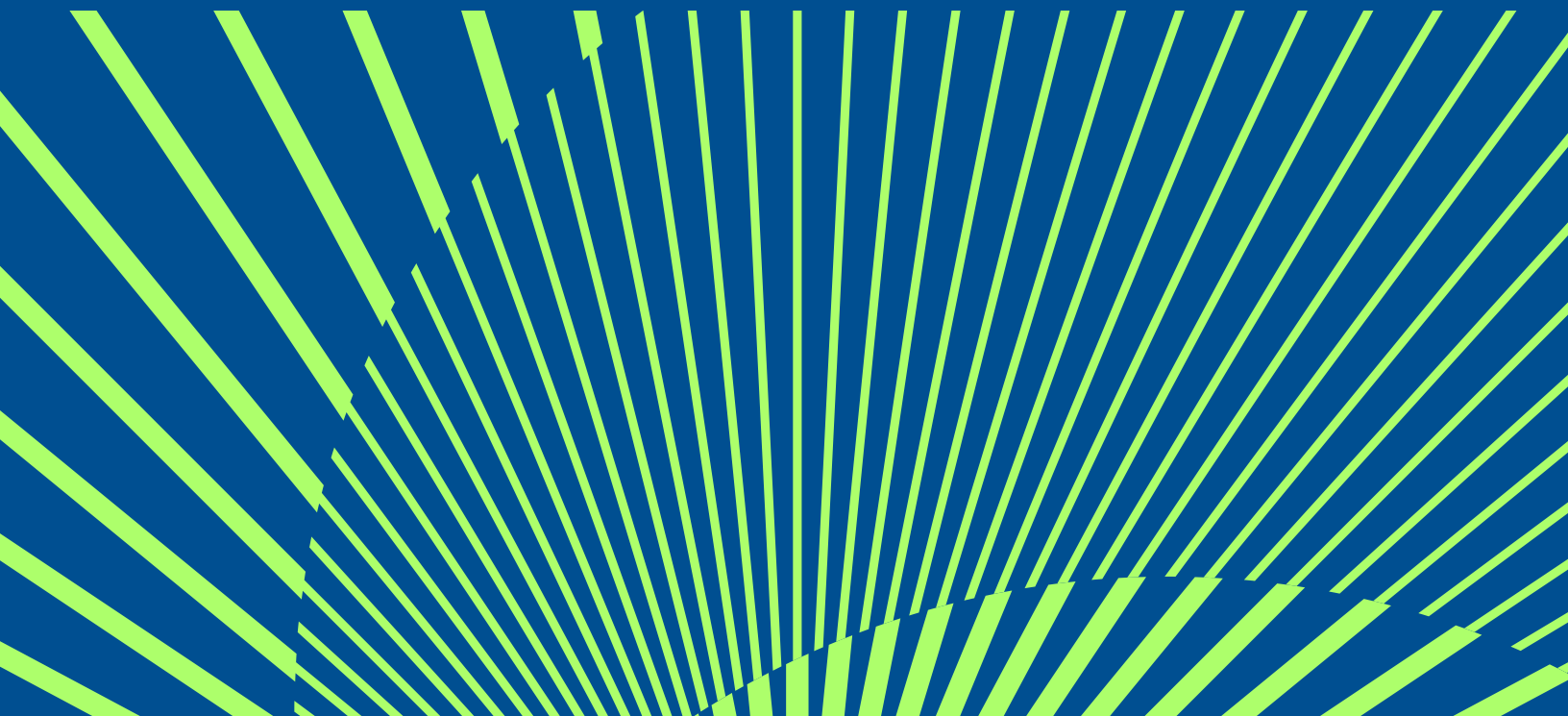




U.S. Chamber of Commerce
Global Innovation
Policy Center

International IP Index

2023 Eleventh Edition





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.

The U.S. Chamber of Commerce is the world's largest business federation representing the interests of more than 3 million businesses of all sizes, sectors, and regions, as well as state and local chambers and industry associations.



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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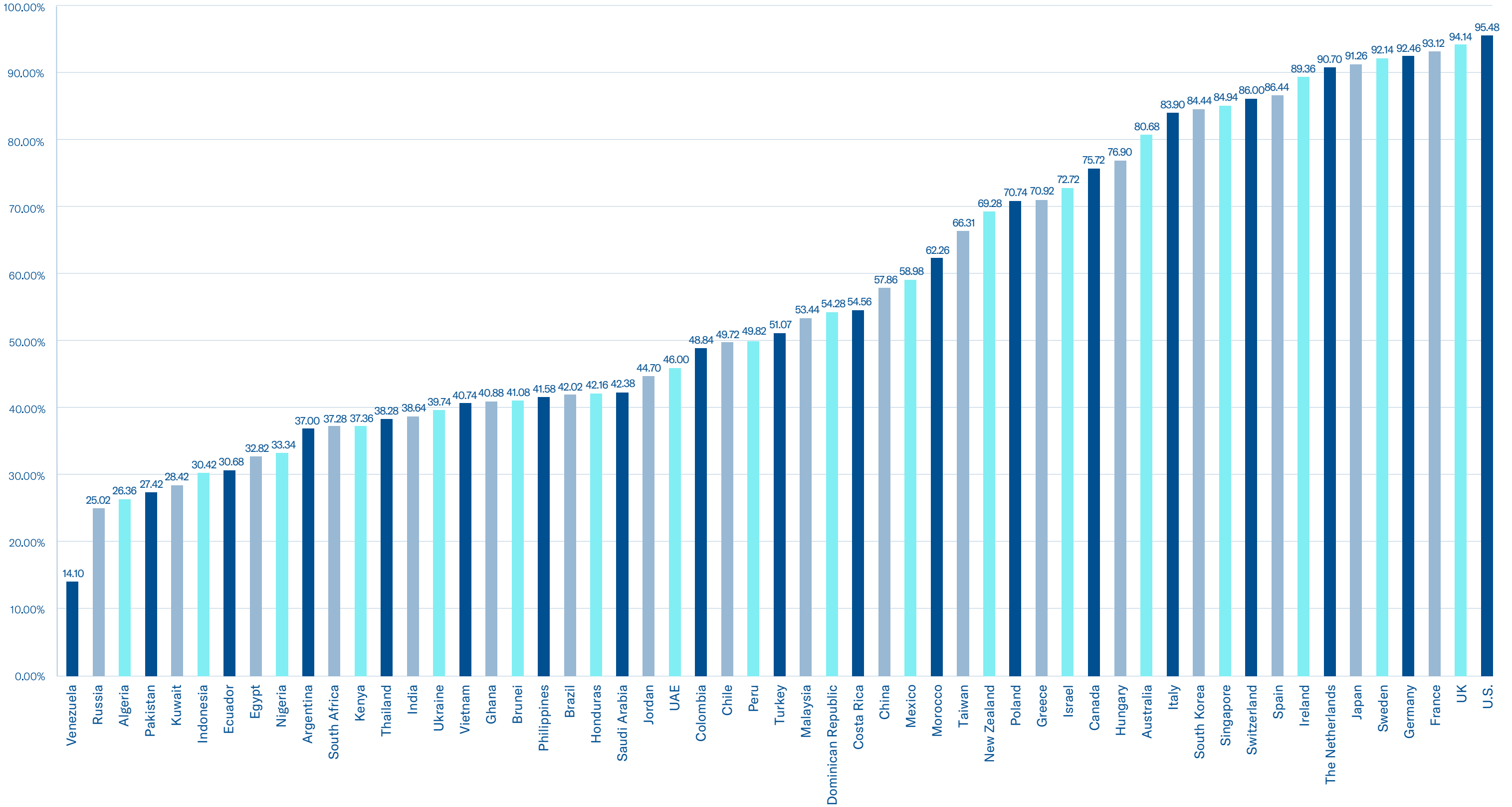
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U.S. Chamber International IP Index 2023, Overall Scores, % Available Score





Foreword

Intellectual property (IP) was critical to how nations, businesses, and individuals managed through and emerged from the COVID pandemic.

Through therapeutics, vaccines, and technology that helped us remain connected, protected, entertained, and informed, IP was pivotal to our ability to work together and for the global economy to recover.

Despite these achievements, policies like the World Trade Organization's move to eliminate IP protection for vaccines incentivize political scapegoating over investing in solutions. This threatens the global framework for IP protections and jeopardizes the future of innovation.

It's important for decision-makers to remember the innovation and creativity ecosystem is not inevitable. From small startups to major corporations, innovators and creators of all stripes depend on a framework of laws that provides a pathway for investments in the exciting, cutting-edge products and services of tomorrow. The hope of a brighter future is only possible through the rule of law.

The International IP Index (Index), created by the U.S. Chamber of Commerce, is a powerful tool for assessing the strength and effectiveness of IP frameworks established by policymakers worldwide. It provides invaluable data that can be used to not only support arguments, but to inspire real policy changes to drive innovation forward and shape a more promising future.

The 2023 Index highlights a crucial turning point in the global IP landscape. As multilateral organizations continue to debate the future of IP and some of the world's major economies—including the United States—propose unsettling policy changes, the decisions to be made by policy makers will carry unprecedented weight.

Policymakers have a choice: they can help spur innovation and creativity or stop it altogether. Those choices can help create jobs and growth or mix the cement of stagnation.

The Index illustrates that the choice is clear: we can harness IP to help deliver the economy of tomorrow. But we must work together to do it.

The Chamber is proud to stand alongside innovators and creators from around the globe urging decision makers to step up and take a leadership role to protect IP rights. The Index serves as a valuable tool to help guide them, with everyone standing to benefit from the fruits of our shared labor.

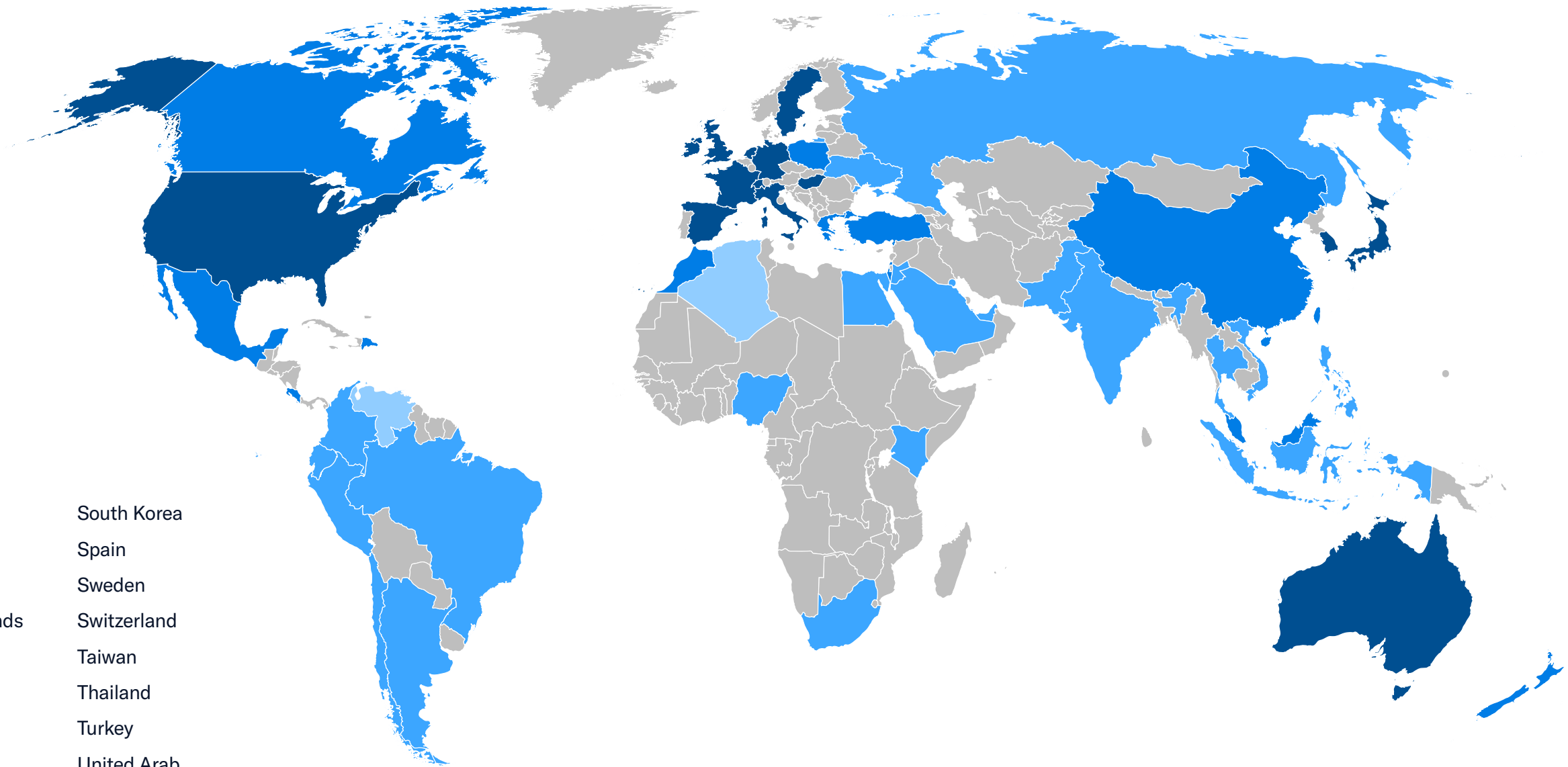


Executive Summary

Now in the eleventh edition, the International IP Index benchmarks the IP framework in 55 global economies across 50 unique indicators. The Index creates a roadmap for economies seeking to strengthen the ecosystem for innovation and creativity through more effective IP standards.

Geographic Coverage

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



Overall Economy Scores



Key Findings



Twenty-eight economies' scores remained unchanged, illustrating that progress to improve global IP protection may be stagnating.



Economies are threatening to weaken the framework for IP-driven innovation through discussions at the multilateral organizations and in capitals.



Mobile technologies like 5G, which helped consumers remain connected during the global pandemic, also generate a significant, positive economic impact.



Building upon the positive momentum on copyright enforcement in the tenth edition of the Index, many economies continued to take steps to address copyright-infringing content online in 2022.

- » However, there was still modest progress to strengthen IP protection in some global markets, with scores improving in 18 economies, while nine took steps backwards.
- » **Morocco, Thailand, and Vietnam** had the largest improvements in their overall score at 2.5%, 2.5%, and 2.02% respectively.
- » Asia had the greatest improvement in the regional average score as a result of score improvements in Malaysia and **Singapore**, in addition to Thailand and Vietnam.
- » **Russia's** score dropped 21.62% as a result of a series of measures taken by Russia targeting international rightsholders.

- » IP was critical to the research & development of innovative vaccines, therapeutics, and diagnostics that underpinned the global response to COVID-19. IP rights facilitated 143 licensing agreements in 31 different countries for COVID-19 therapeutics alone, in turn ensuring that global supply well exceeds demand.
- » Yet, ongoing negotiations within the World Trade Organization (WTO) and World Health Organization (WHO) to waive IP rights will undermine the innovation ecosystem that was pivotal to combatting COVID-19 and threaten the ability to respond effectively to the next major global public health threat.
- » Following the 2021 Executive Order on Promoting Competition in the American Economy and the passage of the Inflation Reduction Act, policymakers in the **United States** are considering changes to the patent framework to address concerns with drug prices that will undermine the U.S. life sciences ecosystem and the many U.S. jobs supported by IP-driven innovation.
- » Likewise, policy proposals under consideration in the **European Union** that condition IP protection, reduce the term of regulatory data protection, and undermine investment in rare disease treatments will jeopardize the EU's long-standing leadership on IP-driven innovation.

- » While the deployment of 5G has already contributed over \$100 billion to U.S. GDP, studies estimate that the 5G standard will contribute \$1.5 trillion to U.S. GDP and create or transform 16 million U.S. jobs by 2025.
- » The continued deployment of 5G and other information and communications technologies (ICT) is dependent upon economies creating an enabling environment through strong IP standards. The Index illustrates how economies with the most effective IP frameworks are more likely to have increased availability of ICT technologies, a stronger digital environment, and greater ability to deploy 5G.
- » However, economies that utilize localization policies, onerous licensing requirements, and forced technology transfer will stymie the development of new ICT and mobile technologies, including 5G.

- » In Latin America, **Peru's** national IP Office (INDECOPI) and **Brazil's** "Operation 404 against piracy" disabled access to hundreds of websites hosting pirated content.
- » In **Canada**, the Federal Court issued a dynamic injunction order requiring Canadian ISPs to disable access to illegal live streaming of National Hockey League matches online.
- » In the **United States**, a U.S. District Court issued injunctions ordering U.S. ISPs to disable access to copyright-infringing content online. However, the U.S. still lacks a comprehensive, modern statutory framework to combat online commercial piracy.

* The Chamber's Patient Access Report will examine the specific impact price controls and market access barriers have access to innovation in the U.S. and foreign markets. The report will be released in March 2023.



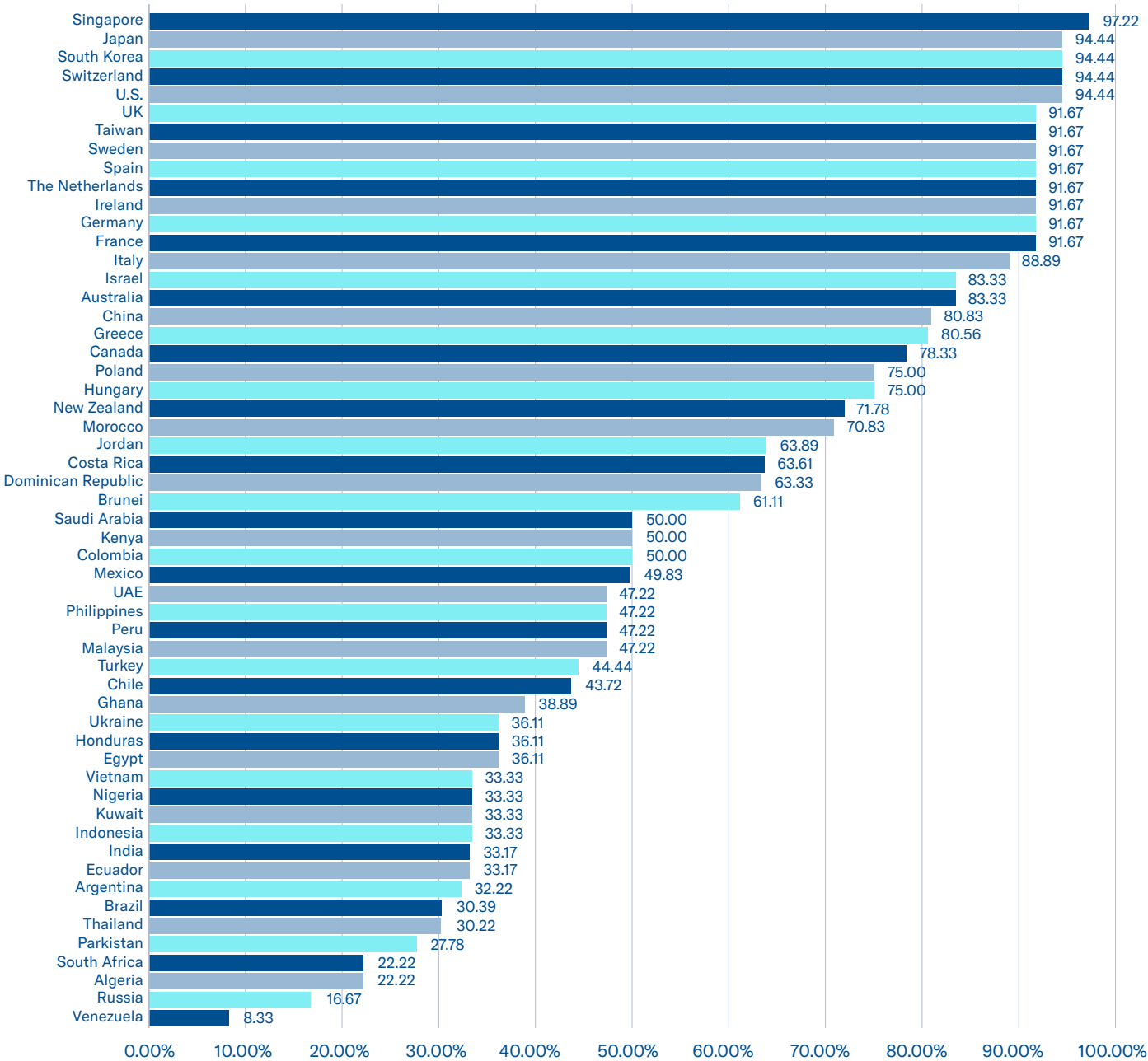
Category-by-Category

Patents, Related Rights, and Limitations

Twenty-three economies achieve a score of 70% or more and 30 economies achieve a score of 50% or more in the patent indicators. The average score on the category is 59.31%, which is the fifth highest scoring category on the Index.

- » While **Brazil's** Supreme court declared that a 10-year term of patent exclusivity was unconstitutional in 2021, in a positive development in 2022, a member of the Brazilian Chamber of Deputies introduced draft legislation to provide a period of patent term restoration.
- » **China's** Supreme Court issued the first judgement related to its early resolution mechanism, which provided clarification on the mechanics of the notification process and the responsibilities of follow-on applicants.
- » In **Malaysia**, amendments to the Patent Act created a defined pathway for post-grant opposition proceedings.

Category 1: Patents, Related Rights, and Limitations, % Available Score



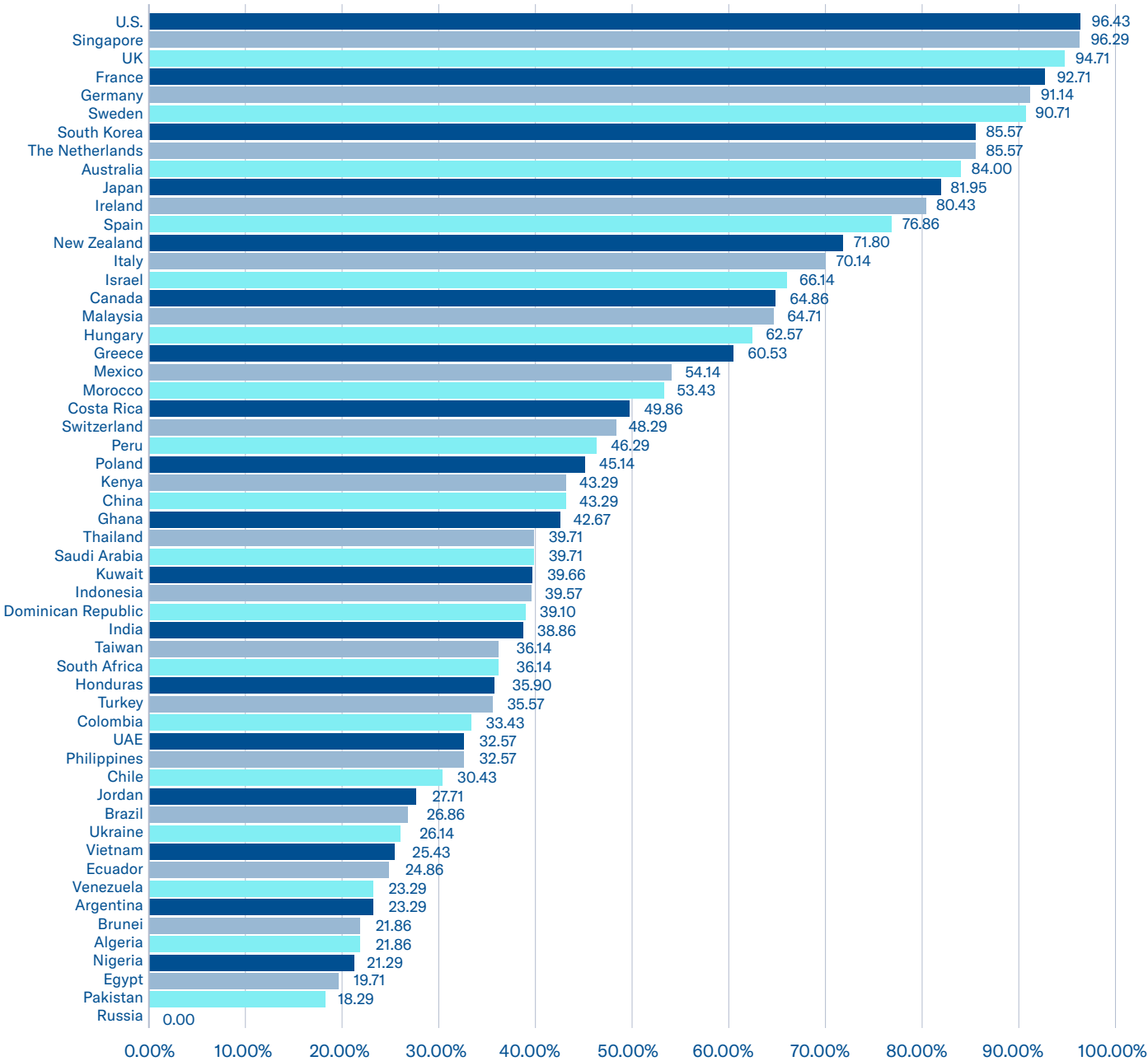


Category-by-Category

Copyrights, Related Rights, and Limitations

- Thirty economies achieve a score of 50% or more on the copyright indicators. The average score on the category is 49.70%.
- » In **Brazil**, the National Telecommunications Agency and the national Film Agency signed a cooperation agreement to create a new administrative injunctive relief mechanism targeting online piracy.
 - » **Thailand** enacted a new Copyright Act that creates a notice-and-takedown system, defines liability for service providers, and creates additional remedies for the circumvention of technological protection measures (TPMs).
 - » **Vietnam** amended the Copyright Law to promote cooperative action against online piracy and provide intermediaries with defined responsibilities related to copyright infringement.

Category 2: Copyrights, Related Rights, and Limitations, % Available Score





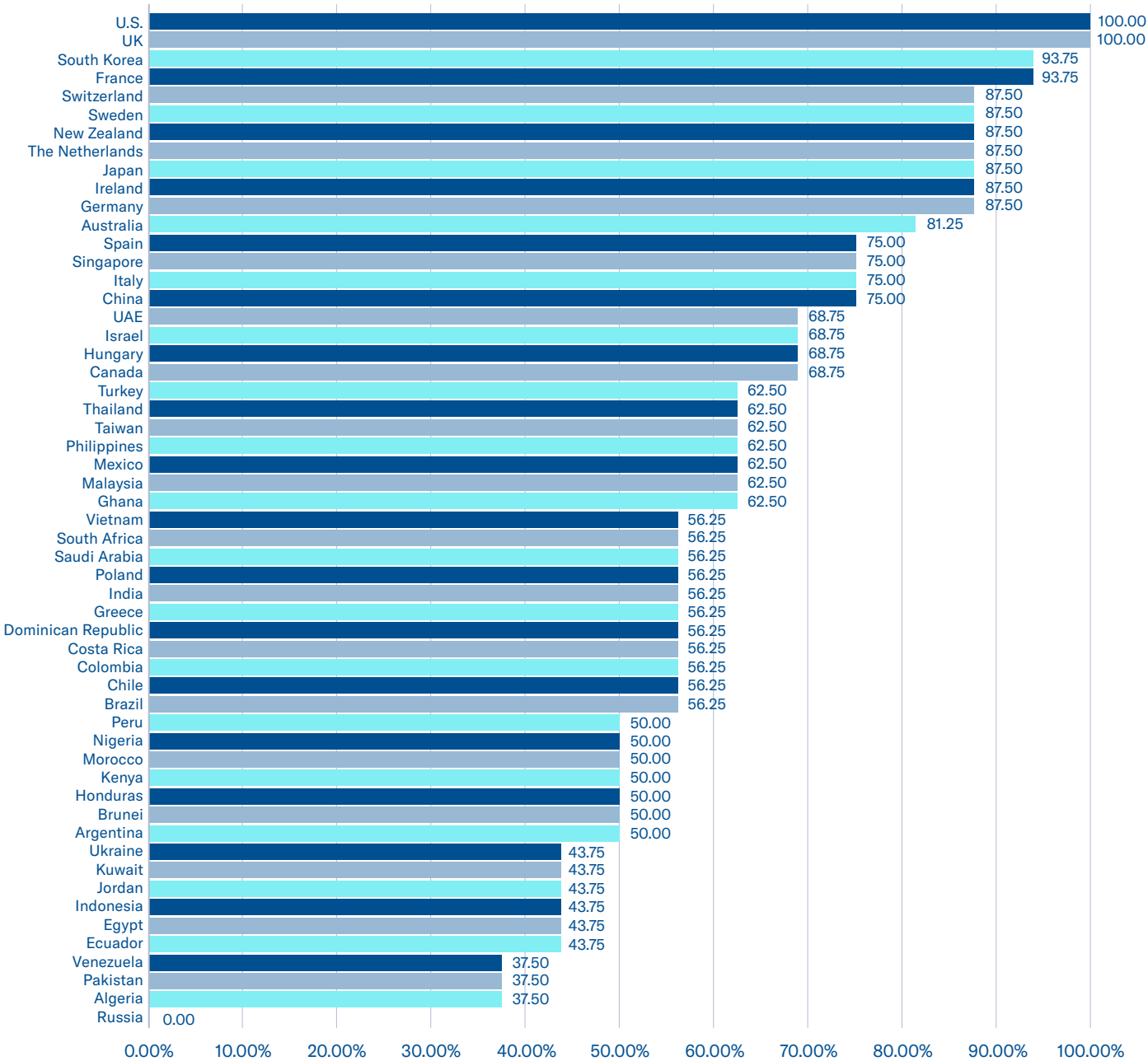
Category-by-Category

Trademarks, Related Rights, and Limitations

Only ten of the 55 sampled economies fail to score 50% or more on this category. Overall, the average score on this category was 62.39%.

- » The **Saudi** Authority for Intellectual Property (SAIP) continued to improve its enforcement efforts by disabling access to over 3,000 websites hosting infringing content and conducted over 5,000 physical in-person visits to investigate the sale of IP-infringing goods.
- » In **France**, a 22-month special operation conducted against the online sale of counterfeit toys and children’s articles resulted in the seizure or take down of over 16 million counterfeit goods.
- » In **Thailand**, the Memorandum of Understanding (MOU) between rightsholders, online retailers, and the Thai Government has resulted in increased enforcement efforts against counterfeit goods available online.

Category 3: Trademarks, Related Rights, and Limitations, % Available Score





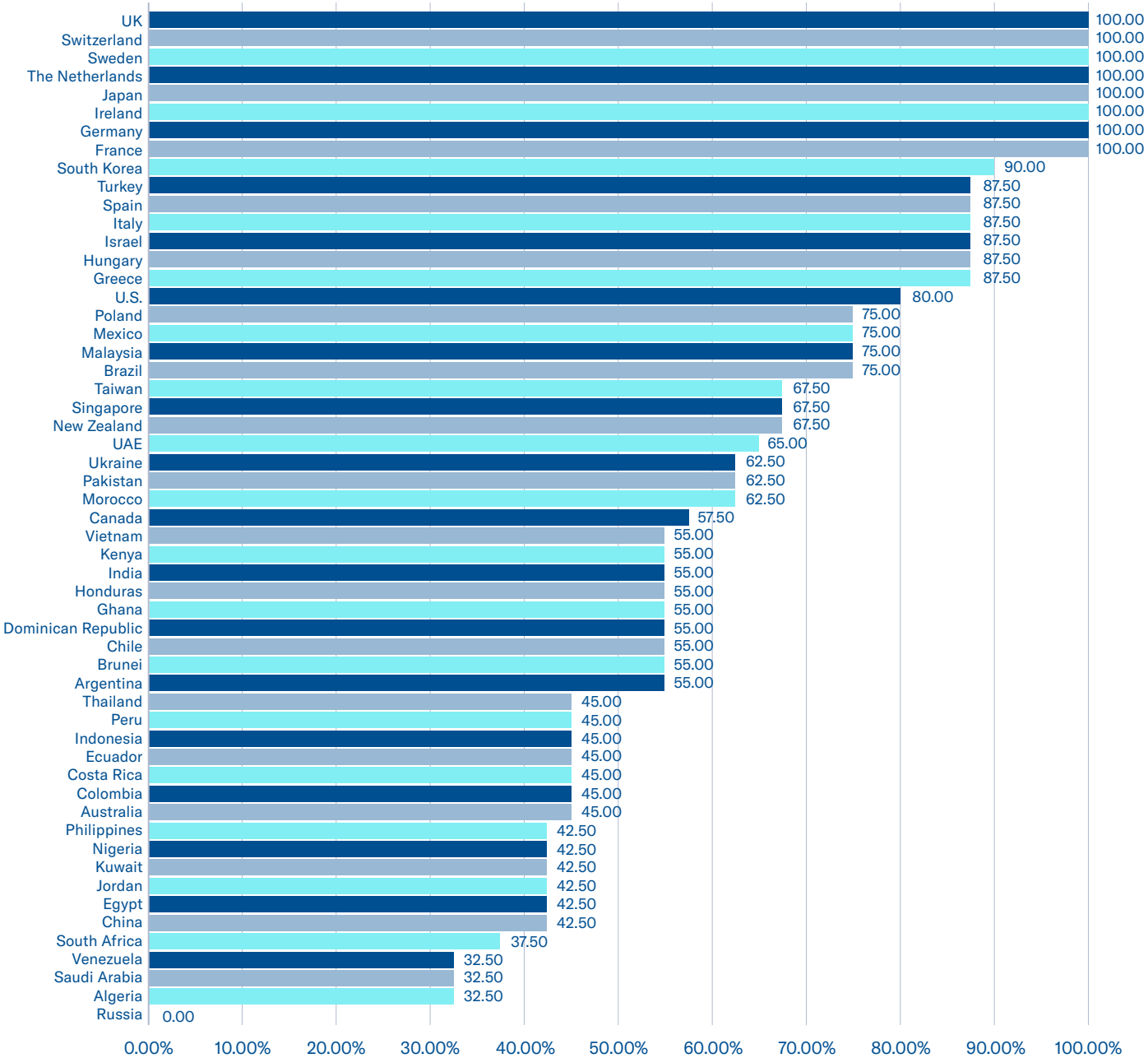
Category-by-Category

Design Rights, Related Rights, and Limitations

Most economies included in the Index have in place some form of statutory law defining design rights and a term of protection for registered design rights. The average score on this category this year was 63.77%.

- » **China and Morocco** both became full contracting parties to the Hague Agreement.
- » **Brazil's** Senate and Chamber of Deputies also approved accession to the Hague Agreement, though the accession has not yet been formalized.

Category 4: Design Rights, Related Rights, and Limitations, % Available Score





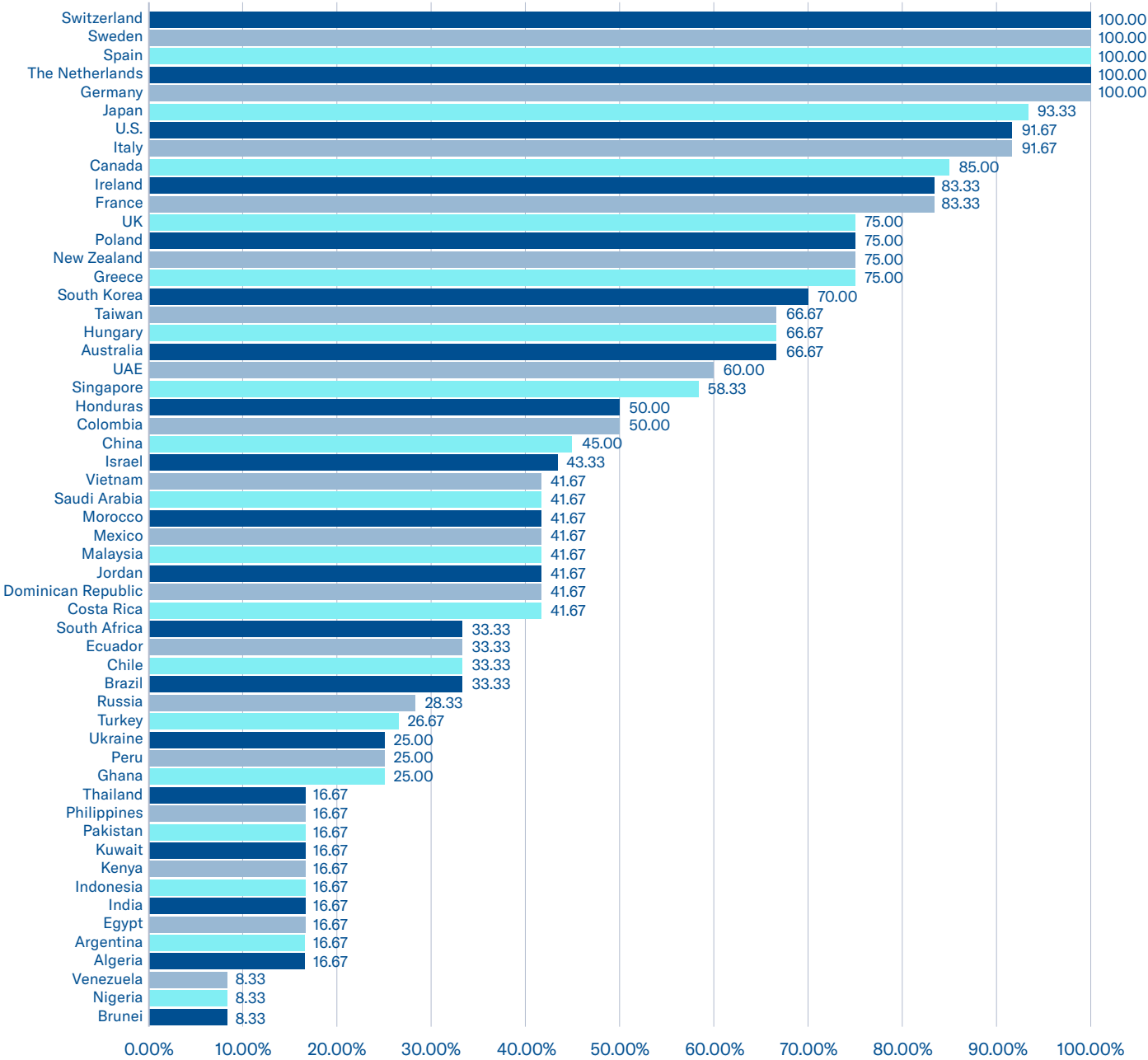
Category-by-Category

Trade Secrets and the Protection of Confidential Information

Overall, only 23 of the 55 economies included in the Index achieved a score of 50% or more on this category while 22 economies achieved a score of 33.33% or less. The average score on this category is the weakest on the Index at 48.97%.

- » While **Vietnam** passed amendments to its Law on Intellectual Property, the amendments did not resolve the lack of clarity on availability of regulatory data protection (RDP).
- » The U.S. State Department’s 2022 *Investment Climate Statement* stated that the **Saudi** Food and Drug Authority and SAIP reaffirmed their support for the availability of RDP in the Kingdom.
- » While the **UAE** published new Executive Regulations in 2022, the regulations did not clarify existing uncertainty around the availability of an eight-year RDP term.

Category 5: Trade Secrets and the Protection of Confidential Information, % Available Score



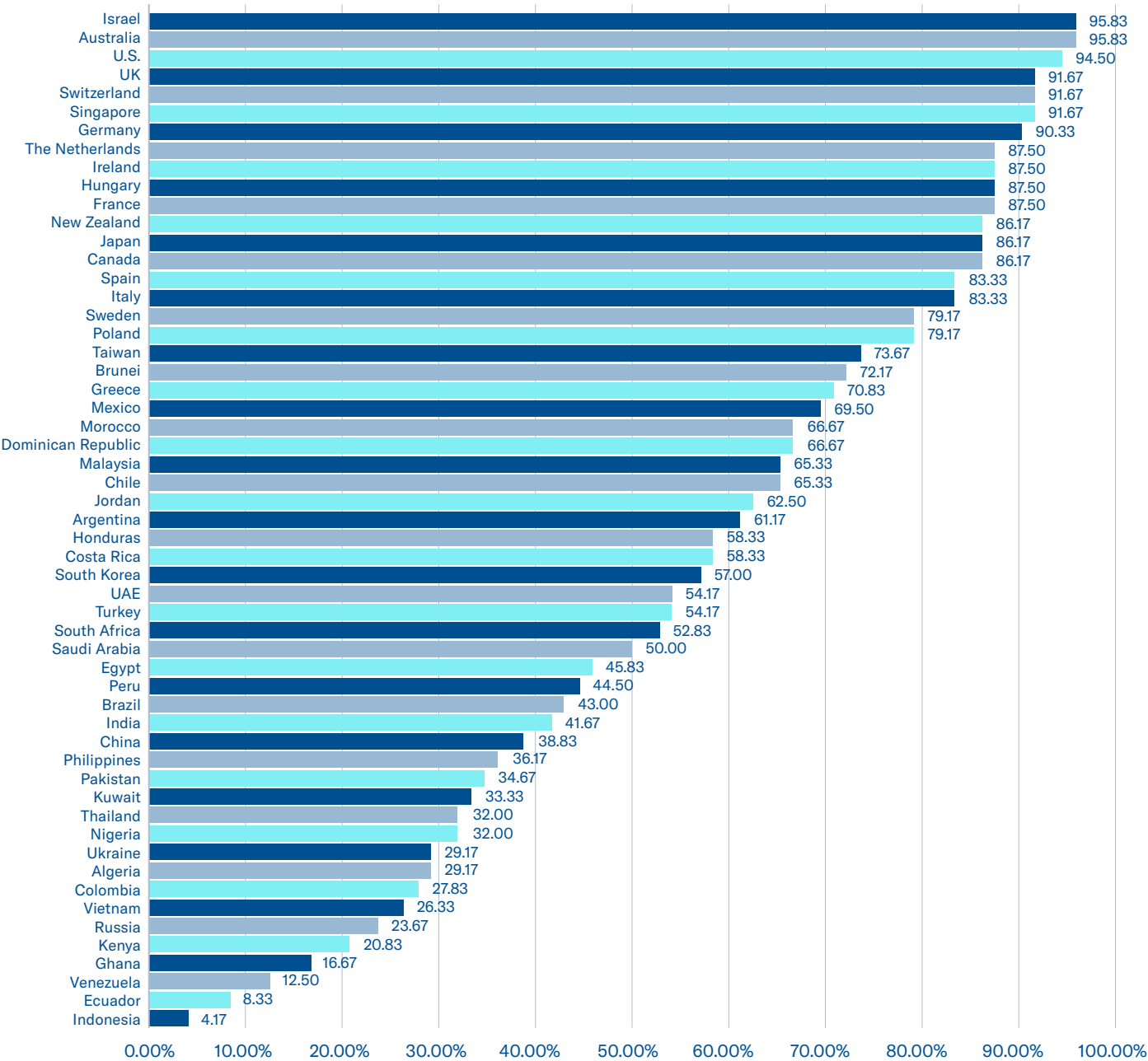


Category-by-Category

Commercialization of IP Assets

- Twenty economies fail to achieve a score of 50% or more, with a 13 scoring 33.33% or less on the category. The average score on this category was 58.62%.
- » **China’s** new Anti-Monopoly Law expands the government’s basis for action against anti-competitive behavior and substantially increases fines and penalties including with respect to IP rights.
 - » Following the WTO ruling on **Turkey’s** discriminatory biopharmaceutical market access and localization policies, the Turkish government committed to implementing the panel’s recommendation in a matter consistent with their WTO obligations.
 - » New legislation in **Thailand** improved the technology transfer environment by providing IP-based incentives for the commercialization of academic and publicly funded research.

Category 6: Commercialization of IP Assets, % Available Score



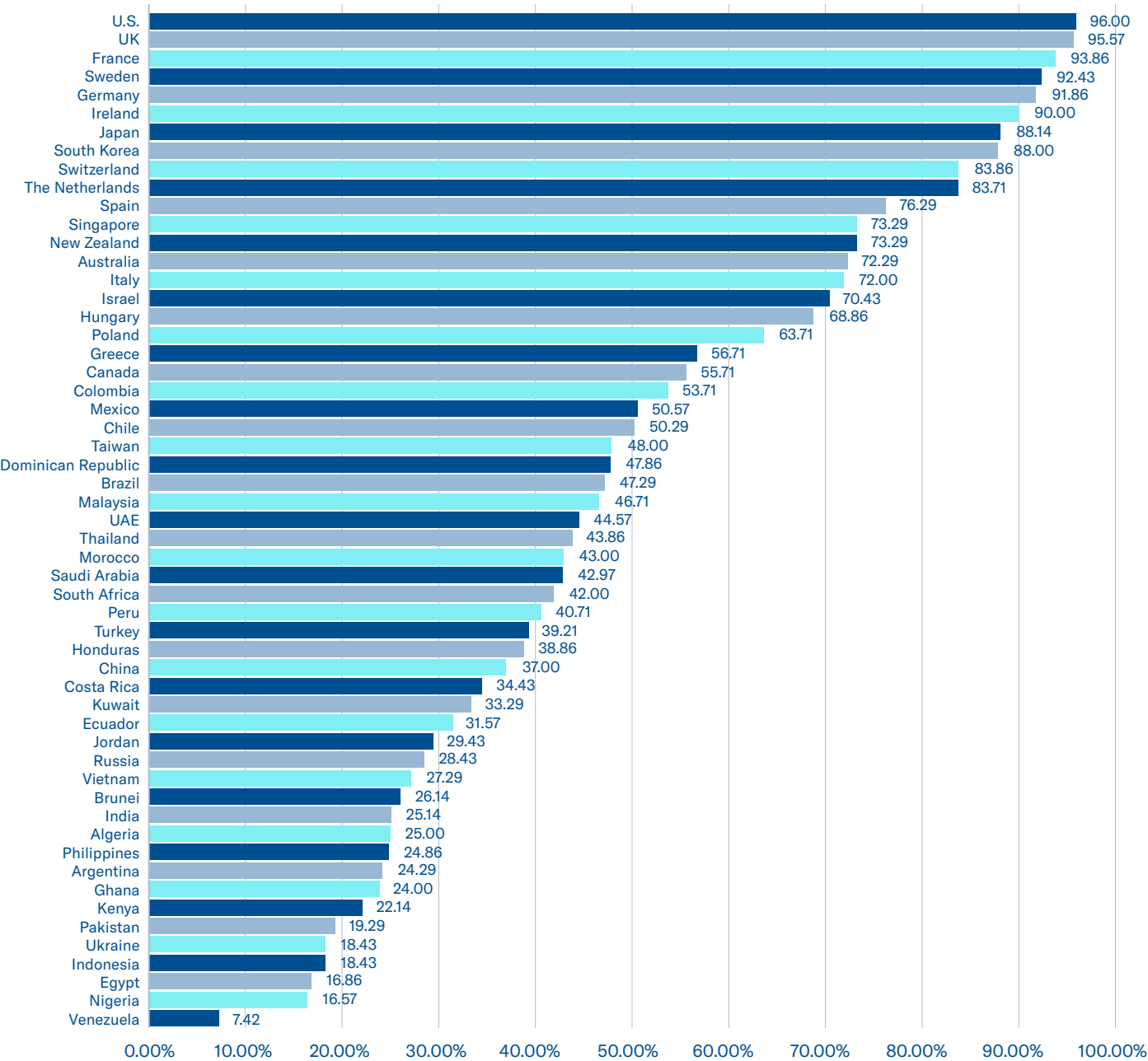


Category-by-Category
Enforcement

A majority of the sampled economies in the Index struggle on this category with only 23 Index economies achieving a score of 50% or more. Only 11 economies achieve a score of 75% or more. The average score on this category is 50.10%.

- » In **Malaysia**, the government has taken action in 500 cases of physical sales of set-top boxes and disabled access to over 2,000 websites.
- » A new law in **Chile**, which entered in to force in January 2022, introduced statutory damages for trademark infringement.
- » In **Indonesia**, the government increased inspections of shopping malls and created a program to certify legitimate physical and online places of commerce.

Category 7: Enforcement, % Available Score





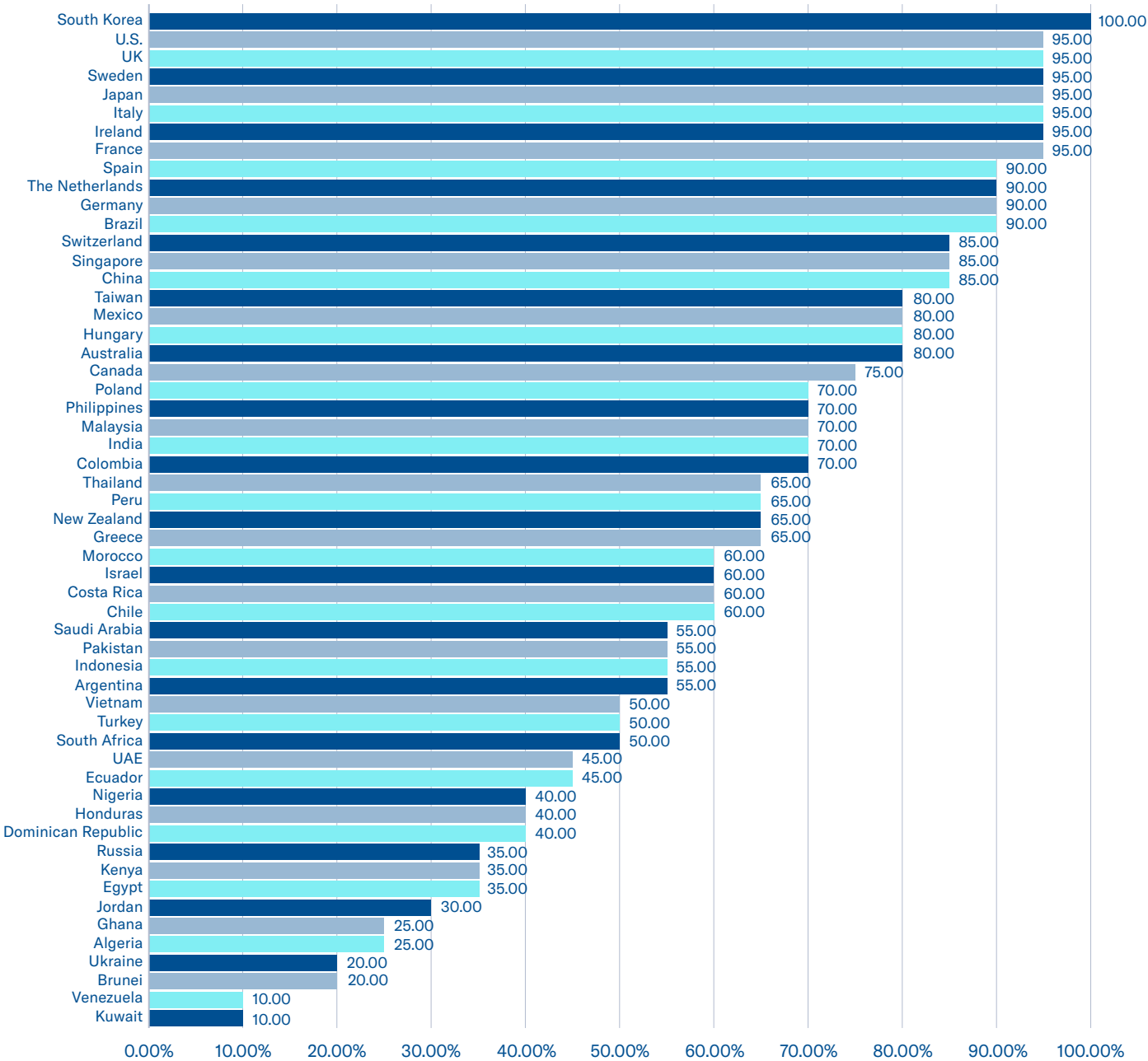
Category-by-Category

Systemic Efficiency

Many economies outperform their overall Index scores on this category, with countries such as **Brazil, Colombia, India,** and the **Philippines** achieving a score 70% or more. Overall, the average score on this category is one of the strongest on the Index, at 62.73%.

- » **Morocco** launched new technical assistance programs for academic researchers, research institutes, and small and medium-sized enterprises (SMEs) on the commercialization of IP assets.
- » The **Korean** Intellectual Property Office provides SMEs with educational and technology assistance programs that has resulted in an increase in patent applications by SMEs.
- » The **UK's** new *IP Counter-Infringement Strategy 2022-2027* seeks to strengthen the UK's already world-class enforcement environment by improving coordination of activities related to IP infringement.

Category 8: Systemic Efficiency, % Available Score





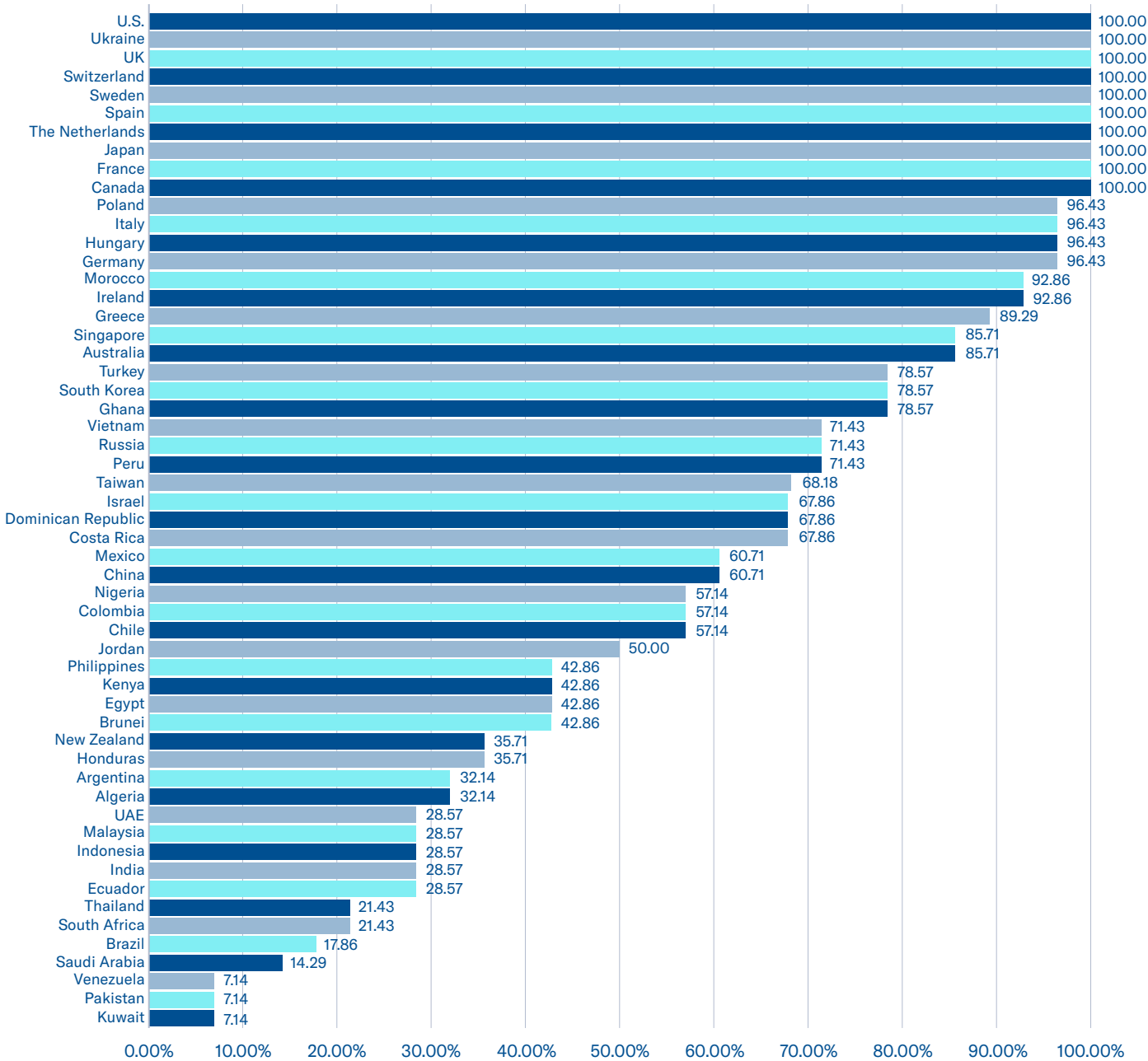
Category-by-Category

Membership and Ratification of International Treaties

Many economies achieve a high score on this category with 22 economies achieving score of 75% or more and 14 economies achieving a score of over 96%. This category remains one of the stronger overall categories on the Index achieving an average score of 62.70%.

- » **Vietnam** and **Thailand** both acceded to parts of the WIPO Internet Treaties in 2022.
- » **Morocco** acceded to the Singapore Treaty and is now a full member of each of the two trademark-related treaties included in the Index.
- » **Chile** acceded to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks.
- » **Nigeria** became a full contracting party to the Convention on Cybercrime with the treaty entering into force in November 2022.

Category 9: Membership and Ratification of International Treaties, % Available Score



Overview of the Eleventh Edition

Now in its eleventh edition, the U.S. Chamber of Commerce's International IP Index continues to provide a critical industry perspective on the IP standards that influence both long- and short-term business and investment decisions worldwide. The Index is a unique and continuously evolving instrument. Not only does it assess the state of the international IP environment, but it also provides a clear roadmap for any economy that wishes to

be competitive in the 21st century's knowledge-based global economy. Large or small, developing or developed, economies from around the world can use the insights about their own national IP environments as well as those 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 55 economies. Together, these 55 economies represent both a geographical cross-section of the world and most of the 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: Eleventh Edition Index Economies by World Bank Region

Asia	Latin America and the Caribbean	Africa and Middle East	Europe and Central Asia	North America
Australia	Argentina	Algeria	France	Canada
Brunei	Brazil	Egypt	Germany	U.S.
China	Chile	Ghana	Greece	
India	Costa Rica	Israel	Hungary	
Indonesia	Colombia	Jordan	Ireland	
Japan	Dominican Republic	Kenya	Italy	
Malaysia	Ecuador	Kuwait	The Netherlands	
New Zealand	Honduras	Morocco	Poland	
Pakistan	Mexico	Nigeria	Russia	
Philippines	Peru	Saudi Arabia	Spain	
Singapore	Venezuela	South Africa	Sweden	
South Korea		UAE	Switzerland	
Taiwan			Turkey	
Thailand			UK	
Vietnam			Ukraine	

Source: World Bank (2022)

In addition to geographic diversity, the Index includes economies from a broad spectrum of income groups as defined by the World Bank. Table 2 provides an overview of all 55 economies sampled according to income group as defined by the World Bank.

Table 2: Eleventh 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
Ghana	China	Saudi Arabia	Chile
Honduras	Colombia	Singapore	France
India	Costa Rica	Taiwan	Germany
Indonesia	Dominican Republic	UAE	Greece
Kenya	Ecuador		Hungary
Morocco	Jordan		Ireland
Nigeria	Malaysia		Israel
Pakistan	Mexico		Italy
Philippines	Peru		Japan
Ukraine	Russia		The Netherlands
Vietnam	South Africa		New Zealand
	Thailand		Poland
	Turkey		South Korea
	Venezuela (2020)		Spain
			Sweden
			Switzerland
			UK
			U.S.

Source: World Bank (2022). The World Bank has temporarily unclassified Venezuela pending the release of national accounts statistics. Consequently, the Index classifies Venezuela per its 2020 classification.

Regional Rankings

Region	Average overall % Index Score
North America	85.60%
Europe and Central Asia	76.14%
Asia	56.42%
Latin America	43.83%
Africa and Middle East	42.04%

Africa and Middle East	Overall Score	Regional Ranking
Israel	72.72%	1
Morocco	62.26%	2
UAE	46.00%	3
Jordan	44.70%	4
Saudi Arabia	42.38%	5
Ghana	40.88%	6
Kenya	37.36%	7
South Africa	37.28%	8
Nigeria	33.34%	9
Egypt	32.82%	10
Kuwait	28.42%	11
Algeria	26.36%	12

Asia	Overall Score	Regional Ranking
Japan	91.26%	1
Singapore	84.94%	2
South Korea	84.44%	3
Australia	80.68%	4
New Zealand	69.28%	5
Taiwan	66.31%	6
China	57.86%	7
Malaysia	53.44%	8
Philippines	41.58%	9
Brunei	41.08%	10
Vietnam	40.74%	11
India	38.64%	12
Thailand	38.28%	13
Indonesia	30.42%	14
Pakistan	27.42%	15

Europe and Central Asia	Overall Score	Regional Ranking
UK	94.14%	1
France	93.12%	2
Germany	92.46%	3
Sweden	92.14%	4
The Netherlands	90.70%	5
Ireland	89.36%	6
Spain	86.44%	7
Switzerland	86.00%	8
Italy	83.90%	9
Hungary	76.90%	10
Greece	70.92%	11
Poland	70.74%	12
Turkey	51.07%	13
Ukraine	39.74%	14
Russia	25.02%	15

Latin America	Overall Score	Regional Ranking
Mexico	58.98%	1
Costa Rica	54.56%	2
Dominican Republic	54.28%	3
Peru	49.82%	4
Chile	49.72%	5
Colombia	48.84%	6
Honduras	42.16%	7
Brazil	42.02%	8
Argentina	37.00%	9
Ecuador	30.68%	10
Venezuela	14.10%	11

North America	Overall Score	Regional Ranking
U.S.	95.48%	1
Canada	75.72%	2



The Global IP Environment in 2022—Major Developments, Overall Index Scores and Category-by-Category Results

International Developments

As noted last year, since the onset of the COVID-19 pandemic, the global IP rights architecture contributed to the rapid availability of lifesaving vaccines and therapies. Decades in development, the existing IP ecosystem stimulated investment in a host of other technological solutions that have kept humans safe, connected, and productive to a degree unimaginable in previous pandemics. However, over the past two years, the global IP rights system has faced serious challenges from

governmental and nongovernmental activists who misrepresent the role that IP rights and IP assets play in driving innovation and supporting the economy and who also blame IP rights for unrelated access challenges. Instead of recognizing how decades of research and development facilitated a response to the pandemic, governmental and nongovernmental activists have used the pandemic to assert their longstanding views and strategies to weaken the protection of IP.

The broader context: The COVID-19 pandemic and the global economy

Even as COVID-19 continued to dominate world affairs in 2022, the global community has availed itself of new and better tools to mitigate the health and socioeconomic impact of the pandemic. This has been most notable with respect to the development of new biopharmaceuticals, including vaccines, antiviral medicines, and other therapeutics.

Global estimates from the Johns Hopkins Coronavirus Resource Center suggest that at the end of 2022, over 13 billion total doses of COVID-19 vaccines had been administered.² In September, the IMF and WHO stopped updating the global “Vaccine Tracker” website. However, the latest available data archived in this website suggest that of the 196 economies included in the database, 74% (145 economies) had secured enough vaccine doses to fully vaccinate 70% of their respective populations.³ (The 70% figure is the baseline used by the IMF and WHO. At the

time data were compiled in September 2022, many economies had achieved a far greater supply of vaccine and had exceeded the 70% figure.)

As the global community moves forward in 2023, the COVID-19 pandemic will continue to have a profound impact on the worldwide economy and on how we interact and live as a globalized society. Individual economies will experience the pandemic’s health and economic impact differently, with varying levels of severity experienced depending on the individual socioeconomic circumstances of that economy. However, three years into this pandemic, the critical takeaway is clear: the global community today is in a far better position to manage the health and socioeconomic impact of the pandemic than it was at the beginning of this crisis. This is in large measure due to the extraordinary efforts of IP-intensive industries and, in particular, the research-based biopharmaceutical industry.



A new paradigm for biopharmaceutical innovation and R&D: The research-based biopharmaceutical industry and the COVID-19 pandemic

At the time of this research, data published by the Pharmaceutical Research and Manufacturers of America (PhRMA) in 2022 showed that 2,142 active clinical trials were taking place globally to test treatments and potential vaccines for COVID-19.⁴ Data from the Biotechnology Innovation Organization housed in their “COVID-19 Therapeutic Development Tracker” show that 710 unique active compounds were in development.⁵ As of December 2022, four vaccines were authorized by the U.S. Food and Drug Administration (FDA) for emergency use or were fully approved.⁶ Inpatient and outpatient treatments and therapies are also available to COVID-19 patients today that were not on the market at the beginning of the outbreak or were originally intended for the treatment of other indications. It is impossible to overstate the enormity of these accomplishments. The speed at which this research has taken place is unprecedented. It shows the extensive scientific capacity developed by the biopharmaceutical and biotech communities and their ability to understand and develop a treatment for a novel virus that was not present in human beings 36 months ago and to scale up manufacturing quickly and decisively. At a scientific, manufacturing, distribution, and organizational level, what the industry together with its partners in academia and the public sector has been able to achieve is remarkable. As many politicians, policymakers, and scientists pointed out when the first vaccine was authorized for emergency use by the FDA, this achievement truly amounts to a modern-day miracle.

The scientific and technological capacity that has allowed industry, public research organizations, and academic researchers to achieve this technological miracle is based on decades of scientific study, R&D investment, and innovation predicated to a large degree on a system of strong, clear, and reliable IP rights. Developing new medicines is a long-term, high-risk, resource-intensive process that includes a high rate of sunken costs such as laboratories, equipment, and researchers. As medicines have become more targeted, technically sophisticated, and effective, the cost of development has risen dramatically.

In 1979, the total cost of developing and approving a new drug stood at USD 138 million. Almost 25 years later, in 2003, this figure was estimated at USD 802 million. A 2012 estimate puts the total cost of drug development at approximately USD 1.5 billion. By 2016, research from Tufts University suggests it cost USD 2.6 billion, on average, to develop a new drug.⁷

International experience and the basic economics of the biopharmaceutical industry show how critical IP rights are to enable this massive investment in the research and development of new medical technologies and products. Patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection (RDP) and special incentives for the protection and production of orphan and pediatric drugs, enable research-based companies to make otherwise unsustainable investments in R&D toward the discovery of

new medicines, medical devices, and therapies. Although public sector funding of early-stage scientific research is critically important, the private sector, without any guarantee of a return on investment, funds and performs the lion’s share of the applied science that turns advances in knowledge into usable products that save lives. For example, a 2021 report commissioned by PhRMA shows that, in 2018, the research-based biopharmaceutical industry invested USD 102 billion R&D.⁸ This compares to a total budget for the National Institutes of Health of USD 35.4 billion, of which only an estimated 8% was invested in research directly related to drug development.

Biopharmaceutical innovation is an extremely high-risk investment. 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 will go on to become a marketable medication. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments. Generic competition from additional market entrants follows later, by design, precisely because these follow-on manufacturers bear none of the costs of early-stage investment, R&D, and product commercialization

carried by the innovator. The resulting system effectively allows generic manufacturers to benefit from the research and investment of the innovating company and offers the innovating company time to recoup its significant investment.

The innovative, scientific, and technological progress that has allowed the global community to function during the COVID-19 pandemic did not emerge overnight. Instead, these technologies and products are the fruit of a preexisting innovation ecosystem that relies on IP rights to enable allocation of resources, formation of partnerships, and transfer of technology on commercial terms. Without strong and clear IP rights, it is unlikely that any of the products and technologies—or the underlying science—that have been essential to keep societies functioning and fighting the COVID-19 pandemic would exist. As the Index and its accompanying Statistical Annex have sought to show over the past decade, the relationship among IP rights, innovation, and the commercialization of new products and technologies is clear and statistically significant.



Taking a wrong turn: The World Trade Organization (WTO) TRIPS waiver

After almost two years of discussion, the WTO approved a waiver of patent rights under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement at the Ministerial Conference in Geneva in June 2022. The final Ministerial Decision allows eligible WTO members “to limit the rights provided for under Article 28.1 of the TRIPS Agreement...by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder.”⁹ The waiver gives members extraordinarily broad latitude to override any relevant patent rights through “any instrument available in the law of the Member such as executive orders, emergency decrees, government use authorizations, and judicial or administrative orders.” Under Paragraph 6, the waiver will remain in effect for at least five years with the possibility of further extension depending on the “exceptional circumstances of the COVID-19 pandemic.”

As the Index stated clearly and unequivocally when the idea for a waiver was first broached in 2020, waiving IP rights will undermine the existing framework that has been critical to the global response to the COVID-19 pandemic. Instead, the waiver will lead to highly negative long-term policy and practical outcomes without meaningfully helping those population groups and economies in need of assistance. Indeed, the way the waiver proposal was framed from the outset and how it has now been executed bears this out.

In October 2020, before a single vaccine was fully tested, reviewed, and authorized as safe and effective by competent scientific and regulatory bodies, a group of WTO members led by India

and South Africa put forth a proposal to waive the greater part of the international IP rights commitments that form the TRIPS Agreement.¹⁰ This first proposal would waive nearly the entirety of the TRIPS Agreement for an undefined period. Specifically, the proposal requested, “In these exceptional circumstances, we request that the Council for TRIPS recommends, as early as possible, to the General Council a waiver from the implementation, application, and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19.” These sections of TRIPS relate to the following IP rights: Section 1: Copyright and Related Rights; Section 4: Industrial Designs; Section 5: Patents; and Section 7: Protection of Undisclosed Information. The only parts of the TRIPS agreement and IP rights that would be unaffected by this proposal were trademarks, geographical indications, and semiconductors (layout designs).

When the initial waiver was agreed to in June 2022, the Ministerial Decision specified, “No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.” In December 2022, the General Council agreed to extend the deadline for discussions, following six months of intense, but deadlocked, negotiations in Geneva.

As the Index and stakeholders pointed out over the past two years, the waiver’s proponents have offered no evidence that IP rights were or would become a barrier to an effective global response to the pandemic. They have merely asserted that

virtually all IP rights were inconsistent with their vision of global equity. It remains unclear to this day how the waiving of IP rights related to patents, copyright protection, industrial designs, and trade secrets would in any way, shape, or form have led to a more successful international response to the COVID-19 pandemic. Waiver proponents continue to assert that waiving IP rights will accelerate global production or will increase local capacity to manufacture vaccines, therapeutics, and diagnostics. However, in practice, a waiver of IP rights will impede ongoing and successful efforts to voluntarily license and scale global production of safe and effective therapeutics and diagnostics.

Voluntary agreements have allowed innovative industry to share its technical expertise with local partners. These agreements, in turn, empower manufacturing partners with the tools to ensure the innovative treatments and medicines are safe and effective for global consumers. There are currently 143 COVID-19 licensing agreements for therapeutics with manufacturers in 31 economies, all supported by the contractual licensing of IP rights, whether on commercial or not-for-profit terms. Moving forward with an expansion of the waiver will undermine existing voluntary licensing agreements, which have been critical to rapidly meeting global demand. Transferring technical expertise is cultivated through sustained education, investment, and collaboration between innovative industry and local partners, which is made possible by the preexisting system of IP rights.

Access to all medicines—not just COVID-19 vaccines and therapeutics—is a complex subject that does not lend itself to generalizing. Access

involves many factors such as health system infrastructure, skilled human resources, health financing, logistics, transportation networks, proper storage and distribution, and a technical drug regulatory capacity. Within this context, the protection of IP plays a relatively small role. For example, most of the medicines viewed as essential (as compiled on essential drugs lists by WHO and numerous individual economies) are off patent and not subject to any form of exclusivity. Yet patients in many economies—not just least developed economies but richer middle-income economies, too—struggle to access these products. Given these are generic, follow-on medicines, IP rights are not an influencing or limiting factor.

With respect specifically to the COVID-19 vaccines, many economies lack the basic health infrastructure and level of development to safely transport, store, and administer these vaccines. Underdeveloped health systems, a lack of trained health care professionals, and the lack of access to basic health services (including many essential medicines) mean that many economies face significant systemic challenges in successfully vaccinating or treating their entire populations.

These challenges have nothing to do with the protection of IP or availability of IP rights.

The International Federation of Pharmaceutical Manufacturers & Associations has noted many of these challenges and how they relate to equitable access to COVID-19 therapeutics.¹¹ These include health system challenges related to financing and procurement, trade and supply chain, limited health care workforce, sanitary and drug regulations, and quality and safety assurance of the biopharmaceutical supply chain.



The implementation of a national or regional vaccination campaign and the management of the pharmaceutical and medical supply chain shed light on non-IP-related barriers, which may impede timely access to medicines. The medical distribution and storage system in place in any given economy directly affects the quality and safety of a pharmaceutical product. Storing medicines at either too high or too low temperatures may have a detrimental impact on the active ingredient, or the excipient compounds used. It is therefore essential that the distributors and dispensers of medicines ensure that the quality of a medicine is not adversely affected under transportation, storage, or actual dispensation. This is of particular importance in economies with a tropical climate where, unless proper storage and transportation conditions are maintained, a medicine's active ingredient will degrade and potentially render it useless.

Many lower- and middle-income economies do not have the physical capacity to store and distribute general vaccines let alone the highly sophisticated mRNA-based COVID-19 vaccines, which, initially, required ultracold storage to retain their efficacy. Vaccines in general must be stored at either refrigerated temperatures (2–8 degrees centigrade) or, if frozen, between –50 and –15 degrees centigrade. For the Pfizer-BioNTech COVID-19 vaccine, storage and handling requirements were initially set at ultracold temperatures between –80 and –60 degrees centigrade. One of the most important positive developments over the past two years has been the collection of data and medical experience showing that it is safe to store the Pfizer-BioNTech vaccine at higher temperatures. The most recent guidance from the U.S. Centers for Disease Control and Prevention states that the Pfizer-BioNTech vaccine can safely be stored in a standard refrigerator for up to 10 weeks.¹² Similarly, the mRNA vaccine developed and manufactured by Moderna can safely be stored in a standard refrigerator for up to 30

days. Unlike the waiving of IP rights under the TRIPS Agreement, this development has had a meaningful impact on the ability of patients around the world to access the Pfizer-BioNTech vaccine.

Overall, it is unclear what positive impact the WTO's Ministerial Decision and waiver of IP rights have had. Although the initial waiver was agreed to as part of an effort to support extraordinary measures amid a global health crisis, the waiver's realization came long after its ostensible purpose was mooted by a large and growing surplus of COVID-19 vaccine supplies. At over 15 billion doses produced, the global manufacturing and supply of COVID-19 vaccines today vastly outpace global demand. The same is true of the supply of therapeutics. Of the 80 million courses of COVID-19 treatment purchased by governments in 2022, only 18 million doses have been administered so far. Indeed, in some cases, individual economies have rejected additional deliveries of COVID-19 vaccines. For example, in November 2021, press reports and public statements by White House officials suggested that the government of South Africa declined additional donations of COVID-19 vaccines.¹³

In fact, the IMF, WHO, and WTO have all suspended their respective monitoring of the global vaccine supply chain because there is no longer a need to monitor it. In May 2022, the "WTO-IMF Vaccine Trade Tracker" was suspended with the website simply stating, "We have stopped collecting the information and will no longer provide updates to the WTO-IMF COVID-19 Vaccine Trade Tracker."¹⁴ Similarly, as mentioned, the "IMF-WHO Vaccine Tracker" was suspended on September 8, 2022.

Furthermore, to date, no country has used the waiver. Paragraph 5 of the Ministerial Decision includes a requirement that members notify the TRIPS Council when making use of the waiver: "For purposes of transparency, as soon as possible after the adoption of the measure, an eligible Member shall communicate to the Council for

TRIPS any measure related to the implementation of this Decision, including the granting of an authorization." Yet, as of December 2022, the TRIPS Council's online database reveals no notifications regarding use of the waiver. Of the 34 notifications filed after the adoption of the Ministerial Decision and retrievable through the WTO TRIPS Council's online database—the "e-TRIPS Gateway"—and categorized under "TRIPS Article 63.2, Patents (including plant variety protection)," none relate to the waiver. Similarly, of the five notifications related to the issuing of compulsory licenses for public health purposes and listed under "TRIPS and Public Health" or the "Paragraph 6 system" search categories, all predate the Ministerial Decision. Although three of these notifications relate to the COVID-19 pandemic, they all predate June 2022 and the issuing of the waiver. Finally, no notifications relate to the waiver categorized under "Other Notifications" in the database; all 88 notifications in this search category predate the Ministerial Decision with the latest being from 2012. Although it is possible that WTO members are using the waiver facility without notifying the WTO, it seems unlikely that zero notifications would be recorded six months after the Ministerial Decision was issued. More likely, as the ample international supply of COVID-19 vaccines and therapeutics suggests, the lack of notifications simply reflects the reality that the waiver is not needed.

As WTO members, international policymakers, and domestic legislators are well aware, the existing IP framework created the architecture for building global capacity for innovation and local production of the products of biopharmaceutical innovation. The ground floors of that architecture can be found in the WTO TRIPS Agreement, whereas many more critical elements are found in this Index. As the Index has documented over the past 11 years, to date, too many economies have resisted the IP standards established by TRIPS, which they have erroneously viewed as a cost rather than as an investment. Consequently, and as this Index has quantified for over a decade, the TRIPS Agreement has never been fully or faithfully implemented by most WTO members. Yet, for economies that wish to be on the front lines for solutions in the next pandemic or other health emergencies, that very same IP architecture, where supported by a rule of law environment, provides all the tools necessary for full and effective participation in the innovation ecosystem, thus enabling allocation of scarce financial resources to risky innovative R&D, facilitating IP licensing for access to critical know-how, and fostering multidirectional technology transfer through contractual partnerships. Continuing negotiations in Geneva to expand the waiver to therapeutics and diagnostics will only serve to further undermine the framework for IP-driven innovation and diminish the world's ability to respond effectively to future pandemics.



Mixed signals: The EU and IP rights

Exhibit 1: The research-based biopharmaceutical industry

As the Index has noted over the past decade, at both the European Union (EU) level and among individual Member States, there is growing uncertainty over the biopharmaceutical IP environment.

On the one hand, many European and national policymakers understand the industry's strategic value and importance as illustrated by the immense contributions and accomplishments in fighting the COVID-19 pandemic. For example, the European Commission recognized the importance of the research-based industry in the 2020 Pharmaceutical Strategy for Europe: "There is a strong and competitive pharmaceutical industry in the EU. Together with other public and private actors, it serves public health and acts as a driver of job creation, trade, and science."¹⁵ The commission is right. As an industry, the research-based biopharmaceutical sector is one of Europe's biggest success stories. European companies are some of the largest, most innovative, and most successful in the world. Not only does this industry have a long track record of producing lifesaving medical innovations that have been, or are currently being, used by millions of patients, but the industry is also an engine of economic growth in the EU. Figures from the European Federation of Pharmaceutical Industries and Associations (EFPIA) show that in 2021, the European research-based industry directly employed around 840,000 people (with over 120,000 in high-skill R&D jobs), invested EUR 41.5 billion in R&D activity, and generated EUR 300 billion in production value.¹⁶

Unfortunately, the strategic value and economic contribution of this industry are not always recognized in the development of IP policies.

To begin with, a high degree of uncertainty continues to surround the availability of patent term restoration in both the **EU** and the **UK**. In July 2019, the supplementary protection certificate (SPC) export and stockpiling waiver entered into force. The waiver allows companies to manufacture generic and biosimilar products in Europe during the effective SPC period for export purposes to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. The SPC manufacturing waiver weakens the scope of the exclusive rights conferred by an SPC and sends a negative signal to the world that the EU is weakening its commitment to IP incentives and innovation. Following the entry into force of the SPC waiver, the score on this indicator was reduced by 0.25 for all EU Member States in the eighth edition of the Index.

Under the terms of its withdrawal from the EU, the UK has maintained the SPC exemption in British law. In 2020, the UK Intellectual Property Office (IPO) held a public consultation on a draft Statutory Instrument that would amend the existing exemption, making it more compatible with UK statute. Unfortunately, despite rightsholders calling for the UK 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 would be operable going forward.

Outside of the EU and UK, the regulation continues to damage international rightsholders. Instead of allowing European generic manufacturers to gain a competitive advantage, other economies are simply emulating the EU. In a wide-ranging set of amendments to the Law on Protection of Rights to Inventions and Utility Models, in 2020, **Ukraine** introduced an export and stockpiling exemption explicitly modeled on EU Regulation 2019/933. Similarly, in 2021, the **Israeli** Ministry of Justice published draft amendments to the Patent Law, "The Patents Law (Amendment No. 14) (Increasing the Competitiveness of the Israeli Economy), 5721-2021." The proposed amendments seek to introduce a manufacturing, export, and stockpiling exemption to the current term restoration regime. Like the Ukraine example, this law refers to and is explicitly modeled on Regulation 2019/933. As the Ukraine and Israel examples show, instead of benefiting the European generics industry, the introduction of the SPC exemption is hurting Europe's research-based industry and has led to a global race toward the bottom in weakening global IP standards.

Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU. As part of the Unitary Patent system and Patent Court, the European Commission issued a "Call for Evidence" consultation in 2022. This document outlines several options for reforming the SPC system, including the potential for introducing a new centralized system of SPC protection and application. At the time of research, no final legislative proposal had been adopted or proposed by the commission. The Index will continue to follow these developments in 2023.

In addition to the SPC system, since 2018, the European Commission has been conducting a regulatory review of the Orphan Regulation and the Paediatric Regulation, which provide special incentives for products developed for rare diseases and children. The regulation includes IP-based incentives and a defined period of market exclusivity. 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 globally for rare diseases.

For example, in the decade before the introduction of special incentives in the United States, only 10 products were approved for market, that is, only one drug per year on average.¹⁷ 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 the development of niche products,¹⁸ 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 the following:



- » Nearly 2,000 orphan designations approved
- » Over 150 orphan medicinal products approved by the European Medicines Agency (EMA) for over 90 rare diseases (up from only 8 orphan products available in 2000)
- » An increase of 85% in the number of rare diseases for which an orphan designation exists in the EU
- » An increase of 88% in clinical research activity on rare diseases between 2006 and 2016, with the EU-5 countries experiencing an even bigger increase of 104% during that period¹⁹

In 2020, the commission published an Inception Impact Assessment with the view of proposing some legislative changes to both the Orphan and Paediatric Regulations. At the time of research, no draft law had been published by the European Commission. Public statements made by commission officials suggest that a final legislative proposal would be presented to the public and European Parliament in the first quarter of 2023.²⁰ When reviewing how and what aspects of the EU Orphan Regulation proposes to change, it is critical that the commission recognize the outlined empirical evidence and positive impact the Orphan Regulation has had over the past two decades. The Orphan Regulation has done exactly what it was intended to do—place more orphan medicines on the EU market. The real challenge facing European policymakers, both regionally and nationally, is to ensure that patients gain effective access to these new medicines. Timely and equitable access to orphan medicines is not guaranteed in the EU, and substantial differences exist among Member States with respect to both the number of products publicly reimbursed and the average time it takes for patients to gain access to them.

This should not be news to the European Commission. In a 2006 assessment report, the commission cited a survey conducted by the European Organisation for Rare Disease (EURORDIS), which found that for a sample of 12 orphan products approved by the end of 2003, only one Member State demonstrated the availability of the entire sample, whereas only half of the sample or less was available in the rest of the then-25 EU Member States.²¹ The report concluded the following:

The full benefits of the EU orphan regulations require optimal synergies between action on Community and on Member State level. Incentives at the European Union level need to be translated into rapid access of patients to the new products throughout the entire Community and they need to be supplemented by incentives at Member States level. In this regard, the past experience was not entirely satisfactory.²²

More recent evidence suggests that not much has changed since 2006. A 2017 study by the Office of Health Economics (a British research institute) compared access to 143 orphan products that were approved for marketing in the EU between 2000 and 2016 across the then EU-5 (including a division among England, Scotland, and Wales that constitute the UK).²³ Overall, the study found the following:

- » Access to authorized orphan products through public reimbursement varied substantially among the sampled Member States, ranging from 93% in Germany to 33% in Wales.
- » The average duration between the granting of marketing authorization by the EMA and reimbursement decision by the national authority was 23.4 months—nearly two years.²⁴

- » The duration is also considerably longer for orphan medicines when compared to nonorphan medicines. For example, in the UK, the median number of months between the marketing authorization and the first NICE appraisal was 20.2 months for orphan medicines compared with 12.7 months for nonorphan medicines.

The bottom line is that the EU Orphan Regulation has been remarkably successful in promoting research into rare diseases and incentivizing the development of orphan medicinal products. IP incentives in other economies—such as the United States—have produced similar positive outcomes. However, the last step—providing patients with rare diseases with actual access to these medicines—is currently the sole responsibility of Member States. As this cited evidence suggests, access to orphan medicinal products is hampered by insufficient reimbursement and long delays, thus resulting in unequal access to care for patients with rare diseases across the EU. Instead of questioning or reviewing the efficacy of the IP incentives enshrined in the Orphan Regulation, the commission and EU policymakers should put more effort and forward thinking into how to address this access barrier more effectively.

This line of thought can also be applied more broadly to access to *all* new and innovative biopharmaceutical products and technologies. The European Commission rightly pointed out in the *Pharmaceutical Strategy for Europe* that “Innovative and promising therapies do not always reach the patient, so patients in the EU still have different levels of access to medicines.” However, just as with access to orphan drugs, substantial differences exist among Member States with respect to both the number of products publicly reimbursed and the average time it takes for patients to gain effective access to them within a given health system. Again, within this context, IP rights play no part. The

design of a given health system’s biopharmaceutical market access policies takes place at the Member State level. Each Member State, through its broader health and biopharmaceutical policies, decides on market access policies and how to control the cost of medicines. Some EU Member States and health systems seek to eliminate barriers to the introduction and use of new products and technologies. Others focus solely on cost containment and do not prioritize patient access to new products and innovation. Proposals for solving the access issue should recognize this fundamental fact that existing IP incentives are not part of the problem.

Since the release of the *2020 Pharmaceutical Strategy for Europe*, the European Commission conducted consultations on the strategy, including impact assessments on the Orphan and Paediatric Regulations and general pharmaceutical legislation. Following the consultations, the commission released a draft Directive and Regulation that includes proposed changes to the EU Pharmaceutical Legislation. Some of the proposed amendments to the EU’s pharmaceutical regulatory framework could further endanger the EU’s leadership position on global IP policy and biopharmaceutical innovation. Among the more troubling provisions are proposals to condition RDP on external factors beyond companies’ control, such as requiring simultaneous launch of new products in every member state, despite disparate approval and pricing timelines.

Specifically, the proposals suggest reducing the baseline term of RDP by two years (from eight to six), with restoration of these lost years of protection contingent upon a number of factors. A year of data protection can be restored if the medicine is launched in all 27 Member States within two years of marketing authorization or if the medicine meets an unmet medical need (which is narrowly defined), respectively.



Additionally, six months of data protection can be added if a relevant and evidence-based comparator is used during the pivotal clinical trials, but the cumulative total of these protection periods is capped at 8 years.

Such “conditionality” of IP or regulatory protection establishes a counterproductive precedent as it makes the availability of such protection contingent upon external factors, including market access. This approach fails to consider factors that determine market access within individual European countries outside the control of companies, including different national regulatory requirements and the varying speed of pricing and reimbursement negotiations.

Furthermore, the proposals include provisions to expand the Bolar Exemption to include health technology assessment (HTA) and pricing and reimbursement processes. Such an expansion of the Bolar exemption is out-of-step with other OECD economies and would be a significant shift beyond allowing generic or biosimilar manufacturers to use a patented product only as needed to demonstrate the bioequivalence or biosimilarity of their product to the innovator product to secure marketing authorization. The expansion of the Bolar exemption to include HTA and pricing and reimbursement processes could further undermine patent enforcement in the EU and trigger automatic price adjustments for innovative products due to the premature launch of patent-infringing generics or biosimilars. It is imperative that any revisions to the European legislation not undermine patent enforcement in the EU and are consistent with international trade commitments, including the WTO TRIPS agreement.

Any changes to the Bolar Exemption must respect the underlying rationale, which was to ensure that generic or biosimilar manufacturers were not unduly delayed from launching their products

due to the need to demonstrate the safety and efficacy of their medicines. The exemption also sought to create a balanced mechanism that includes measures to ensure that innovators are not prejudiced by such delays by SPCs. The proposed expansion of the exemption, coupled with the existing SPC manufacturing waiver, could further undermine the framework for biopharmaceutical innovation in the EU. The European Commission will formally introduce the Pharmaceutical Legislation in the spring of 2023. The Index will closely monitor the proposed strategy for its impact on the innovation ecosystem in the EU.

Finally, at both the Member State level and EU level, there has been a growing focus on exploring compulsory licensing for biopharmaceuticals. In 2017, health authorities in the **Netherlands** promised to explore the use of compulsory licensing for medicines whose price was deemed excessive, acting on the advice included in a report by the Council for Public Health and Society (*Development of New Medicines—Better, Faster and Cheaper*), which encouraged the use of compulsory licensing to strengthen the government’s position in price negotiations.

In **Hungary**, the government introduced an expedited compulsory licensing mechanism for biopharmaceuticals in 2020. In a separate development, a Hungarian manufacturer later that year 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 show the trial was supported by the Hungarian government (the Ministry of Innovation and Technology through a consortium). Industry sources suggest that a compulsory license was granted by the Hungarian authorities in late 2020.

In 2022, the European Commission issued a “Call for Evidence” and public consultation on the current compulsory licensing regime across the EU,

although the rationale is difficult to understand. Each individual EU Member State has national laws in place that address compulsory licensing in line with their WTO commitments. The commission posits in the “Call for Evidence” that there is a pressing need for “coordination and harmonization” at the EU level on compulsory licenses but provides no actual evidence that this is the case. The document simply asserts that the COVID-19 pandemic shows the need for clearer and more “effective” compulsory licensing mechanisms:

The COVID-19 pandemic has underscored the importance of having a strong and balanced IP system (to provide the necessary incentives to develop new treatments and vaccines) and a suitable framework (for sharing technologies, know-how and data). It has also triggered many debates, at national, EU and multilateral level, on the need for effective IP tools to ensure proper and global access to essential technologies in a crisis. Close public-private cooperation based on voluntary solutions for sharing the relevant IP and know-how, e.g., licensing or manufacturing agreements, is the fastest and most effective way to develop and scale up the production of critical medicine and medical supplies. **However, if voluntary arrangements between right holders, third parties (such as manufacturers) and public authorities fail or are unavailable, the use of last-resort tools, namely compulsory licensing, might be needed. A compulsory license issued by a government authorises a party other than the patent holder to use a patented invention without the consent of the patent holder. In particular during a crisis, these tools must be effective to make an orderly EU response possible.**²⁵

But, if anything, the actual evidence and experience from the COVID-19 pandemic show the complete

opposite. As detailed here, the much-discussed proposed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have proven to be completely unnecessary and wholly pointless. The waiver seeks to address a problem of vaccine shortages that does not exist, and no WTO Member appears to be making use of it. Similarly, with respect to compulsory licenses, only one was issued during the pandemic to specifically address a perceived shortage of medicines, and the generic product was never used. However, other licenses were issued on the basis of addressing the cost of a given treatment as opposed to its availability.

The **Israeli** government authorized a compulsory license for the antiviral drug lopinavir/ritonavir in 2020. As noted in previous editions of the Index, when the license was issued, limited clinical evidence showed that lopinavir/ritonavir would be an effective treatment against COVID-19 . After the issuing of the license and importation of generic product from India, no information is publicly available that suggests the generic product was ever distributed to Israeli patients with COVID-19.

Much like the WTO TRIPS waiver, the European Commission’s fascination with expanding involuntary mechanisms for sharing IP through a more “effective” compulsory licensing mechanism is not based on real-world data and need. More broadly, threats and the use of compulsory licensing of medicines as a basis for price negotiations are usually associated with low-income economies with underdeveloped health systems and limited financial resources, not high-income EU Member States with advanced sophisticated health systems.

Issuing a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights, in place to foster investment in biopharmaceutical innovation. Cost is not a relevant justification or basis for compulsory licensing or the overriding of any



granted form of biopharmaceutical exclusivity. Moreover, the use of these types of licenses threatens the very foundation of the EU's position as a global leader in innovation and high-tech industries, including biopharmaceuticals. As the cited data from EFPIA show, as an industry, the research-based biopharmaceutical sector is one of Europe's biggest success stories and includes some of the largest, most innovative, and most successful research-based biopharmaceutical companies in the world. More broadly, the overriding of biopharmaceutical IP rights based on cost and price negotiations sets a wholly negative precedent that may be applied to other industries and sectors. If the EU or individual Member States wish to pay less, or nothing, for medicines using compulsory licenses, it is possible this could be applied next to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases. The Index will monitor these developments in 2023.

Exhibit 2: One step forward and two steps back? The EU's Digital Services Act Package and the digital economy

Over the past two years, the European Commission has been working on a large legislative package regulating digital and internet-based commerce and the provision of related services. The package consists of two new pieces of legislation: the Digital Markets Act (DMA) and the Digital Services Act (DSA). At the time of this research, both acts had been approved by the European Parliament and the European Council. The laws will come into effect on a rolling basis during 2023 and 2024. Both the DMA and DSA introduce substantive changes to the EU's internal market and how digital products and services are produced and traded. Like the General Data Protection Regulation (GDPR), the effect of both laws will stretch beyond the borders of the European Union. The DMA focuses primarily on regulating the activities

of large online platforms and service providers, so-called digital gatekeepers. The law imposes significant compliance and reporting requirements on gatekeeper entities with most of the legislation being delegated to the entity level in the form of self-regulation. Relevant entities—and future potential gatekeepers—are expected to assess and monitor their own compliance under the law and to regularly report to the European Commission. The DMA gives the commission significant powers and the ability to, under Article 30, fine an entity found to be in noncompliance with the law of up to 10% of annual global turnover or as much as 20% in cases of repeat offenders. The DMA's focus on market size and power means that the legislation does not differentiate between the regulatory needs of different businesses and types of digital service providers. Instead, all identified digital operators that match the relevant market power and size definitions under the law must comply with all provisions or risk potential fines and penalties.

Like the DMA, the DSA fundamentally changes how the digital economy operates in the EU. It is also a sprawling piece of legislation granting vast regulatory and monitoring powers to both the European Commission and national regulators. The law is full of definitions and categorizations of different providers of online “intermediary services,” including “caching, mere conduit, hosting, online platforms, very large online platforms, and very large online search engines.” Some of these categories are transplanted from preexisting definitions under the E-Commerce Directive, whereas others are new. Like the DMA, these categories impose various levels of compliance obligations and responsibilities. Generally, the larger the service provider, the more extensive its responsibilities. However, as the regulation's preamble itself acknowledges, these categories are fluid, and entities may, at different moments, be one or another or a combination of these categories with differing levels of accompanying

compliance and reporting responsibilities: “Intermediary services may be provided in isolation, as a part of another type of intermediary service, or simultaneously with other intermediary services. Whether a specific service constitutes a mere conduit, caching or hosting service depends solely on its technical functionalities, that might evolve in time, and should be assessed on a case-by-case basis.” Consequently, an entity's legal obligation and responsibilities may change rather significantly depending on what category of service provider the entity was at a given moment. From an IP rights perspective, one of the key features of the legislation is an updated definition of what an intermediary service provider's responsibilities and liabilities are with regard to illegal and IP-infringing content. As noted over the course of the Index, historically, the EU's E-Commerce Directive combined with other relevant laws (such as the Copyright Directive 2001/29/EC) and their national transposition have defined relevant safe harbors and under what circumstances intermediaries lose relevant protections across EU Member States. In principle, the concept of a safe harbor exemption was available to relevant intermediaries as long as they:

1. did not actively participate in any infringing activity; and
2. once made aware of the infringement, acted expeditiously to remove or disable access to the alleged infringement.

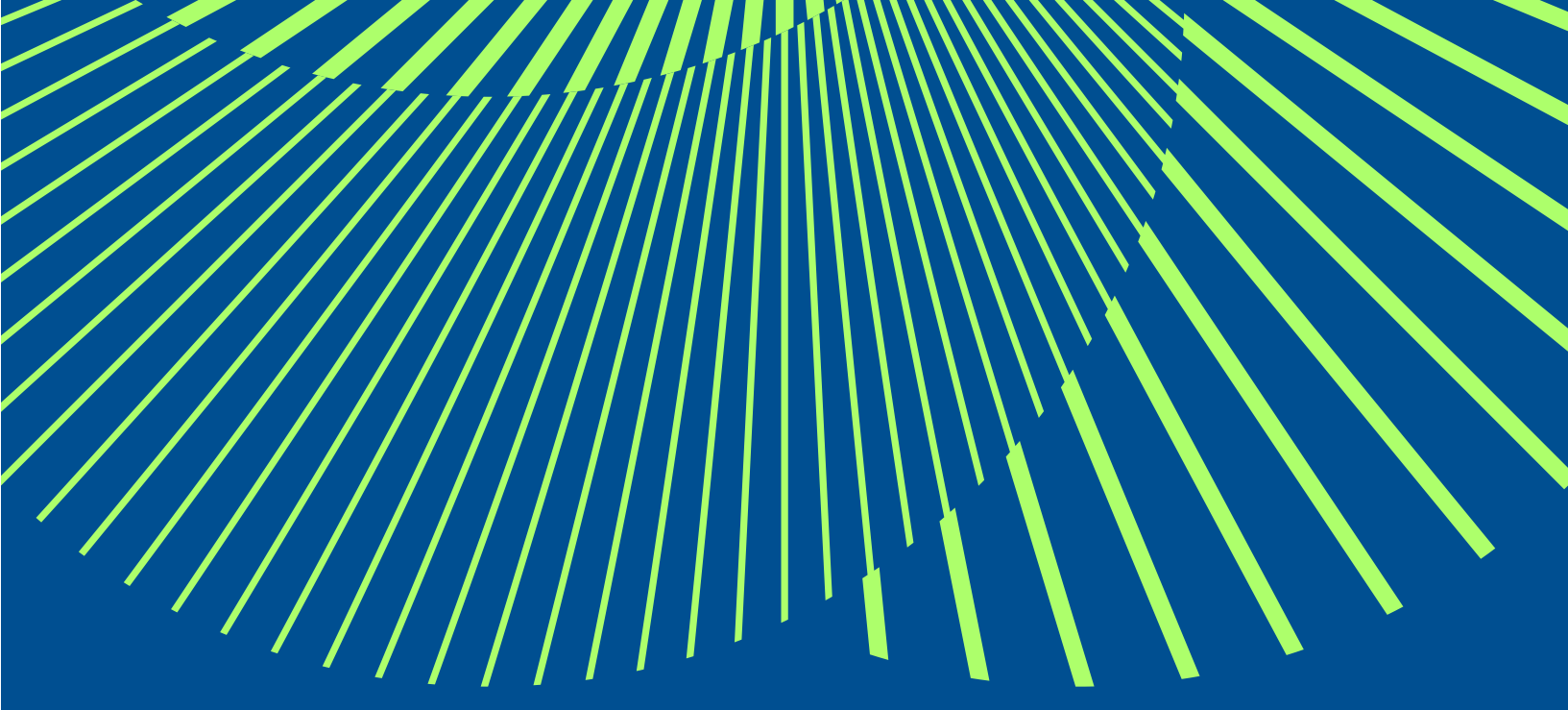
Although the law is more than 20 years old, the rationale behind it remains sound: a desire to balance the need to effectively address potential illicit activity (including the infringement of IP rights) without unduly overburdening intermediaries. However, the world in 2023 is very different from that of the early 2000s. Today, internet penetration and the use of mobile devices are almost ubiquitous across Europe and much of

the developed world. For IP-intensive industries, the shift from the physical to the digital has meant both a change in how IP infringement takes place and scale. Consequently, a growing proportion of IP infringement takes place online. Indeed, the explosion in copyright infringement over the past two decades—whether through downloading, streaming, or some other technology—has mirrored and followed the growth in internet and mobile connectivity. Similarly, the increasing popularity of online shopping has led to a marked growth in the sale of physical counterfeit goods through online marketplaces. The result is that rightsholders both in Europe and globally face a reality where they have little practical recourse against the infringement of their rights. Unfortunately, the DSA does not take this new reality into account. Although the law includes some added responsibilities for intermediaries, particularly larger entities, and an important obligation of online marketplaces to enhance the “traceability of traders” using their platforms, the DSA does not fundamentally change the dynamics of IP enforcement online. It is also unclear how many of the new mechanisms introduced in the law will work in practice. For instance, although the law gives all individuals and entities the right under Article 14 to lodge notifications of illegal content to predefined categories of intermediaries, notifications filed by designated “trusted flaggers” are to be “processed and decided upon with priority and without undue delay.” But given the sheer scale and volume of illegal and IP-infringing content on the internet, what will happen with notifications filed by non-trusted flaggers? Will such notices be addressed in an expeditious fashion or deprioritized by intermediaries in favor of notices filed solely by trusted flaggers? As currently drafted, that is a logical and not unlikely outcome. Furthermore, although the creation of the trusted flagger concept may help standardize and professionalize the notification process, it may also prove to be largely ineffective and, in

fact, act as a barrier to effective enforcement. The creation of what is, in effect, an online enforcement gatekeeper adds a hurdle and layer of bureaucracy to an already elaborate enforcement process.

