the time of research, no implementing regulations or formal

guidelines had been published by the Ukrainian authorities as to what the mechanics and timeline of either opposition mechanism would look like. Once drafted, such regulations and guidelines should include relevant safeguards to avoid the undue delays in patent prosecution experienced in many other jurisdictions. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

16. Government use of licensed software: The use of unlicensed software by the Ukrainian government and public sector entities remains a long-standing challenge. Rights-holders and the U.S. government have for years pointed to the need for fundamental reform and the effective application and implementation of existing requirements that software used by government agencies should be properly and fully licensed. A Ukrainian Cabinet regulation from 2003 banned the use of unlicensed software by government agencies and established procedures for legal access to software. Recent reports suggest that centralized public procurement could be used by the Ukrainian government to ensure the use of licensed software. Still, as the USTR noted in 2020, there continues to be "widespread use of unlicensed software by Ukrainian government agencies." Given the lack of effective action by the Ukrainian government on this issue for the past eight years of the Index, the score on this indicator has been reduced to 0.

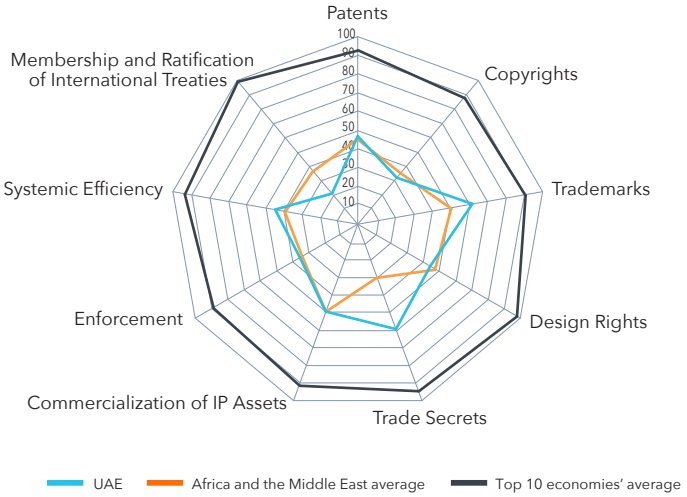
Design Rights, Related Rights, and Limitations

21. Industrial design term of protection: In July 2020, new amendments to trademark and industrial design legislation were passed by the Ukrainian Parliament. Just as with the amendments to Ukraine's patent law, these legislative changes are meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine-European Union Association Agreement. With respect to design rights, the term of protection has been extended from 15 to 25 years. As a result, the score on this indicator has increased to 1.

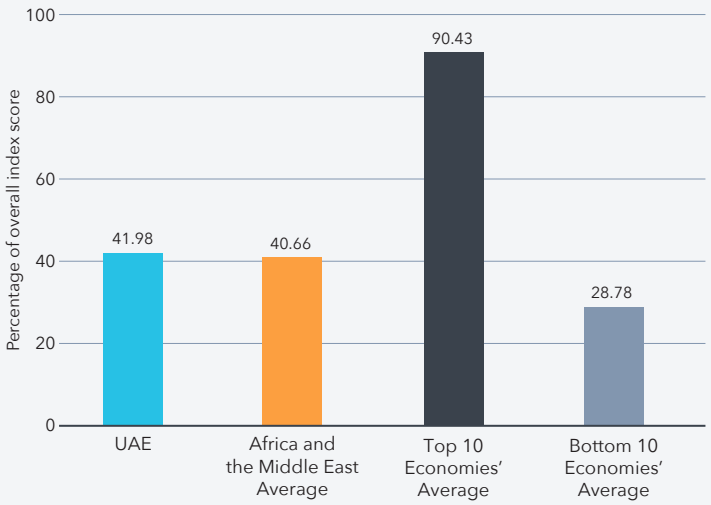
UNITED ARAB EMIRATES

RANK
35/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Defined RDP term introduced in 2020
- ✓ New Foreign Direct Investment Law offers possibility of 100% foreign ownership, granting foreign investors a potential exemption from the requirement of having an Emirati partner holding a minimum of 51% of a company's shares
- ✓ Basic IP protections in place
- ✓ Enhanced anti-counterfeiting efforts, including criminal penalties
- ✓ Awareness-raising and capacity-building efforts on importance and value of IP rights

KEY AREAS OF WEAKNESS

- × RDP term contains a potential exception, establishing a compulsory license (Article 5), potentially out of step with its international obligations.
- × Deep uncertainty over protection for biopharmaceutical patents, as no action has been taken on 2017 approval of two generic versions of a pharmaceutical product still on patent
- × Significant holes in copyright regime—limited online-specific legal framework and enforcement capacity
- × High levels of physical counterfeiting—UAE physical markets listed in USTR's *Out-of-Cycle Review of Notorious Markets*
- × Gaps in customs measures and civil remedies for infringement
- × Limited participation in international treaties

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**4.25**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.28**
10. Term of protection	0.53
11. Exclusive rights	0.50
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.80**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.80

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**3.00**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**2.51**
32. Physical counterfeiting rates	0.33
33. Software piracy rates	0.68
34. Civil and procedural remedies	0.75
35. Pre-established damages	0.00
36. Criminal standards	0.50
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.25**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**1.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 20.99

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

The UAE's overall score has increased from 40.44% (20.22 out of 50) in the eighth edition to 41.98% (20.99 out of 50) in the ninth edition. This reflects a score increase on indicator 25.

Areas of Note

In November 2019, a new Dubai International Financial Centre (DIFC) Intellectual Property Law (No. 4, 2019) came into effect. Situated in Dubai and operating under the umbrella of both the laws of Dubai and the federal framework provided by the UAE, the DIFC is a special economic district with a distinct and, to some extent, independent legal system based on British common law. Founded in 2004, the objective of the DIFC is to provide a base of operations for financial and professional services in the UAE and the broader Middle East region. The purpose of the IP Law is to provide rights-holders with access to the DIFC's jurisdiction and rights of redress within the DIFC. It covers most major IP rights and introduces a new administrative enforcement mechanism through a new executive office, the Commissioner of Intellectual Property. The law empowers the commissioner to take some independent executive enforcement action, including the ability to hear cases and levy fines of up to USD50,000 on potential violations of the law and IP infringement within the DIFC. With respect to the broader legal framework in the Emirates, the Law has no legal bearing on IP rights within the UAE; it is concentrated and valid solely in the confined space of the DIFC. As such, it is not benchmarked to the Index's indicators or included in the overall score for the UAE.

On January 5, 2021, the Gulf Cooperation Council Patent Office announced that, following the 41st Session of the Supreme Council and amendments to the Patent Regulation, the Patent Office would no longer be accepting patent applications. The announcement was unexpected, as the GCC patent application route had been operational for more than two decades. At the time of research, it was unclear what would happen to applications filed prior to the announcement. The Index will continue to monitor these developments in 2021.

Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism: As discussed in earlier editions of the Index, the Ministry of Health Decree 404 provides for an early patent adjudication mechanism for pharmaceuticals. Under the system, the Ministry of Health will deny marketing approval for a product that infringes on a patent existing either in the UAE or in the economy from which the product has been imported. Officials are to either reject an application or hold the application in abeyance until patent protection has expired. In 2017, the UAE government effectively overrode this mechanism and approved for marketing two generic versions of a pharmaceutical product still on patent in the country of origin. At the time of research, no action had been taken to rectify this approval. Consequently, there is deep uncertainty over the provision of basic patent protection in the UAE. In 2020, the Ministry of Health and Prevention issued Ministerial Resolution 321. Article 4 of the resolution includes a requirement that, as part of the market approval process, follow-on applicants provide "evidence that the relevant innovative medicinal product does not have a patent document valid" in the UAE. At the time of research, no further details had been released. It is not clear that this is intended to amount to a proper linkage system whereby the exclusivity status of a reference product is linked to the marketing approval of a follow-on product. It is also unclear what the ramifications are (if any) of non-compliance with this article on the part of a follow-on manufacturer,

the legal responsibilities of the drug regulatory authorities, and the extent to which regulators are expected to play a role in the enforcement of the requirements under this new regulation. Given the difficult history in the UAE outlined above, this is a potentially positive step for improving the biopharmaceutical IP environment and respect for duly granted patent rights. The Index will continue to monitor these developments in 2021.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection term: The protection of biopharmaceutical innovation in the UAE has historically been defined by Ministerial Decree 404 from 2000, which tied the exclusivity status of a product in the UAE to the term of patent protection in the country of origin. The period of protection for applications submitted for marketing approval after January 1, 2000, has been for the remaining term of the patent or patents protecting the drug in its country of origin. As such, there has been no period of RDP defined or recognized in UAE law. This changed in 2020, with the Ministry of Health and Prevention issuing Ministerial Resolution 321. The resolution provides a defined eight-year period of RDP for pre-clinical and clinical data submitted by a new drug applicant. Article 2 of the resolution explicitly states that it is "not permissible" for a follow-on applicant to "obtain the marketing approval for a similar drug product" by relying on a previously submitted dossier. There is, however, some uncertainty over whether the full eight-year RDP term will be available. Specifically, Article 3 allows follow-on applicants to register their products in the last two years of the granted RDP, in what amounts to a so-called "Bolar exemption." Bolar exemptions are normally in place to allow follow-on manufacturers to conduct research and necessary scientific studies to meet regulatory safety and quality requirements in preparation for market approval. Due to the long timelines involved in the drug approval process, the primary goal of these types of exemption is to ensure that there is no undue delay for the launch of a generic follow-on product once the reference product's exclusivity has expired. In the case of the UAE, Article 3 of the resolution does not specify or outline what type of activities follow-on manufacturers can engage in and there is no assurance that the reference product's full eight-year period of data exclusivity will be maintained. There is also a degree of uncertainty regarding the meaning and purpose of Article 5 of the decree. The article states that the relevant drug regulatory authorities may, under "exceptional" circumstances, including "for the purpose of protecting public health," override or disregard an existing term of RDP and approve a follow-on product. It would be beneficial for rights-holders if such exceptional circumstances were more fully defined. Finally, Article 6 of the decree clarifies that any products approved for market prior to the coming into effect of the decree are still subject to the preceding regime under Decree 404. Overall, the introduction of a defined term of RDP is a positive step and a clear improvement in the biopharmaceutical IP environment in the UAE. Providing rights-holders with a full, uninterrupted eight-year term of protection would position the UAE as one of the leaders on biopharmaceutical RDP in the MENA region. On this basis, the score on this indicator has increased substantially from 0 to 0.8.

Commercialization of IP Assets and Market Access

26. Barriers to market access: As noted in previous editions of the Index, in September 2018, the UAE government issued a new Foreign Direct Investment Law through Federal Legislative Decree No. 19 of 2018. The law offered the possibility of 100% foreign ownership, granting foreign investors a potential exemption from the requirement of having an Emirati partner holding a minimum of 51% of a company's shares, established by the

Commercial Companies Law. The law contained a negative list of sectors excluded from its scope, which included natural resource extraction and related industries, banking, insurance, postal services, telecommunication and other audio-visual services, roads, and transportation. At the time of publication, it was also stated that a separate "positive" list would be published outlining which parts of the economy would be open to foreign ownership. In 2019, a broad summary of this positive list was published describing in which economic sectors 100% foreign ownership would potentially be allowed. Further developments occurred in 2020, with the UAE government and Cabinet of Ministers issuing Cabinet Resolution No. (16). This resolution provides more detail on the specific types of economic activity included in the positive list. In total, the list comprises 122 different types of activity and is divided up across three major areas: Agricultural Sector (19 types of activity), Manufacturing Sector (51 types of activity), and Services Sector (52 types of activity). Each area of activity has different capital investment requirements, ranging from minimum levels up to AED100 million (circa USD27 million). There appears to be no local partnership requirements or restrictions on the extent of majority ownership, with Article 4 stating that foreign investors will own 100% of each investment project. However, the resolution does retain certain local content and employment requirements. For example, Article 7 maintains that all foreign investment projects and activities outlined under the list are still subject to the applicable "emiratization" rules as stated by relevant employment laws. There are also non-specified requirements for technology transfer and R&D capacity building. These requirements are not defined and are listed for only certain areas of activity. For example, all activities listed under the Agricultural Sector and Manufacturing Sector (70 activities in total) must "use modern technology" and "contribute in research and development" [sic]. The resolution does not define how these two requirements are to be fulfilled or what constitutes "modern technology." Each area of economic activity is also subject to local licensing requirements, which are subject to local rules and regulations in each emirate. The Index will continue to monitor these developments in 2021. In particular, the Index will monitor the extent to which forced technology transfer and the sharing or divulging of IP is made either a *de jure* or *de facto* requirement for foreign investors to be able to invest and conduct business in the specified areas of economic activity.

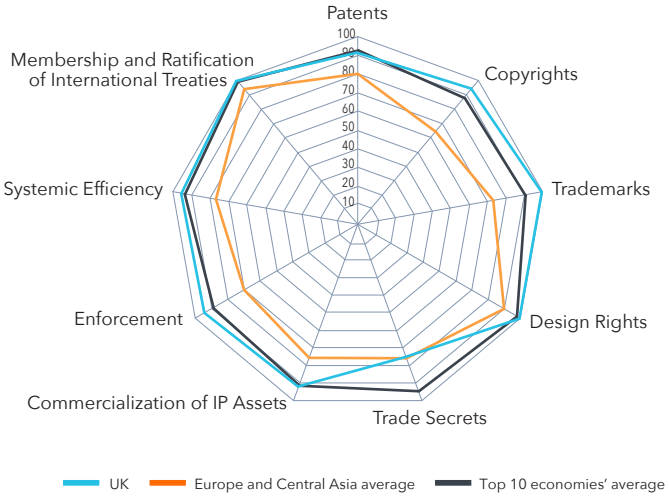
Membership and Ratification of International Treaties

The UAE scores low in its participation in and ratification of international treaties. While its overall score on this category has risen from a score of 1 to 1.5 as a result of the increased number of international treaties included in the Index. The UAE is a contracting party to the WIPO Internet Treaties and the Patent Cooperation Treaty. It is not a contracting party to any of the other treaties included in the Index. Similarly, the UAE has not concluded any post-TRIPS FTAs with substantive IP provisions. The GCC has concluded FTAs with Singapore and EFTA, but neither of these agreements include a dedicated or comprehensive IP chapter. Being a contracting party to key international IP treaties reflects a given economy's broader participation in the international IP community and embrace of the highest IP standards. Most economies benchmarked in the Index are members of two or more of the treaties included in the Index.

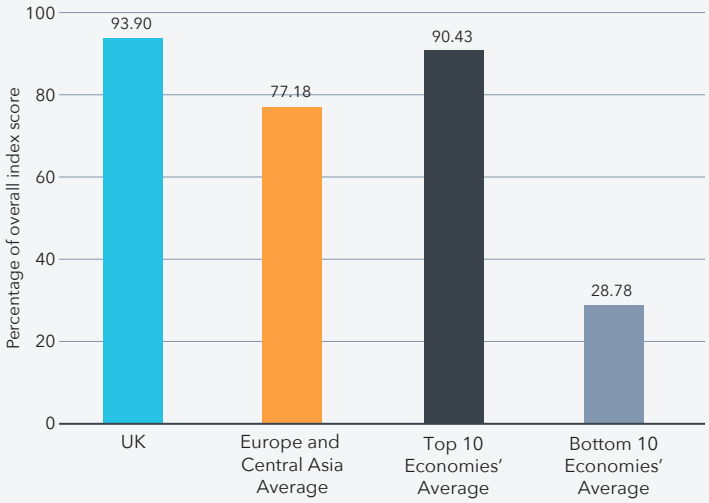
UNITED KINGDOM

RANK 2/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Strong and sophisticated national IP environment
- ✓ A model for injunctive-style relief for rights-holders when battling online infringement
- ✓ Overall strong cross-sectoral enforcement environment, highlighted by the work of a specialist crime unit and cross-industry and government cooperation

KEY AREAS OF WEAKNESS

- × U.K. government has chosen to retain EU SPC exemption for exports of biopharmaceuticals—remains a significant risk to the United Kingdom's research- and IP-based biopharma industry
- × Limited criminal sanctions available for the theft and misappropriation of trade secrets

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**6.63**
10. Term of protection	0.63
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**4.00**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	1.00
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.25**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	1.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.50**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**6.57**
32. Physical counterfeiting rates	0.78
33. Software piracy rates	0.79
34. Civil and procedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 46.95

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

The United Kingdom's overall score has decreased slightly from 93.92% (46.96 out of 50) in the eighth edition to 93.90% (46.95 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Area of Note: Brexit

In January 2020, the United Kingdom formally left the European Union. The final agreement on the terms for its withdrawal—the *Agreement on the Withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community*—includes a separate chapter covering intellectual property. The agreement clarified that holders of European Union trademarks, registered designs, and Community plant variety rights would, without re-examination, be granted equivalent rights in the United Kingdom. In 2020, the UKIPO confirmed that all existing registered EU trademarks, registered Community designs, and registered Community plant variety rights would automatically be registered in the United Kingdom and granted a comparable U.K.-based registration. This arrangement was confirmed by the Trade and Cooperation Agreement concluded between the United Kingdom and EU on December 24, 2020. This agreement includes a chapter on IP. As noted in previous editions of the Index, the U.K. government has recognized the negative impact the uncertainty of the long Brexit process has had vis-à-vis IP rights-holders and has attempted to keep rights-holders abreast of how the United Kingdom's national IP environment will change after Brexit is concluded. In particular, the UKIPO should be commended for its work in issuing and updating guidance documents on key areas of concern to U.K. and international rights-holders. The Index will continue to monitor the separation process and its ramifications for IP rights-holders in the United Kingdom over the coming years.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: 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. As the Index and others have pointed out, there were many troubling assumptions underlying the commission's proposal. Indeed, this was recognized even by several key EU Member States. Most basically, the proposal assumed that there is an actual market and demand for European generic manufacturers. Yet it is not at all clear what this market is or where the demand for generic medicines produced in Europe would come from. 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, events in 2020 suggest that this is exactly what is happening. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, the Ukraine has notably weakened its patenting environment as it relates to biopharmaceuticals. While these legislative changes are meant to better align Ukraine's national IP environment with that of

the EU as part of the 2017 Ukraine-European Union Association Agreement, they will have the opposite effect. Not only do these changes substantially weaken the eligibility for biopharmaceutical patentable subject matter, new procedural barriers to obtaining patent term restoration as well as an export and stockpiling exemption have also been introduced. The latter exemption is modeled on the EU's Regulation 2019/933. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU is that the policy will be emulated by other economies. As the Ukraine example shows, instead of benefiting the European generics industry, the introduction of an SPC exemption will simply end up hurting Europe's research-based industry and lead to a global race toward the bottom in weakening IP standards. From July 2019, Regulation 2019/933 is in force, and the SPC export exemption is now, for all intents and purposes, legal and operational in all EU Member States. Under the terms of its withdrawal from the EU, the United Kingdom has maintained the SPC exemption in U.K. law. In 2020, the UKIPO held a public consultation on a draft Statutory Instrument that would amend the existing exemption, making it more compatible with U.K. statute. Unfortunately, despite rights-holders calling for the U.K. government to reconsider its decision to retain the exemption, in its public response to the consultation, the government reiterated its position that the SPC exemption would be retained and be operable going forward. As a result, the United Kingdom's score on indicator 7 remains 0.75.