There is also the question of the process of designating a trusted flagger. Under Article 19 of the DSA, any entity can be designated as a trusted flagger if it fulfills certain defined criteria. However, the authority for determining which entities qualify lies at the national level and the relevant regulatory authority in each EU Member State, a new body to be called a digital services coordinator. Because the DSA vests so much power and authority in the trusted flaggers, the practical result is that levels of online enforcement will indirectly depend on the effectiveness of each individual Member State's digital services coordinator and their capacity to both expedite the trusted flagger designation process and any investigations and/or disciplinary proceedings for trusted flaggers that have potentially misused or have failed to effectively use their powers. Under such a scenario, instead of harmonizing the digital market in the EU, as is the overarching goal of the DSA, the law will simply produce a postcode lottery across Member States whereby rightsholders' abilities to enforce their IP rights online will rely not on harmonized EU standards but instead on the individual national capabilities of a new regulatory authority.

Finally, it is unclear how the DSA will in practice interact with other EU statutes, specifically Directive 2019/790 on copyright and related rights in the Directive on Copyright in the Digital Single Market (CDSM Directive). As noted in previous editions, the CDSM Directive strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. It also provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability. Although the DSA in its preamble states that the regulation "is without prejudice to the rules of Union law on copyright and related rights...which establish specific rules and procedures that should remain unaffected," at the time of research, those "rules and procedures" had yet to be defined and transposed at the national level in all EU Member States. In conclusion, and like the GDPR, both the DMA and DSA greatly expand the authority and rule-making power of the European Commission over vast parts of the European and, per extension, the global economy. The sprawling nature of the legislation and the inclusion of such a high number of exceptions, carveouts, categorizations, definitions, and determinations to be made on a case-by-case basis will almost guarantee that once operational, the law will have a whole host of unintended consequences both in Europe and beyond. Overall, it remains to be seen whether these new laws will materially improve IP rightsholders' position and ability to protect and enforce their rights in the EU. The Index will continue to monitor these developments in 2023.



Overall Results and Category-by-Category Scores

Up or down? How have economies fared in this edition of the Index? Table 3 shows the overall results for the eleventh edition of the Index and how they compare to last year's edition.

Table 3: Change in Overall Score, Tenth Edition Versus Eleventh edition

Country	Eleventh Edition	Tenth Edition	Change in Overall Score
United States	95.48%	95.48%	0.00%
UK	94.14%	94.14%	0.00%
France	93.12%	92.10%	1.02%
Germany	92.46%	92.46%	0.00%
Sweden	92.14%	92.14%	0.00%
Japan	91.26%	91.26%	0.00%
The Netherlands	90.70%	90.70%	0.00%
Ireland	89.36%	88.84%	0.52%
Spain	86.44%	85.94%	0.50%
Switzerland	86.00%	86.00%	0.00%
Singapore	84.94%	84.44%	0.50%
South Korea	84.44%	83.94%	0.50%
Italy	83.90%	83.40%	0.50%
Australia	80.68%	80.70%	−0.02%
Hungary	76.90%	76.90%	0.00%
Canada	75.72%	75.24%	0.48%
Israel	72.72%	72.74%	−0.02%
Greece	70.92%	70.92%	0.00%
Poland	70.74%	70.74%	0.00%
New Zealand	69.28%	69.28%	0.00%
Taiwan	66.31%	66.29%	0.02%
Morocco	62.26%	59.76%	2.50%
Mexico	58.98%	58.98%	0.00%
China	57.86%	55.86%	2.00%
Costa Rica	54.56%	54.56%	0.00%
Dominican Republic	54.28%	54.28%	0.00%
Malaysia	53.44%	51.90%	1.54%
Turkey	51.07%	51.07%	0.00%
Peru	49.82%	49.32%	0.50%
Chile	49.72%	48.72%	1.00%
Colombia	48.84%	48.84%	0.00%
UAE	46.00%	46.02%	−0.02%
Jordan	44.70%	44.70%	0.00%
Saudi Arabia	42.38%	41.38%	1.00%
Honduras	42.16%	42.18%	−0.02%
Brazil	42.02%	42.02%	0.00%
Philippines	41.58%	41.58%	0.00%
Brunei	41.08%	41.08%	0.00%
Ghana	40.88%	40.88%	0.00%

Country	Eleventh Edition	Tenth Edition	Change in Overall Score
Vietnam	40.74%	38.72%	2.02%
Ukraine	39.74%	39.74%	0.00%
India	38.64%	38.64%	0.00%
Thailand	38.28%	35.78%	2.50%
Kenya	37.36%	37.38%	−0.02%
South Africa	37.28%	37.28%	0.00%
Argentina	37.00%	37.02%	−0.02%
Nigeria	33.34%	31.34%	2.00%
Egypt	32.82%	32.82%	0.00%
Ecuador	30.68%	30.70%	−0.02%
Indonesia	30.42%	30.42%	0.00%
Kuwait	28.42%	27.92%	0.50%
Pakistan	27.42%	27.43%	−0.01%
Algeria	26.36%	26.36%	0.00%
Russia	25.02%	46.64%	−21.62%
Venezuela	14.10%	14.10%	0.00%

Unlike the previous two editions of the Index, where most economies saw their overall scores improve, most economies in 2022 saw no or only marginal changes to their national IP environments. Of the 55 economies included in the tenth and eleventh editions, this year, there was no score change in 28 economies, 18 economies saw an improvement, and in 9 economies the overall Index score dropped. This compares to last year when an overwhelming majority of economies (85%) saw a net improvement in their overall scores. Two of those economies in the tenth edition of the Index—**Nigeria** and the **United Arab Emirates (UAE)**—saw sizeable improvements of 3.94% and 4.04% in their overall scores, respectively. This year, the highest total percentage increase was 2.5%, achieved by the economies of **Morocco** and **Thailand**. Similarly, oof the nine economies whose scores dropped, only one, **Russia**, saw a drop of more than 2%.

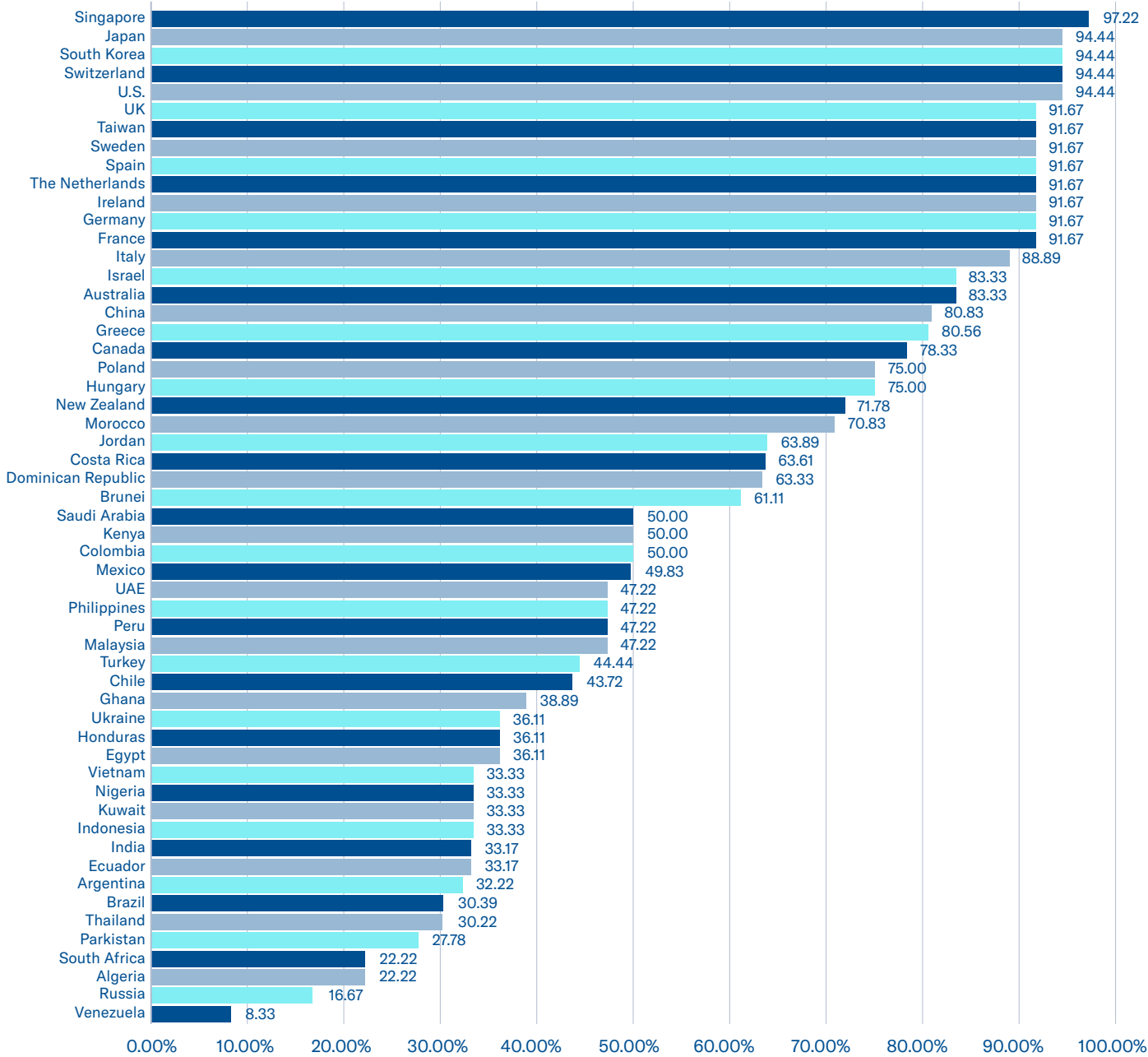
As detailed in its Economy Overview, Russia saw a historic drop of 21.62% in its overall Index score. This is the largest single-year drop recorded in the 11 years of the Index. It comes as the result of Russian authorities largely suspending the protection of IP rights through a series of countersanctions targeting international rightsholders after the invasion of **Ukraine** and the imposition of international political and economic sanctions.

However, the lack of large movements in overall scores does not mean that the global IP environment in 2022 stood still. As the following subsections and the individual Economy Overviews detail, many economies saw significant increases and, in many cases, decreases on individual Index category scores. Furthermore, a striking number of Index economies also put forward policy proposals—both positive and negative—that, if implemented, would amount to substantial overall score changes in coming editions of the Index.

Category 1:
Patents, Related Rights, and Limitations

Figure 1 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.

Figure 1: Category 1: Patents, Related Rights, and Limitations, % Available Score



As in past editions, the overall results for Category 1 are still one of the strongest of all the categories included in the Index. Twenty-three economies achieve a score of 70% or more of the available score, and 30 economies in total achieve a score of 50% or more. The average score in the category is 59.31%, which is the fifth highest scoring category in the Index. As in years past, **Singapore** is ranked number 1, 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 patent-eligible 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 U.S. Patent and Trademark Office (USPTO). Since the Supreme Court decisions in the *Bilski*, *Myriad*, *Mayo*, and *Alice* cases, there has been a high and sustained level of uncertainty about which inventions and discoveries are eligible for patent protection 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 rightsholders 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. The USPTO has recognized this dilemma and has sought to reformulate its position and the approach to be taken by its examiners.

In 2019, the office released new guidance covering Section 101 (patent eligibility) and Section 112 (functional claims) related to computer inventions, the “2019 Revised Patent Subject Matter Eligibility Guidance” (“The Guidance”) and “Examining Computer-Implemented Functional

Claim Limitations for Compliance with 35 U.S.C. 112.” With respect to Section 101 (subject matter eligibility), the guidance provided more of a principle-based analysis of how eligibility would be judged and described the stepwise approach examiners should follow to understand and apply the Supreme Court’s *Alice* and *Mayo* test. As the Guidance rightly pointed 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 Guidance recognized this and sought to clear this up with a revised procedure and process for examiners to follow, to the extent possible without further statutory changes. The USPTO also introduced a “Deferred Subject Matter Eligibility Response pilot program” in response to requests from Congress.

In 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 examined 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 found that, overall, since the introduction of the Guidance, there has been a 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 after the introduction of the Guidance. As the USPTO rightly noted at the time of publication, this is positive news.

Unfortunately, as noted by the Index, uncertainty over what constitutes patent-eligible subject matter has crept into all facets of the American patent system—from initial application and examination to standards of review and invalidity proceedings, whether administratively through the PTAB or through the judiciary. For example, with respect to

the influence and use of the USPTO’s Guidance, the U.S. Court of Appeals for the Federal Circuit has expressly, and repeatedly, stated that the Guidance does not carry the force of statutory law or relevant case law and is therefore not a controlling factor in any patentability analysis carried out by the court.

Efforts to address this fundamental problem in the U.S. patent system continued within both the executive and legislative branches of the federal government in 2022. The USPTO, under the new leadership of Director Kathi Vidal, issued several requests for comments on issues pertaining to patentability, patent-eligible subject matter, and related UPSTO processes and procedures. In June, the agency published *Patent-Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States*. This report, requested by a bipartisan group of senators, details the results of stakeholder feedback gathered in 2021 on the state of patent-eligible subject matter in the United States. After publication of this report, the agency announced that it will seek feedback on current examination practices as captured in the relevant sections of the patent manual (Manual of Patent Examining Procedure 2106).

In a separate development, the USPTO issued a request for comments on *USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights* in October 2022. This follows requests from both the White House and Congress. Specifically, in July 2021, President Joe Biden issued the Executive Order on Promoting Competition in the American Economy. Alleviating anticompetitive behavior in several sectors of the economy, the order asks the FDA and the USPTO to examine the extent to which the patent system “while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.”

As illustrated by the lifesaving innovation and product development witnessed during

the COVID-19 pandemic, biopharmaceutical breakthroughs by American firms are improving health treatment for patients globally and are providing a steady stream of new drugs and health technologies. American research-based biopharmaceutical firms spent an estimated USD 72.4 billion in 2020 on R&D domestically in the United States. This leadership in global biopharmaceutical research and manufacturing also translates into large economic dividends for Americans. Revenues generated by a new blockbuster drug are comparable to the export of 1 million cars. The sector also accounts for and supports 4.5 million jobs.

The basic economics of the biopharmaceutical industry show how critical IP rights are to incentivize and support the development of new medical technologies and products. Research from Tufts University published in 2016 suggests that it costs USD 2.6 billion, on average, to develop a new drug. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will pass through all stages of R&D and will go on to become a marketable drug. Patents and other forms of exclusivity for biopharmaceuticals, such as RDP and special exclusivity incentives for the protection and production of orphan drugs, enable research-based companies to invest these vast sums in R&D and the discovery of new drugs, products, and therapies. It has been clear for many years that American taxpayers and patients are concerned with the cost of prescription medicines and have asked their elected representatives to take appropriate action. However, the cost of drugs is a complex subject that does not lend itself to generalizing. It involves many factors such as health system infrastructure; health financing; and how the American health system itself is organized, financed, and accessed by patients. Within this cost equation, the protection of IP plays a relatively small role. Instead of achieving the goal of lowering costs, proposals that undermine the incentives

that make biopharmaceutical R&D and investment possible risk the very model of innovation that since the mid-1980s have been providing Americans, and patients around the world, with new and better health technologies and medicines.

Finally, in August 2022, Sen. Thom Tillis (R-NC) introduced the Patent Eligibility Restoration Act of 2022. Sen. Chris Coons (D-DE), the chair of the Senate Judiciary Committee Intellectual Property Subcommittee, cosponsored the legislation in September 2022. The proposed legislation marks a significant breakthrough on the legislative front. As Sen. Tillis stated in conjunction with the release of the draft act, “[P]redictable patent rights are imperative to enable investments in the broad array of innovative technologies that are critical to the economic and global competitiveness of the United States, and to its national security.” At the time of research, the proposed act had not been passed by Congress or signed into law by President Biden, but it was referred to the Senate Judiciary Committee for consideration that August.

As noted, this level of uncertainty with respect to patentable subject matter is compounded by a sustained level of unpredictability with respect to post-grant opposition and patent nullity proceedings. 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 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 IPR, which occurs before the PTAB. As noted over the course of the Index, the U.S. government (chiefly through the USPTO) has recognized the unintended effects of the PTAB system and has publicly pledged to work with all stakeholders to address and remedy them. As a result, many important changes have since been introduced.

Examples of these reforms include (1) changing the patent claim construction standard used, moving away from the broadest reasonable interpretation standard to the *Phillips* standard, 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 in U.S. district courts.

Similarly, 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 have 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 USPTO 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 related to the USPTO’s 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*). The U.S. Supreme Court has also been active in shaping how PTAB proceedings take place with several important decisions rendered, including in *SAS Institute Inc. v. Iancu*, *Thryv, Inc. v. Click-to-Call Technologies, LP, et al*, and *Arthrex, Inc. v. Smith & Nephew, Inc*. These efforts have continued in 2022. That June, the USPTO issued a memorandum on PTAB’s decision-making capacity and factors assessed when deciding whether to institute an AIA post-grant proceeding. This was followed up in July with a public consultation and request for comments on several issues pertaining to the PTAB. Several precedential decisions were also issued with respect to director review in the fall and winter of 2022. Similarly, Congress has held hearings, and

several proposals for draft legislation amending the PTAB process have been put forward. At the time of research, no legislative proposals had been passed by Congress or signed into law by President Biden.

In other economies, rightsholders also continued to face uncertainty and a challenging environment.

As detailed over the course of the Index and 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 **UK**. Regulation 2019/933 remains in force, and the SPC export exemption is legal and operational in all EU Member States. With respect to the **UK**, although the British government now has the sovereignty and power to effectively shelve Regulation 2019/933, it has instead chosen to maintain the EU SPC exemption.

In **Brazil**, rightsholders continue to face many basic challenges in registering and protecting patent-eligible subject matter with patentability standards for both biopharmaceutical technologies and computer-implemented inventions (CIIs) outside international norms. Although some CIIs have been granted, generally speaking, computer-related inventions and software are viewed as being nonpatentable subject matter. A new set of patent guidelines published by the Brazilian Patent Office (Instituto Nacional da Propriedade Industrial) (INPI) in 2021 provides some clarifications and examples on existing patentability standards for CIIs (including the fact that CIIs related to artificial intelligence [AI], machine learning, and the Internet of Things may be patentable subject matter). However, overall, these new guidelines do not fundamentally change existing standards. More broadly, across all economic sectors and patent arts, INPI has historically had a backlog of patent applications ranging from 10 to 13 years depending on the field of technology; applications in the biopharmaceutical and information and communication technology (ICT) fields have

traditionally been the worst affected. The past few years have seen a growing level of commitment and efforts by INPI to finally address this backlog. These actions have had a positive impact and have reduced the number of pending applications. At the time of research, the estimated backlog was just under 20,000 applications, down from over 147,000 in 2019. Still, substantial backlogs remain in place, particularly for high-tech industries. Given that INPI has historically struggled to effectively address the extensive backlog and long delays in application processing, the Industrial Property Law had up until 2021 provided innovators in Brazil with a guaranteed minimum term of exclusivity and protection of 10 years from *grant* for standard patents. For years, this provided rightsholders with a proverbial floor of exclusivity and insurance against INPI's endemic delays. However, in a series of decisions in 2021, the Brazilian Supreme Court removed this floor. Not only did the court declare that Article 40 was unconstitutional and would no longer be available or applicable, but the court also stated that the ruling should be retroactively applied but only to granted patents in the biopharmaceutical and health-related fields.

As noted last year, the ruling is a grave blow to Brazil's national IP environment with thousands of biopharmaceutical rightsholders discriminated against and exclusivity periods cut short. Through this decision, not only has the Brazilian Supreme Court further weakened Brazil's already weak standards of patent protection, but the selective retroactive application of the ruling to one field of technology and innovation is a gross violation of Article 27(1) of the TRIPS treaty and established international principles of nondiscrimination. To address this negative impact, in July 2022, Alexis Fonteyne, a member of the Brazilian Chamber of Deputies, presented draft legislation that would provide a period of patent term restoration due to administrative delays during patent examination and prosecution. The enactment of such legislation would be a positive step and

would help counter the negative impact of the Supreme Court's decisions. However, at the time of research, no new legislation had been passed. The Index, again, urges the Brazilian government and lawmakers to immediately address this issue.

Many Index economies also continue to expand and apply definitions of compulsory licensing for biopharmaceuticals that are outside international standards.

In November 2021, the **Indonesian** government issued a government use license for patents related to a COVID-19 treatment. Although the license cites the urgent need to access the medicine, the treatment had already been made available through the patentee's voluntary licensing program. As noted last year and detailed here under Indonesia's Economy Overview, this is the latest negative development that weakens what was already a highly challenging national IP environment for biopharmaceutical rightsholders.

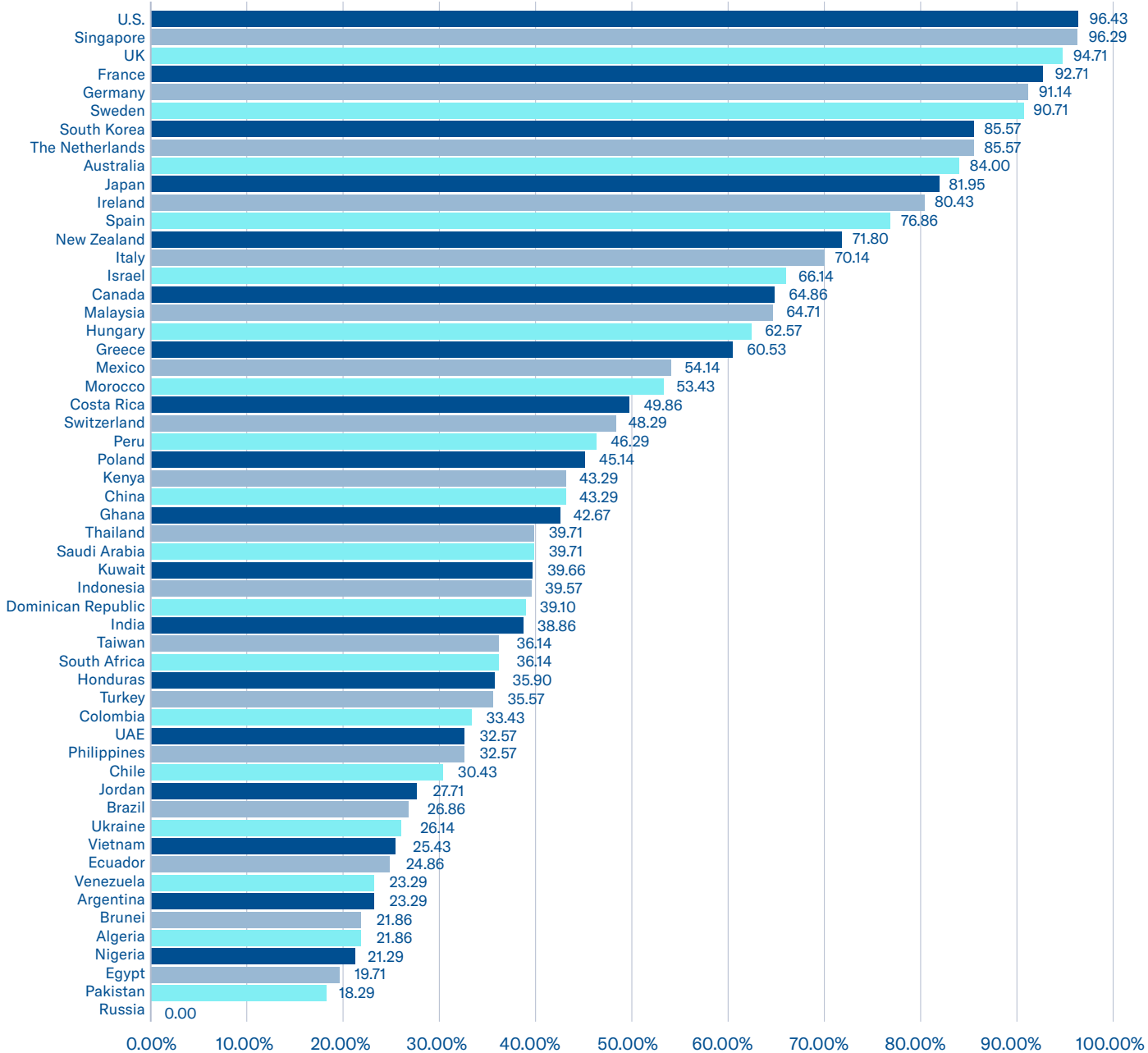
Similarly, in late 2021, an application for the issuing of a compulsory license for the COVID-19 oral antiviral drug Paxlovid was filed with the **Dominican Republic's** Ministry of Health and

national IP office (La Oficina de la Propiedad Industrial). It is unclear on what practical grounds and health emergency the compulsory license application in the Dominican Republic is based. The Dominican Republic ended all COVID-19-related public health restrictions in February 2022. Mortality data compiled by Johns Hopkins University of Medicine in the Coronavirus Resource Center suggest that in the first half of 2022, there had been fewer than 50 total deaths from COVID-19 in the Dominican Republic. Just under 16 million doses of the COVID-19 vaccine had been administered in the population of 11 million, and an estimated 55.43% of the entire population was fully vaccinated with multiple doses. Unlike many other economies in Latin America, the Dominican Republic has no history of using compulsory licensing or the threat of compulsory licensing or similar "declarations of public interest" as biopharmaceutical cost containment tools. Compulsory licensing is not a cost containment tool; cost is not a relevant justification or basis for compulsory licensing under the TRIPS agreement. At the time of research, no license had been granted.

Category 2: Copyrights, Related Rights, and Limitations

Figure 2 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.

Figure 2: Category 2: Copyrights, Related Rights, and Limitations, % Available Score



Historically, Index economies have not performed well in Category 2. This remains the case for the eleventh edition; the average score in the category remains virtually unchanged—49.70% this year compared to 49.57% in last year’s Index. However, in a positive development, the number of economies achieving 50% or more of the available score has increased substantially. In the tenth edition of the Index, 34 of the 55 economies sampled fail to reach 50% of the available score. This year, that has decreased to 25 economies. Consequently, the number of economies achieving a score of 50% or more has increased from 21 to 30. As detailed here and in the individual Economy Overviews, many Index economies saw notable improvements to their copyright environments after legislative reforms and/or stronger enforcement measures. Although challenges remain, this is an important and positive achievement.

One driver of this development and improvement in the Index is the development and increased use of injunctive-relief mechanisms. Ten years ago, rightsholders across the globe were struggling to effectively enforce their copyrights against online piracy. Beginning in the mid- to late 1990s, advances in computer-based technology and the advent of the internet fundamentally changed how creative goods are consumed and accessed by consumers. In a growing number of the world’s economies, internet penetration and the use of mobile devices are almost ubiquitous. Even in developing economies that often lack sophisticated technological infrastructure, consumers can access a growing range of digital services and content through the use of mobile devices. The growth and scale of online piracy since the late 1990s—whether through downloading, streaming, or some other technology—have mirrored this growth in broadband and mobile device connectivity. This scale and volume of online infringement have resulted in a growing burden on rightsholders to effectively protect their content and economic rights. However,

beginning in the early 2010s, rightsholders have identified and successfully applied a new tool in this battle: injunctive-style relief.

Injunctive-style relief gives rightsholders the ability to seek redress for an infringement of copyright either through a court of law or, administratively, with a government authority. The mechanism can look different and work differently depending on the legal jurisdiction, but the result is an order to disable access to the infringing content. The past decade has seen a sharp increase in the number of economies that use this type of mechanism to effectively disable access to infringing content. Today, many **EU Member States, the UK, India, Singapore**, and a host of other Index economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, **Netherlands, Greece, Singapore, India**, and the **UK**.

This positive trend of stronger copyright enforcement continued in 2022.

As noted over the past five editions of the Index, **Peru’s** national IP office, Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual (INDECOPI), has begun to more regularly act against infringing websites and has ordered the disabling of access to copyright-infringing materials. In 2017, INDECOPI ordered the suspension of access to the infringing website *Foxmusica*. Similarly, in 2019, the agency disabled access to six websites at the request of Spanish soccer association *La Liga*. The same year, INDECOPI also ordered the e-commerce

platform *Mercado Libre* to remove the links to 28 ads offering counterfeit products linked to the Pan American Games. In 2021, the agency announced that it had ordered the disabling of access to 10 stream-ripping websites as well as several websites specializing in the unauthorized reproduction and illegal streaming of live sporting events, including professional soccer matches. This action continued in 2022. In July 2022, INDECOPI ordered the suspension of access to 147 websites that provide direct or indirect access to copyright-infringing content. The agency also concluded new training and information-sharing agreements with both the International Federation of the Phonographic Industry and *La Liga*. This marks another year of Peru’s score improving in this category of the Index. Since the seventh edition of the Index, Peru’s score in this category has increased by close to two-thirds, rising from 28.43% in the seventh edition of the Index to 46.29% in this year’s edition. This is due to INDECOPI’s sustained effort at disabling access to infringing content.

In **Brazil**, the past few years have seen a concerted effort to tackle online piracy more effectively. In 2019, the Brazilian government launched Operation Copyright. In 2020 and 2021, the government began Operation 404 Against Piracy. Spearheaded by a special police enforcement unit, the Ministry of Justice, and with international support from the U.S. Embassy and UK law enforcement officials, this special enforcement effort had direct and tangible results. Hundreds of websites and applications offering copyright-infringing content have been shut down, and over 50 search-and-seizure warrants have been issued and executed across 12 Brazilian states with several arrests made.

In 2022, these efforts continued in full force. Media reports suggest that over 500 websites and piracy applications were taken down through the efforts of Operation 404 during the summer months. In a separate development, in August 2022, the heads of Anatel (the National

Telecommunications Agency) and Ancine (the national Film Agency) announced the signing of a cooperation agreement that has the potential to put in place a new administrative injunctive-relief mechanism targeting online piracy. Under the proposed agreement, the two agencies would work together and would disable access to infringing content available online and streamed through set-top boxes. Should the Brazilian authorities move forward and make available a similar mechanism, it would mark a significant positive turning point for creators and rightsholders in Brazil.

In May 2022, the **Canadian** Federal Court issued a dynamic injunction order in the case *Rogers Media Inc. v. John Doe 1*. The order requires Canadian internet service providers (ISPs) to disable access to infringing content online—in this case, the illegal live streaming of National Hockey League matches—identified by the rightsholders in real time. The order is the first of its kind and, if followed by similar rulings, will finally give rightsholders in Canada an effective way of enforcing their rights without delay. In a separate development, in March 2022, the Supreme Court of Canada denied Teksavvy Solutions’ request of appeal with regard to an earlier ruling by the Federal Court of Appeal. The appeal relates to the 2019 case *Bell Media Inc. v. GoldTV.Biz*, in which a Canadian court for the first time ordered a group of ISPs to disable access to websites hosting alleged infringing content. The ruling was upheld by the Federal Court of Appeal in 2021. The Supreme Court’s decision not to hear the case should remove any lingering uncertainty about whether injunctive relief and the disabling of access to infringing content through judicial orders are an acceptable legal pathway of enforcement available to Canadian rightsholders.

In the **United States**, the U.S. District Court for the Southern District of New York in April 2022 issued injunction orders ordering U.S. ISPs to disable access to infringing content being made available online illicitly in the cases *United King*

Film Distribution Ltd et al v. Does 1-10 d/b/a Israel.tv, *United King Film Distribution Ltd et al v. Does 1-10 d/b/a Israeli-tv.com*, and *United King Film Distribution Ltd et al v. Does 1-10 d/b/a Sdarot.com*. The injunction orders stated that access should be disabled to the infringing content and websites both “known today...or to be used in the future by the Defendants.” The widespread availability of injunctive-style relief in the United States combined with access to dynamic injunctions would be a positive development and would allow rightsholders to seek and gain more effective relief against copyright infringement online.

The U.S. Congress and Senate have both been working on reform proposals to the Digital Millennium Copyright Act (DMCA). For example, throughout 2020, the Senate IP Subcommittee—led by chair, Sen. Thom Tillis—held hearings on the possibility of reforming the U.S. copyright environment to deal with digital piracy more effectively. Part of these hearings examined the practices outside the United States and, importantly, the growth and effectiveness of injunctive-style relief mechanisms around the world to disable access to infringing content. These efforts led to the public release of the Strengthening Measures to Advance Rights Technologies Copyright Act of 2022 (SMART Copyright Act). This draft legislation would allow the Library of Congress and other parts of the federal government working with other stakeholders (including the private sector) to designate and identify existing practices and technical measures protecting copyrighted works. By reforming the underlying DMCA legal framework, the draft legislation would seek to incentivize the adoption of new standards and technologies combating digital piracy through public and private sector cooperation. The House Judiciary Committee has also held hearings on copyright reform, most notably in 2020 under the leadership of Chair Jerry Nadler related to the release of the Copyright Office’s Section 512 report.

In early 2022, **Thailand** enacted a new Copyright Act. These amendments included the creation of a notice-and-takedown scheme; the definition of liability for service providers; and additional remedies for the circumvention of technological protection measures, including the manufacture, sale, rental, or importation of circumvention devices. The notice-and-takedown scheme provides a new legal framework that promotes cooperative action against online piracy, thus providing internet intermediaries with defined responsibilities related to copyright infringement and a stepwise process for rightsholders to send notifications directly to relevant and statutorily defined intermediaries. Similarly, the amendments also strengthen existing protection mechanisms for technological protection measures (TPM) and digital rights management (DRM).

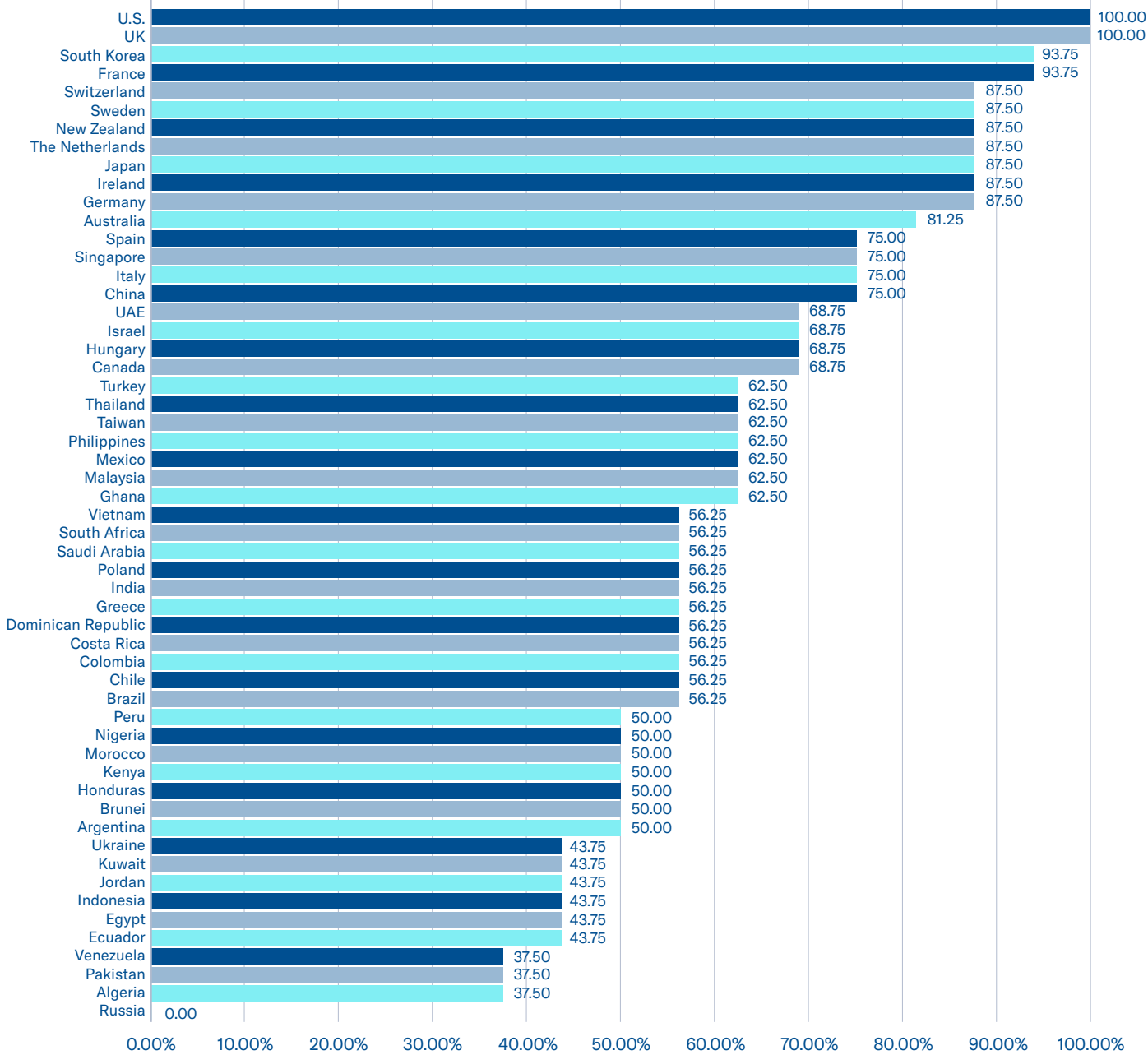
Vietnam also introduced important changes to its copyright law in 2022 as part of a wider package of legislative amendments to the 2005 Law on Intellectual Property (IP Law). Specifically, these amendments introduce a legal framework that promotes cooperative action against online piracy and provides internet intermediaries with defined responsibilities related to copyright infringement. Most notably, under the new law, all intermediaries are “responsible for implementing technical measures and coordinating with competent state agencies and rightsholders to implement measures to protect copyright and related rights in the telecommunications and internet environment.” The amendments also strengthen existing protection mechanisms for TPM and DRM.

Category 3:

Trademarks, Related Rights, and Limitations

Figure 3 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.

Figure 3: Category 3: Trademarks, Related Rights, and Limitations, % Available Score



Most economies sampled in the Index offer basic forms of trademark protection. Only 10 of the 55 sampled economies failed to score 50% or more on this category. Overall, the average score in this category was 62.39%.

Just as with copyright infringement, an increasing share of trademark-infringing activity is taking place online through e-commerce platforms and online shopping. Although many Index economies do not have the appropriate resources, technology, or effective mechanisms in place to combat the increased sale of counterfeit goods online, there are some examples of jurisdictions where relevant legislation, case law, or enforcement practices have established certain obligations on the part of online merchants to take down IP-infringing material upon notification.

As noted over the past few editions of the Index, since its inception in 2017–2018, the Saudi Authority for Intellectual Property (SAIP) has worked on improving the national IP environment and ability of rightsholders to enforce their trademark and brand rights more effectively in **Saudi Arabia**. These efforts have continued in 2021–2022. In May 2022, the authority released its annual enforcement report for 2021. For the calendar year, SAIP received just over 1,200 complaints from rightsholders (1,023 for potential copyright infringement and 194 for alleged trademark infringement) and disabled access to over 2,000 websites from which infringing content was being disseminated. The authority also carried out over 6,000 in-person visits to physical stores investigating the dissemination and sale of IP-infringing goods. At the time of research, the authority had released enforcement statistics for the first half of 2022. During this period, SAIP had disabled access to over 3,000 websites from which infringing content was being disseminated and conducted over 5,000 physical in-person visits. The Index commends SAIP and the Saudi government. This is yet another positive step taken

by SAIP to offer rightsholders an effective and practical route of IP enforcement in Saudi Arabia.

In September 2022, the **French** Directorate-General of Customs and Indirect Taxes announced the results of a 22-month special operation conducted against the online sale of counterfeit toys and children’s articles. In a cross-European operation involving law enforcement in seven EU Member States and Europol, over 16 million counterfeit goods were either seized or taken down online. This is one of the largest operations of its kind ever carried out in the EU, and it was led by the French authorities who initiated the investigation and alerted their European counterparts.

Rightsholders have long faced difficulties in protecting their trademarks and brands in **Thailand**. The availability of physical counterfeit goods is high and, as e-commerce grows, increasing online. In 2019, the national IP office, the Department of Intellectual Property (DIP), held consultations with the major platforms aimed at discussing tools and procedures to tackle online infringement and the sale of counterfeit goods more effectively. The same year, the DIP organized a workshop bringing together rightsholders, internet platforms, and national and foreign enforcement agencies to discuss the platforms’ role in tackling online piracy. The DIP also created a dedicated unit for online violations tasked with furthering dialogue among relevant stakeholders, including online marketplaces.

The 2016 Computer Crime Act included an injunctive-style relief mechanism. In a precedent-setting application, the Ministry of Digital Economy and Society filed a judicial motion and received court approval for the disabling of access to several websites on the basis of infringement of trademark rights in 2020. Up until 2020, this mechanism had exclusively been used by copyright holders and had not been

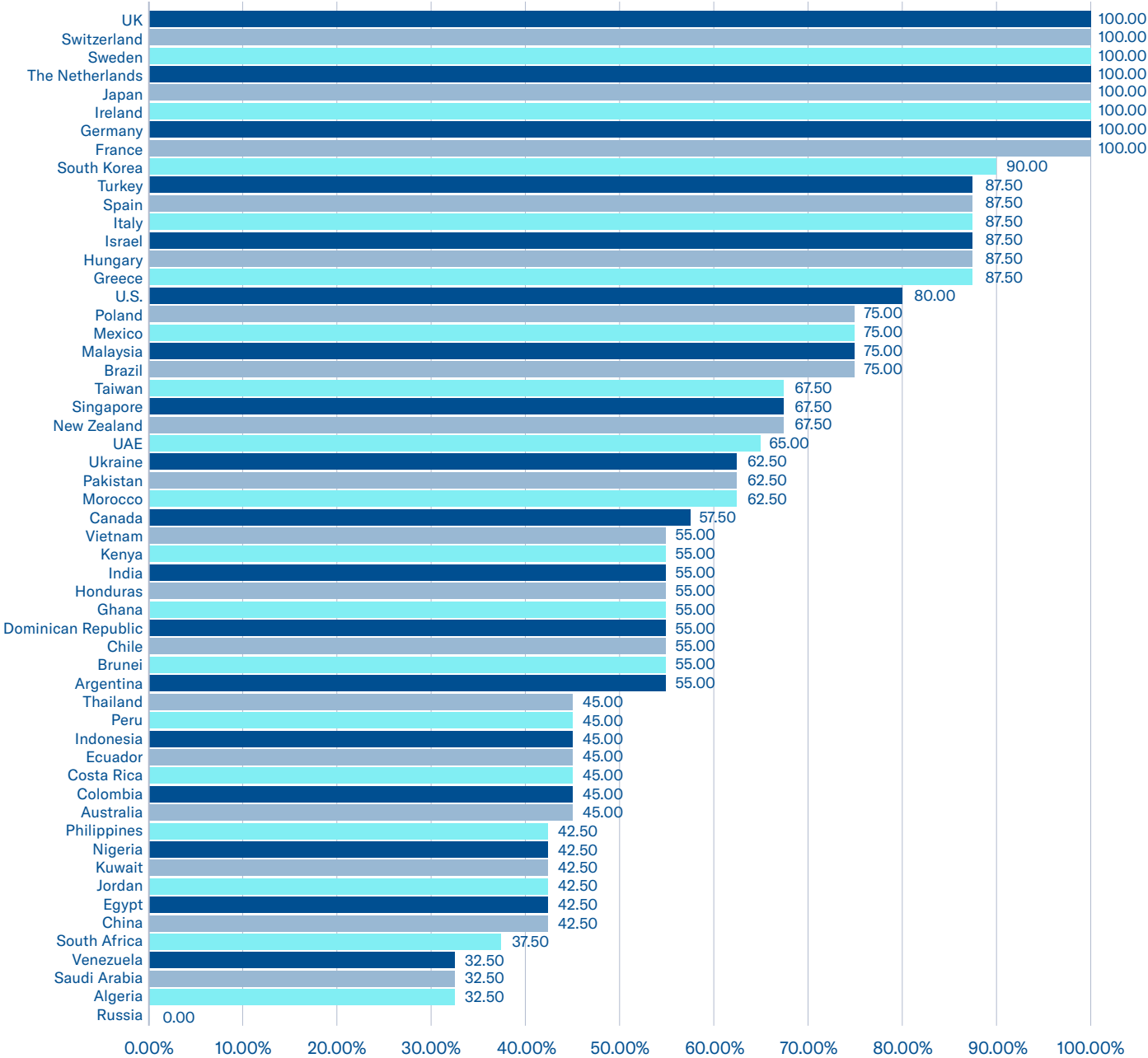
viewed as a way of enforcing rights pertaining to trademarks. In 2021, the Deputy Prime Minister presided over the signing of several Memorandums of Understanding (MOUs) between rightsholders, online retailers, and the Thai government. The purpose of these agreements is to facilitate stronger cooperation among online retailers, rightsholders, and relevant government ministries and agencies in eliminating

counterfeiting and the enforcement of IP rights. Government reports published in 2022 suggest that the MOU is having the desired effect and facilitating greater cooperation between the signatories and increased enforcement efforts against counterfeit goods available online. The Index commends the Thai government and, in particular, the DIP for the leading role it has played in these positive developments.

Category 4: Design Rights, Related Rights, and Limitations

Figure 4 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.

Figure 4: Category 4: Design Rights, Related Rights, and Limitations, % Available Score



Most economies included in the Index have in place some form of statutory law defining design rights and a term of protection for registered design rights. The average score in this category this year was 63.77%. Over the course of the past few years, many economies have reformed relevant laws and regulations pertaining to design rights and, in many cases, have extended the term of protection for registered designs. Often, this has been part of an accession process to the Hague Agreement Concerning the International Registration of Industrial Designs, a treaty included and benchmarked in the Index. This continued in 2022.

In 2022, **China** became a full contracting party to the Hague Agreement with the treaty entering into force in May that same year. In 2022, **Morocco** also acceded to the Geneva Act; it was previously a member of the older treaties that constitute the Hague Agreement. Morocco is now a full contracting party to all acts that together constitute the Hague Agreement.

Although not legally reforming their design rights environment, 2022 saw other Index economies make policy commitments to that effect.

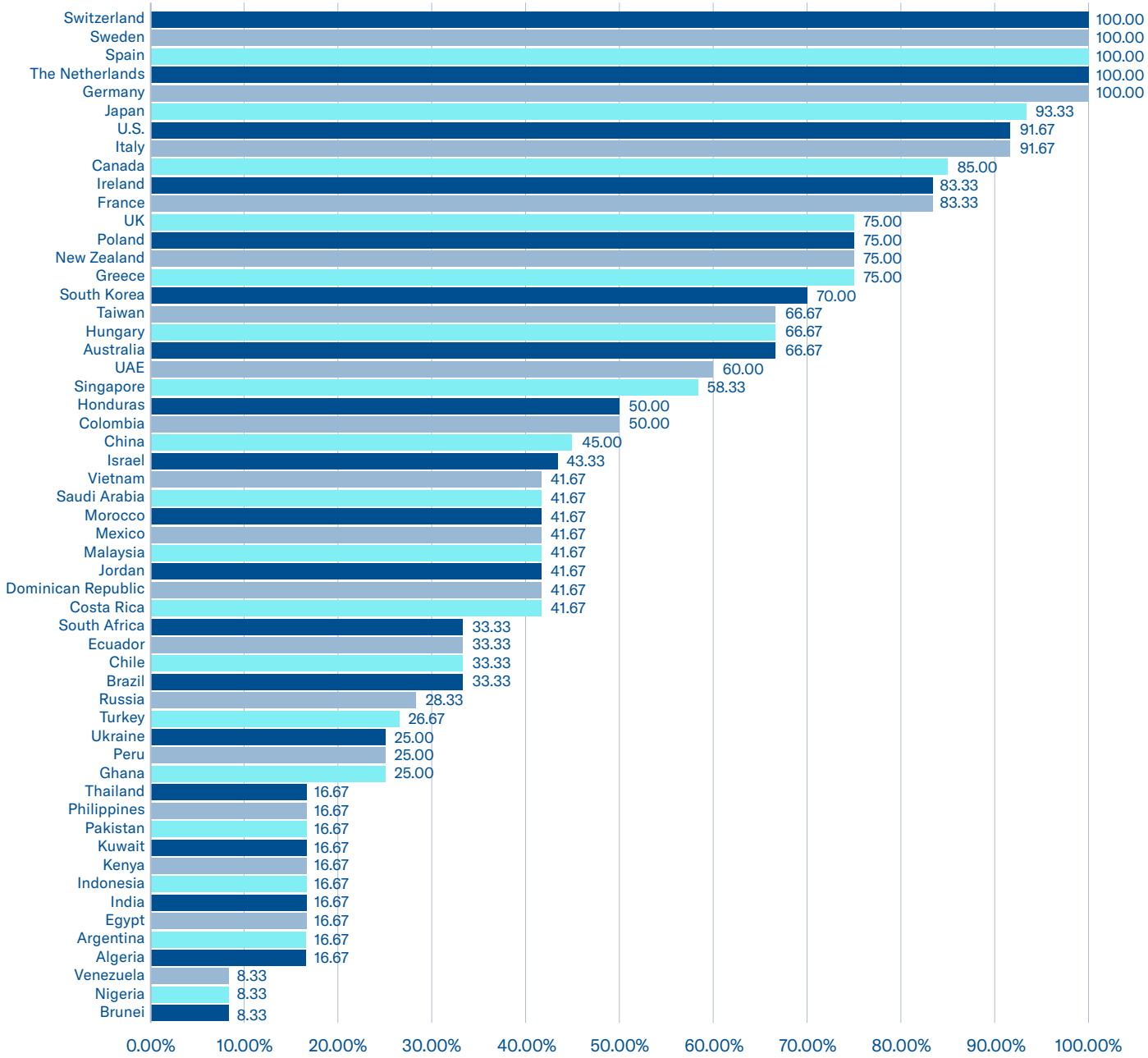
In **Indonesia**, Article 5 of the Industrial Design Law provides a 10-year term of protection for registered designs. This is notably less than the 25-year term benchmark used by the Index. Reports suggest that the government will propose new amendments to the Design Law, and these will include an increase of the total term of protection available up to 15 years. An increase in the term of protection for registered designs will result in a score increase on this indicator.

Similarly, in late 2022, the **Brazilian** Senate passed Decree 274/22, which approves Brazil’s accession to the Hague Agreement. This follows the Chamber of Deputies’ approval during the summer. At the time of research, accession had not been formalized. Brazil’s accession to the Hague Agreement would be a positive development and would result in a score increase on this indicator.

Category 5: Trade Secrets and the Protection of Confidential Information

Figure 5 summarizes the total scores for Category 5. This category measures the strength of the IP environment for trade secrets and confidential information. For trade secrets, the category includes two indicators measuring the availability of civil and criminal sanctions, respectively, in relation to the misappropriation, 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 measures the existence of an RDP term of protection for biopharmaceuticals. The category consists of three indicators with a maximum possible score of 3.

Figure 5: Category 5: Trade Secrets and the Protection of Confidential Information, % Available Score



As noted in past editions of the Index, many economies do not have specific trade secret legislation in place but instead rely on laws related to employment contracts and disclosure of confidential information. Consequently, in many

economies, there are sizeable gaps in protection. Trade secrets are not adequately defined in relevant laws and regulations, and courts have limited experience ruling on cases involving the misappropriation, 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. Likewise, many economies included in the Index do not provide RDP for biopharmaceutical test data submitted during market authorization. Of those that do, many limit or actively attempt to restrict the practical availability of this protection through various terms, conditions, and/or carve-outs. Unfortunately, this trend continued in 2022 with many Index economies failing to adequately address gaps in their primary and secondary legislation in relation to RDP. Overall, only 23 of the 55 economies included in the Index achieved a score of 50% or more in this category. Twenty-two economies achieved a score of 33.33% or less. The average score in this category is the weakest in the Index at 48.97%.

As noted, in mid-2022, **Vietnam** passed a substantive set of amendments to the 2005 Law on Intellectual Property, including changes to its RDP regime. Historically, the Law on Intellectual Property and implementing regulations (Circular No. 05/2010/TT-BYT) have provided a five-year term of RDP for undisclosed biopharmaceutical test data submitted during sanitary registration. However, in practice, this term has often not effectively been made available to rightsholders. Specifically, there has been a lack of clarity on the extent to which follow-on applicants can rely on and benefit from an approved registration file and compare it to the chemical and toxic levels of the substitute, for example, through bioequivalence tests. Such practices of direct or indirect reliance all but negates an innovator’s rights under any RDP regime, including in Vietnam. Unfortunately, the 2022 amendments to the IP law do not add any clarity to this issue. Confusingly, although Article 128(2) seems to state that relevant market authorization authorities cannot approve any

application for follow-on products that rely on already submitted test data during the RDP period, Subsection 3 seems to suggest that such applications are to be accepted but published on the relevant agency’s web portal within a defined period. This does not constitute an RDP regime in line with international standards or best practices.

In **Saudi Arabia**, 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 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 through “indirect reliance” on submitted clinical research data. International standards and best practices for RDP are 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, SAIP released new draft-implementing regulations on how confidential commercial information will be protected in Saudi Arabia. Although SAIP should be applauded for publishing these draft regulations, holding a public consultation, and inviting stakeholder feedback on the matter, as noted in the Index at the time, the regulations themselves were deeply flawed and stood outside established international standards of RDP. Specifically, Article 4(1) of the regulations

stated that any term of protection offered in Saudi Arabia would begin on “the date of the first registration of the preparation *in another country*”. If applied in practice, this would dramatically rewrite existing regulations and would significantly curtail rightsholders’ effective RDP term. The introduction of such a definition and the linking of the exclusivity period in Saudi Arabia to a product’s first global launch would severely limit the availability of RDP in Saudi Arabia and would undermine the incentives for innovation and investment that such exclusivity provides. Moreover, the draft regulations did not allow a period of RDP for new indications. As noted in the Index when the draft regulations were published, 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. In a positive step, in early 2022, SAIP and the Saudi Food and Drug Authority were reported by the U.S. State Department in its 2022 *Investment Climate Statement* to have reaffirmed their support for the availability of regulatory data protection in the Kingdom.

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, had 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 submitted preclinical and clinical data submitted by an original reference applicant. However, it is uncertain whether the full

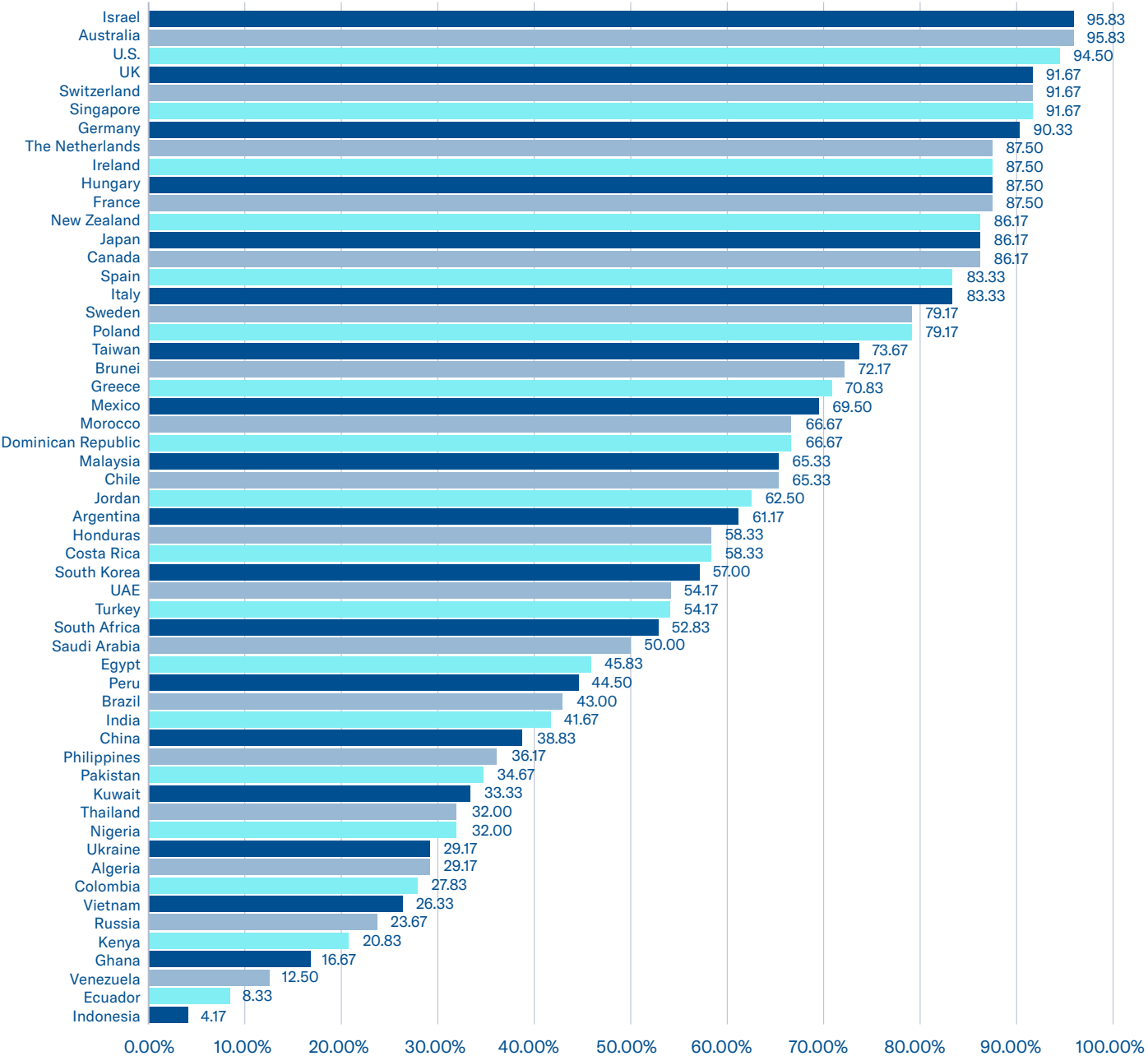
eight-year RDP term will be available. Specifically, Article 3 allows follow-on applicants to register their products in the last two years of the granted RDP in what amounts to a Bolar exemption. Bolar exemptions are normally in place to allow follow-on manufacturers to conduct research and necessary scientific studies to meet regulatory safety and quality requirements in preparation for market approval. Because of 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 are allowed to engage in, and there is no assurance that the reference product’s full eight-year period of data exclusivity will be maintained. The meaning of Article 5 of the decree is also uncertain. 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. At a more basic level, a conflict on the term of protection exists between the 2020 resolution and the new industrial property law, Federal Law No. 11. As noted in last year’s Index, Article 62(2) of the new industrial property law states that the period of protection for confidential information submitted to government agencies will be protected for “a period not exceeding (5) five years.” This is less than the eight-year term in Resolution 321. New executive regulations published in 2022 did not address this issue. Consequently, at the time of research, it remained unclear how the conflicting provisions of Federal Law No. 11 and Resolution 321 would interact and which would take precedence.

Category 6: Commercialization of IP Assets

Figure 6 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.

Figure 6: Category 6: Commercialization of IP Assets, % Available Score



As 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 to commercialize IP assets. Twenty economies of the 55 sampled failed to achieve a score of 50% or more with a full 13 scoring 33.33% or less in the category. The average score in this category was 58.62%. In particular, this is a growing challenge in many emerging markets.

Over the years, rightsholders have faced a growing number of regulatory, procedural barriers and inflexible terms to licensing in **China**. China has historically imposed restrictions on the rights of foreign IP rightsholders to freely negotiate market-based contractual terms in licensing and other technology-related contracts concerning the transfer of technology to China. 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 between the United States and China. As noted at the time in the Index, the 2020 “Economic and Trade Agreement Between the Government of the United States and the Government of the People’s Republic of China” (Phase One Agreement) included dedicated chapters on IP and technology transfer and licensing. After the conclusion of this agreement, China amended and updated most major IP laws and regulations, including with respect to technology transfer and licensing. As a result, China’s scores increased on indicators 26, 27, and 29 in the eighth edition of the Index.

However, since then and despite this legislative progress, licensors and rightsholders have continued to face substantive challenges to doing business in China on a fair, nondiscriminatory basis and on equal terms. Specifically, the past few years have seen a growing trend of rightsholders facing global antisuit injunctions and restrictions on their ability to assert infringement claims in legal jurisdictions outside of China. Chinese courts have increasingly claimed global jurisdiction to set global licensing rates for technologies protected by Standard and Essential

Patents (SEPs), threatening exorbitant fines and withholding access to the Chinese market to prevent foreign patent holders from asserting their rights (in both China and global jurisdictions). The outcomes of these cases have also been cited and referred to as “model” IP rights cases by government authorities.

In 2022, China enacted a new Anti-Monopoly Law. The new law greatly expands the government’s basis for action against anticompetitive behavior and substantially increases fines and penalties, including with respect to IP rights. The new law was accompanied by several new draft rules. Like the underlying legislation, these rules considerably expand the powers of investigation, punishment, and meaning of what constitutes anticompetitive behavior within the context of the exercise of IP rights. They contain not only broad and vague language on what constitutes anticompetitive behavior within an IP rights context but also vest considerable discretion with the anticompetition authorities in identifying and defining such behavior. Furthermore, these definitions of anticompetitive behavior explicitly target SEPs and copyright collection societies.

Similarly, over the past two decades, **Turkish** industrial and economic policy has increasingly been driven by an effort to localize industrial production and R&D. Many of these localization and discriminatory policies have targeted the research-based biopharmaceutical sector. In 2019, the EU 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 Subsidies and Countervailing Measures (SCM) agreements. After a delay caused by the COVID-19 pandemic, the WTO finally issued a panel report in late 2021. Overall, the panel found that Turkey had indeed violated its WTO commitments through the imposition of discriminatory biopharmaceutical market access and localization policies. After a requested suspension of the panel’s work, the dispute was moved to

arbitration, with an arbitration award subsequently issued in August 2022. This award did not materially change the panel’s overall findings and conclusions. In a subsequent communication to the WTO from the Turkish delegation, Turkey committed to “implement the recommendations and rulings of the Arbitrators and the Panel in this dispute in a manner that respects its WTO obligations.” Both the panel’s findings and final arbitration award are a significant development and should mark a positive turning point for affected rightsholders in Turkey.

One area where a growing number of economies are putting in place barriers to trade and localization requirements is the collection and storage of data. For rightsholders across many industries and sectors, such barriers to digital trade raises serious concerns. 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. Yet more economies are introducing restrictions on these flows. This negative trend continued in 2022.

In **China**, the Personal Information Protection Law (PIPL) came into force. The law includes limits and conditions on cross-border transfers of data and imposes local storage requirements on both critical information infrastructure operators and entities handling large volumes of personal data as defined by the Cyberspace Administration of China. Noncompliance with the new law may result in fines of up to 5% of annual sales. Additional restrictions and compliance requirements are imposed on what is termed “large internet platforms.” The PIPL adds to the existing layers of restrictions and barriers to digital trade in China, including the National Security Law, Cybersecurity Law, Security Assessments for Network Products and Services, and the 2020 Biosecurity Law.

In **Saudi Arabia**, there has historically not been a general data localization policy in place or undue restrictions on the international transfer of data.

However, this may now be changing. In late 2021, Saudi Arabia enacted the “Personal Data Protection Law.” The law imposes several new requirements, including the potential localization and local storage of data. As a general rule, Article 29 of the law disallows the transfer of any data from Saudi Arabia to another legal jurisdiction unless under highly specific circumstances. Furthermore, the level of data protection must be at least equivalent in the host jurisdiction as under Saudi law, and the transfer must be approved by the relevant Saudi authority. At the time of research, the implementation of the new law had been postponed to March 2023.

Although the negative developments outweighed the positive, in 2022, there were some pockets of improvement in the environment for the commercialization and licensing of IP assets.

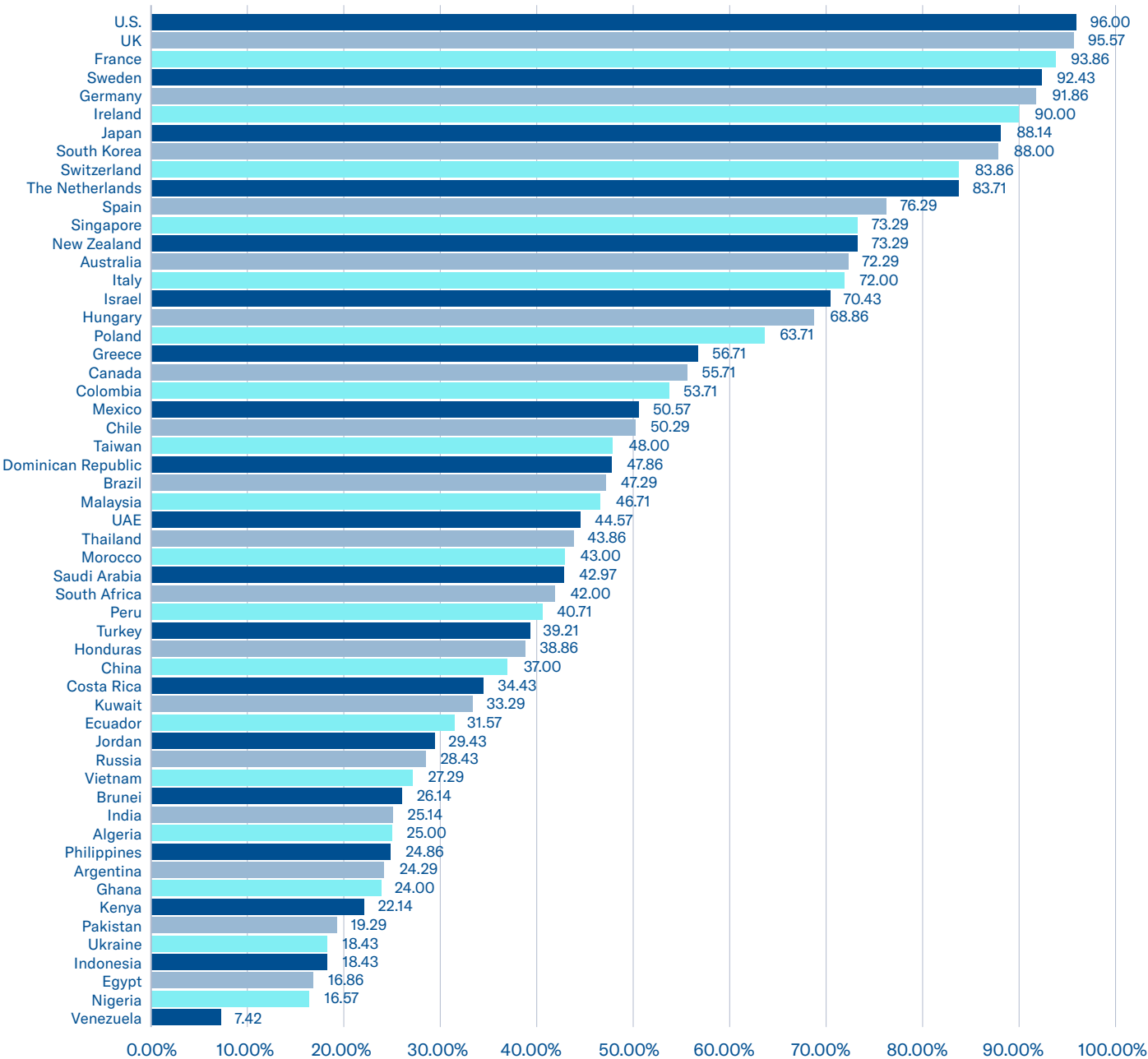
In May 2022, the Thailand Research and Innovation Utilization Promotion Act (TRIUP) came into force in **Thailand**. Years in the making, and modeled on the U.S. Bayh-Dole framework, the new law changes and improves Thailand’s technology transfer environment. Until now, Thailand did not have a national technology transfer framework in place. Instead, different institutions and public research organizations had varying IP policies in place. Under TRIUP, IP rights and rights of commercialization for IP generated with public funding are now generally vested with the creating entities. Consequently, the new law provides IP-based incentives for the commercialization of academic and publicly funded research. Unfortunately, the new legislation was not accompanied by any changes to Thailand’s broader licensing environment. Under TRIUP, the government retains the right to intervene and override granted IP rights through the issuing of compulsory licenses. There has also been no change in the universal requirement of mandatory registration and government review of licensing agreements for most major IP rights, including patents. Nevertheless, the enactment of TRIUP is a positive step and an improvement to Thailand’s technology transfer environment.

Category 7: Enforcement

Figure 7 summarizes the total scores for Category 7. This category measures the prevalence of IP rights infringement, the criminal and civil legal procedures available to rightsholders, 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.

Figure 7: Category 7: Enforcement, % Available Score



As in years past, a majority of the sampled economies in the Index struggle in this category, with only 23 Index economies achieving a score of 50% or more. Only 11 economies achieved a score of 75% or more. The average score in this category is one of the weakest on the Index at 50.10%. In many economies, effective enforcement options are not practically available. Judicial and/or administrative routes of enforcement are overloaded and/or underresourced. With respect to effective border measures, not all Index economies grant their customs authorities, border protection or guards, and/or other designated officials *ex officio* authority to seize suspected counterfeit and pirated goods, including goods in transit, without a formal complaint from a given rightsholder. Still, despite the continued overall poor performance in this category, some positive national developments took place in 2022.

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 **Malaysia**. Both the Malaysian Communications and Multimedia Commission (MCMC) and the Ministry of Domestic Trade and Consumer Affairs (KPDNHEP) have broad authority to censor all manner of content in Malaysia, including those suspected of infringing copyright.

In 2019, the MCMC began targeting websites that provide infringing content through set-top boxes and disabled access to 246 such websites. Criminal enforcement has also increased against

the sales and promotion of illicit set-top boxes, with the first ever successful criminal prosecution taking place in 2021. Also, in 2021, the Intellectual Property High Court in Kuala Lumpur held that the sale, promotion, or dissemination of set-top boxes that allow users to illicitly stream infringing content was a violation of copyright and a civil offense. These positive efforts continued in 2022. To begin with, new amendments to the Copyright Act passed in late 2021 now explicitly target the provision of streaming devices and related services, with criminal sanctions in place of up to 20 years' imprisonment and a fine of MYR 200,000 (approximately USD 40,000). In late 2022, the KPDNHEP and its director of enforcement, Azman Adam, released figures on their enforcement efforts against set-top boxes and streaming devices. From 2018 to September 2022, the Ministry had taken action in over 500 cases of physical sales of set-top boxes and disabled access to over 2,000 websites.

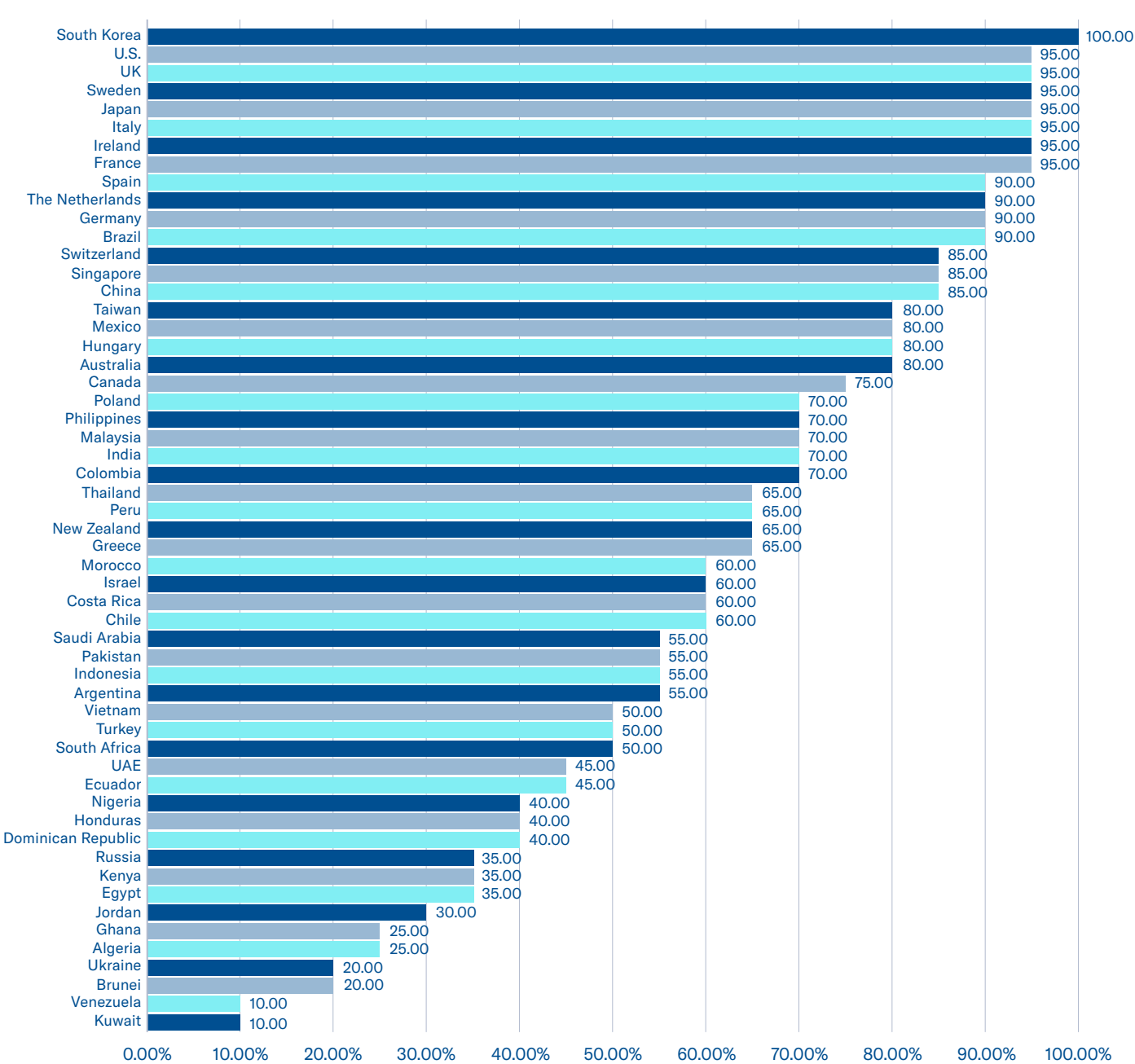
As noted last year, changes to **Chile's** Law 19,309 on Industrial Property—in force since January 2022—also included important changes to IP enforcement. The amendments included the introduction of statutory damages for trademark infringement; Law 19,309 had previously not included any form of preestablished or statutory damages for any major IP right. These positive efforts continued in 2022 with the enactment of Law 21,426. The new law bolsters efforts to combat illicit trade by criminalizing associated aiding and abetting acts and provides new powers to Chilean enforcement authorities.

Category 8:
Systemic Efficiency

Figure 8 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 the regulation-making process; the 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 8: Category 8: Systemic Efficiency, % Available Score



As in previous editions, the majority of sampled economies in the Index performed well in this category, with only 15 economies failing to achieve a score of 50% or above. Indeed, many economies outperform their overall Index scores in this category. This includes several economies that have otherwise challenging national IP

environments, such as **Brazil, Colombia, India,** and the **Philippines**, none of which achieved an overall score of 50% or more. Yet, in this category, they all scored 70% or more. Overall, the average score in this category is one of the strongest in the Index, at 62.73%.

In 2022, these positive efforts continued.

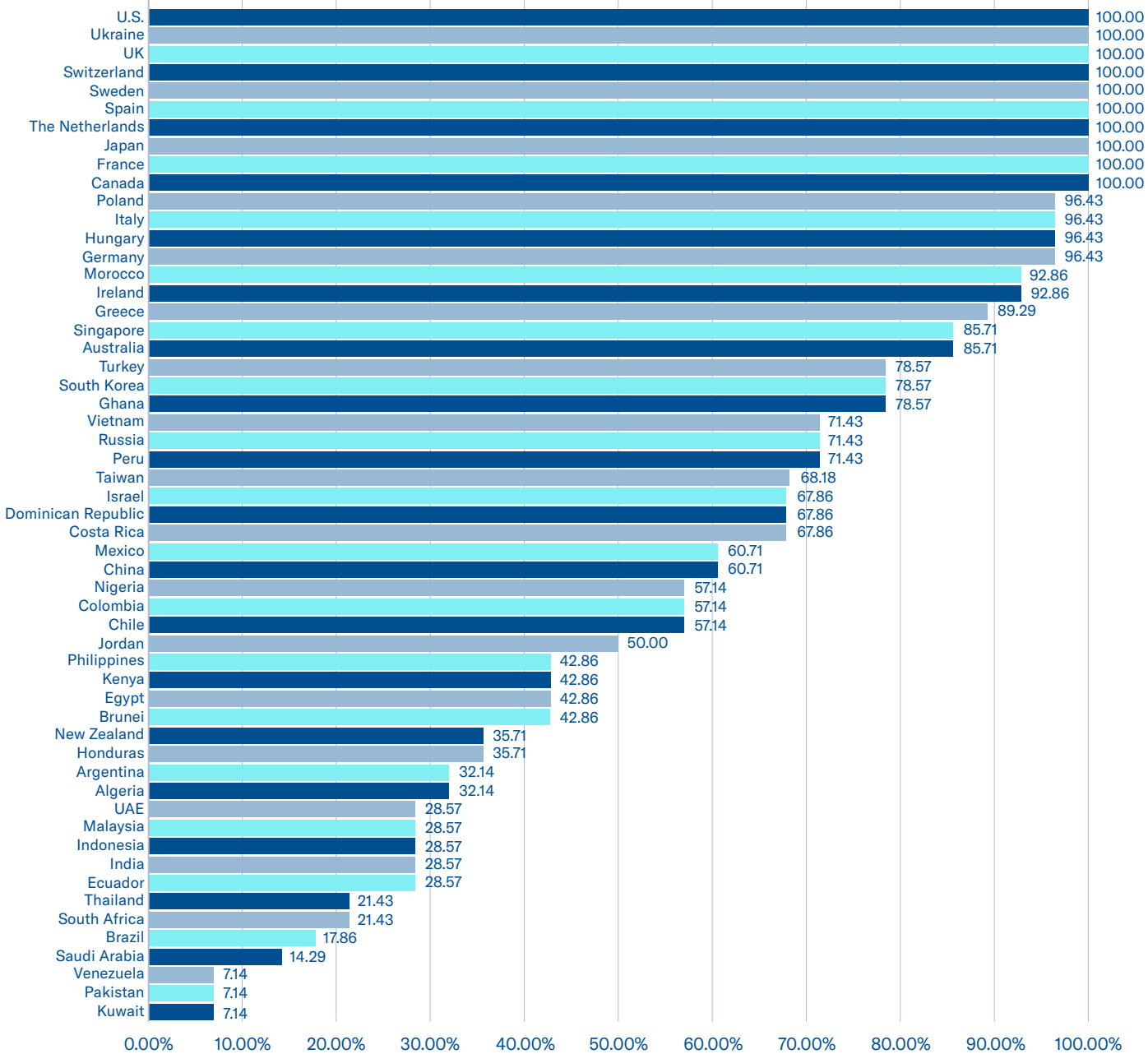
As noted across the Index, in **South Korea**, there has historically been a strong focus on the creation and commercialization of IP as an economic asset. The Korean government actively promotes the creation, registration, and commercialization of IP assets by SMEs. The national IP office (KIPO) provides SMEs with a variety of educational and technical assistance programs, including support to export-oriented SMEs in developing and exploiting their IP rights, with the goal to foster “Global IP Star” companies. KIPO also hosts IP training at regional IP centers (corporate capacity building on leveraging of IP) and IP talent sharing and training projects. Depending on the business area, type of technology, or type of entity, qualifying SMEs can also apply for an accelerated patent examination. The criteria for inclusion have been expanded in recent years and now cover a broad range of entities, including companies that focus on specific technologies—for example, green technologies and technologies related to the fourth industrial revolution—as well as business type. The latter today includes entities that are engaged in export promotion or that qualify as a “venture business” or other defined entity under the Invention Promotion Act. The results of these efforts can be seen in the growth of patent applications by SMEs. According to KIPO’s latest annual report, SMEs have seen the largest increase in total IP registration applications for all major IP rights in Korea over the past two years.

Likewise, **Morocco’s** national IP office, the Moroccan Office of Industrial and Commercial Property (OMPIC), has a pronounced and consistent focus in all its work on promoting the use and commercialization of IP assets, especially with respect to SMEs, universities, and public research organizations. OMPIC offers reduced filing fees for small businesses, educational institutions, and research institutes. On-the-ground support services are available through a network of Technology and Innovation Support Centers (TISC). These support centers offer researchers and institutions technical expertise on the registration and commercialization of IP assets. The TISC concept was first developed by the World Intellectual Property Organization (WIPO) in the late 2000s, and, as of 2022, there were close to 1,300 support centers in 88 economies around the world, with 72 centers in Morocco. In 2022, these efforts were bolstered with OMPIC’s launch of two new technical assistance programs that aimed to, first, provide businesses with an in-depth review of existing IP assets and protections and, second, provide tailored guidance on existing prior art, the patenting process, and key industrial technology trends. These new programs target academic researchers, research institutes, and SMEs.

Category 9: Membership and Ratification of International Treaties

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

Figure 9: Category 9: Membership and Ratification of International Treaties, % Available Score



Over the course of the Index, the number of international IP treaties included in this category has expanded substantially from five to nine. This category remains one of the stronger overall categories in the Index, achieving an average score of 62.70%. This is a notable improvement over time. Many economies have over the course of the Index become contracting parties to international IP treaties and have boosted the overall category score. Many economies achieved a high score in this category: 22 economies scored 75% or higher, with 14 economies achieving a score of over 96%. Despite this overall progress, many high-income economies are not contracting parties to many of the treaties included in the Index. **Kuwait, Saudi Arabia, UAE, Brazil, South Africa,** and **New Zealand** all achieved a score of 36% or less. Of note is Kuwait, which is a contracting party to only one of the nine treaties measured in this category and achieved a total category score of 7.14%, the same as Venezuela.

As in years past, 2022 saw several Index economies improve their score in this category.

To begin with, **Vietnam** and **Thailand** both acceded to parts of the WIPO Internet Treaties in 2022. Vietnam acceded to the WIPO Performances and Phonograms Treaty, and Thailand acceded to the WIPO Copyright Treaty.

In 2022, **Morocco** acceded to the Singapore Treaty and is now a full member of each of the two trademark-related treaties included in the Index.

In 2022, **Chile** acceded to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks.

Finally, in 2022, **Nigeria** became a full contracting party to the Convention on Cybercrime, with the treaty entering into force in November of the same year.

The Future Is Calling (and It's Mobile!):

How IP Rights Enable Innovation and the Development of Telecommunications Technology, 5G, and International Technology Transfer

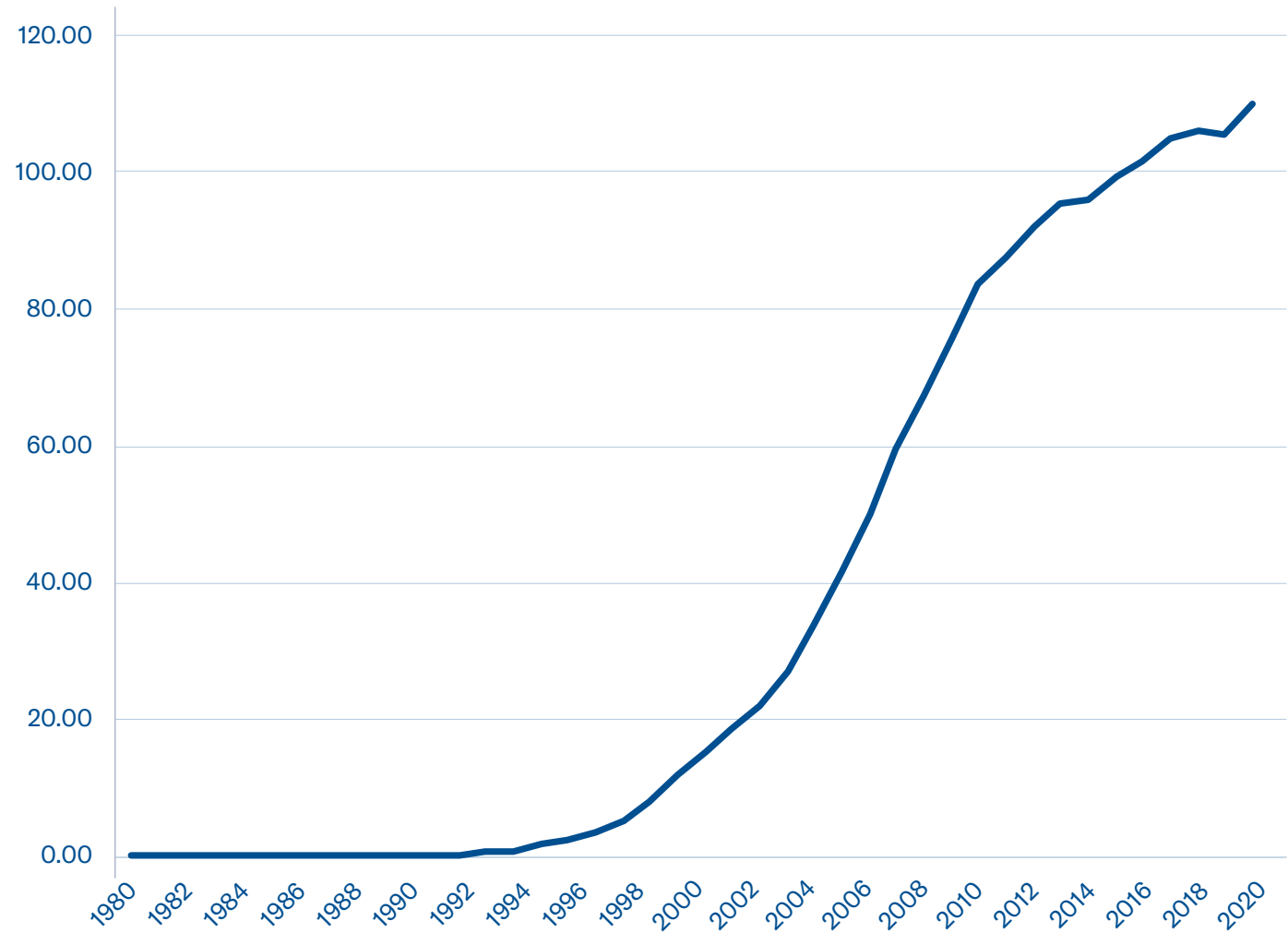


The Global Economy Goes Mobile: Issue Overview

One of the most fundamental shifts in human behavior over the past generation is the growth in the use of mobile telecommunications technologies. Across most of the world, mobile devices are ubiquitous. As Figure 10 shows, data

compiled by the United Nations' International Telecommunication Union (ITU) and housed by the World Bank in the World Development Indicators database show the tremendous growth in the use of mobile technology over the past 20 years.

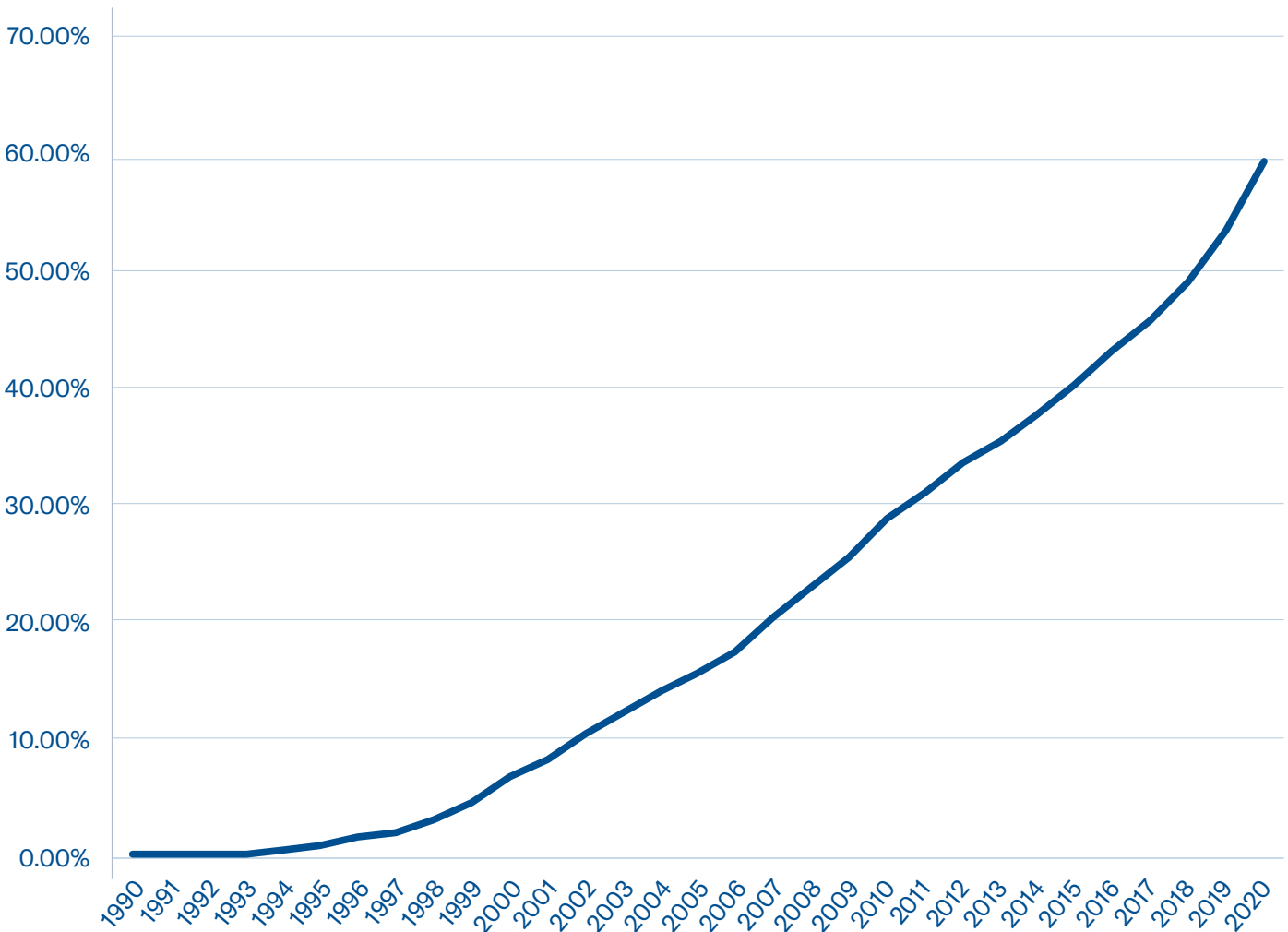
Figure 10: Mobile Cellular Subscriptions (per 100 People), 1980–2021, World Bank, World Development Indicators²⁶



Until the early 2000s, the number of mobile telephone subscribers globally was low, with only a handful of the global population having a cellular subscription. Over the past 15 years, this growth has exploded. In 2021, there were an estimated 110 mobile phone subscribers per 100 people in the world.

As Figure 11 shows, during the same time frame, access to the internet has seen a similar growth trajectory.

Figure 11: Individuals Using the Internet (% of Population) 1980–2020, World Bank, World Development Indicators²⁷





In 2000, less than 10% (6.74%) of the world’s population had used the internet. In 2020, this had grown to an estimated 59.58%.

Together, the growth in the use of mobile technologies and increased access to the internet amount to a revolution in human socioeconomic behavior with a deep and profound impact on the global economy. The most visible result of this behavioral change is that a growing share of global economic activity is going digital and mobile. In virtually all sectors and industries, businesses and economic interaction are today shaped by the combination of the internet and mobile and digital technologies. To begin with, platforms and business models that did not exist a generation ago have been enabled by the advent of mobile and digital technologies. Second, these technologies have transformed traditional retailing and brick-and-mortar stores through the ability to use ICT and internet-based platforms and technologies to better understand markets, consumers, and the world in which they operate. Third, mobile and digital platforms allow companies to more easily access and operate in markets that they would not have been able to enter a generation ago. Finally, such 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 “big data.” Combined with increased computing capacity and the application of new technologies (such as AI and machine learning) that allow us to analyze and better understand data collected, there is the possibility to make significant discoveries and breakthroughs in virtually any area of research and human socioeconomic activity. The bottom line is that how we produce, consume, and interact—nationally and internationally—has been, and continues to be, transformed through mobile and digital technologies.

Central to the growth and use of mobile and digital devices is the physical infrastructure

and technologies that enable users to perform more complex tasks with their mobile devices. In the 1980s, the first mobile devices were large, clunky, and connected via analog networks. They were primarily used for making short calls and had virtually no data or information processing capabilities. Since the late 1990s, the devices themselves and, critically, the physical networks they connect to—and underlying technologies on which mobile communications are based—have become more sophisticated and far more capable. Today, the development and growing deployment of the fifth generation of mobile communications standards (5G) allow users to perform more complex and technically demanding tasks than ever before. Compared to previous generations of mobile communications standards, the greater capacity of the 5G standard allows users and their mobile devices to achieve higher speeds with limited to no latency delays and superior reliability. The result is higher rates of socioeconomic utility and output across all sectors of the economy. Although the future economic impact is set to be the most profound (see following data), the 5G standard and associated socioeconomic usage are already generating a tremendous economic impact. This is particularly the case for the United States, which was one of the pioneers in the development and invention of the standard. For example, the international consultancy PwC estimates that in 2020, 2021, and 2022, the economic impact of the 5G standard was already substantial at over USD 100 billion.²⁸

Indeed, a series of economic impact studies on the benefits of the 5G standard finds that both globally and in high-income regions such as North America and Europe, the economic benefits of 5G are and will continue to be substantial.

For example, in 2020, IHS Markit estimated that across three economic dimensions (the value chain, sales enablement, and net contribution to global GDP), the 5G standard would have a substantial

and sustained positive impact on global economic activity.²⁹ The study estimated that the 5G value chain would “generate \$3.8 trillion of gross output and support 22.8 million new jobs by 2035.” Similarly, under the “sales enablement” category the use and deployment of the 5G standard were expected to generate an estimated USD 13 trillion during the same period. Finally, looking at 5G’s potential contributions to global GDP, IHS Markit found that “the net contribution globally through 2035 (in net present value terms) will amount to about \$2.3 trillion in constant 2016 U.S. dollars.”

Other regional studies echo these findings. In two separate studies, Accenture examined

the economic impact the deployment of 5G networks would have on the U.S. and European economies.³⁰ The authors estimated that from 2021 to 2025, the 5G standard would contribute USD 2.7 trillion in additional gross (sales) output, add as much as USD 1.5 trillion to the GDP, and “create or transform up to 16 million jobs across all sectors of the economy.” Accenture found similar results for the European economy over the same period, with estimated increases of EUR 2.0 trillion in additional gross output (sales) growth, a value-add of up to EUR 1 trillion to European economic output (GDP), and the ability to “create or transform up to 20 million jobs across all sectors of the economy.” These findings are summarized in Figures 12 and 13.