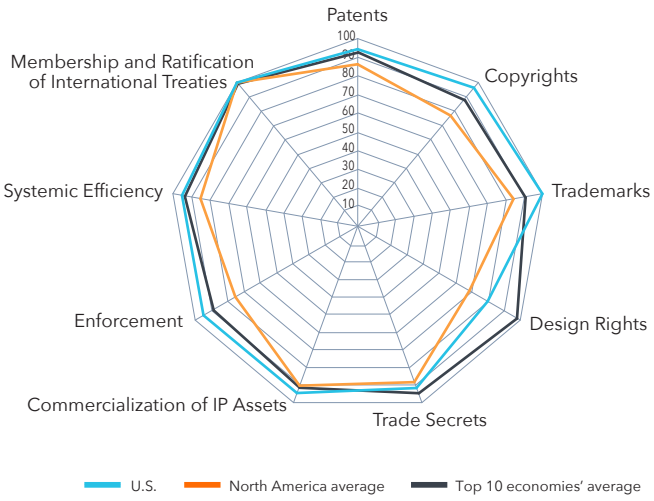
Enforcement

38. Transparency and public reporting by customs authorities of trade-related IP infringement: As an EU Member State and member of the Single Market and Customs Union, customs enforcement activity undertaken by UK border authorities against suspected IP-infringing goods was included and counted in the EU's overall statistics. The Directorate-General for Taxation and Customs Union has for years published an annual report on customs enforcement at the border. These reports include detailed data and analysis of the number of suspected goods seized, their estimated value, and their country of origin. As stated in previous editions of the Index, the EU's work in this area has stood as a model and example for other customs authorities around the world. Following Brexit and the United Kingdom leaving the Customs Union, it is unclear if Her Majesty's Revenue and Customs (HMRC), will continue in this tradition, publishing its own annual report and statistical compendium on IP rights enforcement at the British border. The Index will monitor this in 2021.

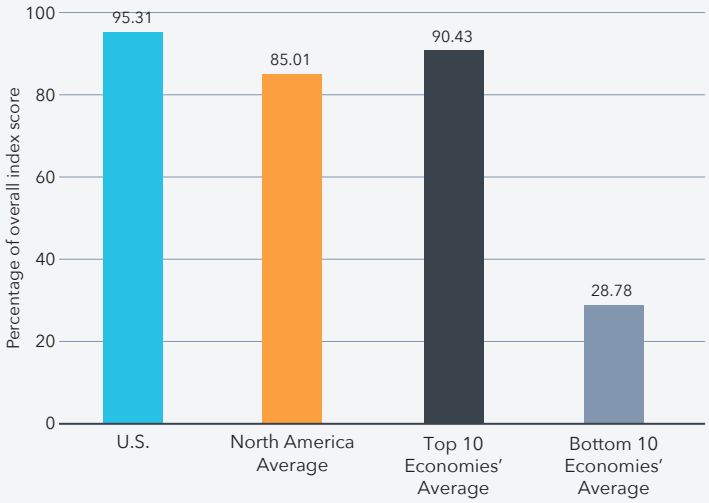
UNITED STATES

RANK
1/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Copyright Office 2020 report on section 512 recognizes need for copyright reform
- ✓ USPTO release in 2019 of new draft guidance covering section 101 patentability and section 112 claims relating to computer inventions—seeks to address uncertainty in patenting system
- ✓ Sector-specific rights and protections in place across all categories of the Index
- ✓ Reform efforts to patent opposition proceedings by USPTO continued in 2020—agency should be commended for efforts to provide a greater balance and address concerns over unpredictability and uncertainty within PTAB process

KEY AREAS OF WEAKNESS

- × Proposals for compulsory licensing as a pharmaceutical cost containment policy
- × Continued uncertainty over patentability for high-tech sectors
- × Lack of a targeted legal basis for addressing online piracy, along the lines of other global leaders

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**8.50**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	1.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**6.75**
10. Term of protection	1.00
11. Exclusive rights	1.00
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**4.00**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	1.00
Category 4: Design Rights, Related Rights, and Limitations	**1.60**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.75**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	0.75

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**5.67**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	1.00
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**6.64**
32. Physical counterfeiting rates	0.79
33. Software piracy rates	0.85
34. Civil and procedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 47.66

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

The United States' overall score has increased slightly from 95.28% (47.64 out of 50) in the eighth edition to 95.31% (47.66 out of 50) in the ninth edition. This reflects a marginal score increase on indicator 32.

Area of Note

Late in 2020, the U.S. Congress passed the Consolidated Appropriations Act, 2021, an end-of-year spending package signed into law on December 27. These legislative changes touch on several major IP laws, including for trademarks and copyright. Specifically, the legislation creates a voluntary small claims process for copyright, enhances penalties for commercial scale streaming piracy, and strengthens the trademark system. The Chamber will monitor future developments as these are implemented.

Patents, Related Rights, and Limitations

2. Patentability requirements: As noted over the course of the Index, since the Supreme Court decisions in the *Bilski, Myriad, Mayo*, and *Alice* cases, there has been a high and sustained level of uncertainty as to what constitutes patentable subject matter in the United States. The USPTO has since 2014 issued and updated patent examination guidelines almost on an annual basis. Lower and circuit court decisions in patent infringement proceedings have not always been consistent. The net result is that rights-holders are left without a clear sense of how decisions on patent eligibility will be made or, when granted patents are subsequently challenged or reviewed either through the courts or through the *inter partes* proceedings within the USPTO, which patent claims will be upheld. Under the leadership of former USPTO Director Iancu, the USPTO has recognized this dilemma and over the past three years sought to re-formulate its position and the approach to be taken by its examiners. The office in January 2019 released new draft guidance covering section 101 patentability and section 112 claims relating to computer inventions, the "2019 Revised Patent Subject Matter Eligibility Guidance" and "Examining Computer-Implemented Functional Claim Limitations for Compliance with 35 U.S.C. 112." With respect to section 101 patentability, the new guidance provides more of a principle-based analysis of how patentability will be judged and describes the stepwise approach examiners should follow to understand and apply the Supreme Court's *Alice/Mayo* test. As the guidance rightly points out, the key challenge for USPTO examiners and courts has been to "consistently distinguish between patent-eligible subject matter and subject matter falling within a judicial exception." The new guidance recognizes this and seeks, to the extent that is possible without further statutory changes, to clear this up with a revised procedure and process for examiners to follow. In April 2020, the USPTO's Office of the Chief Economist published *Adjusting to Alice USPTO Patent Examination Outcomes after Alice Corp. v. CLS Bank International*. This report examines the effect of the 2019 guidance on rates of first office rejections for *Alice*-related technologies—that is, technologies and applications that the USPTO and the U.S. Patent Classifications have defined as containing "abstract ideas." The report finds that, overall, since the introduction of the guidance, there has been a measurable and statistically significant decrease in the number of first office rejections for *Alice*-related technologies. Specifically, the likelihood of receiving a first office rejection decreased by 25% in the 12 months following the introduction of the guidance. As the USPTO rightly notes, this is positive news. Uncertainty over what constitutes patentable subject matter has crept into all facets of the patent system, from initial application and examination to standards of review and invalidity proceedings, whether administratively through

the PTAB or through the judiciary. The Index will continue to monitor this in 2021, as well as the extent to which the guidance has a sustained impact throughout and within all parts of the U.S. patent system.

9. Patent opposition: In an effort to provide a more cost-effective, efficient alternative to judicial proceedings, the 2011 America Invents Act (AIA) introduced new post-grant opposition and patent nullity proceedings. As has been noted in previous editions of the Index, despite the intentions of these new AIA mechanisms, the result has been a sustained level of uncertainty and unpredictability for many patent owners. This has been especially the case with the *inter partes* review (IPR), which occurs before the specialized PTAB within the USPTO. As noted, the U.S. government (chiefly through the USPTO) has recognized the unintended effects of the PTAB system and publicly pledged to work with all stakeholders to address and remedy them. To begin with, the USPTO introduced several important changes in 2018 and 2019. In 2018, USPTO Director Iancu stated that the reform of IPR proceedings was one of the agency's "highest priorities," and that the agency was considering "how and when we institute proceedings, the standards we employ during the proceedings, and how we conduct the overall proceedings. The goal, with whatever action we take, is to increase predictability of appropriately-scoped claims." Following these remarks, important reforms were announced during the year, which included (1) changing the patent claim construction standard used, moving away from the broadest reasonable interpretation standard to the so-called *Phillips* standard, the latter of which is the claim construction standard used in the judiciary since the mid-2000s; (2) a new Trial Practice Guide; and (3) Standard Operating Procedure changes. Using the *Phillips* standard has aligned IPR proceedings with the same claim construction standards that are used in patent infringement proceedings at U.S. district courts. The revised Trial Practice Guide provides greater clarity on the grounds on which a review may be initiated. And, the changes to both SOP 1 and SOP 2 sought to streamline how judges are assigned, the composition of panels, and the way precedent setting opinions are set. Specifically, SOP 2 set up a Precedential Opinion Panel (POP), headed by the director. Since its introduction, the POP has been active in shaping how the IPRs operate, with several of the panel's decisions having been of high procedural importance addressing issues relating to the USPTO director's decisions to institute IPR proceedings (see, for example, *Valve Corp. v Electronic Scripting Products Inc.*) and procedural rules including the declaration of interested parties (*ProppantExpress Investments LLC v Oren Techs. LLC*). These efforts continued in 2020. Several new POP decisions were issued and the USPTO proposed important potential changes to the IPR process. In May, the agency published a "Notice of Proposed Rulemaking" in the *Federal Register*. The notice includes proposed procedural changes incorporating the Supreme Court ruling in *SAS Institute Inc. v Iancu* on how patent validity challenges should be accepted and whether proceedings should be initiated on a select number of claims or all claims. The changes also included a question on whether the presumption in favor of a petitioner should be maintained or eliminated in pre-trial proceedings. Further changes were proposed in October, when the agency published a "Request for Comments on Discretion to Institute Trials before the Patent Trial and Appeal Board" in the *Federal Register*. The proposed changes focus on how the PTAB should deal with serial and parallel petitions. These are instances when the same patent and patent claims are petitioned to be challenged before the board in different petitions. In addition to the USPTO's actions, the Supreme Court was also active in 2020. In April, the court held in *Thryv Inc. v Click-to-Call Technologies LP, et al*. that the timeline for submitting an IPR petition is not subject to judicial review and rests solely with

the PTAB. The decision reverses an earlier judgment by the U.S. Court of Appeals for the Federal Circuit, which held that the decision to hold an IPR proceeding in the case was an error. In October, the Supreme Court also accepted petitions to hear specific aspects relating to the case *Arthrex Inc. v Smith & Nephew Inc.* and whether PTAB judges have been unconstitutionally appointed. While the key issue at hand concerns administrative law and the technical categorization of judges serving on the PTAB, legal analysis suggests that the ramifications of the court's judgment could be significant. A substantial number of PTAB cases were vacated by the Federal Circuit's earlier decision and have been held in abeyance. Overall, the high level of administrative and judicial activity illustrates how U.S. rights-holders continue to face great uncertainty over how patent disputes will be adjudicated and how decisions will be made and upheld within different fora. The Index will continue to monitor these developments in 2021.