Figure 12: Estimated Positive Economic Impact of Deployment of 5G Standard to U.S. and European GDP, USD, 2021–2025

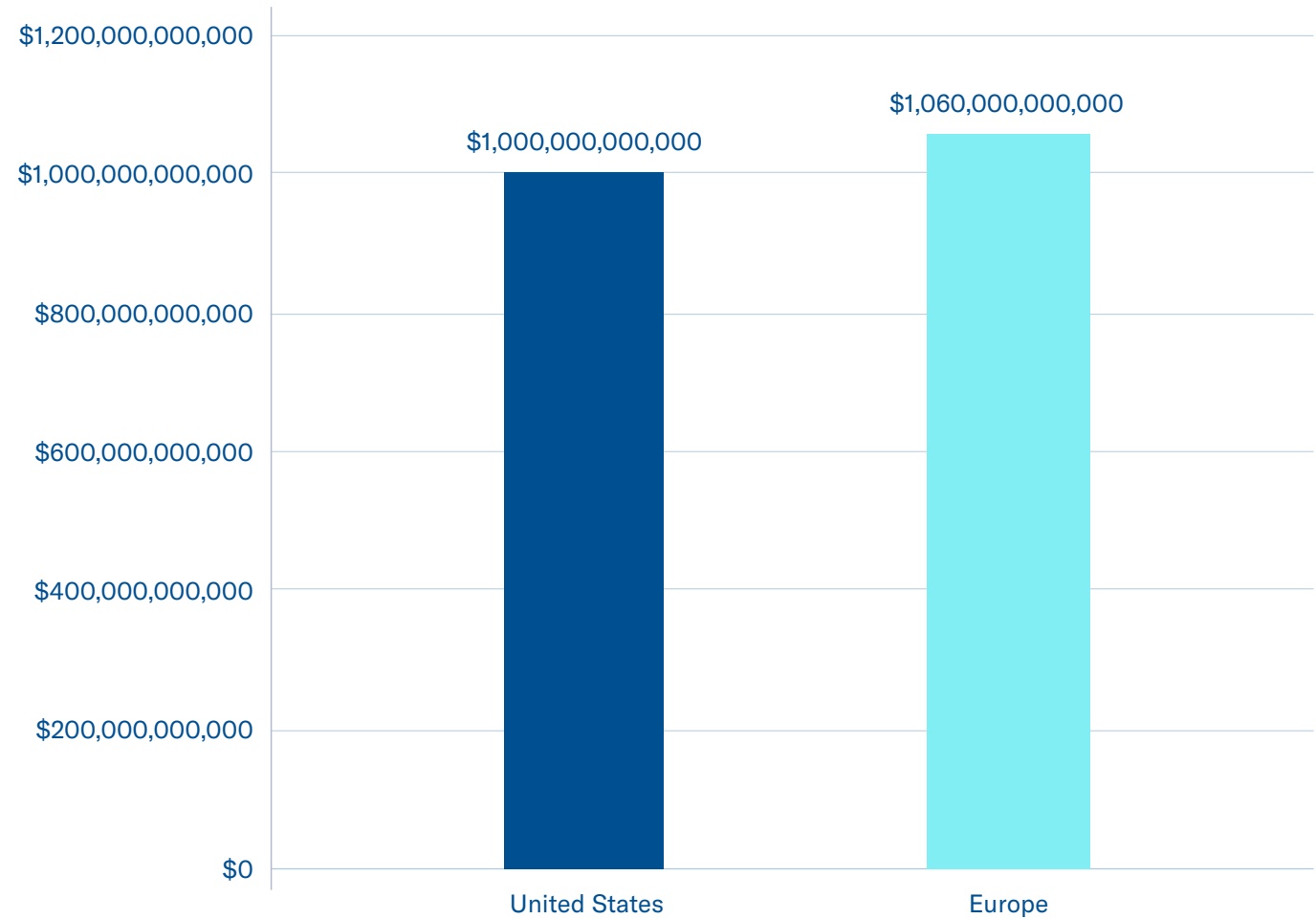
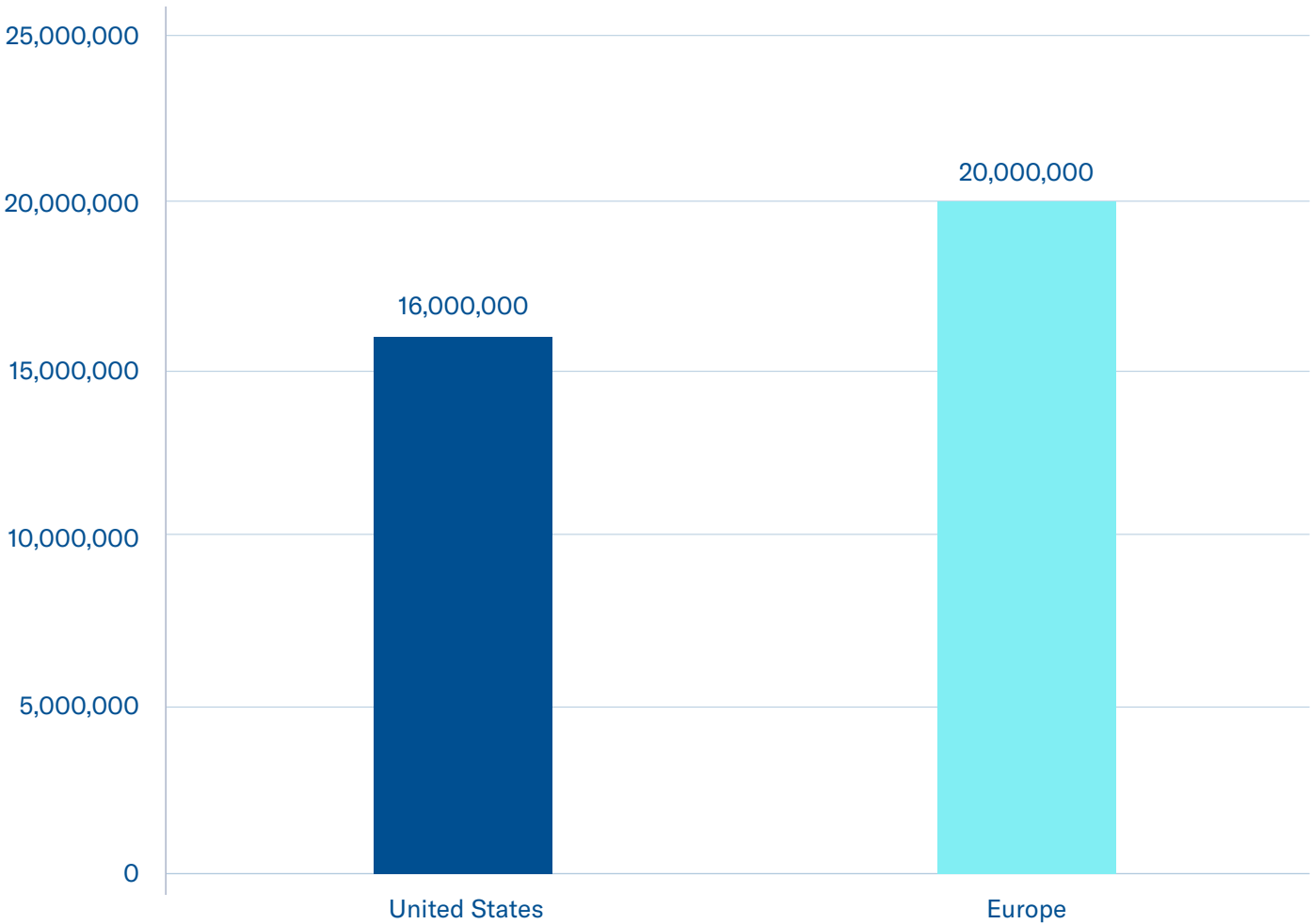




Figure 13: Estimated Number of Jobs Created and/or Transformed Through 5G Deployment, U.S. and Europe, 2021–2025



The 5G Revolution: How IP Rights Enable the Development of Modern ICT and Mobile Communications Infrastructure

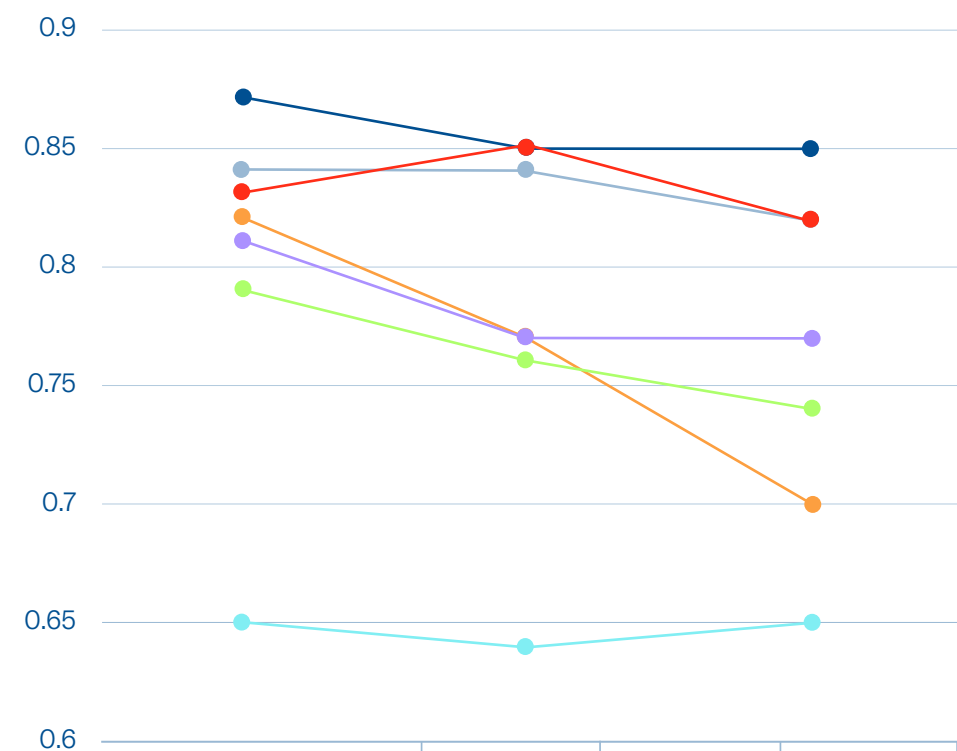
Like all modern high-tech sectors, the development of mobile and ICT communications infrastructure and related technologies, including the latest 5G standard, does not take place in a vacuum. Instead, the development of these cutting-edge technologies relies on a complex ecosystem in which the protection of IP is central. Since 2015, the Index has included a *Statistical Annex* that investigates a series of correlations, or the statistical likelihood of two variables occurring together. The correlations examine the relationship between the strength of national IP environments, as measured by the Index scores, and different types of economic activity, including rates of R&D spending, innovation, technology creation and utilization (including in relation to ICT infrastructure and telecommunications), and creativity. Each correlation is based on the Pearson correlation coefficient (a statistical analysis used to test the relationship between two variables) and provides a value between -1 and 1, which represents the strength of this correlation. The Pearson correlation coefficient shows whether a linear relationship exists between two variables and if it is positive or negative. The strength of a given positive correlation follows this legend:

- » .00 to .19: very weak
- » .20 to .39: weak
- » .40 to .59: moderate
- » .60 to .79: strong
- » .80 to 1.0: very strong

The *Statistical Annex* includes seven correlations that show a strong and sustained relationship over time between levels of IP protection and the development and dissemination of mobile and ICT communications infrastructure and related technologies. These correlations range from measures related to a given economy’s readiness and capacity to benefit from the Fourth Industrial Revolution, available resources and infrastructure for innovation, and knowledge-based outputs. Table 4 lists each correlation and its measured strength over time.



Table 4: Economic Benefits of Improving IP Protection for Mobile and ICT Communications Infrastructure and Related Technologies, Strength of Correlation 2019–2022³¹



	2019	2021	2022
● Association between the Index scores and the Readiness for the Future of Production Assessment, Drivers of Production pillar, Technology & Innovation sub-pillar scores	0.87	0.85	0.85
● Association between the Index's ICT-related indicators scores and the Network Readiness Index, Impact Pillar scores	0.83	0.85	0.82
● Association between the Index ICT-related indicators scores and the Measuring the Information Society Report, 2017 ICT Development Index	0.84	0.84	0.82
● Association between the Index scores and the Observatory of Economic Complexity's Economic Complexity Index	0.82	0.77	0.7
● Association between Index patent-related indicators scores, and triadic patents (total, 1999-2016) per million population	0.65	0.64	0.65
● Association between Index patent-related indicators scores, and the Global Innovation Index 2021, Innovation Output sub-index Knowledge and Technology Output pillar scores	0.79	0.76	0.74
● Association between the Index Scores on ICT-Related Indicators and the GDP Benefit from a 1% Increase in Software Use	0.81	0.77	0.77

As Table 4 illustrates, economies that score higher overall in the Index are also more likely to score substantially higher on measures related to the development and dissemination of mobile and ICT communications infrastructure and related technologies. Notably, all the listed correlations have remained strong or very strong over time and have exhibited a relationship strength of 0.60 or more.

Of the seven correlations in Table 4, two relate directly to the use of ICT hardware and communications infrastructure:

1. Association between the Index ICT-related indicator scores in the *Measuring the Information Society Report*, ICT Development Index
2. Association between the Index's ICT-related indicator scores and the Network Readiness Index Impact Pillar scores

The ICT Development Index measures the level of ICT development in over 170 economies by examining the availability of ICT infrastructure and access, level of ICT usage, and the capability to use ICTs effectively, derived from relevant skills. Economies are benchmarked based on their ICT frameworks' readiness, usage, and impact on the economy. It is produced by the UN's ITU. The Impact Subindex of the *Network Readiness Index* measures economic and social impacts of ICT, including value added, employment, and access to public and private services. It is produced by the Portulans Institute, an independent nonprofit, nonpartisan research and educational institute based in Washington, D.C. As Table 4 shows, these two correlations have consistently shown a strong and sustained relationship ranging from 0.82 to 0.85 between levels of IP protection and the availability and use of ICT

hardware and communications infrastructure.

Comparing other international measures and benchmarks of the availability and use of mobile and ICT communications infrastructure with levels of IP protection as measured by the Index shows similar results.

First published in the *World Bank's World Development Report 2016: Digital Dividends* paper, the Digital Adoption Index (DAI) seeks to measure the extent to which digital technologies are available, adopted, and fit for purpose for their intended users. The DAI is built on three separate subindices that together constitute the overall DAI. The World Bank describes the initiative as follows:

The overall DAI is the simple average of three subindexes. Each subindex comprises technologies necessary for the respective agent to promote development in the digital era: increasing productivity and accelerating broad-based growth for business, expanding opportunities and improving welfare for people, and increasing the efficiency and accountability of service delivery for government.³²

As such, the DAI is an important measure of the state of the digital environment in a given economy, including with respect to the adoption and use of mobile and ICT communications infrastructure. It is worthwhile to examine the relationship between an economy's score in the DAI and its score in the IP Index to assess whether economies with a stronger national IP environment also have a higher rating in the DAI. Table 5 shows how 52 of the 55 economies (the DAI does not cover Algeria, Brunei, or Taiwan) sampled in the 2023 Index fared in the DAI.



Table 5: World Bank Digital Adoption Index 2016 and Index Eleventh Edition Overall Scores

Country	Index Eleventh Edition, Overall Scores	World Bank, Digital Adoption Index, Overall Scores 2016
U.S.	95.48%	74.71%
UK	94.14%	76.40%
France	93.12%	75.40%
Germany	92.46%	83.97%
Sweden	92.14%	83.17%
Japan	91.26%	83.49%
The Netherlands	90.70%	83.85%
Ireland	89.36%	65.88%
Spain	86.44%	76.50%
Switzerland	86.00%	82.24%
Singapore	84.94%	87.06%
South Korea	84.44%	85.78%
Italy	83.90%	76.51%
Australia	80.68%	71.22%
Hungary	76.90%	69.07%
Canada	75.72%	69.11%
Israel	72.72%	78.79%
Greece	70.92%	60.52%
Poland	70.74%	69.03%
New Zealand	69.28%	70.61%
Morocco	62.26%	55.54%
Mexico	58.98%	60.11%
China	57.86%	58.62%
Costa Rica	54.56%	66.28%
Dominican Republic	54.28%	49.84%
Malaysia	53.44%	68.62%
Turkey	51.07%	63.21%
Peru	49.82%	55.35%
Chile	49.72%	75.62%
Colombia	48.84%	63.74%
UAE	46.00%	82.30%
Jordan	44.70%	54.98%
Saudi Arabia	42.38%	66.95%
Honduras	42.16%	42.94%
Brazil	42.02%	68.30%
Philippines	41.58%	49.16%
Ghana	40.88%	45.45%

Country	Index Eleventh Edition, Overall Scores	World Bank, Digital Adoption Index, Overall Scores 2016
Vietnam	40.74%	52.13%
Ukraine	39.74%	53.78%
India	38.64%	51.08%
Thailand	38.28%	61.94%
Kenya	37.36%	45.42%
South Africa	37.28%	63.81%
Argentina	37.00%	68.57%
Nigeria	33.34%	41.87%
Egypt	32.82%	52.58%
Ecuador	30.68%	56.86%
Indonesia	30.42%	45.72%
Kuwait	28.42%	63.46%
Pakistan	27.42%	39.99%
Russia	25.02%	74.41%
Venezuela	14.10%	49.09%

As Table 5 suggests, economies with a stronger national IP environment also tend to achieve a higher score in the DAI. Although there are some notable exceptions—including the **UAE**, which achieves a high score in the DAI but has a weaker national IP environment—most economies with a digital environment that is conducive to achieving socioeconomic developmental goals also have strong IP environments. For example, most of the economies that achieve a score of over 75% in the DAI also have an overall Index score of 80% or more.

Other specific measures related to the adoption of the newest 5G mobile communications standard suggest a similar relationship.

In 2021, the Economist Intelligence Unit (EIU) published *The 5G Readiness Guide Deployment: Strategies, Opportunities and Challenges Across the Globe*.³³ This is a proprietary metric assessing the 5G capacity in 60 economies worldwide. The metric scores economies across six “parameters” related to national 5G capacity:

1. The business environment
2. Spectrum availability
3. The current level of 5G deployment
4. 5G network speed
5. Progress on industry trials of 5G
6. The robustness of 5G policy

Economies’ 5G capabilities for each parameter are assessed as being high, medium, or low. The published and publicly available report contains the full results for 18 total economies, 14 of which are included in the Index. Table 6 compares the results for these 14 economies across all six 5G parameters included in the *Guide* and with their overall score in the eleventh edition of the Index.



Table 6: Economist Intelligence Unit (EIU) 5G Readiness Guide and Index Eleventh Edition overall score

Index Economy	Index Eleventh Edition, Overall Scores	Parameter 1: Business Environment Ranking	Parameter 2: Spectrum Availability	Parameter 3: 5G Deployment	Parameter 4: 5G Network Speed	Parameter 5: Progress in Industry Trials	Parameter 6: Robustness of 5G Policy
U.S.	95.48%	High	High	High	Low	High	Medium
UK	94.14%	High	Medium	High	Medium	High	High
Germany	92.46%	High	High	High	Medium	High	High
Japan	91.26%	High	High	Medium	Medium	High	High
South Korea	84.44%	High	High	High	High	High	High
Canada	75.72%	High	Medium	Low	Medium	High	Medium
Taiwan	66.31%	High	High	High	High	Medium	High
Mexico	58.98%	Medium	Medium	Low	Low	Medium	Medium
China	57.86%	Medium	Medium	Medium	High	High	High
Chile	49.72%	High	High	Low	Low	High	High
UAE	46.00%	High	High	Low	High	High	High
Saudi Arabia	42.38%	Medium	High	Medium	High	High	High
Brazil	42.02%	Medium	Medium	Low	Low	Medium	Medium
South Africa	37.28%	Medium	Low	Low	Low	Low	Medium

Although not a numerical measure, like the DAI, economies with a stronger national IP environment also tend to achieve a higher score in the EIU’s *5G Readiness Guide*. Of the 14 Index economies included in the *Guide*, those scoring 66% or more in the Index received a higher classification across the six parameters. Of the economies scoring less than 66%, only the **UAE** received a classification across the six parameters that was comparable with the other top performers. This difference in performance is particularly pronounced when looking at Parameter 3: 5G Deployment, which measures the extent to which a given economy has deployed a 5G network. Of the economies scoring more than 66% in the Index, only **Canada** received the lowest assessment in the *Guide*. This compares to five of seven economies scoring less than 66%, which were all rated as low 5G deployment.

Summary

As the cited data and evidence show, a strong and measurable relationship exists between the protection of IP and the development and dissemination of mobile and ICT communications infrastructure and related technologies, including 5G. The top-performing economies in the cited correlations and measures are also those economies that consistently score highly in the Index. This includes the **United States, the UK, EU Member States, Switzerland, Singapore, and Japan**. These economies—most notably the **United States**—have also been responsible for a substantial proportion of the R&D that has made modern mobile telecommunications technology possible, including the 5G standard. The performance of these Index economies stands in stark contrast to economies that do not provide the requisite IP protections and achieve a much lower score in the Index. These economies tend to see much lower levels of both the development and dissemination of mobile and ICT communications infrastructure and related technologies.

As noted in past editions of the Index, among the most significant impediments to the effective dissemination and use of mobile and ICT communications infrastructure and related technologies are barriers to licensing. As the next subsection details, not only are such barriers again on the rise in several Index economies, but they are also targeting technologies based on SEPs.



Getting in the Way:

How Barriers to Licensing Continue to Hold Back the Transfer and Use of New Technologies, Innovation, and Global Economic Activity

New technologies can only contribute to economic activity if they are developed into real-life, useful products that can be commercialized in the marketplace. A brilliant invention or technology that sits on the proverbial shelf is unlikely to be economically productive. 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 significant and distinct contribution to the economic strength and well-being of the economies in which they take place. For universities and public research organizations, the transfer process enables public research institutions to obtain access to commercial research funds, state-of-the-art equipment, and leading-edge technologies, while allowing industry to benefit from the extensive knowledge and ingenuity of academic researchers. For less developed economies, international licensing of technology can provide the basis for local technological development and for building a more sophisticated absorptive capacity. Global technology flows and the commercialization of IP assets are thus crucial drivers of innovation. Through licensing, technology is transferred to other actors (public and private) and eventually to the public in the form of new products and services. In other words, licensing facilitates technology diffusion by making usable technologies and content widely available. Many governments—in developed and developing economies alike—understand this and dedicate significant resources

to enhance innovation and technological development and transfer. Innovation-led growth is a strategic and, in many cases, existential goal for virtually all economies included in the Index. However, licensing and technology transfer relies on a supportive and efficient regulatory environment and IP frameworks that minimize red tape, facilitate market-based partnerships, and uphold the integrity of partnerships. As the Index shows, many Index 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. In some cases, Index economies are doing the exact opposite and are imposing new and additional hurdles and barriers.

Localization requirements and barriers to licensing and international technology transfer

Localization policies are the name given to laws, rules, and measures taken by governments to build or increase a domestic economic capacity either generally or in a given industry or area of economic activity. The Office of the U.S. Trade Representative (USTR) defines localization barriers to trade as those “measures designed to protect, favor, or stimulate domestic industries, service providers, and/or intellectual property (IP) at the expense of goods, services, or IP from other countries.”³⁴ Localization policies can vary from the general, such as requiring majority local ownership of any incorporated entities for all industries. The same policies can also be sector-specific with similar mandates but for specific industries.

Frequently, economies seek to “localize” growing domestic industrial capacity to further their own

national interest. Most obviously, developing industrial and economic domestic capacities is linked to the ability of a given economy to supply its population’s needs, both in actual terms and in providing a sense of national autonomy and independence. For many economies, self-sufficiency is critical, particularly in strategic industries or sectors. Second, building local industries provides economies with a basis on which to compete regionally and globally. A strong local industry acts as a springboard for positioning a given economy or industry to compete in international markets, thus enhancing the appeal and production of local actors. Finally, and perhaps most importantly, efforts to grow a given economy’s domestic industrial capacity are an integral facet of economic and societal development. This is particularly pronounced for high-tech industries where developing a local and national high-tech capability is intrinsically linked with an economy’s level of economic development. Most economies wish to strengthen and grow the economic contribution of innovative, technically complex manufacturing and knowledge-intensive industries. Climbing the value chain in this respect not only grows national output but has numerous socioeconomic benefits, including the creation and diffusion of high-skilled human capital.

Requirements for the use of local content and local preferencing have been in place for several years worldwide. Typically, these requirements have been more pronounced for certain industries and sectors. For example, the oil and gas industry has historically been subject to varying requirements of localizing production, such as engaging local communities and/or using local content and/or labor. Economies tend to promote investment in and growth of local industrial activities through a wide range of policies, including rules, regulations, incentives, and sanctions. Such policies may be aimed at domestic entities and foreign companies, with the idea that they would allocate a portion of their operations in a given economy.

Many economies also limit and restrict levels of foreign direct investment and equity ownership. These restrictions and limitations can vary from sector to sector and from economy to economy. Many economies, for example, have extensive negative lists of sectors in which foreign investment is banned or equity ownership is restricted. Notably, localization policies have increasingly targeted high-tech fields such as ICT, telecommunications, internet-based services, biopharmaceuticals, and the creative industries. Increasingly, these localization policies extend to international licensing and the transfer of technology from one jurisdiction to another.

One of the most significant barriers that affects and impedes all facets of licensing and technology transfer—domestic and cross-border—is direct government intervention and setting of licensing terms. Such intervention consists of a centralized, top-down approach that seeks to mandate when and how licensing and technology transfer take place. These interventions can involve burdensome and costly administrative procedures or can comprise legal rules and policies that discriminate against rightsholders. The manner and extent of this intervention will vary from economy to economy, but it often involves the mandatory disclosure and review of all licensing agreements by a government authority. Usually, this review includes the setting of contractual terms (including royalty rates), and, in some cases, licensors are coerced into sharing their technology with local partners.

Many Index economies also place extensive disclosure and registration requirements on licensing parties and require licensing agreements to be recorded and registered with national IP offices. The reasons for this requirement can be relatively innocuous, whereby registration and recording are a way of ensuring third-party awareness and clarity on legal licensing rights in case of future disputes. However, requirements



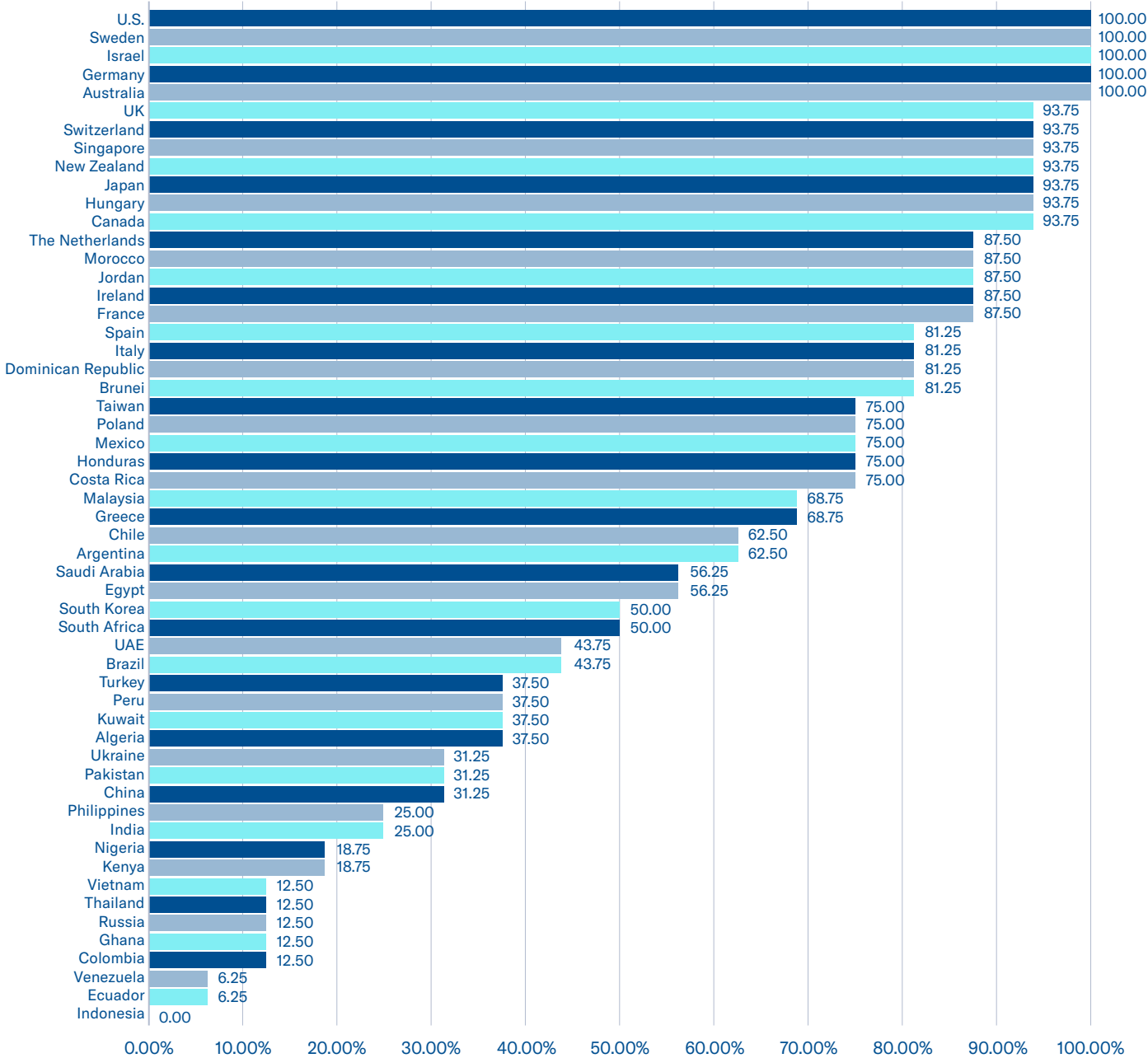
can also be more intrusive, whereby registration requirements are part of a broader effort of governments to impose control and direct oversight over licensing terms. Registration requirements are not contingent or related to an economy’s overall level of development; both developed OECD economies and emerging markets have these requirements in place.

Increasingly, many economies are targeting technologies based on standard and essential patents. SEP-based technologies are central to the future innovation and economic growth of many of the cutting-edge industries that are loosely labeled as making up the “Fourth Industrial Revolution,” including the Internet of Things, AI, robotics, and 3-D printing. For example, AI is used everywhere today, including the cloud, autonomous vehicles, smartphones, and the identification of cancer

cells. Nanotechnology and digital fabrication are applied in material and biomedical sciences, and quantum computing technologies enable big data analysis to be used in everything from drug development to market analysis to the prediction of consumer preferences. SEP-based technologies are central to these products and services and more. As an increasing number of products rely on interconnectivity and the ability to communicate with one another, the underlying SEP-based technologies that make this possible are critical to future global and national economic activity.

Since 2018, the Index has included specific indicators related to localization requirements and barriers to licensing and international technology transfer (indicators 26, 27, 28, and 29). Figure 14 shows the total score for these indicators in this edition of the Index.

Figure 14: Overall Score, Indicators 26, 27, 28, and 29 Isolated



As Figure 14 shows, a wide disparity exists between Index economies’ scores on these indicators. The average (mean) score for economies in the top half is 86.83%. Over 92% of economies (26 of 28) in the top half achieved a score of three-quarters or more. This compares to an average (mean) score

for economies in the lower half at 30.79%. This is a striking difference of over 56%. All but a handful of economies in the lower half scored less than 50%. Of note is that many large emerging markets achieved a weak score on these indicators.



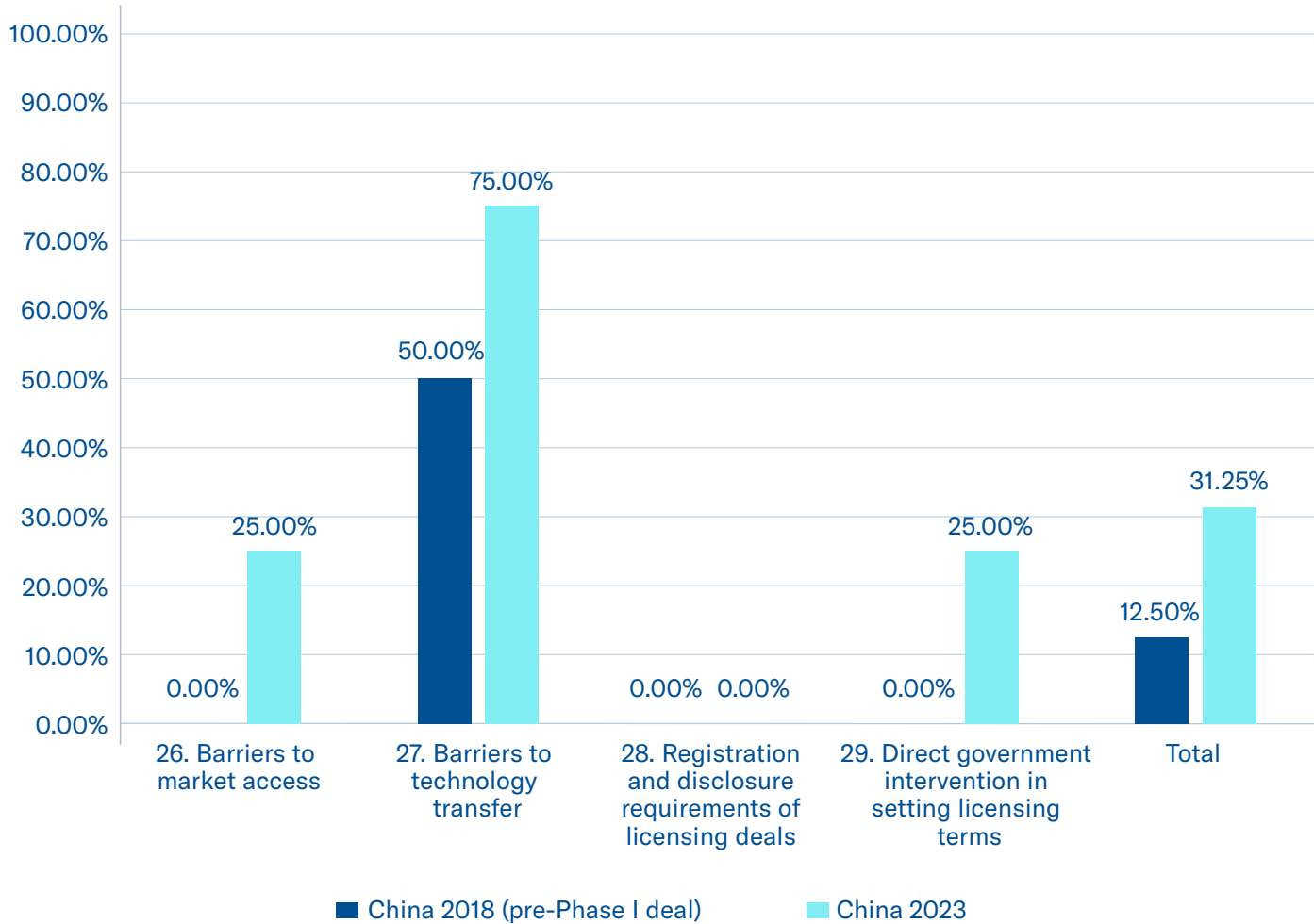
Arguably, no economy is more concerned with technology transfer and generating domestic innovation than **China**. As noted over the course of the Index, China’s model has diverged from international standards through direct government intervention and the use of coercive licensing and other barriers. The Technology Import/Export Regulations (TIER) 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-related and market access–related bi- and plurilateral discussions with China for 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 between the United States and China.

As detailed in previous editions of the Index, in 2019–2020, the Chinese government introduced positive changes to China’s technology transfer and licensing environment. Most importantly, the Foreign Investment Law, the TIER Regulations, and the Joint Venture regime were changed, with many of the most onerous provisions described earlier now removed. Specifically, Article 22 of the Foreign Investment Law states explicitly that the IP rights of foreign entities and investors should be protected and there should be no coercion or forced technology transfer. Similarly, the revised TIER regulations have removed and/or amended provisions to indemnification and ownership and usage of improvements made to a licensed technology.

In 2021, a new Civil Code came into effect. Although this sprawling piece of legislation touches on all aspects of civil law, it also includes specific provisions related to technology transfer and contract law in a dedicated chapter, Chapter 20. Notably, although providing a legal framework and a reference point for technology transfer and licensing contracts, the articles of that 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.” As noted at the time, these changes hold the promise of fundamentally remodeling the nature in which licenses can be drafted and executed between foreign and Chinese entities. As a result, China’s score increased on relevant Index indicators in the eighth edition of the Index. Figure 15 compares China’s Index scores on indicators 26, 27, 28, and 29 before these reforms and after.

Figure 15: China’s Overall Score, Indicators 26, 27, 28, and 29 Isolated, Seventh Edition Versus Eleventh Edition



As Figure 15 shows, China’s reform efforts resulted in a substantial score increase on three of the four measured indicators. Overall, comparing the prereform environment with the score after reforms, China saw an improvement of 18.75%, more than doubling its performance on these indicators.

However, despite this legislative progress, since then, licensors and rightsholders have continued to face substantive challenges to doing business in China on fair, nondiscriminatory, and equal terms. Specifically, the past few years have seen a growing trend of rightsholders facing global antisuit injunctions and restrictions on their ability to assert infringement claims in legal jurisdictions outside China. Chinese courts have increasingly claimed global jurisdiction to set global licensing rates for technologies protected by standard and essential patents, threatening exorbitant fines and withholding access to the Chinese market



to prevent foreign patent holders from asserting their rights (in both China and global jurisdictions). The outcomes of these cases have also been cited and referred to as “model” IP rights cases by government authorities. Such actions violate the spirit of China’s commitment under Chapter 2 of the January 2020 agreement to refrain from directly or indirectly forcing technology transfers. These actions are also contrary to China’s commitments under TRIPS Article 28, which guarantees patent protection rights.

In February 2022, the **EU** filed a request for consultations with China on this issue at the WTO. This was followed in March by requests from **Japan, Canada, and the United States** to join these consultations. At the time of research, no further action had been taken at the WTO. In a separate development, in June 2022, China enacted a new Anti-Monopoly Law. The new law greatly expands the government’s basis for action against anticompetitive behavior and substantially increases fines and penalties. Although Article 8 maintains large carveouts for state entities and businesses that are “vital to the national economy,” Article 41 imposes a nondiscrimination clause on public bodies’ regulation and licensing of “non-local goods,” which could, also apply to foreign producers and promote fairer competition in the Chinese market.

With respect to IP rights, Article 68 states that the “Law applies to undertakings’ abuse of intellectual property rights to eliminate or restrict competition.” The new law was accompanied by several new draft rules, including “provisions on prohibiting abuse of intellectual property rights to exclude and restrict competition.” Like the underlying legislation, this draft rule considerably expands the powers of investigation, punishment,

and meaning of what constitutes anticompetitive behavior within the context of the exercise of IP rights. Specifically, several articles defining anticompetitive behavior—including Articles 15, 16, and 17, which refer explicitly to SEPs and copyright collection societies—contain not only broad and vague language on what constitutes anticompetitive behavior within an IP rights context but also vest considerable discretion with the anticompetition authorities in identifying and defining such behavior. Under these articles, anticompetitive behavior is simply defined as “other abuses of market domination identified by the State Administration for Market Regulation.” As mentioned, SEP-based technologies are central to future innovation and economic growth, both in China and globally. The emergence and broader use of these new technologies are likely to result in an even greater use of SEPs as well as a concomitant increase in the number of potential legal disputes that could hold up the development and use of these new technologies and industries. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new, nor are they unique to China. This is an evolving field of IP policy and jurisprudence for a subject matter that is deeply complex. Each licensing negotiation is unique and should not be subject to prescriptive government action or intervention, whether through direct or indirect pressure. Should rightsholders continue to face challenges in asserting their rights on fair, nondiscriminatory, and equal terms—whether through the Chinese judiciary or administratively through the expanded powers given the anticompetition authorities in the new Anti-Monopoly Law and accompanying rules—this will result in a sharp score decrease on relevant Index indicators and will negate the positive impact of the Phase One Agreement with the United States.

Fewer new products and less innovation: The economic cost of localization requirements and barriers to licensing and international technology transfer

Impeding licensing activity is not cost free. Just like with other impediments to the protection of IP, the restriction of licensing hurts all parties, including licensors, licensees, and the domestic economy in which the licensing is restricted. This subsection looks at some of the international data on licensing flows to assess the impact of technology diffusion regimes that seek to manipulate the licensing process, prioritize local entities, and make licensing overly difficult or insecure. It is worthwhile to use empirical evidence to examine whether these controls on licensing have led to increased rates of diffusion of technologies.

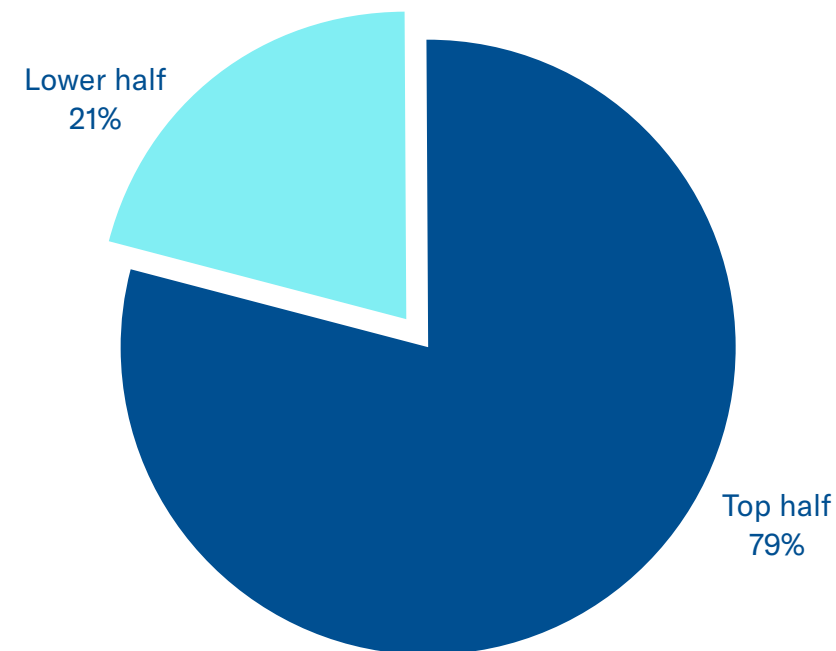
One proxy for technology flows, particularly of the most high-value assets, is to look at rates of international trade in charges for the use of IP (including royalties and license fees). One measure that captures in-flows of technology and various types of IP assets is the World Bank’s indicator on payments by residents to nonresidents for the use of IP rights.³⁵ The World Bank defines these charges for the use of IP as “payments and receipts between residents and non-residents for the authorized use of proprietary rights (such as patents, trademarks, copyrights, industrial processes and designs, including trade secrets, and franchises) and for the use, through licensing agreements, of produced originals or prototypes (such as copyrights on books and manuscripts, computer software, cinematographic works, and sound recordings) and related rights (such as for live performances and television, cable, or satellite broadcast).” The statistics are based on the International Monetary Fund’s *Balance of Payments Statistics Yearbook* and data files. These charges thus include all manner of IP rights that are licensed

internationally. Although other global and economy-specific measures exist, the World Bank’s data provide consistent and global coverage, making it a relatively good proxy for levels of technology transfer and licensing activities. Still, as with all data, there are a few important caveats to bear in mind. The World Bank’s data do not provide a breakdown on the type of IP or licensing agreement. The data do not show the specific types of IP rights being licensed and transferred. Furthermore, what is measured is the total value of licensing, which does not necessarily reflect volume. In some cases, very high-value one-off licensing transactions can thus potentially skew numbers. Still, with these caveats in mind, these data provide a good proxy and approximation of global in-licensing flows.

The World Bank has data available for 50 of the 55 economies included in the eleventh edition of the Index.³⁶ In 2021, the total value in aggregated overall payments (in billion USD) for the use of intellectual property for these economies was almost USD 500 billion (USD 481.2 billion). But which economies saw the highest rates of these in-licensing flows?

Figure 14 showed Index economy scores for indicators related to localization requirements and barriers to licensing and international technology transfer (indicators 26, 27, 28, and 29). As noted, a wide disparity exists between Index economies’ scores on these indicators with a difference in average (mean) score between the top half and lower half of the Index of over 56%. Would this disparity also be visible in rates of licensing as measured by the World Bank’s data? Figure 16 matches and aggregates these payment data into two equal blocks corresponding to the top-half and lower-half performers on indicators 26, 27, 28, and 29 as shown in Figure 14.

Figure 16: Charges for the Use of IP, Payments (Balance of Payments, Billion USD), Total Payments, 2021 or Latest Available Year, 50 Index Economies, World Bank, and Overall Score, Indicators 26, 27, 28, and 29 Isolated, Top Half Versus Lower Half



As Figure 16 shows, almost four-fifths of these in-licensing payments (USD 380.2 billion) emanated from economies with the highest level of IP protection and were in the top half of the Index on indicators related to localization requirements and barriers to licensing and international technology transfer (indicators 26, 27, 28, and 29) as displayed in Figure 14.

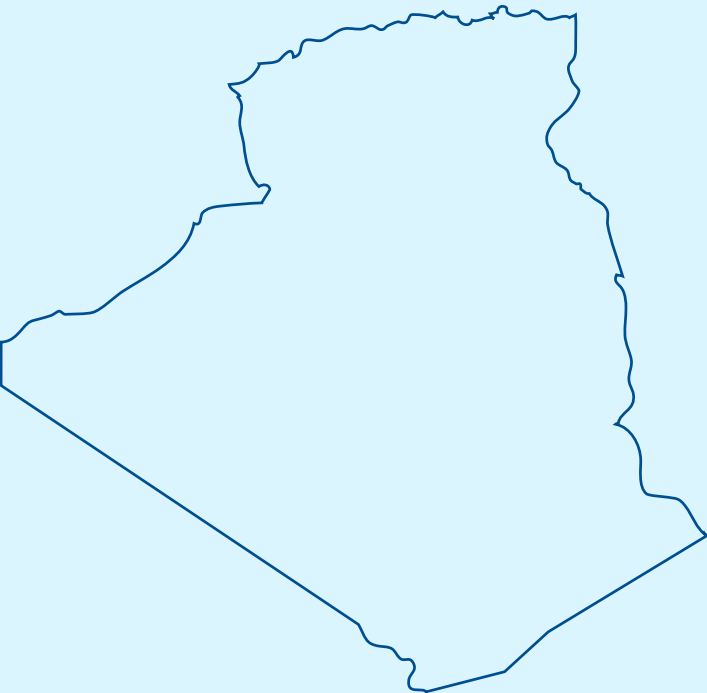
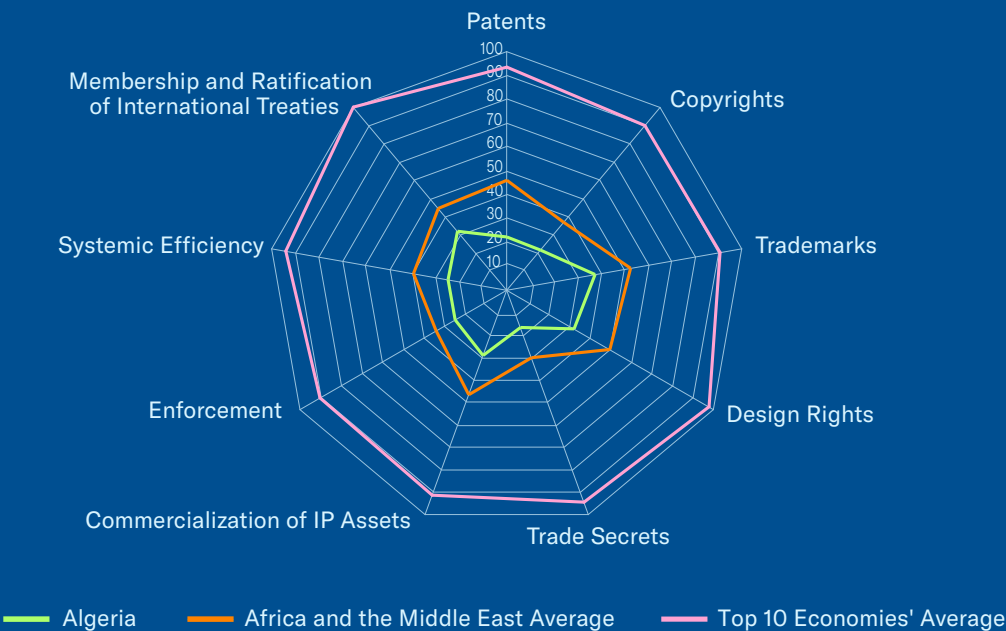
As with all types of economic activity, there is never one explanation. A multitude of factors affect decisions on licensing a given technology into any jurisdiction. These factors can occur at the micro and firm level, such as whether the given licensor has a commercial interest or a preexisting affiliation in a given jurisdiction. Licensing can also be influenced at the macro level, where market size, consumer purchasing power, and ease and attractiveness of doing business are among the chief considerations. Yet, looking at this from

the Index’s perspective, what stands out is the importance of IP protection. The Index economies that overwhelmingly attract the largest number of new technologies, IP assets, and licensing in-flows (as represented by the World Bank’s data) are those that achieve the highest scores on the Index and do not have in place localization requirements or barriers to licensing and international technology transfer. Covering 50 indicators across nine separate categories, the Index has for more than a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products. As Index economies move forward with reforming their economies in 2023 and beyond, we would encourage them to use the findings of the Index and accompanying Statistical Annex as a guide to which policies will promote or undermine technology transfer and licensing.

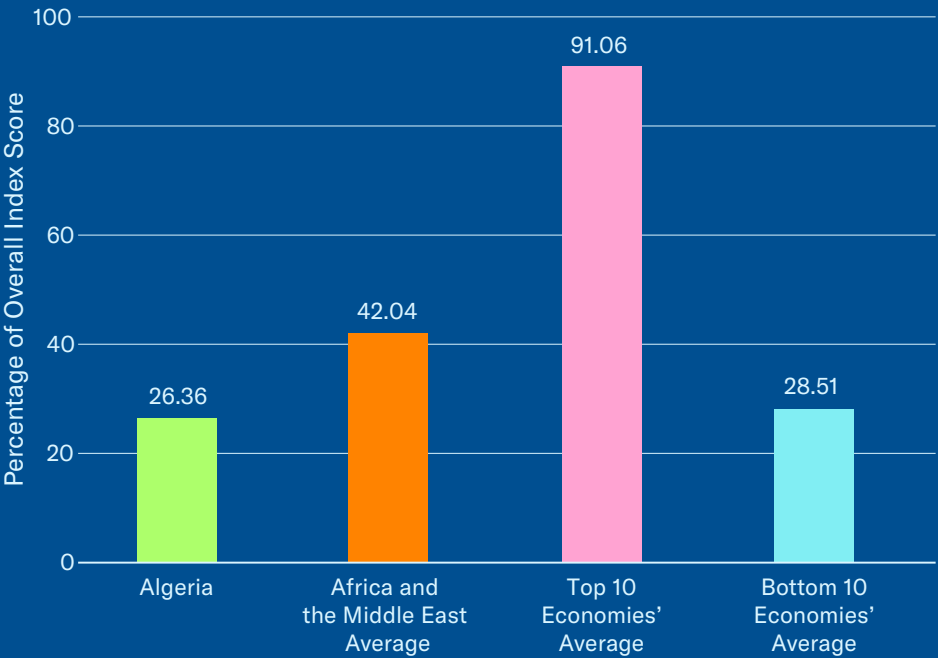
Economy Overviews



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Reforms in 2019 and 2020 removed the 51-49% local ownership rule and 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

Key Areas of Weakness

- Historically difficult localization policy environment with import substitution, bans, and local ownership requirements; 2021 Finance Law appears to reinstate some of these requirements
- Continued lack of clarity on local ownership requirements for biopharmaceutical industry
- 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.00	27. Barriers to technology transfer	0.25
3. Patentability of CIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.25
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.32
9. Patent opposition	0.00	33. Software piracy rates	0.18
Category 2: Copyrights, Related Rights, and Limitations		34. Civil and preceudural remedies	0.25
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.00	37. Effective border measures	0.25
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.25
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	
15. TPM and DRM	0.00	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.00
Category 3: Trademarks, Related Rights, and Limitations		41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.00
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.00	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 13.18			

Spotlight on the National IP Environment

Past Editions versus Current Score

Algeria’s overall score remains unchanged at 26.36% (13.18 out of 50).

Commercialization of IP Assets and Market Access

26. Barriers to market access; and 27. Barriers to technology transfer: As noted over the course of the Index, 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 for 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.

Sector-specific policies have also been in place that limit access to the Algerian marketplace. Most notable are restrictions on the importation of medicines and biopharmaceutical products and technologies, which have been in place since 2008 and have continuously been expanded. To date, hundreds of products have been listed as excluded from import with restrictions being in place for others. Drugs and active pharmaceutical ingredients (APIs) that are not locally manufactured have also been subject to annual import quotas. Recurrent delays in approving such quotas have also disrupted supplies of local manufacturers, undermining their business continuity and viability. Data localization rules are also in effect and require e-commerce operators and platforms to store relevant data locally in Algeria.

Most onerous of all has been strict ownership limitations. Based on a preexisting 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 engaged only in importation (and not domestic manufacturing activities), of which foreigners were previously allowed to own a 70% share. The rule was removed from the Investment Law in 2016 but was later reintroduced in the 2017 Finance Law. Through the 2020 Finance Law, the government in December 2019 removed the 51-49% ownership requirement for nonstrategic industries. The Finance Law did not specify how the elimination of the local ownership requirement would be implemented or which industries would be considered nonstrategic or strategic. In June 2020, a Supplemental Finance



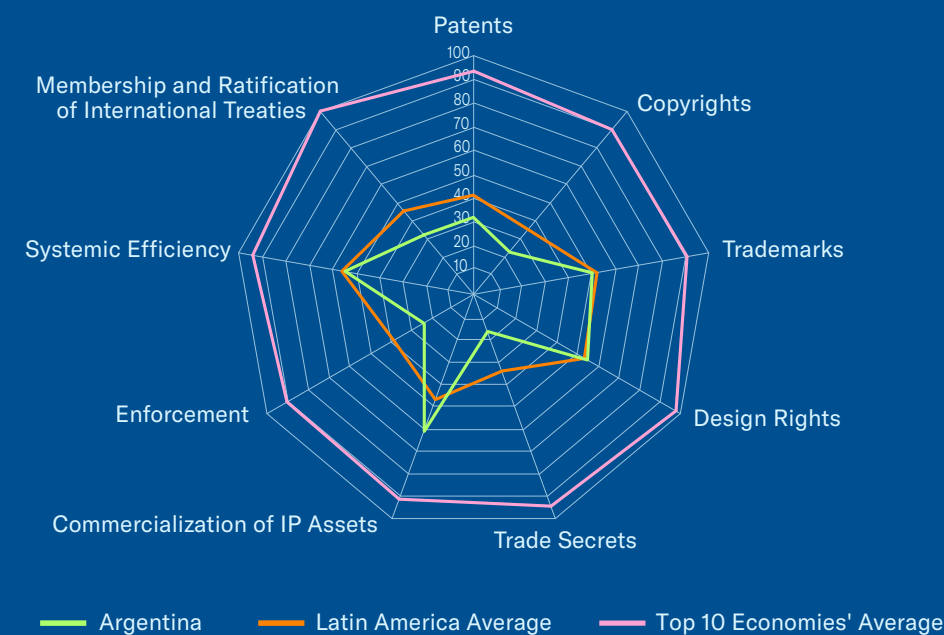
Law was enacted and published in the official gazette. Article 50 of this Law outlined which industries and sectors of the economy were to be considered strategic and still subject to the 51-49% local ownership requirement. These included mining, hydrocarbons, industries relating to national defense, physical infrastructure (railways, ports, and airports), and biopharmaceuticals.

Regarding the biopharmaceutical industry, the law appeared to provide an exception to the local ownership requirement for the research-based industry. However, this exception was not entirely clear and appeared to be contingent on fulfilling several conditions, including a local production requirement. New Finance Laws were issued in December 2020 and June 2021. Both laws have reiterated the conditions of the original Finance Law for the biopharmaceutical 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, and infrastructure including ports, railways, telecommunications, utilities, and the like. It is unusual to have such requirements in place for the biopharmaceutical sector, which is, fundamentally, a truly global industry with new medical technologies discovered, developed, and manufactured around the world. There has since been no further clarification under what circumstances the local majority ownership requirements would not apply in subsequent Finance Laws. Instead, the 2021 Finance Law appears to have imposed a further local partnership requirement on the importation of finished biopharmaceutical products. Article 49 of the law states that, excluding raw materials, Algerian majority ownership is required for the importation and resale of all products and goods in strategic industries, including pharmaceuticals. Algeria's desire to build a greater local biopharmaceutical

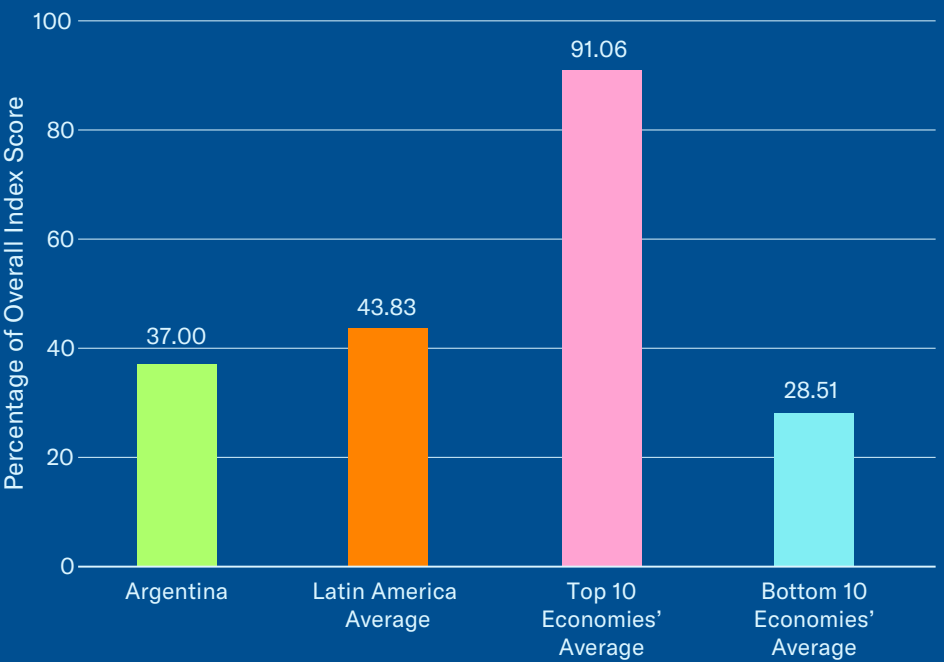
research & development (R&D), innovation, and manufacturing capacity should be applauded. More and more economies around the world are realizing the socioeconomic benefits of having a strong and thriving research-based sector. The reforms to the 2020 Finance Law and elimination of the 51-49% local ownership requirement provide a real opportunity for change. These statutory changes should be followed up with clear implementation of regulations that allow 100% foreign ownership for the research-based biopharmaceutical industry. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Basic framework for IP protection
- Pronounced efforts over the past several years to strengthen international cooperation on IP rights, including through patent prosecution highways (PPHs) and increased technical cooperation with the European Patent Office (EPO)
- Ongoing streamlining of administrative and enforcement bodies
- New 2021 tax incentives for R&D-based activities

Key Areas of Weakness

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



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
2.90		3.67	
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.50
3. Patentability of CIIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	0.90	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.50	1.70	
9. Patent opposition	0.00	32. Physical counterfeiting rates	0.37
Category 2: Copyrights, Related Rights, and Limitations		33. Software piracy rates	0.33
1.63		34. Civil and preceudural remedies	0.25
10. Term of protection	0.63	35. Preestablished damages	0.00
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.50	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	
15. TPM and DRM	0.00	2.75	
16. Government use of licensed software	0.00	39. Coordination of IP rights enforcement	0.50
Category 3: Trademarks, Related Rights, and Limitations		40. Consultation with stakeholders during IP policy formation	0.50
2.00		41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.25	2.25	
Category 4: Design Rights, Related Rights, and Limitations		44. WIPO Internet Treaties	1.00
1.10		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.25
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	1.00
0.50		49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
23. Protection of trade secrets (civil remedies)	0.25	50. Post-TRIPS FTA	0.00
24. Protection of trade secrets (criminal sanctions)	0.25		
25. Regulatory data protection term	0.00		
Total: 18.50			

Spotlight on the National IP Environment

Past Editions versus Current Score

Argentina’s overall score has decreased from 37.02% (18.51 out of 50) in the tenth edition of the Index to 37.00% (18.50 out of 50). This reflects a score decrease on indicator 32.

Patents, Related Rights, and Limitations; and Membership and Ratification of International Treaties

2. Patentability requirements; 3. Patentability of computer-implemented inventions (CIIIs); 8. Membership of a Patent Prosecution Highway (PPH); and 46. Patent Law Treaty and Patent Cooperation Treaty: As noted over the course of the Index, the patenting environment in Argentina is highly challenging for innovators. Patentability restrictions remain a serious and long-standing issue, in particular those concerning biopharmaceutical products and processes as well as CIIIs. In violation of TRIPS Article 27, patentability restrictions introduced in 2012 effectively curtail the issuing of patents for a range of biopharmaceutical inventions. This includes Markush-type patent claims and claims related to compositions, dosages, salts, esters, ethers, polymorphs, and analogous processes. Subsequent guidelines and rules issued by the national IP office Instituto Nacional de la Propiedad Industrial (INPI) have also curtailed the protection of biotechnology-based inventions. Similarly, innovators face substantive hurdles in obtaining patent protection for CIIIs. Section 6 of the Argentine Patent Law excludes computer programs from patentability; copyright is referred to as the primary form of protection for CIIIs. Although Regulation No. 318/2012 allows CIIIs to be patentable under certain conditions, data on patent applications show only a small number of CII applications filed in Argentina over the past four decades.

WIPO patent statistics show that between 1980 and 2018, a total of 1,598 patent applications were published under the categories “Computer technology” and “IT methods for management.” This compares to the 130,737 total applications filed during this period or 1.22% of the total number of applications published. Statistics for the number of patents granted for technology are not available for Argentina, but in most jurisdictions, not all patents published are granted.

More broadly, inventors face excessive processing times and long delays. A substantial backlog of patent applications has existed at INPI for several years with an average time to grant for many high-tech arts (including biopharmaceuticals, chemical, and biotech patents) being close to approximately a decade. To alleviate this backlog, INPI has taken some corrective actions. The agency has created expedited procedures for patent applications already issued elsewhere, has hired more patent examiners, and has been working with WIPO to digitize its patent services. INPI has also made a concerted effort engage in international patent cooperation and harmonization efforts.

Resolution 56/2016 has laid the basis for Argentina’s participation in PPH agreements with other economies’ patent offices. Although Argentina is not a member of the Global Patent Prosecution Highway or IP5 Patent Prosecution Highway, INPI has concluded PPHs with the USPTO, Japan Patent Office (JPO) and the Chinese National Intellectual Property Administration (CNIPA). The INPI has also deepened its cooperation with the EPO. In 2016, it signed a memorandum of understanding of bilateral cooperation focused on enhancing patent examiners’ expertise in the areas of patent procedures and search and examination. Also, in 2018, the INPI concluded a “Reinforced Partnership” agreement with the EPO. Although



these efforts are important steps, they have not always been followed up with further action. For example, the USTR in its *2022 Special 301 Report* noted that, “Argentina continues to struggle with a substantial backlog of patent applications for biotechnological and pharmaceutical inventions” and INPI “continues to operate with a reduced number of patent examiners.” Similarly, the PPH agreement concluded with the United States in 2017 expired in 2020 and has not been renewed.

Finally, Argentina remains one of a handful of Index economies that is not a contracting party to the Patent Cooperation Treaty. Argentina has signed, but not ratified, the treaty. The Patent Cooperation Treaty today has over 150 contracting parties and constitutes one of the most direct and impactful international efforts aimed at helping inventors protect their innovations across the globe. The Index will continue to monitor these developments in 2023.

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. Expedient injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation: As noted over the course of the Index, rightsholders face significant challenges in protecting their copyrighted content in Argentina. The existing legal framework has major gaps, and enforcement remains inadequate. Argentinian law provides only general exclusive rights for authors and creators with limited reference to the online environment. No copyright-specific legal provisions are currently in place with respect to secondary liability related to online piracy or an injunctive-style relief mechanism. There have been isolated

cases of courts ordering the disabling of access to infringing content and websites—in 2014, a court ordered access to the Pirate Bay to be disabled. However, overall, this is not an avenue of copyright enforcement readily available to rightsholders.

With regard to secondary liability and the concept of duty of care, several important court cases have affirmed that ISPs generally do not have secondary liability for copyright infringement. Specific cases include *Rodriguez v Google* (Supreme Court in 2014) and *Gimbutas v Google* (2017). Existing notice-and-takedown mechanisms rely on direct communication from rightsholders with ISPs, internet hosts, and online mediators. Several new laws have been proposed over the course of the Index, but they have all been lacking in key areas. For example, under bills proposed in 2013 and 2016, ISPs would be under no obligation to supervise internet content and would not be held responsible for copyright infringement unless they refused to comply with a judicial order asking them to remove the infringing content. In addition, the scope of this liability would be limited to “flagrantly illegal content,” such as content that facilitates crime, endangers human life, or advocates national or racial hate.

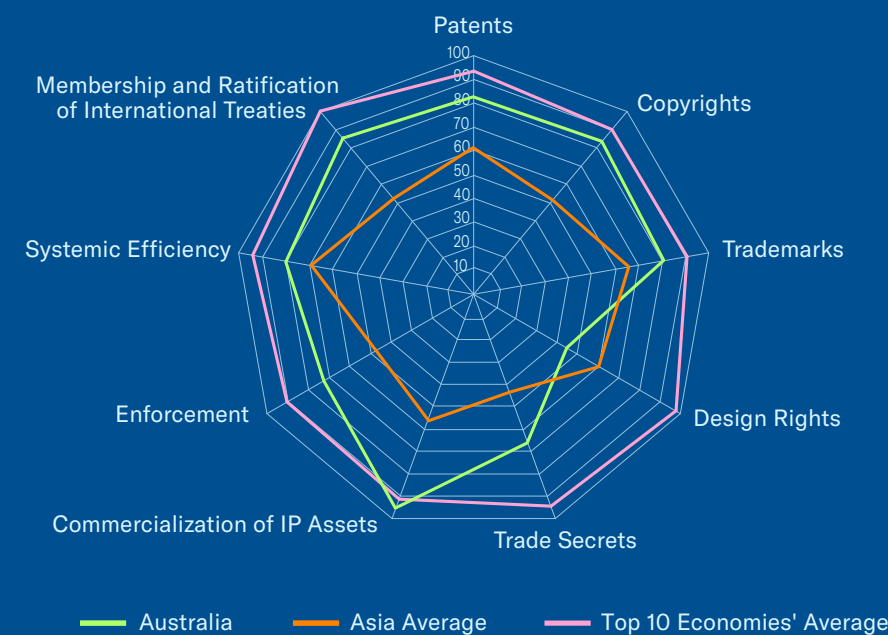
Protection for TPMs and DRMs is also lacking. Argentinian copyright law is supposed to automatically adopt the provisions of international treaties, such as the WIPO Copyright Treaty and the TRIPS Agreement through a “self-executing” process—that is, international treaty provisions take precedence over any inconsistent local laws. In theory, the manufacture or distribution of devices aimed at circumventing TPMs and DRMs is therefore prohibited in Argentina under the country’s WIPO Internet Treaties commitments. However, there is almost no enforcement of laws related to technological protection measures in Argentina. Industry sources have consistently stated that the lack of TPM and DRM enforcement and corresponding

domestic laws have placed Argentina as a top destination and host for circumvention devices. For example, the International Intellectual Property Alliance in its *2022 Special 301* submission reports that peer-to-peer video game piracy in Argentina is among the highest levels in the world. Similarly, these remain high when compared with estimated rates of signal piracy.

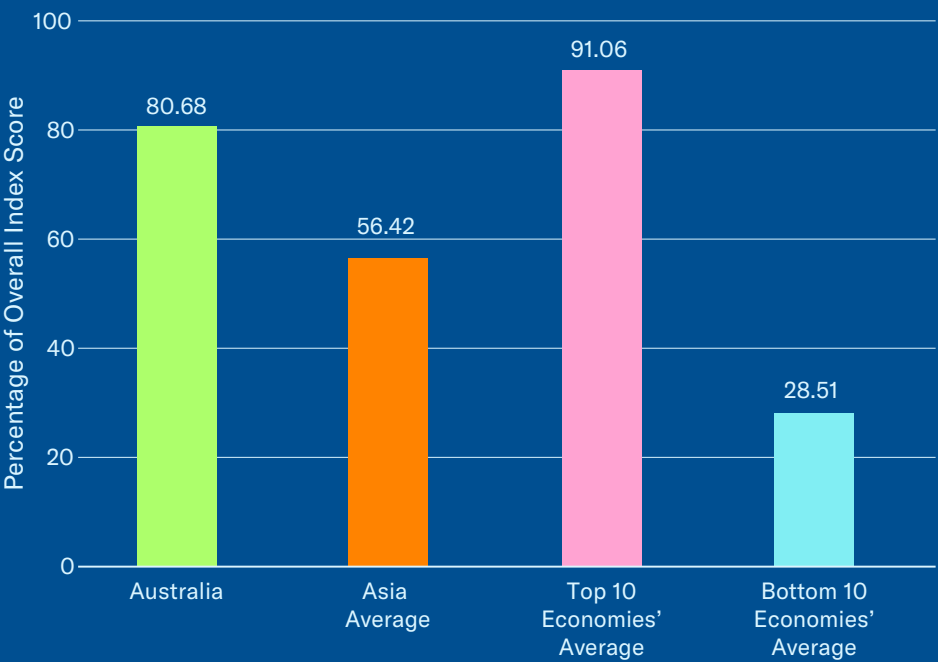
In 2019, the Latin American industry association ALIANZA released the findings from a study of estimated rates of signal piracy and theft in Latin America. The study found that the total pirated or unreported market in Argentina was an estimated 25% of the total number of potential end users. More broadly, criminal enforcement against IP infringement, including copyright violations, is limited in Argentina. Existing penalties are largely nondeterrent, and prosecution is infrequent. On a day-to-day operational level, the notorious La Salada market in Buenos Aires remains operational and is a major trading point for counterfeit goods and pirated content in the region. Online, Cuevana and associated links continue to offer pirated movies and TV shows despite the government’s indictment of a key participant in 2017. Legislative efforts to combat these issues have so far not been successful. In 2019, the government proposed a new penal code to address enforcement inefficiencies. Regarding IP rights, the draft code would provide more standardized criminal sanctions for offenses against most major IP rights. Passage of the bill would be a positive step for Argentina and would result in a score increase on this indicator. However, at the time of this research, no new laws have been passed. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



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
- 2018 National Security Legislation Amendment (Espionage and Foreign Interference) introduced stiff penalties for industrial espionage on behalf of a foreign state entity
- No administrative or regulatory burdens in place hindering licensing activity
- 2019/20 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	7.50	Category 6: Commercialization of IP Assets	5.75
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	5.06
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.74
9. Patent opposition	0.00	33. Software piracy rates	0.82
Category 2: Copyrights, Related Rights, and Limitations	5.88	34. Civil and preceudural remedies	1.00
10. Term of protection	0.63	35. Preestablished damages	0.75
11. Exclusive rights	1.00	36. Criminal standards	0.75
12. Injunctive-type relief	1.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.50	38. Transparency and public reporting by customs	0.50
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	4.00
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.75	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.25	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	6.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.90	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.00	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.75	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.75	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
Total: 40.34			

Spotlight on the National IP Environment

Past Editions versus Current Score

Australia’s overall score has decreased from 80.70% (40.35 out of 50) in the tenth edition of the Index to 80.68% (40.34 out of 50). This reflects a score decrease on indicator 32.

Patents, Related Rights and Limitations

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. This includes the absence of an automatic stay, the certification requirements for both generic producers and innovative patent holders, the absence of a mechanism to notify patent holders of potentially infringing follow-on products; and the historical application of market-sized damages. In 2020, the Therapeutic Goods Administration (TGA) concluded an 18-month consultation on prescription medicine 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 their application is accepted for evaluation by the TGA. The change was designed to create an opportunity for earlier negotiation and resolution of disputes on potential patent infringements before the follow-on product is listed in the pharmaceutical benefits scheme (PBS). Additionally, the TGA announced it will publish a description of major innovative medicine applications that are under evaluation by the TGA. As noted in last year’s edition of the Index, the Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021—passed into law in early 2021—did not include any relevant references to a new patent notification framework, and no proposed legislation

had been published by the TGA or presented to the Australian Parliament. Consequently, it remains unclear whether the new early notification scheme will come into effect. The Index will continue to monitor these developments in 2023.

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 recognized many times in the Index, Australia’s copyright laws have been substantially revised and reformed over the course of the Index. Of note is the manner in which Australia has become a world leader in the enforcement of copyright online through the introduction in 2015 of an injunctive style relief program. Australia’s Copyright Amendment (Online Infringement) Act 2015 (Section 115a) provides for injunctive relief that allows courts to require ISPs to disable access to foreign-hosted sites (or “online locations”) whose primary purpose is to infringe copyright. The provision has been applied in various landmark cases since its introduction. In 2016, federal court decisions regarding Roadshow Film (representing major international film studios) and Foxtel (a pay TV provider) successfully secured injunctions against many ISPs, requiring them to disable access to The Pirate Bay and other websites whose primary function is facilitating infringement. In relation to the issue of “mirror” sites of disabled infringing sites, the court ruled that rolling injunctions were possible but not automatic; courts must supervise injunctions disabling mirror or proxy sites. These positive efforts have continued in the intervening years. In 2017, access to more than 65 sites determined to be conducting or



facilitating “flagrant” copyright infringement and more than 340 alternative domain names was disabled. Similarly, in 2020, a federal court judge ordered the disabling of access to 86 alleged piracy websites. And to continue these strong efforts against copyright piracy, two new major orders were issued at the end of 2021 and early 2022. The cases, *Roadshow Films Pty Ltd v. Telstra Corporation Limited* [2021] FCA 1588 and *Roadshow Films Pty Ltd v. Telstra Corporation Limited* [2022] FCA 134, resulted in the disabling of access to over 130 online piracy access points. These orders again demonstrate Australia’s leadership on this issue and the ability of rightsholders to effectively address and neutralize the negative impact of online copyright infringement.

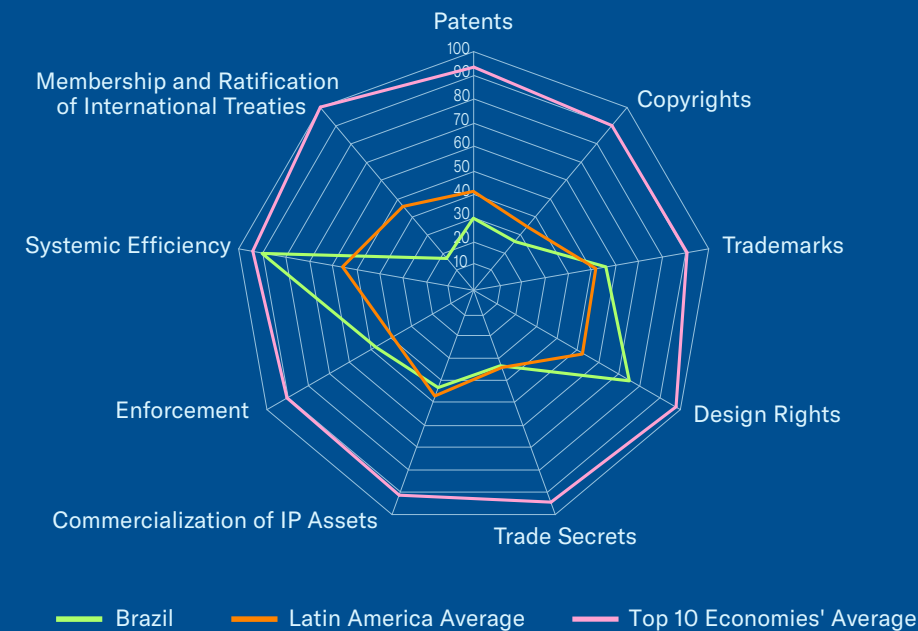
**Commercialization of IP Assets
and Market Access**

27. Barriers to technology transfer; 28. Registration and disclosure requirements of licensing deals; and 29. Direct government intervention in setting licensing terms: There are no substantive barriers to the commercialization of IP assets in Australia. Specific rules and guidelines of commercialization of IP assets from publicly funded research are established in the National Principles of Intellectual Property Management for Publicly Funded Research of 2001 under the Australian Research Council. The Australian government through IP Australia runs the “Source IP” program, “a digital marketplace specifically created to help businesses and researchers collaborate by facilitating quick and easy contact,” which provides businesses with access to public sector inventions and technology available for licensing and identifies collaboration opportunities. It also promotes patent licensing and collaboration in public research institutions. With respect to registration requirements, although it is possible to register licensing agreements with the relevant IP authorities, it is not a legal requirement. Similarly, the Australian government does not intervene or

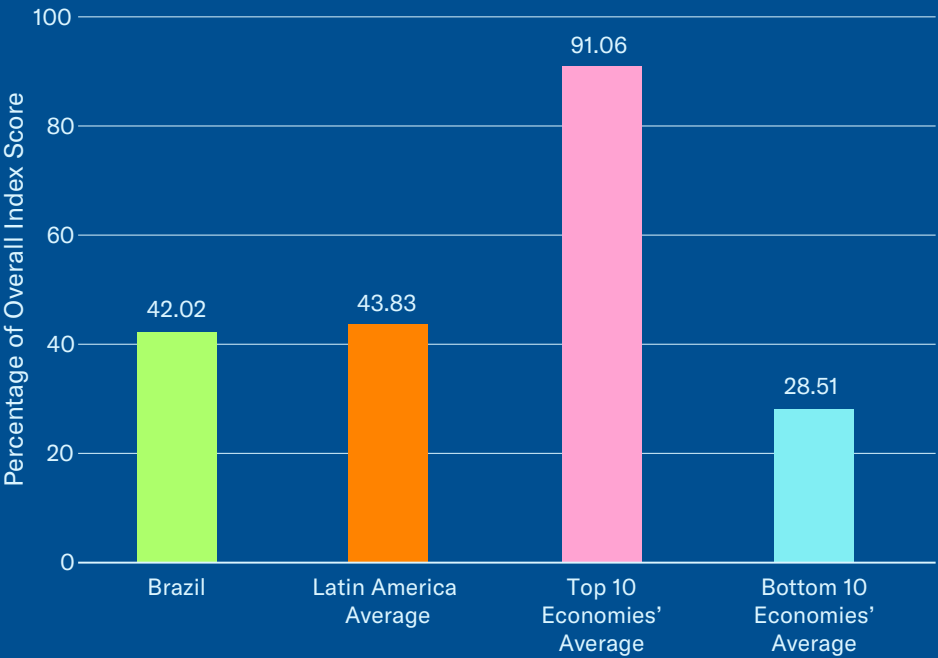
impose direct restrictions on licensing activity for IP rights or international technology transfer.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- “Operation Copyright” and “Operation 404 against piracy” continued in 2022 – key enforcement efforts with Brazilian police and international authorities disabling access to infringing online content
- In December of 2022, Brazil adhered to the Hauge Agreement
- INPI’s 2019 patent backlog plan ‘*Plano de Combate ao Backlog de Patentes*’ seeks to eliminate long-standing registration backlogs
- INPI released first ever study of IP intensive industries’ national economic impact in Brazil in 2021
- Law nº 14.195/2021 changed Brazil’s IP Law so that ANVISA’s prior consent on patent applications is no longer required
- Continuation and improvement of the Pilot-Project Patent Prosecution Highway (PPH)

Key Areas of Weakness

- Article 40 invalidation by the Supreme Court in 2021: without an instrument to replace Article 40, the measure weakens Brazil’s patenting standards and retroactively targets the biopharmaceutical industry; this remains unaddressed in 2022
- Compulsory licensing amendments for health emergency broadens existing emergency powers and authority and potentially generates legal uncertainty
- Key life sciences IP rights missing in the Brazilian Legislative framework, including patent term restoration and RDP, and, overall, a challenging patentability environment exists
- Limited participant in international IP efforts—only a full contracting party to two of nine treaties included in the Index
- Significant budget cuts to INPI approved by the Brazilian Congress



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	2.74	Category 6: Commercialization of IP Assets	2.58
1. Term of protection	1.00	26. Barriers to market access	0.75
2. Patentability requirements	0.00	27. Barriers to technology transfer	0.50
3. Patentability of CIIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.00
4. Plant variety protection	0.74	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.33
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	3.31
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.53
9. Patent opposition	0.50	33. Software piracy rates	0.53
Category 2: Copyrights, Related Rights, and Limitations	1.88	34. Civil and preceudural remedies	0.25
10. Term of protection	0.63	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.50
12. Injunctive-type relief	0.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.75
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	4.25
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	2.25	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	1.25
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	0.00
Category 4: Design Rights, Related Rights, and Limitations	1.50	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.00	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.50	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 21.01			

Spotlight on the National IP Environment

Past Editions versus Current Score

Brazil's overall score remains unchanged at 42.02% (21.01 out of 50).

Patents, Related Rights, and Limitations

2. Patentability requirements and 3. Patentability of computer-implemented inventions (CIIs): As noted in previous editions of the Index, rightsholders face many basic challenges in registering and protecting patent-eligible subject matter in Brazil. To begin with, patentability standards for both biopharmaceutical technologies and CIIs are outside international norms. Although some CIIs have been granted, computer-related inventions and software are viewed as being non-patentable subject matter. A set of patent guidelines published by the Brazilian Patent Office (INPI) in 2021 (*Diretrizes de Exame de Pedidos de Patente envolvendo Invenções Implementadas em Computador*) provides some helpful clarifications and examples on existing patentability standards for CIIs (including the fact that CIIs related to artificial intelligence, machine learning, and the Internet of Things may be patentable subject matter), but overall, these new guidelines do not fundamentally change existing standards.

More broadly, across all economic sectors and patent arts, INPI has historically had a backlog of patent applications ranging from 10 to 13 years depending on the field of technology; applications in the biopharmaceutical and ICT fields have traditionally been the worst affected. The past few years have seen a growing level of commitment and efforts by INPI to finally address this backlog but 2022 budget cuts INPI threaten to change its ability to continue improving the backlog. In 2019, a new initiative was announced, the Backlog Fight Plan (*Plano de Combate ao Backlog de Patentes*). INPI has passed several administrative resolutions over

the past few years, all aimed at accelerating the decision-making and patent prosecution process for applications with and without existing prior art searches and documentation. These actions have had a positive impact and have reduced the number of pending applications. At the time of research, the estimated backlog was just under 20,000 applications, down from over 147,000 in 2019. Of the 147,000 applications in the backlog identified by INPI in 2019, just under half, 72,000, had received a decision by mid-2022, whereas just over 60,000 applications had been definitively archived. The remaining applications were under review. INPI should be commended for finally tackling this long-standing bottleneck. Given that INPI has historically struggled to effectively address the extensive backlog and long delays in application processing, the Industrial Property Law (Law nº 9.279/1996) had provided innovators in Brazil with a guaranteed minimum term of exclusivity and protection of 10 years from *grant* for standard patents until 2021.

Article 40 of the referred law stated that the term of protection shall “not be less than 10 (ten) years for an invention patent and 7 (seven) years for a utility model patent, beginning on the date of granting, unless the INPI has been prevented from examining the merits of the application by a proven pending judicial dispute or for reasons of *force majeure*.” For years, Article 40 provided rightsholders with a proverbial floor of exclusivity and insurance against INPI's endemic delays. However, in a series of decisions in the spring of 2021, the Brazilian Supreme Court removed this provision. Not only did the court declare that Article 40 was unconstitutional and would no longer be available or applicable, but the court also stated that the ruling should be retroactively applied but only to granted patents in the biopharmaceutical and health-related fields. As noted last year, the ruling is a grave blow to Brazil's national IP environment, with thousands



of biopharmaceutical rightsholders discriminated against and exclusivity periods cut short. Through this decision, the Brazilian Supreme Court has not only further weakened Brazil's standards patent protection, but the selective retroactive application of the ruling to one field of technology and innovation institutes legal uncertainty and violates Article 27(1) of the TRIPS Treaty and established international principles of nondiscrimination.

To address this negative impact, in July 2022, Alexis Fonteyne, a member of the Brazilian Chamber of Deputies, presented a proposed legislation (Bill 2.056/2022) that would provide a period of patent term restoration due to administrative delays during patent examination and prosecution. The enactment of such legislation would be a positive step. However, at the time of research, no new legislation had been passed. The Index urges the Brazilian government and lawmakers to immediately address this issue. Large application backlogs and unreasonably long application processing times are not unique to Brazil or INPI, and a variety of mechanisms can resolve those issues. Such mechanisms could include, for example, the introduction of a new statutory defined variable term of adjustment, as Bill 2.056/2022 proposes, or a patent validation mechanism with other major IP offices. As a result of the weakening of the patenting environment and rightsholders' inability to continue to secure a 10-year minimum period of patent protection, Brazil's score on indicators 2 and 3 were reduced to 0 last year. The Index will continue to monitor these developments in 2023.

6. Legislative criteria and use of compulsory licensing of patented products and technologies:

As has been detailed in the Index, Brazilian health and pharmaceutical policy has historically had a strong focus on localizing industrial production, R&D, and cost controls through the overriding of IP rights. The relevant sections of the Industrial Property Law (Law nº 9.279/1996) provide a broad basis for compulsory licensing beyond the

use of this mechanism solely for public health emergencies that do not involve commercial consideration. Moreover, this mechanism also includes a domestic manufacturing criterion that can form the basis for the issuing of a compulsory license. As noted in past editions of the Index, these sections have been used in the past during price negotiations with foreign biopharmaceutical innovators to reduce their prices in light of the threat of approving the manufacturing of local generic versions of patented medicines. For example, the 2007 issuing of a compulsory license for the production of efavirenz by the Lula administration came one day after failed price negotiations with the manufacturer.

However, compulsory licensing and the overriding of property rights are 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 and is to be used only after all other options for negotiating pricing and supply have been exhausted.

Unfortunately, the focus on compulsory licensing as a public policy tool in Brazil has intensified in the past few years. Several amendments to the Industrial Property Law were signed into law in late

2021, with many more under discussion. Passed amendments included provisions broadening the government's emergency powers and authority to issue compulsory licenses, setting the percentage of royalties to be paid in licensing fees, and expanding the compulsory licensing mechanism to also cover patent applications. In a positive development, not all these legal changes will come into effect. Specifically, legal provisions related to technology transfer were first vetoed by then President Bolsonaro whose veto was subsequently upheld by both chambers of the National Congress in the summer of 2022. Nevertheless, combined with the previously discussed Supreme Court ruling and the lack of action on the part of the Brazilian government and legislature to effectively address the court's actions, the expansion of the compulsory licensing regime in Brazil further weakens what was already a challenging environment for biopharmaceutical innovators. The Index will continue to monitor these developments in 2023.

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. Expedient injunctive-style relief and disabling of infringing content online: The Brazilian Copyright Act provides basic exclusive rights and protection with relatively limited provisions in place addressing the issue of online infringement. Brazil does not have a formalized and comprehensive notice-and-takedown system in place. Historically, there has been some cooperation between ISPs and rightsholders, but this is piecemeal, ad hoc, and not systematic. Although primarily concerned with issues of data privacy and network neutrality, the 2014 *Marco Civil da Internet* (Internet Bill of Rights, Law No. 12,965) did contain some provisions related to the protection of content and copyright online. Specifically, Section 3 and

Articles 18–20 of the act provide a broad safe harbor provision for ISPs related to third-party infringement, with ISPs required to act and make infringing content unavailable only once a court order has been issued unambiguously finding that the content is infringing.

Given that the Brazilian justice system generally suffers from long processing times and high costs of litigation, the need for a court order stands in the way of a practical and workable mechanism ensuring the expeditious removal of infringing content. Similarly, there has historically been no dedicated or defined administrative or judicial pathway in place to provide injunctive style relief for copyright holders. As a result, and as has been noted over the course of the Index, industry data and consumer surveys have consistently shown that Brazil remains a central piracy hub in Latin America, with online infringement growing as broadband penetration and the use of mobile technologies grow. For example, 2019 data from the regional industry entertainment association ALIANZA suggest that Brazil remains the largest market for online piracy in Latin America with over 7 billion recorded web visits to online sources of piracy alone in the surveyed period. This was almost a 20% increase in traffic compared to 2017. Brazil was estimated to be the third largest consumer of pirated content in the world. Similarly, local media reports from 2021 suggested that about one-third of Brazilian internet users access infringing content online. Physical piracy also remains a real challenge to rightsholders. For example, the video game industry has long noted that the trade in pirated and modified video games and devices remains a key piracy challenge in Brazil. Several markets in São Paulo have been included in the USTR's *Review of Notorious Markets for Counterfeiting and Piracy* (2021). Unfortunately, copyright enforcement and an effective deterrence against piracy have historically been lacking. As mentioned, there are long backlogs in the Brazilian justice system, and the majority of those



arrested on suspicion of criminal IP infringement never face criminal charges or prosecution; charges are either dropped or suspended.

There have been isolated areas of success—for example, against physical piracy in São Paulo through the “City Free of Piracy Project”—but overall, copyright enforcement has remained a challenge. As noted in previous editions of the Index, this is now changing with the launch of several, dedicated enforcement operations against IP-infringing websites, vendors, and suspected criminals. For example, “Operation Copyright,” an initiative by the Brazilian Federal Police to tackle copyright piracy, was launched in 2019. Reports suggest that the police took coordinated action in five Brazilian states, shutting down torrent sites and seizing equipment and suspected goods. In 2020 and 2021, “Operation 404 against piracy” was launched. Spearheaded by a special police enforcement unit and the Ministry of Justice, with international support from the U.S. embassy and UK law enforcement officials, this special enforcement effort has had direct and tangible results. Hundreds of websites and applications offering copyright-infringing content have been shut down, and over 50 search and seizure warrants have been issued and executed across 12 Brazilian states with several arrests made. In 2022, these efforts continued in full force. Media reports suggest that over 500 websites and piracy applications were taken down through the efforts of Operation 404 during the summer.

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

a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the UK, India, Singapore and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, and the UK. They have proven to be effective in reducing the availability of copyright-infringing content within these jurisdictions. Should the Brazilian authorities move forward and make available a similar mechanism, it would mark a significant positive turning point for creators and rightsholders in Brazil and would result in score increases on indicators 11 and 12. These are positive developments, and the Index will continue to monitor this activity in 2023.

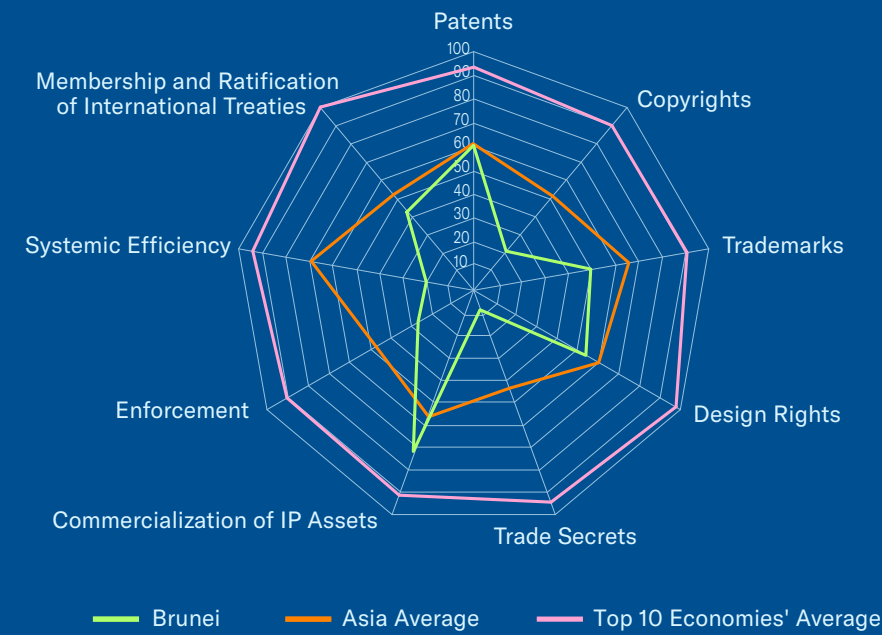
Membership and Ratification of International Treaties

49. The Hague Agreement Concerning the International Registration of Industrial Designs:

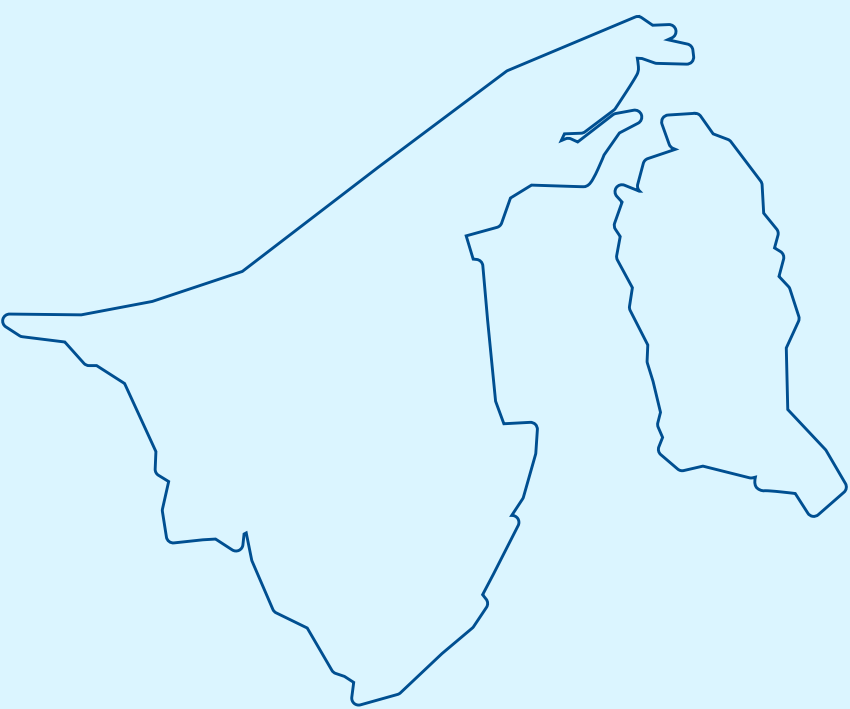
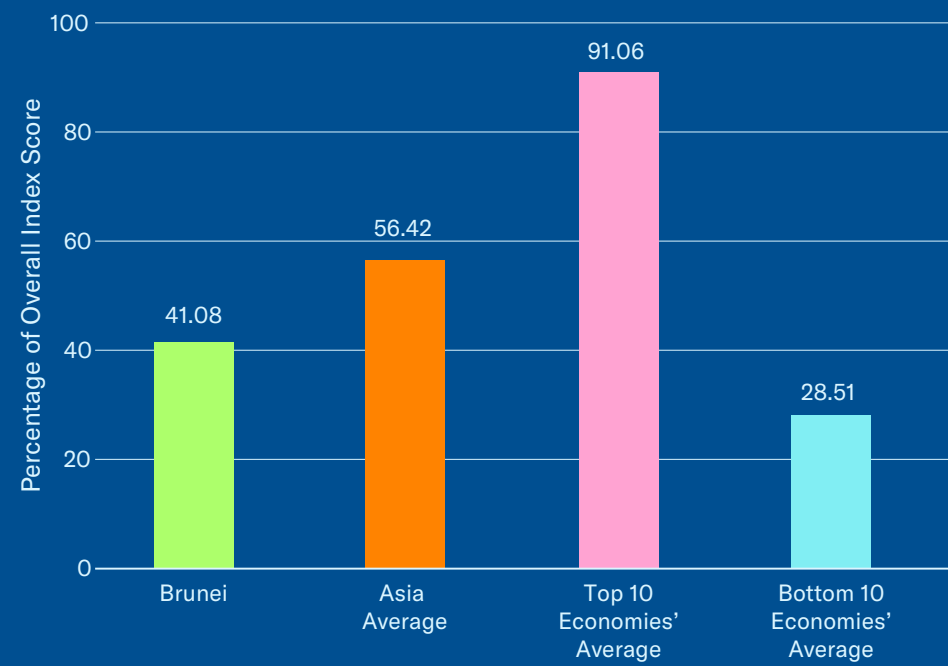
In late 2022, the Brazilian Senate passed Decree 274/22, which approves Brazil’s accession to the Hague Agreement. This follows the Chamber of Deputies approval during the summer. At the time of research, accession had not been formalized. Brazil’s accession to the Hague Agreement would be a positive development and would result in a score increase on this indicator.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Acceded to WIPO Internet Treaties in 2017
- Major IP reforms over the past decade, including establishing the Brunei IP Office (BrulPO)
- Removed from Special 301 Report
- PPH agreement is in place with Japan
- No fundamental administrative or regulatory barriers are 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	5.50	Category 6: Commercialization of IP Assets	4.33
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.75	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.75	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.33
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	1.83
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.47
9. Patent opposition	0.50	33. Software piracy rates	0.36
Category 2: Copyrights, Related Rights, and Limitations	1.53	34. Civil and preceudural remedies	0.25
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.50
12. Injunctive-type relief	0.00	37. Effective border measures	0.00
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	1.00
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	0.25
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.00
Category 3: Trademarks, Related Rights, and Limitations	2.00	41. Educational campaigns and awareness raising	0.25
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	3.00
20. Frameworks against online sale of counterfeit goods	0.00	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.10	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.25	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.00	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 20.54			

Spotlight on the National IP Environment

Past Editions versus Current Score

Brunei’s overall score remains unchanged at 41.08% (20.54 out of 50).

Enforcement; Membership and Ratification of International Treaties

37. Effective border measures; and 50. Post-TRIPS FTA: Being a contracting party to key international IP treaties reflects a given economy’s broader participation in the international IP community and embracing of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adheres to established standards and best practices. As noted in past editions of the Index, Brunei’s score in this category of the Index has increased substantially from a score of 0 in the fourth edition of the Index (the first year Brunei was included) to now achieving a score of 3, or 42.86%, of the total available score. This is notably higher than many high-income economies, such as New Zealand and the UAE, as well as some of Southeast Asia’s biggest economies such as Malaysia and Indonesia.

Of note is Brunei becoming a contracting party to the Hague Agreement in 2013 and to the Madrid Protocol in 2017. Both treaties have better aligned Brunei’s IP standards with international best practices and have improved rightsholders’ abilities to register and protect their rights across the world. The direct impact of this can be seen in the marked increase in registration activity at the BrulPO, which has seen a substantial increase in the number of applications for both trademark and design rights registration.

Overall, Brunei is a contracting party to the WIPO Internet Treaties; the Protocol Relating to the Madrid Agreement Concerning the International

Registration of Marks; the Patent Cooperation Treaty; and the Hague Agreement Concerning the International Registration of Industrial Designs. Brunei is not a contracting party to the Singapore Treaty on the Law of Trademarks; the Patent Law Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; or the Convention on Cybercrime, 2001.

With respect to post-TRIPS international trade agreements with substantial IP rights provisions, Brunei is a contracting party to both the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and the Regional Comprehensive Economic Partnership (RCEP) agreement. The CPTPP was finalized in 2018 and is now in force in the majority of the 11 member economies. At the time of research, Brunei had not ratified the treaty. The RCEP agreement came into force on January 1, 2022. As one of the first 10 economies to ratify the agreement in late 2021, the RCEP is in force in Brunei. Both the CPTPP and RCEP include dedicated IP chapters. The text of the CPTPP retains important aspects of the original Trans-Pacific Partnership’s IP provisions, including, for example, provisions related to trade secrets and border enforcement. However, numerous critical provisions have been suspended, including for patentable subject matter, biopharmaceutical-specific IP rights, such as regulatory data protection and copyright protection and enforcement, as well as protections related to satellite and cable signals. As a result, the CPTPP does not conform to the modern standards of other post-TRIPS international trade agreements, and no score has been allocated to Brunei under this indicator. Similarly, the RCEP, as currently constituted, does not conform to the modern standards of other post-TRIPS international trade agreements. Like the CPTPP, it does not include or refer to modern standards of IP protection for important IP-intensive industries, including

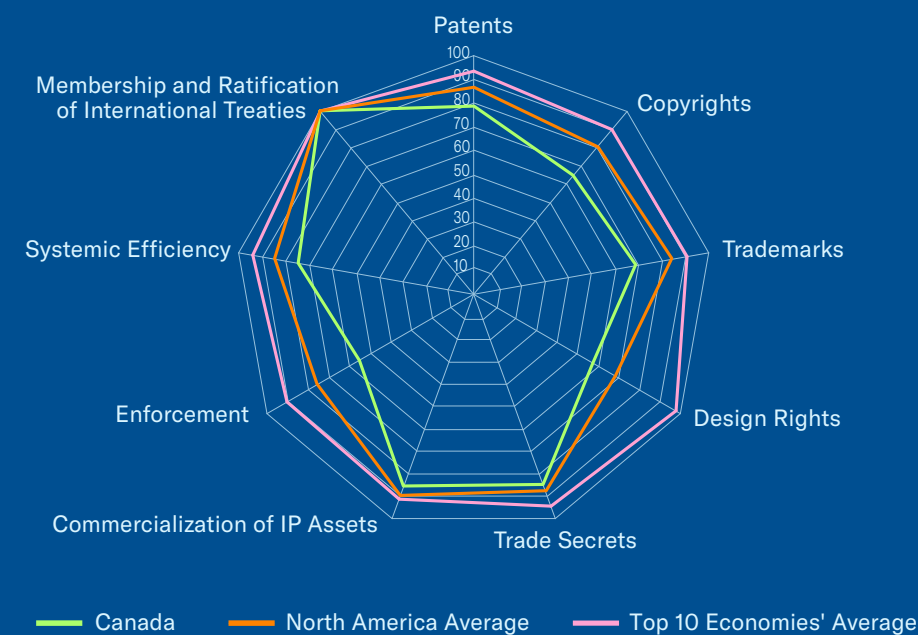


the life sciences sector and copyright-based industries, and no score has been allocated to Brunei under this indicator. Nevertheless, like the CPTPP, the RCEP refers to some important IP protections currently lacking in Brunei. Specifically, both agreements provide a clear and unambiguous requirement that border officials in all contracting parties have the right to take *ex officio* action against suspected infringing goods. The CPTPP includes transshipped goods or goods in transit under such action, whereas the RCEP does not. Neither current Bruneian trademark nor copyright law provide customs officials with clear *ex officio* authority to act against goods suspected of IP infringement.

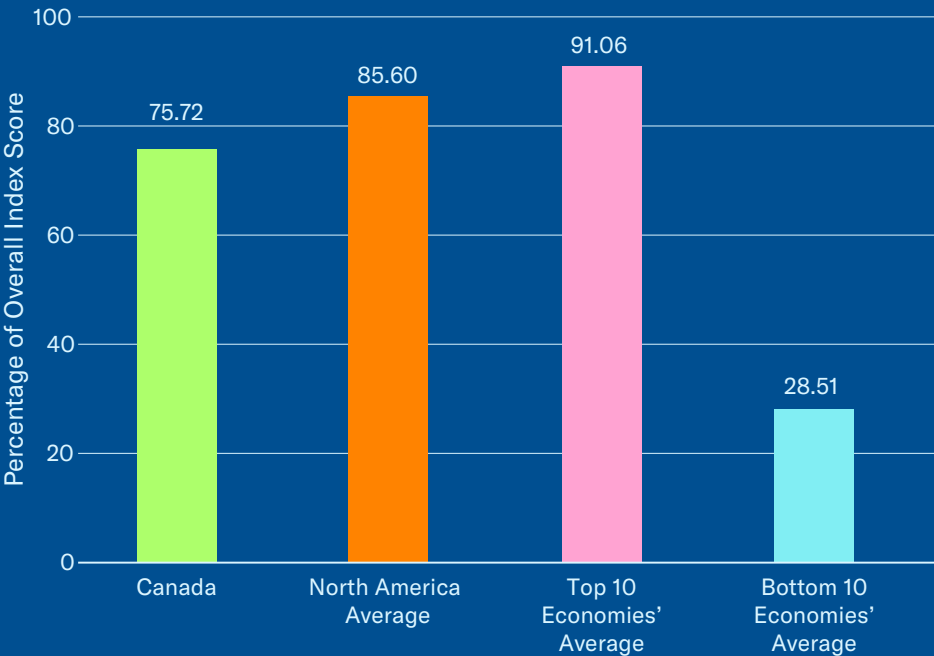
Section 82 of the Trademark Law and Sections 109-110 of the Copyright Order require rights-holders to submit a notice objecting to the importation of infringing goods before an official may detain or suspend the goods. However, contrary to other jurisdictions, no comprehensive system is in place whereby rightsholders can record their registered trademarks and copyrighted goods, thus forming the basis for action against suspected infringing goods for an extended period. The Copyright Order provides a limited time frame of five years, during which customs authorities will treat specified goods as being infringing goods, yet this is only available to published and literary works. Section 109 makes clear that this five-year maximum period is not available for “sound recording or film.” Published public guidance by the European Commission suggests that the detention of suspected infringing goods by Bruneian customs authorities is rare. Should the these referenced provisions of the CPTPP and RCEP agreements be incorporated into existing Bruneian statute, this would result in a score increase on indicator 37. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- In May 2022, the Federal Court issued a potentially precedent-setting dynamic injunction order in the case *Rogers Media Inc. v. John Doe 1*, thus signifying further strengthening of copyright enforcement in Canada
- The 2020 Federal Court of Appeal case creates a path for injunctive-style relief against online piracy
- The U.S.-Mexico-Canada Agreement (USMCA) took effect in 2020, which resulted in a 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 aligns Canada's patentability environment with international standards
- Significant damages awarded in precedent setting 2017 Federal Court case with regard to Canada's DRM provisions

Key Areas of Weakness

- Continued uncertainty over existing interpretation of educational exceptions to copyright; 2021 Supreme Court decision in *Access Copyright* case adds more layers of uncertainty and legal complexity
- The federal government potentially recognized the dire impact of this uncertainty, stating in a 2022 budget that it would "work to ensure a sustainable educational publishing industry, including fair remuneration for creators and copyright holders..."
- Comprehensive Economic and Trade Agreement (CETA) amendments to the Patent Act introducing patent term restoration includes restrictive eligibility requirements and an export claw-out, which effectively undermines biopharmaceutical exclusivity
- Deficiencies with respect to pharmaceutical patent enforcement remain unaddressed in Patented Medicines (Notice of Compliance) Regulations (PMNOC)



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	7.05	Category 6: Commercialization of IP Assets	5.17
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.75	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.25	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.30	Category 7: Enforcement	3.90
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.62
9. Patent opposition	0.75	33. Software piracy rates	0.78
Category 2: Copyrights, Related Rights, and Limitations	4.54	34. Civil and preceudural remedies	0.50
10. Term of protection	0.79	35. Preestablished damages	0.50
11. Exclusive rights	0.50	36. Criminal standards	0.50
12. Injunctive-type relief	0.75	37. Effective border measures	0.75
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.25
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	3.75
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	2.75	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	0.75	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.15	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.55	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.75	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.80		
Total: 37.86			

Spotlight on the National IP Environment

Past Editions versus Current Score

Canada’s overall score has increased from 75.24% (37.62 out of 50) in the tenth edition to 75.72% (37.86 out of 50). This reflects a score increase on indicator 12 and a score decrease on indicator 32.

Area of Note

Biopharmaceutical rightsholders continue to face challenges in exercising their IP rights and granted periods of exclusivity in Canada. A growing focus on rigid cost control and minimizing overall biopharmaceutical spending exists 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) evaluation methodology. These reform efforts have focused almost exclusively on cost and expenditure reduction. Although successful legal challenges have limited the scope of some of these proposals, the changes to the basket of economies the PMPRB uses for international price comparisons has been retained and is now in effect. Specifically, the reforms have expanded the size of the basket and removed the United States and Switzerland as comparator economies. New economies added are Australia, Belgium, Japan, the Netherlands, Norway, and Spain. Given the strict price controls in place in many of these new economies and the removal of the United States and Switzerland as comparator economies, 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. These changes came into force on July 1, 2022. The Index will continue to monitor the impact the implementation of the new pricing methodology has on Canada’s innovative ecosystem, which

has traditionally experienced delayed access to the newest innovative medicines.

In response to the COVID-19 pandemic, Canadian policymakers at all levels of government have rightly recognized the strategic nature of the research-based biopharmaceutical industry and the socioeconomic value it brings to Canada. At the federal level, the government in 2021 launched the *Biomanufacturing and Life Sciences Strategy*. Significantly, the strategy seeks explicitly to make Canada a more “attractive destination for leading life sciences firms to establish and grow.” Similarly, in 2022, the province of Quebec—Canada’s second largest by population—released *Quebec Life Sciences Strategy*, a similar document seeking to encourage local biopharmaceutical R&D and innovation within the province’s broader health policy. As the Index has detailed over the past decade, the biopharmaceutical IP environment in Canada could in many respects be strengthened and aligned with best practices in the United States, the European Union, and leading Asian economies. Similarly, adequate pricing and reimbursement policies for biopharmaceuticals would also improve the competitiveness of the Canadian environment, one of the primary objectives of the government’s life sciences strategies. The Index will continue to monitor these developments in 2023.

Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online: In 2019, a Canadian court ordered a group of ISPs to disable access to websites hosting alleged infringing content. The case was appealed in 2020, and a final verdict was issued in 2021, with the Federal Court of Appeal upholding the granted injunction. As noted in last year’s Index, the Federal Court of Appeal ruling is of real significance to Canadian



rightsholders because not only did the court clearly affirm the right to injunctive relief and the disabling of access to infringing content online under existing Canadian statute, but it also affirmed, both in principle and in the specific circumstances of this case, that where clear *prima facie* evidence of infringement is taking place, injunctive relief did not interfere with the principles of net neutrality or freedom of expression. Moreover, both the Court of Appeal and lower court judgment recognized the possibility and need for amendments to the order with respect to relevant domain names and website addresses as the infringing parties would seek to circumvent it. In response to such activity, many economies around the world are introducing “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that reenters the public domain by simply being moved to a different online access point. In a positive and hopefully precedent-setting decision, the federal court in May 2022 issued just such a dynamic injunction order in the case *Rogers Media Inc. v. John Doe 1*. The order requires Canadian ISPs to disable access to infringing content online—in this case, the illegal live streaming of National Hockey League matches—identified by the rightsholders in real time. The order is the first of its kind, and, if followed by similar rulings, will finally give rightsholders in Canada an effective way of enforcing their rights without delay. In a separate development, the Supreme Court of Canada in March 2022 denied Teksavvy Solutions’ request for appeal with regard to the Federal Court of Appeal’s 2021 upholding of the initial 2019 order. The Supreme Court’s decision not to hear the case should remove any lingering uncertainty as to whether injunctive relief and the disabling of access to infringing content through judicial orders are an acceptable legal pathway of enforcement available to Canadian rightsholders. As a result of these developments, the score on this indicator has increased by 0.25.

13. Scope of limitations and exceptions to

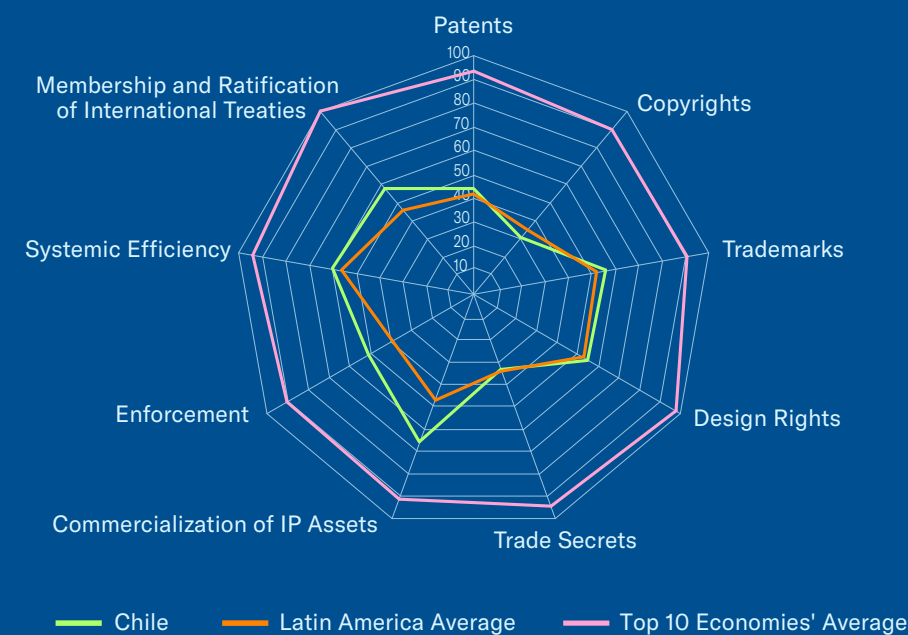
copyrights and related rights: As has been noted repeatedly in the Index over the past decade, the 2012 amendments to the Copyright Act considerably broadened Canada’s framework for exceptions to copyright, including the expansion of education and personal-use exceptions. Canadian Supreme Court decisions that same year also widened the scope of the judicial interpretation of existing exceptions to the extent that continued compatibility with the Berne three-step test was highly questionable. Unfortunately, neither a series of statutory reviews conducted by the Canadian Parliament nor a 2021 Supreme Court decision has effectively addressed this issue. Not only did the Supreme Court ruling not alter the long-standing negative dynamics and long-term consequences of the 2012 Copyright Act amendments and Supreme Court decisions, but it also adds even more layers of uncertainty and legal complexity to an already convoluted and tangled area of Canadian copyright law. As the Index and others pointed out following Parliament’s amendments to the Copyright Act and Supreme Court decisions in 2012, at best, the changes to Canada’s copyright regime would lead to a higher level of uncertainty for publishers and, at worst, a shrinking of their industry and business model.

Today, it is clear that both have occurred. Industry figures suggest that the Canadian publishing industry has suffered greatly over the past decade, with estimated uncompensated copying outside of fair dealing amounting to over CAD200 million. The net effect of the reforms and 2012 Supreme Court rulings has been a contraction in the publishing sector, with the Canadian publishing industry and individual rightsholders reporting publishing income decreasing substantially. The bottom line is that after 10 years of litigation and uncertainty, Canadian rightsholders have failed to achieve effective redress for the clear violation of their copyright or gain any further understanding of what constitutes fair dealing and what does not within the context of education. In 2022, the federal

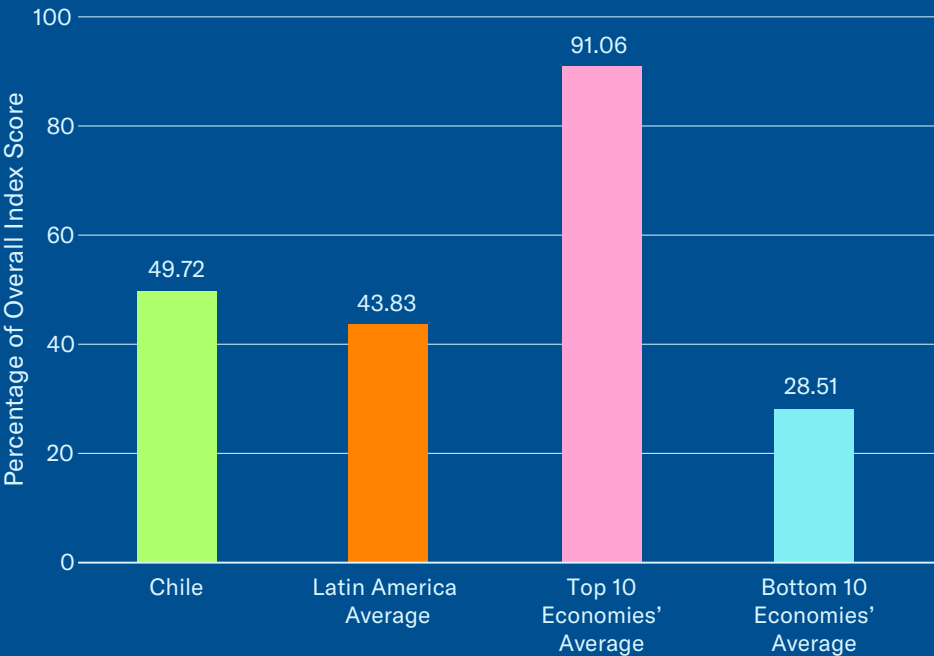
government appears to have finally recognized the dire impact of the 2012 amendments and subsequent Supreme Court rulings. In the 2022 budget *A Plan to Grow Our Economy and Make Life More Affordable*, the government stated plainly that it would “work to ensure a sustainable educational publishing industry, including fair remuneration for creators and copyright holders, as well as a modern and innovative marketplace that can efficiently serve copyright users.” The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Joined the Madrid Protocol in 2022
- IP law amendment (Law 19,309) passed in 2021 extends term of protection for design rights and improves enforcement environment
- Joined Global Patent Prosecution Highway (GPPH) in 2020
- Stronger efforts to increase transparency and public reporting of customs' enforcement activities
- Commitment to improve the IP environment through international trade agreements
- Efforts to streamline IP registration
- Promotion of IP commercialization

Key Areas of Weakness

- Uncertainty on accessibility of term restoration with new IP law amendments (Law 19,309)
- Threat of compulsory licensing based on cost considerations for COVID-19 and HCV drugs persists
- 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, although some success in disabling access to infringing websites



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	3.94	Category 6: Commercialization of IP Assets	3.92
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	0.74	29. Direct government intervention in setting licensing terms	0.75
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.70	Category 7: Enforcement	3.52
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.57
9. Patent opposition	0.25	33. Software piracy rates	0.45
Category 2: Copyrights, Related Rights, and Limitations	2.13	34. Civil and preceudural remedies	0.50
10. Term of protection	0.63	35. Preestablished damages	0.50
11. Exclusive rights	0.25	36. Criminal standards	0.50
12. Injunctive-type relief	0.50	37. Effective border measures	0.25
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.75
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	3.00
15. TPM and DRM	0.00	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.50
Category 3: Trademarks, Related Rights, and Limitations	2.25	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	4.00
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.10	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.00	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
Total: 24.86			

Spotlight on the National IP Environment

Past Editions versus Current Score

Chile's overall score has increased from 48.72% (24.36 out of 50) in the tenth edition to 49.72% (24.86 out of 50). This reflects a score increase on indicator 45.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies:

Chile has, over the course of the Index, shifted its policies on the use of compulsory licenses and has embraced the use of these licenses as a potential 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 license based on cost were endorsed by the outgoing government. In 2018, the Chamber of Deputies approved a resolution that requested the use of compulsory licenses for drugs formulated with sofosbuvir. Subsequently, 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 issued by the Chamber of Deputies with the same request was approved later the same year, and, in response to that request, the new Minister of Health issued Resolution 1165 rejecting the patentee's challenge to Resolution 399/2018.

In 2019, President Sebastian Pinera urged Congress to approve the Drugs Act II (*Ley de Farmacos*

II) as one of the measures of the National Drug Policy that seeks to improve the availability of drugs and reduce out-of-pocket costs. During the bill's long iteration through Congress, new provisions were added that put IP rights at risk. Specifically, provisions of the act greatly extend the reach of nonvoluntary licenses and incorporate discretionary elements, such as "shortage" or "economic inaccessibility" of products, as a legitimate ground for issuing a license. The draft also included provisions that effectively reduce a rightsholder's use of its trademarks in the course of trade. At the time of this research, the legislation was still pending in the Chilean Congress. Separately, individual members of Congress have 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 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. This was followed up with a legislative proposal and a 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; 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.” As stated repeatedly in the Index, 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 the subsequent General Council decision allowing for 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” to be used only after all other options for negotiating pricing and supply have been exhausted. As Chile and the global community move forward in 2023 and beyond, it is clear that the COVID-19 pandemic will continue to have a profound impact on the global economy and on how we interact and live as a global society. Undermining IP rights through the use and threats of compulsory licensing is counterproductive and is more likely to leave the world, including Chile, more vulnerable to the next global health challenge.

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. Technological protection measures (TPM) and digital rights management (DRM) legislation: As noted over the course of the Index, rightsholders face significant challenges in protecting their copyrighted content in Chile. As a contracting party to both the WIPO Internet Treaties and the 2003 United States-Chile Free Trade Agreement (FTA), Chile is obliged to provide a minimum standard of copyright protection for rightsholders that is currently not available. Both the U.S. FTA and WIPO Internet Treaties contain several important standards and measures related to copyright enforcement in the internet and digital realm, including a defined notice-and-takedown mechanism for communication service providers; extensive TPM and DRM protection provisions; definitions of obligations pertaining to related rights; protection against satellite piracy; and general civil and criminal enforcement procedures for all IP rights, including copyrights. But years after ratification of the FTA and over two decades after accession to the WIPO Internet Treaties, major gaps still exist in Chile’s legal framework, and current enforcement remains inadequate.

To begin with, Chile’s notice-and-takedown procedure does not meet the requirements of its FTA obligation with the United States. Under current Chilean law, ISPs are required to remove infringing content only on having “effective knowledge” (meaning that notice must be issued by a court, not by a rightsholder). Consequently, rightsholders’ ability to practically benefit from and use the takedown system is extremely limited. In addition, although Law No. 20,435 introduced a voluntary system under which ISPs are to forward notices from rightsholders to suspected infringers, this has over the course of the Index shown to be ineffective. With regard to injunctive-style relief, there is a possibility of achieving an injunction through a court order, but no defined or practical enforcement route, whether administrative or judicial, is available

to rightsholders. The availability of injunctive-style relief is hampered by the same lack of clear and practical rules and procedures that affects other forms of copyright enforcement in Chile.

With regard to TPM and DRM, despite ratification of the WIPO Internet Treaties and the U.S.-Chile FTA, copyright law still only protects against the circumvention of, or interference with, ISPs. Circumvention by other parties is not illegal, nor is the manufacture, distribution, or sale of circumvention devices. Proposals have been put forward in the National Congress to amend existing statutes and introduce more robust measures—including in 2021—but, overall, no meaningful action has taken place regarding the existing DRM and TPM legal framework over the course of the Index. This lack of a framework remains a key weakness in Chile’s copyright environment. Although positive, a new signal piracy law enacted in 2018 does not address the issue of circumvention devices. The result is that Chile has, over the course of the Index, maintained high levels of estimated copyright infringement. For example, BSA | The Software Alliance’s estimated rates of the use of unlicensed software suggest that Chile has, since 2011, had a remarkably high rate of software piracy for a high-income OECD Member State. The rate has stayed between 55% and 61% over the course of the 11 previous editions of the Index (in 2018, it was an estimated 55%). This compares to an average estimated rate of 26% for OECD Members in Western Europe and 16% for North America. Chile’s estimated rate of software piracy is also higher than the regional average for Latin America, which in 2018, stood at an estimated 52%. This occurs, although, on a per capita basis, Chile is one of the wealthiest economies in the region. Similarly, more recent data suggest that Chile remains a piracy hub in Latin America, with online infringement growing. In 2020, the regional industry association ALIANZA released findings on online piracy for the Latin America region. As part of annual piracy rankings conducted by the British research

consultancy and web monitoring firm Muso, the findings suggest that Chile is a large market for online piracy in Latin America with over 1 billion recorded web visits to online sources of piracy—a per capita rate of 95 visits per person. Although Brazil is the largest total market for online piracy in Latin America—at over 7 billion web visits during the same period—on a per capita basis, Chile’s rate is almost double: 95 visits per person in Chile versus 58 visits per person in Brazil. As the USTR noted in the 2022 *Special 301 Report*, “It has been over 18 years since the Chile FTA entered into force ... [and] it remains critical that Chile show tangible progress in addressing the long-standing Chile FTA implementation issues and other IP issues.” The Index will continue to monitor Chile’s efforts at reforming its copyright environment in 2023.

Enforcement

35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement; and 36. Criminal standards including minimum imprisonment and minimum fines: As noted last year, the *Ley Corta de INAPI* reform package and changes to Law 19,309 on Industrial Property—in force since January 2022—also included significant changes to Chile’s IP enforcement environment. The amendments included the introduction of statutory damages for trademark infringement (Law 19,309 had previously not included any form of preestablished or statutory damages for any major IP right). Instead, damage calculations had been based on general rules of civil compensation, which grants courts wide sway in assessing damages, including loss of profits. With last year’s amendments added, it is now possible, in the case of proven trademark infringement, for a rightsholder to opt for a preestablished form of damages up to 2,000 monthly tax units per infringement (circa USD 120,000). Furthermore, with regard to criminal sanctions, the insertion of a new Article 28b introduces a minimum



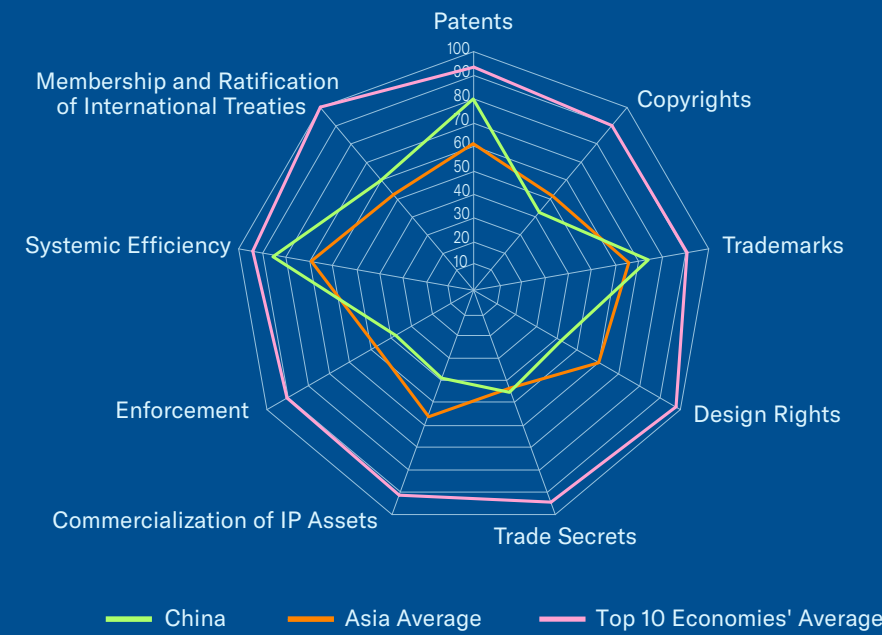
prison sentence for trademark infringement and commercial counterfeiting. Previously, such offenses had been subject only to fines. These positive efforts continued in 2022 with the enactment of Law 21,426. The new law bolsters efforts to combat illicit trade by criminalizing associated aiding-and-abetting acts and provides new powers to Chilean enforcement authorities. The Index will monitor the extent to which these new power—and the amendments to Law 19,309 enacted last year—will improve the enforcement environment for IP rights in Chile in 2023.

**Membership and Ratification
of International Treaties**

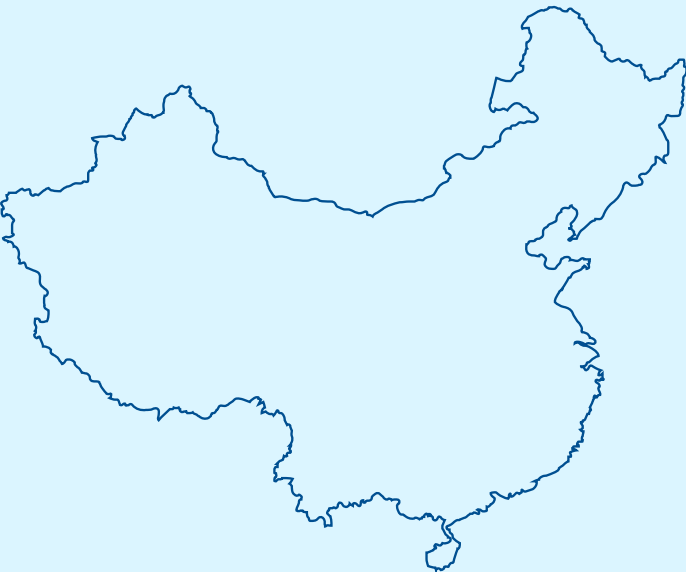
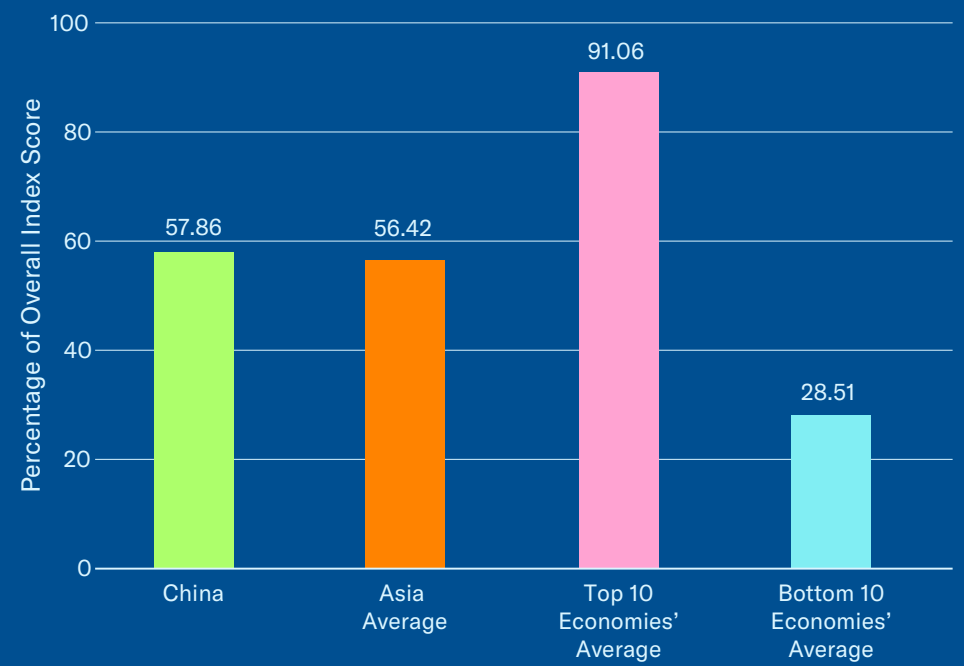
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks: In 2021, the Chilean Senate approved Chile to sign up for and join the Madrid Protocol. Subsequently, Chile acceded to and became a new contracting party of the protocol in May 2022. As a result, the score on this indicator has increased by 0.5.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Reform of IP laws following Phase One Agreement with the United States
- 2020 Patent Law amendment aims to improve the environment for biopharma and other patent-dependent industries and extends the term of protection for design patents
- 2020 Copyright Law amendments improve the copyright environment
- Positive changes in 2019-2020 on tech transfer and licensing through amendments to Foreign Investment Law and Technology Import and Export Regulations
- 2019 Trademark Law amendment seeks to address issue of bad faith filings
- 2019 Anti-Unfair Competition Law amendment seeks to strengthen protection of trade secrets
- Strong efforts to raise awareness and leverage value of IP rights in academic and private spheres

Key Areas of Weakness

- Despite positive changes in 2019-2020, continued challenges exist with regard to technology transfer and the licensing environment for SEPs; growing trend of rightsholders facing global anti-suit injunctions and restrictions on their ability to assert infringement claims in legal jurisdictions outside China
- 2022 Anti-Monopoly Law greatly expands the government's basis for action against anti-competitive behavior and substantially increases fines and penalties; draft rules contain broad language on what constitutes anti-competitive behavior within an IP rights context and vest considerable discretion with the anti-competition authorities in identifying and defining such behavior
- Uncertainty over implementing rules for biopharmaceutical linkage mechanism and patent term restoration
- Despite improved enforcement efforts, levels of IP infringement remain 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 business environment



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	7.28	Category 6: Commercialization of IP Assets	2.33
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.75	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.00
4. Plant variety protection	0.78	29. Direct government intervention in setting licensing terms	0.25
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.33
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	2.59
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.00
9. Patent opposition	0.25	33. Software piracy rates	0.34
Category 2: Copyrights, Related Rights, and Limitations	3.03	34. Civil and preceudural remedies	0.50
10. Term of protection	0.53	35. Preestablished damages	0.50
11. Exclusive rights	0.75	36. Criminal standards	0.25
12. Injunctive-type relief	0.00	37. Effective border measures	0.00
13. Cooperative action against online piracy	0.50	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	4.25
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.50
Category 3: Trademarks, Related Rights, and Limitations	3.00	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	4.25
20. Frameworks against online sale of counterfeit goods	0.75	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.85	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.35	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.60		
Total: 28.93			

Spotlight on the National IP Environment

Past Editions versus Current Score

China’s overall score has increased from 55.86% (27.93 out of 50) in the tenth edition to 57.86% (28.93 out of 50). This reflects a score increase on indicator 49.

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 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 existing Drug Registration Regulations. 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 preexisting 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 was 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, Chinese drug regulatory authorities—the China’s National Medical Products Administration (NMPA), formerly China FDA – 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 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, and China’s score on this indicator was reduced by 0.25 in the eighth edition of the Index. In 2020, China again committed in the Phase One Agreement (Article 1.11) to adopt a form of patent linkage. To this effect, a new set of patent amendments was passed into law in October 2020. Article 76 of this updated Patent Law outlined the new mechanism, which offers both a potential judicial route of enforcement as well as administrative enforcement through CNIPA. In 2021, this new regime came into effect with implementing regulations published by the NMPA, the CNIPA, and a relevant judicial interpretation from the Chinese Supreme Court. The “Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial)” and State Intellectual Property Office Announcements 435 and 436 outline the administrative process and available remedies.

As detailed in previous editions, the early-resolution mechanism introduced in China, is strictly speaking, not a “linkage mechanism” whereby a drug regulatory authority conditions the approval of a follow-on biopharmaceutical product on there being no relevant period of market exclusivity in place for the underlying reference product. Instead, China’s early-resolution system places the emphasis of monitoring and early resolution on rightsholders and follow-on applicants. Specifically, under Articles 6 and 7 of the “Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial),” follow-on applicants must offer one of four declarations on the exclusivity status of the underlying reference product. Rightsholders then have a defined 45-day period to initiate legal action on the basis that the follow-on applicant’s declaration is objectionable. Such legal action may be filed either through the judiciary and civil proceedings or through a new administrative trial process within CNIPA. Under Article 8, an automatic 9-month waiting



period is triggered with NMPA upon the initiation of a legal action and subsequent submission of a notification of acceptance from either the relevant judicial authorities or CNIPA. Although the drug regulatory technical review process of the follow-on applicant will continue during this time, no marketing approval will take place. The 45-day notice period for a rightsholders lodging an objection is rather short, but, in principle, this early resolution mechanism bears some promise.

However, the regulations have notable gaps. To begin with, the nine-month automatic NMPA waiting period is not extendable or contingent on obtaining a final ruling either from a court of law or through the administrative patent trial process within CNIPA. Article 9(4) of the “Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial)” simply states that if no final judgment has been received by NMPA from the relevant authorities within the prescribed nine-month waiting period and the technical review process is completed, the drug registration application will be transferred for processing and final approval in line with standard procedures. Consequently, there is no guarantee that relevant legal proceedings before a Chinese court or CNIPA will be concluded within the nine-month period. There is a real possibility that no effective resolution will be reached within that time frame and that the follow-on product will be approved for market by NMPA. Additionally, the nine-month waiting period is both shorter than previous draft proposals, which had a period of 24 months, and equivalent to timelines in the United States and Singapore, where the period is 30 months. Finally, the nine-month waiting period is not available for all types of biopharmaceuticals, including biologics.

In 2022, the first judicial proceedings were concluded related to this early-resolution system. The case had initially been filed in late 2021 with the Beijing IP Court and was concluded following an appeal to the Supreme Court with a final judgment

issued in August 2022. The case focused primarily on the validity of the underlying patent claims and not the early resolution process itself. However, the Supreme Court’s judgment provided useful reference to and clarification on the mechanics of the notification process and responsibilities of follow-on applicants. The broader policy conclusion from both the initial judgment and the appeal is that rightsholders may be able to achieve a judgment within the previously described nine-month waiting period. The Index will continue to monitor these developments in 2023 and the extent to which rightsholders for all forms of biopharmaceuticals can effectively and practically seek redress before the marketing of a follow-on product in a process that is fair and transparent to all parties.

7. Patent term restoration for pharmaceutical products: As noted in last year’s Index, new draft amendments to the Patent Law were passed in 2020. 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. As of late 2022, no final implementing regulations had been published regarding the specific circumstances that would be recognized or the requirements that would need to be met for restoration to be granted, including, for example, the types of delays that would be recognized as justifying such restoration. As noted in previous editions of the Index, it is essential that term restoration is not made contingent on the first global launch taking place in China. Instead, like in other jurisdictions where term restoration is available, “new” biopharmaceutical products should be defined as those newly approved for market in China. The Index will continue to monitor these developments in 2023.

Commercialization of IP Assets and Market Access

26. Barriers to market access: As noted in previous editions of the Index, rightsholders have over the

years faced a growing number of regulatory and procedural barriers in China that impede technology flows, R&D cooperation, and digital trade. With respect to data localization requirements and barriers to digital trade, these intensified in 2021 and 2022 with the coming into force of the Personal Information Protection Law (PIPL). The law includes limits and conditions on cross-border transfers of data and imposes local storage requirements on both Critical Information Infrastructure Operators and entities handling large volumes of personal data as defined by the Cyberspace Administration of China. Noncompliance with the new law may result in fines up to 5% of annual sales.

Additional restrictions and compliance requirements are imposed on what is termed “large internet platforms.” The PIPL adds to the existing layers of restrictions and barriers to digital trade in China, including the National Security Law, Cybersecurity Law, Security Assessments for Network Products and Services, and 2020 Biosecurity Law. For rightsholders across many different industries and sectors, these barriers to digital trade raises serious questions and concerns. The ICT and internet revolutions have fundamentally changed how human beings interact socially and economically. In virtually all industries, business and economic interaction is 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 “big data.” Combined with increased computing capacity and the application of new technologies (such as artificial intelligence and machine learning) that allow us to analyse and better understand data collected, there is the possibility to make significant discoveries and breakthroughs in virtually any area of research and human socioeconomic activity. Cross-border flows of data are ingrained in countless services consumers use, with numerous digital, automated, and virtual services relying

on the seamless movement and storage of data in various locations. Public policies related to national data management must recognize this reality and be formulated accordingly. These issues remained unresolved in 2022. The Index will continue to monitor these developments in 2023.

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: As noted in previous editions of the Index, rightsholders have over the years faced a growing number of regulatory and procedural barriers and inflexible terms to licensing in China that impede technology flows and R&D cooperation. China has imposed restrictions on the rights of foreign IP rightsholders 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 (TIER) 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 plurilateral discussions with China for 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 between the United States and China.

As detailed in previous editions of the Index, in 2019 and 2020, there were significant positive changes to China's technology transfer and licensing environment. Most importantly, the Foreign Investment Law and the TIER 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 previously now removed. Specifically, Article 22 of the Foreign Investment Law states explicitly that the IP rights of foreign entities and investors should be protected and that there should be no coercion or forced technology transfer. Similarly, the revised TIER regulations have removed and/or amended provisions to indemnification and ownership and usage of improvements made to a licensed technology.

In 2021, a new Civil Code came into effect. Although this sprawling piece of legislation touches on all aspects of civil law, it also includes specific provisions related 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." As noted at the time, these changes hold the promise of fundamentally remodeling the nature in which licenses can be drafted and executed between foreign and Chinese entities. As a result, China's score increased on indicators 26, 27, and 29 in the eighth edition of the Index.

However, licensors and rightsholders continue to face substantive challenges to doing business in China on fair, nondiscriminatory, and equal terms. Specifically, the past few years have seen a growing trend of rightsholders facing global anti-suit injunctions and restrictions on their ability to assert infringement claims in legal jurisdictions outside China. Chinese courts have increasingly claimed global jurisdiction to set global licensing rates for technologies protected by Standard and Essential Patents (SEPs), threatening exorbitant fines and withholding access to the Chinese market to prevent foreign patent holders from asserting their rights (in both China and global jurisdictions). The outcomes of these cases have also been cited and referred to as "model" IP rights cases by government authorities. Such actions violate the spirit of China's commitment to refrain from forcing, whether directly or indirectly, technology transfers under Chapter 2 of the January 2020 Agreement, as well as TRIPS Article 28, which guarantees patent protection rights. In February 2022, the European Union filed a request for consultations with China on this issue at the WTO. This was followed in March by requests from Japan, Canada, and the United States to join these consultations. At the time of research, no further action had been taken at the WTO.

In a separate development, in June 2022, China enacted a new Anti-Monopoly Law. The new law greatly expands the government's basis for action against anti-competitive behavior and substantially increases fines and penalties. Although Article 8 maintains large carve-outs for state entities

and businesses that are "vital to the national economy," Article 41 imposes a nondiscrimination clause on public bodies' regulation and licensing of "non-local goods," which could, potentially, apply also to foreign producers and promote fairer competition in the Chinese market. With respect to IP rights, Article 68 states that the "Law applies to undertakings' abuse of intellectual property rights to eliminate or restrict competition." The new law was accompanied by several new draft rules, including "Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition." Like the underlying legislation, this draft rule considerably expands the powers of investigation, punishment, and meaning of what constitutes anti-competitive behavior within the context of the exercise of IP rights. Specifically, several articles defining anti-competitive behavior—including Articles 15, 16, and 17, which refer explicitly to SEPs and copyright collection societies—contain not only broad language on what constitutes anti-competitive behavior within an IP rights context but also vest considerable discretion with the anti-competition authorities in identifying and defining such behavior. Under these articles, anti-competitive behavior is defined as "Other abuses of market domination identified by the State Administration for Market Regulation." SEP-based technologies are central to future innovation and economic growth, both in China and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater utilization of SEPs as well as a concomitant increase in the number of potential legal disputes that could hold up the development and use of these new technologies and industries.

However, disputes between licensors and licensees on what constitutes fair, reasonable, and

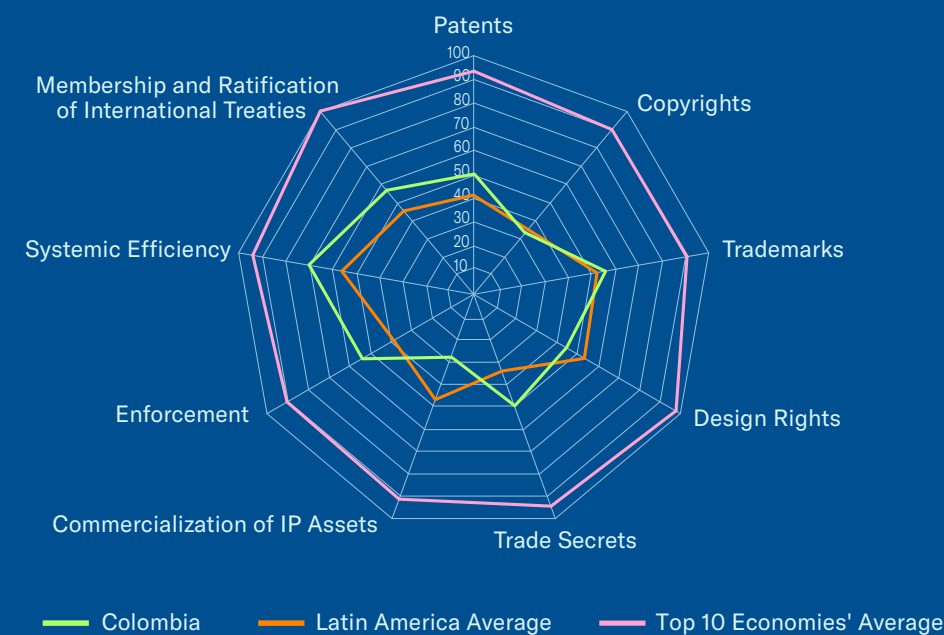
nondiscriminatory licensing terms are not new, nor are they unique to China. This is an evolving field of IP policy and jurisprudence for a subject matter that is deeply complex. Each licensing negotiation is unique and should not be subject to prescriptive government action or intervention, whether through direct or indirect pressure. Should rightsholders continue to face challenges in asserting their rights on fair, nondiscriminatory, and equal terms—whether through the Chinese judiciary or administratively through the expanded powers given the anti-competition authorities in the new Anti-Monopoly Law and accompanying rules—this will result in a sharp score decrease on relevant Index indicators and will negate the positive impact of the Phase One Agreement with the United States. The Index will continue to monitor these developments in 2023.

Membership and Ratification of International Treaties

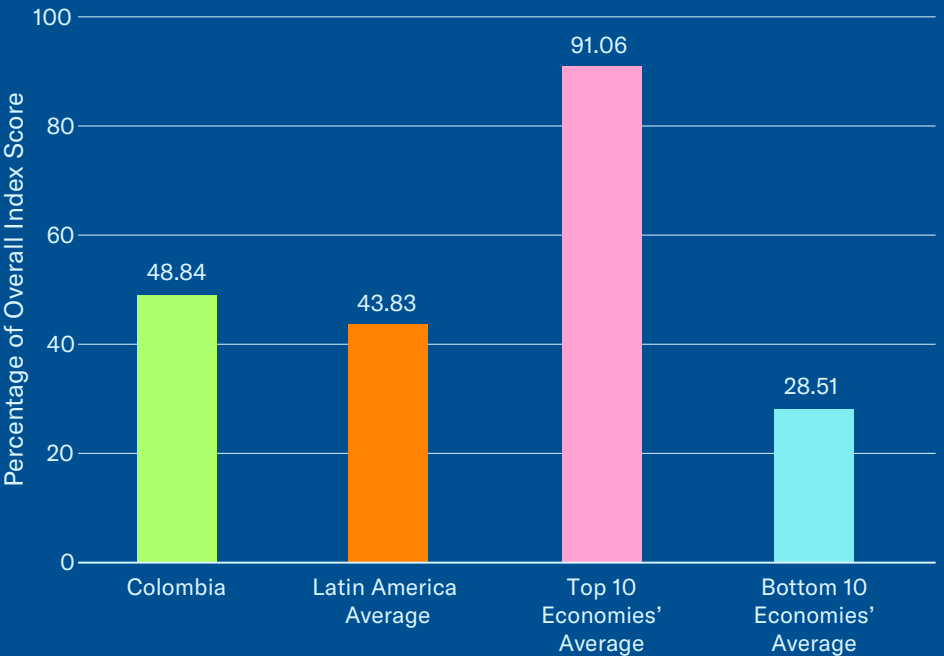
49. The Hague Agreement Concerning the International Registration of Industrial Designs: In 2022, China became a full contracting party to the Hague Agreement with the treaty entering into force in May of the same year. As a result, the score on this indicator has increased from 0 to 1.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Stronger copyright enforcement efforts through the National Directorate of Copyright (DNDA) injunctive-style relief action against online piracy
- Acceded to Convention on Cybercrime in 2020
- The 2019 Colombian Constitutional Court issued a ruling (Ruling C-345-19) recognizing the constitutionality of statutory damages for copyright infringement introduced by 2018 amendments to the 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 interagency IP enforcement and to raise public and stakeholder engagement in IP policymaking and education

Key Areas of Weakness

- History of use of compulsory license regime to leverage price reduction for biopharmaceuticals, including 2020 emergency COVID-19 laws, which provide an exceptionally 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 or delayed prosecution of and penalties for IP infringement



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	4.50	Category 6: Commercialization of IP Assets	1.67
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.25
3. Patentability of CIIs	0.50	28. Registration and disclosure requirements of licensing deals	0.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.25	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	3.76
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.49
9. Patent opposition	0.25	33. Software piracy rates	0.52
Category 2: Copyrights, Related Rights, and Limitations	2.34	34. Civil and preceudural remedies	0.50
10. Term of protection	0.84	35. Preestablished damages	0.50
11. Exclusive rights	0.25	36. Criminal standards	0.50
12. Injunctive-type relief	0.25	37. Effective border measures	0.75
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.50
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	3.50
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.75
Category 3: Trademarks, Related Rights, and Limitations	2.25	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	4.00
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.90	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.50	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.50	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
Total: 24.42			

Spotlight on the National IP Environment

Past Editions versus Current Score

Colombia’s overall score remains unchanged at 48.84% (24.42 out of 50).

Area of Note

In late 2021, the government of Colombia approved a new *National Intellectual Property Policy*. The document, CONPES 4062, was drafted and released by the National Planning Department (*Departamento Nacional de Planeación*) and outlines Colombia’s strategic direction and policy goals with respect to the protection of IP for the foreseeable future. The policy seeks to foster an environment that enables the creation and commercialization of IP assets; encourage the greater use of the national IP system to protect these assets; improve the administration and systemic efficiency of the national IP system; and increase harmonization with international standards. Overall, it is an ambitious document touching upon IP policies across the board. The policy and accompanying itemized Annex A contain 63 individual action items, including potential changes to the legal and regulatory environment. Key areas covered by the action items are potential legislative changes to existing copyright law (relating to TPM exceptions); the introduction of preestablished damages for copyright infringement through the issuing of new implementing regulations; greater efforts at cross-government coordination of IP enforcement; stronger awareness-raising efforts, particularly related to the licensing and commercialization of IP assets; and the potential joining of several international treaties, including the WIPO-administered Singapore Treaty on the Law of Trademarks and Patent Law Treaty, both of which are benchmarked in the Index.

The Colombian government should be congratulated for taking such a holistic approach to reforming the entire innovation and IP policy

ecosystem through this long-term structural reform effort. As the economic data and analysis in the Index’s accompanying Statistical Annex and the experiences of other economies strongly suggest, IP rights 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. Focusing on international best practices and the extent to which Colombia’s national IP system can adopt and adhere to such practices is of particular importance.

Full participation in the global IP system, PPH initiatives, and increased cooperation between IP offices can improve and harmonize the administration and functioning of the international IP system to help inventors and rightsholders domestically and internationally. Colombia has made noticeable strides on this front in the past few years. A PPH has been in place with the USPTO since 2012, and several other PPH agreements have been concluded since then, including with the Korean Intellectual Property Office, the Spanish Patent and Trademark Office, and with other Forum for the Progress and Integration of South America (PROSUR) economies. Colombia joined the Global Patent Prosecution Highway in 2017 and became a contracting party to the Convention on Cybercrime in 2020. Still, of the nine international treaties benchmarked in the Index, Colombia is not a contracting party to four: 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 (Colombia is a contracting party to International Convention for the Protection of New Varieties of Plants [UPOV] 1978); and the Hague Agreement Concerning the International Registration of Industrial Designs.



More broadly, as has been noted over the past ten editions of the Index, current Colombian IP laws and regulations could be reformed and better aligned with international best practices. Patentability standards continue to be restrictive and outside of international norms, especially for biopharmaceuticals and CII; the protection of copyright remains underdeveloped to face the challenges of the internet era; and estimated levels of physical and online counterfeit goods remain high. Rightsholders also face basic challenges with respect to technology transfer, licensing the use of IP assets, and the commercialization of IP assets. As such, the U.S. Chamber of Commerce stands ready to work with the Colombian government as it moves forward in implementing the *National Intellectual Property Policy* in 2023 and beyond.

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, the 2001 Doha Ministerial Declaration, and the subsequent General Council decision concerning Paragraph 6. The provision allows Colombian authorities to define public health emergencies broadly and to actively seek out compulsory licenses. Article 70 also allows compulsory licenses on grounds outside extreme circumstances, including industrial or commercial objectives.

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 in 2016, which set 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. After 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; it instead identified the entire class of hepatitis C products. Local legal analysis suggests that Colombian authorities have taken no further action. Still, at the time of research, the situation remained unresolved. As such, it imposes yet another layer of uncertainty on rightsholders’ ability to make use of their granted exclusive rights fairly and effectively in Colombia.

Furthermore, in March 2020, Decree 476 was issued by the Colombian government in response to the COVID-19 pandemic. Although the decree did not explicitly amend existing legislation related to compulsory licensing, Article 1, Subsection 1.7 of the decree grants the Minister of Health broad and full authority to make a Declaration of Public Interest related to any and all “medicines, medical devices, vaccines, and other health technologies that are used for the diagnosis, prevention, and treatment of COVID-19.” As mentioned, although not legally a compulsory license, such declarations essentially nullify any existing IP protection and carry the same practical impact of eliminating rightsholders’ ability to freely use a granted exclusivity.

The same logic is present in a legislative proposal introduced in 2020 in the Colombian Senate, Bill 372 on Pharmaceutical Safety. The proposed legislation seeks to address the manifold biopharmaceutical challenges posed by the COVID-19 pandemic. Although the draft bill seeks to address the complex issue of securing biopharmaceuticals and medical supplies in the midst of an international health emergency, it includes an exceptionally broad basis for the overriding of IP rights through both automatic compulsory licenses for health technology goods deemed “essential” and the suspension of any and all IP rights through executive fiat. At the time of research, the bill was still pending, having undergone a semi face-to-face Public Hearing in March 2021. As stated repeatedly in the Index, compulsory licensing and the overriding of property rights are 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 the 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

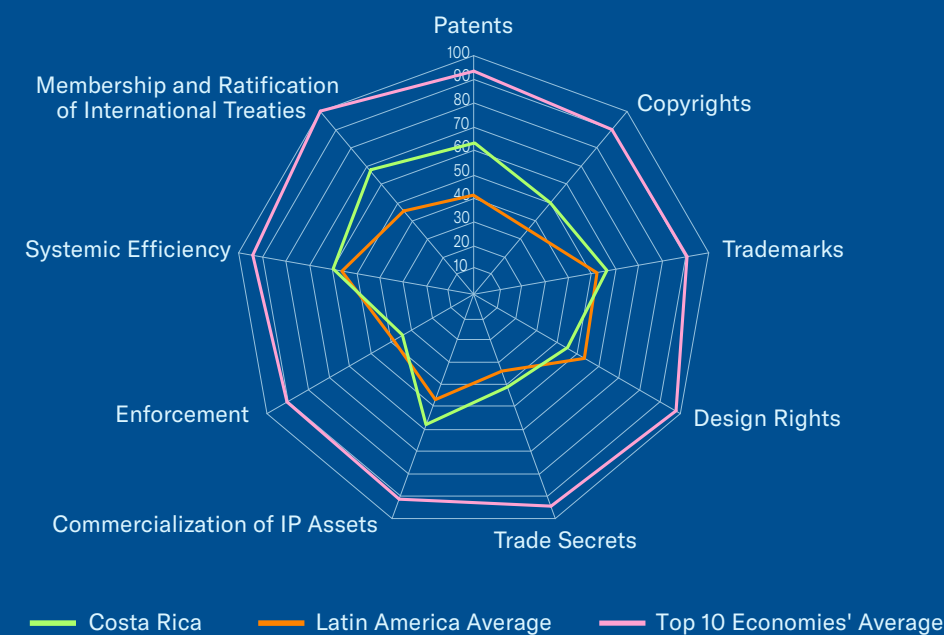
decision (concerning Paragraph 6 of the Doha Declaration) underscores that these provisions are not in any way intended for industrial or commercial objectives, and, if used, it is expected that they would be aimed solely at protecting public health. In addition, Article 31 and the Doha Declaration suggest that compulsory licensing represents a “measure of last resort” and is 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 2023.

Trade Secrets and the Protection of Confidential Information

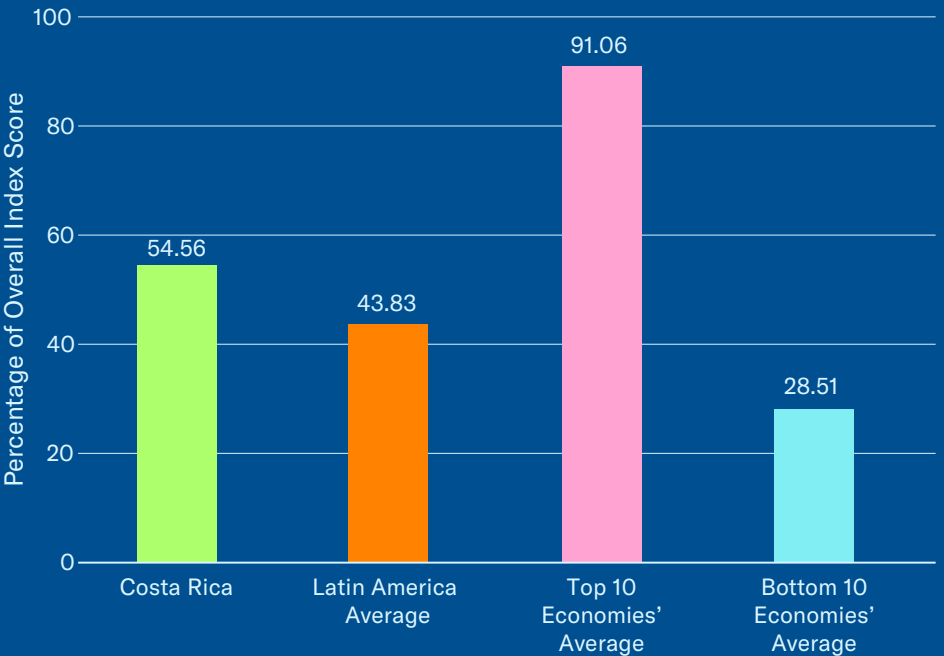
25. Regulatory data protection (RDP) term: As has been noted in previous editions of the Index, a degree of uncertainty exists regarding the provision of RDP for submitted biopharmaceutical test data in Colombia. Decree 2085 of 2002 provides for a five-year period of RDP for both biopharmaceuticals and agrochemicals. Although less than international best practices and the benchmark 10-year period used in the Index, this is in line with Colombia’s commitments under the U.S.-Colombia FTA. However, reports suggest that this protection is not fully available for all biopharmaceuticals. For example, Decree 1782, signed in 2014, which modifies the registration process for biological medicines, does not discuss RDP for biologics. As a result, with regard to RDP, the legislation introduces ambiguity as to whether five years of protection will be afforded to biologics under the new regime. Similarly, industry reports from the past few years suggest that the Colombian drug regulatory agency INVIMA has changed its administrative standards and that RDP is not being consistently granted to eligible products. The negative effect is the same for Colombian and foreign innovators. If rightsholders continue to face administrative barriers in accessing their statutory defined and granted term of RDP, the score on this indicator will be reduced to 0.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Implementation of software management tools for the public sector; addresses long-standing issue of use of unlicensed software
- Expanded support for awareness raising and IP rights-related 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 is slow and lacks effectiveness
- Inadequate penalties for IP infringement



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	5.73	Category 6: Commercialization of IP Assets	3.50
1. Term of protection	1.00	26. Barriers to market access	0.75
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.75	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.25	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.48	Category 7: Enforcement	2.41
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.49
9. Patent opposition	0.25	33. Software piracy rates	0.42
Category 2: Copyrights, Related Rights, and Limitations	3.49	34. Civil and preceudural remedies	0.25
10. Term of protection	0.74	35. Preestablished damages	0.50
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.25	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	3.00
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	0.50
Category 3: Trademarks, Related Rights, and Limitations	2.25	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	4.75
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.90	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.25	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
Total: 27.28			

Spotlight on the National IP Environment

Past Editions versus Current Score

Costa Rica’s overall score remains unchanged at 54.56% (27.28 out of 50).

Systemic Efficiency

40. Consultation with stakeholders during IP policy formation: Through various laws and administrative actions, the government of Costa Rica has shown its commitment to public transparency and the principle of public consultations during the legislative process (IP rights included). Costa Rica has a clearly defined system of public consultation process in place whereby the public and key stakeholders should be allowed to comment and consult on proposed regulatory and legal changes. This is captured in the Public Administration Law, which requires a period of publication and consultation for all draft changes with a commenting period of, normally, 10 days. Since 2012, Costa Rica has been a national member of the *Open Government Partnership* (OGP), a multilateral organization seeking to further government transparency and public participation in government across the world. Since 2015, the National Open State Commission has been in place. The Commission has as its mandate to work across the government in actively promoting increased transparency, access to public information, and participation in the development and administration of primary and secondary legislation.

The Commission is also the lead agency in developing action plans in line with Costa Rica’s commitments as a member of the OGP. These efforts have continued and have been strengthened with the newly inaugurated administration of President Rodrigo Chaves Robles. One of President Chaves Robles’ first acts was the issuing of Decree 43,525. The decree includes a dedicated focus on improving citizen and

stakeholder engagement and participation in the policy and lawmaking process. Specifically, Article 3, Subsections (c) and (d) refer explicitly to the need for “participation,” “collaboration,” and co-creation” through strong and sustained engagement between the public sector, citizens, the private sector, and other relevant non-state stakeholders. As noted by the OECD, there has historically been some uncertainty as to the extent to which Costa Rican government departments and agencies regularly and consistently invite public participation through a consultation process in a systematic fashion. The Index will continue to monitor these developments in 2023.

Membership and Ratification of International Treaties

Being a contracting party to key international IP treaties reflects a given economy’s broader participation in the international IP community and embracing of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adheres to established standards and best practices. Costa Rica’s score in this category of the Index has increased from a score of 2.5, or 62.50%, in the sixth edition of the Index (the first year Costa Rica was included) to now achieving a score of 4.75, or 67.86%, of the total available score. This is notably higher than many high-income economies, such as New Zealand and the UAE, as well as some of Latin America’s largest economies, including Argentina and Brazil. Overall, Costa Rica is a contracting party and has acceded to 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. Costa Rica is a signatory to, but has not ratified, the Singapore Treaty on the Law of Trademarks. Costa Rica is not a contracting party

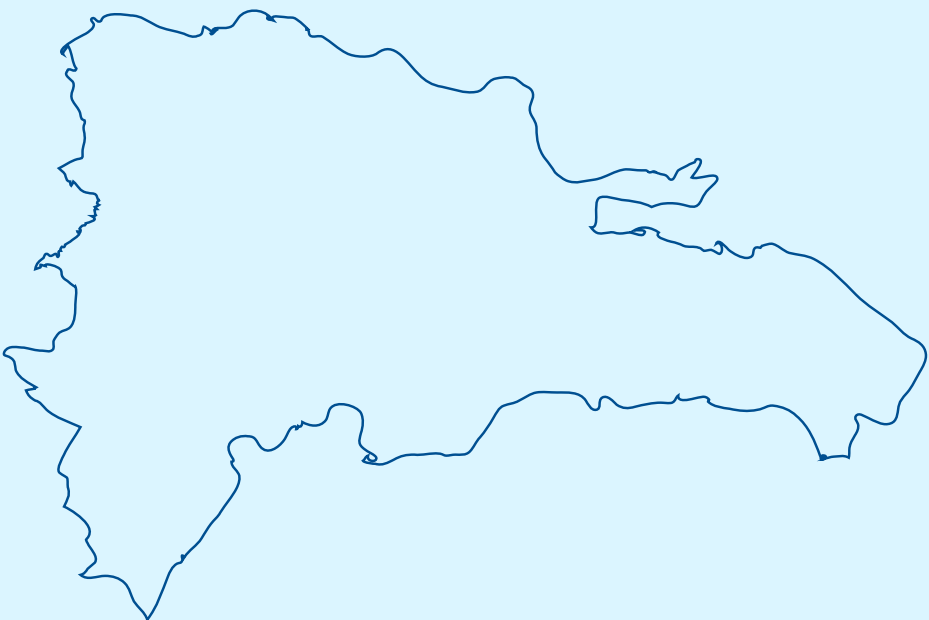
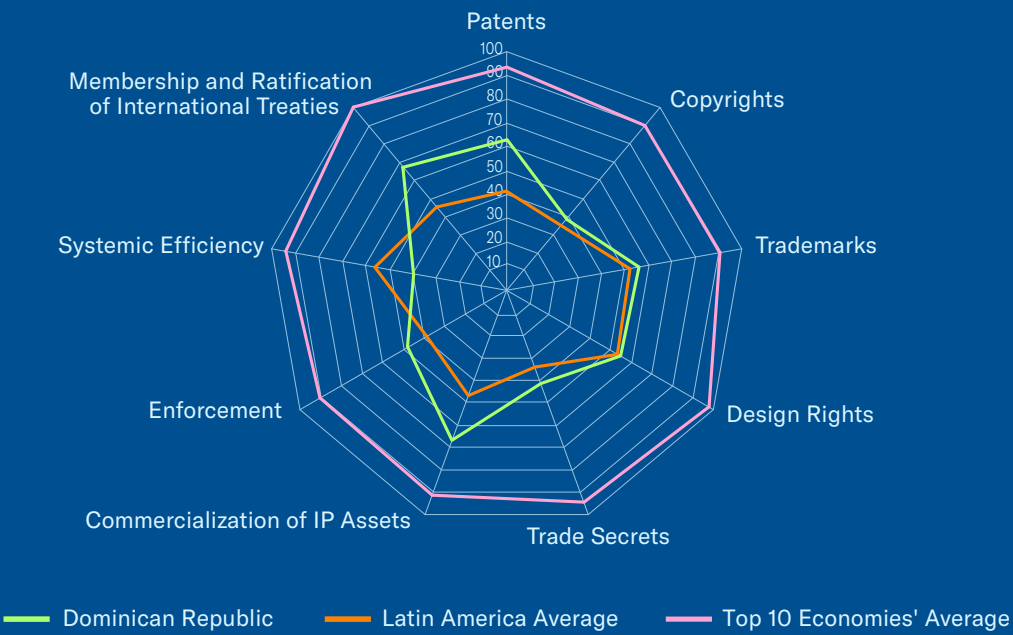


to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Patent Law Treaty; or the Hague Agreement Concerning the International Registration of Industrial Designs. Costa Rica is also a contracting party to the Dominican Republic–Central America Free Trade Agreement (CAFTA-DR).

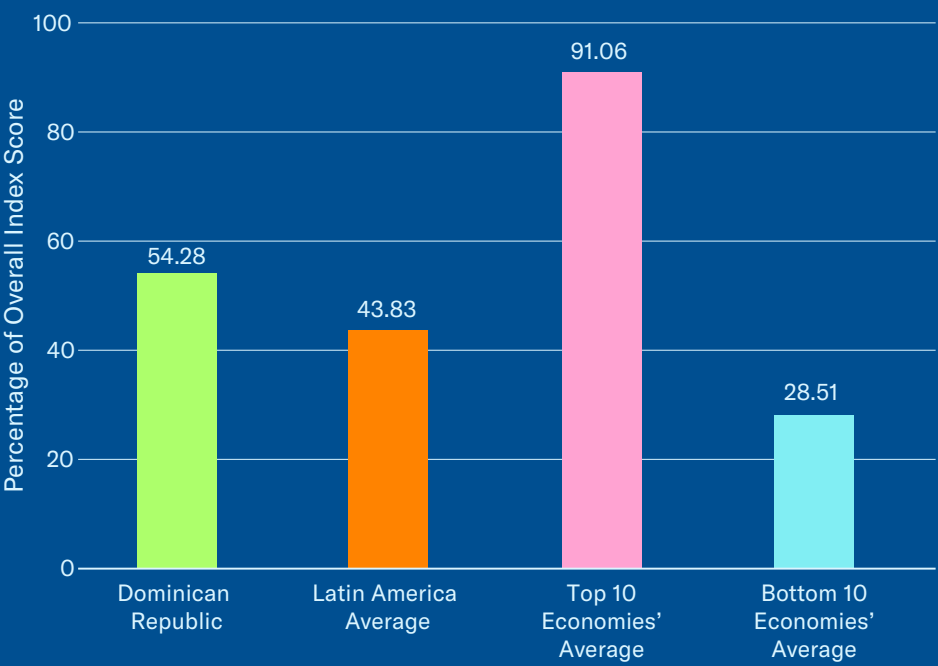
In 2022, the new government announced that it would seek to increase the number of FTAs to which Costa Rica is a contracting party. In separate public appearances, President Robles and the Minister of Trade, Manuel Tovar, outlined the possibility of joining both the Pacific Alliance and CPTPP. Although the CPTPP does not conform to the modern standards of other post-TRIPS international trade agreements, it contains some important aspects of the original Trans-Pacific Partnership’s IP provisions. If adopted and implemented by Costa Rica, these provisions could strengthen its national IP environment. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- CAFTA membership fundamentally improved the 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 CIIIs
- 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
5.70		4.00	
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.70	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.50	3.35	
9. Patent opposition	0.50	32. Physical counterfeiting rates	0.35
Category 2: Copyrights, Related Rights, and Limitations		33. Software piracy rates	0.25
2.74		34. Civil and preceudural remedies	0.50
10. Term of protection	0.74	35. Preestablished damages	0.50
11. Exclusive rights	0.25	36. Criminal standards	0.50
12. Injunctive-type relief	0.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.75
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	
15. TPM and DRM	0.50	2.00	
16. Government use of licensed software	0.50	39. Coordination of IP rights enforcement	0.25
Category 3: Trademarks, Related Rights, and Limitations		40. Consultation with stakeholders during IP policy formation	0.75
2.25		41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.25	4.75	
Category 4: Design Rights, Related Rights, and Limitations		44. WIPO Internet Treaties	1.00
1.10		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	1.00
1.25		49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
23. Protection of trade secrets (civil remedies)	0.50	50. Post-TRIPS FTA	1.00
24. Protection of trade secrets (criminal sanctions)	0.25		
25. Regulatory data protection term	0.50		
Total: 27.14			

Spotlight on the National IP Environment

Past Editions versus Current Score

The Dominican Republic's overall score remains unchanged at 54.28% (27.14 out of 50).

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In late 2021, an application for the issuing of a compulsory license for the COVID-19 oral antiviral drug PF-07321332/ritonavir (brand name Paxlovid) was filed with the Dominican Ministry of Health and national IP office, Oficina Nacional de la Propiedad Industrial (ONAPI). The application was submitted by the organization “Knowledge Ecology International.” Paxlovid is an investigational therapy developed by Pfizer used to treat COVID-19. In clinical trials, the drug has proven highly effective at preventing the onset of severe illness related to COVID-19. In late 2021 and early 2022, the drug received conditional marketing authorization in both the United States and the European Union. It is unclear on what practical grounds and health emergency the compulsory license application in the Dominican Republic is based. The Dominican Republic ended all COVID-19–related public health restrictions in February 2022. Mortality data compiled by Johns Hopkins University of Medicine in the “Coronavirus Resource Center” suggests that in the first half of 2022, there had been fewer than 50 total deaths from COVID-19 in the Dominican Republic. Just under 16 million doses of the COVID-19 vaccine had been administered in the Dominican Republic with a population of 11 million, and an estimated 55.43% of the entire population has been fully vaccinated with multiple doses.

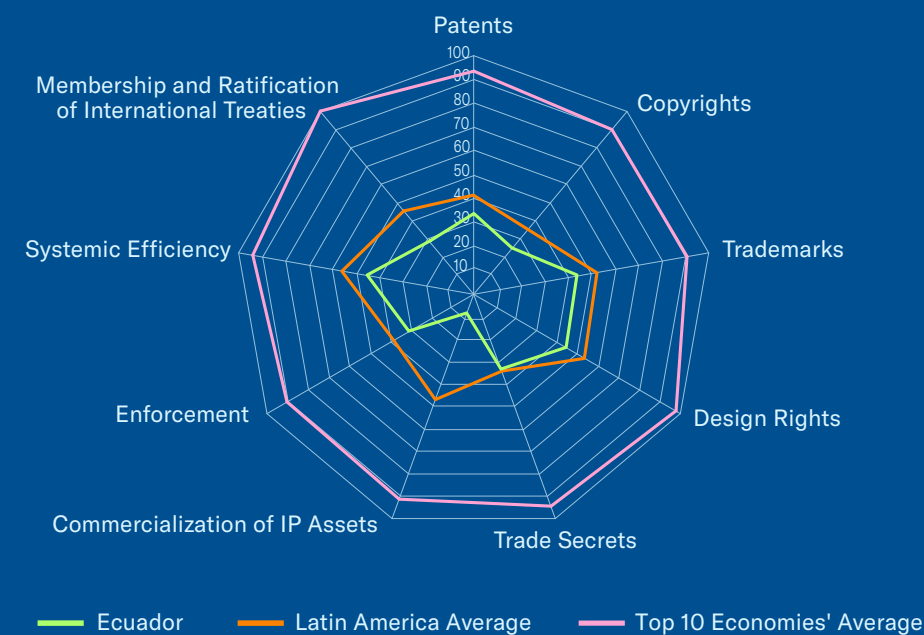
Aggregated data from the onset of the pandemic collected by the WHO suggest that a cumulative total of 4,383 COVID-19 related deaths occurred in the Dominican Republic. Standardized on a per

capita basis, this is a total of 40.40 deaths per 100,000 people in the population. This is less than half of the global average (81.81 per 100,000 people in the population), over seven times less than the United States (306.92 per 100,000 people in the population), and roughly comparable to South Korea (48.55 per 100,000 people in the population).

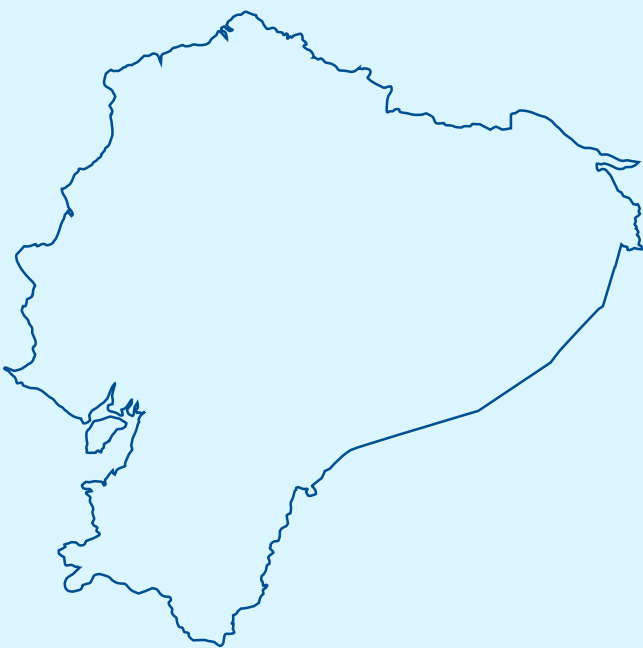
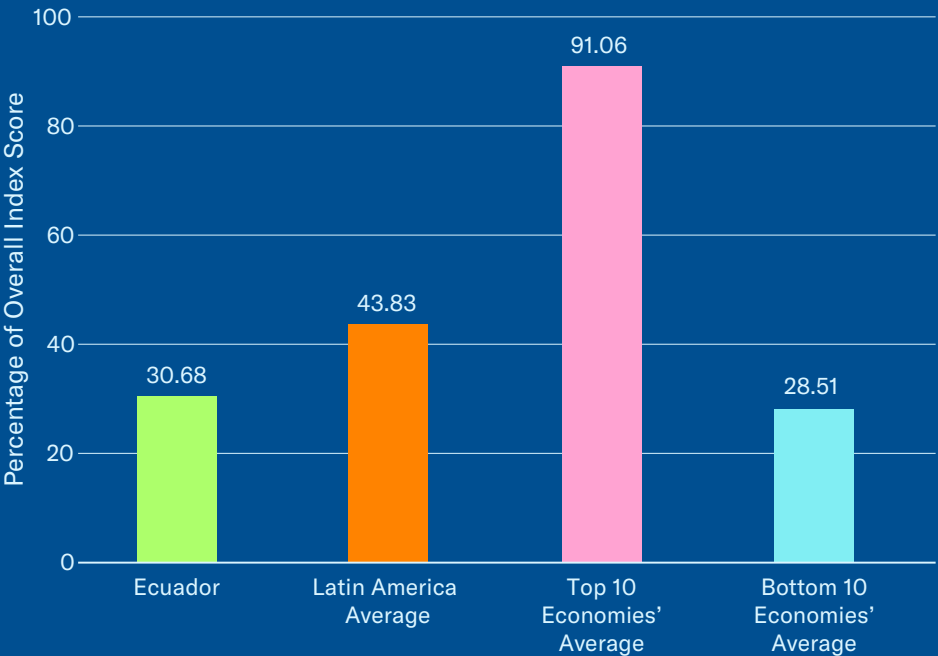
Unlike many other economies in Latin America, the Dominican Republic has not used compulsory licensing or the threat of compulsory licensing or similar “declarations of public interest” as biopharmaceutical cost containment tools. TRIPS Article 31, the amendments introduced in the 2001 Doha Ministerial Declaration, and the 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. Compulsory licensing is not a cost-containment tool; cost is not a relevant justification or basis for compulsory licensing under the TRIPS agreement. 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 is to be used only after all other options for negotiating pricing and supply have been exhausted. At the time of research, no license had been granted. The Index will monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Strengthened support for SMEs through WIPO- World Economic Forum (WEF) “Inventor Assistance Program”
- National IP authority SENADI ordered local ISPs to disable access to several websites hosting infringing and unlicensed content
- Five-year term of RDP defined in law *Código Ingenios*
- Limited re-criminalization of IP rights through 2016 criminal law amendments
- Member of PPH

Key Areas of Weakness

- Implementing regulations potentially undermine *Código Ingenios* RDP term of protection
- Plant variety protection term shorter than the 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 are missing, including patent term restoration and mechanisms for early patent dispute resolution
- *Código Ingenios* imposes additional limits on patentability and amount of non-patentable subject matter
- Persistently high levels of piracy— estimated 68% software piracy rate
- Ecuador has a low score for its participation and ratification of international treaties



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	2.99	Category 6: Commercialization of IP Assets	0.50
1. Term of protection	1.00	26. Barriers to market access	0.00
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.25
3. Patentability of CIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.00
4. Plant variety protection	0.74	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.25
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	2.21
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.39
9. Patent opposition	0.25	33. Software piracy rates	0.32
Category 2: Copyrights, Related Rights, and Limitations	1.74	34. Civil and preceudural remedies	0.25
10. Term of protection	0.74	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.25	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.25
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	2.25
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	0.25
16. Government use of licensed software	0.00	40. Consultation with stakeholders during IP policy formation	0.25
Category 3: Trademarks, Related Rights, and Limitations	1.75	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	2.00
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.90	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.00	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.50
25. Regulatory data protection term	0.50		
Total: 15.34			

Spotlight on the National IP Environment

Past Editions versus Current Score

Ecuador’s overall score decreased from 30.70% (15.35 out of 50) in the tenth edition to 30.68% (15.34 out of 50). This reflects a score decrease on indicator 32.

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 14. Scope of limitations and exceptions to copyrights and related rights: As has been documented over the course of the Index, rightsholders face significant challenges in protecting their content in Ecuador. The existing legal copyright framework has major gaps, and enforcement remains inadequate.

In 2016, Ecuador’s National Assembly passed the *Código Orgánico de Economía Social del Conocimiento, la Creatividad y la Innovación* (*Código Ingenios*). The legislation touches on all facets of IP rights, R&D, and innovation. As noted at the time, many of the provisions of this law conflicted with Ecuador’s old Intellectual Property Law and its international treaty obligations, including the TRIPS Agreement and the European Union’s Trade Agreement with Colombia and Peru (to which Ecuador acceded in 2016). With regard to copyright and related rights, the *Código Ingenios* materially weakened existing copyright protections and made what was already a challenging situation for rightsholders even more difficult. This is particularly the case regarding statutory exceptions to copyright. The *Código Ingenios* introduced several substantial changes in both the number and extent of exceptions and limitations. The number of defined statutory exceptions increased

considerably with Article 212 defining 29 different exceptions. This includes broad educational and personal use exceptions not only for individuals but for nonprofits and, potentially, small enterprises. In addition, Articles 133-139 provide specific exceptions related to computer software. Finally, the *Código Ingenios* introduced a new concept of “fair use” style exceptions. These exceptions fall firmly outside international standards as captured by the Berne Convention’s three-step test.

In 2020, Implementing Regulations for the *Código Ingenios* were released by the Ministry of Higher Education, Science, Technology, and Innovation. Unfortunately, these regulations did not effectively address these challenges. The USTR in 2022 reported that relevant Ecuadorian authorities were planning additional revisions to these Implementing Regulations. However, at the time of research, no further changes had been announced in 2022.

More broadly, Ecuador has over the past decade acted to decriminalize IP infringement. In 2013, amendments to the Intellectual Property Law removed criminal penalties and sanctions for copyright and trademark infringement altogether; as a result, Ecuador’s enforcement environment was incompatible with its international treaty obligations. In late 2015, amendments to the Penal Code were introduced with new limited sanctions put in place for the commercial infringement of trademarks and copyrights. Subsequent legislative changes have increased these penalties, but, in practice, the enforcement environment has not improved materially and remains challenging.

Physical counterfeit goods remain widespread with, for example, the La Bahia outdoor market in Guayaquil (Ecuador’s largest city) being listed in the USTR’s *Review of Notorious Markets*. Similarly, digital piracy, online infringement, and the circumvention of TPM and DRM have shown



no signs of abating over the course of the Index. Ecuador has maintained a relatively high rate of estimated software piracy over the past half decade. In 2014, this was an estimated 68%; the latest estimate from BSA is unchanged at 68%. Estimated rates of signal piracy are also high. For example, in 2019, the Latin American industry association ALIANZA released the findings from a study of estimated rates of signal piracy and theft in Latin America. The study found that the total pirated or unreported market in Ecuador was an estimated 25% of the total number of potential end users.

Although mechanisms for civil and administrative enforcement remain available under the *Código Ingenios*, rightsholders face significant challenges accessing them. The judicial process is drawn out, with legal redress being difficult to obtain and, by international standards, unpredictable. Administrative remedies are available through the National Service of Intellectual Rights (SENADI); however, rightsholders have reported that, in practice, such administrative recourse mechanisms remain unpredictable. Still, some pockets of improvement exist. SENADI has, over the past few years, ordered the disabling of access to several websites hosting infringing and unlicensed content. The first order came in 2019 following a request made by local rightsholders Fox Latin America and the Spanish national soccer league *Liga Nacional de Fútbol Profesional*. SENADI justified its decision and authority in the 2016 *Código Ingenios* and the Telecommunications Act. Although no specific article in the *Código* pertains to the disabling of infringing content or a description of how this administrative mechanism would work, SENADI cited the broad administrative enforcement powers given to it under Article 10 of the law. As noted, this was a positive development that resulted in a score increase on indicator 12. It was hoped that this administrative enforcement route would become available to rightsholders more broadly and would provide a clear and expeditious path for creators to effectively enforce

their IP rights. And although additional orders were issued and applied in 2021, it remains unclear the extent to which this administrative enforcement pathway has become an institutionalized feature of SENADI's enforcement activity.

The past decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the UK, India, Singapore and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, and the UK. They have proven to be effective in reducing the availability of copyright-infringing content within these jurisdictions. As the SENADI continues to develop its copyright enforcement capabilities, the Index urges the office to examine this growing number of examples and best practices from across the world.

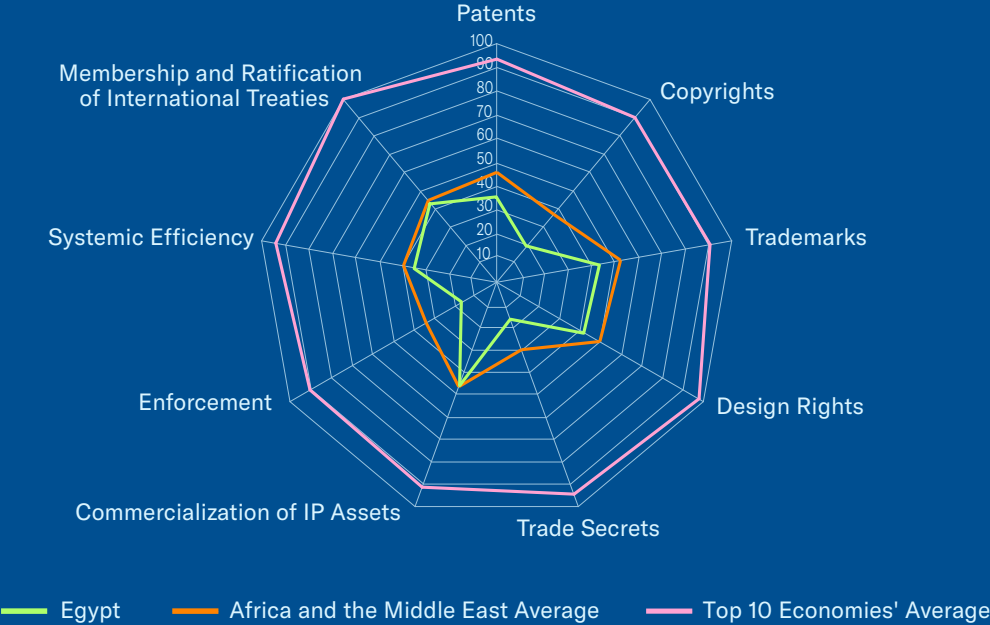
Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: As noted in the sixth edition of the Index, in a positive move, the 2016 *Código Ingenios* introduced a defined term of protection for submitted biopharmaceutical test data during the market authorization approval process. Until this time, Ecuador did not provide an effective term of regulatory data protection. Although Article 191 of the old Intellectual Property Law provided a basis for the protection of submitted biopharmaceutical test data, no term of protection was specified in

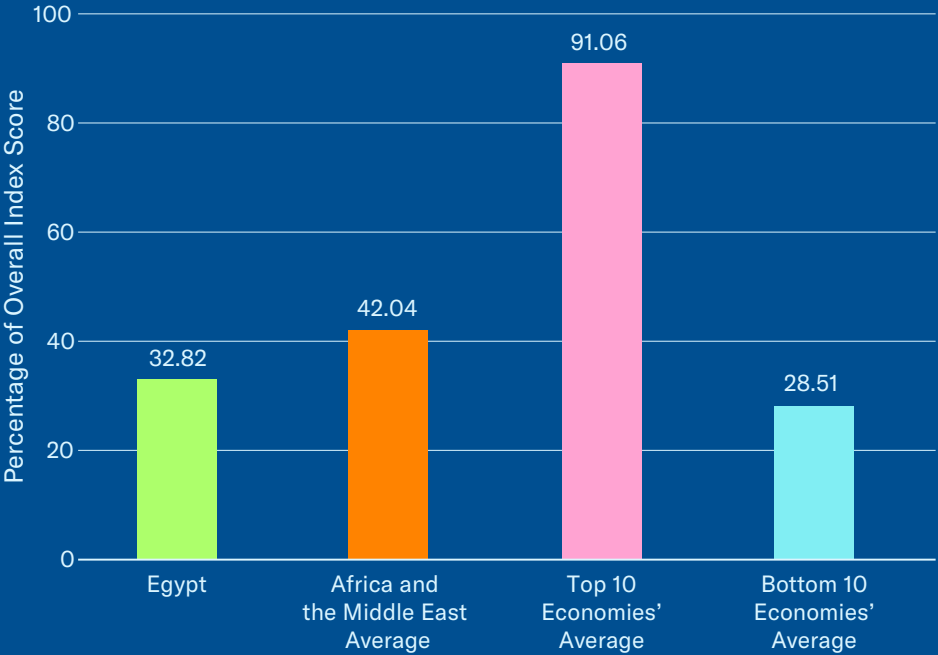
this legislation. Now, Article 509 of the *Código Ingenios* clearly defines a five-year term of regulatory data protection. As a result, Ecuador's score on this indicator increased in 2017. In 2020, Implementing Regulations for the *Código Ingenios* were released. These regulations provide further detail on how the RDP term of protection will be administered in Ecuador, including relevant terms and conditions. As noted in last year's Index, Articles 364-374 of the regulations appear to provide considerable carveouts and potential exceptions to the protection of undisclosed information. This includes a broad basis for authorizing access to undisclosed information to third parties on the basis of “public interest, national emergency situations, or extreme urgency.” These issues remained unresolved in 2022. A failure to provide an effective term of protection in line with existing statutory law will result in a score decrease on this indicator. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Joined the 1991 UPOV agreement in 2020
- Since 2015, a PPH has been in place with the JPO
- Relative freedom to patent CII and support from government agencies
- Relatively strong push from the government to raise awareness of counterfeit products, particularly medicines
- New electronic patent filing system becomes operational, improving Egypt's technical capacity and quality of service

Key Areas of Weakness

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



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
1. Term of protection	1.00	26. Barriers to market access	0.75
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.50	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.27
9. Patent opposition	0.00	33. Software piracy rates	0.41
Category 2: Copyrights, Related Rights, and Limitations		34. Civil and precluded remedies	0.25
10. Term of protection	0.38	35. Preestablished damages	0.00
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.00	37. Effective border measures	0.00
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	0.00	40. Consultation with stakeholders during IP policy formation	0.25
Category 3: Trademarks, Related Rights, and Limitations		41. Educational campaigns and awareness raising	0.25
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	0.00
Category 4: Design Rights, Related Rights, and Limitations		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00	Total: 16.41	

Spotlight on the National IP Environment

Past Editions versus Current Score

Egypt’s overall score remains unchanged at 32.82% (16.41 out of 50).

Area of Note

In a positive development for rightsholders and inventors both in Egypt and across the world, in 2022, the Egyptian Patent Office’s (EGPO) new electronic patent filing system became operational. Applicants and existing patent rightsholders will now be able to conduct most of their patent-related business with the patent office electronically. The initiative grew out of a bilateral cooperation project between South Korea and Egypt. EGPO has, over the past decade, focused on improving its technical capacity and the quality of the services offered to its users. Since 2013, the office has, under the Patent Cooperation Treaty, been an International Searching Authority. It has also put in place several cooperation and capacity-building programs with other leading patent offices, most notably with the Spanish Patent Office. As essential as these administrative and operational improvements are, changes to the existing legal framework should also be part of these reform efforts. Egypt has not seen substantive changes to its IP laws, including for patents and related rights, since the early 2000s. As the economic data and analysis in this Index’s accompanying *Statistical Annex* and the experiences of other economies show, 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. In a further positive development, in September 2022, Egypt’s Prime Minister announced a new National IP Strategy that will hopefully drive reform

and alignment with international standards.

Yet, as noted this year and over the course of the Index, Egypt’s national IP environment lacks many fundamental rights and incentives. Patentability standards continue to be outside of international norms, and many sector-specific IP rights are absent, especially for biopharmaceuticals. As noted here, the protection of copyright remains underdeveloped and ill-suited to the challenges of the internet era. Levels of physical and online counterfeit goods remain high, but relevant enforcement mechanisms are weak and largely non-deterrent. Similarly, Egypt’s participation in international IP treaties could be more extensive. Being a contracting party to key IP treaties reflects a given economy’s broader participation in the international IP community and embracing of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adheres to established standards and best practices.

As noted in past editions of the Index, although Egypt’s score in Category 9: Membership and Ratification of International Treaties has increased substantially from a score of 0 in the fifth edition of the Index (the first year Egypt was included) to now achieving a score of 3, or 42.86%, of the total available score, Egypt is only a contracting party to four of the nine IP treaties included in the Index. Furthermore, Egypt has not concluded a post-TRIPS FTA with substantive IP provisions. Covering 50 indicators across nine separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop to commercialize their ideas and products. As EGPO and the Egyptian government continue to pursue their reform program, we encourage them to use the findings



of the Index and accompanying Statistical Annex as a guide to IP reforms in 2023 and beyond.

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 15. Technological protection measures (TPM) and digital rights management (DRM) legislation: As has been noted in past editions, rightsholders face significant challenges in protecting their content in Egypt. The existing legal copyright framework has major gaps, and enforcement remains inadequate. Book 3 of Law 82 “Pertaining to the Protection of Intellectual Property Rights” provides standard exclusive rights. The law does not provide specific remedies or rights within an online or digital context. For example, the law does not include any notification-and takedown system for online infringement, and Article 181 of the law contains only rudimentary TPM and DRM protection measures with, for instance, distribution not listed as an offense. With respect to injunctive-style relief and the disabling of access to infringing content, access to individual websites can be ordered disabled by the relevant Egyptian authorities. For example, access to several websites was disabled in 2019, including “EgyBest,” a streaming site. However, the government issued no official explanation or announcement on what basis the access was disabled. As such, no established mechanism or pathway (judicial or administrative) is in place that rightsholders can use to combat online piracy and infringement.

The 2018 Anti-Cyber and Information Technology Crimes Law provides direct authorization for the Egyptian government to order disabling of any website or web-based activity. However, the law deals primarily with cybercrime related to national security and terrorism, not copyright infringement.

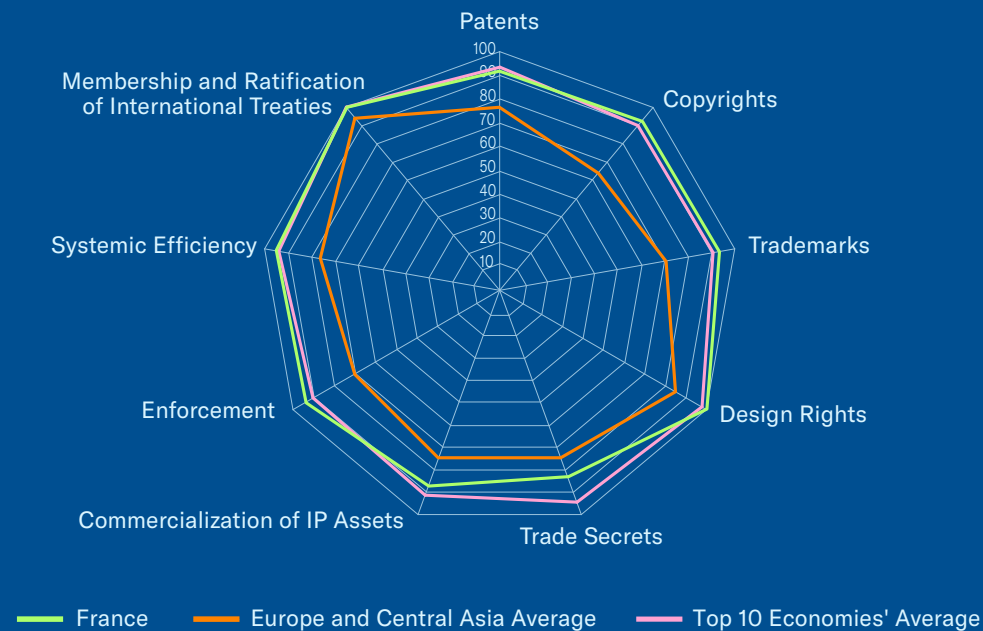
Civil remedies, criminal standards, and mechanisms for determining damages are in place in existing law but are relatively low and are not consistently applied or enforced. Basic civil remedies are in place for the infringement of all IP rights, including the issuing of injunctions and the seizure of profits from infringing goods, but judicial enforcement is difficult because Egypt’s court system is overburdened. Litigation in Egypt is common and largely paper-based, which has resulted in a large backlog of cases and court proceedings; it can take years to reach a verdict in a given case. Criminal sanctions are available under existing copyright and trademark laws, but these sanctions are relatively lenient; for example, businesses engaging in infringement can be ordered closed but only for a maximum period of six months.

The levels of physical counterfeiting and online piracy are high. The BSA estimates that Egypt’s software piracy rate is 59%; this has remained virtually unchanged since 2009. Looking at global customs data, the OECD and the European Union Intellectual Property Office (EUIPO) found in the 2021 report *Global Trade in Fakes: A Worrying Threat, Illicit Trade* that Egypt was a major source of counterfeit goods, including leather articles and handbags, fake footwear, and fake jewelry. Similarly, the U.S. government has for years highlighted the high prevalence of copyright piracy, including signal piracy, in Egypt.

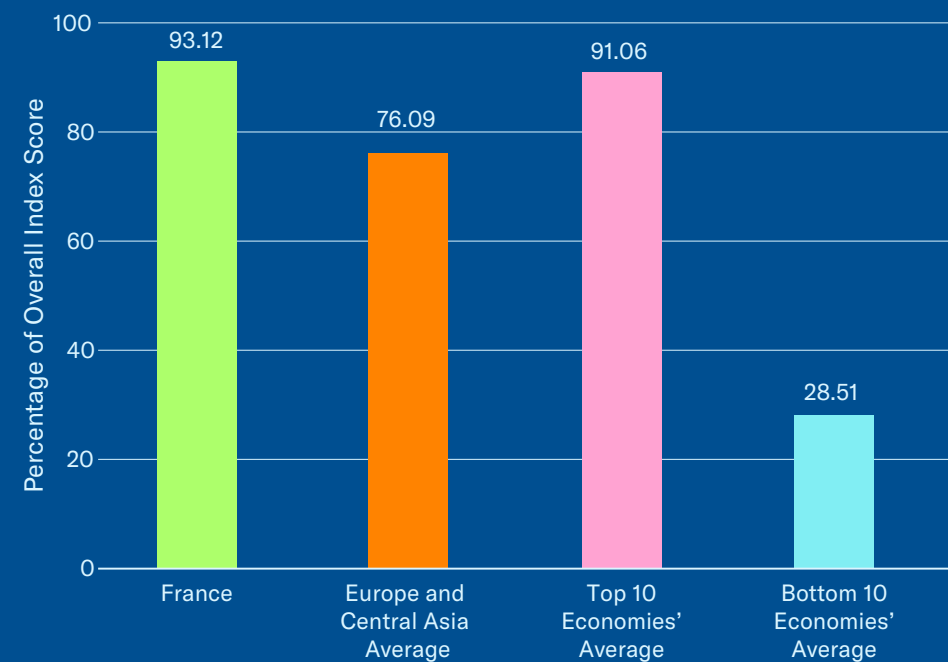
Some positive developments occurred in 2022. Specifically, in June, an international rightsholders’ coalition, the Alliance for Creativity and Entertainment, announced that, together with local Egyptian law enforcement, it had successfully disabled access to a significant source of pirated sports content in Egypt. Several streaming sites were reported to have been disabled, domain names were seized, and arrests were made. Considering the many enforcement challenges in Egypt, these are positive developments, and the Index will continue to monitor this activity in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Under Law 2021-1382, copyright enforcement powers have been expanded to allow the French Copyright Authority (HADOPI) to take quicker action against mirror sites; establish a blacklist of repeat infringing hosts and websites; expedite disabling of access following judicial order; and introduce an expedited pathway for infringement of live sports broadcasting
- Generous R&D and IP-specific tax incentives are 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 is 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 the EU's research and IP-based biopharma industry



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.25	Category 6: Commercialization of IP Assets	5.25
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	6.57
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.89
9. Patent opposition	1.00	33. Software piracy rates	0.68
Category 2: Copyrights, Related Rights, and Limitations	6.49	34. Civil and preceudural remedies	1.00
10. Term of protection	0.74	35. Preestablished damages	1.00
11. Exclusive rights	1.00	36. Criminal standards	1.00
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	4.75
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.75	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.75	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.75	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	2.00	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.50	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.75	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.75	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 46.56			

Spotlight on the National IP Environment

Past Editions versus Current Score

France’s overall score has increased from 92.10% (46.05 out of 50) in the tenth edition to 93.12% (46.56 out of 50). This reflects a score increase on indicators 11 and 32.

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): Since the late 2000s, the French government has introduced several policies aimed at reducing online copyright infringement. In 2009, the government introduced a new set of anti-piracy laws and created 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 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. In 2012, Socialist presidential candidate Francois Hollande’s electoral campaign agenda sought to dismantle the HADOPI. In 2015, an amendment to dissolve HADOPI was initially adopted by the French National Assembly but later removed by the Senate. Most recently, the agency’s powers had been questioned by several internet-rights groups, which argued that HADOPI’s remit was unconstitutional and a violation of consumers’ rights and privacy.