Copyrights, Related Rights, and Limitations

13. Availability of frameworks that promote cooperative action against online piracy: Section 512 of the Digital Millennium Copyright Act (DMCA) provides a notification mechanism whereby rights-holders can work together with hosts, service providers, and internet mediators (including ISPs) to address issues of online infringement. Although over 20 years old, the rationale behind the law remains sound: a desire to balance the need to effectively address potential copyright infringement without unduly overburdening service providers. However, the world today is very different than in 1998 and, as a practical matter, it is questionable whether the law remains effective. At the time the legislation was passed, the global market for copyrighted products was fundamentally different than today. In 1998, music sales in the United States totaled almost USD14 billion. Of this, sales of physical compact discs accounted for 83.3% of the total. In 2018, total music sales in the United States was less than USD10 billion and compact discs accounted for 7.1% of total sales. Digital downloads and streaming services (ad supported and paid) constituted close to 70% of total sales volume. More broadly, internet penetration in the United States and the use of mobile devices was still at an early stage in the late 1990s and not ubiquitous as it is now. Today, more than eight out of 10 Americans own a smartphone and internet penetration is near universal, with 90% of Americans having access to the internet. The growth of online copyright infringement since 1998—whether through downloading, streaming, or some other technology—has mirrored this growth in internet connectivity. The adverse economic impact on the content industry has been staggering. A report by NERA Consulting (commissioned by the U.S. Chamber of Commerce's GIPC) found that global online piracy costs the American economy nearly USD30 billion in lost sales each year. Since 2015, the United States Copyright Office has been carrying out a public study of section 512. The office has held several public roundtables and accepted empirical submissions from the public. Some of the papers submitted show the challenging reality creators and copyright holders face. For example, in 2016, the American Association of Independent Music, the Future of Music Coalition, and the Copyright Alliance all submitted survey evidence to the office suggesting that (1) there was a high level of infringement taking place; (2) DMCA notices sent out were not being effectively acted on; and (3) there was a high level of reoccurrence—i.e., infringing content taken down would be re-posted or re-appear on the notified service providers website. Unlike other jurisdictions—including the European Union, Singapore, and emerging markets like Russia and India—rights-holders in the United States face great difficulty in obtaining an injunction disabling access to infringing content. Instead, rights-holders must pursue infringement claims through traditional litigation and court

proceedings. These can often be lengthy and expensive. And while the past few years have seen several important cases judged or settled in favor of rights-holders—see, for example, the cases involving BMG and Cox Communications or UMG Recordings et al. and Grande Communications—this underscores the wider point that effective redress is no longer available through the section 512 notification-and-takedown system. Indeed, in 2020, the Copyright Office recognized that this situation is no longer tenable, and reform is needed. In May, the office published the results of its multi-year public study. Overall, the report rightly concludes that "Congress' original intended balance has been tilted askew." The office makes several important observations and recommendations on how the current system could be improved. The report also notes the growing use of injunctive-style relief mechanisms around the world and so-called dynamic injunctions but recommends further study of these and other "alternative stakeholder proposals." In parallel to the Copyright Office's work, the U.S. Congress and Senate have both been working on reform proposals to the DMCA throughout the year. The Index will continue to monitor these developments in 2021.

Design Rights, Related Rights, and Limitations; and Enforcement

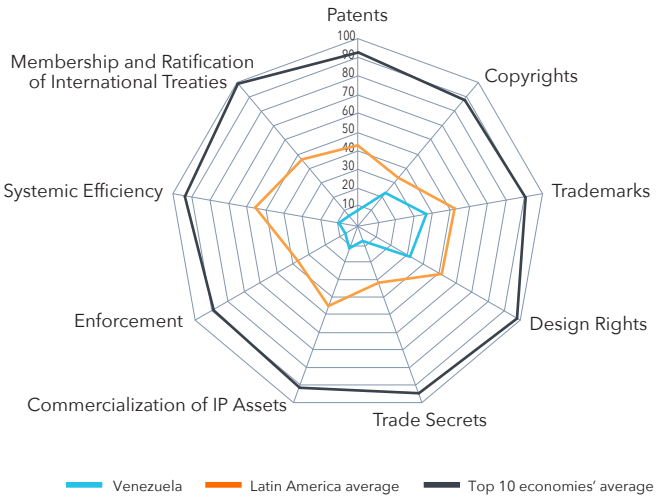
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights; 37. Effective border measures: Design rights and IP rights pertaining to industrial design are becoming increasingly important to rights-holders across the world. Statistics from WIPO on total design applications (direct and via the Hague System) from the mid-1990s until today show the number of applications globally growing from less than 200,000 in 1995 to over 1 million in 2018. In the United States, the number of design patent applications has shown similar growth, increasing from just over 15,000 applications in 1995 to over 45,000 in 2018. The increasing importance of design right protection is also reflected in the sharp increase in goods infringing design rights. As the global economy becomes more connected and interlinked, the spread and availability of counterfeit goods is also increasing. In 2016, the OECD estimated that the international trade in counterfeit and pirated goods represented almost half a trillion USD, the equivalent of 2.5% of global trade. In the latest available update to this estimate released in the 2019, *Trends in Trade in Counterfeit and Pirated Goods*, the OECD and EUIPO now find that the value of the international trade in counterfeit and pirated goods could amount to 3.3% of global trade. Customs and enforcement data from around the world reveals that a large portion of counterfeit goods are designed goods. This includes different types of clothing and apparel, watches, sunglasses, handbags, and similar accessories. Most customs authorities have experience dealing with traditional trademark and copyright enforcement, and in many economies offer rights-holders the ability to record their rights with national customs authorities. However, with respect to design rights, this option is not always available. The EU is one of the few jurisdictions where it is possible to file a request for customs action (both in individual Member States and in all Member States) specifying both registered and unregistered design rights as the right to be protected. This is currently not possible in the United States. As has been noted by a growing number of rights-holders, counterfeiters are increasingly becoming more sophisticated, often bypassing trademark infringement when importing infringing products into the United States. To address this gap in current legislation, a group of U.S. senators introduced the Counterfeit Goods Seizure Act of 2019' in December of that year. The proposed bill would give U.S. Customs and Border Protection the authority to act against goods that are suspected to infringe registered design patents just as they are authorized to do with respect to suspected

trademark- and copyright-infringing goods. U.S. Customs and Border Protection has long provided a global leadership role when it comes to the enforcement of IP rights and the fight against counterfeiting. Adding this capacity to the existing border enforcement framework would be a positive step and give border agents an additional tool in the fight against counterfeiting. At the time of research, no legislative action had been taken on the bill, and it was unclear how the proposed legislation would fare in a new Congress. The Index will continue to monitor these developments in 2021.

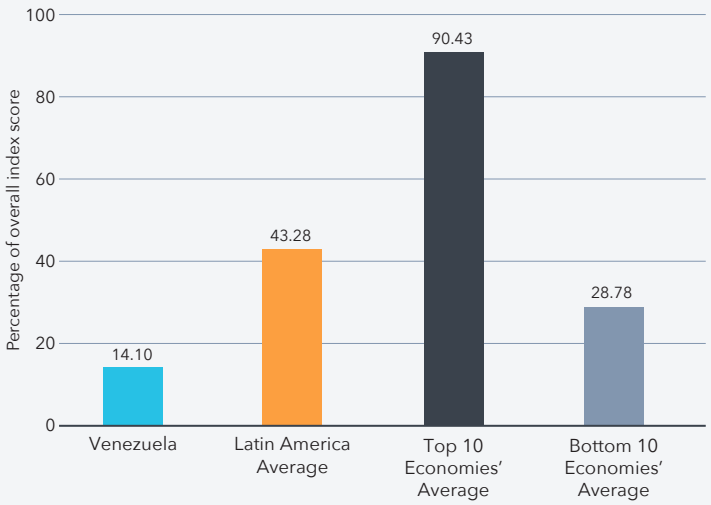
VENEZUELA

RANK
53/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Basic copyright, trademark, and industrial design frameworks in place
- ✓ Awareness-raising and capacity-building efforts on importance and use of IP rights

KEY AREAS OF WEAKNESS

- × Very weak patent framework, with sector-specific patents and other IP rights not available
- × Major holes in copyright protection, notably in the digital sphere
- × Trademark legislation does not directly address unregistered marks, with limited recognition of well-known marks
- × Enforcement generally poor—penalties insufficient and administrative inaction
- × Government interference and regulatory barriers to commercialization of IP assets

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**0.75**
1. Term of protection	0.50
2. Patentability requirements	0.00
3. Patentability of CIIs	0.25
4. Plant variety protection	0.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.63**
10. Term of protection	0.63
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. Digital rights management	0.00
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**1.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.00
Category 4: Design Rights, Related Rights, and Limitations	**0.65**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.25**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.00
25. Regulatory data protection term	0.00

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**0.75**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.00
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**0.52**
32. Physical counterfeiting rates	0.16
33. Software piracy rates	0.11
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.00
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**0.50**
39. Coordination of IP rights enforcement	0.00
40. Consultation with stakeholders during IP policy formation	0.00
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.00
Category 9: Membership and Ratification of International Treaties	**0.50**
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

TOTAL: 7.05

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Venezuela's overall score has decreased slightly from 14.22% (7.11 out of 50) in the eighth edition to 14.10% (7.05 out of 50) in the ninth edition. This reflects a marginal score decrease on indicator 32.

Area of Note

As has been noted in previous editions, rights-holders in Venezuela face a highly uncertain and challenging business environment. This has not improved in 2020 and, in light of the COVID-19 pandemic, conditions have actually deteriorated. Politically, the environment remains fraught, with portions of the Venezuelan government ceasing to function amid a constitutional stand-off between the government and the opposition. In 2018, the Venezuelan IP Office suspended its services and ceased operations for months. While the agency has since resumed operations, the COVID-19 pandemic resulted in a suspension of services and several notable changes to Venezuela's legal environment. Of particular note is the adoption, in October 2020, of a new national economic plan through an "anti-blockade" law. While aiming to open up Venezuela to foreign investment, the law effectively increases the government's control over all facets of the economy. The law also contains a broad confidentiality clause whereby any actions in relation to the economy taken by the government are to potentially remain confidential and outside public scrutiny.