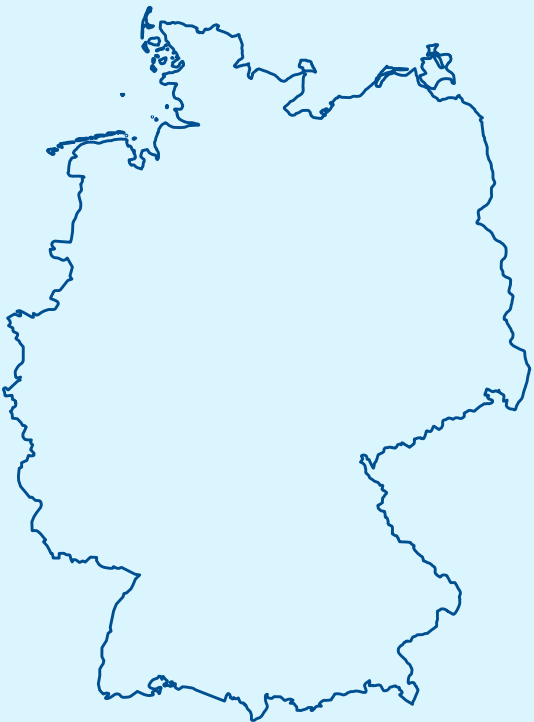
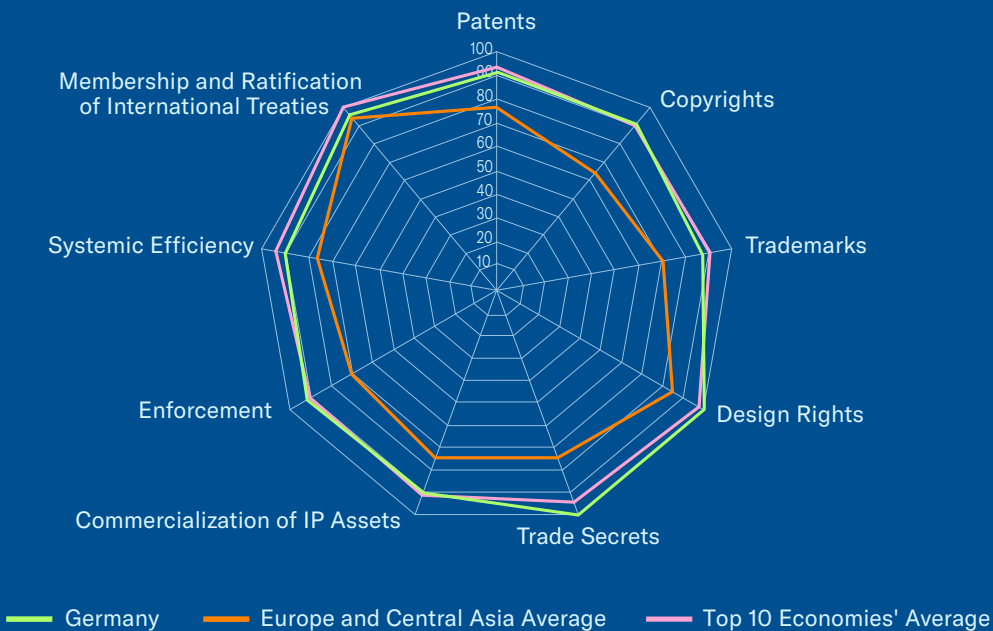
Despite these efforts to question the agency’s remit and its legitimacy, HADOPI has continued its work. Since 2011, the agency has sent out over 14 million infringement notices and has had a sustained and positive impact on reducing levels of copyright piracy in France. For example, in 2021, the agency estimated that infringement through peer-to-peer technology has decreased by over 60% since 2009. These positive efforts continued in 2022. Since the beginning of the year, HADOPI has combined with the *Conseil supérieur de l’audiovisuel* (Superior Audiovisual Council) to form a new regulatory entity, the *Autorité de régulation de la communication audiovisuelle et numérique*. As part of the merger and the accompanying legal changes under Law 2021-1382, HADOPI’s enforcement powers have been expanded. These legal changes now improve the agency’s ability to take quicker action against so-called mirror sites; establish a blacklist of repeat copyright-infringing hosts and websites; help expedite the disabling of access to infringing websites following a judicial order; and create an expedited pathway for addressing the infringement of copyright relating to live sports broadcasting. As a result of these changes, the score on this indicator has increased by 0.25.

Trademarks, Related Rights, and Limitations

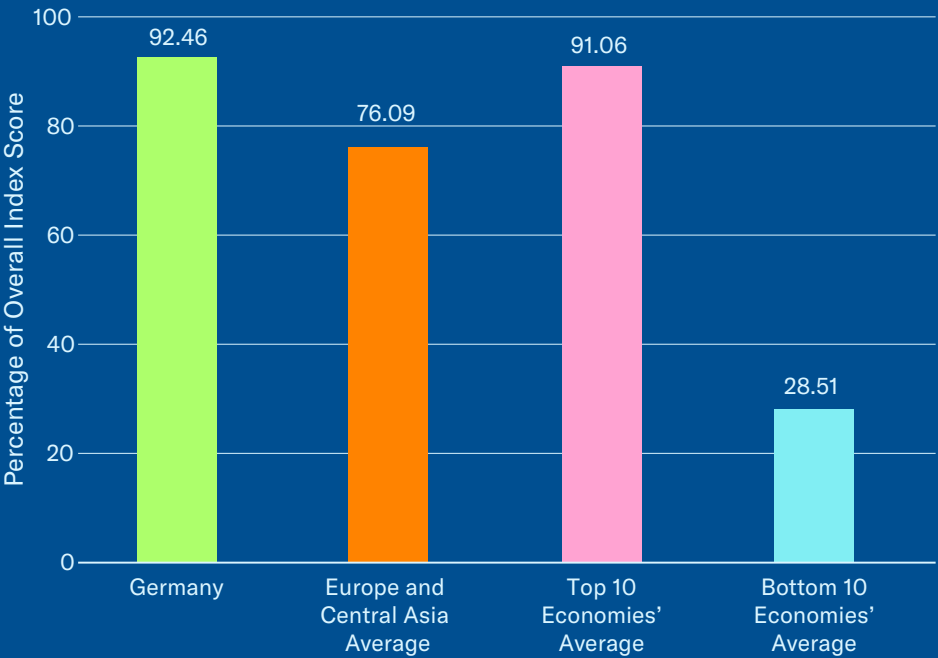
20. Availability of frameworks that promote action against online sale of counterfeit goods: In September 2022, the Directorate-General of Customs and Indirect Taxes announced the results of a 22-month special operation conducted against the online sale of counterfeit toys and children’s articles. In a cross-European operation involving law enforcement in seven EU Member States and Europol, over 16 million counterfeit goods were either seized or taken down online. This is one of the largest operations of its kind ever carried out in the EU, and it was led by the French authorities who initiated the investigation and alerted their European counterparts. As a result of this positive action, the score on this indicator has increased by 0.25.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Introduction of new R&D tax credits
- Advanced and sophisticated national IP environment
- Sector-specific IP rights are 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 the EU's research and IP-based biopharma industry
- Patent Law Treaty signed but not ratified



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.25	Category 6: Commercialization of IP Assets	5.42
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	6.43
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.88
9. Patent opposition	1.00	33. Software piracy rates	0.80
Category 2: Copyrights, Related Rights, and Limitations	6.38	34. Civil and preceudural remedies	1.00
10. Term of protection	0.63	35. Preestablished damages	0.75
11. Exclusive rights	1.00	36. Criminal standards	1.00
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.75	Category 8: Systemic Efficiency	4.50
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.50	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	6.75
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	2.00	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	3.00	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	1.00	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 46.23			

Spotlight on the National IP Environment

Past Editions versus Current Score

Germany's overall score remains unchanged at 92.46% (46.23 out of 50).

Patents, Related Rights, and Limitations

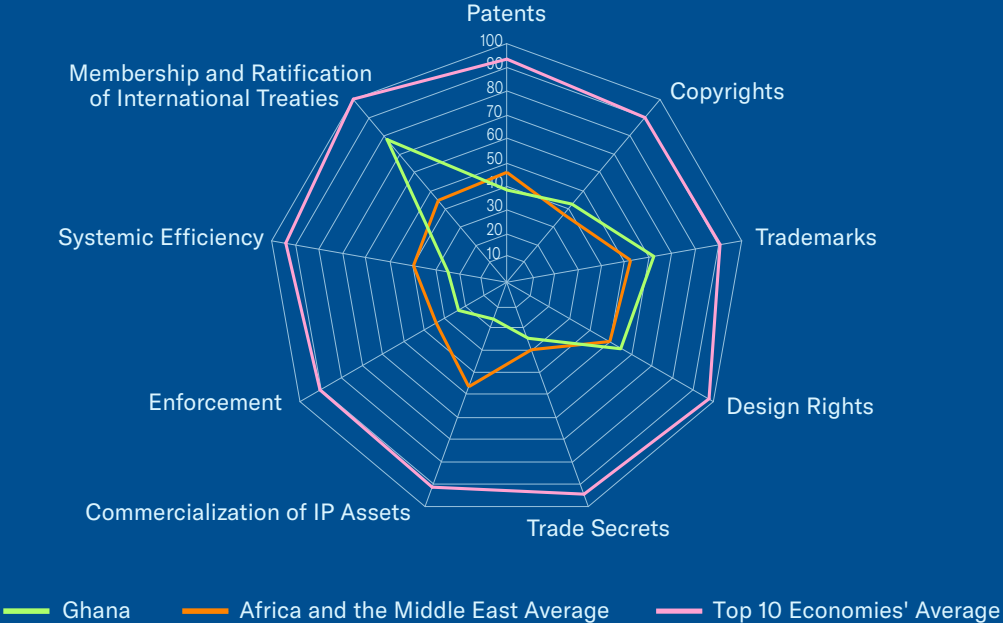
The past year has seen several important procedural developments with regard to Germany's patenting environment. In the second half of 2021, the Bundestag passed a set of amendments to the Patent Act. All these amendments have now come into effect, with the latest becoming operational in the summer of 2022. Although these amendments do not fundamentally change the legal environment for patents in Germany, they clarify certain points of law. For example, the most substantive change is the incorporation of the idea of "proportionality" in the availability of injunctive relief. As the amendments and accompanying explanatory memorandum make clear, this proportionality analysis or test is only to be applied in exceptional circumstances. These amendments codify what had largely been established in relevant German case law.

Other important procedural changes include the formalization and greater use of virtual interactions with the German Patent and Trademark Office (DPMA). It will now be possible to allow relevant parties to attend hearings and official meetings with the DPMA in person or virtually. Progress was also made with respect to Germany's participation in the Unified Patent Court (UPC). Since 2017, there has been uncertainty about Germany's participation in the court. Although both the German Bundestag and Federal Council had approved relevant legislation on Germany's accession to the UPC in 2020, several constitutional complaints had been lodged and were pending with the German Federal Constitutional Court. These complaints were finally dismissed in 2021. Subsequently,

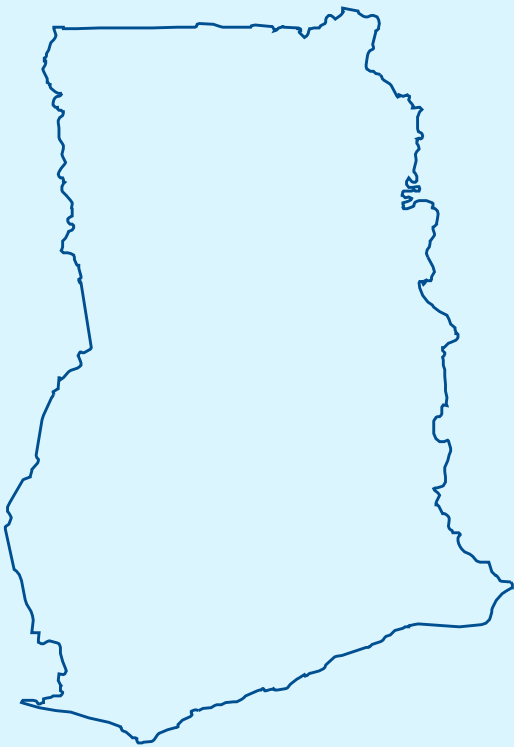
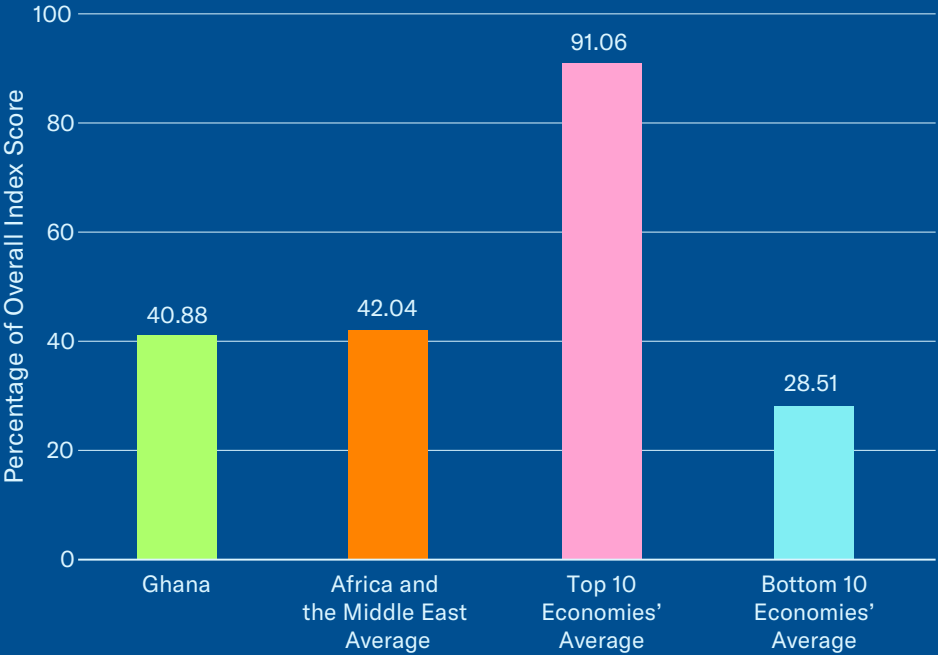
at the end of September 2021, the federal government formally deposited its instrument of ratification. Although important areas of law and practical operation must still be finalized—especially with respect to the mechanics of a new patent term restoration system—the availability of a unitary European patent in all contracting parties, with a corresponding single judicial authority in the form of the UPC, will offer patent rightsholders in Germany, and beyond, tremendous benefits and will be a boon to European innovation and economic development.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Contracting party to most international IP treaties included in the Index; joined UPOV 1991 in 2021
- Member of African Regional Intellectual Property Organization (ARIPO)
- ARIPO patentability guidelines allow high-tech claims (both Swiss-style biopharmaceutical claims and CILs)
- New Plant Variety Protection Act 2020
- Electronic Transactions Act 2008 includes definition and description of liability for service providers and intermediaries, including potential court-ordered injunctive-style relief
- WTO TRIPS member

Key Areas of Weakness

- Legal framework remains rudimentary for most IP rights, with many key IP rights and incentives unavailable
- Enforcement environment remains highly fraught with counterfeit and IP-infringing goods widely available—physical and online
- High levels of counterfeit and substandard medicines
- Judicial enforcement is characterized by long delays



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
3.50		1.00	
1. Term of protection	1.00	26. Barriers to market access	0.50
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.00
3. Patentability of CIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.00	1.44	
9. Patent opposition	0.75	32. Physical counterfeiting rates	0.44
Category 2: Copyrights, Related Rights, and Limitations		33. Software piracy rates	NA
2.99		34. Civil and preceudural remedies	0.25
10. Term of protection	0.74	35. Preestablished damages	0.25
11. Exclusive rights	0.50	36. Criminal standards	0.25
12. Injunctive-type relief	0.25	37. Effective border measures	0.25
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	
15. TPM and DRM	0.50	1.25	
16. Government use of licensed software	0.50	39. Coordination of IP rights enforcement	0.25
Category 3: Trademarks, Related Rights, and Limitations		40. Consultation with stakeholders during IP policy formation	0.25
2.50		41. Educational campaigns and awareness raising	0.25
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.50	5.50	
Category 4: Design Rights, Related Rights, and Limitations		44. WIPO Internet Treaties	1.00
1.10		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	1.00
0.75		49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
23. Protection of trade secrets (civil remedies)	0.50	50. Post-TRIPS FTA	0.00
24. Protection of trade secrets (criminal sanctions)	0.25		
25. Regulatory data protection term	0.00		
Total: 20.03			

Spotlight on the National IP Environment

Past Editions versus Current Score

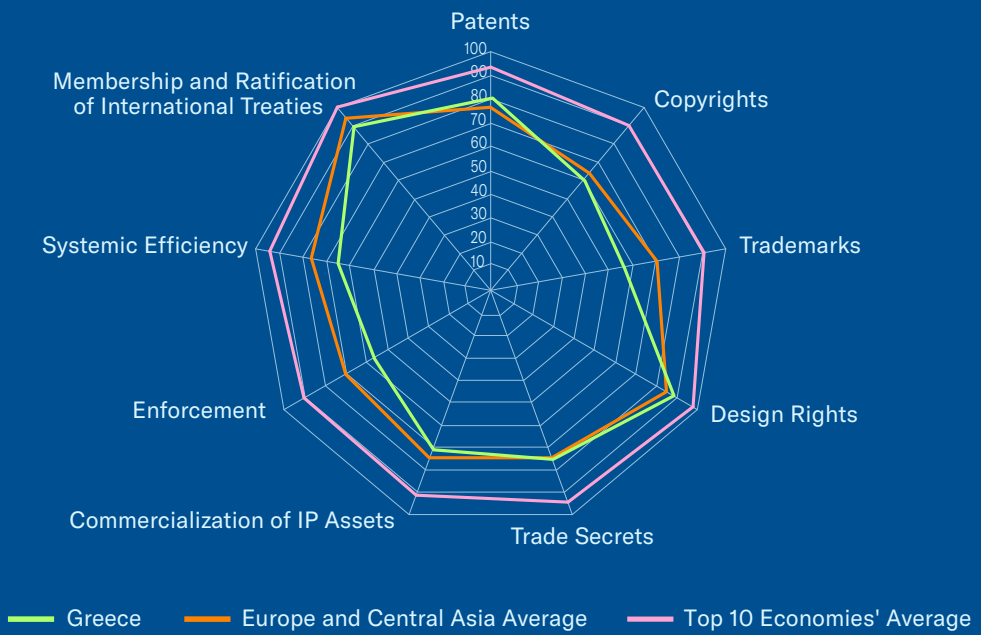
Ghana’s overall score remains unchanged at 40.88% (20.03 out of 50).

Commercialization of IP Assets and Market Access

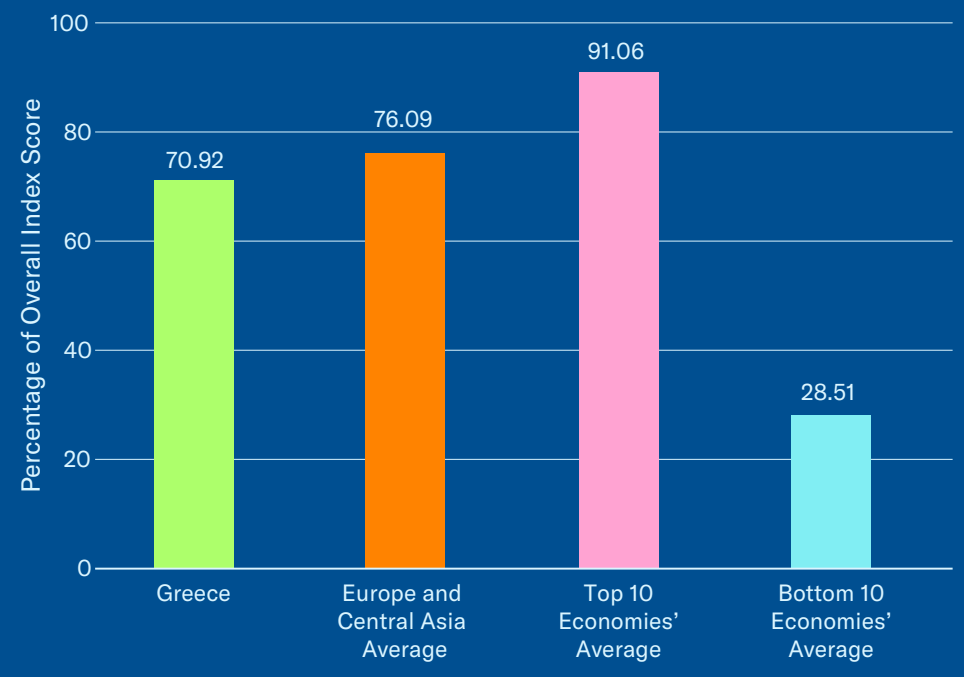
27. Barriers to technology transfer; 28. Registration and disclosure requirements of licensing deals; and 29. Direct government intervention in setting licensing terms: Ghanaian law and practice impose several barriers to the international transfer of technologies and inhibit the execution of licensing transactions. To begin with, under the Ghana Investment Promotion Centre Act 2013, all technology transfer agreements must be registered and reviewed by the Centre. Section 37 of the act grants the Centre the power to “review the agreement,” and, upon registration, the right to “monitor and ensure compliance with the terms and conditions of the agreement.” Registration requirements, terms, and conditions are outlined in more detail under the “Technology Transfer Regulations.” These regulations impose detailed restrictions on licensing transactions and technology transfer agreements, including the length of the agreement; relevant compensation (including restrictions on royalty rates, management fees, technical service fees, etc.); and a host of other restrictions on contractual arrangements. Moreover, all licensing agreements must also be registered with the relevant registrar to be enforceable against third parties, including patent-based licensing contracts under Section 29(5) of the Patents Act.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Continued strong efforts in 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 from 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

- 2019 changes to compulsory licensing regime, which introduced price considerations as a basis for issuing licenses, are out of line with international standards
- High levels of online piracy
- BSA estimated rates of the use of unlicensed software suggests that since 2011, Greece has 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%)—compared 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 the EU's research and IP-based biopharma industry
- Registration requirement for licensing deals in Greece



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	7.25	Category 6: Commercialization of IP Assets	4.25
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.25
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	3.97
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.58
9. Patent opposition	1.00	33. Software piracy rates	0.39
Category 2: Copyrights, Related Rights, and Limitations	4.24	34. Civil and preceudural remedies	0.50
10. Term of protection	0.74	35. Preestablished damages	0.25
11. Exclusive rights	0.50	36. Criminal standards	0.25
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	0.50	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.75	Category 8: Systemic Efficiency	3.25
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.75
Category 3: Trademarks, Related Rights, and Limitations	2.25	41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	6.25
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.75	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.25	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.75	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.50	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 35.46			

Spotlight on the National IP Environment

Past Editions versus Current Score

Greece’s overall score remains unchanged at 70.92% (35.46 out of 50).

Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online: As noted in previous editions, rightsholders 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 rightsholders. Over the past few years, the Greek government has attempted to address 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. Where infringement is found, the committee can order the relevant parties and ISPs or internet mediators to remove and/or disable access to the infringing materials, even if the server or host is located outside of Greece.

In 2018, the committee issued its first substantive ruling ordering the disabling of access to 38 websites enabling or hosting infringing content, including The Pirate Bay. These positive efforts have continued in the past few years, with both changes to existing legislation strengthening the powers of the committee and the continued disabling of infringing websites. Since the initial rulings, the committee had made decisions and has ordered that access be disabled for a total of 65 infringing websites.

Unlike other economies where a similar injunctive-style relief mechanism has been established, in Greece, there was initially no “dynamic” element to the disabling of access orders. In effect, infringing sites and hosts could simply change their domain names, thus forcing rightsholders to go through a similar process again. In 2020, legislative amendments were passed addressing this deficiency. Under Article 25 of Law 4708/2020, the committee’s powers were expanded and ensure 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) issued a press release emphasizing the importance of this new dynamic capacity and the powers granted to the committee. The Minister of Culture and Sports, 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 efforts set a positive example for other Index economies struggling with high rates of online infringement. The Ministry of Culture and Sports and the Hellenic Copyright Organization should be applauded for their efforts.

Commercialization of IP Assets and Market Access

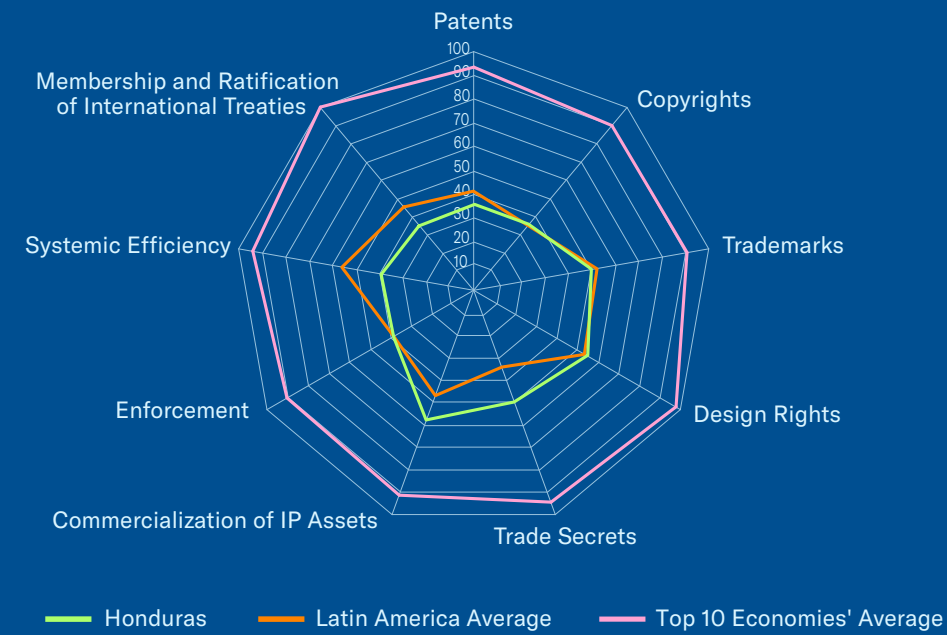
31. Tax incentives for the creation of IP assets: Greek tax law provides both a generous R&D super deduction and IP-specific tax incentives in the form of a patent box. The R&D incentive consists of a 200% super deduction, which can be claimed on qualifying expenditures carried out during an entity’s normal business activities. The patent box regime is based on a pre-defined tax deferral of up to three years. Qualifying entities can defer relevant applicable taxes on income derived from products and services based on a patented technology. In



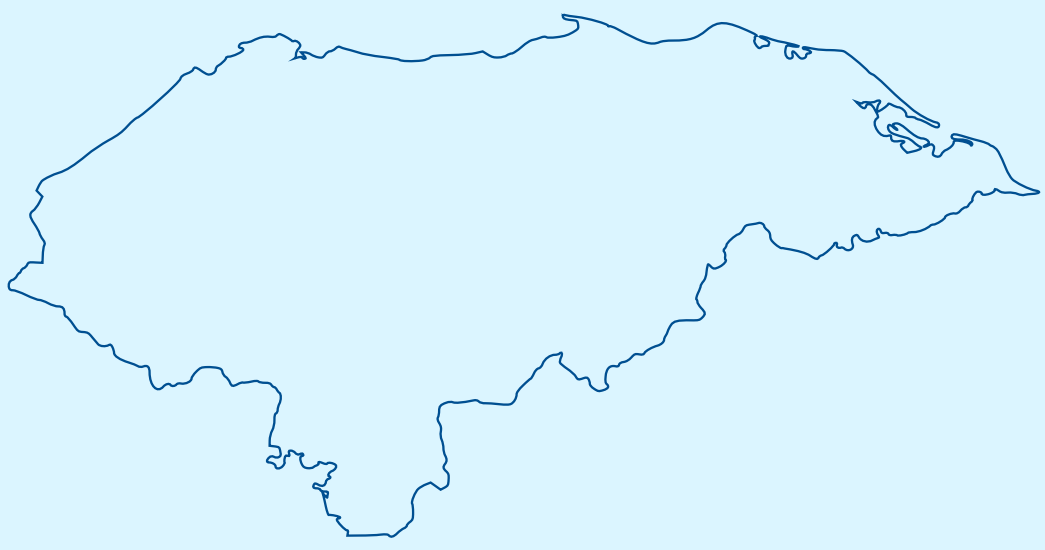
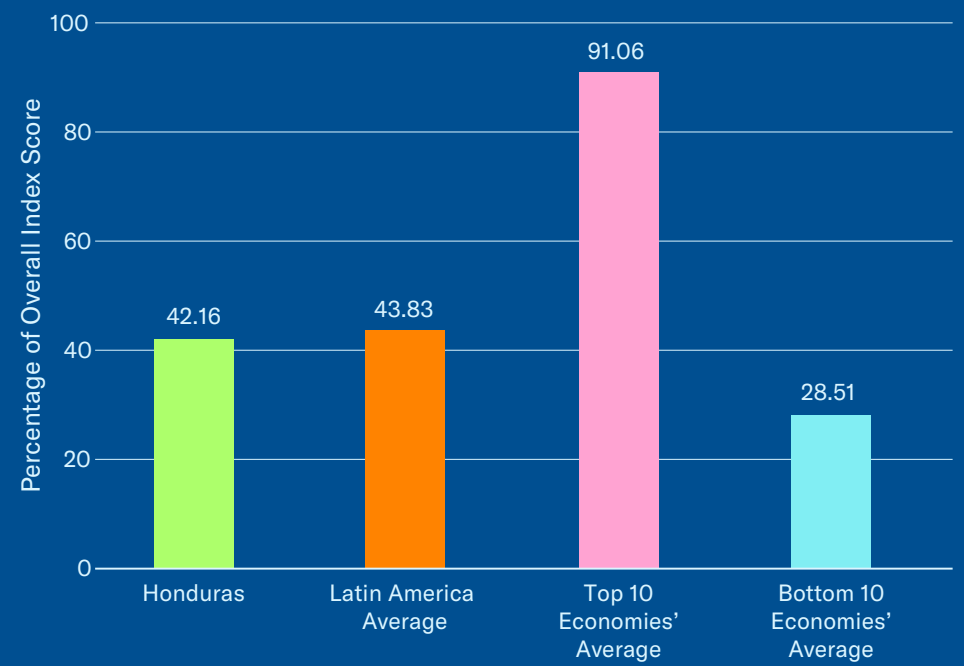
December 2021, Law 4864 aligned the Greek patent box regime with the OECD's Base Erosion and Profit Shifting Project, specifically the adoption of a nexus approach to patent boxes. Implementing Regulations published in 2022 (Ministerial Decision No. 79628 EX 2022) further defined these changes and applicable requirements.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- CAFTA membership fundamentally improved the national IP environment
- Plant variety protection in place
- No evidence of active government intervention in technology transfer or licensing
- Regularly conducts awareness campaigns and extensive technical assistance programs to support SMEs and regional IP support offices
- Actively supports the registration and commercialization of IP assets through its 15 CATI support centers

Key Areas of Weakness

- Patentability standards outside international norms—key problem areas include second-use claims for biopharmaceuticals and patent protection for CILs
- Uncertainty over access to statutory period of RDP: 2018 implementing regulations (Acuerdo No. 024-2018) provide a broad basis for overriding exclusivity
- Challenging enforcement environment, particularly regarding online and digital content
- 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 government
- BSA's estimated rates of software piracy are among the highest in the region at 75%
- Signal piracy and theft are among the highest in Latin America: total pirated or unreported market in Honduras estimated at 50% of total number of potential end users



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	3.25	Category 6: Commercialization of IP Assets	3.50
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.50
3. Patentability of CIIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	2.72
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.47
9. Patent opposition	0.25	33. Software piracy rates	0.25
Category 2: Copyrights, Related Rights, and Limitations	2.51	34. Civil and preceudural remedies	0.50
10. Term of protection	0.76	35. Preestablished damages	0.50
11. Exclusive rights	0.25	36. Criminal standards	0.50
12. Injunctive-type relief	0.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	2.00
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.25
Category 3: Trademarks, Related Rights, and Limitations	2.00	41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.00
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	2.50
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.10	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.50	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.50	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
Total: 21.08			

Spotlight on the National IP Environment

Past Editions versus Current Score

Honduras’ overall score decreased from 42.18% (21.09 out of 50) on the tenth edition of the Index to 42.16% (21.08 out of 50). This reflects a score decrease on indicator 32.

Patents, Related Rights, and Limitations

2. Patentability requirements; and 3. Patentability of computer-implemented inventions (CIIs): The Honduran Industrial Property Law defines patentable subject matter in Articles 4-10. Article 6 states that an “invention shall be patentable when it is susceptible to industrial application, when it is novel and has inventive level.” Non-patentable subject matter is defined under Articles 5 and 7. The patentability of high-tech arts (including biopharmaceuticals and CIIIs) is restricted in law and in practice. Local legal analysis suggests that Swiss-style claims for second-use biopharmaceutical inventions are not accepted and that software is primarily protected through copyright. Specifically, patents for CII claims are seldom granted. Like other CAFTA economies, Honduras’ Industrial Property Law excludes computer software from patentable subject matter. Article 5(7) states that “computer programs” as such are not considered inventions and are excluded subject matter not eligible for patent protection. This is in contrast to Honduras’ commitments under the 2006 CAFTA-DR. Article 15.9(1) states clearly that “Each Party shall make patents available for any invention, whether a product or a process, in all fields of technology, provided that the invention is new, involves an inventive step, and is capable of industrial application.” Many other jurisdictions have similar patentability standards in place as Honduras but allow patents for CIIIs as long as the relevant claims lead to or have a technical effect. The relevant parts of the patent manual used by Central American

IP offices (Manual de Organización y Examen de Solicitudes de Patentes de Invención) do not explicitly discuss the extent to which CIIIs and computer software having a technical effect are patentable. However, looking at patent statistics housed by WIPO for Honduras, a small number of patent applications (patent publications by technology) were under the categories “Computer technology” and “IT methods for management.” Between 1996 and 2015, five patent applications were published under the categories “Computer technology” and “IT methods for management.” This compares to a total number of 1,319 total applications during this time period, or 0.38% of the total number of applications published.

7. Patent term restoration for pharmaceutical products: Term restoration for pharmaceutical products is not offered through the Industrial Property Law or other relevant Honduran statute. This is in contrast to Honduras’ commitments under the CAFTA-DR. Under Article 15.9(6), this agreement includes a clear requirement that all contracting parties provide a term of patent restoration “to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party.” Honduras’ implementing legislation (Decree16 2006, the “Law on the Implementation of the Free Trade Agreement, Dominican Republic, Central America and United States”) does not contain an equivalent requirement.

Systemic Efficiency

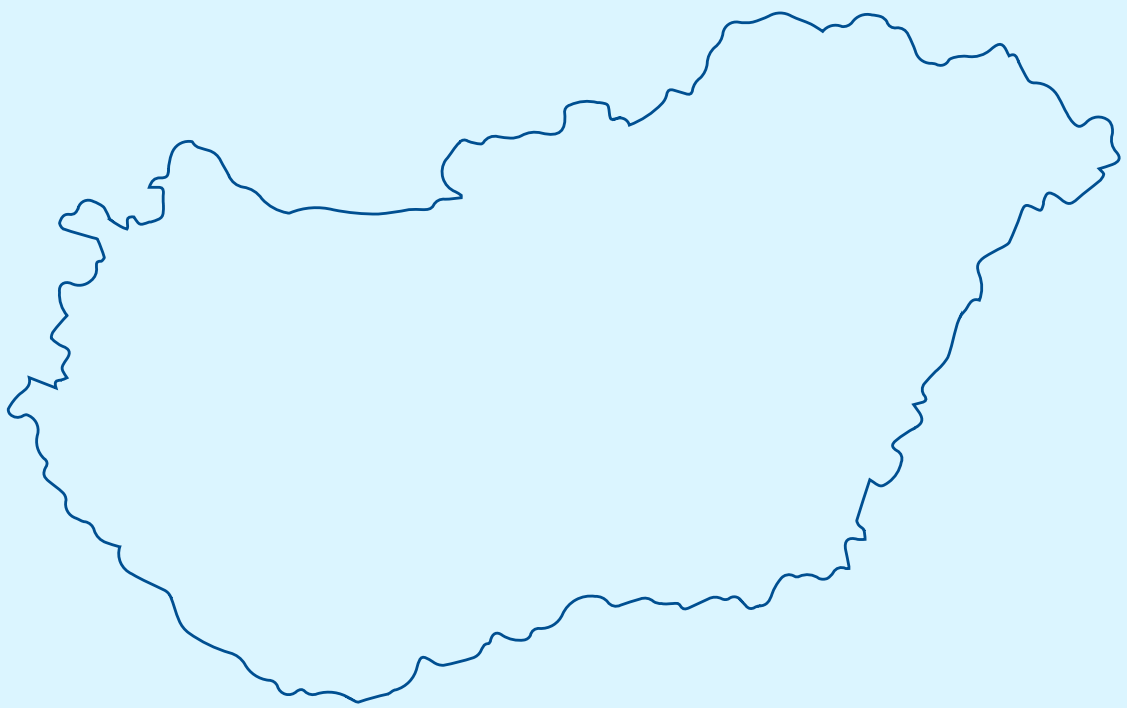
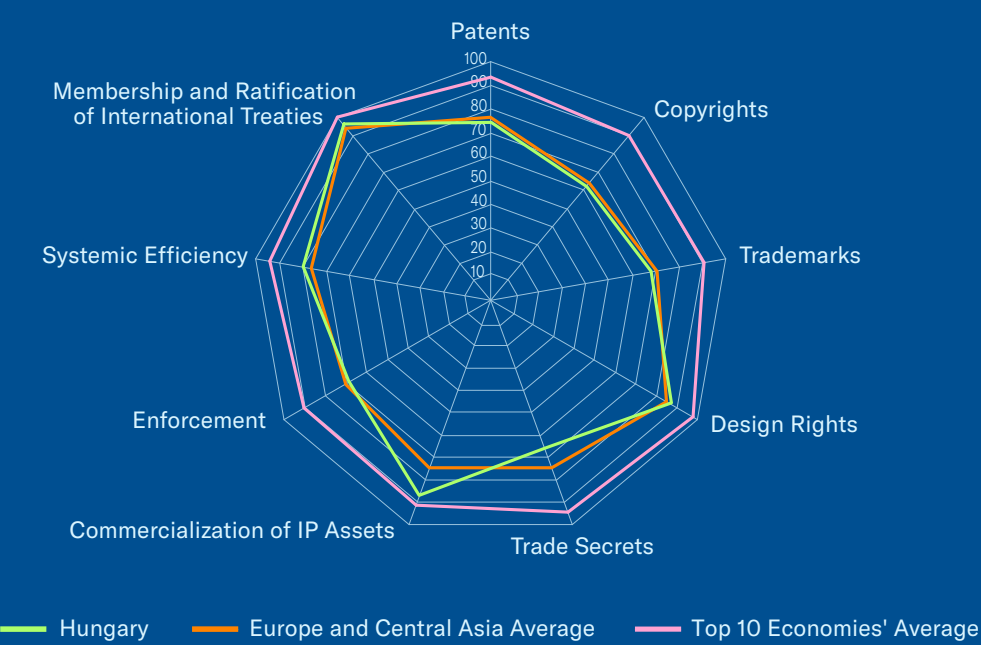
42. Targeted incentives for the creation and use of IP assets for SMEs: Recognition is growing in Honduras of the importance of SMEs and micro, small, and medium-sized enterprises (MSMEs) in the creation, dissemination, and commercialization of IP assets. Although the Directorate of Intellectual



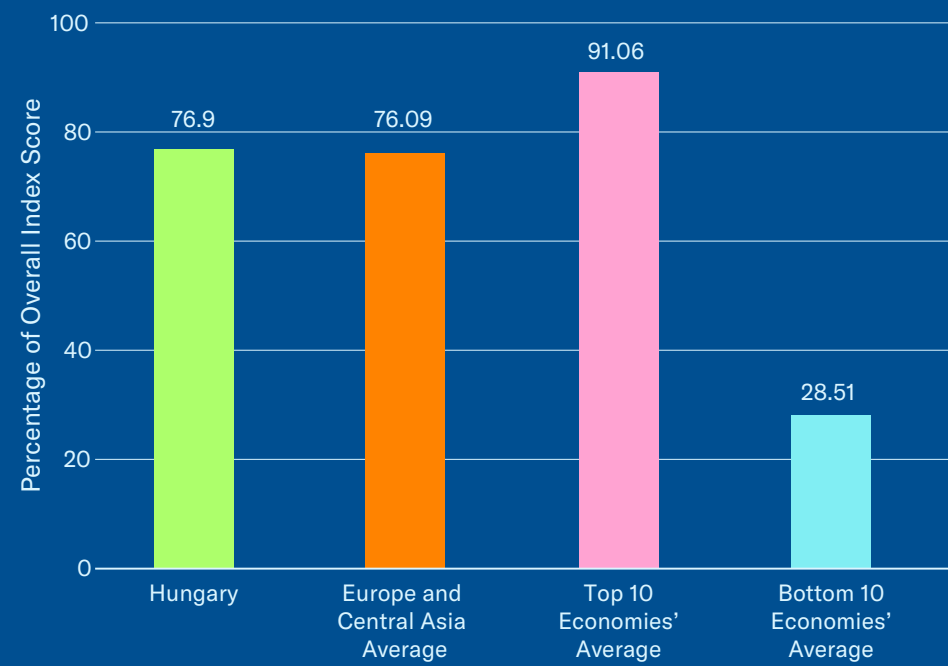
Property and National Registry (Instituto de la Propiedad) do not offer registration discounts or fast-track registration for SMEs, both regularly conduct awareness-raising campaigns and facilitate educational activities. These activities include an extensive technical assistance program and recurring awareness campaigns aimed at SMEs. There are several examples from the past half decade of the directorate organizing, hosting, or supporting a range of campaigns, seminars, conferences, and educational activities with SMEs, students, and other regional IP offices and WIPO. Furthermore, the National Registry actively supports 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. 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 over the past few years, and, as of 2022, Honduras had 15 support centers. This is almost three times more than in neighboring Costa Rica, which has six. One of the existing centers is based out of the office of the General Directorate of Intellectual Property. The CATI concept was developed by WIPO through its Technology and Innovation Support Centers (TISCs) in 2009-10, and, as of 2022, 88 economies (including Honduras) had established a local TISC office.



Category Scores



Overall Score in Comparison



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 are in place
- Fairly strong and sophisticated IP system is conferred through EU membership
- Sector-specific IP rights are in place

Key Areas of Weakness

- Basis for overriding of patent rights and exclusivity of remdesivir in late 2020 has still not been made public or official by the Hungarian government
- Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to Hungary's and the EU's research and IP-based biopharma industry
- Challenging enforcement environment—particularly regarding online and digital content
- Consultation mechanisms are in place, but time offered to make submissions is relatively short



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	6.75	Category 6: Commercialization of IP Assets	5.25
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.75	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	0.75	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	4.82
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.68
9. Patent opposition	1.00	33. Software piracy rates	0.64
Category 2: Copyrights, Related Rights, and Limitations	4.38	34. Civil and preceudural remedies	0.50
10. Term of protection	0.63	35. Preestablished damages	0.50
11. Exclusive rights	0.50	36. Criminal standards	0.50
12. Injunctive-type relief	0.75	37. Effective border measures	1.00
13. Cooperative action against online piracy	0.75	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.75	Category 8: Systemic Efficiency	4.00
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.75
Category 3: Trademarks, Related Rights, and Limitations	2.75	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	6.75
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.75	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.00	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.75	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 38.45			

Spotlight on the National IP Environment

Past Editions versus Current Score

Hungary’s overall score remains unchanged at 76.90% (38.45 out of 50).

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. 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.

In a separate development, in October 2020, a Hungarian manufacturer 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 was supported by the Hungarian government (the Ministry of Innovation and Technology through a consortium). As noted in previous editions of

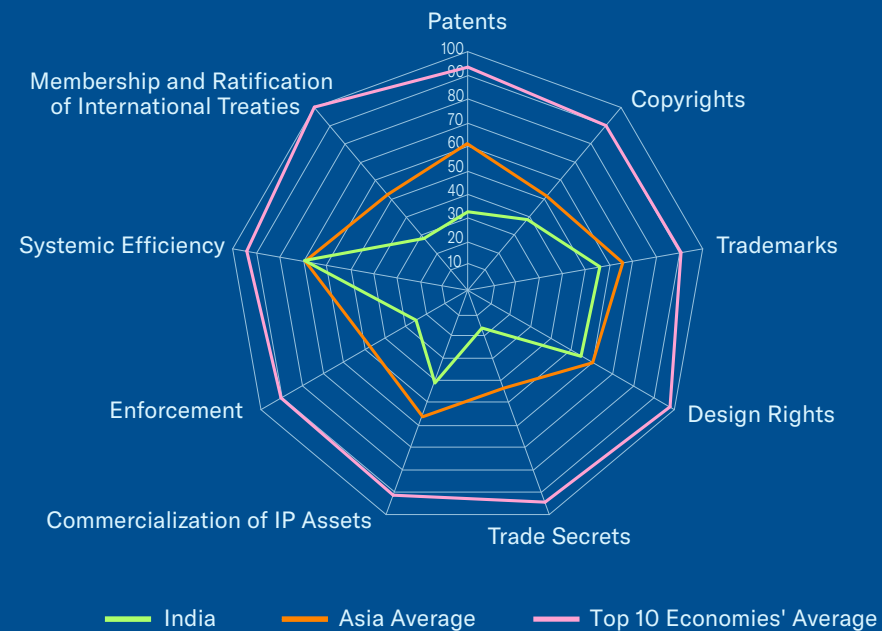
the Index, it was unclear on what legal basis this research, manufacturing, and clinical trial took place. That remains the case to date. Industry sources suggest that a compulsory license was granted by the Hungarian authorities in November 2020. As both TRIPS Article 31 and the Doha Declaration make clear, the issuing of a compulsory license represents a “measure of last resort.” It is not clear that this was the situation in Hungary in late 2020, and it is certainly not the case today.

Systemic Efficiency

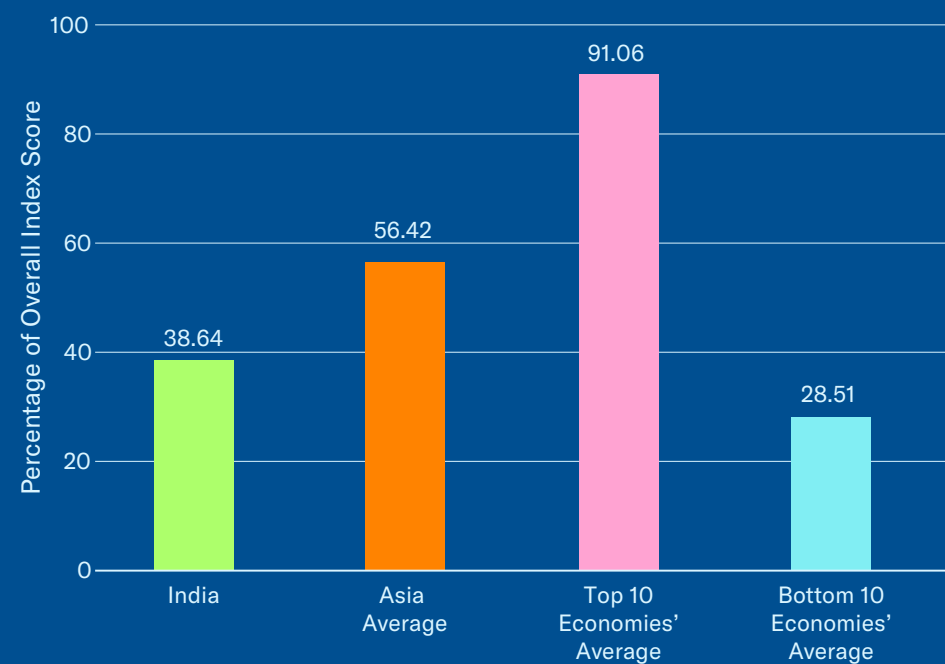
39. Coordination of IP rights enforcement: Since 2008, Hungary has had in place a National Board Against Counterfeiting established through government decision 1002/2008 and Decree No. 287/2010 (XII. 16.) The board’s members have historically included representatives from both the public and private sector, and its work was overseen by the HIPO, which acted as the secretariat and steering office. In addition to awareness raising, data collection, and training, one of the board’s main areas of activity was the cross-government coordination of IP enforcement. The board has over the years been active and involved in developing several anti-counterfeiting strategies and public outreach initiatives. In 2022, it was announced that the board would cease to operate as an independent entity and that its activities would be absorbed into the wider work of the HIPO. At the time of research, it was unclear how, or if, HIPO would continue carrying out the board’s work related to cross-government IP enforcement coordination. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Streamlined Form 27 in 2020
- Continued strong efforts in copyright piracy through the issuing of “dynamic” injunction orders
- 2019 precedent case law 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 regarding the negative impact of piracy and counterfeiting

Key Areas of Weakness

- The 2021 dissolution of the Intellectual Property Appellate Board, combined with the long-standing issue of an underresourced and overstretched judiciary, raises serious concerns about rightsholders’ ability to enforce their IP rights in India and to resolve IP-related disputes
- Carriers to licensing and technology transfer, including strict registration requirements
- Limited framework for the protection of biopharmaceutical IP rights
- Patentability requirements are outside international standards
- No RDP or patent term restoration for biopharmaceuticals is available
- Lengthy pre-grant opposition proceedings
- Previously used compulsory licensing for commercial and nonemergency situations
- Limited participation in international treaties



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	2.99	Category 6: Commercialization of IP Assets	2.50
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.00	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.75	28. Registration and disclosure requirements of licensing deals	0.00
4. Plant variety protection	0.74	29. Direct government intervention in setting licensing terms	0.25
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	1.76
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.34
9. Patent opposition	0.00	33. Software piracy rates	0.42
Category 2: Copyrights, Related Rights, and Limitations	2.72	34. Civil and preceudural remedies	0.25
10. Term of protection	0.47	35. Preestablished damages	0.25
11. Exclusive rights	0.50	36. Criminal standards	0.25
12. Injunctive-type relief	1.00	37. Effective border measures	0.25
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.00	Category 8: Systemic Efficiency	3.50
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	0.25
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	2.25	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	2.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.10	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 19.32			

Spotlight on the National IP Environment

Past Editions versus Current Score

India's overall score remains unchanged at 38.64% (19.32 out of 50).

Patents, Related Rights, and Limitations

2. Patentability requirements; and 9. Patent opposition: As has been noted in previous editions of the Index, over the past few years the Indian government has taken steps to improve its national IP environment, including in relation to the processing of patent applications in a more timely manner. In 2016, the Ministry of Commerce and Industry and the Department of Industrial Policy and Promotion released the *National Intellectual Property Rights Policy*. This document outlines the strategic direction and policy goals of the Indian government with respect to the protection of IP. As noted at the time, the Policy addressed several important gaps in India's national IP environment, including the need for strengthening administrative capacities at India's IP offices and reducing processing times for patent and trademark applications. Since then, considerable energy has been put into decreasing pendency rates for patent and trademark applications. More staff have been hired, and resources have been invested in modernizing and improving the administrative capacities of the Office of the Controller General of Patents, Designs, and Trademarks. Although these efforts have resulted in some improvement, rightsholders still face substantial delays and processing times for patent and trademark applications. Recognizing this, the Prime Minister's Economic Advisory Council (EAC-PM), issued the report *Why India Needs to Urgently Invest in its Patent Ecosystem* in the summer of 2022. The report rightly recognizes the centrality of IP rights to modern economic development: "An evolved Intellectual Property Rights regime is the basic requirement for a knowledge-based

economy. Technological innovation and scientific research require a robust patenting system. India is seeing a surge in start-ups and unicorns, and an efficient IP system is an essential prerequisite for a healthy startup ecosystem." This view echoes the sentiments expressed last year by the Parliamentary Standing Committee on Commerce in its report *Review of the Intellectual Property Rights Regime in India*. In what marks a welcome shift in Indian policymakers' views of the purpose of IP rights, both these reports acknowledge the strong link between economic activity, innovation, and the protection of IP rights and the centrality of this nexus to the Indian economy.

The EAC-PM report focuses on the administration of the IP system and long pendency times. The report rightly acknowledges that there have been improvements in decreased processing times and pendency rates, but, overall, the Office of the Controller General of Patents, Designs, and Trademarks' performance is behind other major economies. Specifically, the EAC-PM report points to the need for additional examiners, investments, and, critically, a clear delineation of processing time frames and deadlines. It is especially welcome news that the report acknowledges the detrimental impact the current opposition system has on patent processing times.

Section 25 of the Patents Act outlines the procedures and requirements for initiating opposition proceedings. The law provides for both pre- and post-grant oppositions. The procedures are similar; the key difference is that pre-grant opposition can be initiated by "any person," whereas post-grant opposition must be initiated by an interested party. The pre-grant opposition mechanism in India has long been criticized for adding significantly to the already lengthy patent prosecution timelines. In this respect, the EAC-PM report's suggestion to clearly define timelines



during patent prosecution, including for opposition proceedings, is to be commended. However, like the 2016 *National Intellectual Property Rights Policy*, the EAC-PM's report did not examine the need for more extensive legislative reform. For example, the report does not address the challenges and uncertainties rightsholders face when it comes to protecting their patent rights (particularly in the biopharmaceutical sector) or introducing international best practices and new sector-specific IP rights, such as regulatory data protection for submitted biopharmaceutical test data. Still, the EAC-PM's proposed reforms are significant and have the potential to improve India's national IP environment and lead to a score increase on the Index. The Index will continue to monitor these developments in 2023.

Copyrights, Related Rights, and Limitations

13. Cooperative action against online piracy:

In June 2022, the Ministry of Electronics and Information Technology issued a press release with new proposed amendments to the Information Technology (Intermediary Guidelines and Digital Media Ethics Code) Rules, 2021. Both the original 2021 rules and 2022 proposed amendments are aimed primarily at larger entities termed “significant social media intermediaries” and platforms. The purpose of the 2022 amendments is to clarify the rights and responsibilities of users and providers of many online services. Although not specific to copyright and the creative industries, the rules refer to IP rights and copyright specifically. Under Section 3(b), intermediaries are obliged to not only inform users of each intermediaries’ rules and conditions of use, including the illegality of any illicit activity conducted over or through the platform, such as the infringement of IP rights, but also to “ensure compliance” with those terms of use. With respect to copyright infringement specifically, it is unclear how these proposed rules would interact with the underlying legislation (the Information Technology Act), the current

Copyright Act, and existing case law. The notice-and-takedown mechanism under the 2000 Information Technology Act and subsequent 2008 amendments relate only to expeditious removal of infringing material upon notification.

In the Copyright Act, the burden on intermediaries is even less pronounced with any removal being only for an initial period of 21 days, with a court order required for any further action. Equally, existing case law on the matter has explicitly stated that no burden or requirement exists under either law for intermediaries to take proactive action against potentially illicit and IP rights–infringing activity. That was the unmistakable conclusion from the 2015 Supreme Court decision *Shreya Singal v. Union of India*. In a case primarily centering on the constitutionality of Section 66A of the Information Technology Act and its potential limitations on free speech, the court also outlined a detailed interpretation of the meaning of Section 79 of the Information Technology Act, which sets the framework for exemptions from liability of internet intermediaries, including the requirements for expeditious removal of infringing material. The court held that it was not up to the intermediary to make a judgment as to the potential infringing nature of a piece of information referred to in a notice. Rather, the court stated that this determination needed to be made through the judiciary and specifically that a court order needed to have been “passed asking it [the intermediary] to expeditiously remove or disable access to certain material.” The Index will continue to monitor these developments in 2023.

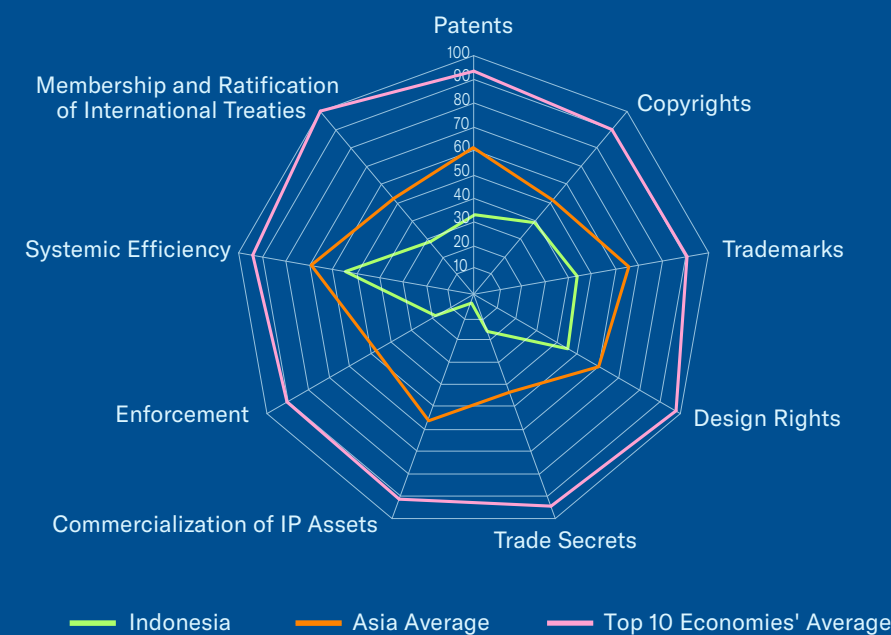
14. Scope of limitations and exceptions to

copyrights and related rights: As noted over the course of the Index, exceptions, and limitations to copyright in India are interpreted broadly and are outside of international standards as established through the Berne three-step test. The 2012 Copyright Act amendments broadened India's exceptions in a manner that seems to

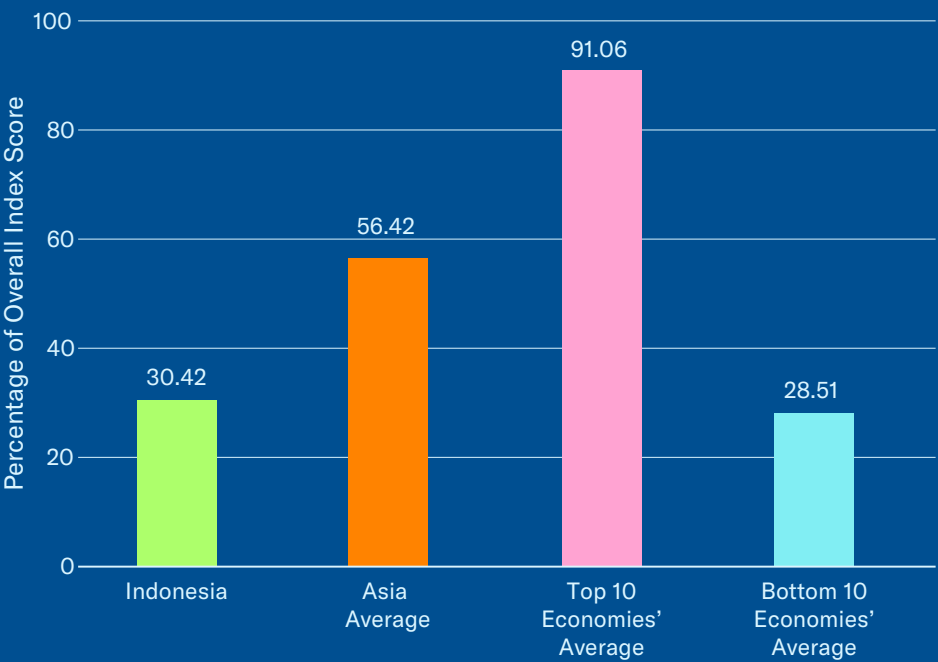
be incompatible with the Berne three-step test, specifically the expansion of the private use exception to “private and personal” use. Under the 2012 amendments to the Copyright Act, India also expanded its compulsory and statutory license regime for the use of copyrighted works. This includes under Article 31(D), which refers to the use of musical works and sound and recordings for radio and television broadcasting. As rightsholders have pointed out repeatedly since, the net effect of the expansion of copyright exceptions is to, in effect, negate the exclusive rights of copyright owners and to imperil the legitimate markets for creative works.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Omnibus Job Creation Bill modifies general technology transfer and localization requirement of 2016 Patent Act to include importation
- Continued strong efforts by Directorate General of Intellectual Property to improve enforcement environment
- 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

- Government use license issued in 2021 for patents related to COVID-19 treatment
- History of using compulsory licensing for commercial and nonemergency situations—2018/19 Regulations go beyond the stated goals and circumstances for the issuing of compulsory licenses under the TRIPS Agreement
- 2020 Presidential Regulation, Number 77, further expands compulsory licensing and emergency use provisions
- Significant barriers are in place for licensing and commercialization of IP assets, including technology transfer
- Biopharmaceutical patentability standards are outside international norms
- 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	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 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. TPM and DRM	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 and 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 and 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
Total: 15.21	

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	1.29
32. Physical counterfeiting rates	0.37
33. Software piracy rates	0.17
34. Civil and preceudural remedies	0.25
35. Preestablished 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, ct 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

Spotlight on the National IP Environment

Past Editions versus Current Score

Indonesia’s overall score remains unchanged at 30.42% (15.21 out of 50).

Patents, Related Rights, and Limitations

2. Patentability requirements: Indonesia’s patenting environment has been marred by deep uncertainty since the Indonesian Parliament passed a wide-ranging patent law in 2016 (Law 13 2016). Since then, there have been reports that both the executive and legislative branches of the Indonesian government have been working on revising the Patent Law. For example, the U.S. government reported in the 2022 *Investment Climate Statement* that fresh reform efforts are underway in 2022. In 2020, the Indonesian Parliament passed a wide-ranging legislative package, the Omnibus Job Creation Bill (*Undang-Undang Omnibus Cipta Kerja*). The bill deleted Article 20 of the 2016 Patent Act, which made the granting of a patent conditional on localizing manufacturing and/or R&D in Indonesia. As noted in last year’s edition, although unexpected, the removal of this article would have been a positive step and would help alleviate some of the uncertainty with respect to Indonesia’s patenting environment. Although the final passed version of the law did not eliminate the working requirement, Article 107(2) defined the use and “implementation” of patents in Indonesia as including domestic creation, importation, or the licensing of the relevant invention. In late 2021, the Indonesian Constitutional Court ruled that the Omnibus Bill was unconstitutional. Specifically, the court held that the way the legislation had been drafted and a lack of public participation in its development rendered it in breach of the constitution. The court order gave the government two years to remedy these flaws. It remains unclear whether the old draft legislation will be

enacted again or whether a new Omnibus Bill will be developed and passed. The Index will continue to monitor these developments in 2023.

6. Legislative criteria and use of compulsory licensing of patented products and technologies: Since the mid-2000s, the Indonesian government has issued several “government use” compulsory licenses overriding existing biopharmaceutical patents primarily for hepatitis and HIV drugs, and, most recently, for treatments related to COVID-19. The 2016 amendments to the Patent Act included changes with respect to compulsory licensing, thus expanding a regime that was already outside international standards and highly permissive. Subsequent implementing regulations and presidential decrees have further expanded the basis on which involuntary licenses can be issued.

In November 2021, the Indonesian Government issued a government use license for patents related to a COVID-19 treatment. While the license cites the urgent need to access the medicine, the treatment had already been made available through the patentee’s voluntary licensing program. As noted last year, this development further weakens what was already a highly challenging national IP environment for biopharmaceutical rightsholders. Over time, the use of compulsory licenses or similar mechanisms to override IP rights will simply hollow out the national IP environment and incentives for future biopharmaceutical innovation. The negative effect will be the same for Indonesian and foreign innovators.

Design Rights, Related Rights, and Limitations

21. Industrial design term of protection: Article 5 of the Industrial Design Law provides a 10-year term of protection for registered designs. This is notably less than the 25-year term benchmark used by the Index. Reports suggest that the



Directorate General of Intellectual Property (DGIP) and government will propose new amendments to the Design Law, and these will include an increase of the total term of protection available up to 15 years. An increase in the term of protection for registered designs will result in a score increase on this indicator. The Index will continue to monitor these developments in 2023.

Enforcement

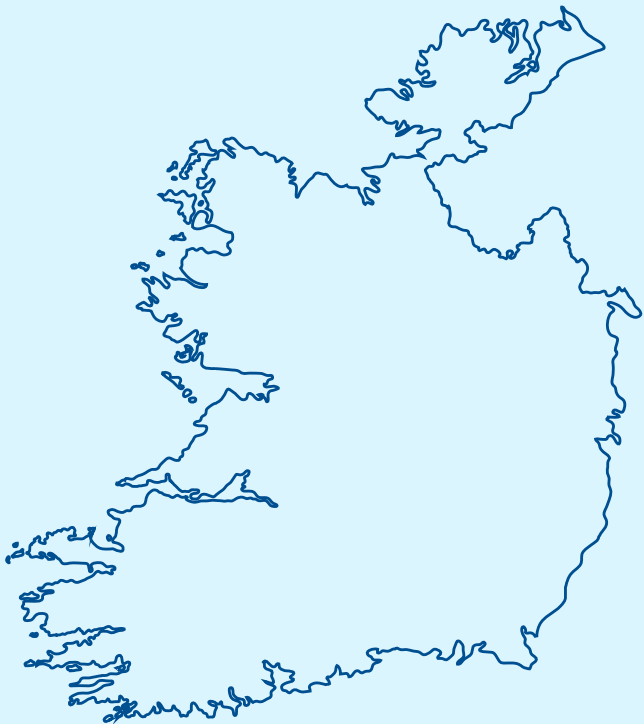
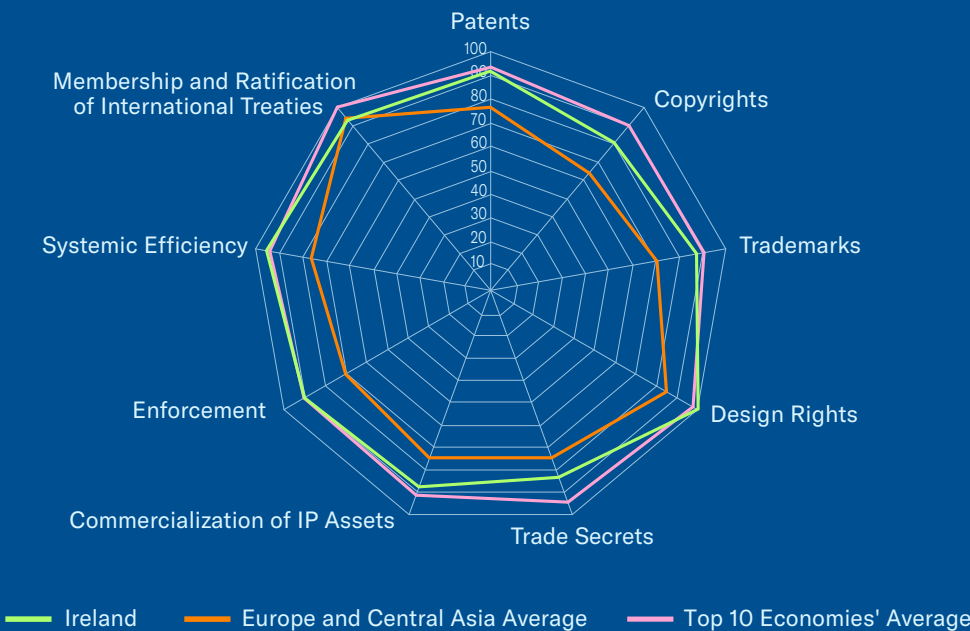
As discussed in last year’s Index, in what is otherwise a highly challenging environment for the enforcement of all major IP rights, Indonesia’s DGIP continues to work on improving the enforcement environment. In 2021, DGIP launched several new initiatives. This includes programs to increase anti-counterfeiting activity at shopping malls and to facilitate direct cooperation with international rightsholders and law enforcement, including the FBI; create a dedicated interagency taskforce tasked with coordinating enforcement leading to the removal of Indonesia from the USTR’s Priority Watch List; create a dedicated anti-copyright piracy team within the IP office; and facilitate greater transparency through the creation of a dedicated web portal with data and statistics on cross-agency IP enforcement activity, including that of customs and police.

In 2022, DGIP applied some of these new policies. Specifically, the interagency taskforce—named the Intellectual Property Operations Task Force—has been launched. Like the existing National IP Taskforce (established under Presidential Decree No. 4 of 2006) the IP Operations taskforce includes representatives from across the government. Activity has also increased with respect to the inspection of shopping malls and a program of certifying legitimate physical and online places of commerce. Local reports suggest that the government is also considering introducing a form of “landlord liability” on online platforms and intermediaries. At the time of research, no

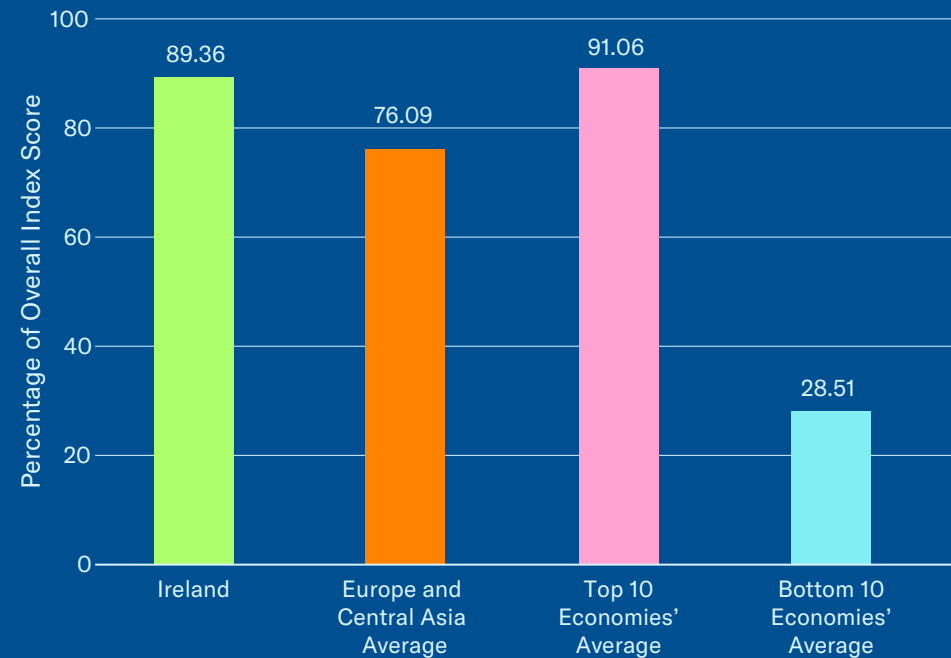
legislative changes had been made. The DGIP and its leadership team should be congratulated on these efforts. The active implementation of these new measures should lead to an improvement in the enforcement environment in Indonesia. The Index will monitor the application and success of these new initiatives in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Transposition of EU Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive)
- 2018 transposition 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 the EU's research and IP-based biopharma industry



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.84
9. Patent opposition	1.00	33. Software piracy rates	0.71
Category 2: Copyrights, Related Rights, and Limitations		34. Civil and preceudural remedies	1.00
10. Term of protection	0.63	35. Preestablished damages	1.00
11. Exclusive rights	0.75	36. Criminal standards	0.75
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.75	Category 8: Systemic Efficiency	
15. TPM and DRM	0.75	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.75	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations		41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	0.50
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.50	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00	Total: 44.68	

Spotlight on the National IP Environment

Past Editions versus Current Score

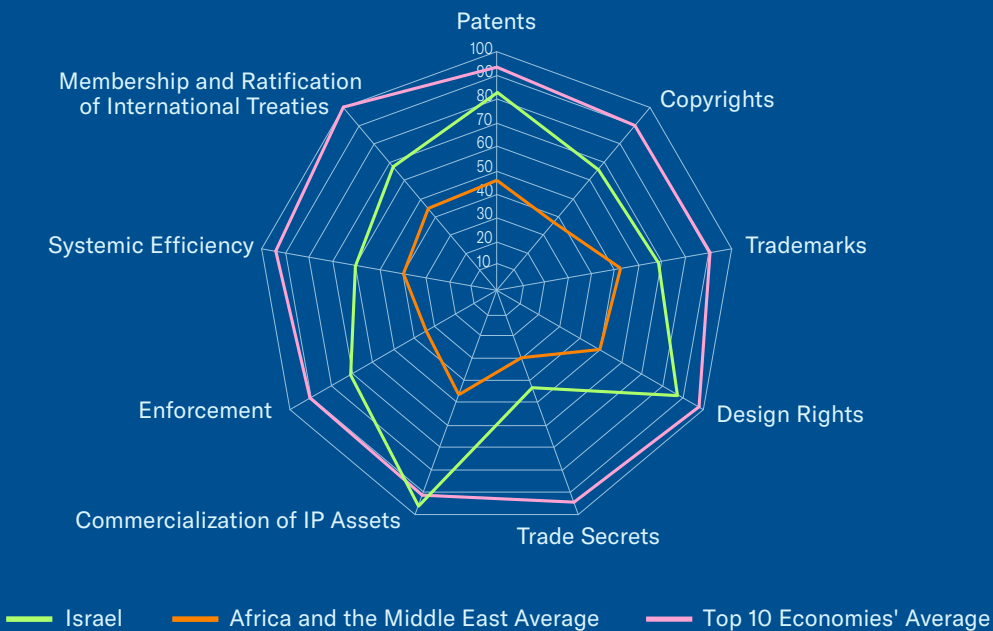
Ireland’s overall score has increased from 88.84% (44.42 out of 50) in the tenth edition to 89.36% (44.68 out of 50).

Copyrights, Related Rights, and Limitations

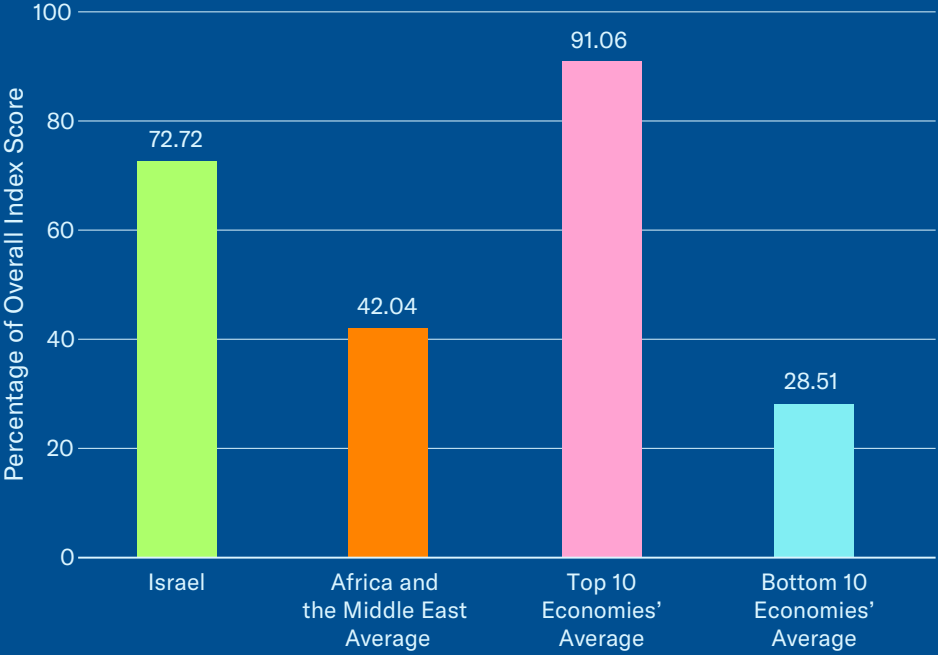
13. Availability of frameworks that promote cooperative action against online piracy: As has been detailed in previous editions of the Index, like many other EU Member States, Ireland has been in the process of transposing and implementing EU Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive) over the past three years. In late 2021, the government released “Statutory Instrument No. 567, European Union (Copyright and Related Rights in the Digital Single Market) Regulations 2021.” These regulations transpose the CDSM Directive into Irish Law. The regulations broadly follow the scope of the underlying directive, particularly with regard to responsibilities and requirements under Article 17. The regulations maintain existing exceptions and limitations provided under Irish and European copyright law and jurisprudence, and they also strengthen protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. The regulations also provide a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability. As a result of this transposition, the score on this indicator has increased by 0.25.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2019 copyright amendments strengthen enforcement against online infringement and introduce possibility of injunctive-style relief
- Global leader on 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 is an 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

- 2021 proposed amendments to Patent Law introducing a manufacturing, export, and stockpiling exemption to the current patent term restoration regime
- 2020 issuing of compulsory license 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 biologics



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	7.50	Category 6: Commercialization of IP Assets	5.75
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	4.93
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.70
9. Patent opposition	0.00	33. Software piracy rates	0.73
Category 2: Copyrights, Related Rights, and Limitations	4.63	34. Civil and preceudural remedies	0.75
10. Term of protection	0.63	35. Preestablished damages	0.75
11. Exclusive rights	0.75	36. Criminal standards	0.75
12. Injunctive-type relief	0.75	37. Effective border measures	0.75
13. Cooperative action against online piracy	0.50	38. Transparency and public reporting by customs	0.50
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	3.00
15. TPM and DRM	0.00	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	2.75	41. Educational campaigns and awareness raising	0.25
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.75	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	4.75
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	0.50
Category 4: Design Rights, Related Rights, and Limitations	1.75	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.30	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.00	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.30		
Total: 36.36			

Spotlight on the National IP Environment

Past Editions versus Current Score

Israel's overall score has decreased from 72.74% (36.37 out of 50) in the tenth edition to 72.72% (36.36 out of 50). This reflects a score decrease on indicator 32.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: Up until 2014, Israel did not offer patent restoration for pharmaceutical products. In 2014, following long discussions with the USTR regarding Israel's Special 301 status and the development of a memorandum of understanding with the U.S. government, the Israeli Knesset amended the Patent Law, introducing a five-year maximum term of restoration. In 2021, the Israeli Ministry of Justice published draft amendments to the Patent Law, "The Patents Law (Amendment No. 14) (Increasing the Competitiveness of the Israeli Economy), 5721-2021." The proposed amendments seek to introduce a manufacturing, export, and stockpiling exemption to the current term restoration regime. The law refers to and is explicitly modeled on a similar carve-out introduced by the European Commission through Regulation 2019/933, which has been operational in the EU since 2019. In the Israeli 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. This is a highly negative development and comes on the heels of the Israeli government's 2020 authorization of a compulsory license for the antiviral drug lopinavir/ritonavir. As noted in previous editions of the Index, when the license was issued, limited clinical evidence showed that lopinavir/ritonavir would be an effective treatment against COVID-19 or that the use of such an extreme measure would be justified.

After the issuing of the license and importation of generic product from India, no publicly available information suggests that the generic product was ever distributed to Israeli patients with COVID-19.

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 the 2010 memorandum of understanding with the U.S. government, Israel made significant improvements in key areas of biopharmaceutical IP protection, including in relation to regulatory data protection, patent term restoration, and legal remedies for infringement. 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. As importantly, the IP reforms have not had a negative impact on the domestic generics industry. Contrary to common perceptions and received 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. The introduction of a manufacturing and export exemption to the existing patent term restoration regime would be a significant setback. Beginning in the eighth edition of the 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 to the current baseline rate of five years' term restoration used in the United States, the 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. At the time of research, the proposed Israeli Patent Law amendments had not been passed into law. Should these legislative changes take place, Israel's score on this indicator will be reduced from 1 to 0.75.

9. Patent opposition: Israeli patent law provides for a pre-grant form of opposition to pending patent applications. The examination of a patent application's eligibility for registration is conducted by the Israeli Patent Office within a time frame of 18 months from the filing date, upon which the application is published online for public scrutiny. Once published, a period of three months is granted, during which third parties are permitted to file an opposition to the patent application. Upon filing of a notification of opposition, a period of 13 months is granted to the opposing party to submit the causes, arguments, and supporting evidence for the opposition, and for responses by both parties. Thus, the examination of a patent application can be extended by an additional 16 months, not including the process of reexamination 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. Recognizing these deficiencies, in late 2016, the Ministry of Justice and the Patent Office published a public call

for comments and suggestions regarding their intention to review the existing pre-grant system and to curtail these generous timelines. This was followed up in 2021 with a new public consultation and proposed regulatory amendments. Although not in final draft regulatory form, overall, these amendments recognized the excessive time taken in Israeli patent opposition proceedings and the need for clearer procedural demarcations and limits on the length of these proceedings. In 2022, the Patent Office hosted a follow-up roundtable discussion with relevant stakeholders. At the time of research, no finalized regulations had been published or further legislative action had been taken. As the Index has stated in the past, reducing the length of opposition proceedings in Israel would be a positive development and would mark a potential shift and recognition by Israeli policymakers of the costs the pre-grant system imposes on inventors and Israeli consumers. Instituting such changes would result in a score increase on this indicator. The Index will continue to monitor these developments in 2023.

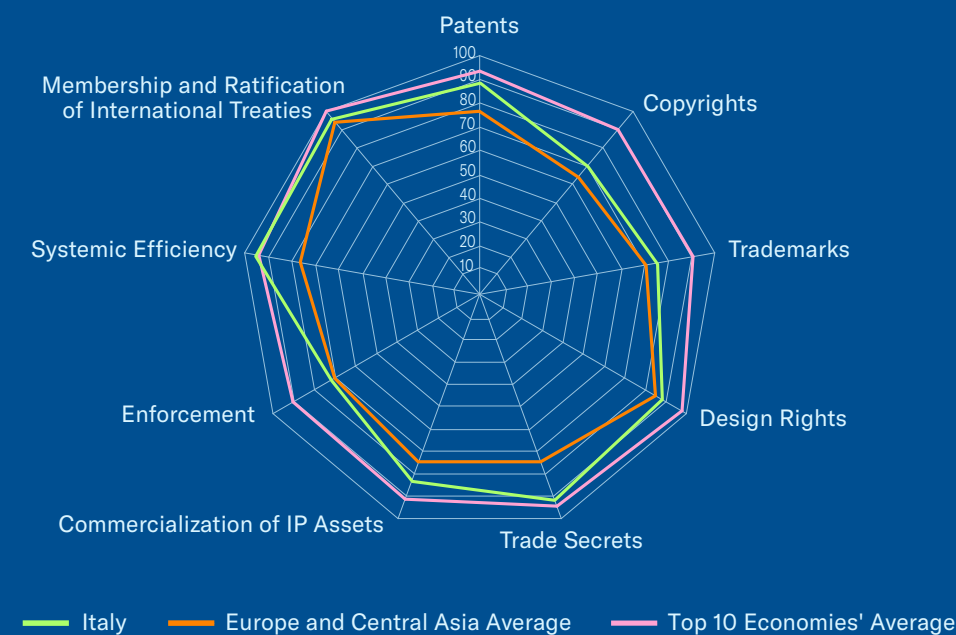
Membership and Ratification of International Treaties

Being a contracting party to key international IP treaties reflects a given economy's broader participation in the international IP community and embracing of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adheres to established standards and best practices. Israel's score in this category of the Index has increased from a score of 1, or 25%, in the fourth edition of the Index (the first year Israel was included) to now achieving a score of 4.75, or 67.86%, of the total available score. Although higher than some other high-income economies, such as New Zealand and the UAE, Israel's score is notably lower than many OECD economies. Virtually all EU Member States, Japan, the United States, and Canada achieve a score of 90% or more on this category.

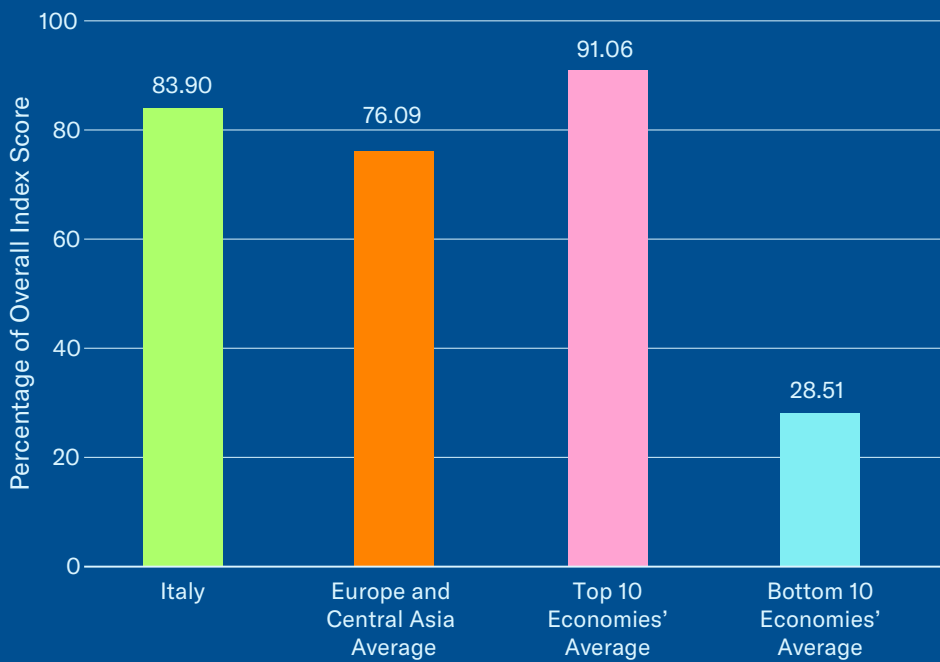
Overall, Israel is a contracting party and has acceded to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Patent Cooperation Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; the Convention on Cybercrime, 2001; and the Hague Agreement Concerning the International Registration of Industrial Designs. Israel is a signatory to, but has not ratified, the WIPO Internet Treaties or the Patent Law Treaty. Israel is not a contracting party to the Singapore Treaty on the Law of Trademarks. Israel is a contracting party to several post-TRIPS bi and plurilateral FTAs. This includes full FTAs and economic partnership agreements with Ukraine, Colombia, the EU, the UK, and Canada. Although some of these agreements include dedicated IP chapters—for instance, in 2018, a new IP chapter was added to the Canada-Israel FTA—they do not conform to the modern IP standards of other post-TRIPS international trade agreements. In May 2022, the government of Israel and UAE announced an economic partnership agreement. This follows the historic Abraham Accords Peace Agreement of 2020, which established diplomatic relations between Israel and the UAE. Public announcements by the Israeli Ministry of Economy and Industry suggest that this economic partnership agreement will include a dedicated section on IP rights. At the time of research, a finalized version of the agreement had not been published and made available to the public.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Transposition of EU Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive)
- Generous R&D and IP-specific tax incentives in place
- 2020 data protection law will potentially impose new localization requirements
- 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 the EU's research and IP-based biopharma industry



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.00	Category 6: Commercialization of IP Assets	5.00
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.75	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	5.04
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.72
9. Patent opposition	1.00	33. Software piracy rates	0.57
Category 2: Copyrights, Related Rights, and Limitations	4.91	34. Civil and preceudural remedies	0.75
10. Term of protection	0.66	35. Preestablished damages	0.50
11. Exclusive rights	0.50	36. Criminal standards	0.50
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	4.75
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.75	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.00	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	0.75	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	6.75
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.75	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.75	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.75	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 41.95			

Spotlight on the National IP Environment

Past Editions versus Current Score

Italy’s overall score has increased from 83.40% (41.70 out of 50) in the tenth edition to 83.90% (41.95 out of 50). This reflects a score increase on indicator 13.

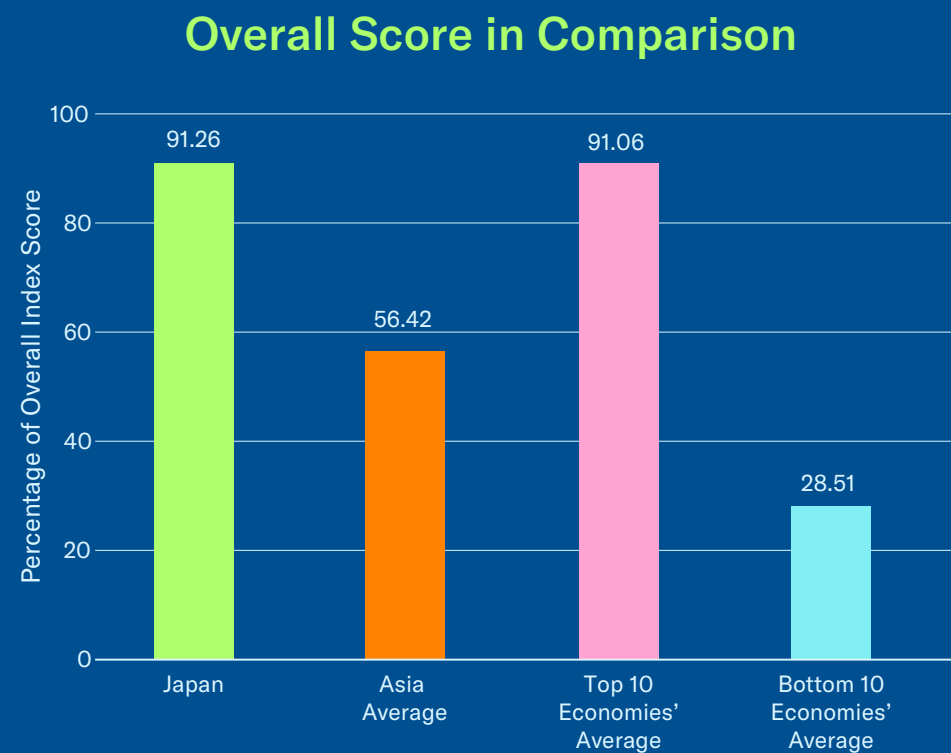
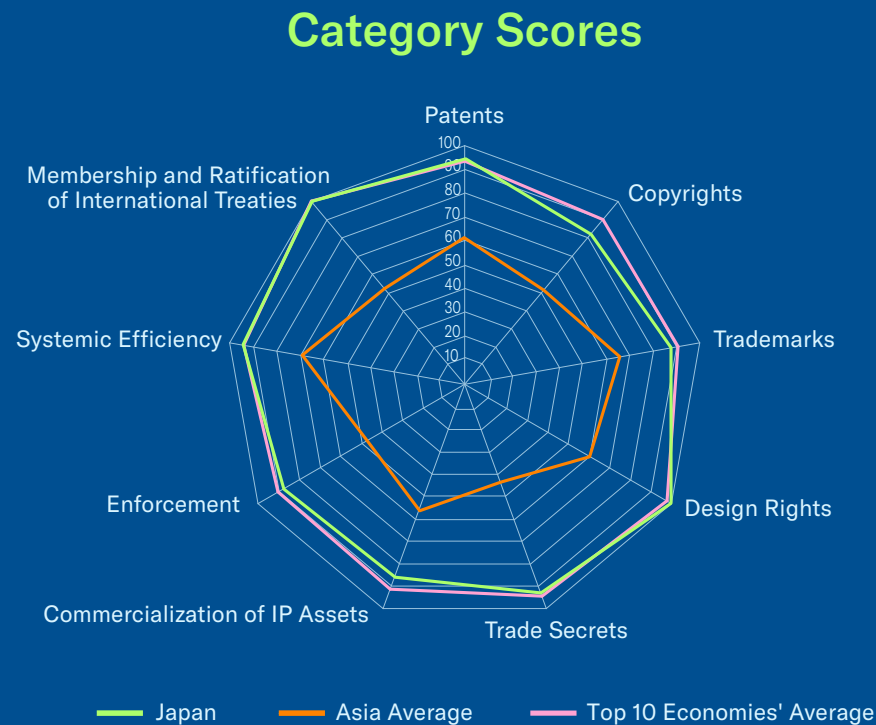
Area of Note

As part of its national response to the launch of the European Commission’s “Action Plan on Intellectual Property,” the Italian government is reforming parts of its national IP system. In 2021, the Minister of Economic Development, Giancarlo Giorgetti, signed a legislative decree formally adopting a new “Strategic Plan on Industrial Property” for 2021-23. Part of this plan includes legislative changes to the Industrial Property Code. Specifically, the Italian Senate considered proposed amendments under Bill 2631 that would promote greater digitization and simplification of the Italian Patent and Trademark Office’s work and would also seek to incentivize the transfer and commercialization of new technologies from public institutions. At the time of research, the draft legislation had not been passed into law. The Index will continue to monitor these developments in 2023.

Copyrights, Related Rights, and Limitations

13. Availability of frameworks that promote cooperative action against online piracy: Like many other EU Member States, Italy has for the past three years been in the process of transposing and implementing EU Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). In 2020, the Italian Senate (European Affairs Chamber) approved a draft version of the law and transmitted it back to the government with comments. This was followed up in 2021 with the promulgation of Law 53, 2021 (*Legge di delegazione europea 2019-*

2020) delegating power to the government to issue implementing legislation for relevant EU laws (including the CDSM). Additionally, in late November 2021, the government published a legislative decree giving effect to these legislative changes with relevant amendments to Italian copyright law. The November 2021 decree broadly follows the scope of the underlying EU Directive, particularly with regard to responsibilities and requirements under Article 17. The decree maintains existing exceptions and limitations provided under Italian and European copyright law and jurisprudence, and it also strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. The decree also provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability. As a result of this transposition, the score on this indicator has increased by 0.25.



Key Areas of Strength

- Continued strong copyright enforcement efforts
- 2020 amendments to Copyright Act continue to strengthen copyright environment
- Design Act amendments came into effect in 2020, increasing term of protection
- 2019 copyright amendments 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
- Japan has signed and acceded to all international IP treaties included in the Index
- 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 in place, such as a patent box regime
- Remedies against online copyright infringement remain underdeveloped compared to other OECD economies



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.50	Category 6: Commercialization of IP Assets	5.17
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	6.17
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.83
9. Patent opposition	1.00	33. Software piracy rates	0.84
Category 2: Copyrights, Related Rights, and Limitations	5.74	34. Civil and preceudural remedies	0.75
10. Term of protection	0.74	35. Preestablished damages	0.75
11. Exclusive rights	1.00	36. Criminal standards	1.00
12. Injunctive-type relief	0.50	37. Effective border measures	1.00
13. Cooperative action against online piracy	0.50	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	4.75
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.50	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	2.00	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.80	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	1.00	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.80		
Total: 45.63			

Spotlight on the National IP Environment

Past Editions versus Current Score

Japan’s overall score remains unchanged at 91.26% (45.63 out of 50).

Commercialization of IP Assets and Market Access

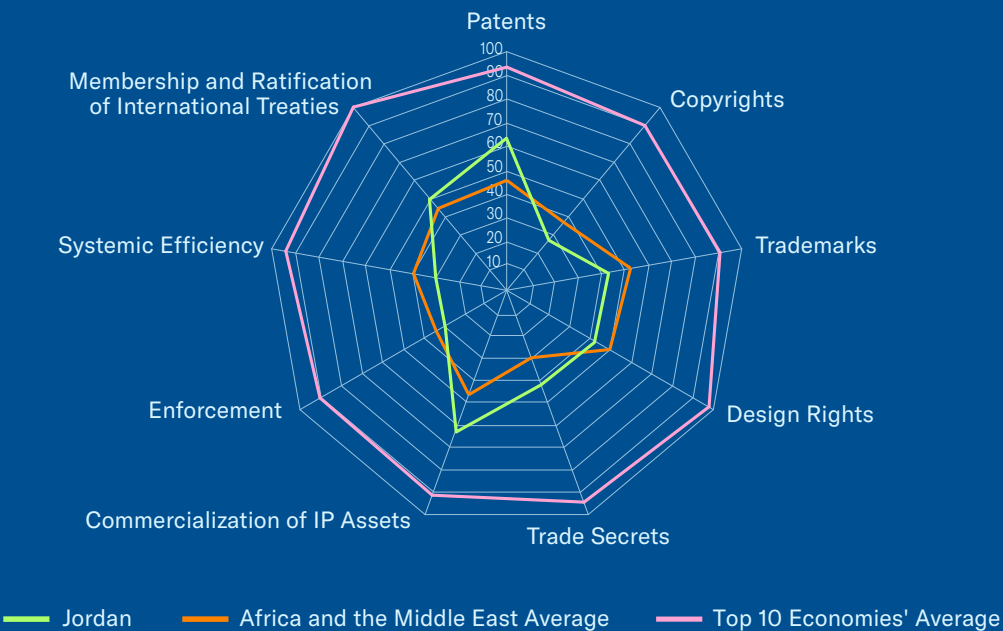
28. Direct government intervention in setting licensing terms: As discussed in previous editions of the Index, an area of growing interest to Japanese industrial and competition policy has been the centrality of Standard and Essential Patents (SEPs) to future innovation and economic growth. In 2018, the Japanese Patent Office (JPO) released the document *Guide to Licensing Negotiations Involving Standard Essential Patents*, and the Japanese government’s work in this field continued in 2021 and 2022. In early 2021, the Ministry of Economy, Trade, and Industry (METI)’s Competition Enhancement Office and the Intellectual Property Policy Office convened a “Study Group on Licensing Environment of Standard Essential Patents” consisting of external experts and industry representatives for a series of meetings. Later in the year, the group published the results of these discussions in an interim report. This work continued in 2022 with the publication of two new documents—a new and updated *Guide to Licensing Negotiations Involving Standard Essential Patents* produced by the JPO and a new stand-alone document titled *Good Faith Negotiation Guidelines for Standard Essential Patent Licenses* produced by METI. Both publications were released after a lengthy public consultation process with domestic and foreign stakeholders. Like the preceding work by METI and the JPO, both documents rightly point out the growing importance of SEPs to future economic activity, both globally and in Japan. Although neither document claims to have any legal weight or standing, unlike the JPO’s *Guide*, METI expects parties in Japan to make use of its *Good Faith Negotiation Guidelines*. The document explicitly states that:

The Guidelines are the norms of good faith negotiations provided by the Japanese government to be followed by SEP holders and implementers involved in SEP licensing negotiations, including Japanese patents, to realize an appropriate licensing environment through improvement of transparency and predictability of the negotiations. The Guidelines are not legally binding and do not guarantee that, even if followed, negotiations can be judged to be in good faith in each individual case as there are no clear global rules for SEP licensing negotiations. However, METI expects that various parties related to SEP licensing negotiations, such as those in the negotiations and the judiciary, utilize the Guidelines, because METI established the Guidelines considering opinions of domestic and foreign companies, etc., industries and experts on intellectual property and competition law in Japan.

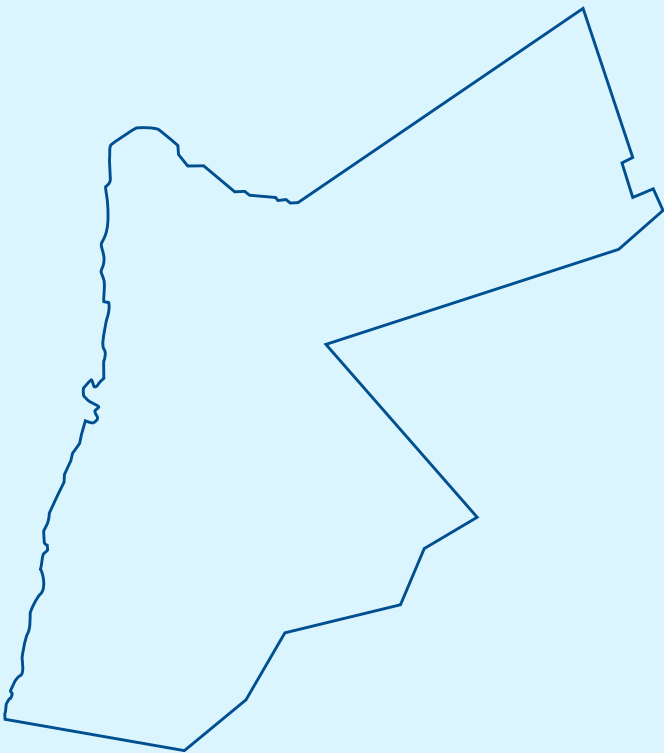
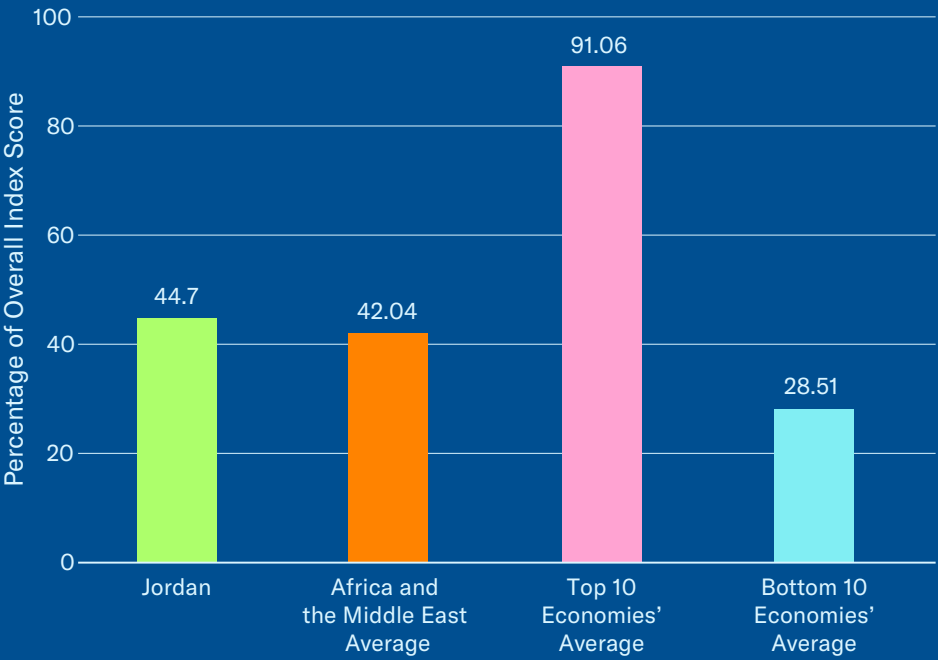
As the Index noted in 2018, in connection with the JPO’s publication of the first edition of the *Guide to Licensing Negotiations Involving Standard Essential Patents*, METI and the JPO should be commended for rightly identifying the importance of SEPs to future economic activity, global growth, and innovation. However, this is an evolving field of IP policy and jurisprudence for a subject matter that is deeply complex. The introduction of any type of direct government intervention and management of the SEP negotiating process would be highly damaging and would undermine the central tenet of both the JPO’s and METI’s analysis: that each individual SEP licensing negotiation is shaped by a unique set of facts and legal and commercial circumstances. As such, it is critical that policymakers, whether in Japan or elsewhere, tread carefully and refrain from being overly prescriptive or restrictive. It is clear that there are real challenges to the SEP licensing process and that it is likely these challenges will only intensify in the years to come. The right solutions are less clear. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



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

- To R&D or IP-specific tax incentives in place
- To 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 CILs



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	5.75	Category 6: Commercialization of IP Assets	3.75
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.25	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	1.00	30. IP as an economic asset	0.25
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	2.06
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.36
9. Patent opposition	0.00	33. Software piracy rates	0.45
Category 2: Copyrights, Related Rights, and Limitations	1.94	34. Civil and preceudural remedies	0.25
10. Term of protection	0.44	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	1.50
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.25
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.25
Category 3: Trademarks, Related Rights, and Limitations	1.75	41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	3.50
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.85	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.25	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
Total: 22.35			

Spotlight on the National IP Environment

Past Editions versus Current Score

Jordan’s overall score remains unchanged at 44.70% (22.35 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; and 13. Availability of frameworks that promote cooperative action against online piracy: The Jordanian Copyright Act provides basic exclusive rights. Articles 8 and 9 define rightsholders’ exclusive rights and rights to exploit their creative work. The law does not include specific reference to the internet or mechanisms that address online infringement. No notice-and-takedown system is in place. No established mechanism exists for gaining injunctive-style relief within the context of copyright infringement. This makes online infringement difficult for rightsholders to effectively counter. As part of the 2001 U.S.-Jordan FTA, Jordan introduced relevant DRM and TPM legislation. Article 55 of the Copyright Act clearly outlaws the use, sale, manufacture, and distribution of circumvention devices. But, as in many other economies in the Middle East, the scale of both physical and online copyright infringement is substantial. A 2015 article on media piracy in Jordan published in the *International Journal of Engineering Science* included two separate surveys of internet users. Although the sample size was relatively small (less than 200 respondents), both surveys found a high number of Jordanian internet users engaged in some sort of infringing activity, including the downloading of pirated music, film, and software. Of those respondents who spent the most time on the internet per day (estimated at four hours or more), close to 70% said

they engaged in some form of infringing activity. Similarly, looking at software piracy, the latest BSA estimates suggest that 55% of software in Jordan is pirated; only marginally down from 2011’s 58%. As in many other parts of the world, the infringement of copyrighted content through set-top boxes and illicit streaming devices is also becoming more widespread in the wider Middle East and Jordan. The USTR in the 2021 *Review of Notorious Markets for Counterfeiting and Piracy* included reference to a Jordanian entity “Spider,” which sells pirate set-top-boxes and streaming devices. As the Jordanian government continues to improve the quality of the Kingdom’s digital infrastructure—including the rolling out of 5G telecommunications services beginning in 2022—more Jordanians will be able to access and use internet services. But without more effective legal remedies and enforcement measures, copyright infringement is also likely to keep growing. The Index will continue to monitor these developments in 2023.

Membership and Ratification of International Treaties

Being a contracting party to key international IP treaties reflects a given economy’s broader participation in the international IP community and embracing of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adheres to established standards and best practices. Jordan’s overall score in this category has increased, rising from a score of 2 in the sixth edition of the Index (the first year Jordan was included) to now achieving a score of 3.5. As a proportion of the available score for this category, Jordan’s performance has stayed the same at 50% of the available score. Although this is higher than many of the other Index economies from the Middle East and North Africa (MENA)

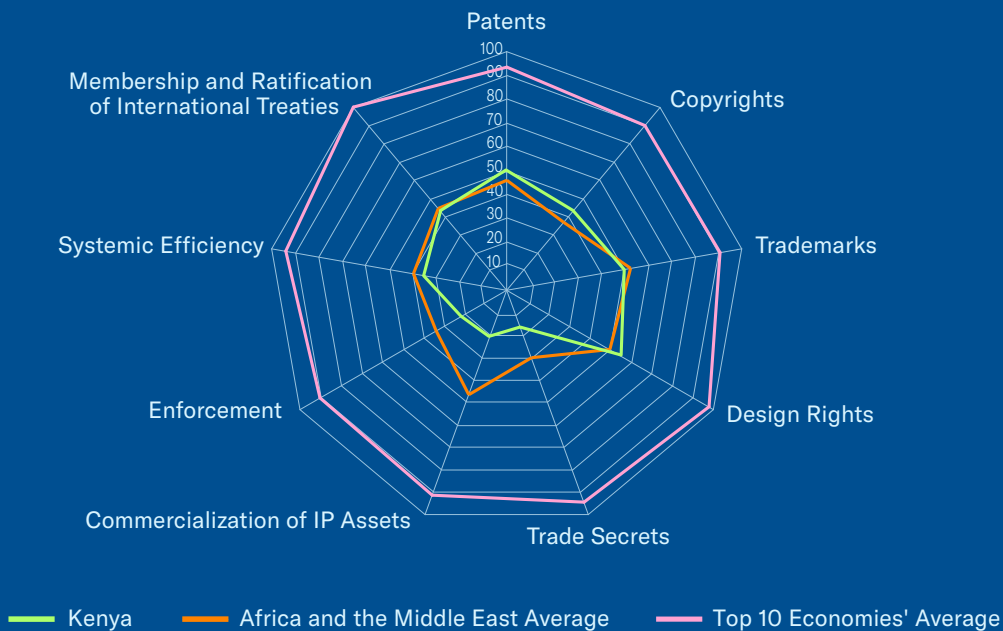


region—including Algeria and Saudi Arabia, which both score below 50% on this category—many other middle-income economies sampled in the Index achieve notably higher scores. This includes both Morocco and Ghana, which achieve a score of over 75% on this category.

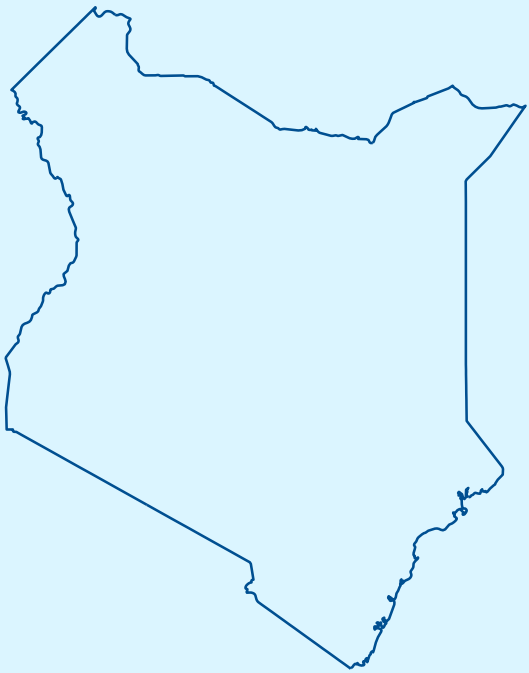
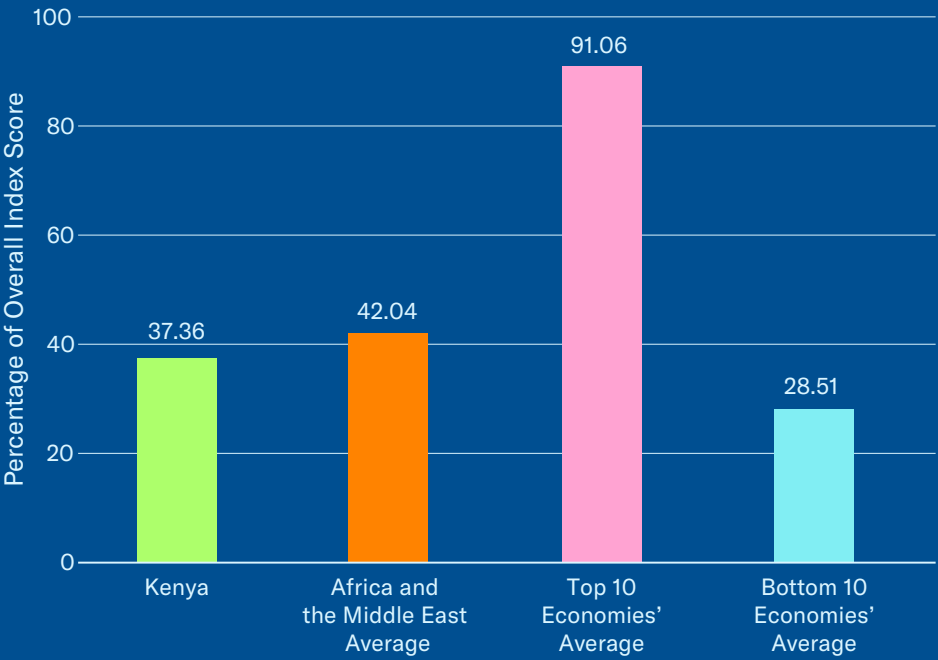
Jordan is a contracting party to the WIPO Internet Treaties; the Patent Cooperation Treaty; and the International Convention for the Protection of New Varieties of Plants, Act of 1991. Jordan is not a contracting party to the Singapore Treaty on the Law on Trademarks; the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Patent Law Treaty; the Convention on Cybercrime; or the Hague Agreement Concerning the International Registration of Industrial Designs. The 2001 U.S.-Jordan FTA contains a separate and distinct IP chapter. Over the past 21 years, this agreement has greatly strengthened the national IP environment in Jordan and contributed to the growth and development of the Jordanian economy.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2021 Anti-Counterfeit Amendment Regulations allow rightsholders to register their rights with the Anti-Counterfeit Authority
- 2020 Anti-Counterfeit Act amendments strengthen enforcement powers
- 2019 copyright amendments strengthen protection of copyright in Kenya
- Basic IP framework in place, including several sector-specific rights
- Dedicated IP bodies and enforcement agencies
- Decent efforts to improve knowledge and frameworks for proper use and commercialization of IP assets

Key Areas of Weakness

- Data Protection (General) Regulations 2021 do not provide clarity on potential data localization requirements under the 2019 Data Protection Act
- Draft IP Bill 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	4.50	Category 6: Commercialization of IP Assets	1.25
1. Term of protection	1.00	26. Barriers to market access	0.50
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.25
3. Patentability of CIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	1.55
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.29
9. Patent opposition	0.75	33. Software piracy rates	0.26
Category 2: Copyrights, Related Rights, and Limitations	3.03	34. Civil and preceudural remedies	0.25
10. Term of protection	0.53	35. Preestablished damages	0.00
11. Exclusive rights	0.50	36. Criminal standards	0.25
12. Injunctive-type relief	0.25	37. Effective border measures	0.25
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.25
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	1.75
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.25
Category 3: Trademarks, Related Rights, and Limitations	2.00	41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	3.00
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	0.50
Category 4: Design Rights, Related Rights, and Limitations	1.10	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 18.68			

Spotlight on the National IP Environment

Past Editions versus Current Score

Kenya’s overall score has decreased from 37.38% (18.69 out of 50) in the tenth edition to 37.36% (18.68 out of 50). This reflects a score decrease on indicator 32.

Copyrights, Related Rights, and Limitations

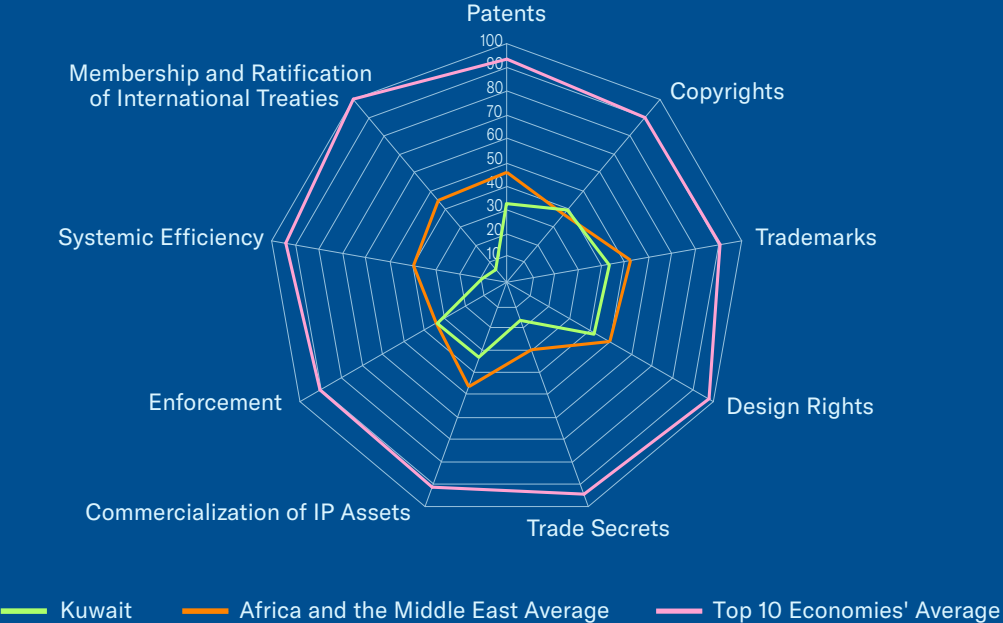
11. Legal measures that provide necessary exclusive rights preventing infringement of copyrights and related rights (including web hosting, streaming, and linking; 12. Expeditious injunctive-style relief and disabling of infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy: The Copyright Act has historically provided for only basic exclusive rights to redress copyright infringement, with limited reference to the digital and/or online sphere. As detailed in previous editions of the Index, this changed in 2019 with the passing and signing into law of the Copyright (Amendment) Act. These amendments introduced new copyright enforcement mechanisms, including clear definitions of ISP and service providers’ liability, as well as an injunctive-style relief mechanism. Under the law, ISPs should not in any way modify or promote infringing material nor should they have actual knowledge of its existence. The law also requires ISPs upon receipt of a takedown notice to notify the infringers and to remove or limit access to copyright-infringing material within 48 hours from receiving a notification. Criminal penalties—fines of up to KES500,000 (about USD5,000) and/or imprisonment for up to five years—apply to intermediaries who fail to take down infringing content. Service providers are also liable for any losses or damages resulting from noncompliance. Copyright holders are also able to apply to the High Court for an interim relief when they have reasonable grounds to believe their rights are being infringed in or outside

Kenya. Such relief may include orders requiring an ISP to cease enabling, facilitating, hosting, or making available the infringing content. The orders may also require the ISP to disable the infringer’s access to its services. In addition to these changes, the Amendment Act also extended copyright protection to computer programs and criminalized the circumvention of technical protection measures or the manufacture of devices to circumvent technical protections. As a result of this positive action, the scores on indicators 11, 12, and 13 increased in the eighth edition of the Index.

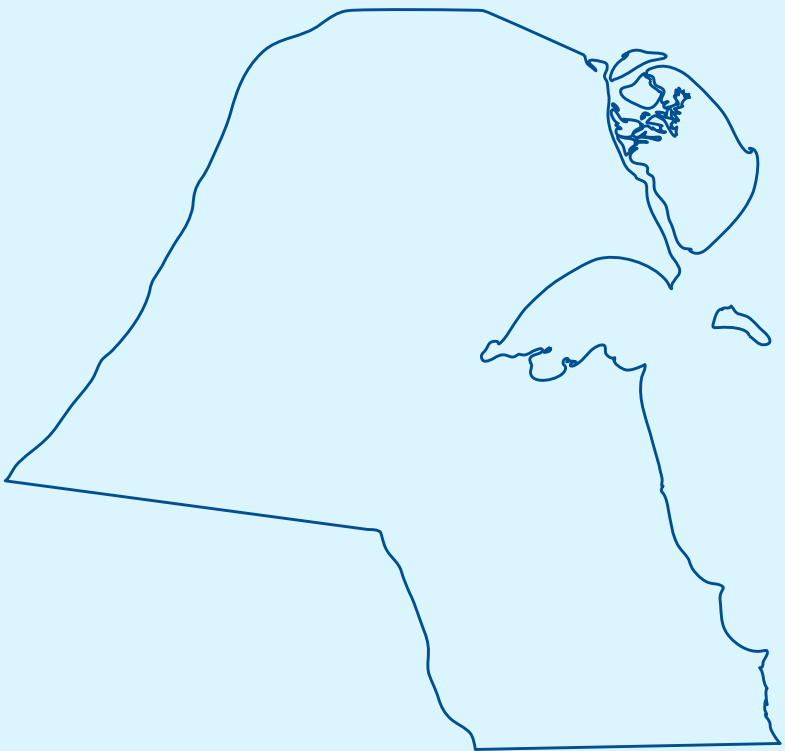
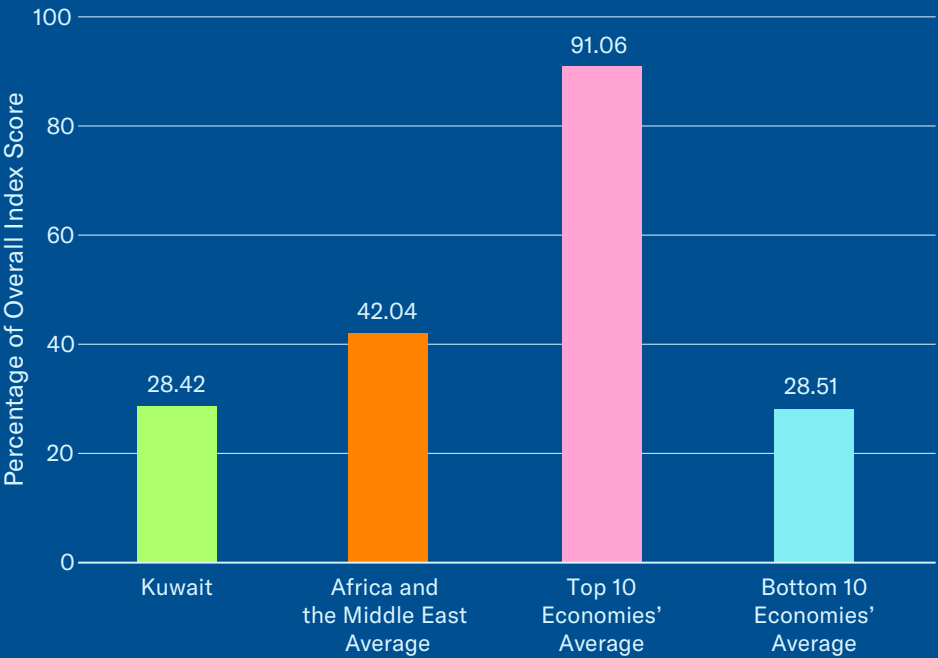
In late 2021 a fresh set of legislative changes—the Copyright Amendment Bill 2021—was presented in the National Assembly. Although the primary aim of these amendments was, first, the creation of a “National Rights Registry” for the public registration of copyrighted works and, second, the creation of a revenue-sharing formula between creators of “ring back tunes” and users, the bill would also roll back much of the positive changes introduced in 2019. Specifically, the proposed bill would repeal the existing provisions related to an ISP’s potential secondary liability and notice-and-takedown mechanism as well as rightsholders’ ability to obtain injunctive relief. At the time of research, the final version of the bill signed into law in April 2022 (the Copyright (Amendment) Act, 2022) had left these sections untouched. As noted over the course of the Index, rightsholders in Kenya have long struggled with high and persistent levels of copyright piracy with the high availability of physical and digital pirated music, film, and other copyrighted content. The repeal of an ISP’s potential secondary liability, the existing notice-and-takedown mechanism, and rightsholders’ ability to obtain injunctive relief would have significantly weakened what is already a difficult copyright enforcement environment in Kenya and would have resulted in score decreases on related indicators. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- New administrative copyright enforcement option available in 2022 through National Library
- Basic IP framework in place
- Participant in regional patent and trademark harmonization efforts through GCC

Key Areas of Weakness

- Uncertainty over future of GCC patent and how/whether regional patenting route will continue to exist
- Most sector-specific rights are missing
- Barriers in place for licensing and technology transfer
- No R&D or IP-specific tax incentives in place
- To targeted incentives for the creation and use of IP assets for SMEs
- Limited participant in international treaties



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	3.00	Category 6: Commercialization of IP Assets	2.00
1. Term of protection	1.00	26. Barriers to market access	0.00
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	0.00	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	2.33
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.40
9. Patent opposition	0.25	33. Software piracy rates	0.43
Category 2: Copyrights, Related Rights, and Limitations	2.78	34. Civil and preceudural remedies	0.25
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.50	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.25
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	0.50
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.00
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.25
Category 3: Trademarks, Related Rights, and Limitations	1.75	41. Educational campaigns and awareness raising	0.25
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.00
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	0.50
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	0.00
Category 4: Design Rights, Related Rights, and Limitations	0.85	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 14.21			

Spotlight on the National IP Environment

Past Editions versus Current Score

Kuwait's overall score has increased from 27.92% (13.96 out of 50) in the tenth edition to 28.42% (14.21 out of 50). This reflects a score increase on indicator 12.

Area of Note

In January 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 accept patent applications. The announcement was unexpected because the GCC patent application route had been operational for more than two decades. This was followed up with an announcement by the GCC Secretariat in April 2021. Under this announcement, new amendments to the GCC Patent Regulation were issued whereby a new regional application pathway would replace the old regulation. Under this system, the regional GCC patent was abolished. Instead, future patent applications will be routed through individual GCC member states. Once granted by the GCC Patent Office, relevant patents will be valid only in the underlying national jurisdiction. This system was formalized in late 2021 with the issuing of new Implementing Regulations. The Index will continue to monitor these developments in 2023.

In 2016, the Kuwaiti Patent Office stopped accepting national patent applications. This followed the implementation of Law No. 71 2013 through Implementing Regulations 115/2016. The two pieces of legislation in effect repealed the old patent law and replaced it with the patent regime in place under the GCC. With the changes to the GCC Patent Office, news reports suggest that the Kuwaiti Patent Office (under the Trademark Control Department, Ministry of Commerce) has resumed operations and is

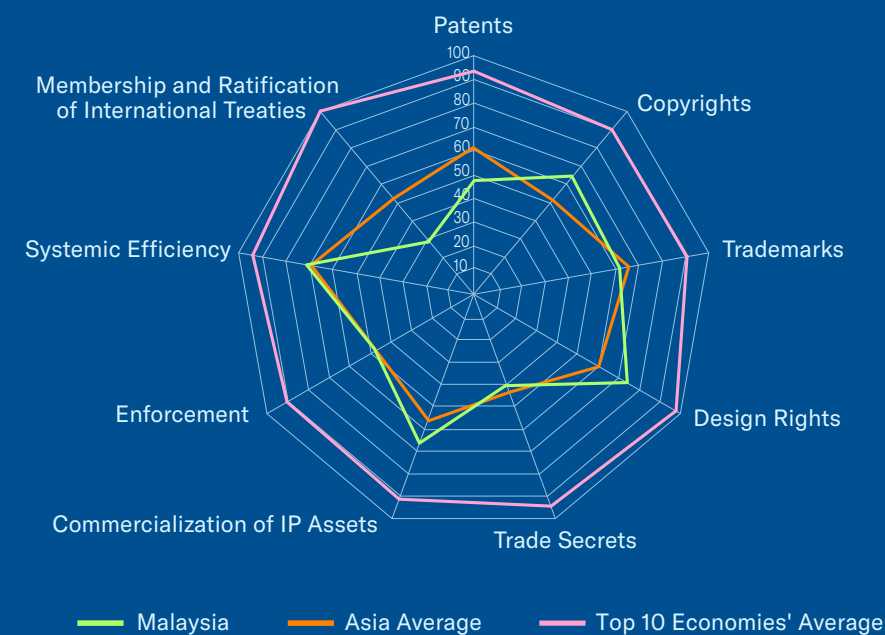
processing new applications, and several patents were granted in 2021 and 2022. The Index will continue to monitor these developments in 2023.

Copyrights, Related Rights, and Limitations

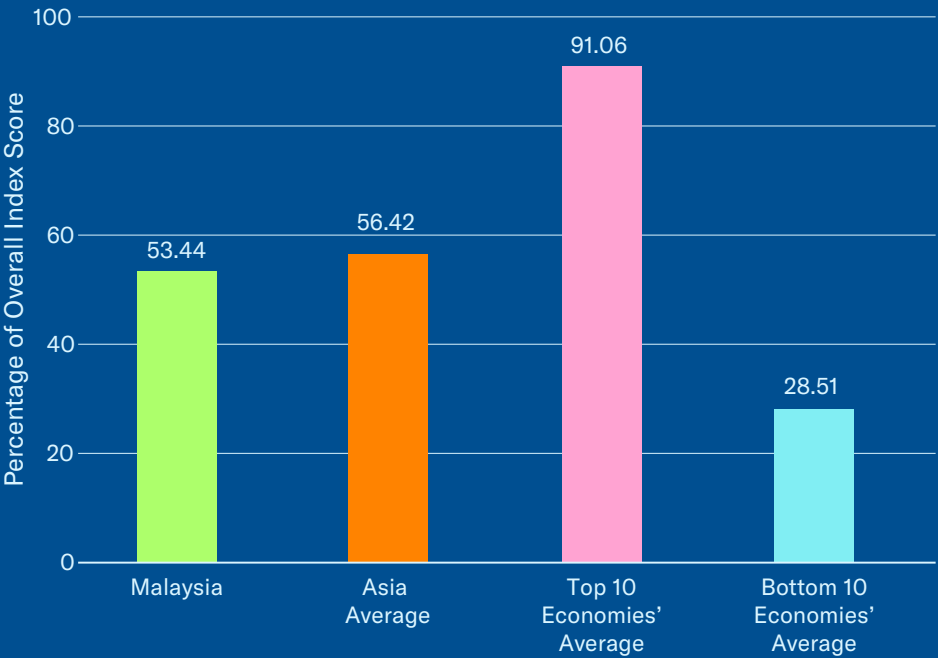
12. Expeditious injunctive-style relief and disabling of infringing content online: As noted in previous editions of the Index, in 2019, a new copyright law, Law 75 on Copyright and Related Rights, was passed. Law 75 makes some potentially important changes to Kuwait's copyright regime with respect to new avenues for enforcement. Specifically, Article 36 grants a broader type of administrative enforcement authority to designated officials compared with the provisions in the older Copyright Law. Kuwait's National Library administers the national system of copyright and now also offers rightsholders the option of filing copyright infringement complaints directly with it through an online portal. This administrative enforcement option comes on top of a parallel mechanism through the Communications and Information Technology Authority (CITRA). Since 2014-2015, new laws relating to telecommunications and cybercrime have invested vast powers in 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. CITRA offers a dedicated web portal where online requests for the disabling of websites can be requested, including on the basis of IP infringement. In 2022, the USTR removed Kuwait from the Special 301 Watch List based largely on the positive impact these direct complaint mechanisms have had. As a result, the score on indicator 12 has increased by 0.25.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Strong enforcement efforts against infringing set-top boxes continued through Malaysian Communications and the Multimedia Commission and Ministry of Domestic Trade and Consumer Affairs
- 2022 amendments to the Patent Act create a defined pathway of post-grant opposition proceedings
- 2020 Trademark Act amendments strengthen the enforcement environment
- 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 the 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 breakthrough medicine to treat hepatitis C
- *De facto* RDP full term of protection is not offered to new products
- Patent term restoration is not offered



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	0.25	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.53
9. Patent opposition	0.50	33. Software piracy rates	0.49
Category 2: Copyrights, Related Rights, and Limitations		34. Civil and preceudural remedies	0.50
10. Term of protection	0.53	35. Preestablished damages	0.50
11. Exclusive rights	0.75	36. Criminal standards	0.75
12. Injunctive-type relief	0.75	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.75	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	
15. TPM and DRM	0.75	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations		41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.50	Total: 26.72	

Spotlight on the National IP Environment

Past Editions versus Current Score

Malaysia’s overall score has increased from 51.90% (25.95 out of 50) in the tenth edition to 53.44% (26.72 out of 50). This reflects score increases on indicators 9, 32, and 36.

Patents, Related Rights, and Limitations

9. Patent opposition: Up until 2022, patent opposition proceedings were not available under Malaysian law. The Patent Act did not offer the possibility of any type of opposition proceeding (pre- or post-grant), and no administrative mechanism existed for challenging the validity of any granted patent claim or instituting nullity proceedings. Instead, Section 56(1) of the Patent Act stated that any challenges to the validity of a patent had to go through a court of law. Amendments to the Patent Act in 2022 created a defined pathway of post-grant opposition proceedings. Under a new Section 55A, any interested party may, within a prescribed period after the publication of the grant of a patent, file a notice of opposition with the Patent Registrar’s office. Under a new Section 56A, interested parties are precluded from filing parallel invalidation proceedings through the judiciary. The institution of an administrative opposition pathway holds the promise of providing a more timely and cheaper option for resolving claims of patent invalidity. As such, these amendments amount to a potential improvement in Malaysia’s patenting environment. As a result, the score on this indicator has increased by 0.5.

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); 12. Expeditious disabling of infringing content online; and 36. Criminal standards including minimum imprisonment and minimum fines: 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 Malaysia. For example, a 2019 survey commissioned by the Asia Video Industry Association’s Coalition Against Piracy found that a quarter of those surveyed owned a set-top box that could be used to access and stream illegal content. The survey also found that 60% of those who purchased the set-top box with the intent of streaming illicit content canceled all or some of their legally purchased content and television subscriptions.

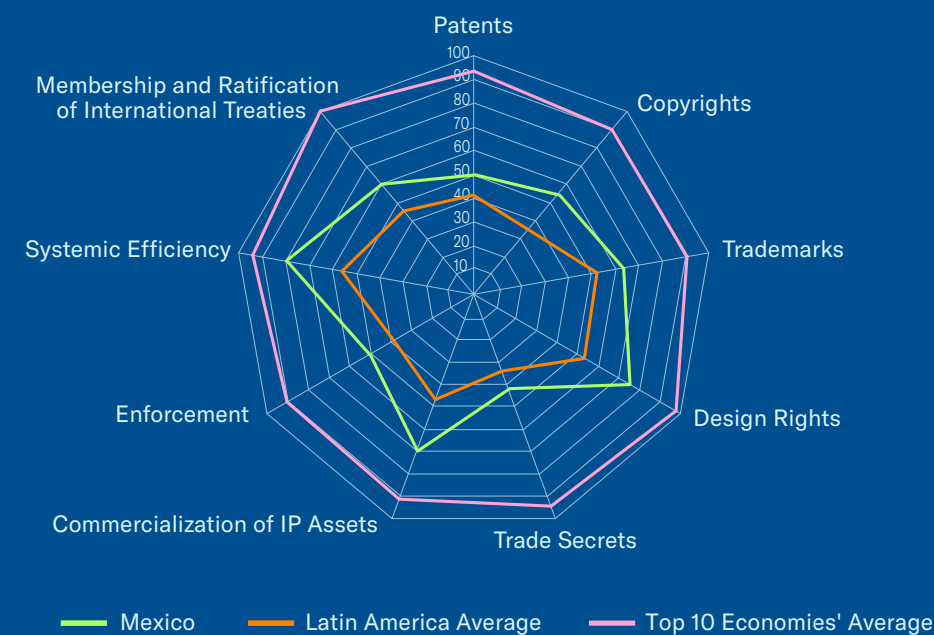
Both the Malaysian Communications and Multimedia Commission (MCMC) and the Ministry of Domestic Trade and Consumer Affairs (KPDNHEP) have broad authority to censor all manner of content in Malaysia, including that suspected of infringing copyright. In 2019, MCMC began targeting websites that provide infringing content through set-top boxes and disabled access to 246 such websites. Criminal enforcement has also increased against the sales and promotion of illicit set-top boxes with the first ever successful criminal prosecution taking place in 2021. Additionally, in 2021, the Intellectual Property High Court in Kuala Lumpur held that the sale, promotion, or dissemination of set-top boxes that allow users to illicitly stream infringing content was a violation of copyright and civil offense. These positive efforts continued in 2022.



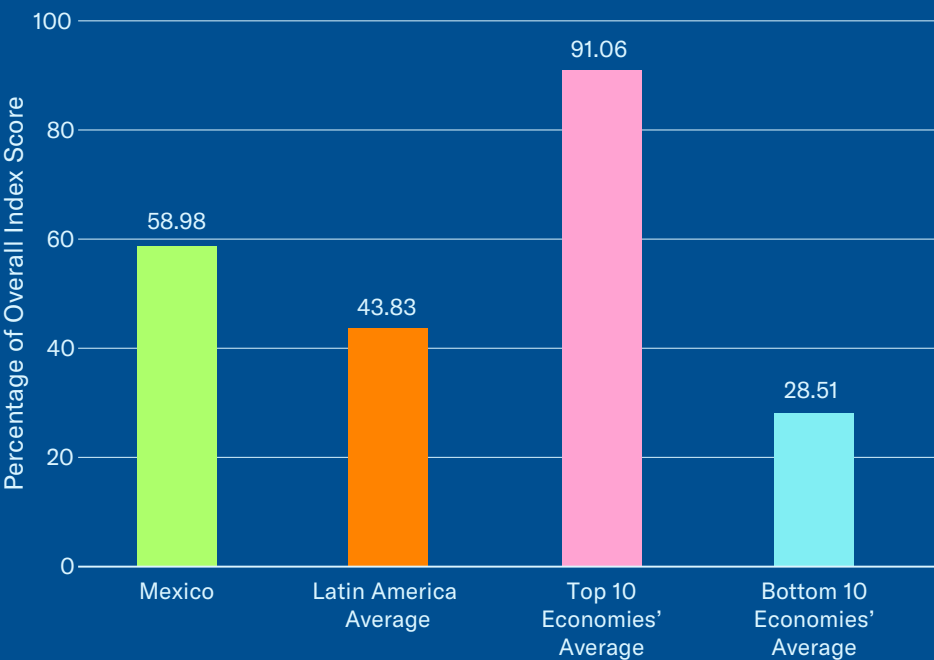
To begin with, new amendments to the Copyright Act passed in late 2021 now explicitly target the provision of streaming devices and related services with criminal sanctions in place of up to 20 years' imprisonment and a fine of MYR200,000 (approximately USD 40,000). In late 2022, KPDNHEP and its Director of Enforcement, Azman Adam, released figures on their enforcement efforts against set-top boxes and streaming devices. From 2018 to September 2022, the Ministry had taken action in over 500 cases of physical sales of set-top boxes and disabled access to over 2,000 websites. As a result of these positive efforts, the score on indicator 36 has increased by 0.25.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Mexican Institute of Industrial Property (IMPI) published 2021 study on economic impact of IP-intensive industries in Mexico: analysis carried out with EUIPO and modeled on EPO and USPTO studies
- 2020 amendments to Industrial Property Law implement some provisions of USMCA
- 2020 amendments to Federal Law on Copyright 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 to 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	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 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. TPM and DRM	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 and 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 and 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
Total: 29.49	

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	3.54
32. Physical counterfeiting rates	0.53
33. Software piracy rates	0.51
34. Civil and preceudural remedies	0.50
35. Preestablished 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	4.00
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	1.00
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, ct 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

Spotlight on the National IP Environment

Past Editions versus Current Score

Mexico’s overall score remains unchanged at 58.98% (29.49 out of 50).

Patent Rights, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism: Although a 2003 Presidential Decree introduced a basic system for early adjudication of disputes related to biopharmaceutical patent infringement and the marketing of a follow-on product, as noted over the course of the past 10 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 rightsholders’ ability to secure damages effectively (reaching a total of around 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.

Through the USMCA, Mexico is bound 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.”

As noted in previous editions of the Index, 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 Mexico’s Federal Commission for the Protection against Sanitary Risk (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 implementing regulations or guidelines had been issued by either agency. A proposal for a revised linkage regime was put forth by the Chamber of Deputies in 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 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 2023.



Copyrights, Related Rights, and Limitations

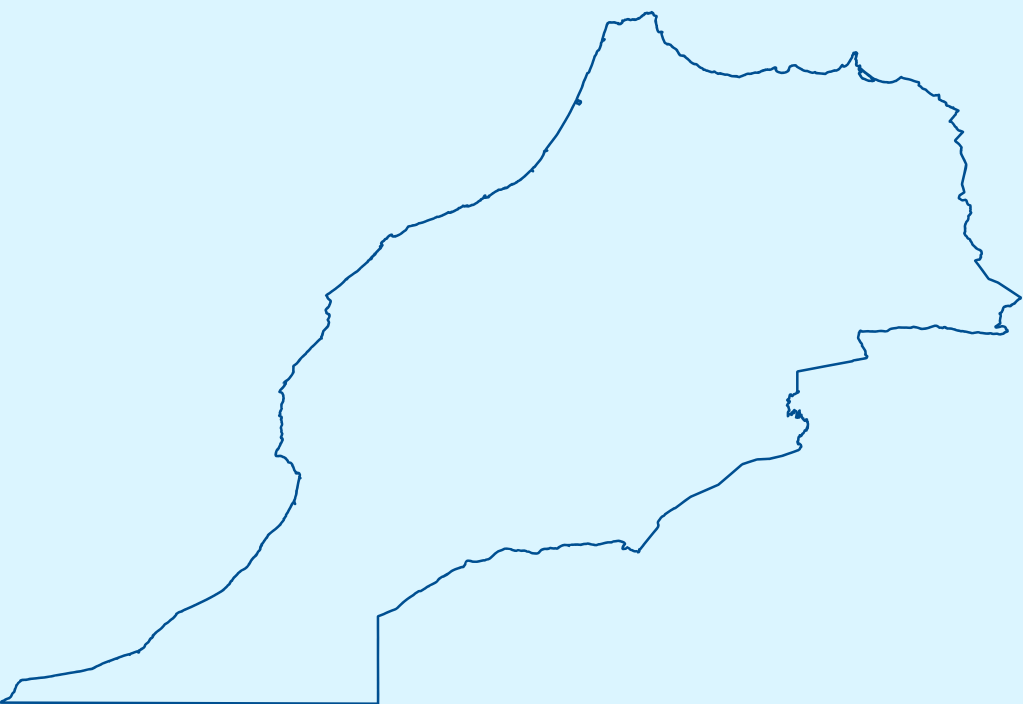
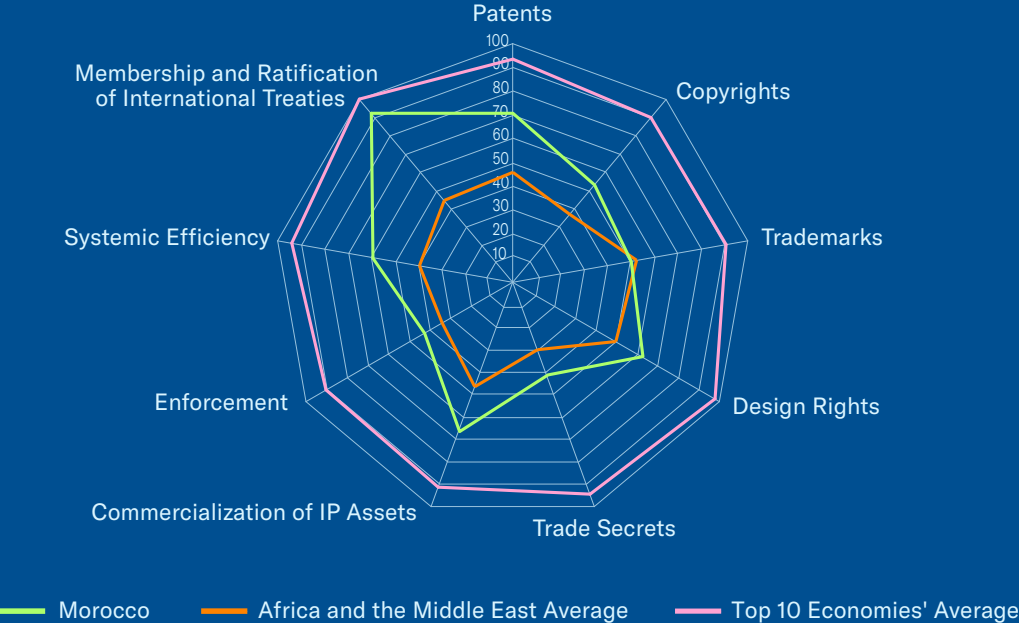
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and 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 USMCA contains several provisions that would strengthen standards of copyright protection in Mexico, including with regard to digital rights management and technological protection measures, cable and satellite piracy, and the introduction of a notice-and-takedown regime. In 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 into the internet and the digital environment. Specific changes include i) a new notification system whereby ISPs are obliged to act expeditiously and to remove suspected content upon receiving a notification (Articles 114 and 232); ii) robust DRM and TPM provisions outlawing the use, manufacture, sale, importation, distribution, or otherwise offering to the public circumvention devices and technologies (Article 232); and iii) making illegal the use, manufacture, import or other form of distribution of satellite signal decoders (Article 145). These are positive developments and have resulted in score increases on indicators 11, 13, and 15 in the ninth edition of the Index.

However, as noted at the time, some parts of the amendments remain unclear. For example, with respect to potential ISP liability for infringing content, Article 114(8) is clear that ISPs will not be responsible for any damages caused by potential copyright infringement as long as they act expeditiously and in good faith to remove infringing content and take measures to prevent the same infringing content from reappearing. However, in the same article, Subsection V, the law states that the “inability of an Internet Service Provider to meet the requirements set forth in this article by itself does not generate liability for damages for violations of copyright and related rights protected by this Law.” For any notification system to be effective in addressing online infringement, it must be clear what the responsibilities and legal expectations are for each affected party. At the time of research, no implementing regulations or further guidance had been issued.

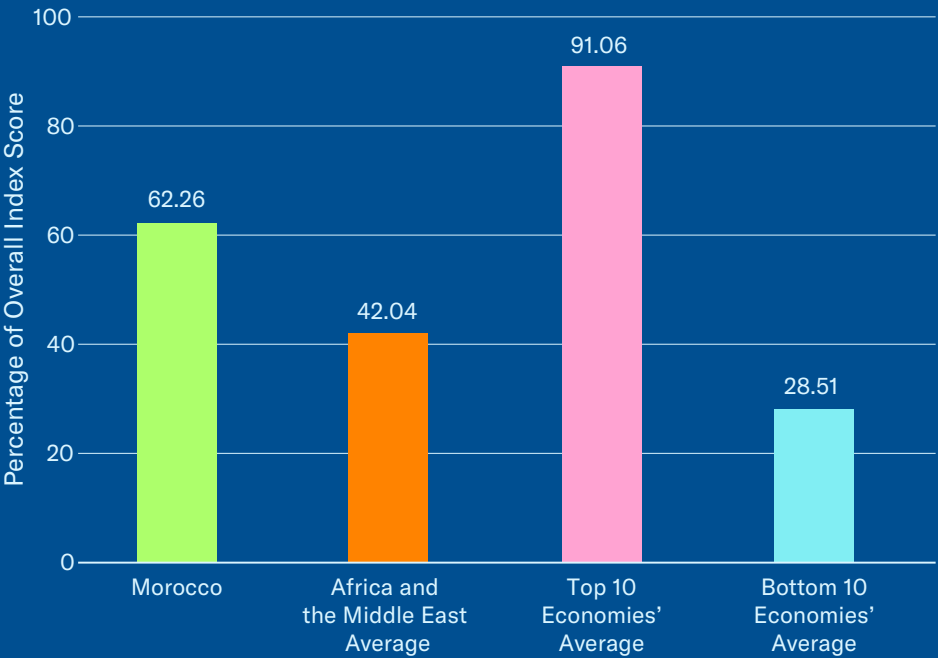
In a separate development, IMPI and national and international rightsholders signed several partnership agreements in 2022. In a series of meetings held throughout the summer and fall, collaboration agreements were signed with the Mexican Audiovisual Producers Rights Management Entity, the Entertainment Software Association, the Business Software Alliance , and Mercado Libre. These agreements are aimed at facilitating stronger enforcement against online piracy and the circulation of counterfeit goods in Mexico. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2022 accession to Singapore Treaty and Geneva Act (part of the Hague Agreement)
- Fairly well-developed national IP system—highest performing middle-income economy in Index
- Strong protections for patents and related rights
- U.S.-Morocco FTA and agreements with the EU have encouraged Morocco to strengthen its IP environment and related standards
- PPH in place with Spain
- Moroccan Industrial and Commercial Property (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 CILs



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 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. TPM and DRM	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 and 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 and 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
Total: 31.13	

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	3.01
32. Physical counterfeiting rates	0.40
33. Software piracy rates	0.36
34. Civil and preceudural remedies	0.25
35. Preestablished 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	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	0.50
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	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	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, ct 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

Spotlight on the National IP Environment

Past Editions versus Current Score

Morocco’s overall score has increased from 59.76% (29.88 out of 50) in the tenth edition to 62.26% (31.13 out of 50). This reflects score increases on indicators 42, 45, and 49.

Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs: The Intellectual Property Corporation of the Moroccan Office of Industrial and Commercial Property (OMPIC) has a pronounced and consistent focus in all its work on promoting the use and commercialization of IP assets, especially with respect to SMEs, universities, and public research organizations. OMPIC offers reduced filing fees for small businesses, educational institutions, and research institutes. Morocco has offered applicants on-the-ground support services through its network of TISC support centers. These support centers offer researchers and institutions technical expertise on the registration and commercialization of IP assets. WIPO first developed the TISC concept in the late 2000s, and, as of 2022, there were close to 1,300 support centers in 88 economies around the world, with 72 centers in Morocco. In 2022, these efforts were bolstered when OMPIC launched two new technical assistance programs that aim to provide businesses with an in-depth review of existing IP assets and protections and offer tailored guidance on existing prior art, the patenting process, and key industrial technology trends. These new programs target academic researchers, research institutes, and, especially, SMEs. As a result of these efforts, the score on this indicator has increased by 0.25.

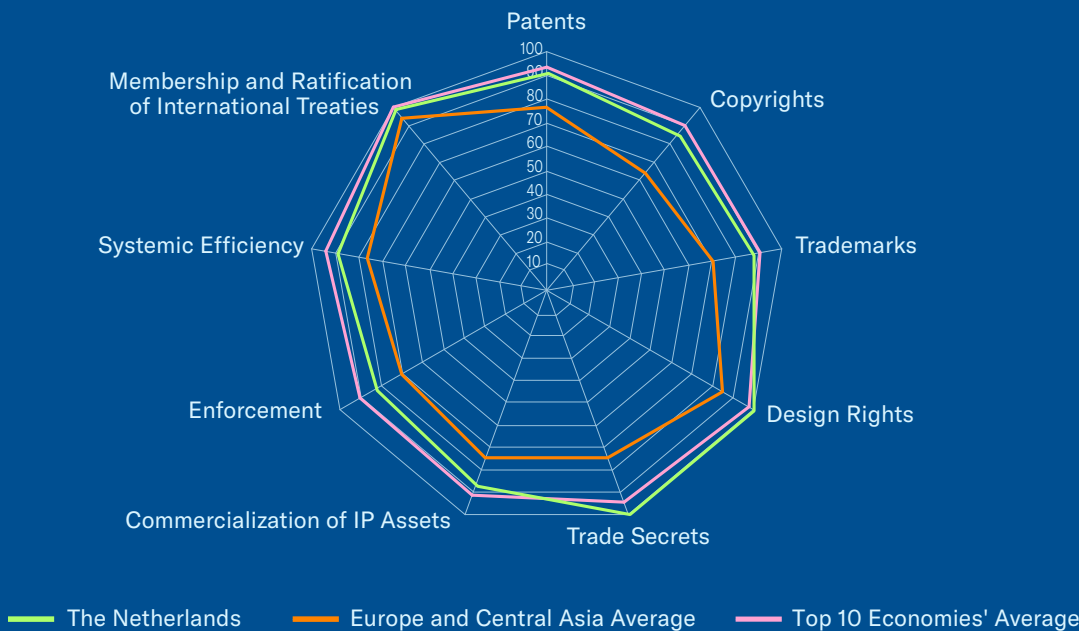
Membership and Ratification of International Treaties

45. Singapore Treaty on the Law on Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; and **49. The Hague Agreement Concerning the International Registration of Industrial Designs:** In 2022, Morocco acceded to the Singapore Treaty and is now a full member of each of the two trademark-related treaties included in the Index. In 2022, Morocco also acceded to the Geneva Act. It is now a full contracting party to all acts that together constitute the Hague Agreement. As a result, the score on each of these indicators has increased by 0.5, respectively.

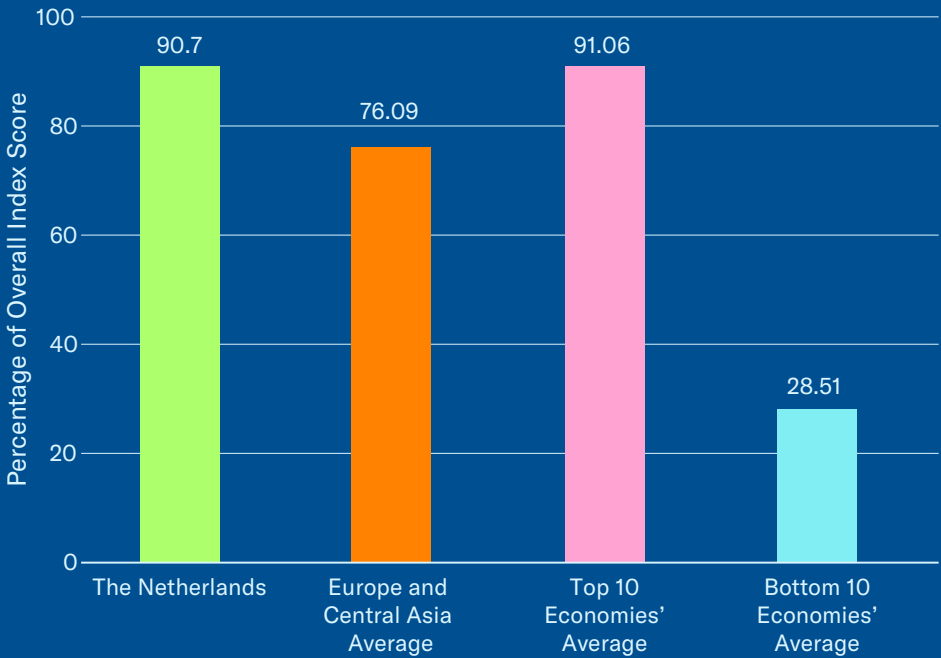
Morocco’s score on this category of the Index has increased from a score of 2, or 50%, in the sixth edition of the Index (the first year Morocco was included) to now achieving a score of 6.5, or 92.86%, of the total available score. This is notably higher than many high-income economies, such as New Zealand, the UAE and Australia, and comparable to the score achieved by most developed OECD economies. Overall, Morocco is a contracting party and has acceded to all the international IP treaties benchmarked in the Index, except for the Patent Law Treaty. Morocco is also a contracting party to the U.S.-Morocco FTA of 2004, which contains a separate and distinct IP chapter. This agreement has been pivotal in strengthening Morocco’s national IP environment, including for biopharmaceuticals and copyright-related industries.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Continued leader on copyright enforcement—private-public initiatives led by national copyright foundation BREIN and Dutch government
- 2018 transposition of EU Trade Secrets Directive 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 the 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.25	Category 6: Commercialization of IP Assets	5.25
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	5.86
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.83
9. Patent opposition	1.00	33. Software piracy rates	0.78
Category 2: Copyrights, Related Rights, and Limitations	5.99	34. Civil and preceudural remedies	1.00
10. Term of protection	0.74	35. Preestablished damages	0.75
11. Exclusive rights	1.00	36. Criminal standards	0.50
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.75	Category 8: Systemic Efficiency	4.50
15. TPM and DRM	0.75	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.75	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.50	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	2.00	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	3.00	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	1.00	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 45.35			

Spotlight on the National IP Environment

Past Editions versus Current Score

The Netherlands’ overall score remains unchanged at 90.70% (45.35 out of 50).

Copyrights, Related Rights, and Limitations

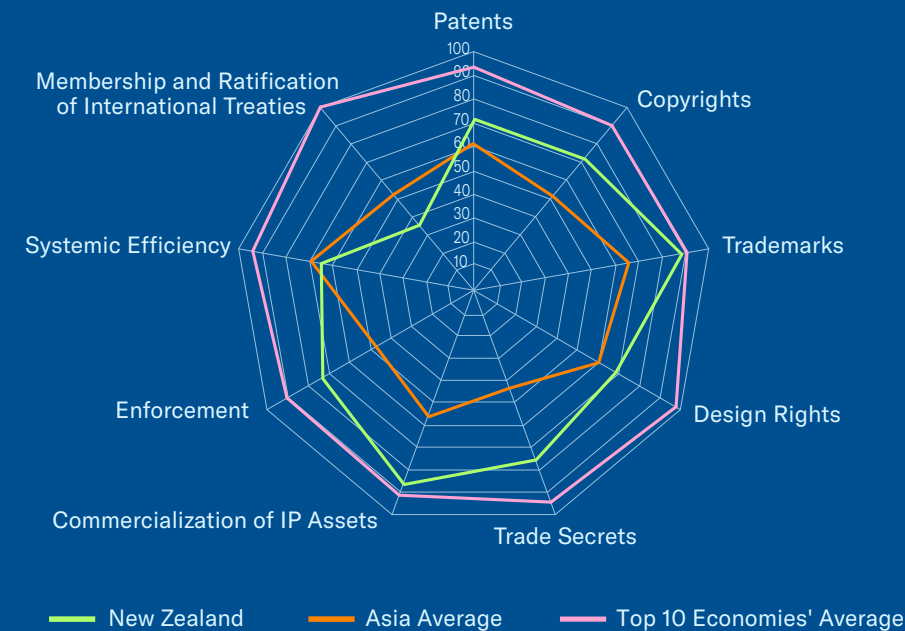
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 12. Expeditious injunctive-style relief and disabling of infringing content online: As noted in previous editions of the Index, over the past decade, the Netherlands and EU have introduced and implemented a range of new mechanisms and powers to help combat online infringement. The positive impact of these efforts can be seen in the Netherlands’ score change on Category 2: Copyrights, Related Rights, and Limitations. Over the past five editions of the Index, the Netherlands’ score has increased from 78.43% in the sixth edition (the first year the Netherlands was included) to 85.57% in this year’s edition. This is an increase of 7.14%. This positive trend began in the mid-2010s with several important legal precedents set at both the national Dutch level and at the EU level through the Court of Justice of the European Union (CJEU). In addition to redress through the judiciary, rightsholders have also seen their legal powers strengthened in the Netherlands through the transposition of EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive). Coming into effect in 2021, the final version of the law broadly follows the scope of the underlying directive, particularly regarding responsibilities and requirements under Article 17. The law maintains existing exceptions and limitations provided under Dutch and European copyright law and jurisprudence, and it strengthens protections for creators online

by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. It also provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability.

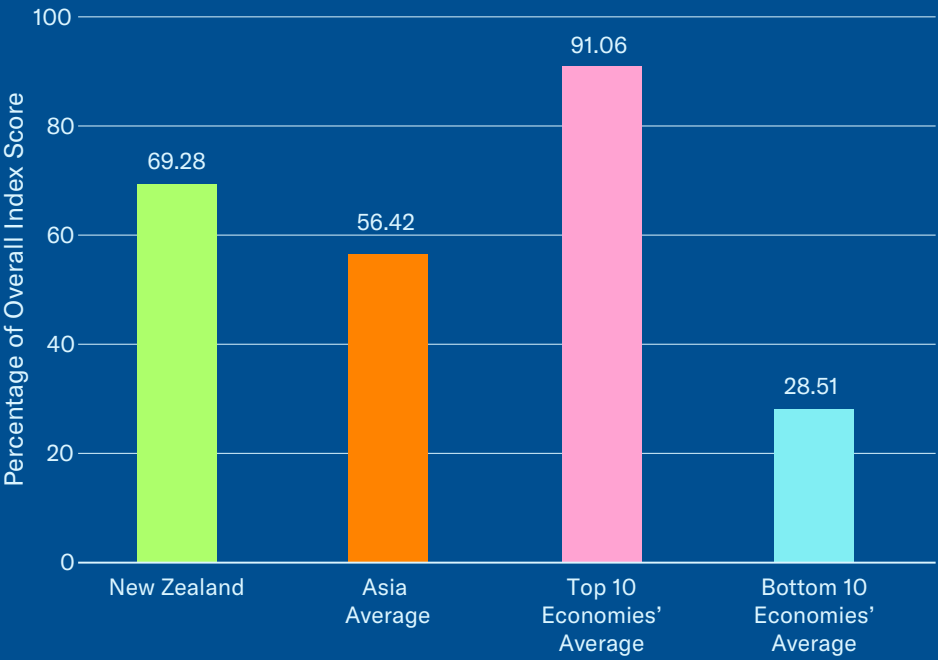
These efforts have continued over the past year with the Dutch copyright foundation BREIN taking the lead. Brokered by the Dutch government, in late 2021, BREIN concluded a legal “Covenant” with the largest Dutch ISPs on a standardized process for the implementation and application of injunctive relief court orders. Under this agreement, any court order requiring the disabling of access to illicit sites through one ISP is to be followed and adhered to by all ISPs that are party to the agreement. BREIN was also successful in taking legal action against the sale of internet TV subscription services that link to infringing content. Reports by the foundation suggests that its anti-piracy activities are having a real and lasting impact on the provision and use of copyright-infringing content in the Netherlands. Since the court-ordered disabling of access to The Pirate Bay was issued, Dutch visits to the website have dropped by an estimated 95%.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- R&D tax incentives passed in 2019
- Legislative amendments following ratification of the CPTPP provide border officials with clear *ex officio* authority
- Fairly sophisticated national IP environment with strengths across most categories of the Index
- To 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 the Copyright Tribunal and most being dismissed on technicalities
- No patent term restoration in place for biopharmaceuticals
- Limited membership of international IP treaties



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	6.46	Category 6: Commercialization of IP Assets	5.17
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.75	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	0.96	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	5.13
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.79
9. Patent opposition	0.25	33. Software piracy rates	0.84
Category 2: Copyrights, Related Rights, and Limitations	5.03	34. Civil and preceudural remedies	1.00
10. Term of protection	0.53	35. Preestablished damages	0.75
11. Exclusive rights	0.75	36. Criminal standards	0.75
12. Injunctive-type relief	0.25	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.75	38. Transparency and public reporting by customs	0.50
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	3.25
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	0.50
16. Government use of licensed software	0.75	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.50	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	2.50
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.35	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.25	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.75	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.50		
Total: 34.64			

Spotlight on the National IP Environment

Past Editions versus Current Score

New Zealand’s overall score remains unchanged at 69.28% (34.64 out of 50).

Copyrights, Related Rights, and Limitations

10. Copyright (and related rights) term of protection; and 12. Expeditious disabling of infringing content online: In March 2022, Prime Minister Jacinda Ardern announced the conclusion of negotiations and the signing of a new comprehensive trade agreement with the UK. The New Zealand-UK FTA is a wide-ranging FTA that includes a separate and distinct chapter dedicated to the protection of IP. The FTA includes some potentially positive changes to New Zealand’s copyright environment. To begin with, the agreement would align and increase the current headline term of copyright protection in New Zealand with European and British standards. Specifically, Article 17.48 would provide a term of protection of an author’s life plus 70 years. For anonymous and/or works that cannot be linked to the life of an individual, the term of protection would be 70 years after the creation of the work and/or making it available to the public. However, this term extension will not be available for at least another 15 years. Article 17.48(10) of the agreement states that: “The obligations in this Article [term extension] shall only commence applying 15 years after the date of entry into force of this Agreement.” This is surprising and disappointing, as it is not clear why there is a need for such a postponement. Postponing the implementation of some obligations in a concluded FTA is usually reserved for lower-income developing economies that may need additional time to develop the technical capacity and institutional capabilities necessary to implement these obligations. That is not the case in New Zealand, which should have no difficulty amending the relevant statute and

administering a new extended term of copyright protection. Still, irrespective of when the term extension takes place, the introduction of a longer term of copyright protection in New Zealand would result in a score increase on indicator 10.

The new FTA also includes an important obligation to provide copyright holders the ability to seek injunctive-style relief through the judiciary. Articles 17.67 and 17.70 define this right of redress for all relevant IP rights, and Article 17.82 defines this specifically within the context of copyright and enforcement against online piracy. Article 17.82 states unambiguously that “Each Party shall ensure that injunctions as provided for in Article 17.67 (Provisional and Precautionary Measures) and Article 17.70 (Injunctions): (a) are available against an OSP, where its online services are used by a third party to infringe an intellectual property right; and (b) include injunctions requiring that OSPs disable access to infringing content.” The implementation of this right into New Zealand statute would be a notable achievement and would result in a score increase on indicator 12.

The past decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the UK, India, Singapore, India, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, and the UK.



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 rightsholders in enforcing their rights. Current New Zealand law does not explicitly provide this right of action to copyright holders. Indeed, in 2018, New Zealand's Ministry of Business, Innovation and Employment (MBIE) in the document *Issues Paper Review of the Copyright Act 1994* noted as much. The MBIE also recognized the difficulties that creators and rightsholders face today because of online infringement and the lack of effective enforcement mechanisms currently available in New Zealand: "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."

With respect to injunctive-style relief, the Ministry noted that, as a practical and established enforcement route, this is not currently available to rightsholders in New Zealand: "Whether copyright owners and their licensees are able to obtain website-blocking injunctions in New Zealand is uncertain. Copyright owners may be able to apply for a website-blocking injunction by relying on section 92B of the Copyright Act, Rules 2.1 and 1.6 of the High Court Rules and the High Court's inherent jurisdiction, but this is yet to be tested in the courts." Given not only this current lacuna in New Zealand copyright law, but also the fact that the provision of injunctive-style relief is so clearly and explicitly defined in the New Zealand-UK FTA, it is surprising to see that the draft implementing

law presented to Parliament by the New Zealand government in June 2022, the "United Kingdom Free Trade Agreement Legislation Bill," did not include any reference to injunctive relief or relevant amendments to the Copyright Act. It is difficult to see how New Zealand will be able to fulfill its obligations under the New Zealand-UK FTA if the draft implementing law is not amended to also include such an elemental part of the trade agreement's IP chapter. The Index will continue to monitor these developments in 2023.

Membership and Ratification of International Treaties

50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices: As mentioned, the New Zealand-UK FTA is a wide-ranging FTA that includes a separate and distinct chapter dedicated to the protection of IP. In addition to provisions related to copyright protection, the treaty also requires contracting parties to join the Hague Agreement Concerning the International Registration of Industrial Designs; New Zealand is currently not a contracting party. Like both the CPTPP and RCEP agreement—two treaties New Zealand recently concluded—the New Zealand-UK FTA also requires contracting parties to give *ex officio* authority to relevant customs and border officials to take action against suspected IP-infringing goods. However, unlike both the CPTPP and RCEP, Article 17.74(11) of the New Zealand-UK FTA explicitly excludes these powers against goods in transit: "It is understood that there shall be no obligation to apply the procedures described in this Article to imports of goods put on the market in another country by, or with the consent of, the right holder, *or to goods in transit.*" This is a curious omission and weakness in the treaty.

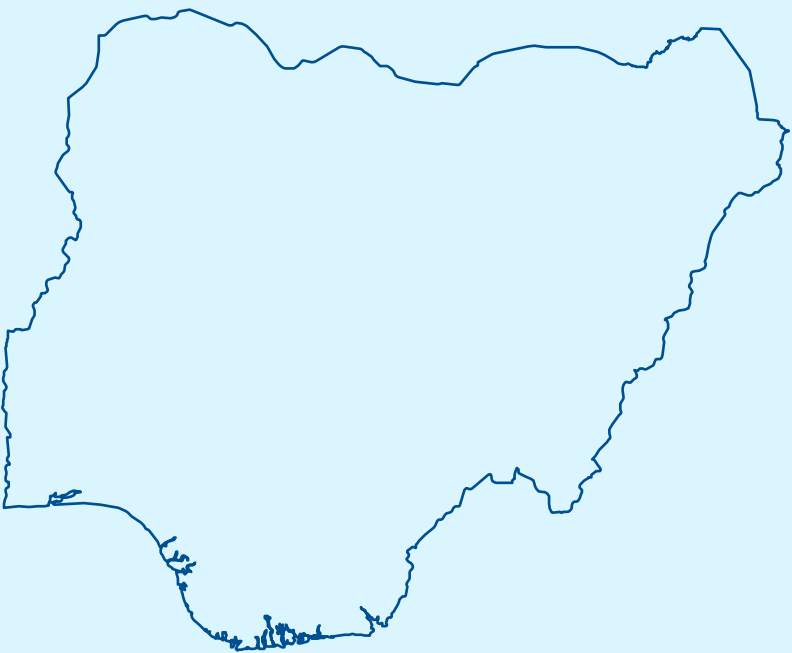
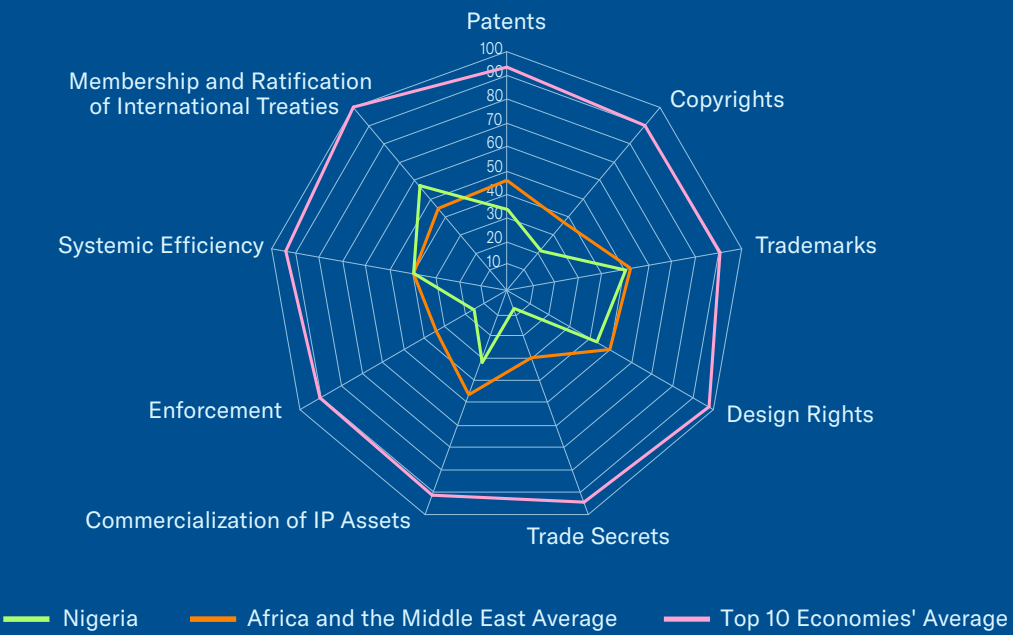
Similarly, unlike many other post-TRIPS FTAs, the New Zealand-UK FTA does not contain substantial protections for the life sciences

sector. The treaty does not contain patent term restoration for regulatory delays in obtaining marketing approval for biopharmaceutical products. As noted over the course of the Index, New Zealand is one of the few high-income developed OECD economies that does not provide restoration for biopharmaceutical products for loss of patent term time due to delays caused by the marketing approval process. In the UK, a maximum five-year term of restoration is provided through Supplementary Protection Certificates (SPCs) and has been in place for decades.

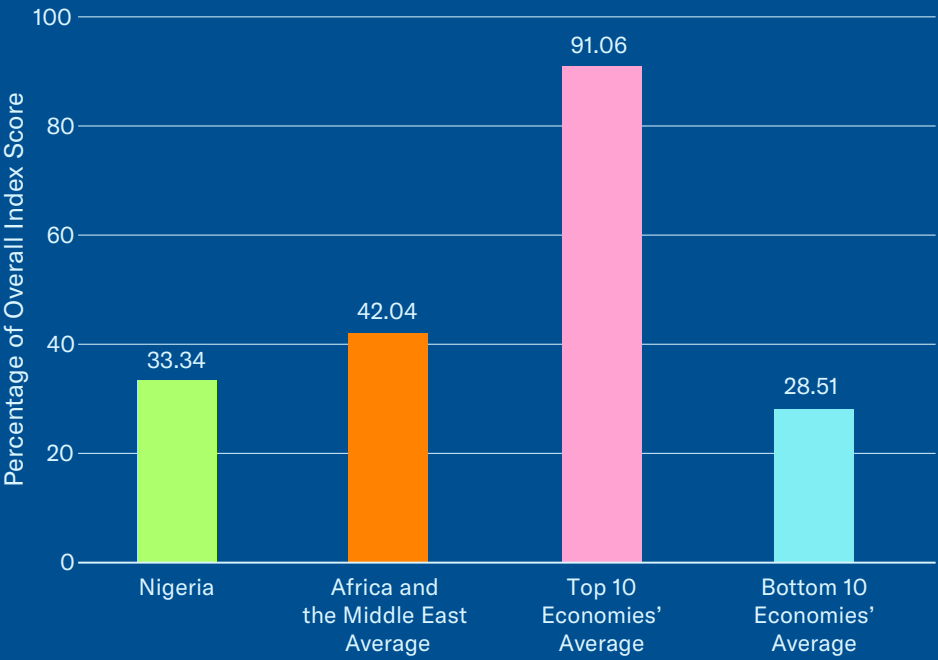
In a separate development, in July 2022, the European Commission and government of New Zealand announced the conclusion of negotiations for a new FTA with the EU. At the time of research, the terms of the treaty were still to be finalized. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Joined the Convention on Cybercrime in 2022
- Plant Variety Protection Act 2021
- Joined the UPOV 1991 in 2021
- Ratified the WIPO Internet Treaties in 2017
- Despite an overall challenging environment, ongoing enforcement efforts by NCC are encouraging

Key Areas of Weakness

- Overall weak and limited legal and regulatory framework, with no major forms of IP rights 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
- Socialization barriers and restrictions in place on technology transfer and licensing activities—these barriers 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	Score
Category 1: Patents, Related Rights and Limitations	3.00
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and 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. TPM and DRM	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 and 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 and 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
Total: 16.67	

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	1.16
32. Physical counterfeiting rates	0.21
33. Software piracy rates	0.20
34. Civil and preceudural remedies	0.25
35. Preestablished 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	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	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, ct 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	0.00

Spotlight on the National IP Environment

Past Editions versus Current Score

Nigeria’s overall score has increased from 31.34% (15.67 out of 50) in the tenth edition to 33.34% (16.67 out of 50). This reflects a score increase on indicator 48.

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. Technological Protection Measures (TPM) and Digital rights management (DRM) legislation: The current Copyright Act provides rightsholders with general and basic exclusive rights; it contains only limited references to the online space in copyright and related law, including the 2015 Cybercrime Bill. For example, there is no provision in the Copyright Act or other relevant legislation instituting a notice-and-takedown mechanism, injunctive-style relief, or any copyright-specific TPM and DRM provisions. Part 3, Section 11 of the 2008 Guidelines for the Provision of Internet Service, published by the Nigerian Copyright Commission (NCC), provides some protection for copyrighted content online. These guidelines include a notice-and-takedown mechanism, safe harbor provisions for ISPs, and a general obligation of ISPs to disconnect subscribers upon notification that subscribers are using the “services contrary to the requirements of these Guidelines or other applicable laws or regulation.” However, it has never been clear what practical force these guidelines have or their effective application, as they do not carry the force of statutory law.

Similarly, Nigeria does not have in place TPM or DRM legislation outlawing the use, sale, manufacture, and distribution of circumvention devices used to infringe on copyright. Part III of the 2015 Cybercrimes (Prohibition and Prevention) Act contains language making it an offense to use or make available any “devices primarily designed to overcome security measures in any computer, computer system or network.” But these are not specific to copyright, and no evidence shows that these provisions are being used to counter copyright provisions. More broadly, piracy is widespread, and rightsholders face significant challenges in enforcing their rights. The BSA estimates that the software piracy rate in Nigeria is 80%, virtually unchanged over the past decade. With the 2017 accession to the WIPO Internet Treaties, there has been an added sense of urgency to amend Nigeria’s copyright laws to bring them in line with Nigeria’s international obligations. In 2018, the Federal Executive Council (Nigeria’s Cabinet) approved a draft copyright bill that was subsequently sent for review to Nigeria’s parliament, the National Assembly. Draft versions of this bill are available for public review and include only limited reference to copyright protection extending to the internet as well as a rudimentary notification and safe harbor regime for ISPs.

In contrast, draft legislation introduced in the National Assembly in 2021 (Senate Bill 688) contained many important updates and reforms. Specifically, the draft legislation included explicit references to copyright protection online; new copyright-specific provisions related to TPM and DRM; an injunctive-style relief mechanism by which access to infringing content can be disabled upon application; and a comprehensive notice-and-takedown mechanism that includes clearly defined safe harbors and circumstances under which legal liability arises. The draft law provided clear and unambiguous powers to the NCC to disable



access to infringing content online. The bill also recognized the need for more dynamic action and included a “stay-down” responsibility on the part of service providers to ensure that any infringing content that has been removed will not be reloaded.

Unfortunately, it is less clear that other provisions of the legislation will improve Nigeria’s copyright environment. Most notably are a long list of copyright exceptions. These exceptions contain limited references to the Berne three-step-test and some potentially broad exceptions for educational, private, and research use. In August 2022, following passage by both the lower and upper chambers, the entire Nigerian National Assembly passed the bill “Act to Repeal the Copyright Act CAP LFN 2004 and to Re-enact the Copyright Act 2022.” At the time of research, the bill had not yet become law as it awaited executive branch consent and President Buhari’s signature. Once signed into law, these legislative changes will result in score increases on indicators 11, 12, 13, and 15. The Index will continue to monitor these developments in 2023.

**Membership and Ratification
of International Treaties**

48. Membership of the Convention on Cybercrime, 2001: In July 2022, Nigeria became a full contracting party to the Convention on Cybercrime with the treaty entering into force in November of the same year. As a result, the score on this indicator has increased from 0 to 1.

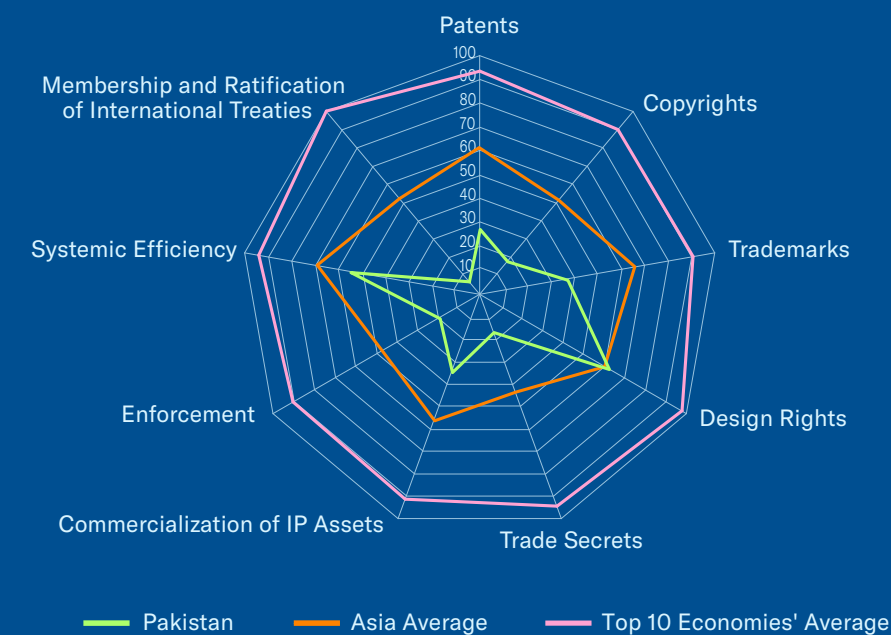
Nigeria’s score in this category of the Index has increased from 1.5, or 37.50%, in the second edition of the Index (the first year Nigeria was included) to 4, or 57.14%, of the total available score. This is notably higher than many other major emerging economies, including Brazil and South Africa. Overall, Nigeria is a contracting party and has acceded to the WIPO Internet Treaties; the Patent Cooperation Treaty; the Patent Law Treaty; the International Convention

for the Protection of New Varieties of Plants, Act of 1991; and the Convention on Cybercrime, 2001. Nigeria is not a contracting party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Singapore Treaty on the Law of Trademarks; or the Hague Agreement Concerning the International Registration of Industrial Designs.

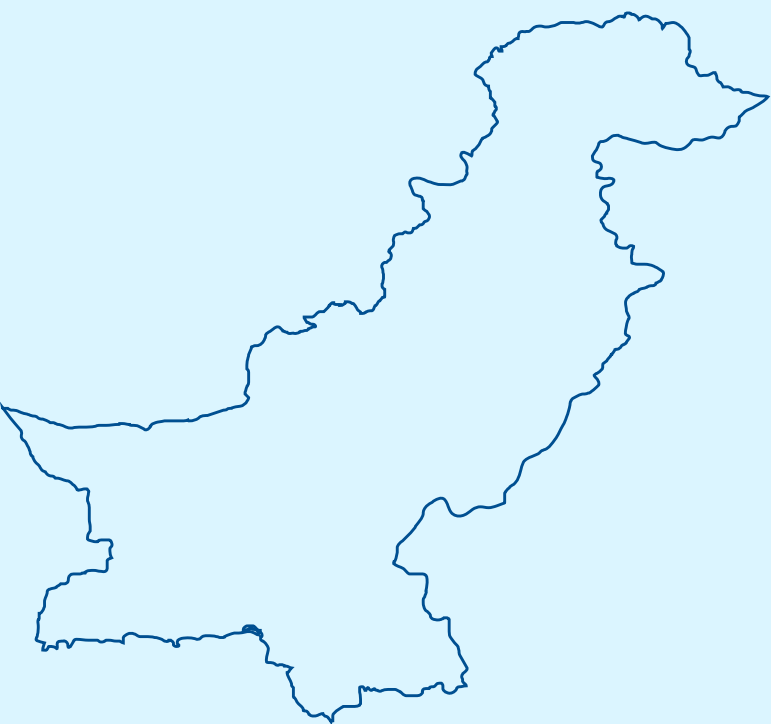
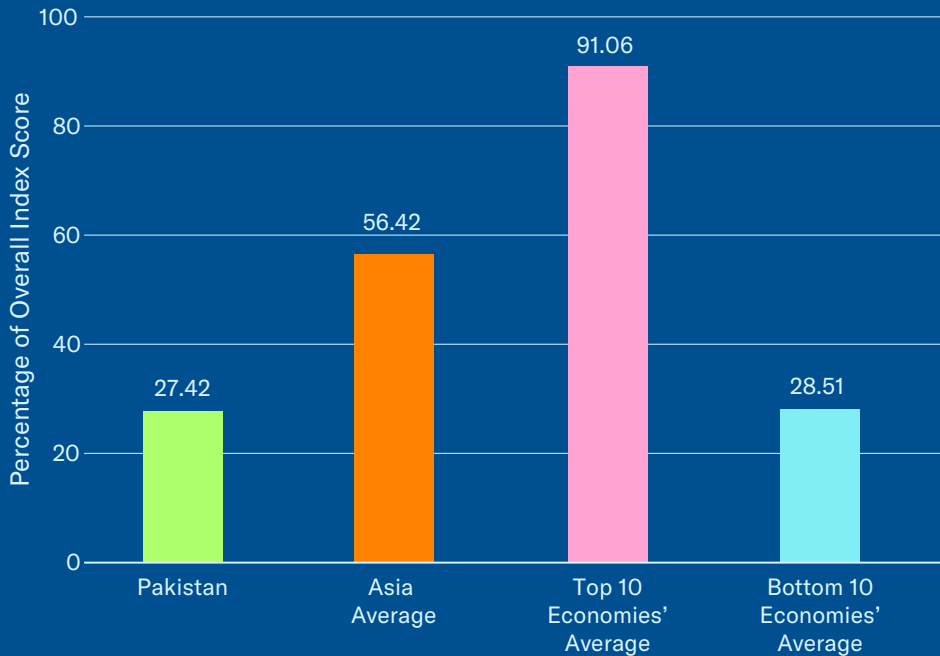
Nigeria is a contracting party to the African Continental Free Trade Area, signed by 44 African countries in March 2018. The agreement holds the potential to fundamentally revolutionize economic activity in Africa by reducing barriers to trade and economic interaction across the entire continent. Parts of the Free Trade Area (Phase I) came into force in 2019. At the time of research, 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.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2021 accession to Madrid Protocol
- 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 (although efforts to improve are underway)
- High counterfeiting and piracy rates—latest BSA estimates put software piracy at 83%



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	2.50	Category 6: Commercialization of IP Assets	2.08
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.25
3. Patentability of CIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.25
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.33
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	1.35
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.18
9. Patent opposition	0.00	33. Software piracy rates	0.17
Category 2: Copyrights, Related Rights, and Limitations	1.28	34. Civil and preceudural remedies	0.25
10. Term of protection	0.53	35. Preestablished damages	0.00
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	2.75
15. TPM and DRM	0.00	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.50
Category 3: Trademarks, Related Rights, and Limitations	1.50	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	0.50
20. Frameworks against online sale of counterfeit goods	0.00	44. WIPO Internet Treaties	0.00
Category 4: Design Rights, Related Rights, and Limitations	1.25	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	0.00
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 13.71			

Spotlight on the National IP Environment

Past Editions versus Current Score

Pakistan’s overall score has decreased from 27.43% (13.72 out of 50) in the tenth edition to 27.42% (13.71 out of 50). This reflects a score decrease on indicator 32.

Area of Note

Public reporting suggests that Pakistan is in the process of reforming various parts of its national IP environment, including statutory laws related to patents, copyrights, and trademarks. At the time of research, it was still unclear what the final draft laws would look like. Through the USPTO and its local mission, the U.S. government has been providing relevant Pakistani authorities (including the Intellectual Property Organization of Pakistan, IPO-Pakistan) with technical assistance and capacity building on IP rights. As noted over the course of the Index, Pakistan’s national IP environment lacks many fundamental rights and incentives. Patentability standards continue to be outside of international norms, especially for biopharmaceuticals and CII; the protection of copyright remains underdeveloped and ill-suited to the challenges of the internet era; levels of counterfeit goods remain high, and relevant enforcement mechanisms are weak and non-deterrent. Rightsholders also face basic challenges with respect to technology transfer, licensing the use of IP assets, and the commercialization of IP assets. Covering 50 indicators across nine separate categories, the Index has for over a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products. As the government and parliament of Pakistan pursue a program of national IP rights reforms, we would encourage them to use the findings of the Index and accompanying Statistical Annex as a guide in 2023 and beyond.

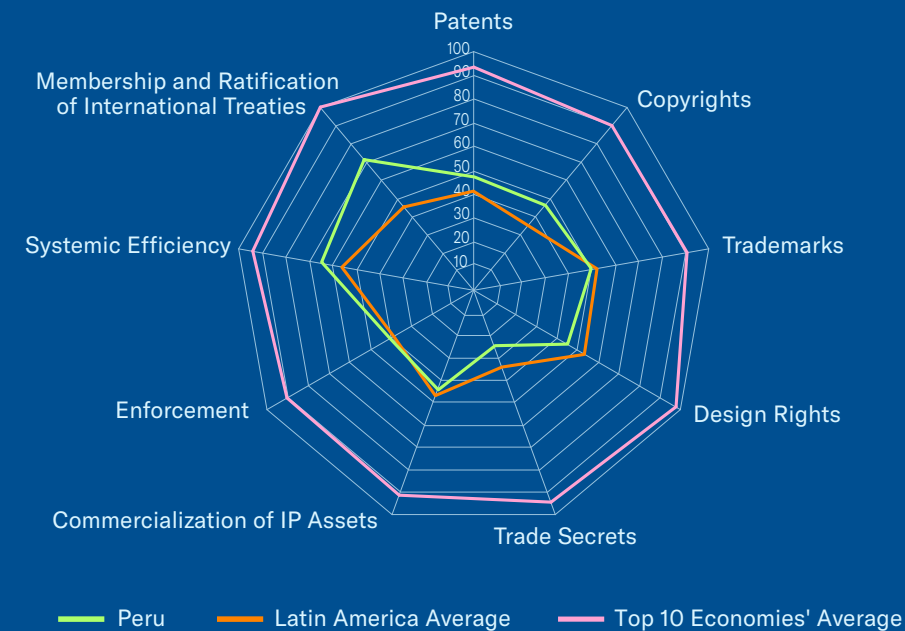
Commercialization of IP Assets and Market Access

30. IP as an economic asset: There is growing interest and recognition in government policymaking on the value of encouraging innovation and the development and transfer of new technologies to and within Pakistan. Both IPO-Pakistan and other agencies, such as the Higher Education Commission, are actively engaged in building new domestic programs and partnerships at universities and research institutes with the aim of creating, registering, and commercializing new IP assets and technologies in Pakistan. The National University of Science and Technology signed the first-ever IP licensing agreement from a Pakistani university to transfer its IP to an industry partner in 2018. With financial support from the Higher Education Commission, several universities have adopted IP policies and have established Offices of Research, Innovation and Commercialization for technology transfer and IP management.

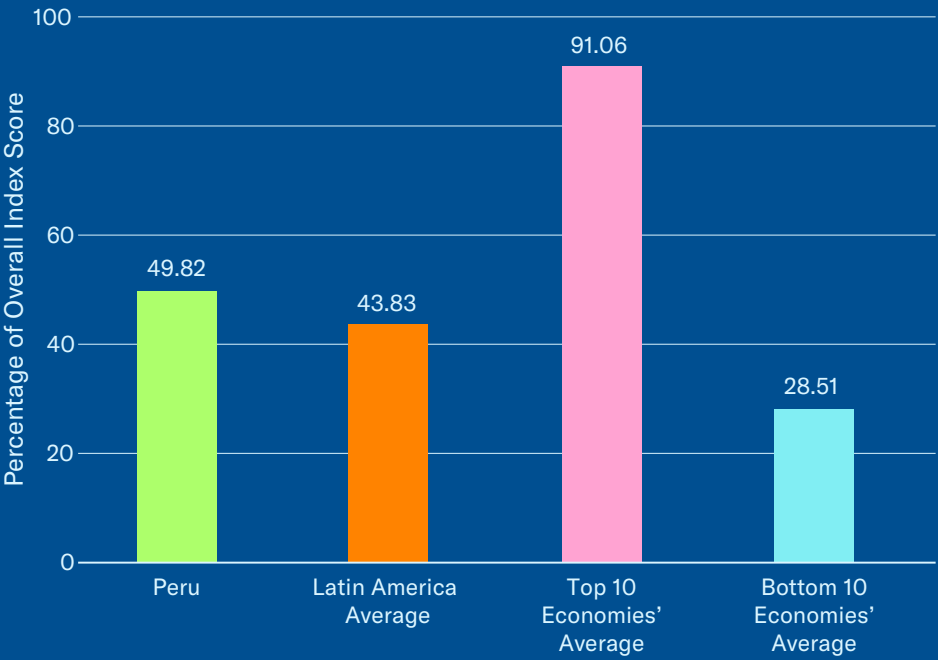
IPO-Pakistan has similarly supported the establishment of several TISCs around the country. These support centers offer researchers and institutions technical support and expertise on the registration and commercialization of IP. WIPO first developed the TISC concept in the late 2000s, and, as of 2022, there were close to 1,300 support centers in 88 economies around the world, with 36 centers operating in Pakistan. These efforts have continued in 2022. In February, IPO-Pakistan signed new agreements establishing TISC centers with two universities in the Sindh province. In conjunction with these efforts, more universities are including IP rights as part of their teaching curriculum. Reports by the U.S. government suggest that this now includes both Lahore University of Management Sciences and the International Islamic University in Islamabad.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Continued injunctive-style relief copyright enforcement by national IP office INDECOPI in 2022
- 2021 Decree 063-2021 strengthens public consultation and stakeholder participation in the lawmaking and regulatory process
- INDECOPI support for SMEs strengthened in 2021: new technical assistance and IP asset identification programs were created
- Joined the Global Patent Prosecution Highway in 2019
- In 2019, INDECOPI, 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 on the importance of IP protection

Key Areas of Weakness

- Compulsory licenses actively being considered for biopharmaceuticals based on cost
- Administrative and regulatory barriers still 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	4.25	Category 6: Commercialization of IP Assets	2.67
1. Term of protection	1.00	26. Barriers to market access	0.75
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.25
3. Patentability of CIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.25
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.25
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	2.85
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.47
9. Patent opposition	0.00	33. Software piracy rates	0.38
Category 2: Copyrights, Related Rights, and Limitations	3.24	34. Civil and precluded remedies	0.25
10. Term of protection	0.74	35. Preestablished damages	0.25
11. Exclusive rights	0.50	36. Criminal standards	0.50
12. Injunctive-type relief	0.75	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.50
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	3.25
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.75
Category 3: Trademarks, Related Rights, and Limitations	2.00	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	5.00
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.90	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.75	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.25		
Total: 24.91			

Spotlight on the National IP Environment

Past Editions versus Current Score

Peru's overall score has increased from 49.32% (24.66 out of 50) in the tenth edition to 49.82% (24.91 out of 50). This reflects a score increase on indicator 12.

Copyrights, Related Rights, and Limitations

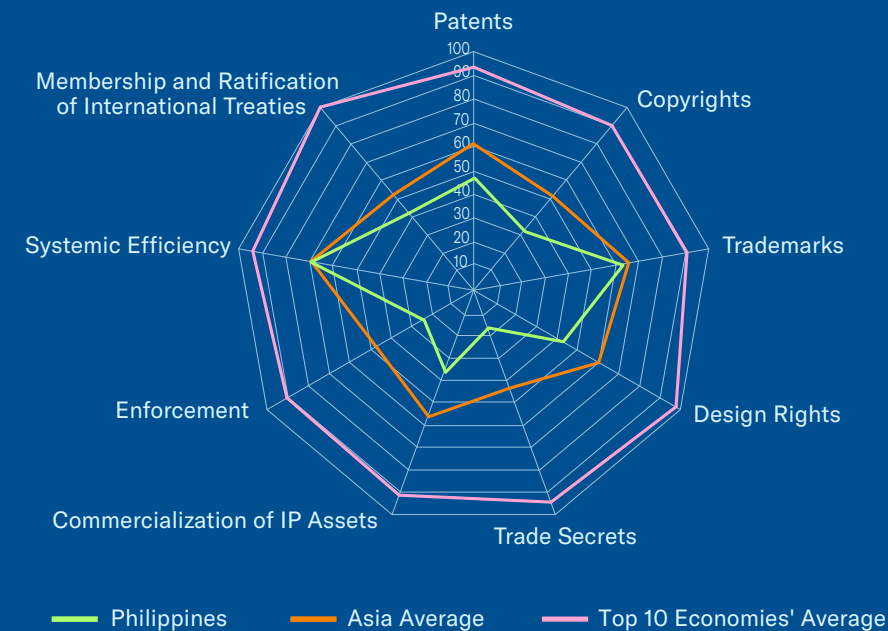
12. Expeditious injunctive-style relief and disabling of infringing content online: As noted over the past five editions of the Index, the national IP office INDECOPI has begun to more regularly act against infringing websites and has ordered the disabling of access to copyright-infringing materials. In 2017, INDECOPI ordered the suspension of access to the infringing website *Foxmusica*. Similarly, in 2019, the agency disabled access to six websites at the request of the Spanish soccer association *La Liga*. In the same year, INDECOPI also ordered the e-commerce platform *Mercado Libre* to remove the links to 28 ads offering counterfeit products linked to the Pan American Games. In 2021, the agency announced that it had ordered the disabling of access to 10 stream-ripping websites as well as several websites specializing in the unauthorized reproduction and illegal streaming of live sporting events, including professional soccer matches. This positive action has continued in 2022.

In July, INDECOPI ordered the suspension of access to 147 websites that provided direct or indirect access to copyright-infringing content. The agency also concluded new training and information-sharing agreements with both the International Federation of the Phonographic Industry and *La Liga*. Because of this continued and sustained level of copyright enforcement, the score on indicator 12 has increased by 0.25. This marks another

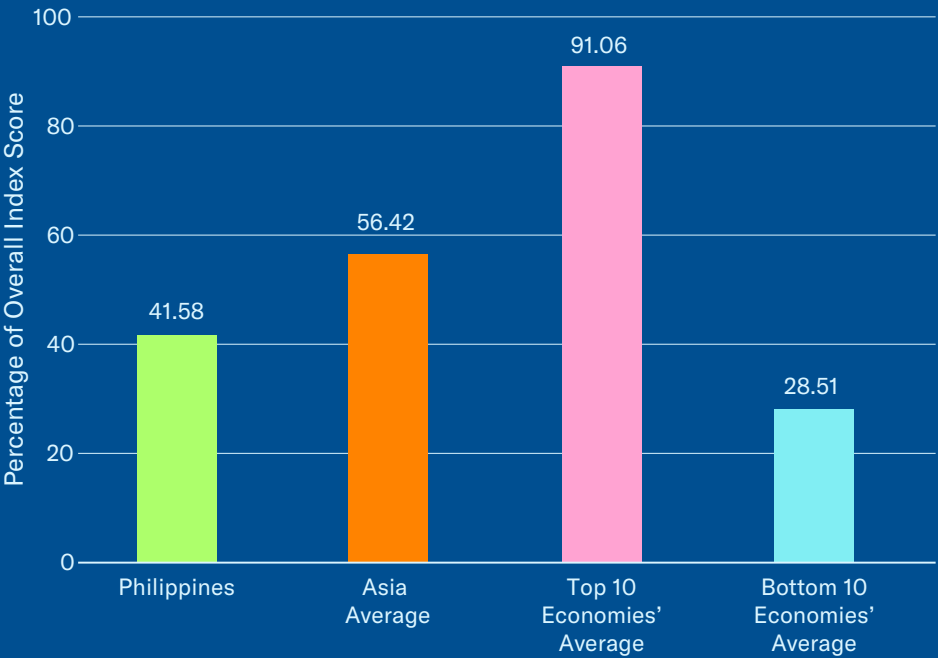
year of Peru's score improving in this category of the Index. Since the seventh edition of the Index, Peru's score in this category has increased by close to two-thirds, rising from 28.43% in the seventh edition of the Index to 46.29% in this year's edition. This is mainly because of INDECOPI's sustained effort at disabling access to infringing content. The Index commends the government of Peru and INDECOPI for this notable improvement.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- IPOPHL continued stronger IP enforcement efforts online in 2022
- 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
- BSA estimates software piracy to be at 64%



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	4.25	Category 6: Commercialization of IP Assets	2.17
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.25
3. Patentability of CIIs	0.50	28. Registration and disclosure requirements of licensing deals	0.25
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.25
5. Pharmaceutical-related enforcement	0.25	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	1.74
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.38
9. Patent opposition	0.50	33. Software piracy rates	0.36
Category 2: Copyrights, Related Rights, and Limitations	2.28	34. Civil and preceudural remedies	0.25
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.25	37. Effective border measures	0.00
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.25
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	3.50
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.75
Category 3: Trademarks, Related Rights, and Limitations	2.50	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	3.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.85	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 20.79			

Spotlight on the National IP Environment

Past Editions versus Current Score

The Philippines’ overall score remains unchanged at 41.58% (20.79 out of 50).

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

12. Expeditious disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; 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 Intellectual Property Office of the Philippines (IPOPHL) has expanded its powers of enforcement and is actively partnering with rightsholders to more effectively combat physical counterfeiting and online infringement. In 2021, IPOPHL adopted new rules through Memorandum Circular 2020-049. These changes explicitly recognize and include the electronic, online, or digital spheres within IPOPHL’s enforcement remit. Upon receiving a complaint about potential infringement, IPOPHL now has the power to order the termination of the infringing activity and, in the case of infringement taking place online or through electronic means, to refer the matter to the National Telecommunications Commission (NTC) for the disabling of access to the relevant online or electronic source. Instead of 60 days, alleged infringers now have 72 hours to comply with an IPOPHL enforcement order.

IPOPHL has also agreed on a new enforcement partnership with the NTC and a selection of the largest ISPs in the Philippines. Similarly, an agreement was reached between rightsholders, IPOPHL, and the leading Filipino e-commerce platforms Lazada and Shopee. Under a memorandum of understanding, all parties agreed to use a standardized notification process

whereby access to links and advertisements to suspected infringing goods would be disabled. These positive efforts have continued in 2022.

In April, IPOPHL signed new memorandums of understanding with several regional and international rightsholders, including the Asia Video Industry Association and the Motion Picture Association. The purpose of these agreements is to facilitate information sharing and the increased use of IPOPHL’s expanded authority to request the disabling of access to infringing web content through the NTC on a “rolling” basis. The greater use of injunctive relief and the disabling of access to copyright-infringing content through the introduction of a rolling or dynamic scheme would be a highly positive development and would result in further score increases following last year’s increase on indicators 12 and 13.

IPOPHL also announced the positive impact last year’s anti-counterfeiting agreement had on e-commerce. Across both Lazada and Shopee, rates of enforcement had increased, with the number of takedown requests and requests acted upon having increased by between 118% and 400%.

Finally, in July, the Philippine Congress passed the Philippine Creative Industries Development Act. The new law codifies the government’s commitment to the creative sector and its potential as an engine for economic growth and development. A key provision of the act is the establishment of a new Creative Industries Development Council that is to oversee and encourage the further development of the creative economy in the Philippines. The council is to include both public and private sector representation. Although the new law does not contain any revisions or strengthening of existing IP laws, it recognizes the centrality of IP rights to the creative sector. Specifically, under Section 7, Subsection D, the council is empowered



to “assist in the monitoring and protection of intellectual property rights of Filipino creative industry stakeholders.” The Index will continue to monitor these developments in 2023.

Enforcement; Membership and Ratification of International Treaties

37. Effective border measures; and 50. Post-TRIPS

FTA: Being a contracting party to key international IP treaties reflects a given economy’s broader participation in the international IP community and embracing of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adheres to established standards and best practices. Overall, the Philippines is a contracting party to five of the nine international treaties included in the Index: the WIPO Internet Treaties; the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Patent Cooperation Treaty; and the Convention on Cybercrime, 2001. The Philippines is not a contracting party to the Singapore Treaty on the Law of Trademarks; the Patent Law Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; or the Hague Agreement Concerning the International Registration of Industrial Designs.