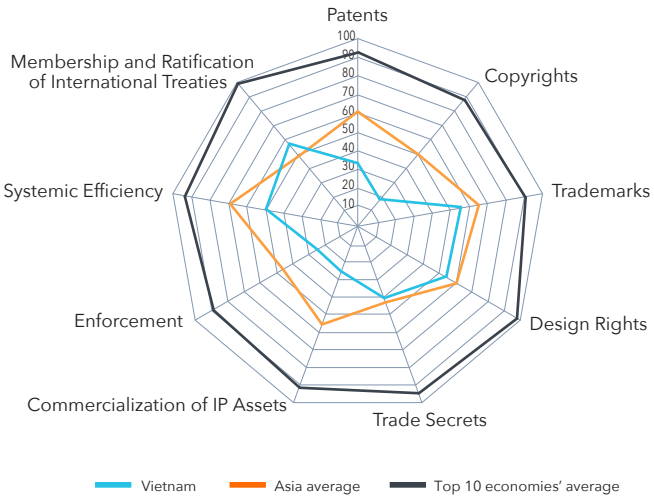
Trademarks, Related Rights, and Limitations

19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks: Beginning in February 2020, Venezuela's Autonomous Service of Intellectual Property (SAPI), switched to using only the Nice classification system of goods and services for trademark registration. This replaces the dual classification system (national and Nice) that had been in place up until 2020. This measure—introduced by SAPI's Official Notice DG-001-2020—is meant to harmonize trademark applications in Venezuela with international applications and accelerate their approval.

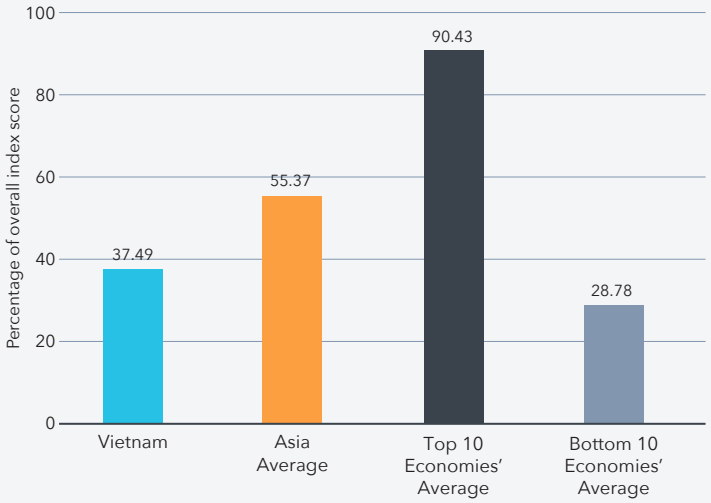
VIETNAM

RANK
41/53

Category Scores



Overall Score in Comparison



STRENGTHS & WEAKNESSES

KEY AREAS OF STRENGTH

- ✓ Ratified EU-Vietnam FTA in 2020
- ✓ Basic IP protections and enforcement framework in place
- ✓ Growing integration into international IP platforms—for example, through EU-Vietnam FTA
- ✓ Long-standing effort to coordinate IP enforcement

KEY AREAS OF WEAKNESS

- × Inadequate protection of life science patents, with challenging enforcement environment
- × Gaps in copyright protection, including lack of measures to address online infringements
- × High physical counterfeiting rates and online infringement—BSA estimates a software piracy rate of 74%
- × Proposed market access and other requirements create uncertainty for digital content platforms, including through proposed revisions to Decree 06/2016
- × Enforcement generally poor—penalties insufficient in practice, and the system suffers from administrative inaction

INDICATOR SCORES

INDICATOR	SCORE
Category 1: Patents, Related Rights and Limitations	**3.00**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**1.28**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.00
15. Digital rights management	0.25
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

INDICATOR	SCORE
Category 6: Commercialization of IP Assets	**1.58**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.33
Category 7: Enforcement	**1.78**
32. Physical counterfeiting rates	0.27
33. Software piracy rates	0.26
34. Civil and procedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**4.00**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

TOTAL: 18.74

SPOTLIGHT ON THE NATIONAL IP ENVIRONMENT

Past Editions versus Current Scores

Vietnam's overall score has increased from 36.62% (18.31 out of 50) in the eighth edition to 37.49% (18.74 out of 50) in the ninth edition. This reflects a score increase on Indicator 50.

Area of Note

In late 2020, the Ministry of Science and Technology published a set of draft amendments to the 2005 Law on Intellectual Property (IP Law). At the time of research, the ministry and relevant Vietnamese authorities were holding a series of meetings and consultations with key stakeholders on the draft legislation. The amendments seek to align Vietnam's IP Law with both the EU FTA and CPTPP and fulfill its treaty obligations under both. It is a positive step that the Vietnamese government is so actively engaging with stakeholders in the reform efforts. As has been noted over the course of the Index, Vietnam's IP Law needs reform and modernization. Adopting the IP provisions of the EU FTA and the CPTPP would help strengthen Vietnam's national IP environment. The draft IP Law does contain some positive features. For example, draft provisions relating to copyright would potentially strengthen the protection of copyright online as well as improve the TPM and DRM environment. However, in other aspects, the draft articles are more problematic. For example, with respect to patent rights, Articles 112 and 112a, including the various "options" listed under the articles, would, first, institutionalize a pre-grant opposition system and, second, introduce a long list of potential grounds for patent opposition and invalidation including everything from substantive objections to procedural errors. Similarly, provisions relating to biopharmaceutical IP rights are confusing. As noted below under indicator 7, with respect to patent term restoration, the main thrust of the legislative interpretation of Article 12.40 under the EU FTA (including the draft IP Law) is to provide compensation to a rights-holder in the form of a reduction in annual patent renewal fees for any relevant period of delay. Draft Article 131a, option 2, appears to provide a potential period of term restoration of up to two years. However, sub-section 2 of the draft article appears to also condition this term restoration on a minimum of two-year delay in the relevant Vietnamese drug regulatory authority's **first** response to a market authorization application. Conditioning the availability of restoration on such conditions would in effect mean that, for all practical intents and purposes, term restoration would not be made available to rights-holders in any meaningful way. The Index will continue to monitor these developments in 2021.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: Historically, Vietnamese IP law has not offered biopharmaceutical rights-holders any term restoration for patent exclusivity lost during the market approval process. This changed with the conclusion of negotiations and signing of the Free Trade Agreement between the EU and Vietnam in 2015. Article 12.40(2) of the Agreement states clearly that the contracting parties "shall provide for an adequate and effective mechanism to compensate the patent owner for the reduction in the effective patent life resulting from unreasonable delays" during regulatory review and market authorization proceedings. Sub-sections (2) and (3) of the article outline how this compensatory mechanism can extend the term of granted patent rights for a period of between two to five years. In June 2020, the Vietnamese National Assembly formally ratified the treaty through Resolution 102/2020/QH14 and the Agreement is now in effect. Annex 3 of Resolution 102 outlines the features of Vietnam's term restoration program. Unfortunately, it is not clear from this annex what type, if any, restoration will be offered or the exact terms upon which such

an extension will be granted. Specifically, instead of a period of patent term restoration, the annex appears to provide rights-holders with a reduction in annual patent renewal fees for any relevant period of delay. While positive, this does not correspond to a mechanism of term restoration. It is also not clear what constitutes "undue delay." The research-based biopharmaceutical industry is one of the world's leading sources of R&D investment. Unfortunately, the draft IP Law published at the end of 2020 (detailed above under the "Area of Note" sub-section) does not provide an effective mechanism of term restoration. The Index will continue to monitor these developments in 2021.

Membership and Ratification of International Treaties

50. Post-TRIPS FTA: In June 2020, the Vietnamese National Assembly formally ratified the Free Trade Agreement between the EU and Vietnam through Resolution 102/2020/QH14 and the Agreement is now in effect. As has been detailed over the course of the Index, this agreement has the potential to strengthen Vietnam's national IP environment. Annex 3 of Resolution 102 did include some reforms. In addition to the introduction of the concept of patent term restoration for biopharmaceuticals (as detailed above under indicator 7), the resolution also introduced changes to existing trademark statute and examination practices relating to industrial design. Annex 3 of the resolution improves the ability of rights-holders to cancel bad faith registrations by removing this time limit for filing invalidation proceedings. Vietnam has been plagued by bad faith filings for years, with rights-holders unable to effectively address this issue. Local legal analysis suggests that this measure should have an immediate impact and strengthen rights-holders' ability to protect and enforce their registered marks. As noted above, at the time of research, the Ministry of Science and Technology and relevant Vietnamese authorities were holding a series of meetings and consultations with key stakeholders on a set of draft amendments to the IP Law. As a result of the ratification of the EU-Vietnam FTA, the score on this indicator has increased by 0.5.

APPENDIX: METHODOLOGY, SOURCES, AND INDICATORS EXPLAINED

The Index consists of 50 indicators across nine separate categories:

1. Patents, Related Rights, and Limitations
2. Copyrights, Related Rights, and Limitations
3. Trademarks, Related Rights, and Limitations
4. Design Rights, Related Rights, and Limitations
5. Trade Secrets and the Protection of Confidential Information
6. Commercialization of IP Assets and Market Access
7. Enforcement
8. Systemic Efficiency
9. Membership and Ratification of International Treaties

As in previous editions, these categories are for ease of organizing the Index and have no statistical impact on weightings or on an economy's overall score in the Index. Each indicator is explained in more detail below.

SCORING METHODOLOGY

As in previous editions of the Index, each indicator can score values between 0 and 1, and the cumulative score of the Index ranges from a minimum of 0 to a maximum of 50. Indicators can be scored using three distinct methods: binary, numerical, and mixed.

When an indicator is of a binary nature, each indicator is assigned either the value 0, if the particular IP component does not exist in a given economy, or 1, if the particular IP component does exist in a given economy.