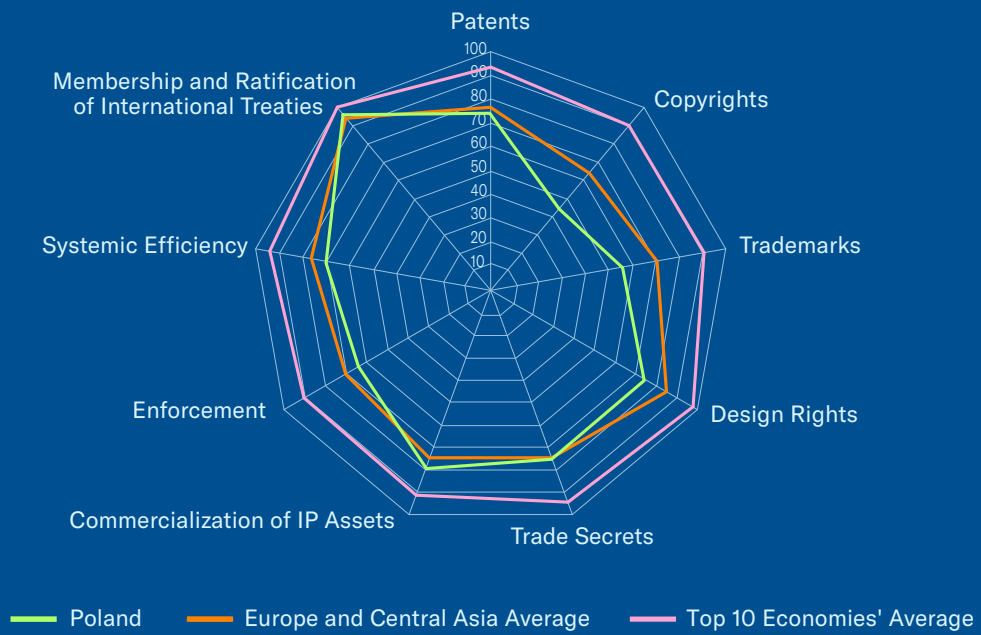
With respect to post-TRIPS international trade agreements with substantial IP rights provisions, the Philippines is a contracting party to the RCEP agreement. The RCEP agreement came into force on January 1, 2022. As of September 2022, the Philippines had not ratified the agreement. The RCEP as currently constituted does not conform to the modern standards of other post-TRIPS international trade agreements. It does not include or refer to modern standards of IP protection for important IP-intensive industries—including the life sciences sector and copyright-based industries—and no score has been allocated to the Philippines under this indicator. Nevertheless, the

RCEP references some important IP protections currently lacking in the Philippines. Specifically, it provides a clear and unambiguous requirement that border officials in all contracting parties have the right to take *ex officio* action against suspected infringing goods. Although positive, the RCEP does not include transshipped goods or goods in transit under such action.

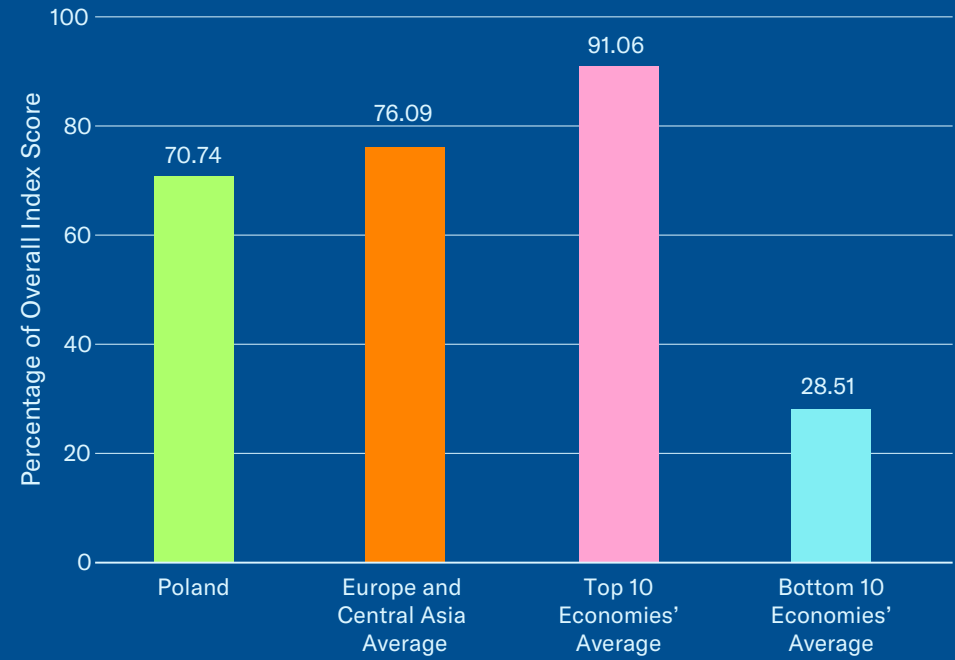
As noted in previous editions of the Index, existing Filipino statute and customs regulations do not provide clear *ex officio* authority for customs and border officials to proactively and regularly take *ex officio* action against suspected goods. Customs Administrative Order 06-2002 provides the rules and regulations for the Bureau of Customs to act against IP infringing goods. It implements relevant provisions of both the IP Code and TRIPS Agreement. The order outlines the primary process, which is to guide customs seizure activity against IP-infringing goods, which is the registration of relevant IP rights with the Bureau of Customs. The order offers the possibility for IP rightsholders who have not registered their relevant IP rights to request seizure action to be taken, but this is only to be allowed in “meritorious cases” and in ports outside of Manila. The order also allows, but does not require, that customs officials carry out “random checks.” But this does not amount to *ex officio* authority. Subsequent orders have not expanded or further defined this power in relation to goods intended for the domestic Filipino market or in transit. Should this provision of the RCEP agreement be incorporated into existing Filipino statute, it would result in a score increase on indicator 37. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- R&D tax incentives are in place
- 2018 transposition of EU Trade Secrets Directive harmonizes Polish trade secret law with EU standards
- Legal framework for IP protection is 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 the 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	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 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. TPM and DRM	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 and 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 and 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
Total: 35.37	

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	4.46
32. Physical counterfeiting rates	0.67
33. Software piracy rates	0.54
34. Civil and preceudural remedies	0.50
35. Preestablished 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, ct 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

Spotlight on the National IP Environment

Past Editions versus Current Score

Poland’s overall score remains unchanged at 70.74% (35.37 out of 50).

Area of Note

Poland is in the process of reforming various parts of its national IP environment, including statutory laws related to patents, design rights, and trademarks. At the time of research, no new laws had been enacted, but a draft Industrial Property Law was published by the Ministry of Economic Development and Technology in late spring of 2022. The draft sets out significant changes to the administration of the Polish national IP environment, including registration and maintenance fees, and seeks to further harmonize the existing legal framework with current EU standards. For example, under the proposed bill, definitions of industrial design and associated rights will be fully harmonized with the relevant European statute. Similarly, a new trademark opposition procedure modeled on EU standards is to be introduced. The proposed bill also includes a potentially significant change to the licensing environment in Poland. Under the old Industrial Property Act, the registration of licensing agreements is required for the agreement to be valid against third parties. Local legal analysis suggests that licensing agreements need to be submitted as part of the registration. Under the new draft law, this requirement appears to have been eliminated; Article 289 of the bill does not specify or include this language. Should this registration requirement be eliminated under law and in practice, Poland’s score on indicator 28 will increase. The Index will continue to monitor the legislative process and the development of a finalized bill in 2023.

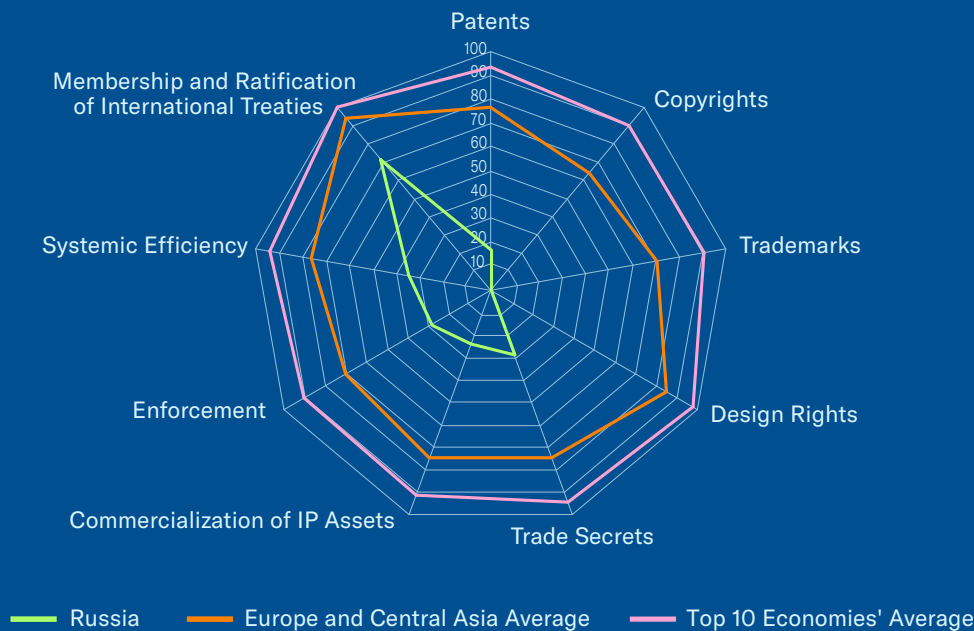
Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy: As detailed over the course of the Index, rightsholders face challenges in enforcing their copyrights in Poland. Polish copyright law provides standard exclusive rights for authors, but measures that target the digital and online sphere are more limited than in other EU Member States. Specifically, the legal framework on both notice and takedown and injunctive-style relief are underdeveloped. The Polish Act on Providing Services by Electronic Means (2002), which implements the E-Commerce Directive, provides limited liability for persons (including ISPs) who disable access to infringing stored data when a court or “other competent authority” has ordered it. The same mechanism exists if the ISP is made aware of the infringing stored data through a formal notice. However, there have been only some instances of courts enforcing this provision.

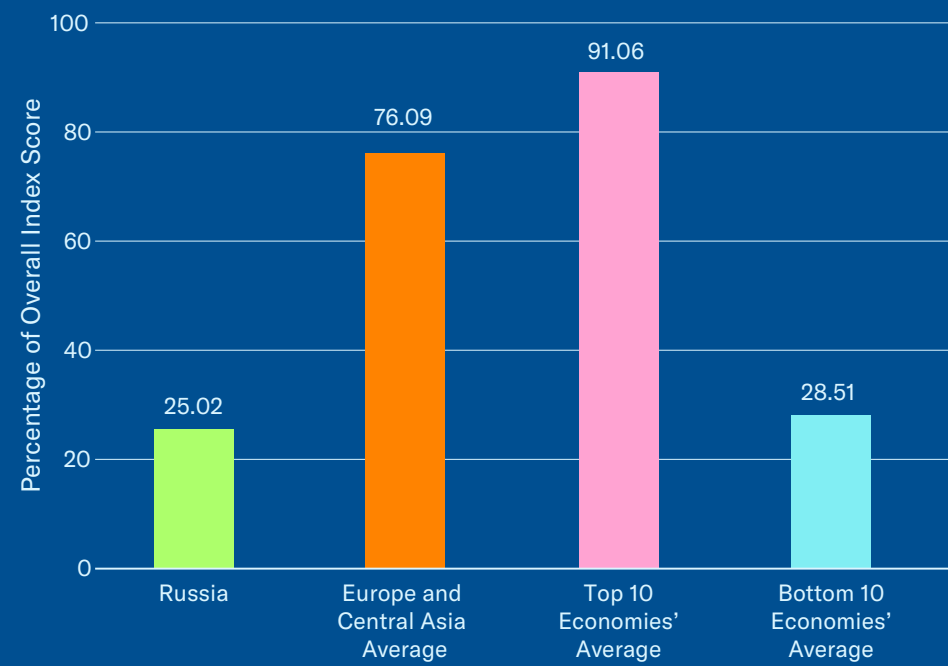
With respect to the transposition and implementation of EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive), the Polish government challenged the legality of the directive before the Court of Justice of the European Union (CJEU) and the responsibilities defined under Article 17. In 2022, the CJEU issued a final verdict rejecting the Polish challenge, declaring that “the obligations imposed on online content-sharing service providers in Article 17(4) of Directive 2019/790 do not disproportionately restrict the right to freedom of expression and information of users of those services.” At the time of research, it was unclear how the Polish government would respond and what any potential Polish transposition of the directive would look like. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- The past few years have seen new copyright laws passed, strengthening rightsholders' 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

- 2022 federal laws 46-FZ and 213-FZ nullify existing duly granted IP protection under Civil Code Part IV for all major IP rights covered in the IP Index
- Deep and abiding uncertainty over the extent to which rightsholders will, in practice, at any point in the future be able to register and enforce their IP rights in Russia
- Continued weakening of the 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: compulsory license issued in 2020 and new 2021 amendments to Civil Code Part IV broaden existing basis for action
- Administrative and regulatory barriers in place for licensing activities, including direct government intervention
- Increasingly punitive localization requirements targeting ICT and the biopharmaceutical sector
- 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



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	1.50	Category 6: Commercialization of IP Assets	1.42
1. Term of protection	0.00	26. Barriers to market access	0.00
2. Patentability requirements	0.00	27. Barriers to technology transfer	0.00
3. Patentability of CIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	0.00	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.25
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	1.99
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.36
9. Patent opposition	0.50	33. Software piracy rates	0.38
Category 2: Copyrights, Related Rights, and Limitations	0.00	34. Civil and preceudural remedies	0.00
10. Term of protection	0.00	35. Preestablished damages	0.00
11. Exclusive rights	0.00	36. Criminal standards	0.25
12. Injunctive-type relief	0.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.50
14. Limitations and exceptions	0.00	Category 8: Systemic Efficiency	1.75
15. TPM and DRM	0.00	39. Coordination of IP rights enforcement	0.25
16. Government use of licensed software	0.00	40. Consultation with stakeholders during IP policy formation	0.50
Category 3: Trademarks, Related Rights, and Limitations	0.00	41. Educational campaigns and awareness raising	0.25
17. Term of protection	0.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.00	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.00	Category 9: Membership and Ratification of International Treaties	5.00
20. Frameworks against online sale of counterfeit goods	0.00	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	0.00	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	0.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	0.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.85	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.60		
Total: 12.51			

Spotlight on the National IP Environment

Past Editions versus Current Score

Russia’s overall score has decreased from 46.64% (23.32 out of 50) in the tenth edition to 25.02% (12.51 out of 50). This reflects score decreases on indicators 1, 2, 3, 4, 7, 10, 11, 12, 13, 15, 17, 18, 19, 21, 22, 23, 27, 34, and 35.

Area of Note

Over the course of 2022, the Russian government has made significant negative changes to its national IP environment, affecting most major IP rights benchmarked in the Index. To begin with, under Federal Laws 46 and 213, Decrees 79, 81, 95, 299, and 322, and Decree Order 430, the Russian government has targeted the IP rights of rightsholders and of entities or organizations “associated with foreign states who commit unfriendly actions against Russian legal entities and individuals.” This includes either the suspension or severe restriction of the payment of licensing fees, royalties, and any other associated payments in relation to the use of a patented technology, utility model, or industrial design. Specifically, Decree 322 restricts rightsholders’ ability to receive and remit funds abroad and also outlines how preexisting licensing payments should be made. Although the decree exempts certain industries, including food products, medicines, and medical equipment, it limits the ability to remit funds outside of Russia and denominates all transactions to be in Russian rubles.

Decree 299 targets potential royalty payments to rightsholders for compulsory licenses. Specifically, the decree has reduced the amount of compensation to be paid to relevant rightsholders in cases whereby a compulsory license is issued under Article 1360 of the Civil Code Part IV. As detailed in previous editions of the Index, the compulsory licensing regime in Russia has been

expanded in recent years. In 2021, the Russian Duma passed, and President Putin signed into law fresh amendments to the Civil Code Part IV. These changes amended Article 1360 and inserted a further justification for the overriding of any granted rights related to patents, utility models, and industrial designs. The Russian government now has exceptionally broad powers of justification to issue a compulsory license and override duly granted IP protections.

More broadly, in March 2022, the Russian government adopted Federal Law No. 46-FZ. Article 18, Subsection 13 of the law effectively suspends any protection under the Russian Civil Code for, what was at the time still to be determined and defined, groups of IP-based goods and services. The law sweepingly states that “a list of goods (groups of goods) in respect of which certain provisions of the Civil Code of the Russian Federation on the protection of exclusive rights to the results of intellectual activity expressed in such goods, and the means of individualization with which such goods are marked, cannot be applied.” In June 2022, President Putin signed into law amendments to Article 18 of the law through Federal Law No. 213-FZ. These amendments appear to further broaden the suspension of IP rights under the Civil Code Part IV by stating that “It is not a violation of the exclusive right to the results of intellectual activity or means of individualization, the use of the results of intellectual activity, expressed in goods (groups of goods), the list of which is established in accordance with clause 13 of part 1 of this article, as well as the means of individualization with which such goods are marked.”

At the end of March, the Russian government issued Resolution 506 (signed by Prime Minister Mishustin). This resolution appears to limit the suspension of protection under the Civil Code



Part IV to Articles 1359(6) and 1487, both of which relate specifically to parallel imports and Russia’s preexisting legal regime with respect to the national exhaustion of IP rights. However, government resolutions are subordinate regulatory and administrative legal mechanisms. They do not carry the force of statutory Russian federal law, and they can be revoked or altered at any time. Subsequent government announcements throughout 2022 have clarified the goods that are subject to the parallel importation regime. At the time of research, this list was still subject to change, but as currently constituted, the list included a broad range of consumer goods products, medical goods, automotive parts, electronics, and other staple goods. As a result of these actions, there is deep and abiding uncertainty over the extent to which rightsholders will, in practice, at any point in the future be able to register and enforce their IP rights in Russia. Federal laws 46-FZ and 213-FZ not only nullify existing duly granted IP protection in Russia on a discriminatory basis but pose substantial health and safety risks to Russian consumers through the adoption of a wholesale regime of parallel importation. As a result of these actions, the scores on indicators 1, 2, 3, 4, 7, 10, 11, 12, 13, 15, 17, 18, 19, 21, 22, 23, 27, 34, and 35 have been reduced to 0. The Index will continue to monitor these developments in 2023.

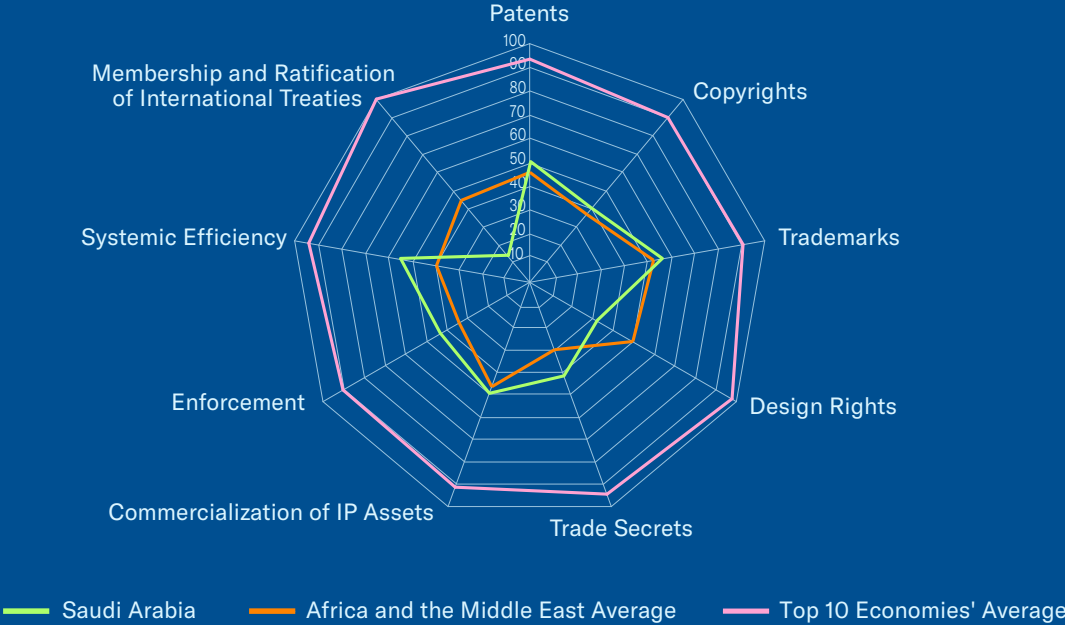
Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism: Despite the broader suspension of IP rights across Russia over the past year, as noted earlier, the Federal Service for Intellectual Property (ROSPATENT) reiterated its commitment to the development of a register of the current exclusivity status of registered biopharmaceutical products in 2022. Since 2019, Russian authorities have discussed the introduction of an administrative mechanism linking the approval of a follow-on medicine with the expiration of the exclusivity of a reference

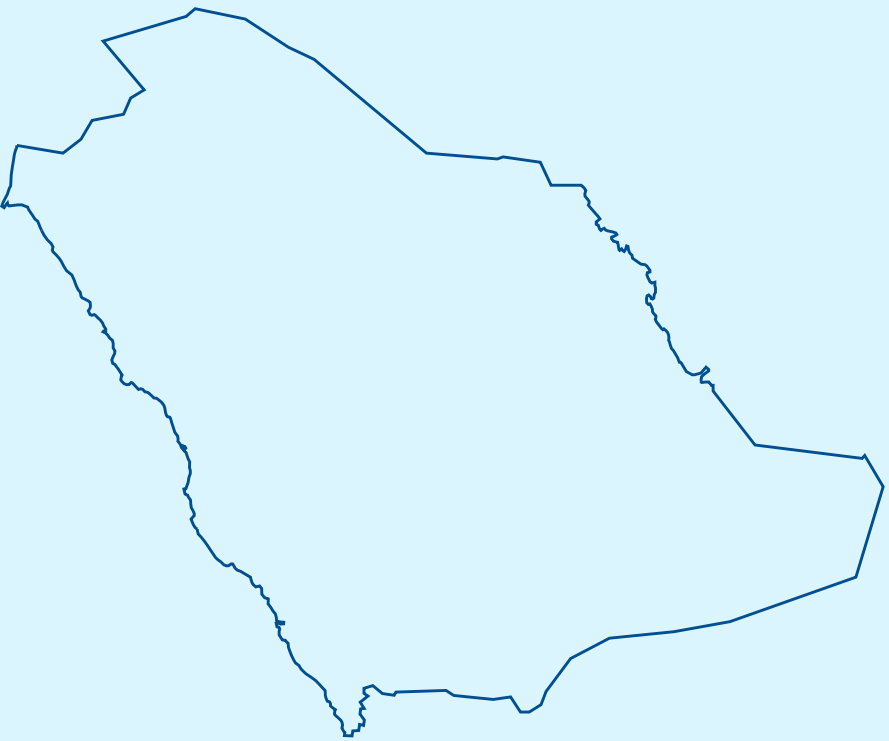
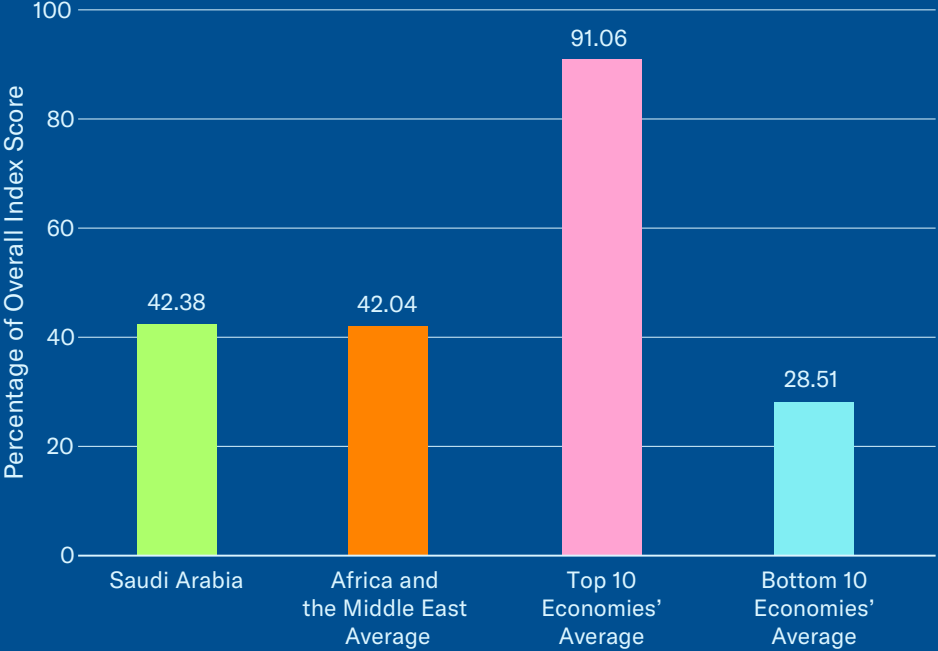
product. As noted last year, although a positive development, at the time of research, there was still no primary or secondary legislation outlining what the pre-marketing patent enforcement mechanism would look like. Given the broader deterioration in Russia’s biopharmaceutical IP environment, the introduction of a functioning linkage regime that provides rightsholders 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 Russia and would result in a score increase on this indicator.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- SAIP continues to assume leadership on IP policy and enforcement; marked increase in online copyright and trademark enforcement in 2021-2022
- SAIP has put in place an ambitious reform agenda and is revamping the administration of the Kingdom's national IP environment
- SAIP is leading and coordinating IP enforcement on 2021 National Committee for the Enforcement of Intellectual Property Rights
- Joined multiple PPHs in 2019-2020
- Increased consultation and awareness-raising activities in 2019
- 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 SFDA actions in 2017
- Significant gaps in copyright legal framework, chiefly relating to protections 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



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	4.50	Category 6: Commercialization of IP Assets	3.00
1. Term of protection	1.00	26. Barriers to market access	0.50
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	0.75	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	3.01
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.48
9. Patent opposition	0.75	33. Software piracy rates	0.53
Category 2: Copyrights, Related Rights, and Limitations	2.78	34. Civil and preceudural remedies	0.50
10. Term of protection	0.53	35. Preestablished damages	0.00
11. Exclusive rights	0.50	36. Criminal standards	0.50
12. Injunctive-type relief	0.75	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.50
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	2.75
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.50
Category 3: Trademarks, Related Rights, and Limitations	2.25	41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	1.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	0.00
Category 4: Design Rights, Related Rights, and Limitations	0.65	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.25	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.50		
Total: 21.19			

Spotlight on the National IP Environment

Past Editions versus Current Score

Saudi Arabia’s overall score has increased from 41.38% (20.69 out of 50) in the tenth edition to 42.38% (21.19 out of 50). This reflects score increases on indicators 12 and 20.

Area of Note

In January 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 accept patent applications. The announcement was unexpected because the GCC patent application route had been operational for more than two decades. This was followed up with an announcement by the GCC Secretariat in April 2021. Under this announcement, new amendments to the GCC Patent Regulation were issued whereby a new regional application pathway would replace the old regulation. Under this system, the regional GCC patent was abolished. Instead, future patent applications will be routed through individual GCC member states. Once granted by the GCC Patent Office, relevant patents will be valid only in the underlying national jurisdiction. This system was formalized in late 2021 with the issuing of new Implementing Regulations. The Index will continue to monitor these developments in 2023.

Additionally, in December 2022, Saudi’s Crown Prince launched a new National Intellectual Property Strategy for the Kingdom. The Strategy includes four pillars: IP creation, IP administration, IP commercialization, and IP protection. The Strategy notes the importance of effective IP standards to spurring innovation and creativity, fostering economic growth, and attracting great investment in the Kingdom. Through the Strategy, the Saudi government seeks to achieve the goals included in Vision 2030, including

improving the Kingdom’s position in the Global Competitiveness Index by 2030. The Index will monitor the implementation of the Strategy in 2023.

Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism: In November 2022, the Saudi FDA in cooperation with the Saudi Authority for Intellectual Property (SAIP) published “The Procedure to Deal with Patents When Registering Generic Products in Saudi Food and Drug Authority (SFDA)”. This document outlines a new procedure to be followed by the SFDA when registering a follow-on drug application. The procedure states that follow-on applicants must submit a statement (Annex 1) stating that the follow-on application does not infringe any existing IP rights. This declaration is to be accompanied by a “Freedom to operate” analysis and certification that no outstanding patent exclusivity is in place by an IP agent licensed by SAIP.

The publication of this new procedure is a positive move by the SFDA. If implemented and applied in practice, it would address some of the uncertainty rightsholders have faced since 2019. However, the new procedure does not, strictly speaking, introduce a “linkage” regime, whereby a drug regulatory authority conditions the approval of a follow-on biopharmaceutical product on there being no relevant period of market exclusivity in place for the underlying reference product. The procedure does not contain a notification mechanism to the relevant rightsholders or an automatic stay period ensuring a period in which any dispute can be resolved before the approval and launch of the follow-on product.

The linking of the approval of follow-on biopharmaceutical products to the exclusivity status of a reference product is an effective way



of achieving a balance between the protection of pharmaceutical exclusivity (usually but not always through patent protection) and stimulating early market entry of follow-on generic products. Linkage ensures that any disputes are resolved before 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 because 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 rightsholders with a meaningful and real ability to stop follow-on products from being launched when a granted term of exclusivity is in place would be a substantial improvement to the biopharmaceutical IP environment in Saudi Arabia. The Index will monitor these developments in 2023.

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

12. Expeditious disabling of infringing content online; and 20. Availability of frameworks that promote action against online sale of counterfeit goods: As noted over the course of the Index, rightsholders have historically faced significant challenges in protecting their copyrighted content and trademarks in Saudi Arabia. Relevant laws and regulations are not well developed, and the

illicit use of IP-infringing material has remained high. With respect to copyright, current Saudi law provides for only basic exclusive rights and protection of creative works. Although 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 more specifically address the issue of online infringement.

Historically, the Ministry of Culture and Information has sporadically disabled access to web content, including copyright-infringing content, but this has been on an ad hoc basis. Consequently, estimated rates of physical and online piracy have remained high. For example, the estimated rate of software piracy by the Business Software Alliance for 2018 was 47%; only a small change from the 2009 estimated rate of 51%. Similarly, with respect to the protection of brands and trademarks, enforcement has historically been a challenge. As noted in the past few editions of the Index, this may now be changing. Since its inception in 2017-2018, SAIP has worked on improving the national IP environment and rightsholders’ ability to enforce their rights more effectively. In 2019, SAIP announced that over 160 cases of alleged copyright infringement had been referred to the relevant Saudi enforcement authorities and that fines and penalties had been imposed. SAIP has also made the disabling of access to infringing content (copyright and trademark related) part of its enforcement remit. SAIP offers a portal through which rightsholders can directly communicate any suspected online infringement. SAIP will then take enforcement action. In 2020, SAIP announced that it had disabled access to 231 websites from which infringing content was disseminated. These efforts have continued in 2021-2022.

In May 2022, SAIP released its annual enforcement report for 2021. For the calendar year, SAIP received just over 1,200 complaints from rightsholders (1,023 for potential copyright infringement and 194 for alleged trademark infringement) and disabled access to over 2,000 websites from which infringing content was disseminated. SAIP also made over 6,000 in-person visits to physical stores to investigate the dissemination and sale of IP-infringing goods. This activity has continued in 2022.

At the time of research, SAIP had released enforcement statistics for the first half of the year. During this period, SAIP had disabled access to over 3,000 websites from which infringing content was disseminated and conducted over 5,000 physical in-person visits. The Index commends SAIP and the Saudi government. This is yet another positive step taken by the SAIP to offer rightsholders an effective and practical route of IP enforcement in Saudi Arabia. As a result, the scores on indicators 12 and 20 have increased by 0.25, respectively.

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 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 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 through the use of “indirect reliance” on submitted clinical research data. International standards and best practices for RDP are 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, SAIP released new draft implementing regulations on how confidential commercial information will be protected in Saudi Arabia. Although SAIP should be applauded for publishing these draft regulations, holding a public consultation, and inviting stakeholder feedback on the matter, as noted in the Index at the time, the regulations themselves were deeply flawed and stood outside established international standards of RDP. Specifically, Article 4(1) of the regulations stated that any term of protection offered in Saudi Arabia would begin on “the date of the first registration of the preparation *in another country*. [Emphasis added]” If applied in practice, this would dramatically rewrite existing regulations and significantly curtail rightsholders’ effective RDP term. The introduction of such a definition and the linking of the exclusivity period in Saudi Arabia to a product’s first global launch would severely limit the availability of RDP in Saudi Arabia and undermine the incentives for innovation and investment such exclusivity provides. Moreover, the draft regulations did not allow a period of RDP for new indications. As noted in the Index, when the draft regulations were published, 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. In a positive step, the U.S. State Department’s 2022 *Investment Climate Statement* noted that SAIP and SFDA have reaffirmed their support for the availability of regulatory data protection in the Kingdom. The Index will continue to monitor these developments in 2023.



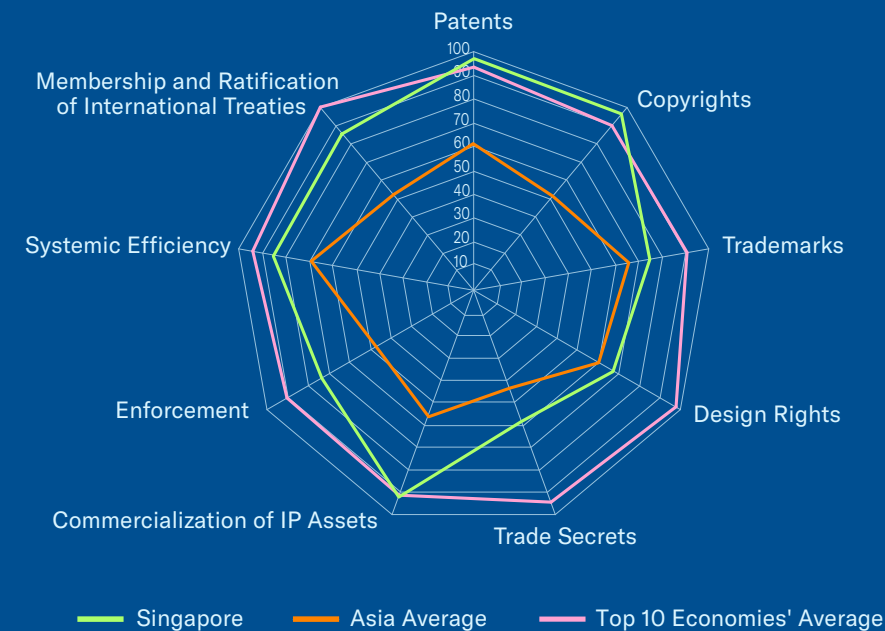
Commercialization of IP Assets and Market Access

26. Barriers to market access: There is a strong focus in Saudi economic and industrial policy on increasing rates of local content and local employment in all sectors of the economy. Increasing local content is a key tenant of the *Vision 2030* program and applies horizontally to all industrial and service value chains. Since the launch of the Vision, some IP-intensive sectors have been targeted, including biopharmaceuticals with, for example, key targets of the *National Transformation Plan*, including goals of substantially increasing the value of local biopharmaceutical manufacturing.

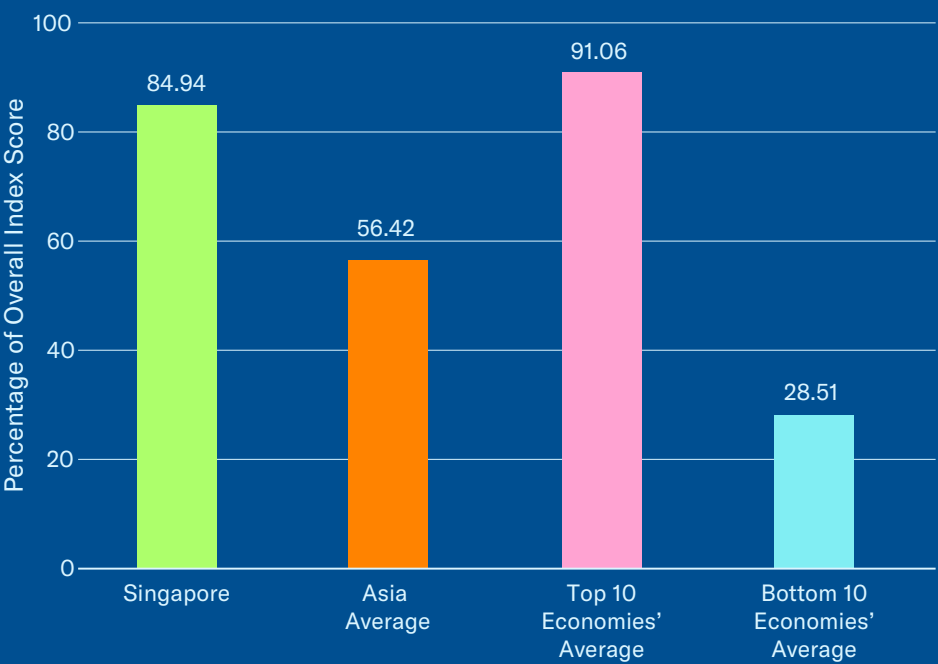
With respect to data localization, there has historically not been a general data localization policy in place or undue restrictions on the international transfer of data. However, this may now be changing. In late 2021, Saudi Arabia enacted the “Personal Data Protection Law.” The law imposes several new requirements, including the potential localization and local storage of data. As a general rule, Article 29 of the law disallows the transfer of any data from Saudi Arabia to another legal jurisdiction unless under highly specific circumstances. Such circumstances include the preservation of life; the protection of public health; existing Saudi international treaty obligations; or circumstances yet to be defined and identified by relevant Saudi regulators. Furthermore, the level of data protection must be at least equivalent in the host jurisdiction as under current Saudi law, and the transfer must be approved by the relevant Saudi authorities. At the time of this research, the implementation of the new law had been postponed to March 2023. For rightsholders across many different industries and sectors, these potential barriers to digital trade raise serious questions and concerns. The Index will monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- New Copyright Act contains substantial liability provisions relating to sale and distribution of set-top boxes
- Implementation of R&D and IP tax incentives scheme in 2019
- Advanced national IP framework in place
- Global leader in online copyright enforcement—continued strong efforts in 2022
- Singapore is an 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% but is still high for developed high-income economy
- Lack of transparency and data on customs seizures of IP-infringing goods



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.75	Category 6: Commercialization of IP Assets	5.50
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	1.00	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	5.13
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.65
9. Patent opposition	0.75	33. Software piracy rates	0.73
Category 2: Copyrights, Related Rights, and Limitations	6.74	34. Civil and preceudural remedies	1.00
10. Term of protection	0.74	35. Preestablished damages	1.00
11. Exclusive rights	1.00	36. Criminal standards	0.75
12. Injunctive-type relief	1.00	37. Effective border measures	0.75
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	0.25
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	4.25
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.00	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	6.00
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.35	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.75	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
Total: 42.47			

Spotlight on the National IP Environment

Past Editions versus Current Score

Singapore’s overall score has increased from 84.44% (42.22 out of 50) in the tenth edition to 84.94% (42.47 out of 50). This reflects a score increase on indicator 15.

Copyrights, Related Rights, and Limitations

14. Scope of limitations and exceptions to copyrights and related rights: As noted in last year’s Index, other amendments included in the Copyright Act relate to current and new exceptions to copyright. To begin with, the new act changes the limitations and exceptions regime from a “fair dealing” framework to one of “fair use.” The new law also provides additional definitions of what constitutes an exception and limitation to copyright. For example, one positive change included in the new law is a clarification on the extent to which text and data mining is allowed for research purposes. This is an important area of future economic activity, as advances in computational power and new technological advancements in artificial intelligence (AI) and machine learning allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. However, as noted last year, the effect of other exceptions is less clear cut. Specifically, Section 204 broadens existing educational exceptions to include digital materials found online. Under the new law, educational institutions and students are now, as a general rule, able to use any and all materials found on the internet without seeking the explicit permission from the rightsholder. Given the vast quantity of information available online—much of it made available through illicit means and without rightsholders’ permission or even their knowledge—there is a clear risk that this exception will lead to a greater use of infringing materials. The act includes some limitations on the exception. For

instance, under Subsection 204(2)(g), if users are made aware that the material is of an infringing nature, there is a clearly defined obligation to cease the use of the material and to take reasonable actions to prevent its further communication to the public. Likewise, through Subsection 204(2)(f), an indirect access control measure is also in place in the sense that works accessed on the internet can only be circulated through the network that is operated by or through an educational institution and which access is limited to staff and students. Still, it remains unclear how effective the limitations on this usage would be in practice. The Index will continue to monitor these developments in 2023.

15. Technological protection measures (TPM) and Digital rights management (DRM) legislation: Since 2016, the Ministry of Law and the Intellectual Property Office of Singapore (IPOS) have held public consultations on potential changes to the Copyright Act. In 2019, the two agencies released the report *Singapore Copyright Review Report*, which summarized the findings of the preceding three years’ work and the result of these consultations. As the report rightly pointed out, the world of 2019 is very different from 1987 when the Copyright Act was enacted: “Technological and market changes in the digital age have significantly affected how creative works are created, distributed, and consumed.” The *Copyright Review Report* made several recommendations on changing both the substance and more technical and operational aspects of Singapore’s copyright regime. Specifically, the *Report* recognized some of the remaining legal gaps with respect to enforcement capabilities and set-top boxes in Singapore. As in many other economies benchmarked in the Index, Singapore has seen an explosion in the growth and use of these physical boxes and the internet-based applications that provide users with copyright-infringing content. Conclusion 16 of the *Report*

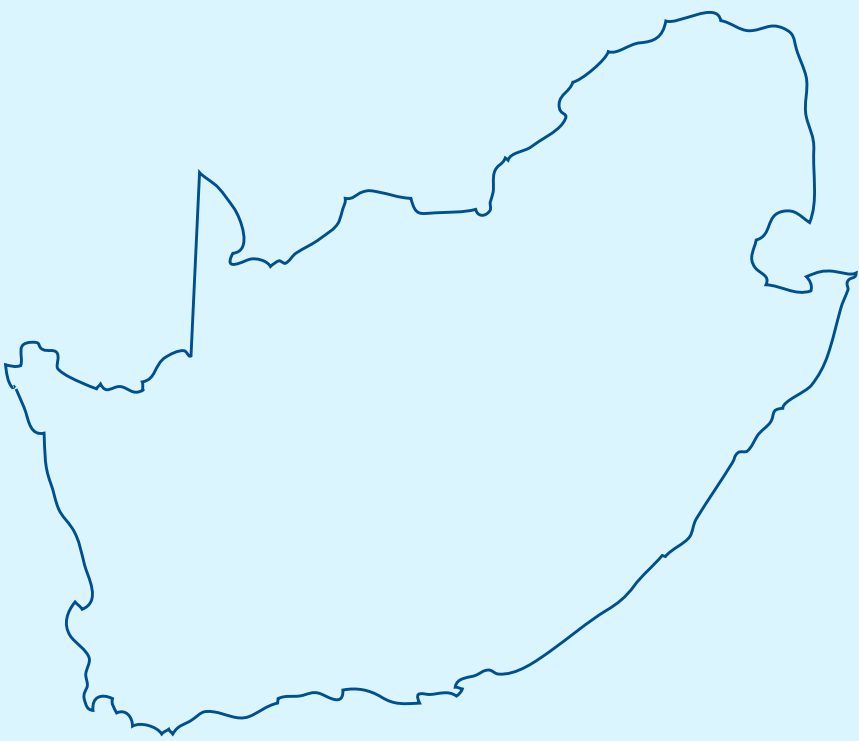
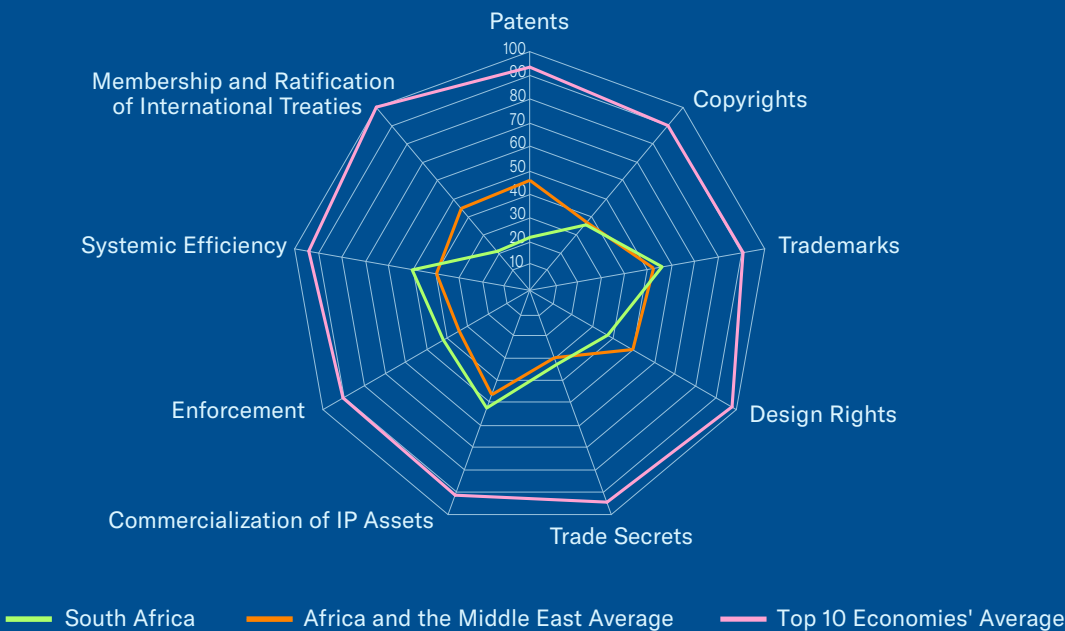


recommended passing new legislation that would introduce civil and criminal liability on any persons who “willfully make, import for sale, commercially distribute, or sell” such set-top boxes.

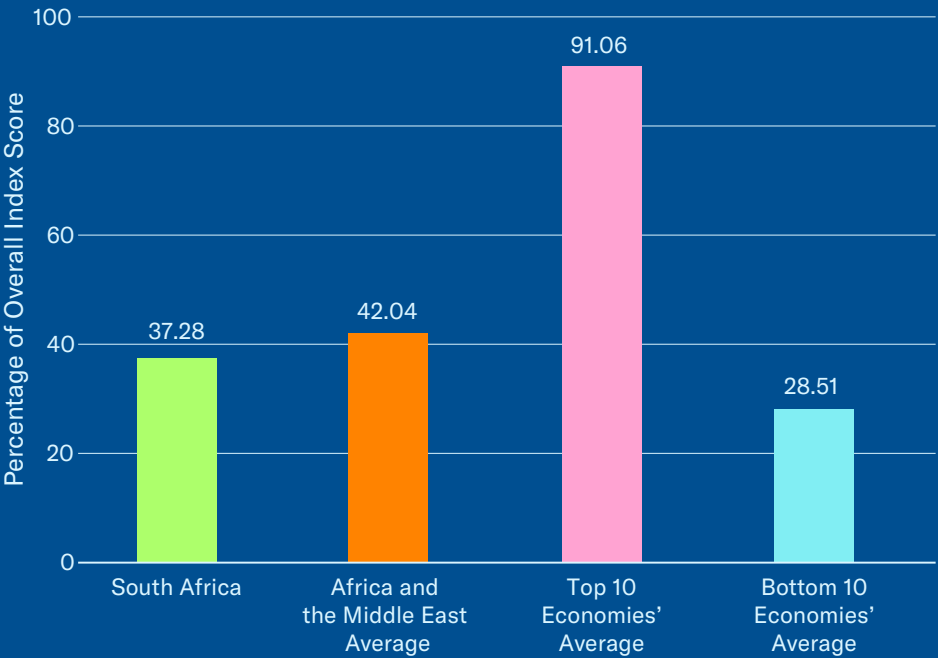
After another set of stakeholder consultations in 2020-2021, a draft Copyright Act was published by the Ministry of Law with a final bill passed and in effect since December 2021. The new Copyright Act adopts many of the *Report’s* recommendations and contains substantial liability provisions relating to the sale and distribution of set-top boxes. Specifically, Section 150 now criminalizes the infringement of copyright through the act of making, selling, or distributing a physical device or related service that can be used to illicitly access copyrighted material. Under Section 447, anyone convicted of infringement under Section 150 is liable for a fine of between SGD100,000 and SGD200,000 (USD70,000-USD100,000) and/or imprisonment of up to five years. As a result of this positive action, the score on this indicator has increased by 0.25.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2021 Cyber Crime Act strengthens potential criminal sanctions for the misappropriation and illicit accessing of trade secrets and confidential information
- Basic IP framework in place
- Relatively low level of software piracy—32%—compared to other African economies

Key Areas of Weakness

- Growing emphasis on localization and local content requirements in economic and industrial policy
- *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 the restricting of patentability of pharmaceuticals
- Proposed copyright amendments create uncertainty for rightsholders through expansive “fair use” definitions
- Major gaps in laws and enforcement across all categories of the Index



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	2.00	Category 6: Commercialization of IP Assets	3.17
1. Term of protection	1.00	26. Barriers to market access	0.50
2. Patentability requirements	0.00	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.25
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	2.94
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.51
9. Patent opposition	0.00	33. Software piracy rates	0.68
Category 2: Copyrights, Related Rights, and Limitations	2.53	34. Civil and preceudural remedies	0.50
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.50	36. Criminal standards	0.50
12. Injunctive-type relief	0.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.50	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	2.50
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.25
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.75
Category 3: Trademarks, Related Rights, and Limitations	2.25	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	1.50
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	0.50
Category 4: Design Rights, Related Rights, and Limitations	0.75	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.50	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.00	48. Membership of the Convention on Cybercrime, 2001	0.50
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.50	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 18.64			

Spotlight on the National IP Environment

Past Editions versus Current Score

South Africa’s overall score remains unchanged at 37.28% (18.64 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); 14. Scope of limitations and exceptions to copyrights and related rights; and 15. Technological protection measures (TPM) and Digital rights management (DRM) legislation: As discussed in previous editions of the Index, South Africa has over the past decade been engaged in reforming its copyright framework with draft amendments considered for both the Copyright Act and the Performers’ Protection Act. In 2019, a bill was approved by both the National Assembly and the National Council of Provinces and was sent to President Ramaphosa for his assent. However, the president refused to sign the draft law, citing its potential unconstitutionality, and sent it back to the National Assembly for further review. In 2021, this draft bill was formally rescinded by the National Assembly, and the legislative process started again. A fresh set of stakeholder consultations were held in late 2021 and early 2022 by the Department of Trade, Industry and Competition, and a new draft law was passed by the National Assembly in June 2022. At the time of research, the president had not signed any finalized piece of legislation into law. As the Index has detailed since the first draft amendments were published, the proposed legislation has always suffered from several serious deficiencies. South African policymakers correctly identified the need to modernize the existing copyright laws; this remains as true today as in 2015 when the efforts began. Unfortunately,

none of the draft amendments, including the latest iteration, fundamentally address the current shortcomings in South Africa’s copyright regime. Instead, they add more uncertainty and potential difficulties for rightsholders. Most notably, all draft amendments have been consistent in their aim to introduce a new, more expansive system of exceptions and limitations to copyright.

For many years, there has been a lack of clarity in South Africa on what constitutes infringement of copyright and what is fair reproduction and use, with no relevant full definition in the current Copyright Act and only limited case law. All draft copyright amendments have expanded the current exceptions regime. The latest drafts have introduced a new general doctrine of “fair use” exceptions to all copyrighted work as well as several remarkably broad statutory exceptions and limitations, particularly for educational use. Exceptions and limitations to copyright should be considered against the three-step test embodied in the Berne Convention and the WTO TRIPS Agreement. Yet, as noted by the Index throughout the review of the draft law, it was always unclear how the new exceptions and proposed system of fair use would work in practice without negating the exclusive rights of copyright owners and imperiling the legitimate markets for creative works.

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



draft legislation still does not include additional enforcement measures, such as the disabling of access through an injunctive-style relief program.

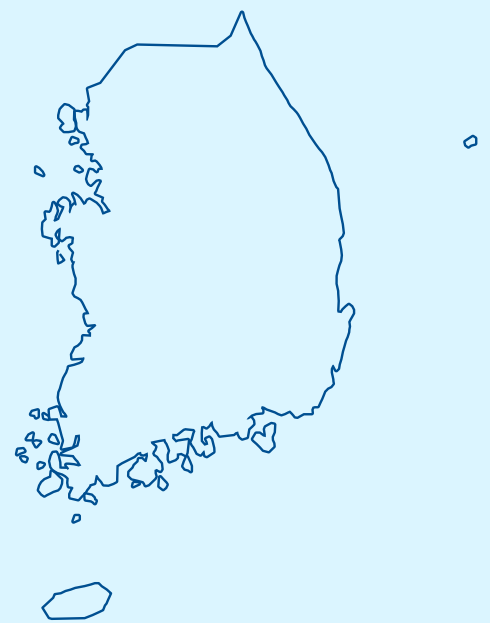
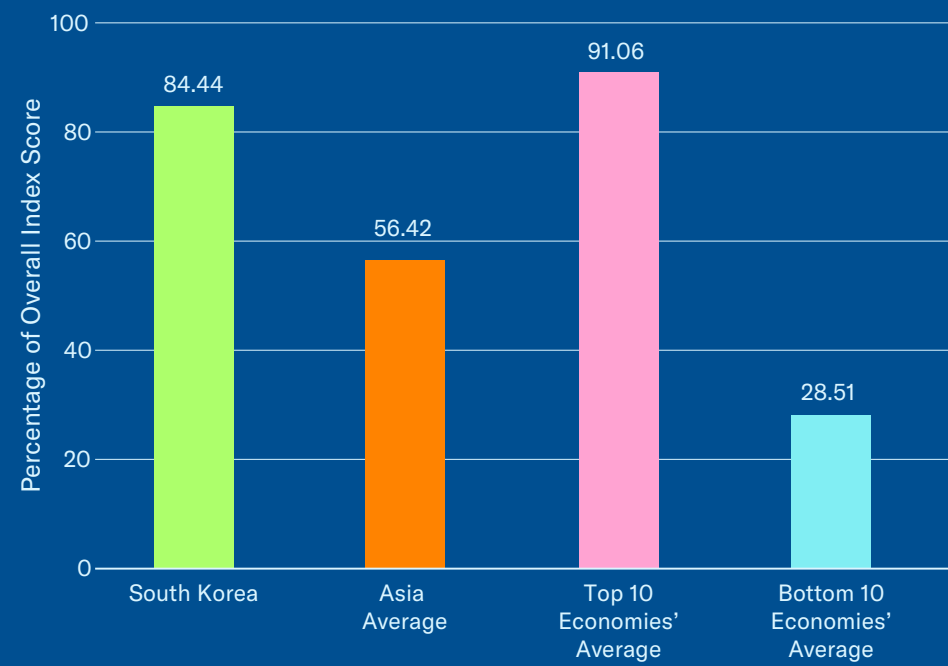
The past decade has seen a sharp increase in the number of economies that use judicial or administrative mechanisms to effectively disable access to infringing content. South Africa would be well served to introduce a similar mechanism to combat online piracy. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Increasingly active stance toward combating online piracy; stands as an example to southeast Asia and emerging markets
- Amendments to the Unfair Competition Prevention and Trade Secret Protection Act in 2020 strengthened criminal sanctions for trade secret theft
- Amendments to the Patent Act and Unfair Competition Prevention and Trade Secret Protection Act in 2020 strengthened the basis for which damages can be awarded for patent and trade secret infringement
- Patenting standards are in line with international best practices
- Relatively robust legal framework for trademark and design protection
- Membership in Global PPH and IP5 and new post-grant patent opposition mechanism streamline the patent office
- KIPO provides SMEs with a variety of educational and technical assistance programs as well as the 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.50	Category 6: Commercialization of IP Assets	3.42
1. Term of protection	1.00	26. Barriers to market access	0.50
2. Patentability requirements	1.00	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.25
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	6.16
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.73
9. Patent opposition	1.00	33. Software piracy rates	0.68
Category 2: Copyrights, Related Rights, and Limitations	5.99	34. Civil and preceudural remedies	0.75
10. Term of protection	0.74	35. Preestablished damages	1.00
11. Exclusive rights	1.00	36. Criminal standards	1.00
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.75	Category 8: Systemic Efficiency	5.00
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.75	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	5.50
20. Frameworks against online sale of counterfeit goods	1.00	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.80	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	0.80	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.10	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.75	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.75	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.60		
Total: 42.22			

Spotlight on the National IP Environment

Past Editions versus Current Score

South Korea's overall score has increased from 83.94% (41.97 out of 50) in the tenth edition to 84.44% (42.22 out of 50) in the eleventh edition. This reflects a score increase on indicator 42.

Copyrights, Related Rights, and Limitations

Over the past decade, South Korea has taken an increasingly active stance toward combating online piracy. In 2009, amendments to the Copyright Act introduced a graduated warning system operated by the Ministry of Culture, Sport, and Tourism and the Korean Communication Commission (KCC). Under the law, the KCC sends three sets of notices to infringing users and online service providers and can order the suspension of users' accounts for up to six months if an inadequate response is secured. Korea also has in place an administrative mechanism for responding to rightsholders' requests for removing access to infringing content online. The legal basis is found in Article 102(2)f of the Korean Copyright Act, which provides limited liability for ISPs that respond to a court or related administrative body order to delete or disable access to infringing content. This order comes from the KCC but is based on a request from the Korean Copyright Commission (which in turn responds to rightsholder notices of infringing content and sites). Industry reports suggest that more than 400 infringing websites have been disabled in Korea under this mechanism. A 2016 study by the Motion Picture Association found on average a 90% drop in visits to disabled sites within three months of an order to disable access. In addition, the data suggested a 15% drop in visits to infringing websites and a 50% reduction for peer-to-peer sites following three instances of disabling a given site.

The result of these reforms has been that copyright piracy in Korea has decreased substantially. This has been achieved at the same time as internet connectivity and speed have increased manifold with more Koreans than ever accessing content online. At the same time, the creative sector in Korea has flourished. For example, the 2012 WIPO commissioned study, *The Economic Contribution of Copyright-Based Industries in the Republic of Korea*, found that the copyright industries made a substantial contribution to both national economic output and employment. Looking at economic impact, this was estimated at 9.89% of total national economic output (gross domestic product) in Korea and 6.24% of total employment. More recent research suggests that the economic impact of Korea's cultural industries and the creative economy was substantial and valued at over USD12 billion in exports in 2019. As such, Korea stands as an example to southeast Asia and emerging markets around the world of what strong and consistent protection of copyright can achieve in terms of stimulating innovation, cultural production, and income-generating economic activity. In 2021, the Ministry of Culture, Sports and Tourism announced that Korea's copyright environment and the Copyright Act would be reformed. At the time of research, no formal legislative proposal had been revealed. The Index will continue to monitor these developments in 2023.

Commercialization of IP Assets

26. Barriers to market access: South Korea is a relatively open economy. No economy-wide mandatory localization requirements, significant or systematic import substitution policies, or bans are in place. Similarly, no policies are in place that mandate the sharing of proprietary technology or divulging IP assets as a precondition for full market access. There are, however, restrictions on foreign investment and ownership with some



sectors of the Korean economy completely closed off. For many other sectors, foreign investment is capped at a minority ownership amount.

As noted over the course of the Index, with respect to barriers to digital trade, Korea imposes several direct and indirect requirements that result in significant barriers to foreign entities. Relevant legislation, including the Personal Information Protection Act 2011, allows cross-border data transfers, but the conditions for consent and disclosure requirements are high. As the USTR noted in the 2022 *National Trade Estimate Report on Foreign Trade Barriers*, these “restrictions pose barriers to the cross-border provision of internet-based services that depend on data storage and processing services ... and effectively privilege Korean over foreign suppliers in any data-intensive sector without materially contributing to privacy protection.” Local storage requirements for the public sector are also in place under the 2015 Promotion of Cloud Computing and Protection of Users Act and the Cloud Security Assurance Program. These cloud storage restrictions effectively mean that non-Korean entities are *de facto* unable to participate in the Korean government’s recently announced plans for a full digital migration.

Further sector-specific data transfer and storage restrictions are also in place for financial services, satellite mapping, and payment services. For rightsholders 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 consumers interact socially and economically. In virtually all industries, business and economic interaction is 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 “big data.”

Combined with increased computing capacity and the application of new technologies (such as artificial intelligence and machine learning) that allow us to analyze and better understand data collected, there is the possibility to make significant discoveries and breakthroughs in virtually any area of research and human socioeconomic activity. Cross-border data flows are ingrained in countless services relied on by consumers and businesses with numerous digital, automated, and virtual services relying on the seamless movement and storage of data in various locations. Public policies related to national data management must recognize this reality and be formulated accordingly. Whether directly or indirectly, the *de jure* or *de facto* mandating of local data storage and processing is likely to lead to fewer digital services being available in South Korea and less innovation in many critical sectors, including IP- and knowledge-intensive industries. The Index will continue to monitor these developments in 2023.

Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs: As has been noted across the Index, South Korea has historically had a strong focus on the creation and commercialization of IP as an economic asset through government economic innovation and industrial policy. This is particularly pronounced within R&D-intensive industries, such as technology, ICT, and biotechnology, where Korea’s public and private sectors have both invested significant resources in building world-leading infrastructure and incentives to innovate and commercialize new IP assets.

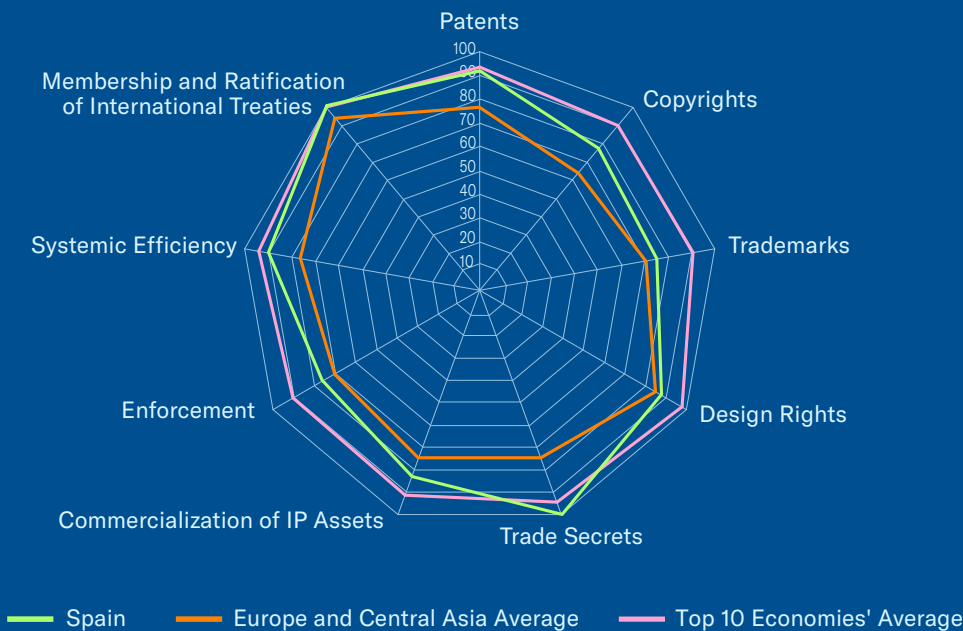
The Korean government actively promotes the creation, registration, and commercialization of IP assets by SMEs. The Korean Intellectual Property Office (KIPO) provides SMEs with a variety of educational and technical assistance programs, and reduced filing fees are available for qualifying SMEs. Technical assistance programs

include support to export-oriented SMEs in developing and exploiting their IP rights, with the goal to foster “Global IP Star” companies. KIPO also hosts IP training at regional IP centers (corporate capacity building on leveraging of IP) and IP talent sharing and training projects. Depending on the business area, type of technology, or type of entity, qualifying SMEs can also apply for accelerated patent examination.

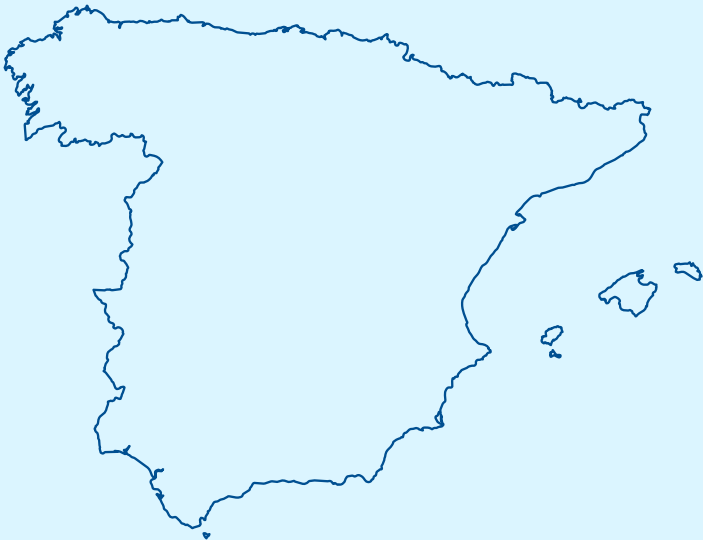
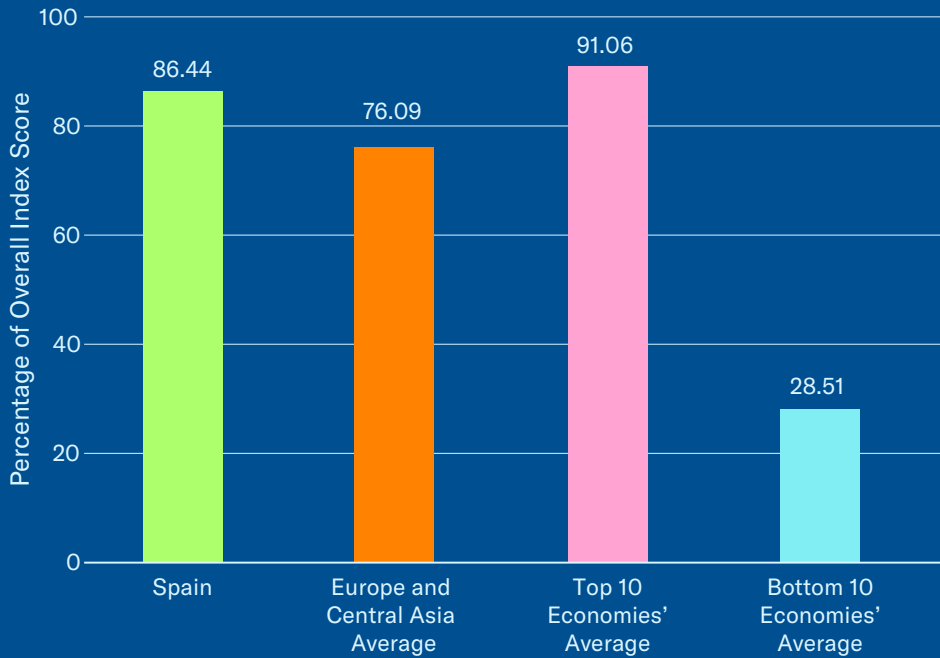
The criteria for inclusion have been expanded in recent years and now cover a broad range of entities, including companies that focus on specific technologies—for example, green technologies and technologies related to the fourth industrial revolution—as well as business type. The latter today includes entities that are engaged in export promotion or qualify as a “venture business” or other defined entity under the Invention Promotion Act. The results of these efforts can be seen in the growth of patent applications by SMEs. According to KIPO’s latest annual report, SMEs have seen the largest increase in total IP registration applications for all major IP rights in Korea over the past two years. In the two-year period before the COVID-19 pandemic (2018-2019), SMEs accounted for 26.6% of all applications. In the two-year period since the outbreak of the pandemic (2020-2021), SMEs now account for 29.8% of all applications. Looking at individual IP rights, the increases are even larger. For example, with respect to patent applications, the growth in the number of applications was just under 25%. This compares to a growth rate of 8.3% for the category “large enterprises.” Similarly, looking at applications for trademark registration, the growth in the number of applications by SMEs dwarfs that of larger companies by 43.7% to 15%. As a result of these positive efforts, the score on this indicator has increased by 0.25.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Royal Decree-Law 24/2021 transposes EU Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive)
- 2021 Protocol to Strengthen the Protection of Intellectual Property Rights further strengthens Spanish enforcement efforts
- 2019 trade secret law is operational—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
- Advanced IP system in place as an EU Member State
- Sector-specific rights are 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 the EU’s research and IP-based biopharma industry
- Counterfeiting and piracy levels remain high compared to other EU economies—software piracy estimated at 42%



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.25	Category 6: Commercialization of IP Assets	5.00
1. Term of protection	1.00	26. Barriers to market access	0.75
2. Patentability requirements	1.00	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	5.34
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.76
9. Patent opposition	1.00	33. Software piracy rates	0.58
Category 2: Copyrights, Related Rights, and Limitations	5.38	34. Civil and preceudural remedies	0.75
10. Term of protection	0.63	35. Preestablished damages	0.50
11. Exclusive rights	0.75	36. Criminal standards	0.75
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.75	Category 8: Systemic Efficiency	4.50
15. TPM and DRM	0.75	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.00	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	0.75	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.75	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	3.00	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	1.00	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 43.22			

Spotlight on the National IP Environment

Past Editions versus Current Score

Spain’s overall score has increased from 85.94% (42.97 out of 50) in the tenth edition to 86.44% (43.22 out of 50). This reflects a score increase on indicator 13.

Copyrights, Related Rights, and Limitations

13. Availability of frameworks that promote cooperative action against online piracy: As noted over the course of the Index, for many years, the protection of copyrighted material online has been a serious challenge for rightsholders in Spain. Historically, most digital content accessed has been infringing, with the consumption of unauthorized content particularly visible in the areas of TV, gaming, and sports. To address these challenges, the Spanish government has since the early 2010s embarked on a series of copyright reform efforts, including significant legislative changes and stronger enforcement at both the administrative and judicial levels. Key changes include amendments to the Intellectual Property Act and the Criminal Code in 2014-2015, introduction of the Sinde Act of 2012, and several royal decrees. The Sinde Act created a notification regime whereby the Spanish Intellectual Property Commission may receive notices from copyright owners and determine which should be sent on to relevant ISPs, who then should either disable access to the identified content within 72 hours of the notice or have the case brought before a court of law. The powers of the commission and of this administrative enforcement route have been strengthened over the past few years, and today, the commission has the power to close a webpage for up to one year without a judicial order.

Substantial fines have also been introduced in cases of noncompliance. At the same time, as the commission has expanded its administrative

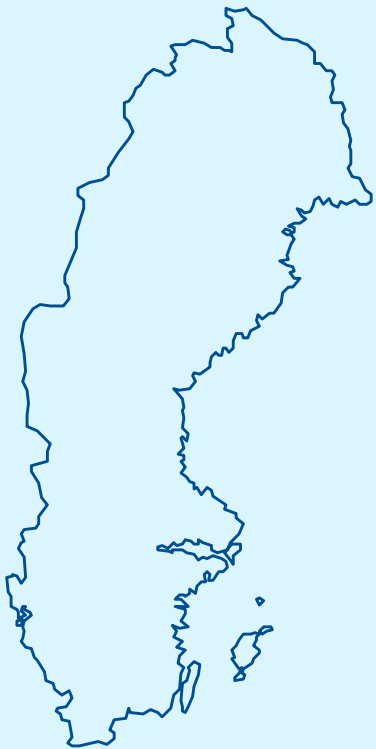
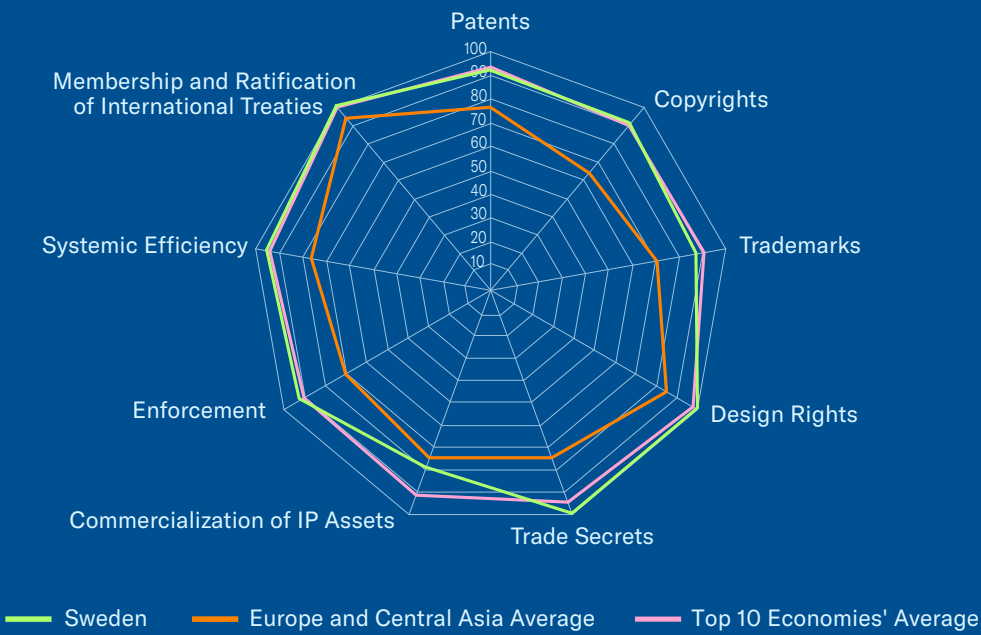
remit and enforcement efforts, there have been stronger enforcement efforts through Spanish courts. Like in many other EU Member States, rightsholders in Spain are now able to effectively seek redress through the judiciary. Over the past few years, Spanish courts have issued several orders to ISPs in relation to sites linking to pirated content, including The Pirate Bay.

In 2021, a new “Protocol to Strengthen the Protection of Intellectual Property Rights” was signed by representatives of the content industry and representatives for the largest telecommunications service providers in Spain. The purpose of the protocol is to improve existing enforcement procedures and to specifically address the issue of mirror sites.

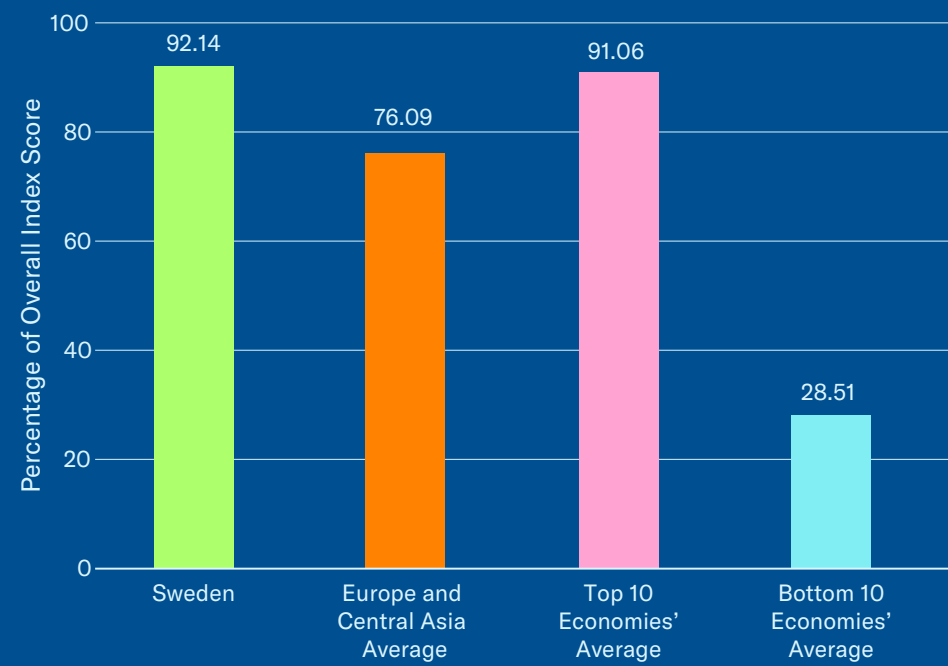
Finally, like many other EU Member States, Spain has for the past three years been in the process of transposing and implementing EU Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). In late 2021, Royal Decree-Law 24/2021 was issued by the government and came into force. This omnibus decree transposed the CDSM Directive into Spanish law, including relevant amendments to underlying copyright legislation. The decree broadly follows the scope of the EU Directive, particularly with regard to responsibilities and requirements under Article 17. The decree maintains existing exceptions and limitations provided under Spanish and European copyright law and jurisprudence, and it also strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. The decree provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability. As a result of this transposition, the score on this indicator has increased by 0.25.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2021 accession to Convention on Cybercrime
- Strong and sophisticated national IP environment
- Online copyright enforcement has improved over the past few years with stronger police enforcement and precedent-setting court decisions on ISP responsibility
- 2020 case law 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 the EU's research and IP-based biopharma industry



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.25	Category 6: Commercialization of IP Assets	4.75
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	6.47
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.91
9. Patent opposition	1.00	33. Software piracy rates	0.81
Category 2: Copyrights, Related Rights, and Limitations	6.35	34. Civil and preceudural remedies	0.75
10. Term of protection	0.60	35. Preestablished damages	1.00
11. Exclusive rights	1.00	36. Criminal standards	1.00
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	0.75	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	4.75
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.50	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	2.00	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	3.00	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	1.00	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 46.07			

Spotlight on the National IP Environment

Past Editions versus Current Score

Sweden's overall score remains unchanged at 92.14% (46.07 out of 50).

Copyrights, Related Rights, and Limitations

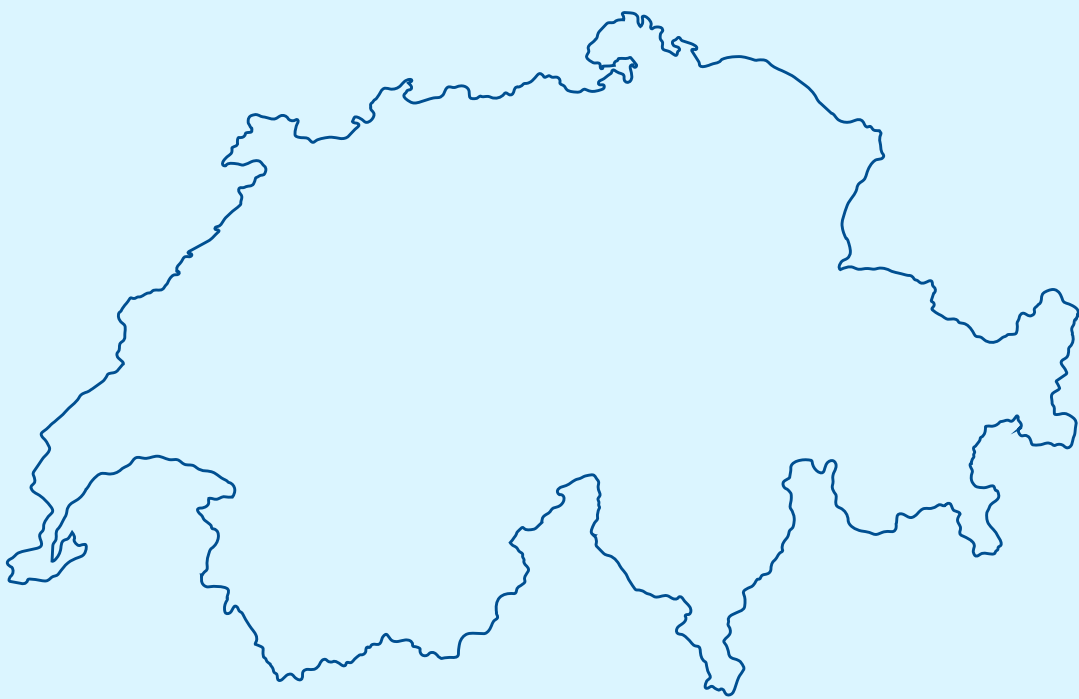
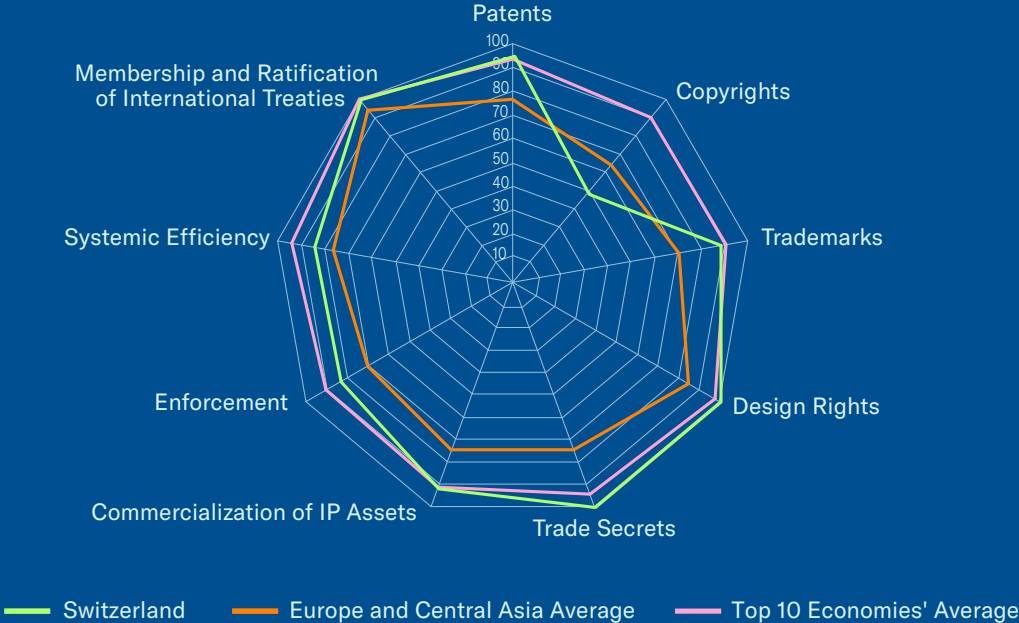
13. Availability of frameworks that promote cooperative action against online piracy: As has been detailed in previous editions of the Index, like all other EU Member States, Sweden has for the past three years been in the process of transposing EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive). A first draft of the implementing law was published in late 2021 by the Ministry of Justice, with a final draft published in July 2022. The draft law broadly follows the scope of the underlying directive, particularly regarding responsibilities and requirements under Article 17. The law maintains existing exceptions and limitations provided under Swedish and European copyright law and jurisprudence, and it also strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. It provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability. One positive change in the proposed law is a clarification on the extent to which text and data mining are allowed for research purposes. This is an important area of future economic activity, as advances in computational power and new technological advancements in AI and machine learning allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. At the time of research, the draft law had not been enacted and was still under review. The Index will continue to monitor these developments in 2023.

Commercialization of IP Assets and Market Access

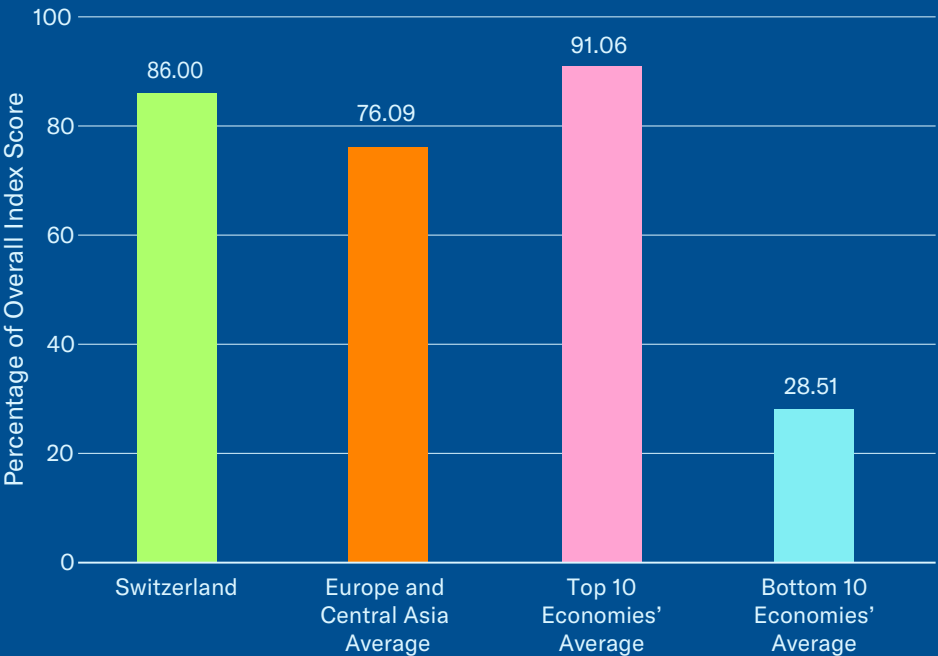
31. Tax incentives for the creation of IP assets: Swedish tax law does not offer any targeted R&D or IP-specific tax incentives. No general R&D tax incentive or patent or IP box incentive exists. Instead, the Swedish tax code offers a complex tax credit for social security charges related to R&D staff. These charges can be reduced by about 10% per qualifying employee. In this respect, Swedish tax law stands in contrast to the majority of European economies included in the Index, most of which have clear R&D tax incentives in place and dedicated patent or innovation boxes that provide tax relief on qualifying income. In fact, several European economies have introduced such measures in the past few years. For example, in 2020, Germany introduced a new R&D tax incentive law allowing qualifying entities to be reimbursed a portion (up to 25%) of qualifying R&D expenditure. Similarly, in 2019, Switzerland introduced both an R&D super deduction and a patent box regime based on OECD guidelines. Should Sweden introduce similar measures, its score on this indicator would improve.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2019 R&D and IP tax incentives 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

- 2020 copyright law amendments only partially address issue of online infringement; do not include option to disable 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.50	Category 6: Commercialization of IP Assets	5.50
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	5.87
8. Membership of a Patent Prosecution Highway	1.00	32. Physical counterfeiting rates	0.83
9. Patent opposition	1.00	33. Software piracy rates	0.79
Category 2: Copyrights, Related Rights, and Limitations	3.38	34. Civil and preceudural remedies	0.75
10. Term of protection	0.63	35. Preestablished damages	0.75
11. Exclusive rights	0.50	36. Criminal standards	0.75
12. Injunctive-type relief	0.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	0.50	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	4.25
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	3.50	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	2.00	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	3.00	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	1.00	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
Total: 43.00			

Spotlight on the National IP Environment

Past Editions versus Current Score

Switzerland’s overall score remains unchanged at 86.00% (43.00 out of 50).

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. However, in 2020, new copyright law amendments became law. As the Index has noted throughout this drawn-out legislative process, 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 introduced new measures to fight piracy. Specifically, the amendments require ISPs to both remove and keep infringing content off their servers. Article 39d of the Copyright Act inserted 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 has publicly stated that this requirement 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 law also attempted to address the issue of the 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. However, as the Index also noted at the time, this does not apply to civil proceedings, which, under the new law, can be filed only once criminal proceedings have commenced. Furthermore, the amendments did 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 to include the downloading and sharing of infringing content, as confirmed by the Swiss government and existing case law. 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, no distinction is made regarding whether 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 to this day. Indeed, the Federal Institute of Intellectual Property clearly stated at the time of enactment of the 2020 amendments that the changes to Swiss copyright law did 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 remains unclear what the legal consequences, if any, will be for internet



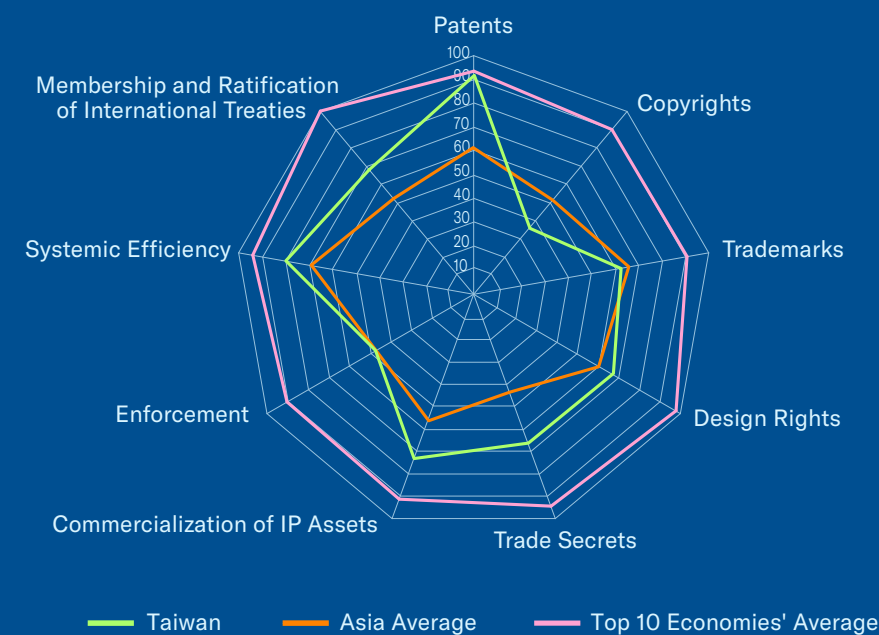
hosts that fail to comply with the conditions of Article 39d or under what circumstances a refusal to comply with the law is acceptable.

In sum, the reforms remain a real missed opportunity for rightsholders in Switzerland and internationally. Although the amendments addressed some of the shortcomings in the existing legal framework, they did not fundamentally change the dynamics of copyright enforcement and online piracy in Switzerland. Notably, the amendments did not include any requirement or option for the disabling of access to illegal content whether through the judiciary or an administrative mechanism.

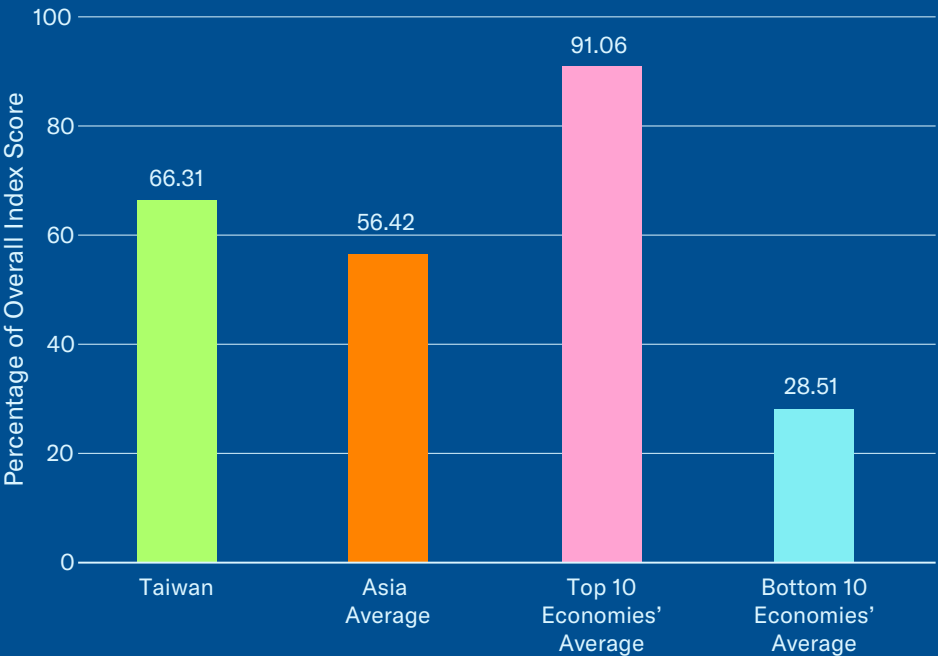
The past decade has seen a sharp increase in the number of economies that use judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the UK, India, Singapore, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, the UK, and Canada. These limitations and questions about the ultimate effectiveness of the Swiss amendments and rightsholders’ ability to enforce their rights remained unaddressed in 2022. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Continued strong support for SMEs developing IP assets through TIPO fast-track examination procedure and expanded technical assistance
- 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
- Although 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; 2022 Copyright Act amendments do not fundamentally address this
- New Copyright Act introduces unprecedentedly broad exceptions regime related to educational, personal use, and nonprofit copyright exceptions
- Relatively high rates of online piracy and physical counterfeiting



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	8.25	Category 6: Commercialization of IP Assets	4.42
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	0.75
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	1.00	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	3.36
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.45
9. Patent opposition	0.75	33. Software piracy rates	0.66
Category 2: Copyrights, Related Rights, and Limitations	2.53	34. Civil and preceudural remedies	0.50
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.25	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.75
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	4.00
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.75
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	1.00
Category 3: Trademarks, Related Rights, and Limitations	2.50	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.75
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	3.75
20. Frameworks against online sale of counterfeit goods	0.50	44. WIPO Internet Treaties	0.75
Category 4: Design Rights, Related Rights, and Limitations	1.35	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.00	48. Membership of the Convention on Cybercrime, 2001	0.50
23. Protection of trade secrets (civil remedies)	0.75	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.50
24. Protection of trade secrets (criminal sanctions)	0.75	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.50		
Total: 32.16			

Spotlight on the National IP Environment

Past Editions versus Current Score

Taiwan’s overall score has increased from 66.29% (32.15 out of 48.5) in the tenth edition to 66.31% (32.16 out of 48.5). This reflects a score increase on indicator 32.

Area of Note

In mid-2022, Taiwan passed amendments to most major IP laws, including the Patent Act, Copyright Act, Trademark Act, and the National Security Act, the latter of which relates to the protection of trade secrets and industrial espionage. The legislative package is in anticipation of Taiwan joining the CPTPP. As detailed here with respect to the most consequential changes, overall, this is a mixed package. Although some improvements have been made to Taiwan’s national IP environment—including the stiffening of criminal penalties for industrial espionage—the most substantive changes relate to the protection of copyright. As detailed here, these legislative changes raise more questions and concerns than provide solutions to Taiwan’s long-standing problems with the infringement of copyright. Covering 50 indicators across nine separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products. As the Taiwanese government and Legislative Yuan work on implementing these new laws and consider additional legislative changes, we encourage them to use the findings of the Index and accompanying Statistical Annex as a guide.

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; 14. Scope of limitations and exceptions to copyrights and related rights; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation: As has been noted over the course of the Index, rightsholders face significant challenges in protecting their content in Taiwan. The existing legal framework has major gaps, and enforcement remains inadequate. The Copyright Act has historically provided for standard exclusive rights, including reproduction and performance. In 2009, amendments to the Copyright Act introduced a notice-and-takedown mechanism including safe harbors for ISPs that remove access to infringing sites or forward notices from rightsholders to infringing users. However, much ambiguity surrounded how the mechanism should be implemented. For instance, it was not clearly defined what infringements ISPs should take action against, nor was it explained how ISPs should handle or respond to notices. In practice, although evidence suggests that local ISPs frequently respond to rightsholder notices, the law does not provide a mechanism for addressing foreign content, which has become major source of online piracy.

Efforts have been made on the ground to improve levels of enforcement, and relevant Taiwanese authorities have been active. A special IPR Police Force has been created, and the Taiwanese Intellectual Property Office (TIPO) has recognized copyright infringement as a major challenge and acted accordingly. 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.



The U.S. State Department has 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. In light of these challenges, amendments to the Copyright Act aimed at modernizing protection have been under review for close to a 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 provided under its fair use doctrine for education, libraries, software, and antenna systems. The proposed amendments also expanded criminal liabilities beyond possession or distribution of physical goods to works more broadly, including digital works. The proposed revisions were never acted upon by the Legislative Yuan and have remained dormant.

In 2019, smaller reforms were passed by the Yuan. Amendments to Articles 87 and 93 strengthen existing DRM and TPM provisions by punishing manufacturers, importers, and distributors of pirated TV boxes with up to two years imprisonment and/or a fine. In 2020 and 2021, this piecemeal reform effort continued with TIPO releasing for public comment a new batch of draft amendments and a finalized draft Copyright Act approved by the Executive Yuan.

In large measures, these amendments were passed in 2022. Although some provisions strengthen the enforcement framework, overall, these enacted amendments do not fundamentally change the dynamics of copyright enforcement and online piracy in Taiwan. To begin with, the most far-reaching changes in the new Copyright Act relate to the law's exceptions and limitations regime. Under revised Articles 44-63 and 65, the new legislation introduces an unprecedentedly broad exceptions regime related

to educational, personal use, and nonprofit copyright exceptions. Specifically, Articles 46, 46bis, 47, 51, and 55 seem to allow the wholesale use of copyrighted material for these purposes.

Such exceptions go well beyond the three-step test originating in the Berne Convention because they directly and materially affect a rightsholder's ability to exploit their work. These new exceptions also affect technological protection measures. Specifically, Article 80ter (9) allows the circumvention of technological protection measures if it is done in accordance or fulfillment with any of the exceptions outlined under the new exceptions and limitations regime. Given the new expansive definitions introduced for copyright exceptions related to education, personal use, and nonprofit entities, it would now appear that the circumvention of TPM and DRM protection in Taiwan is lawful if it is done by an educational institution or on a nonprofit basis.

A lack of clarity also exists regarding the protection of sound recordings and relevant exclusive rights attached to such performances under Article 26 and Article 26bis. Fundamentally, the 2022 amendments do not effectively address long-standing challenges, and Taiwan continues to lack many legal tools for more effective copyright enforcement. Specifically, although Article 100 now includes digital piracy as an actionable criminal offense not requiring a formal complaint—provided certain thresholds of estimated economic damage are met—the new Copyright Act does not include a defined and copyright-specific mechanism of injunctive-style relief whether through the judiciary or administratively.

The past decade has seen a sharp increase in the number of economies that use judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the UK, India, Singapore and a host of other economies have introduced measures that

allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, and the UK. They have proven to be effective in reducing the availability of copyright-infringing content within these jurisdictions.

Considering this, Taiwan's long and winding path to finally enacting changes to its Copyright Act feels like a lost opportunity. The Index and other industry stakeholders have for years documented the many challenges that rightsholders in Taiwan face in effectively enforcing their copyright, yet instead of improving the legal environment, the new amendments to the Copyright Act have arguably made a difficult situation even worse through the expansion of copyright exceptions and limitations. The Index will continue to monitor Taiwan's efforts to improve its copyright environment in 2023 and the extent to which enacted changes that affect indicators 14 and 15 have a negative impact on rightsholders in Taiwan.