Numerical indicators are those indicators that, for example, measure terms of exclusivity or are based on a quantitative source. Terms of exclusivity are calculated by dividing the actual term of exclusivity of each relevant indicator by a standard baseline. For example, the standard baseline used for the copyright term is that of 95 years provided in the United States to orphan works.[27] If an economy has a copyright term of 95 years, the value it scores in this indicator is 1. If it has a copyright term of less than 95 years, then the value is less than 1. Details of the individual baselines used for different types of IP rights are provided below.

Where there are no adequate baselines and the legislative or regulatory existence of an indicator is not sufficient to determine its actual use or application, the score for that indicator will be mixed. The final score for that indicator will be based on an even split between

- primary and/or secondary legislation (regulation) in place; and
- the actual application and enforcement of that primary and/or secondary legislation.

Mixed indicators are the majority of indicators used in the Index. The use of mixed indicators provides flexibility when scoring and allows the Index to more effectively accommodate gray areas in economy performance for a given indicator. Specifically, it is possible to assign a partial score, rather than only a 0 or 1. There are five possible scores available within a mixed indicator: 0, 0.25, 0.5, 0.75, and 1. The range of scores available for mixed indicators means that greater nuance can be used when individual indicators are scored; the practical end result is that economies can receive partial scores for an indicator, which in some cases are a better approximation of their given reality.

Finally, there are also a few instances in which rather than the *de jure* and *de facto* existence of a single element, a mixed indicator is split between two separate elements. For example, in Category 9: Membership and Ratification of International Treaties, the indicators are

measured by the signature and ratification or accession to a given international treaty. Thus, 0.5 is given for being a signatory of a treaty and 0.5 for ratifying or acceding to that treaty. This is also the case for indicator 7. This indicator consists of two distinct variables: (1) the existence of a term of patent restoration for pharmaceutical products due to the prolonged research, development, and regulatory approval periods for such products; and (2) the existence of any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. Of the available score for this indicator, 0.75 is allocated to the existing term of protection compared with the current baseline rate of five years term restoration used in the United States, EU, and Japan. The remaining 0.25 is allocated on the basis of a given economy providing any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes.

BASELINES USED

When possible, the Index uses baseline values, measures, and models. These values are based on best practices regarding terms of protection, enforcement mechanisms (*de jure* and *de facto*), and/or model pieces of primary or secondary legislation that can be found at the national and international levels. Where no adequate baselines are found in international law or treaties, the baselines and values used are based on what rights-holders view as an appropriate environment and level of protection.

MEASURING COUNTERFEITING AND PIRACY

Indicators 32 and 33 of the Index measure rates of physical counterfeiting and software piracy, respectively. There are several challenges when attempting to measure piracy and counterfeiting.

First, illegal activities are inherently difficult to measure and quantify with a high level of accuracy. Estimates will out of necessity be based on variables such as physical seizures and surveys. This is particularly the case for online piracy.

Second, studies of rates of piracy and counterfeiting are often either specific to one or a handful of economies, or are global and do not provide data at an individual economy level. The result is a relative paucity in the number of studies that measure and compare levels of piracy and counterfeiting with a sample of economies sufficient to make large-scale comparisons empirically robust.

Finally, because measures of piracy and counterfeiting are inexact, estimates of their economic impact can vary widely depending on the methodology and data samples used.[28]

Up until the fourth edition, the Index had relied on two main sources for measuring piracy and counterfeiting:

- The OECD's General Trade-Related Index of Counterfeiting of Economies, which measures the relative rates of physical counterfeiting[29]

IP Rights Baselines

BASELINES	BASELINE IN YEARS	LEGISLATION MODEL
Basic patent protection	20	TRIPS
Copyrights	95	United States
Trademarks	10	WIPO
Regulatory data protection	10	EU
Patent term restoration	5	EU / United States / Japan
Design rights	25	EU

- Software piracy rates compiled by the Business Software Alliance (2018 being the latest published survey)

These sources are both robust and internationally recognized measures. Furthermore, they cover a large sample of economies, providing a sound basis for both cross- economy comparisons and long-term use within the Index. And both the BSA software piracy rates and the GTRIC-e Index are numerical measures and can be transposed into two respective scores.

Still, there are caveats with the use of these measures, in particular the GTRIC-e.

First, the GTRIC-e Index measures the relative rates of physical counterfeiting and is based on international trade statistics and customs interception data. Crucially, the GTRIC-e does not take into account or measure domestically produced products or pirated digital products. The practical result is that several economies with relatively low levels of customs interception of counterfeit goods, yet high levels of domestically produced counterfeit goods or high levels of online piracy, can rank quite well within the GTRIC-e. This may not present an accurate reflection of their overall piracy and counterfeiting environment.

To address this challenge, the fourth edition of the Index incorporated a new proprietary Global Measure of Physical Counterfeiting. The measure was developed by the U.S. Chamber of Commerce and Pugatch Consilium to provide a new global measure of physical trade-related counterfeiting. This measure of physical counterfeiting is also being used for this edition of the Index and provides the basis for the score on indicator 32.

The measure provides a total and per economy estimate for each of the 53 economies included in the Index of rates of physical trade-related counterfeiting. The full details of the building of the model, methodology, sources used, and an assessment of the wider threat of physical counterfeiting is provided in the report *Measuring the Magnitude of Global Physical Counterfeiting* available on the GIPC's and U.S. Chamber of Commerce's website.

In brief, the methodology of the Global Measure of Physical Counterfeiting builds on that developed by the OECD and the GTRIC-e. To obtain a unique estimate for each of the 53 economies included, the Global Measure of Physical Counterfeiting uses a proprietary metric that applies three weighted factors in order to provide a holistic take on the propensity for counterfeiting in the selected economies.

The first factor is a sub-set of the scores for the indicators within Category 7: Enforcement. These include

- the existence of civil and procedural remedies, including injunctions, damages for injuries, and destruction of infringing and counterfeit goods, as well as their effective application;
- the existence of pre-established damages and/or mechanisms for determining the amount of damages generated by infringement;
- criminal standards, including minimum imprisonment and minimum fines, in place and their application;
- effective border measures (measured by the extent to which goods in transit suspected of infringement may be detained or suspended, as well as the existence of *ex officio* authority); and
- transparency and public reporting by customs authorities of trade-related IP infringement.

To capture the level of counterfeiting taking place within a given economy, the weight of this factor is 50% of the score for indicator 32.

The second factor incorporates the most recent updates to the OECD's GTRIC-e benchmark discussed in detail above.

The third factor used is the rate of perceived corruption within an economy, as measured by Transparency Inter-

national's Corruption Perceptions Index. This is based on the assumption that a strong relationship exists between corruption and counterfeiting—i.e., authorities in economies that struggle with corruption tend to also overlook or place less emphasis on combating criminal activities, including counterfeiting.

Together these two factors constitute the remaining 50% of the score for indicator 32.

The BSA survey expresses an economy's software piracy rate as a percentage. Within the Index, the reverse of the BSA software piracy percentage is used as the score for indicator 33; the higher the BSA software piracy rate is in an economy, the lower its score on the Index. For example, if economy X has an estimated software piracy rate of 90% according to the BSA, it receives a score of 0.10 for indicator 33 within the Index.

SOURCES

Scoring in the Index is based on both qualitative and quantitative evidence. In order to provide as complete a picture of an economy's IP environment as possible, this evidence is drawn from a wide range of sources. All sources used are publicly and freely available and are accessible to all. The following is an outline of the different types of sources used.

Government

Sources from government branches and agencies include

- primary legislation;
- secondary legislation (regulation) from executive, legislative, and administrative bodies;
- reports from parliamentary committees and government agencies, including patent or intellectual property offices as well as enforcement agencies; and
- internal departmental guidelines, policies, assessments, and audits.

Legal

Sources from judicial authorities and legal practitioners include

- court cases and decisions,
- legal opinions written by judges, and
- legal analysis and opinions written by legal practitioners.

International Institutions and Third Parties

These sources include

- data, studies, and analysis from international organizations such as the OECD, WTO, WIPO, and others;
- publicly available reports, studies, and government submissions by industry organizations; and
- reports from non-governmental and consumer organizations.

Academic

Academic sources include

- academic journals, books, and published manuscripts; and
- legal journals.

News

News sources include

- newspapers,
- news websites, and
- trade press.

In addition to the above listed resources, over the course of the past few years, more and more governments and economies have started making submissions directly to the GIPC and U.S. Chamber of Commerce. These submissions include everything from updates on legislative and regulatory initiatives to details of various government policies such as anti-piracy initiatives as well as data and statistics on anti-counterfeiting and activities to fight online piracy.

We welcome these submissions and endeavor to use them together with all other available information to provide the most accurate depiction possible of the national IP environment in each of the economies sampled.

We wish to thank the governments and economies that have made these submissions and welcome all economies covered in the Index to consider doing so. The only criterium we use—just as for all the resources used in the Index—is that these sources and materials submitted to us need to be publicly available and in the public domain.

INDICATORS EXPLAINED

This section explains how each indicator in the Index is measured and scored.

Category 1: Patents, Related Rights, and Limitations

The indicators included in this category relate to patent protection and related rights and limitations.

1. Term of protection: Measured by the basic patent term offered in the TRIPS Agreement. This is a numerical indicator.

2. Patentability requirements: Measured by the extent to which patentability requirements are in line with international standards of novelty, inventive step, and industrial applicability.[30] Measured by (1) existing *de jure* patentability guidelines and regulations and (2) *de facto* standards established through the application of these guidelines and regulations through the examination process and judicial review. This is a mixed indicator.

3. Patentability of computer-implemented inventions (CIIs): Measured by the extent to which primary and/or secondary legislation explicitly allows for the patentability of CIIs. This is a mixed indicator.

4. Plant variety protection, term of protection: Measured by the maximum term of protection offered with the baseline term of protection being not less than 20 years (25 years for trees and vines) in accordance with the International Convention for the Protection of New Varieties of Plants.[31] This is a numerical indicator.

5. Pharmaceutical-related patent enforcement and resolution mechanism: Measured by the existence of primary and/or secondary legislation (such as a regulatory and/or administrative mechanism) that provides a transparent pathway for adjudication of patent validity and infringing issues prior to the marketing of a generic or biosimilar product. This score is evenly divided between the existence of a relevant mechanism and its application/enforcement. If no mechanism is in place, the maximum score that can be achieved is 0.5. Such a score is based on the extent to which *de facto* practices (such as expeditious preliminary injunctive relief) are in place that achieve a similar result. This is a mixed indicator.

6. Legislative criteria and use of compulsory licensing of patented products and technologies: Measured by the extent to which primary and/or secondary legislation on the use of compulsory licensing (on the basis of the essential facilities doctrine) and its application/enforcement is transparent and consistent with the following criteria: (1) the issuing should exclude any requirement for domestic manufacturing; (2) should not apply to patented innovations that have not yet reached the market; (3) in the case of biopharmaceutical products, the use of compulsory licensing under the framework of TRIPS provisions on public health should not be for commercial purposes, such as for price negotiations or in support of domestic industries; and (4) adequate and well-defined recourse mechanisms should be in place for parties affected by the issuing of the license. This is a binary indicator.

7. Patent term restoration for pharmaceutical products: Measured using two distinct variables: (1) the existence of a term of patent restoration for pharma-

ceutical products due to the prolonged research, development, and regulatory approval periods for such products; and (2) the existence of any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. Of the available score for this indicator, 0.75 is allocated to the existing term of protection compared with the current baseline rate of five years term restoration used in the United States, EU, and Japan. The remaining 0.25 is allocated on the basis of a given economy providing any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. This indicator does not include other forms of patent term restoration that are granted on the basis of prolonged examination periods, including for the granting of patents. This is a mixed indicator.

8. Membership of a Patent Prosecution Highway (PPH): Measured by whether an economy's relevant IP or patent office has joined international efforts toward streamlining and improving patent prosecution by membership of a PPH. Given the three main tracks of international PPH (PPH, Global Patent Prosecution Highway, and IP5 Patent Prosecution Highway), economies will be scored differently depending on their level of participation and membership of the different tracks. Economies that are members of either (or both) the Global Patent Prosecution Highway or IP5 Patent Prosecution Highway will receive a full score of 1. Economies that are members of a PPH and have bilateral and multilateral agreements to this effect will receive a score of 0.5.

9. Patent opposition: Measured by the availability of mechanisms for opposing patents in a manner that does not unduly delay the granting of a patent (in contrast to a right of opposition before the patent is granted) and ensures fair, transparent, and expeditious opposition proceedings. This is a mixed indicator.

Category 2: Copyrights, Related Rights, and Limitations

The indicators included in this category relate to copyright protection and related rights and limitations.

10. Copyright (and related rights) term of protection: Measured by the baseline term of protection for anonymous works, which is the term afforded in the United States of 95 years. Terms of protection are measured as the minimum term allowed by copyright law. Where there are different minimum terms of protection for different forms of copyright, all major terms are added together and divided by 95. This is a numerical indicator.

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking): Measured by the extent to which economies (1) have in place laws and procedures that provide necessary exclusive rights and (2) apply these laws to prevent, deter, and remedy online infringement of copyright and related rights. This is a mixed indicator.

12. Expeditious injunctive-style relief and disabling of infringing content online: This Measured by the existence and extent of an official national government administrative or judicial injunctive relief mechanism available to rights-holders. The mechanism should provide for the effective and timely disabling of access to websites that seem to exist solely to offer or make available infringing content online. Such a mechanism should be based on a clear, transparent, expeditious, and standardized procedure and include due process protections. This is a mixed indicator.

13. Availability of frameworks that promote cooperative action against online piracy: Measured by the existence of clear standards for the limitation of liability for copyright and related rights infringement by ISPs that expeditiously remove infringing material upon obtaining knowledge of it, in the context of an overall system that does not unduly burden ISPs, pro-

motes cooperation between them and rights-holders to address online piracy, and respects and protects users' rights. This is a mixed indicator.

14. Scope of limitations and exceptions to copyrights and related rights: Measured by the extent to which exceptions and limitations are consistent in text and in application with the three-step test originating in the Berne Convention (Berne three-step test).[32] The score for this indicator is evenly divided between legislation and application in the court system. This is a mixed indicator.

15. Digital rights management legislation: Measured by the extent to which (1) economies have passed primary and/or secondary legislation relating to DRM and technological protection measures and (2) this legislation is applied. This is a mixed indicator.

16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software: Measured by the extent to which (1) policies and guidelines are in place stipulating the use of only licensed proprietary software and (2) these policies and guidelines are applied. This is a mixed indicator.

Category 3: Trademarks, Related Rights, and Limitations

The indicators in this category relate to trademark protection, design rights, and related rights and limitations.

17. Trademarks term of protection (renewal periods): Measured by the renewal term of protection being offered, with the baseline term being 10 years as provided by the Singapore Treaty on the Law of Trademarks. This is a numerical indicator.

18. Protection of well-known marks: Measured by the extent to which existing laws and regulations and/or *de facto* practices allow for trademark protection through use of the mark, regardless of whether the trademark owner registers the mark. This is a mixed indicator.

19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks: Measured by the extent to which economies (1) have in place laws and procedures that provide necessary causes of action to address violations of a trademark owner's rights (such as infringement of registered trademarks, unfair competition, false designation of origin, false advertising, dilution of famous trademarks, cybersquatting, and violation of rights associated with a corresponding trade dress) that create a likelihood of public confusion as to source, sponsorship, or affiliation; and (2) apply these laws to prevent, deter, and remedy infringement of trademarks and related rights. This is a mixed indicator.

20. Availability of frameworks that promote action against online sale of counterfeit goods: Measured by the existence of clear rules and standards for the expeditious removal of trademark-infringing material by online service providers upon obtaining knowledge of the infringement, in the context of an overall system that does not unduly burden such providers, promotes cooperation between them and rights-holders to address the infringement of trademark rights, and respects and protects consumers' rights. This score is evenly divided between the existence of relevant primary and/or secondary legislation and its application/enforcement. In the absence of a legal or regulatory framework, a score of up to 0.5 can be allocated based on the existence and effectiveness of voluntary industry standards and practices in place. This is a mixed indicator.[33]

Category 4: Design Rights, Related Rights, and Limitations

The indicators in this category relate to design rights and related rights and limitations.

21. Industrial design term of protection: Measured by the maximum term of protection being offered (including renewable periods), with the baseline term being 25 years, which is the maximum term afforded in the European Union. This is a numerical indicator.

22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights: Measured by the extent to which economies (1) have in place laws and procedures that provide necessary exclusive rights (including making, marketing, trading, and use of an industrial design); and (2) apply these laws to prevent, deter, and remedy infringement of industrial design rights. This is a mixed indicator.

Category 5: Trade Secrets and the Protection of Confidential Information

The indicators in this category relate to trade secrets, related rights and limitations, and the protection of confidential information.

23. Protection of trade secrets (civil remedies): Measured by the existence of (1) legislation that offers protection for trade secrets or confidential business information and (2) the application of this legislation in the court or law enforcement system. This is a mixed indicator.

24. Protection of trade secrets (criminal sanctions): Measured by the existence of (1) legislation that provides criminal sanctions for the misappropriation, improper acquisition, use, or disclosure of trade secrets or confidential business information; and (2) the application of this legislation and effective access to these remedies. This is a mixed indicator.

25. Regulatory data protection (RDP) term: Measured by the optimal desired term, which is the term of exclusivity used by the EU for new biopharmaceutical products containing new active ingredients regardless of molecular size and/or complexity.[34] This is a numerical indicator.

Category 6: Commercialization of IP Assets and Market Access

The indicators in this category seek to measure the extent to which a given national IP environment recognizes the value of IP as an asset and encourages the commercialization of IP regardless of its national origins.

26. Barriers to market access: Measured by the extent to which laws and regulations or *de facto* practices make access to an economy's market contingent on the sharing and/or disclosure of intellectual property and know-how with a local/domestic entity. This is measured by (1) the extent to which existing laws and procedures make market access contingent on the sharing/disclosure of intellectual property and know-how; and (2) the application of such laws or, in the absence of such laws, the existence of *de facto* practices and standards that achieve a similar effect. This is a mixed indicator.

27. Barriers to technology transfer: Measured by the extent to which laws and regulations or *de facto* practices act as barriers to technology transfer and commercialization activities of publicly funded and supported research. This is a mixed indicator.

28. Registration and disclosure requirements of licensing deals: Measured by the extent to which licensing agreements must be registered and/or disclosed with relevant authorities to carry legal effect. This is a mixed indicator.

29. Direct government intervention in setting licensing terms: Measured by the extent to which relevant government authorities directly intervene and set licensing terms between licensee and licensor.[35] This can be done through, for example, governmental preapproval for any licensing agreement between two parties as well as government intervention in the setting of licensing terms, including royalty rates. This is a mixed indicator.

30. IP as an economic asset: Measured by the extent to which relevant institutions (including, for example, public and private institutions for higher education as well as national IP offices) in a given economy are actively engaged in capacity building and training on how to use IP as a commercial and economic asset. Examples of capacity building include academic (university/ter-

tiary level) courses on the commercialization and use of IP as an economic and financial asset as well as the extent to which national IP offices host and/or engage in similar training programs. This is a mixed indicator.

31. Tax incentives for the creation of IP assets: Measured by the extent to which governments provide tax incentives for the creation and use of IP assets. This indicator consists of three layers corresponding to an equal share of the available score:

- **Layer 1:** Consists of economies offering general tax incentives for the creation of IP assets through, for example, general R&D incentives and/or tax credits
- **Layer 2:** Based on whether incentives are targeted specifically at the creation of IP through, for example, innovation and patent boxes
- **Layer 3:** The extent to which the above described incentives are not hampered by onerous localization and/or administrative requirements linked to the availability and use of the tax incentive or mechanism

Category 7: Enforcement

The indicators in this category measure the prevalence of IP rights infringement, the criminal and civil legal procedures available to rights-holders, the authority of customs officials to carry out border controls and inspections, and transparency of customs authorities' actions.

32. Counterfeiting piracy rates: Measured by estimated rates of general trade-related physical counterfeiting using the U.S. Chamber's Global Measure of Physical Counterfeiting. This is a numerical indicator.