Trade Secrets and the Protection of Confidential Information

24. Protection of trade secrets (criminal sanctions): As noted in previous editions of the Index, in 2019, the Taiwanese Legislative Yuan passed a new trade secrets law. The new law replaced the 2013 Trade Secrets Protection Act. It provided several important updates, including introducing criminal penalties for trade secret violations; stronger protection for foreign rightsholders; and better protection for confidential information during criminal investigations. Since the law's enforcement, criminal prosecution rates

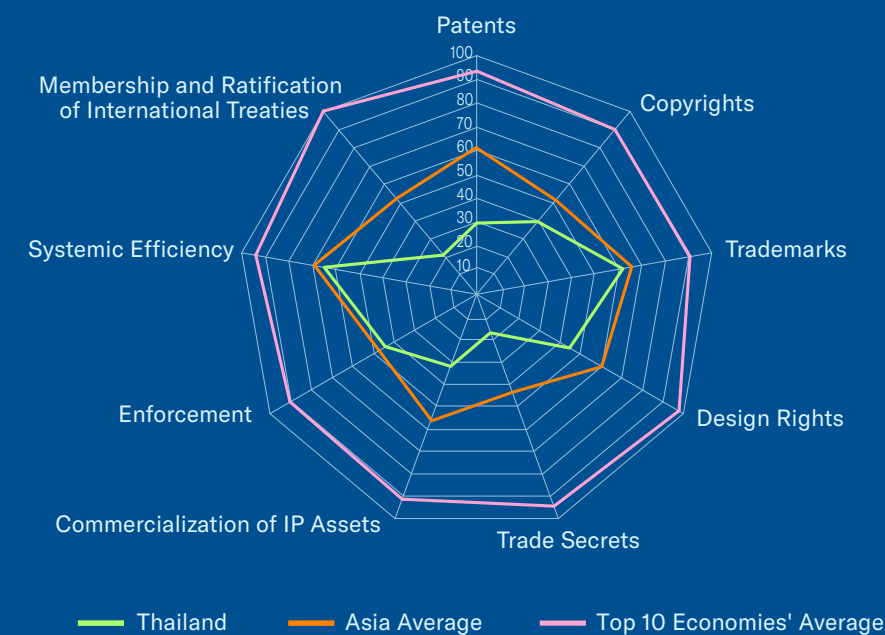
have increased. The protection of trade secrets and confidential information has been further enhanced by 2022 amendments to the National Security Act. The new law targets economic espionage of what are termed “national core technologies” and includes criminal sanctions of fines between TWD1 million and 100 million (USD30,000-3 million) and prison sentences of up to 12 years. The Index will monitor how this law is applied in 2023 and beyond.

Membership and Ratification of International Treaties

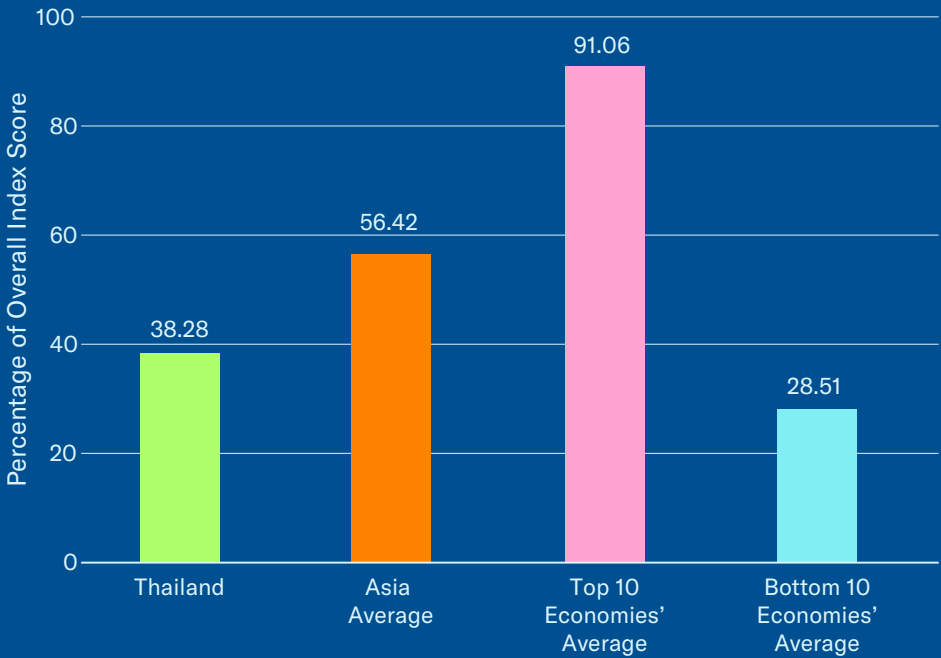
Taiwan is a full member of the WTO but is not eligible for membership in the UN or affiliated institutions, including WIPO. Taiwan is therefore unable to join and become a contracting party to any WIPO-administered treaty. Taking into consideration these political hurdles to Taiwan becoming a contracting party to many of the treaties included in the Index, since the fifth edition of the Index, Taiwan has 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 maximum score for Taiwan in this category is 5.5 and not 7. Overall, Taiwan's maximum available score in the Index is therefore 48.5, not 50.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2022 Copyright Act amendments introduce notice-and-takedown scheme and additional remedies for the circumvention of technological protection measures, including the manufacture, sale, rental, or importation of circumvention devices
- 2022 Thailand Research and Innovation Utilization Promotion Act (TRIUP) improves technology transfer environment
- Injunctive-style relief mechanism under Computer Crime Act used against trademark infringement in 2020
- Higher damages awarded in IP infringement proceedings in 2019 and 2020
- Customs Act amendments have resulted in greater anti-counterfeiting efforts against infringing goods in-transit in 2018 and 2019
- Thailand 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 the Thai government
- Basic level of protection and registration system in place for copyrights, trademarks, and designs

Key Areas of Weakness

- Inadequate patent protection and gaps in patentability for high-tech arts, including life sciences and CIIIs
- History of long patent backlogs
- Many sector-specific IP rights are missing, including patent term restoration for biopharmaceuticals and RDP
- History of the use of compulsory licensing for biopharmaceuticals
- High physical counterfeiting and digital piracy rates—software piracy estimated at 64%
- Limited participation in international treaties



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	2.72	Category 6: Commercialization of IP Assets	1.92
1. Term of protection	1.00	26. Barriers to market access	0.00
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.00
4. Plant variety protection	0.72	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	3.07
8. Membership of a Patent Prosecution Highway	0.50	32. Physical counterfeiting rates	0.48
9. Patent opposition	0.00	33. Software piracy rates	0.34
Category 2: Copyrights, Related Rights, and Limitations	2.78	34. Civil and preceudural remedies	0.25
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.50	37. Effective border measures	0.75
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.75
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	3.25
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	0.50	40. Consultation with stakeholders during IP policy formation	0.50
Category 3: Trademarks, Related Rights, and Limitations	2.50	41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	1.50
20. Frameworks against online sale of counterfeit goods	0.75	44. WIPO Internet Treaties	0.50
Category 4: Design Rights, Related Rights, and Limitations	0.90	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
Total: 19.14			

Spotlight on the National IP Environment

Past Editions versus Current Score

Thailand’s overall score has increased from 35.78% (17.89 out of 50) in the tenth edition to 38.28% (19.14 out of 50). This reflects score increases on indicators 13, 15, and 27.

Area of Note

As noted in the Index, Thailand is currently in the process of reforming various parts of its national IP environment, including statutory law, implementing regulations, and IP office examination manuals. As detailed here, in 2022, many of these draft changes were passed into law in a new Copyright Act. Revisions to the Patent Act have also been ongoing for years with several iterations of draft proposals put forward since 2018. At the time of research, reports suggest a draft Patent Act was being finalized. Key changes would include measures to reduce processing times and the current backlog by streamlining the registration process. The draft changes are also set to include important changes to the protection of design rights in anticipation of Thailand’s accession to the Hague Agreement. As the Thai government and the National Assembly pursue a program of national IP rights reforms, we encourage them to use the findings of the Index and accompanying Statistical Annex as a guide in 2023 and beyond.

Copyrights, Related Rights, and Limitations

13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation: As has been noted over the course of the Index, rightsholders face significant challenges in protecting their content in Thailand. Historically, major gaps have existed in the legal framework, and enforcement has been largely ineffective.

In anticipation of Thailand’s accession to the WIPO Internet Treaties, amendments to the Copyright Act and changes to the Computer Crime Act have been put forward. In early 2022, many of these amendments were finally passed into law in a new Copyright Act. These amendments include the creation of a notice-and-takedown scheme; the definition of liability for service providers; and additional remedies for the circumvention of technological protection measures, including the manufacture, sale, rental, or importation of circumvention devices.

The notice-and-takedown scheme provides a new legal framework that promotes cooperative action against online piracy, thus providing internet intermediaries with defined responsibilities related to copyright infringement and a stepwise process for rightsholders to send notifications directly to relevant and statutorily defined intermediaries. Up until now, under Section 20.3 of the Computer Crime Act 2017, copyright holders had needed to submit a complaint to the Department of Intellectual Property (DIP) which conducted preliminary investigations and then passed the case on to the Ministry of Digital Economy and Society. With the Minister’s approval, the copyright holder could request a competent court to issue a disabling order. Because of this convoluted process, the procedure has not provided timely redress for copyright infringement.

Recognizing this challenge, the amended act instead enables copyright holders to make their takedown requests directly to ISPs, whose timely response will protect them from liability. Similarly, the amendments also strengthen existing protection mechanisms for TPM and DRM. These are positive steps and something on which Thai authorities can build. As a result of these changes, the scores on indicators 13 and 15 have increased by 0.25, respectively.



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, rightsholders have long faced difficulties in protecting their trademarks and brands in Thailand. The availability of physical counterfeit goods is high and, as e-commerce grows, is increasing online. In 2019, the DIP held consultations with the major platforms aimed at discussing tools and procedures to tackle online infringement and the sale of counterfeit goods more effectively. The same year, the DIP organized a workshop that brought together rightsholders, internet platforms, and national and foreign enforcement agencies to discuss the platforms' role in tackling online piracy. The DIP also created a dedicated unit for online violations tasked with furthering dialogue among relevant stakeholders, including online marketplaces.

In a precedent-setting application of an injunctive-style relief mechanism introduced in the 2016 Computer Crime Act, in 2020, the Ministry of Digital Economy and Society filed a judicial motion and received court approval for the disabling of access to several websites on the basis of infringement of trademark rights. Up until 2020, this mechanism had exclusively been used by copyright holders and had not been viewed as a way of enforcing rights pertaining to trademarks.

In 2021, the Deputy Prime Minister presided over the signing of a memorandum of understanding (MOU) between rightsholders, online retailers, and the Thai government. The purpose of the MOU is to facilitate stronger cooperation among online retailers, rightsholders, and relevant government ministries and agencies in eliminating counterfeiting and enforcing IP rights. Government reports suggest that the MOU is having the desired

effect and is facilitating greater cooperation among the signatories and increased enforcement efforts against counterfeit goods available online. The Index commends the Thai government and, in particular, the DIP, for the leading role it has played in these positive developments.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer: In May 2022, the Thailand Research and Innovation Utilization Promotion Act (TRIUP) came into force. Years in the making and modeled on the U.S. Bayh-Dole framework, the new law changes and improves Thailand's technology transfer environment. Technology transfer activities based on academic-industry and public private sector collaborations provide a significant and distinct contribution to the economic strength and well-being of economies in which such activities take place. The process enables public research institutions to obtain access to commercial research funds, state-of-the-art equipment, and leading-edge technologies, while allowing industry to benefit from the extensive knowledge and ingenuity of academic researchers.

In the United States, the Patent and Trademark Law Amendments Act of 1984 and 1986—commonly referred to as the Bayh-Dole Act—and the Stevenson-Wydler Technology Innovation Act (later amended by the Federal Technology Transfer Act of 1986 and the Technology Transfer Commercialization Act in 2003) have been instrumental in incentivizing technology transfer and contributing to increased rates of national economic activity. For example, a 2015 study estimating the economic contribution of licensing activity by American academic institutions found that the contribution of academic licensing to gross industrial output in the United States ranged from USD282 to 1,180 billion (measured in 2009 USD). Contributions to national gross domestic product were equally significant and estimated

at between USD130 and 518 billion (measured in 2009 USD). The study also found that this licensing activity was responsible for between 1.1 million and 3.8 million person years of employment.

IP-intensive industries, including software, ICT, the life sciences, and biotechnology, have thrived because of the legislation. An instructive example is the biopharmaceutical industry, which since the 1980s has developed extensive R&D partnerships and cooperation with universities, higher education, and research institutes. From the perspective of universities and technology development, the life sciences play a critical role in universities' commercial activities and account for most of their licensing income. For instance, figures calculated by Nature magazine for a sample of the major research institutions in the United States showed how, of the USD860 million of licensing income received in 2014, over 85% (USD734 million) came from the life sciences.

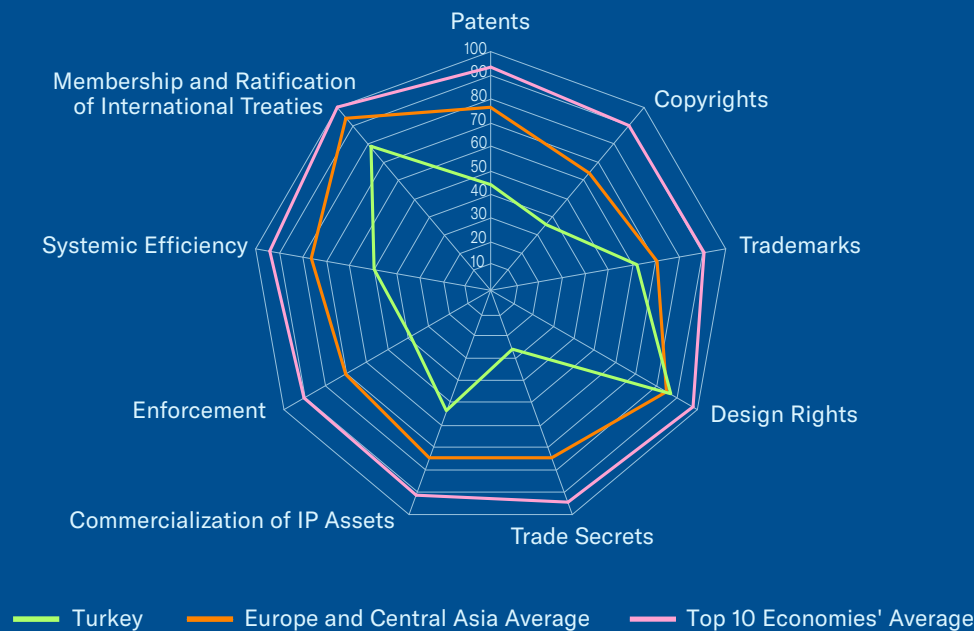
Up until 2022, Thailand did not have a national technology transfer framework in place. Instead, different institutions and public research organizations had varying IP policies in place. Under TRIUP, IP rights and rights of commercialization for IP generated with public funding are now generally vested with the creating entities. Consequently, the new law provides IP-based incentives for the commercialization of academic and publicly funded research. Unfortunately, the new legislation was not accompanied by any changes to Thailand's broader licensing environment. Under TRIUP, the government retains the right to intervene and override granted IP rights through the issuing of compulsory licenses. There has also been no change in the universal requirement of mandatory registration and government review of licensing agreements for most major IP rights, including patents. Nevertheless, the enactment of TRIUP is a positive step toward and improvement to Thailand's technology transfer environment. As a result, the score on this indicator has increased by 0.25.

Membership and Ratification of International Treaties

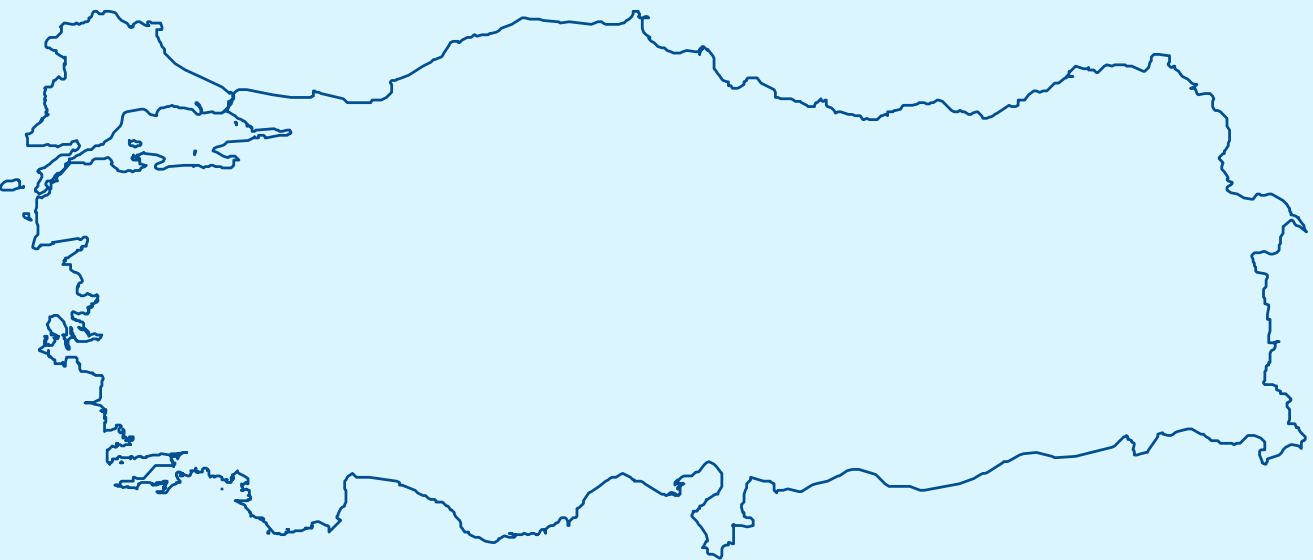
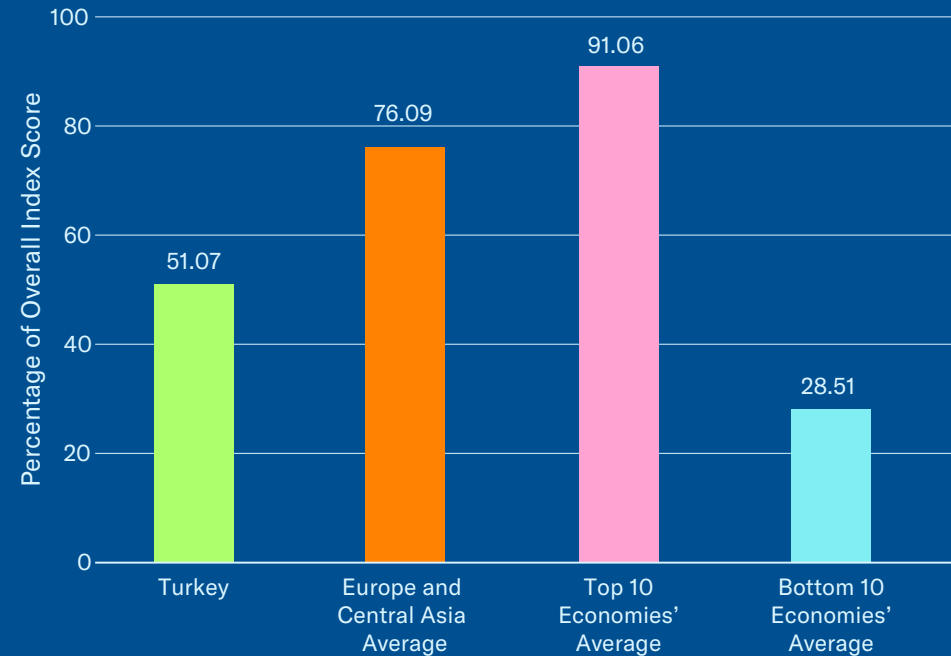
44. WIPO Internet Treaties: In 2022, Thailand acceded to the WIPO Copyright Treaty. As a result, the score on this indicator has increased by 0.5.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Turkey has over the years sought to align its national IP environment with EU standards
- Active promotion of the 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 are becoming more prominent part of industrial and economic policy targeting high-tech sectors
- RDP not being granted to biologics
- Key gaps persist in copyright environment and patent protection and enforcement
- For biopharmaceuticals, industrial localization policies have fused with IP policy and broader health policy on the pricing and procurement of medicines
- High counterfeiting and software piracy rates—56% in the latest BSA estimates



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
4.00		3.25	
1. Term of protection	1.00	26. Barriers to market access	0.00
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.50
3. Patentability of CIIs	0.50	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.50	2.74	
9. Patent opposition	0.50	32. Physical counterfeiting rates	0.30
Category 2: Copyrights, Related Rights, and Limitations		33. Software piracy rates	0.44
2.49		34. Civil and preceudural remedies	0.25
10. Term of protection	0.74	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.25	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.75
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	
15. TPM and DRM	0.25	2.50	
16. Government use of licensed software	0.50	39. Coordination of IP rights enforcement	0.50
Category 3: Trademarks, Related Rights, and Limitations		40. Consultation with stakeholders during IP policy formation	0.50
2.50		41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.75	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.25	5.50	
Category 4: Design Rights, Related Rights, and Limitations		44. WIPO Internet Treaties	1.00
1.75		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights and industrial design rights	0.75	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	1.00
0.80		49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
23. Protection of trade secrets (civil remedies)	0.25	50. Post-TRIPS FTA	0.00
24. Protection of trade secrets (criminal sanctions)	0.25		
25. Regulatory data protection term	0.30		
Total: 25.53			

Spotlight on the National IP Environment

Past Editions versus Current Score

Turkey’s overall score remains unchanged at 51.07% (25.53 out of 50).

Commercialization of IP Assets and Market Access

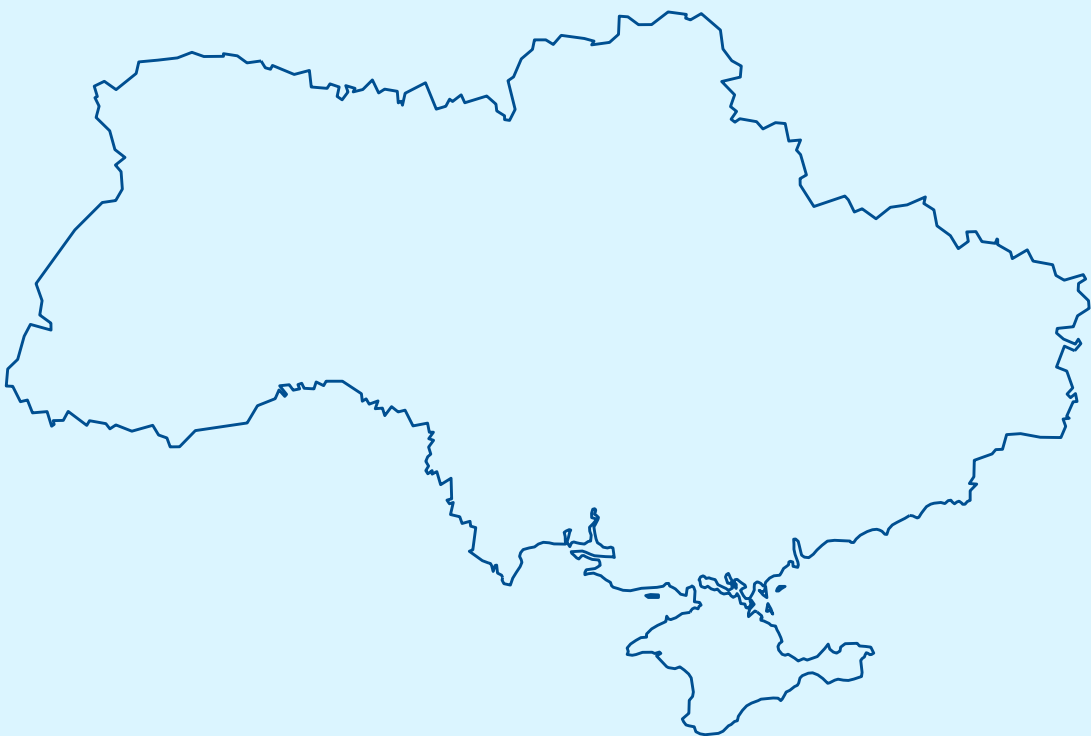
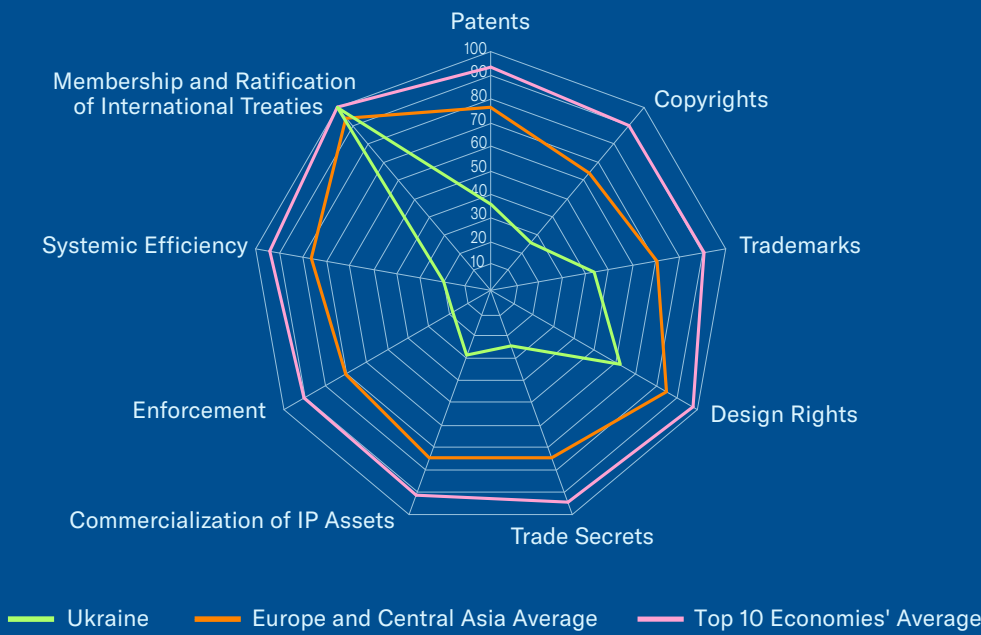
26. Barriers to market access: Over the past two decades, Turkish industrial and economic policy has increasingly been driven by an effort to localize industrial production and R&D. A major part of these efforts has been localization and import substitution policies that actively discriminate against foreign entities and favor domestic Turkish companies. The Turkish government actively uses public procurement policies as a form of incentivizing localization and discriminating against foreign bidders. As detailed over the course of the Index, many of these localization and discriminatory policies have targeted the research-based biopharmaceutical sector. 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 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 GATT, TRIMS, TRIPS, and SCM agreements. After a delay caused by the COVID-19 pandemic, the WTO finally issued a panel report in late 2021. Overall, the panel found that Turkey had indeed violated its WTO commitments through the

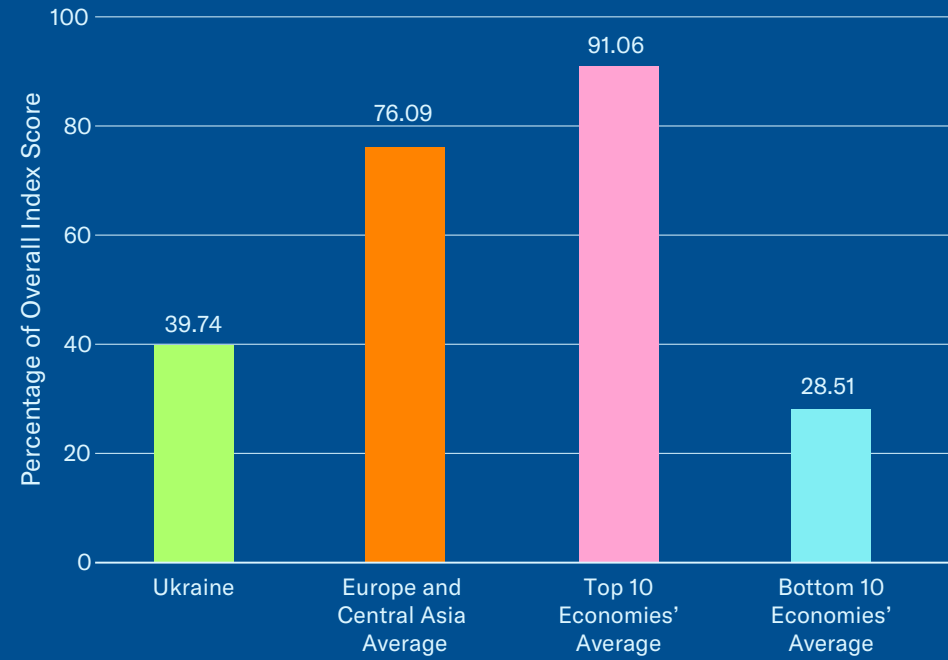
imposition of discriminatory biopharmaceutical market access and localization policies. After a requested suspension of the panel’s work, the dispute was moved to arbitration with an arbitration award subsequently issued in August 2022. This award did not materially change the panel’s overall findings and conclusions. In a subsequent communication to the WTO from the Turkish delegation, Turkey committed to “implement the recommendations and rulings of the Arbitrators and the Panel in this dispute in a manner that respects its WTO obligations.” Both the panel’s findings and the final arbitration award are a significant development and should mark a positive turning point for affected rightsholders in Turkey. The Index will monitor the extent to which the Turkish government fully abides and implements the WTO’s conclusions and recommendation in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2020 amendments to the law on design rights extend term of protection to 25 years
- Growing body of case law on protection of trade secrets
- Amendments to Customs Code strengthens enforcement capacity
- Efforts to align IP legislation to EU standards and implement FTA with the EU
- 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

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



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	3.25	Category 6: Commercialization of IP Assets	1.75
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.00	27. Barriers to technology transfer	0.25
3. Patentability of CIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.25
5. Pharmaceutical-related enforcement	0.25	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	1.29
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.34
9. Patent opposition	0.25	33. Software piracy rates	0.20
Category 2: Copyrights, Related Rights, and Limitations	1.83	34. Civil and precluded remedies	0.25
10. Term of protection	0.58	35. Preestablished damages	0.00
11. Exclusive rights	0.25	36. Criminal standards	0.25
12. Injunctive-type relief	0.00	37. Effective border measures	0.25
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	1.00
15. TPM and DRM	0.25	39. Coordination of IP rights enforcement	0.25
16. Government use of licensed software	0.00	40. Consultation with stakeholders during IP policy formation	0.25
Category 3: Trademarks, Related Rights, and Limitations	1.75	41. Educational campaigns and awareness raising	0.25
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
18. Protection of well-known marks	0.50	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.00	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.25	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.75	48. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.25	49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.00	50. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
Total: 19.87			

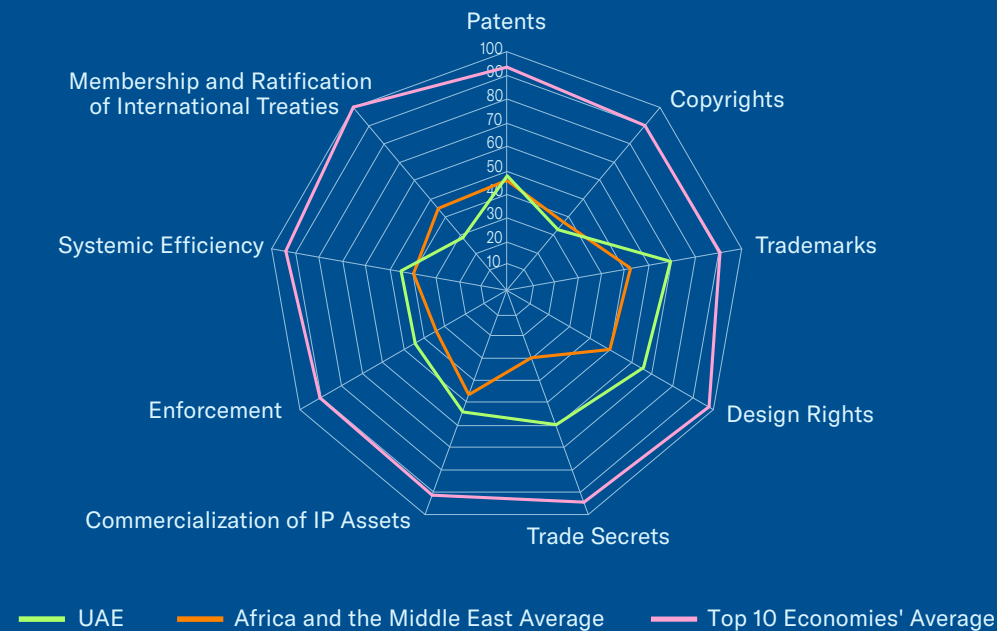
Spotlight on the National IP Environment

Past Editions versus Current Score

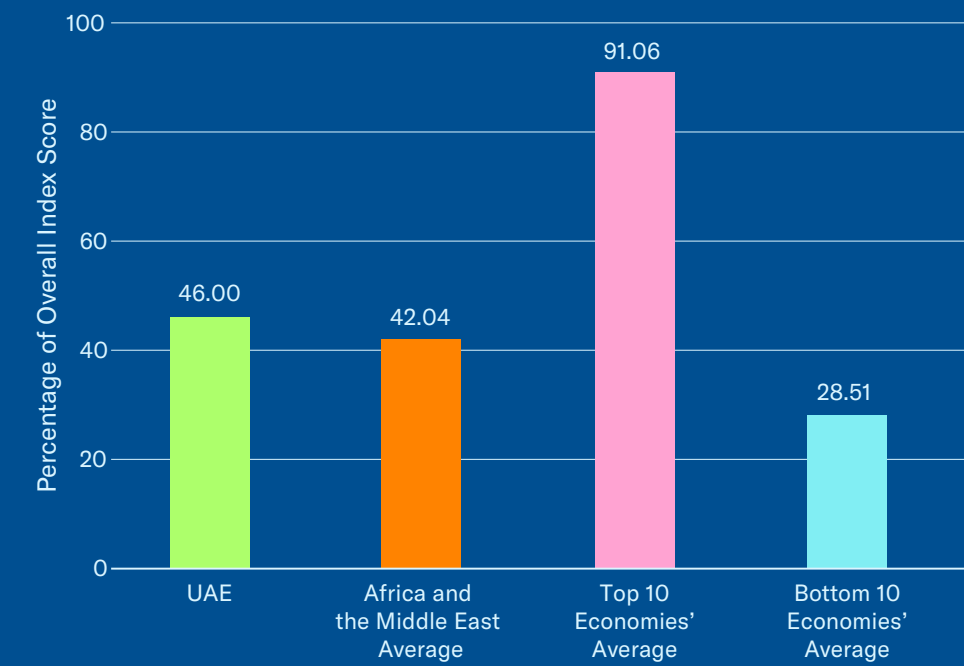
Given the Russian military invasion into Ukraine and a state of martial law being in effect since February 2022, no Index evaluation has been carried out for the eleventh edition, and Ukraine's overall score has been frozen at 39.74% (19.87 out of 50).



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Term of protection for design rights extended in 2021
- Acceded to Madrid Protocol in 2021
- 2021 Trademark Law improves environment for well-known marks and raises potential damages
- 2021 Trademark Law provides stronger border measures against counterfeit goods
- Defined RDP term introduced in 2020
- Foreign Direct Investment Law offers possibility of 100% foreign ownership and grants 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

- 2022 Copyright Law and implementing Cabinet Decision No. 47/2022 do not fundamentally change the legal dynamic in the UAE—do not include a notice-and-takedown mechanism or a defined and copyright-specific mechanism of injunctive-style relief
- 2022 Executive Regulations for Industrial Property Law (Federal Law 11) do not clarify under what circumstances a compulsory license may be issued
- 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 because no action has been taken on 2017 approval of two generic versions of a pharmaceutical product still on patent
- 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	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations	4.25	Category 6: Commercialization of IP Assets	3.25
1. Term of protection	1.00	26. Barriers to market access	0.25
2. Patentability requirements	0.50	27. Barriers to technology transfer	0.50
3. Patentability of CIIIs	0.50	28. Registration and disclosure requirements of licensing deals	0.50
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.50
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	3.12
8. Membership of a Patent Prosecution Highway	0.00	32. Physical counterfeiting rates	0.44
9. Patent opposition	0.25	33. Software piracy rates	0.68
Category 2: Copyrights, Related Rights, and Limitations	2.28	34. Civil and preceudural remedies	0.75
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.50	36. Criminal standards	0.50
12. Injunctive-type relief	0.00	37. Effective border measures	0.50
13. Cooperative action against online piracy	0.00	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.50	Category 8: Systemic Efficiency	2.25
15. TPM and DRM	0.50	39. Coordination of IP rights enforcement	0.25
16. Government use of licensed software	0.25	40. Consultation with stakeholders during IP policy formation	0.50
Category 3: Trademarks, Related Rights, and Limitations	2.75	41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
18. Protection of well-known marks	0.75	43. IP-intensive industries, national economic impact analysis	0.25
19. Exclusive rights and trademarks	0.75	Category 9: Membership and Ratification of International Treaties	2.00
20. Frameworks against online sale of counterfeit goods	0.25	44. WIPO Internet Treaties	1.00
Category 4: Design Rights, Related Rights, and Limitations	1.30	45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.80	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.80	48. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.50	50. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.80		
Total: 23.00			

Spotlight on the National IP Environment

Past Editions versus Current Score

The UAE’s overall score has decreased from 46.02% (23.01 out of 50) in the tenth edition to 46.00% (23.00 out of 50). This reflects a score decrease on indicator 32.

Area of Note

In January 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. This was followed up with an announcement by the GCC Secretariat in April 2021. Under this announcement, new amendments to the GCC Patent Regulation were issued whereby a new regional application pathway would replace the old regulation. Under this system, the regional GCC patent was abolished. Instead, future patent applications will be routed through individual GCC member states. Once granted by the GCC Patent Office, relevant patents will be valid only in the underlying national jurisdiction. This system was formalized in late 2021 with the issuing of new Implementing Regulations. The Index will continue to monitor these developments in 2023.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: As noted in last year’s Index, a new industrial property law, Federal Law No. 11, was introduced and came into effect in 2021. As described last year, Article 25 and the basis for overriding granted rights through the issuing of a compulsory license

appear to have been broadened and patent rights weakened. Under the new law, the nonworking justification has been broadened whereby a rightsholder’s “insufficient use” of a patented technology may be used as a legal basis for the issuing of a compulsory license. In 2022, new Executive Regulations were issued for Law 11. Unfortunately, these regulations have not clarified under what circumstances a compulsory license may be issued. The Index will continue to monitor these developments in 2023 and the extent to which rightsholders are able to continue to obtain and maintain patent protection for their inventions.

Copyrights, Related Rights, and Limitations

10. Copyright (and related rights) term of protection; 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. Technological protection measures (TPM) and digital rights management (DRM) legislation: As has been noted over the course of the Index, rightsholders face significant challenges in protecting their content in the UAE. Gaps exist in the legal framework, and enforcement remains partial. The Copyright Law has historically provided standard exclusive rights, including reproduction and performance, but with little specific reference to the online environment. For example, no statutory notice-and-takedown mechanism or a defined copyright-specific route is in place for injunctive-style relief. Industry reports suggest that there is inconsistent cooperation from the main ISPs.



Some additional enforcement activity has taken place through the Telecommunication Regulatory Authority (TRA). The TRA's internet guidelines also include the violation of IP rights in the list of prohibited content categories, and the authority has disabled access to infringing content online on an ad hoc basis. But, overall, this activity has been piecemeal and ad hoc.

With respect to the trade in physical counterfeit goods, including copyright-infringing goods, the UAE has long been identified as a central hub for the transshipment of counterfeit goods. The OECD and EUIPO in the 2021 *Global Trade in Fakes: A Worrying Threat* found that the UAE was one of the top provenance economies for counterfeit products in the world. Similarly, several UAE markets are included in the USTR's *Review of Notorious Markets for Counterfeiting and Piracy*.

With respect to the protection of technological protection measures and digital rights management, existing statute has been basic and rudimentary in nature. For instance, Article 38 of the Copyright Law outlined only basic violations of manufacturing and importation and did not clearly criminalize the act of circumvention itself. More broadly, rightsholders have for years faced difficulties in collectively organizing and managing their copyright protected assets. In late 2021, the UAE enacted a new Copyright Law (Federal Decree-Law no. 38 of 2021) with corresponding Implementing Regulations (Cabinet Decision No. 47/2022) published in May 2022. The UAE government has rightly identified the creative industries and the protection of copyrighted content as a strategic asset, and it should be congratulated for seeking to update the legal framework. On a positive note, Article 40 of the law contains potentially stronger DRM and TPM provisions, including criminalizing the “disrupting or impairing of any technical protection or electronic data aiming at regulating and managing the rights prescribed

by this Decree-Law.” Furthermore, Articles 32-34 and the Implementing Regulations provide for collective management of copyrights. However, overall, the new law does not fundamentally change the legal dynamic. The law does not include a notice-and-takedown mechanism, nor does it contain a defined and copyright-specific mechanism of injunctive-style relief.

The past decade has seen a sharp increase in the number of economies that use judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the UK, India, Singapore and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, and the UK. They have proven to be effective in reducing the availability of copyright-infringing content within these jurisdictions. The Index will continue to monitor these developments in 2023.

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, no period of RDP is defined or recognized in UAE law.

As noted in the Index, this changed in 2020 when the Ministry of Health and Prevention issued Ministerial Resolution 321. The resolution provides a defined eight-year period of RDP for submitted preclinical 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 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 “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 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 are allowed to engage in, and there is no assurance that the reference product's full eight-year period of data exclusivity will be maintained.

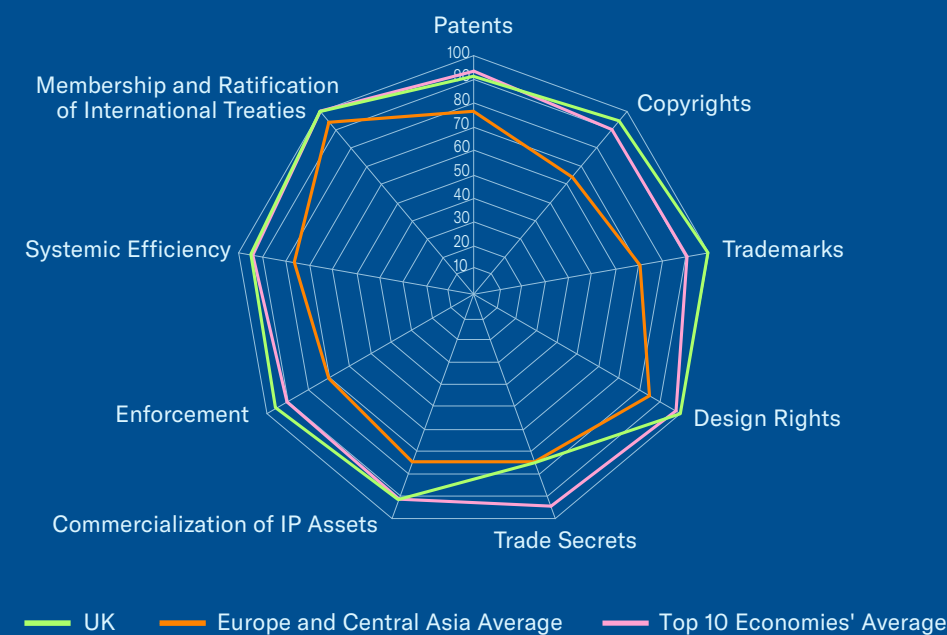
There is also a degree of uncertainty regarding the meaning and purpose of Article 5 of the decree. The article states that the relevant drug regulatory authorities may, under “exceptional” circumstances, including “for the purpose of protecting public health,” override or disregard an existing term of RDP and approve a follow-on product. At a more basic level, a conflict exists in the term of protection between the 2020 resolution and the new industrial property law, Federal Law No. 11. As noted last year, Article 62(2) of the new industrial property law states that the period of protection for confidential information submitted

to government agencies will be protected for “a period not exceeding (5) five years.” This is less than the eight-year term in Resolution 321. New Executive Regulations published in 2022 did not address this issue. Consequently, at the time of research, it remained unclear how the conflicting provisions of Federal Law No. 11 and Resolution 321 would interact and which would take precedence.

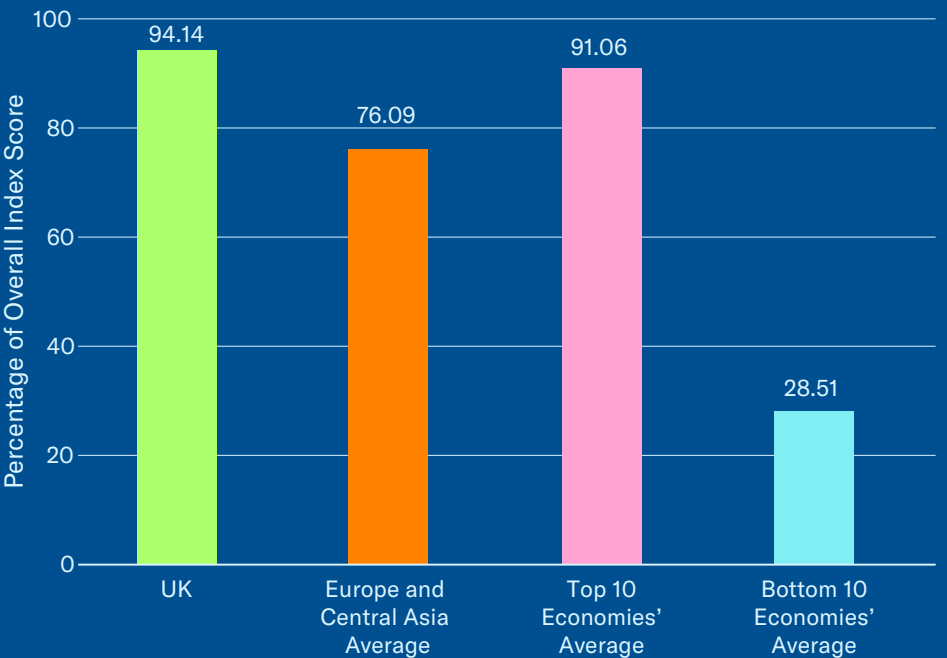
As the Index stated last year, the introduction of a defined term of RDP was a positive step and a clear improvement in the biopharmaceutical IP environment in the UAE. Providing rightsholders with a full, uninterrupted eight-year term of protection would position the UAE as one of the leaders on biopharmaceutical RDP in the MENA region. Should the term of RDP be reduced from eight years to five years of protection, in line with the new provisions of Federal Law No. 11, the score on this indicator will be reduced. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- Strong and sophisticated national IP environment
- The UK is a model for injunctive-style relief for rightsholders 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

- UK government chose to retain EU SPC exemption for exports of biopharmaceuticals—remains a significant risk to the UK's research and IP-based biopharma industry
- Limited criminal sanctions are available for the theft and misappropriation of trade secrets



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
8.25		5.50	
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	1.00	27. Barriers to technology transfer	1.00
3. Patentability of CIIs	1.00	28. Registration and disclosure requirements of licensing deals	0.75
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	0.50	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	1.00
7. Pharmaceutical patent term restoration	0.75	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	1.00	6.69	
9. Patent opposition	1.00	32. Physical counterfeiting rates	0.90
Category 2: Copyrights, Related Rights, and Limitations		33. Software piracy rates	0.79
6.63		34. Civil and preceudural remedies	1.00
10. Term of protection	0.63	35. Preestablished damages	1.00
11. Exclusive rights	1.00	36. Criminal standards	1.00
12. Injunctive-type relief	1.00	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	
15. TPM and DRM	1.00	4.75	
16. Government use of licensed software	1.00	39. Coordination of IP rights enforcement	1.00
Category 3: Trademarks, Related Rights, and Limitations		40. Consultation with stakeholders during IP policy formation	1.00
4.00		41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	1.00	7.00	
Category 4: Design Rights, Related Rights, and Limitations		44. WIPO Internet Treaties	1.00
2.00		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	1.00
2.25		49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
23. Protection of trade secrets (civil remedies)	1.00	50. Post-TRIPS FTA	1.00
24. Protection of trade secrets (criminal sanctions)	0.25		
25. Regulatory data protection term	1.00		
Total: 47.07			

Spotlight on the National IP Environment

Past Editions versus Current Score

The UK’s overall score remains unchanged at 94.14% (47.07 out of 50).

Commercialization of IP Assets and Market Access

31. Tax incentives for the creation of IP assets: British tax law has historically offered generous R&D tax incentives and a dedicated patent box scheme that has been in place since 2013. R&D incentives have been provided through a super deduction for qualifying expenditure for small companies, with larger business entities being entitled to a R&D expenditure credit. The patent box scheme provides an effective rate of 10% corporation tax on income generated by the underlying patent asset. Over the past two years, the government has been reviewing the mechanics of these incentives. In 2022, draft legislation was introduced to widen the scope of these incentives but also to introduce a new territoriality limitation. The stated purpose of the amendments is to ensure that the incentives stimulate innovation and R&D inside the UK. However, given that a growing proportion of high-tech R&D is multijurisdictional in nature—including, for example, clinical trials for new medicines and medical technologies—under a new proposed Section 1138A, exemptions are allowed for qualifying expenditure that takes place outside of the UK. Additional potential changes to the R&D tax incentives scheme were announced in late 2022 in the British Chancellor’s “2022 Autumn Statement.” These changes include a proposed increase in the headline rate of the R&D expenditure credit for larger entities but a reduction in qualifying incentives for smaller entities. At the time of research, it was unclear what the final reform package would look like. The Index will continue to monitor these developments in 2023.

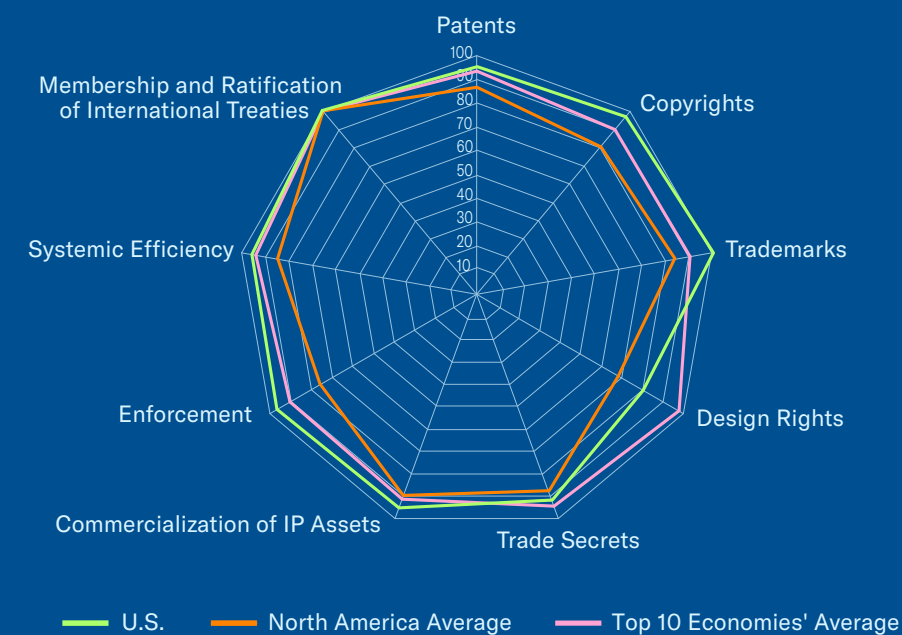
Systemic Efficiency

39. Coordination of IP rights enforcement efforts: As noted in previous editions of the Index, the UK has an impressive and well-developed enforcement framework that combines government and law enforcement with private sector efforts. With respect to the coordination of IP enforcement, the UK has both a dedicated cross-governmental IP enforcement strategy and coordinating group led by the Intellectual Property Office (IPO). The UK IP Crime Strategy has traditionally set the government’s high-level goals and overall policy direction and has been supplemented by additional strategy documents and efforts led by the IPO. In terms of enforcement coordination, this is primarily done through the UK IP Crime Group, also led by the IPO. The group is made up of representatives from industry, UK enforcement agencies, and other parts of the government. The body meets regularly to coordinate enforcement activities, identify and disseminate best practices, and raise public awareness of IP crime.

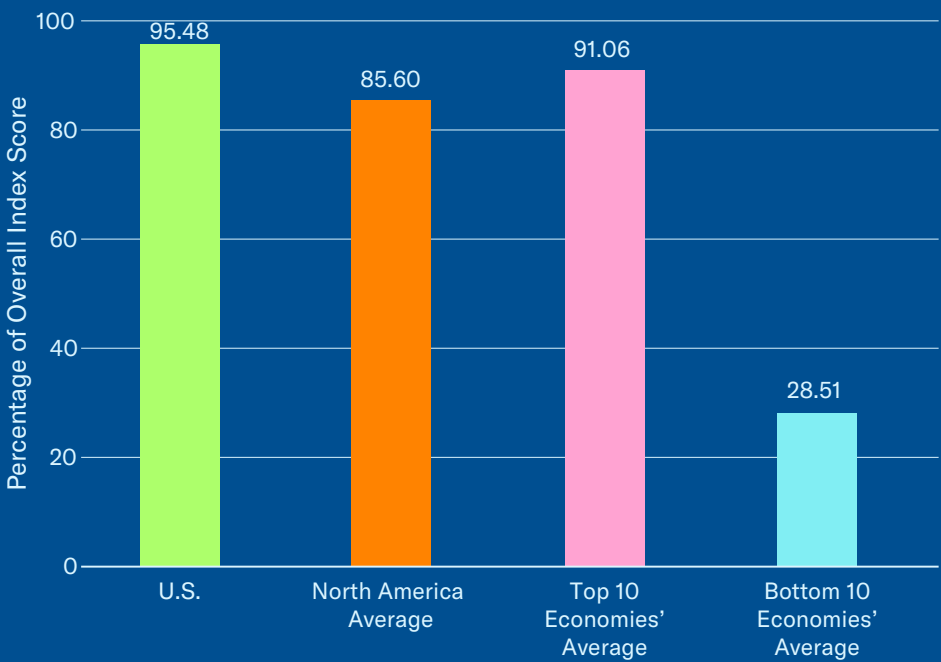
In 2022, the government published a new IP enforcement and coordination strategy, the *Intellectual Property (IP) Counter-Infringement Strategy 2022-2027*. The Strategy zeroes in on an increasingly important area of IP enforcement: improving intelligence activities relating to IP infringement. This five-year plan adds to the existing enforcement framework in place and underscores the UK’s commitment to improving its already world-class enforcement environment. As criminal enterprises and the IP infringement environment evolve and become more technically sophisticated and multilayered, so too must enforcement mechanisms and efforts to combat this infringement, in the UK and beyond. The IPO and the British government should be congratulated for their continued efforts to put IP enforcement at the forefront.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2020 Copyright Office report on Section 512 recognized need for copyright reform, spurring bipartisan and bicameral Congressional interest
- USPTO released new guidance in 2019 covering Section 101 subject matter eligibility and Section 112 claims related to software 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 nullity and opposition proceedings by USPTO continued in 2022—agency should be commended for its efforts to provide a greater balance and to address concerns over unpredictability and uncertainty within the PTAB process

Key Areas of Weakness

- Proposals for compulsory licensing as a pharmaceutical cost-containment policy
- Proposed changes to scientific research access policies by the Office of Science and Technology Policy (OSTP)
- Continued uncertainty over patentability for high-tech sectors
- Lack of a targeted legal basis for addressing online commercial piracy along the lines of other global leaders



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
8.50		5.67	
1. Term of protection	1.00	26. Barriers to market access	1.00
2. Patentability requirements	0.75	27. Barriers to technology transfer	1.00
3. Patentability of CIIIs	1.00	28. Registration and disclosure requirements of licensing deals	1.00
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	1.00
5. Pharmaceutical-related enforcement	1.00	30. IP as an economic asset	1.00
6. Legislative criteria and use of compulsory licensing	1.00	31. Tax incentives for the creation of IP assets	0.67
7. Pharmaceutical patent term restoration	1.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	1.00	6.72	
9. Patent opposition	0.75	32. Physical counterfeiting rates	0.87
Category 2: Copyrights, Related Rights, and Limitations		33. Software piracy rates	0.85
6.75		34. Civil and preceudural remedies	1.00
10. Term of protection	1.00	35. Preestablished damages	1.00
11. Exclusive rights	1.00	36. Criminal standards	1.00
12. Injunctive-type relief	0.75	37. Effective border measures	1.00
13. Cooperative action against online piracy	1.00	38. Transparency and public reporting by customs	1.00
14. Limitations and exceptions	1.00	Category 8: Systemic Efficiency	
15. TPM and DRM	1.00	4.75	
16. Government use of licensed software	1.00	39. Coordination of IP rights enforcement	1.00
Category 3: Trademarks, Related Rights, and Limitations		40. Consultation with stakeholders during IP policy formation	1.00
4.00		41. Educational campaigns and awareness raising	1.00
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
18. Protection of well-known marks	1.00	43. IP-intensive industries, national economic impact analysis	1.00
19. Exclusive rights and trademarks	1.00	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	1.00	7.00	
Category 4: Design Rights, Related Rights, and Limitations		44. WIPO Internet Treaties	1.00
1.60		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights and industrial design rights	1.00	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	1.00
2.75		49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
23. Protection of trade secrets (civil remedies)	1.00	50. Post-TRIPS FTA	1.00
24. Protection of trade secrets (criminal sanctions)	1.00		
25. Regulatory data protection term	0.75		
Total: 47.74			

Spotlight on the National IP Environment

Past Editions versus Current Score

The United States’ overall score remains unchanged at 95.48% (scoring 47.74 out of 50).

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 patent-eligible subject matter 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. As a result, rightsholders 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.

The USPTO has recognized this dilemma and has sought to reformulate its position and the approach to be taken by its examiners. In 2019, the office released new 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,” respectively. With respect to Section 101 (subject matter eligibility), the guidance provided more of a principle-based analysis of how subject matter eligibility would be judged, and it described the stepwise approach examiners should follow to understand and apply the Supreme Court’s *Alice/Mayo* test. As the guidance rightly pointed 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 guidance recognized this and sought, 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 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 examined 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 found that, overall, since the introduction of the guidance, a measurable and statistically significant decrease has occurred 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 noted at the time of publication, this is positive news.

Unfortunately, as noted repeatedly by the Index, uncertainty over what constitutes patentable subject matter has crept into all facets of the American patent system, from initial application and examination to standards of review and invalidity proceedings, whether administratively through the Patent Trial and Appeals Board (PTAB) or through the judiciary. For example, with respect to the influence and use of the USPTO’s guidance, the U.S. Court of Appeals for the Federal Circuit has expressly, and repeatedly, stated that the guidance does not carry the force of statutory law or relevant case law and is therefore not a controlling factor in any patentability analysis carried out by the court.



Efforts to address this fundamental problem in the U.S. patent system continued within both the executive and legislative branches of the federal government in 2022. To begin with, the USPTO, under the new leadership of Director Vidal, issued several requests for comments on issues pertaining to patentability, patentable subject matter, and related USPTO processes and procedures. In June, the agency published *Patent-Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States*. This report, requested by Congress, details the results of stakeholder feedback gathered in 2021 on subject matter eligibility in the United States. Following the publication of this report, the agency announced that it will be seeking feedback on current examination practices as captured in the relevant sections of the patent manual (Manual of Patent Examining Procedure 2106).

In a separate development, in October, the USPTO also called for comments on patentability issues relating to biopharmaceutical patents. This follows requests from both the White House and Congress. Specifically, in July 2021, President Biden issued the Executive Order on Promoting Competition in the American Economy. Alleging anti-competitive behavior in several sectors of the economy, the Order asks the FDA and USPTO to examine the extent to which the patent system “while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law.” In the summer, the Senate Judiciary Committee advanced draft legislation requiring greater cooperation and information sharing between the USPTO and FDA. The Interagency Patent Coordination and Improvement Act of 2022 would establish an interagency taskforce between the two for “purposes of sharing information and providing technical assistance with respect to patents, and for other purposes.”

As detailed across numerous editions of the Index and most clearly illustrated by the life-saving innovation and product development witnessed during the COVID-19 pandemic, biopharmaceutical breakthroughs by American firms are improving health treatment for patients globally, providing a steady stream of new drugs and health technologies. Since 2000, American companies have developed more than 550 new medicines, or roughly half of all drugs launched globally. American research-based biopharmaceutical firms spent an estimated USD72.4 billion in 2020 on R&D domestically in the United States. This leadership in global biopharmaceutical research and manufacturing also translates into large economic dividends for Americans. Revenues generated by a new blockbuster drug are comparable to the export of 1 million cars. The sector also accounts for and supports 4.5 million jobs. The basic economics of the biopharmaceutical industry show how critical IP rights are to enable investment and collaboration in the development of new medical technologies and products.

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. A 2012 estimate points to the total cost of drug development being approximately USD1.5 billion. Tufts University research from 2016 suggests that it costs USD2.6 billion, on average, to develop a new drug. 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. Patents and other forms of exclusivity for biopharmaceuticals, such as RDP and special exclusivity incentives for the protection and production of orphan drugs, enable research-based companies to invest these vast sums in R&D and the discovery of new drugs, products, and therapies. Moreover, legally recognized and enforceable IP rights are foundational to the contractual

relationships that define the world-leading U.S. biopharmaceutical innovation ecosystem.

It has been clear for many years that American taxpayers and patients are concerned with the cost of prescription medicines and want their elected representatives to take appropriate action. However, the cost of drugs is a complex subject that does not lend itself to generalizing. It involves many different factors such as health system infrastructure, health financing, and how the American health system itself is organized, financed, and accessed by patients. Within this cost equation, the protection of IP plays a relatively small role. Instead of achieving the goal of lowering costs, proposals that undermine biopharmaceutical R&D investment and collaboration risk the very model of innovation that since the mid-1980s has provided Americans and patients around the world, with new and better health technologies and medicines. In August 2022, Senator Thom Tillis introduced the “Patent Eligibility Restoration Act of 2022,” later joined by Senator Chris Coons as a cosponsor. The proposed legislation marks a significant breakthrough on the legislative front. As Senator Tillis stated in conjunction with the release of the draft act, “Predictable patent rights are imperative to enable investments in the broad array of innovative technologies that are critical to the economic and global competitiveness of the United States, and to its national security.” At the time of research, the proposed act had not been passed by Congress or signed into law by President Biden. The Index will continue to monitor these developments in 2023.

9. Patent Opposition: 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 PTAB. As noted over the course of the Index, the U.S. government (chiefly through the USPTO) has recognized the unintended effects of the PTAB system and has publicly pledged to work with all stakeholders to address and remedy them. As a result, many important changes have since been introduced. Examples of these reforms include i) changing the patent claim construction standard used and moving away from the broadest reasonable interpretation standard to the *Phillips* standard, which is the claim construction standard used in the judiciary since the mid-2000s; ii) a new Trial Practice Guide; and iii) Standard Operating Procedure (SOP) changes.

Using the *Phillips* standard has aligned IPR proceedings with the same claim construction standards used in patent infringement proceedings in U.S. district courts. Similarly, 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 have also sought to streamline how judges are assigned, how panels are composed, and how precedent-setting opinions are set. Specifically, SOP 2 sets up a “Precedential Opinion Panel” (POP) headed by the USPTO 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 and addressing issues related to the USPTO’s 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*). The U.S. Supreme Court has also been active in shaping how PTAB proceedings take place with several important decisions rendered, including in *SAS Institute Inc. v. Iancu*, *Thryv, Inc. v. Click-to-Call Technologies, LP, et al*, and *Arthrex, Inc. v. Smith & Nephew, Inc.* These efforts have continued in 2022.



Under the new leadership of Director Vidal, in June, the USPTO issued a memorandum on PTAB’s decision-making capacity and factors assessed when deciding whether to institute an AIA post-grant proceeding. This was followed up in July with a public consultation and request for comments on several issues pertaining to the PTAB. Similarly, Congress has held hearings, and several proposals for draft legislation amending the PTAB process have been put forward. This includes the 2019 “STRONGER Patents Act” proposal and the 2021 “Restoring America Invents Act,” both of which would seek to reform the PTAB process. The “STRONGER Patents Act recognized the “unintended consequences of the comprehensive 2011 reform” and the need for structural reforms. At the time of research, no legislative proposals had been passed by Congress or signed into law by President Biden. The Index will continue to monitor these developments in 2023.

Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online; and
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 rightsholders 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 it was in 1998, and, as a practical matter, due to massive technological changes, it is questionable whether the law remains effective.

At the time the legislation was passed, the global market for copyrighted products was fundamentally different. In 1998, music sales in the United States

totaled almost USD14 billion; sales of physical compact discs accounted for 83.3% of this total. Since then, the way Americans access music has transformed. In 2018, total music sales in the United States were 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 as ubiquitous as it is now. The growth of online copyright infringement since 1998—whether through downloading, streaming, or some other technology—has mirrored this growth in internet connectivity. The scale and volume of online infringement has resulted in a growing strain on the notice-and-takedown mechanism instituted through the DMCA. Rightsholders have increasingly found themselves confronting a different reality than that envisioned by the legislation, one where there is limited practical recourse to take effective action against online infringement.

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 Global Innovation Policy Center found that global online piracy costs the American economy nearly USD30 billion in lost sales each year.

Since 2015, the U.S. Copyright Office has conducted a public study of Section 512. The office has held several public roundtables and has accepted empirical submissions from the public. Some of these papers submitted show just how challenging a 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: i) a high level of infringement was taking place; ii) DMCA notices issued were

not effectively acted upon; and iii) there was a high level of recurrence, i.e., infringing content that was taken down would be reposted or would reappear on the notified service providers website.

In 2020, the Copyright Office published the results of its multiyear public study. Overall, the report rightly concludes that “Congress’s 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 dynamic injunctions but recommends further study of these and other “alternative stakeholder proposals.” Unlike other jurisdictions—including the European Union, Singapore and emerging markets like Russia and India—rightsholders in the United States have historically faced difficulty in obtaining an injunction to disable access to infringing content.

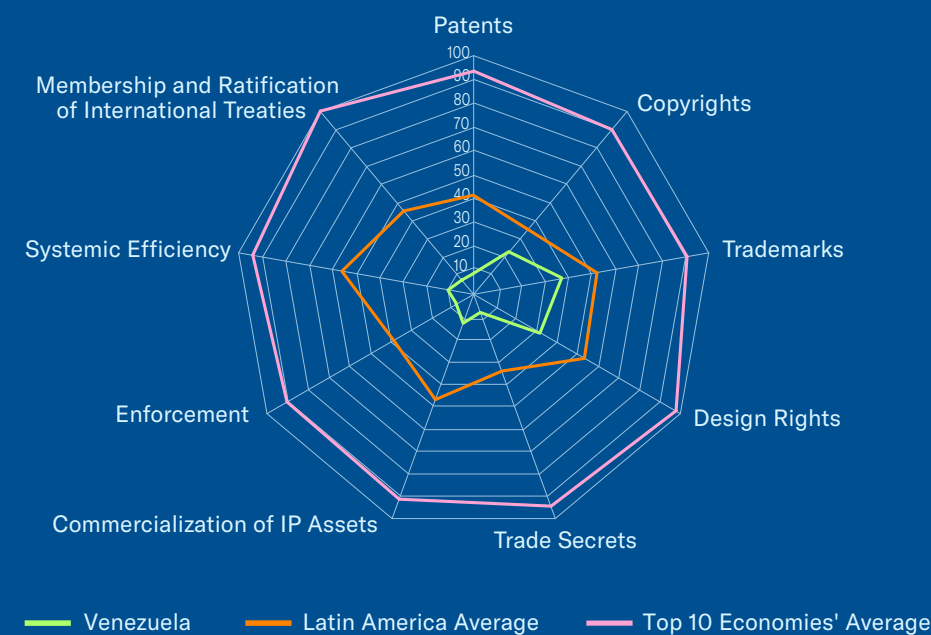
In parallel to the Copyright Office’s work, the U.S. Congress and Senate have both been working on reform proposals to the DMCA. For example, throughout 2020, the Senate IP Subcommittee—led by its Chair, Senator Thom Tillis—held hearings on the possibility of reforming the U.S. copyright environment to deal with digital piracy more effectively. Part of these hearings examined the practices outside the United States and, importantly, the growth and effectiveness of injunctive-style relief mechanisms around the world to disable access to infringing content. These efforts led to the public release of the “Strengthening Measures to Advance Rights Technologies Copyright Act of 2022” (SMART Copyright Act). This draft legislation would allow the Librarian of Congress and other parts of the federal government working with other stakeholders (including the private sector) to designate and identify existing practices and technical measures protecting copyrighted works. By reforming the underlying DMCA legal

framework, the draft legislation would seek to incentivize the adoption of new standards and technologies combating digital piracy through public and private sector cooperation. The House Judiciary Committee has also held hearings on copyright reform, most notably in 2020 under the leadership of Chairman Jerry Nadler regarding the release of the Copyright Office’s Section 512 report.

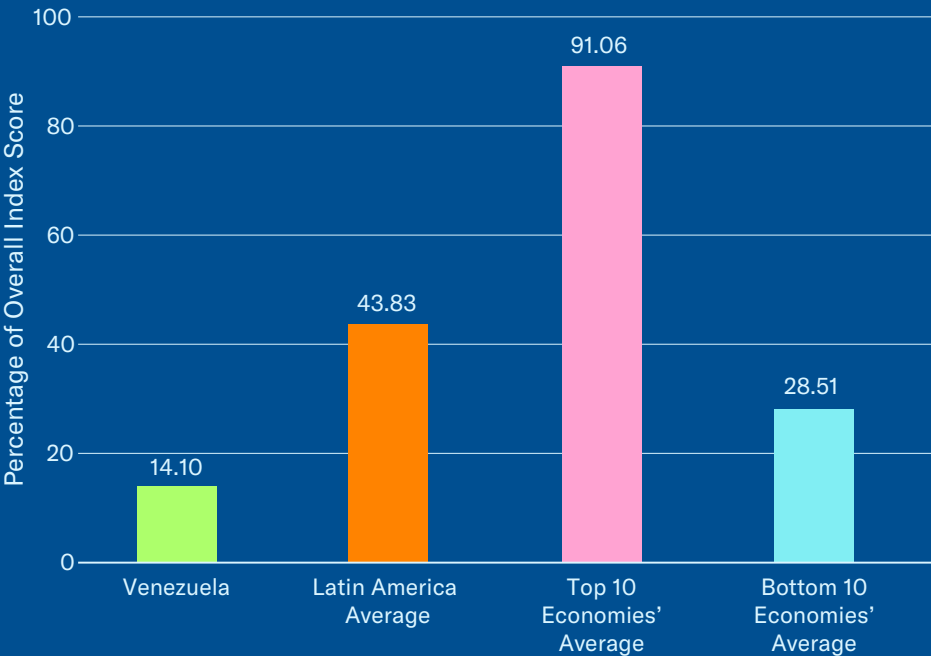
In a separate 2022 development, the U.S. District Court for the Southern District of New York issued injunction orders ordering U.S. ISPs to disable access to infringing content being made available online illicitly in the cases *United King Film Distribution Ltd et al. v. Does 1-10 d/b/a Israel. tv*, *United King Film Distribution Ltd et al. v. Does 1-10 d/b/a Israeli-tv.com*, and *United King Film Distribution Ltd et al. v. Does 1-10 d/b/a Sdarot. com*. The injunction orders stated that access should be disabled to the infringing content and to websites both “known today ... or to be used in the future by the Defendants.” The widespread availability of injunctive-style relief combined with access to dynamic injunctions would be a positive development and would allow rightsholders to seek and gain more effective relief against copyright infringement online. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

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

Key Areas of Weakness

- 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 is generally poor—insufficient penalties and administrative inaction persist
- Government interference and regulatory barriers to commercialization of IP assets persists



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
0.75		0.75	
1. Term of protection	0.50	26. Barriers to market access	0.00
2. Patentability requirements	0.00	27. Barriers to technology transfer	0.00
3. Patentability of CIIIs	0.25	28. Registration and disclosure requirements of licensing deals	0.25
4. Plant variety protection	0.00	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.50
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.00
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.00	0.52	
9. Patent opposition	0.00	32. Physical counterfeiting rates	0.16
Category 2: Copyrights, Related Rights, and Limitations		33. Software piracy rates	0.11
1.63		34. Civil and preceudural remedies	0.25
10. Term of protection	0.63	35. Preestablished damages	0.00
11. Exclusive rights	0.25	36. Criminal standards	0.00
12. Injunctive-type relief	0.00	37. Effective border measures	0.00
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.25	Category 8: Systemic Efficiency	
15. TPM and DRM	0.00	0.50	
16. Government use of licensed software	0.25	39. Coordination of IP rights enforcement	0.00
Category 3: Trademarks, Related Rights, and Limitations		40. Consultation with stakeholders during IP policy formation	0.00
1.50		41. Educational campaigns and awareness raising	0.50
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.00
19. Exclusive rights and trademarks	0.25	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.00	0.50	
Category 4: Design Rights, Related Rights, and Limitations		44. WIPO Internet Treaties	0.50
0.65		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.40	46. Patent Law Treaty and Patent Cooperation Treaty	0.00
22. Exclusive rights and industrial design rights	0.25	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	0.00
0.25		49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
23. Protection of trade secrets (civil remedies)	0.25	50. Post-TRIPS FTA	0.00
24. Protection of trade secrets (criminal sanctions)	0.00		
25. Regulatory data protection term	0.00		
Total: 7.05			

Spotlight on the National IP Environment

Past Editions versus Current Score

Venezuela’s overall score remains unchanged at 14.10% (7.05 out of 50).

Patents, Related Rights, and Limitations

As has been noted in previous editions of the Index, rightsholders in Venezuela have for many years faced a highly uncertain and challenging business environment. The Venezuelan economy has contracted substantially over the past decade, and inflation has run rampant for years. The World Bank’s *Doing Business* report has ranked Venezuela in the bottom of its overall “Ease of Doing Business” scores for the past decade. In 2010, Venezuela ranked 177th out of 183 economies; in 2020, it ranked 188th out of 190 economies. With respect to its national IP environment, Venezuela lacks most basic laws and protections and has been ranked last in the Index since it was first included in the fourth edition. The existing legal framework enshrined in the 1955 Industrial Property Law predates the TRIPS Agreement, let alone more modern IP frameworks and international best practices.

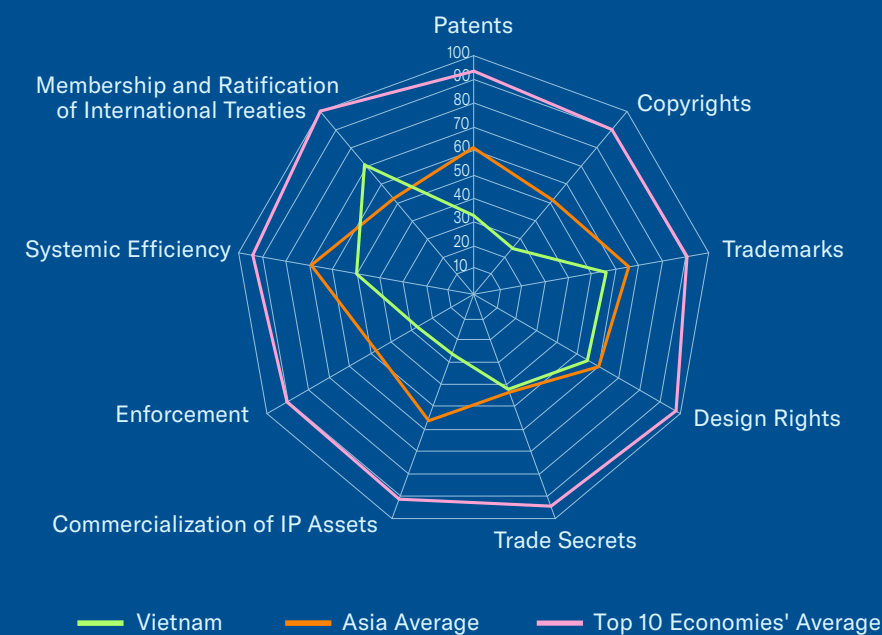
With respect to patents, related rights, and limitations, the legal standards of patentable subject matter remain firmly outside of existing international standards. In violation of TRIPS Article 27, chemical preparations, the use of natural substances, second use, and new forms of pharmaceutical inventions have been explicitly excluded from patentable subject matter. Inventions created using public funds or public means have also not been patentable. The standard term of protection for patents has also been half of the TRIPS minimum of 20 years, with Venezuela remaining at 10 years.

Aside from the legal framework, practically speaking, it has been nearly impossible for inventors to obtain patent protection over the past two decades. The granting of pharmaceutical patents was suspended in 2002, and, subsequently, the Venezuelan Autonomous Intellectual Property Service (SAPI) stopped processing and granting patents for all arts and technologies. In a new and encouraging development, however, local reports suggest that the SAPI has over the past year begun to process and grant patents again. The office also published a new and updated patent manual (*Guía para el examen de solicitudes de Patentes de Invención*) in July 2022. Importantly, this manual refers explicitly to both TRIPS patentability standards and a 20-year minimum term of protection for granted patents. However, the manual also references more restrictive definitions of patentability criteria included in the Industrial Property Law and the 2022 amendments to the Law of Science, Technology, and Innovation (Gazette 6,693, 2022). These definitions and criteria are different from that of TRIPS Article 27, which states unequivocally that “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.”

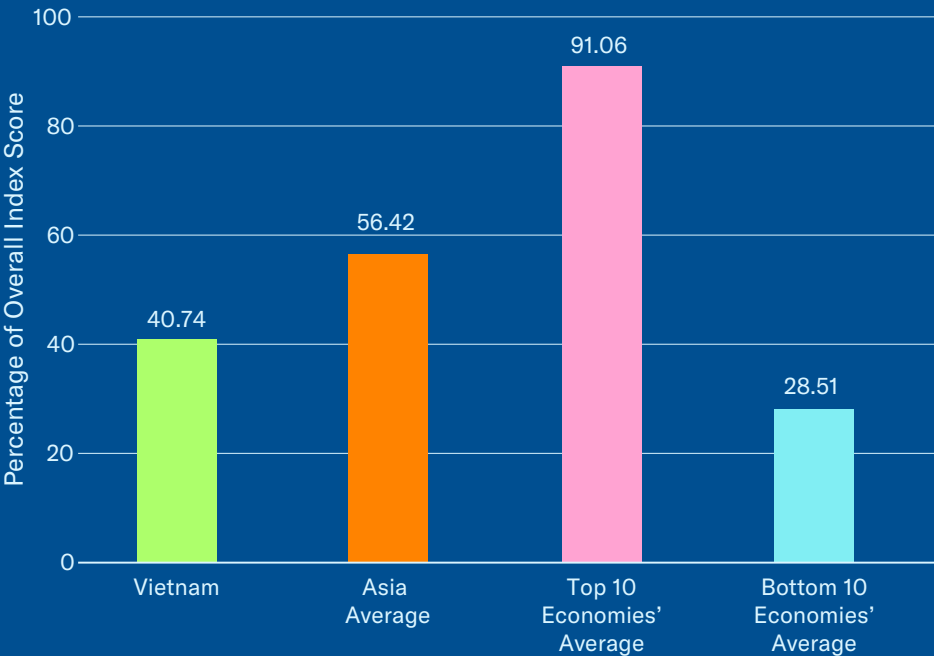
Nevertheless, should rightsholders be able to obtain patent protection under TRIPS standards for a minimum term of 20 years in accordance with Venezuela’s WTO obligations, this would mark a significant and positive improvement in Venezuela’s national IP environment and would result in a score increase on indicators 1 and 2. The Index will continue to monitor these developments in 2023.



Category Scores



Overall Score in Comparison



Key Areas of Strength

- 2022 amendments to Law on Intellectual Property (IP Law) improve copyright protection
- Acceded to WIPO Performances and Phonograms Treaty in 2022
- Acceded to WIPO Copyright Treaty in 2021
- Ratified EU-Vietnam FTA in 2020
- Basic IP protections and enforcement framework in place
- Growing integration into international IP platforms—e.g., 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
- 2022 amendments notwithstanding, gaps remain in copyright protection, including a lack of measures to address online infringements
- High physical counterfeiting rates and online infringement—BSA estimates a software piracy rate of 74%
- Restrictions in place on digital trade and cross-border data transfers through Law on Cybersecurity
- Enforcement generally poor; penalties insufficient in practice; administrative inaction



Indicator	Score	Indicator	Score
Category 1: Patents, Related Rights and Limitations		Category 6: Commercialization of IP Assets	
3.00		1.58	
1. Term of protection	1.00	26. Barriers to market access	0.00
2. Patentability requirements	0.25	27. Barriers to technology transfer	0.25
3. Patentability of CIIIs	0.00	28. Registration and disclosure requirements of licensing deals	0.25
4. Plant variety protection	1.00	29. Direct government intervention in setting licensing terms	0.00
5. Pharmaceutical-related enforcement	0.00	30. IP as an economic asset	0.75
6. Legislative criteria and use of compulsory licensing	0.00	31. Tax incentives for the creation of IP assets	0.33
7. Pharmaceutical patent term restoration	0.00	Category 7: Enforcement	
8. Membership of a Patent Prosecution Highway	0.50	1.91	
9. Patent opposition	0.25	32. Physical counterfeiting rates	0.40
Category 2: Copyrights, Related Rights, and Limitations		33. Software piracy rates	0.26
1.78		34. Civil and preceudural remedies	0.25
10. Term of protection	0.53	35. Preestablished damages	0.25
11. Exclusive rights	0.25	36. Criminal standards	0.50
12. Injunctive-type relief	0.25	37. Effective border measures	0.25
13. Cooperative action against online piracy	0.25	38. Transparency and public reporting by customs	0.00
14. Limitations and exceptions	0.00	Category 8: Systemic Efficiency	
15. TPM and DRM	0.50	2.50	
16. Government use of licensed software	0.00	39. Coordination of IP rights enforcement	0.75
Category 3: Trademarks, Related Rights, and Limitations		40. Consultation with stakeholders during IP policy formation	0.50
2.25		41. Educational campaigns and awareness raising	0.75
17. Term of protection	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
18. Protection of well-known marks	0.25	43. IP-intensive industries, national economic impact analysis	0.50
19. Exclusive rights and trademarks	0.50	Category 9: Membership and Ratification of International Treaties	
20. Frameworks against online sale of counterfeit goods	0.50	5.00	
Category 4: Design Rights, Related Rights, and Limitations		44. WIPO Internet Treaties	1.00
1.10		45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	46. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights and industrial design rights	0.50	47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Membership of the Convention on Cybercrime, 2001	0.00
1.25		49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
23. Protection of trade secrets (civil remedies)	0.50	50. Post-TRIPS FTA	1.00
24. Protection of trade secrets (criminal sanctions)	0.25		
25. Regulatory data protection term	0.50		
Total: 20.37			

Spotlight on the National IP Environment

Past Editions versus Current Score

Vietnam’s overall score has increased from 38.72% (19.36 out of 50) in the tenth edition to 40.74% (20.37 out of 50). This reflects score increases on indicators 13, 15, 32, and 44.

Area of Note

As noted in past editions of the Index, Vietnam has for the past several years been reforming its national IP environment. In mid-2022, Vietnam passed a substantive set of amendments to the 2005 Law on Intellectual Property (IP Law). The amendments seek to align Vietnam’s IP Law with both the EU FTA and CPTPP and to fulfill its treaty obligations under both. As detailed here with respect to the most consequential changes, overall, this is a mixed package. Although some improvements have been made to Vietnam’s national IP environment, including with respect to the protection of copyright, many of these legislative changes raise more questions and concerns than provide solutions to Vietnam’s long-standing national IP challenges. Covering 50 indicators across nine separate categories the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products. As the Vietnamese government works on implementing these new laws and considers additional legislative changes, we encourage them to use the findings of the Index and accompanying Statistical Annex as a guide.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products: As noted in previous editions of the Index, Vietnamese law has historically not provided restoration for pharmaceutical products for loss

of patent term time because of delays caused by the marketing approval process. Under the EU FTA, the government of Vietnam committed to introducing a clearly defined period of term restoration. This is not reflected in the 2022 amendments to the IP Law. Instead, the main thrust of the amendments and Article 131(a) is to provide compensation to a rightsholder in the form of a reduction in annual patent renewal fees for any relevant period of delay. This does not constitute term restoration. Consequently, Vietnam’s score on this indicator remains unchanged at 0.

9. Patent opposition: Vietnam has historically provided a system of pre-grant opposition to patent applications through Circular No. 1 2007. An opposition may be filed at any time after the publication of a patent application up to the patent grant. Under Article 112(a), this has now been codified in the IP Law. As such, Vietnam’s score on this indicator remains unchanged at 0.25.

Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation: As has been noted over the course of the Index, rightsholders face significant challenges in protecting their content in Vietnam. The legal framework has major gaps, and enforcement has been largely ineffective. The 2012 Joint Circular on Stipulations on the Responsibilities for Intermediary Service Providers in the Protection of Copyright and Related Rights on the Internet and Telecommunications Networks has required various ISPs (including social media networks) to issue warnings to infringing users. However, their secondary liability for copyright infringement has never been legally defined, and



limited incentives have been in place for ISPs and internet intermediaries to effectively address copyright infringement and online piracy.

With regard to disabling access to infringing content online, no defined administrative or court-based regime is in place. There have been ad hoc examples of the Ministry of Culture, Sports and Tourism taking action in the past against some notorious websites, but this is not systematic or through a defined process. As a result, online copyright enforcement is poor, with widespread use of copyright infringing content. This has been noted repeatedly by both the creative sector and the U.S. government. For example, the USTR noted in the *2022 Special 301 Report* that “online piracy, including the use of piracy devices and applications to access unauthorized audiovisual content, remains a significant concern” in Vietnam. The 2022 IP Law amendments address some of these long-standing challenges. Article 198(b) introduces a legal framework that promotes cooperative action against online piracy and provides internet intermediaries with defined responsibilities relating to copyright infringement. Most notably, under Subsection 2, all intermediaries are “responsible for implementing technical measures and coordinating with competent state agencies and rightsholders to implement measures to protect copyright and related rights in the telecommunications and Internet environment.” Similarly, the amendments also strengthen existing protection mechanisms for TPM and DRM. These are positive steps and something Vietnamese authorities can build on in addressing the long-standing challenges that rightsholders face in protecting their content in Vietnam. As a result of these changes, the scores on indicators 13 and 15 have increased by 0.25, respectively.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection term: Historically, the Law on Intellectual Property and implementing regulations (Circular No. 05/2010/TT-BYT) have provided a five-year term of regulatory data protection for undisclosed biopharmaceutical test data submitted during sanitary registration. However, in practice, this term has often not effectively been made available to rightsholders. Specifically, there has been a lack of clarity on the extent to which follow-on applicants can rely on and benefit from an approved registration file and compare it to the chemical and toxic levels of the substitute, for example, through bioequivalence tests.

Such practices of direct or indirect reliance all but negate an innovator’s rights under any RDP regime, including in Vietnam. Unfortunately, the 2022 amendments to the IP Law do not add any clarity to this issue. Confusingly, although Article 128(2) seems to state that relevant market authorization authorities cannot approve any application for follow-on products that rely on already submitted test data during the RDP period, Subsection 3 seems to suggest that such applications are to be accepted but published on the relevant agency’s web portal within a defined period. This does not constitute an RDP regime in line with international standards or best practices.

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 to 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. A 2012 estimate points to the total cost of drug development being approximately USD1.5 billion. Tufts University research from 2016 suggests that it costs USD2.6 billion, on average, to develop a new drug. International experience and the basic economics of the biopharmaceutical industry show how critical IP rights are to incentivize and support this research and development of new medical technologies and products. In particular, patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection, 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 will 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, research and development, and product commercialization. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws.

The government of Vietnam should be congratulated for adopting and clearly providing a defined term of RDP. This is a clear signal that policymakers understand the nature of biopharmaceutical R&D and the necessary incentives needed to develop new life-saving products and technologies. However, undermining these incentives through various conditions and potential carve-outs is counterproductive. Over time, such action will simply hollow out the national IP environment and incentives for future biopharmaceutical innovation. The

negative effect will be the same for Vietnamese and foreign innovators. Should rightsholders continue to face challenges in obtaining their legally granted period of RDP, the score for this indicator will be reduced to 0.

Membership and Ratification of International Treaties

44. WIPO Internet Treaties: In 2022, Vietnam acceded to the WIPO Performances and Phonograms Treaty. As a result, the score on this indicator has increased by 0.5.



Appendix: Methodology, Sources, and Indicators Explained

The Index consists of 50 indicators across nine 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; and
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 as follows.

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 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.³⁷ 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 as follows.

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. Five possible scores are 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.

A few instances also exist where 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 is given for ratifying or acceding to that treaty. This is also the case for indicator 7, Patent term restoration for pharmaceutical products. This indicator consists of two distinct variables: i) 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 ii) 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. The available score of 0.75 for this indicator is allocated to the existing term of protection compared to 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 rightsholders view as an appropriate environment and level of protection.

IP Rights Baselines

Baseline	Baseline in Years	Legislation Model
Basic patent protection	20	TRIPS
Copyrights	95	U.S.
Trademarks	10	WIPO
Regulatory data protection	10	EU
Patent term restoration	5	EU/U.S./Japan
Design rights	25	EU

Measuring Counterfeiting and Piracy

Indicators 32 and 33 of the Index measure rates of physical counterfeiting and software piracy, respectively. Attempting to measure counterfeiting and piracy has several challenges.

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 counterfeiting and piracy 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 counterfeiting and piracy with a sample of economies sufficient to make large-scale comparisons empirically robust.

Finally, because measures of counterfeiting and piracy are inexact, estimates of their economic impact can vary widely depending on the methodology and data samples used.³⁸

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

- » The OECD’s General Trade-Related Index of Counterfeiting of Economies (GTRIC-e), which measures the relative rates of physical counterfeiting; and³⁹
- » Software piracy rates compiled by the Business Software Alliance (BSA) (2018 is the latest published survey).

These sources are both robust and internationally recognized measures. Furthermore, they cover a large sample of economies, thus 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, particularly 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. It 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 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 are 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 economies included, the Global Measure of Physical Counterfeiting uses a proprietary metric that 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: 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 preestablished 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 earlier.

The third factor used is the rate of perceived corruption within an economy, as measured by Transparency International'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. 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 available and are freely available and 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 and 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 nongovernmental organizations and consumer organizations.

Academic

Academic sources include:

- » Academic journals, books, published manuscripts; and
- » Legal journals.

News

News sources include:

- » Newspapers;
- » News websites; and
- » Trade press.

In addition to these listed resources, over 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 and 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 of the national IP environment in each of the economies sampled.

We thank the governments and economies that have made these submissions and welcome all economies covered in the Index to consider doing so. The only criterion we use, just as for all 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. **Patent term of protection**—Measured by the basic patent term offered in the TRIPS Agreement. This is a numerical indicator.
2. **Patentability requirements**—The extent to which patentability requirements are in line with international standards of novelty, inventive step, and industrial applicability.⁴⁰ Measured by i) existing *de jure* patentability guidelines and regulations and ii) *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 being 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.⁴¹ 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 before 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 mechanisms are 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 or enforcement is transparent and consistent with the following criteria: i) the issuing should exclude any requirement for domestic manufacturing; ii) the issuing should not apply to patented innovations that have not yet reached the market; iii) 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 iv) 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**—This indicator consists of two distinct variables: i) 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 ii) 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. The available score of 0.75 for this indicator is allocated to the existing term of protection compared to 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 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)**—This indicator measures if 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 i) have in place laws and procedures that provide necessary exclusive rights and ii) 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 indicator measures the existence and extent of an official national government administrative or judicial injunctive relief mechanism available to rightsholders. 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 should 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, promotes cooperation between them and rightsholders 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).⁴² The score for this indicator is evenly divided between legislation and application in the court system. This is a mixed indicator.
15. **Technological protection measures (TPM) and digital rights management (DRM) legislation**—Measured by the extent to which economies have i) passed primary and/or secondary legislation relating to TPM and DRM and ii) 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 i) policies and guidelines are in place stipulating the use of only licensed proprietary software and ii) 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 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 i) 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), which create a likelihood of public confusion as to source, sponsorship, or affiliation; and ii) 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 rightsholders 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 or 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.⁴³

Category 4: Design Rights, Related Rights, and Limitations

The indicators in this category relate to design rights, related rights, and limitations.

21. **Industrial design term of protection**—Measured by the maximum term of protection 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 i) have in place laws and procedures that provide necessary exclusive rights (including making, marketing, trading, and use of an industrial design) and ii) 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 i) legislation that offers protection for trade secrets or confidential business information and ii) 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 i) legislation that provides criminal sanctions for the misappropriation, improper acquisition, use, or disclosure of trade secrets or confidential business information and ii) the application



of this legislation and effective access to these remedies. This is a mixed indicator.

25. **Regulatory data protection 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.⁴⁴ 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**—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 or domestic entity. This is measured by the extent to which i) existing laws and procedures make market access contingent on the sharing or disclosure of intellectual property and know-how and ii) 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**—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**—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**—The extent to which relevant government authorities directly intervene and set licensing terms between licensee and licensor.⁴⁵ This can be done through, for example, governmental preapproval for any licensing agreement between two parties or government intervention in the setting of licensing terms, including royalty rates. This is a mixed indicator.
30. **IP as an economic asset**—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 or tertiary level) courses on the commercialization and use of IP as an economic and financial asset and 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**—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—incentives are targeted specifically at the creation of IP through, for example, innovation and patent boxes.

- » Layer 3—the extent to which these incentives are not hampered by onerous localization and/or administrative requirements linked to the availability and use of the tax incentives or other mechanisms

Category 7: Enforcement

The indicators in this category measure the prevalence of IP rights infringement, the criminal and civil legal procedures available to rightsholders, the authority of customs officials to carry out border controls and inspections, and transparency of customs authorities' actions.

32. **Physical counterfeiting 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 i) the existence of civil and procedural remedies, including injunctions, damages for injuries, and destruction of infringing and counterfeit goods, and ii) their effective application. This indicator also reflects administrative enforcement measures where applicable. This is a mixed indicator.
35. **Preestablished 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 i) actual legislation is in place and ii) 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 rightsholder. This is a mixed indicator.

38. **Transparency and public reporting by Customs authorities of trade-related IP infringement**—The extent to which customs authorities in a given economy publish statistics and data on trade-related IP infringement. This indicator measures i) the extent to which data are published on a regular and systematic basis and ii) the level of detail of these data. This is a mixed indicator.

Category 8: Systemic Efficiency

The indicators in this category seek to measure how a national IP system works.

39. **Coordination of IP rights enforcement efforts**—The existence of coordinated efforts of 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 that provides cross-governmental coordination to national IP enforcement efforts. This is a mixed indicator.
40. **Consultation with stakeholders during IP policy formation**—This indicator measures 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**—This indicator measures i) the extent to which national governments engage in educational campaigns and awareness raising



on the positive socioeconomic impact of IP rights and the negative impact the infringement of these rights has on creators, innovators, and the national economy and ii) 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—This indicator measures 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, national economic impact analysis—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 i) the mapping and measuring of the economic impact and importance of IP-intensive industries to national economic activity are taking place and ii) 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 a signatory of and has ratified or acceded to international treaties on the protection of IP. Some international treaties only allow for accession, i.e., membership is either conferred or it is 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.⁴⁶

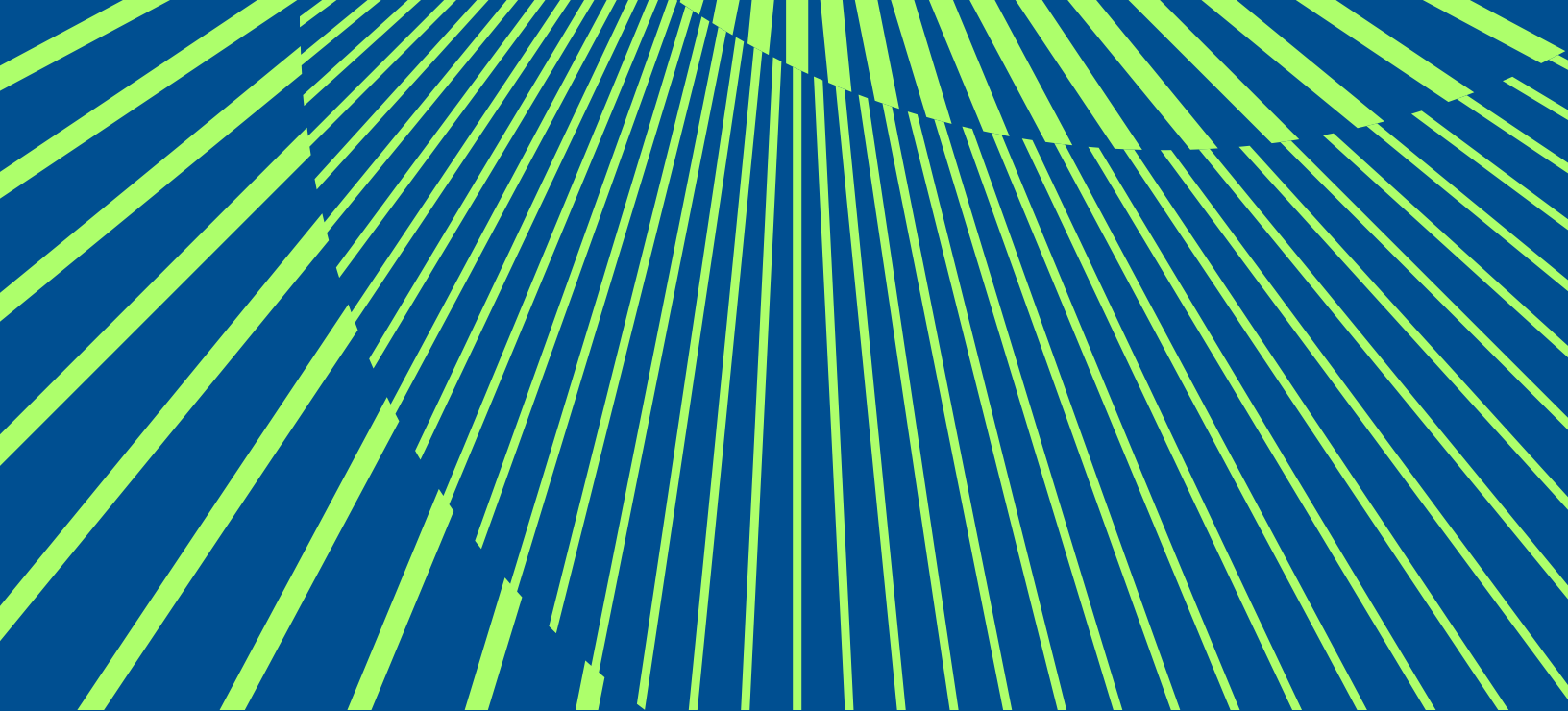
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices—This is a mixed indicator.

Endnotes

1. Note that the World Bank’s geographic classifications have been somewhat amalgamated. Middle East and North Africa have been combined with Sub-Saharan Africa, and East Asia and Pacific have been combined with South Asia. See World Bank (2022), “Country and Lending Groups.”
2. Johns Hopkins, Coronavirus Resource Center, Coronavirus COVID-19 for Systems Science and Engineering (CSSE) at Johns Hopkins University.
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37. 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 the author plus an additional number of years (i.e., in cases where the rightsholder is unknown or has already died). Accordingly, 95 years is the minimum term applied in U.S. law.
38. These difficulties in 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 based on both physical and digital software piracy. Nevertheless, many academic and industry-supported studies 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. 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, most 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. 56-8; and Smith, M.D., & Telang, R. (2012), *Assessing the Academic Literature Regarding the Impact of Media Piracy on Sales* (Social Science Research Network 2012).
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40. 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.”
41. Act of 1991, International Convention for the Protection of New Varieties of Plants, Article 19, Duration of the Breeder’s Right
42. The Berne three-step test generally requires that limitations and exceptions to copyrights should be i) confined to special cases ii) do not conflict with a normal exploitation of the work and iii) do not unreasonably prejudice the legitimate interests of the rights holder. (TRIPS Agreement, Article 13.)
43. 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 (VeRO) Program, which allows rightsholders 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>.
44. 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 or 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 of 10 years (8+2) of marketing exclusivity.
45. This indicator is not concerned with commercial litigation brought by private parties and settled by an independent judiciary.
46. The Hague Agreement Concerning the International Registration of Industrial Designs consists of 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.



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