33. Software piracy rates: Measured by rates of software piracy. This is a numerical indicator.

34. Civil and procedural remedies: Measured by (1) the existence of civil and procedural remedies, including injunctions, damages for injuries, and destruction of infringing and counterfeit goods; and (2) their effective application. This indicator also reflects administrative enforcement measures where applicable. This is a mixed indicator.

35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement: This is a mixed indicator.

36. Criminal standards including minimum imprisonment and minimum fines: Measured by the extent to which (1) actual legislation is in place and (2) it is applied (i.e., where reliable source material is available, the actual level of prosecution and penalties applied). This is a mixed indicator.

37. Effective border measures: Measured by the extent to which border guards have the *ex officio* authority to seize suspected counterfeit and pirated goods, including goods in transit, without complaint from the rights-holder. This is a mixed indicator.

38. Transparency and public reporting by customs authorities of trade-related IP infringement: Measured by the extent to which customs authorities in a given economy publish statistics and data on trade-related IP infringement. This indicator measures (1) the extent to which data is published on a regular and systematic basis, and (2) the level of detail of this data. This is a mixed indicator.

Category 8: Systemic Efficiency

The indicators in this category seek to measure the manner in which a national IP system actually works.

39. Coordination of IP rights enforcement efforts: Measured by the existence of coordinated efforts at IP rights enforcement at the national government level. This indicator measures the extent to which a national government institution or formalized structure is in place providing cross-governmental coordination to national IP enforcement efforts. This is a mixed indicator.

40. Consultation with stakeholders during IP policy formation: Measured by the extent to which stakeholders (public, private, national, and international) have the right and opportunity to contribute comments and submissions on proposed changes to IP laws and regulations made by a given economy's national government. This is a mixed indicator.

41. Educational campaigns and awareness raising: Measured by (1) the extent to which national governments engage in educational campaigns and awareness raising on the positive socio-economic impact of IP rights and the negative impact the infringement of these rights has on creators, innovators, and the national economy; and (2) the extent to which these campaigns and awareness-raising efforts (if in place) are systematic and sustained over time. This is a mixed indicator.

42. Targeted incentives for the creation and use of IP assets for SMEs: Measured by the extent to which a given economy's national IP system provides special incentives for SMEs for the creation, registration, and use of IP assets. Examples of such incentives include fast-track registration procedures, reduced filing fees, and technical assistance targeting SMEs. This is a mixed indicator.

43. IP-intensive industries and national economic impact analysis: Measured by the extent to which the relevant authorities in a given economy seek to map and measure the economic impact and importance of IP-intensive industries to their national economies. Economies are scored on the basis of the following: (1) that the mapping and measuring of the economic impact and importance of IP-intensive industries to national economic activity is taking place; and (2) the extent to which such mapping and measuring is systematic and occurs on a periodic and recurring basis. This is a mixed indicator.

Category 9: Membership and Ratification of International Treaties

Generally, the indicators in this category are mixed and measure whether an economy is (1) a signatory of and (2) has ratified or acceded to international treaties on the protection of IP. Some international treaties allow only for accession—i.e., membership is either conferred or not. The following treaties each make up one indicator, with some indicators consisting of two treaties.

44. WIPO Internet Treaties: These consist of the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. Respectively, they cover and clarify the use of copyright in a digital environment and the moral and economic rights of performers and producers of phonograms. This is a mixed indicator.

45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks: This is a mixed indicator with half of the score allocated for membership and ratification of each individual treaty.

46. Patent Law Treaty and Patent Cooperation Treaty: This is a mixed indicator with half of the score allocated for membership and ratification of each individual treaty.

47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991: This is a binary indicator.

48. Membership of the Convention on Cybercrime, 2001: This is a mixed indicator.

49. The Hague Agreement Concerning the International Registration of Industrial Designs: This is a mixed indicator.[36]

50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices: This is a mixed indicator.

NOTES

1. Note that the World Bank's geographic classifications have been somewhat amalgamated: Middle East and North Africa has been combined with Sub-Saharan Africa, and East Asia and Pacific has been combined with South Asia. See: World Bank (2020), "Country and Lending Groups."
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11. The Innovation Capability Pillar in the World Economic Forum's *Global Competitiveness Report 2019* measures a wide array of indicators influencing economies' ability to generate innovative outputs, including R&D spending, multi-stakeholder collaboration in research, dispersion of specialized clusters, inventive activity, and buyer sophistication. See World Economic Forum, *The Global Competitiveness Report 2019*.
12. Innovative output is measured by the *Global Innovation Index* Innovation Output sub-index score. The Innovative Output sub-index accounts for knowledge and technology outputs, knowledge impact including labor productivity and high-tech outputs, and the diffusion of knowledge including high-tech and ICT exports as well as licensing fees and FDI outflows.
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14. Mestre-Ferrandiz, D., et al. (2012), "The R&D Cost of a New Medicine," Office of Health Economics: London, 2012, p. v.
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18. MPugatch (2011), "The Strength of Pharmaceutical IPRs vis-à-vis Foreign Direct Investment in Clinical Research: Preliminary Findings," *Journal of Commercial Biotechnology*, Vol. 17, No. 4, 2011, p. 311.
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22. Early-phase clinical trial activity is measured as the gross number of phase I and phase II clinical trials to date per economy, as registered in the clinicaltrials.gov database, standardized per million population. Life sciences -related indicators, indicator: 1-2, 5-9, 17-20, 23-29, 32, 34-39, 45-46, 50.
23. Overall scores of Scientific American WorldView are based on performance in seven categories: Productivity, Intellectual Property Protection, Enterprise Support, Intensity, Education/ Workforce, Foundations, and Policy and Stability. Data is not available for Algeria, Brunei, Colombia, Costa Rica, Dominican Republic, Ecuador, Egypt, Jordan, Kenya, Morocco, Nigeria, Pakistan, Peru, Venezuela, and Vietnam. Source: Scientific American WorldView (2016).
24. U.S. FDA website, "Developing Products for Rare Diseases & Conditions."
25. Maher, P. D., and Haffner, M. (2006), "Orphan Drug Designation and Pharmacogenomics: Options and Opportunities," *BioDrugs*, Vol. 20, 2006, p. 71.
26. There have also been other agreements that, although containing some important IP provisions, are fundamentally weaker than these agreements. These includes the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), the EU-Mercosur Association Agreement, and the Indonesia Australia Comprehensive Economic Partnership Agreement. In particular, the EU-Mercosur Agreement was disappointing. Although technically a post-TRIPS FTA that does contain a separate IP chapter, its IP provisions are notably weaker compared with current international standards and other post-TRIPS agreements concluded by the EU. The treaty does not include any substantive provisions regarding patent rights, copyright provisions are relatively limited, and border measures are notably weak.
27. Many economies have a copyright term that is measured by the life of an author plus an additional number of years. Given the difficulties in measuring and estimating an average life of an author, and thus an average term of protection, this indicator uses only minimum terms, which are applied in lieu of the life of author plus an additional number of years (i.e., in cases in which the rights-holder is unknown or has already died). Accordingly, 95 years is the minimum term applied in U.S. law.
28. These difficulties of measuring piracy are particularly pronounced for online piracy. No comprehensive studies exist that measure and compare rates of online piracy for a large sample of economies. Because of this, the indicators measuring piracy and counterfeiting in the Index are primarily based on physical piracy and counterfeiting, with the data from BSA being based on both physical and digital software piracy. Nevertheless, there are a number of academic and industry-supported studies that measure rates of online piracy and its economic impact either on a global basis or for a few large economies. For example, a 2011 study commissioned by NBCUniversal and produced by Envisional found that 23% of global internet traffic was estimated to be infringing in nature. Similarly, a 2011 report by Frontier Economics estimated the total value of counterfeit and pirated products in 2008 and forecast for 2015 to be $455-650 billion and $1,220-1,770 billion, respectively. Out of this total, digitally pirated products were estimated at $30-75 billion in 2008 and forecast to be $80-240 billion in 2015. Furthermore, this report found that online piracy in the United States made up a large share of this digital piracy figure. For 2008, the report estimated that $7-20 billion worth of digitally pirated recorded music was consumed in the United States, with an additional $1.4-2 billion of digitally pirated movies also consumed. Finally, the vast majority of academic papers and economic analyses have found that online piracy and file sharing has had a negative impact on media sales, including music. For details, see Envisional (2011), *Technical Report: An Estimate of Infringing Use of the Internet*, Cambridge, 2011, p. 2; Frontier Economics (2011), *Estimating the Global Economic and Social Impacts of Counterfeiting and Piracy*, London, 2011, pp. 56-58; and Smith, M. D., and Telang, R. (2012), *Assessing the Academic Literature Regarding the Impact of Media Piracy on Sales,* Social Science Research Network, 2012.
29. OECD (2016), *Trade in Counterfeit and Pirated Goods*, pp. 110-111.
30. International and best practices are defined here as those principles established in TRIPS Article 27: "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."
31. Act of 1991, International Convention for the Protection of New Varieties of Plants, Article 19, Duration of the Breeder's Right.

32. The Berne three-step test generally requires that limitations and exceptions to copyrights should be (1) confined to special cases, (2) which do not conflict with a normal exploitation of the work, and (3) do not unreasonably prejudice the legitimate interests of the rights-holder. (TRIPS Agreement, Article 13).
33. Examples of voluntary and industry-based standards include those standards and policies used in the United States and elsewhere by providers such as eBay. The latter has a system in place—the Verified Rights Owner Program—that allows rights-holders to protect their intellectual property through a process of notification and takedown in which eBay is notified of the infringement and promptly removes the material from its website. Full details of the system are available at http://pages.ebay.com/vero/intro/index.html.
34. Half (0.5) of the available score is based on the term available for biologics or large-molecule compounds. If a country's relevant legislation/regulation either *de jure* or *de facto* does not cover such compounds, then the maximum score that can be achieved in this indicator is 0.5. The baseline numerical term used is that by the EU: 10 years (8 + 2) of marketing exclusivity.
35. This indicator is not concerned with commercial litigation brought by private parties and settled by an independent judiciary.
36. The Hague Agreement Concerning the International Registration of Industrial Designs consists of several separate acts, specifically the Hague Agreement of 1960 (Hague Act) and the Geneva Act of 1999. The score for this indicator is evenly assessed between membership and accession to both treaties.