U.S. Chamber of Commerce
Global Innovation
Policy Center

International IP Index

2024 Twelfth Edition

U.S. Chamber of Commerce

The U.S. Chamber of Commerce's Global Innovation Policy Center 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.

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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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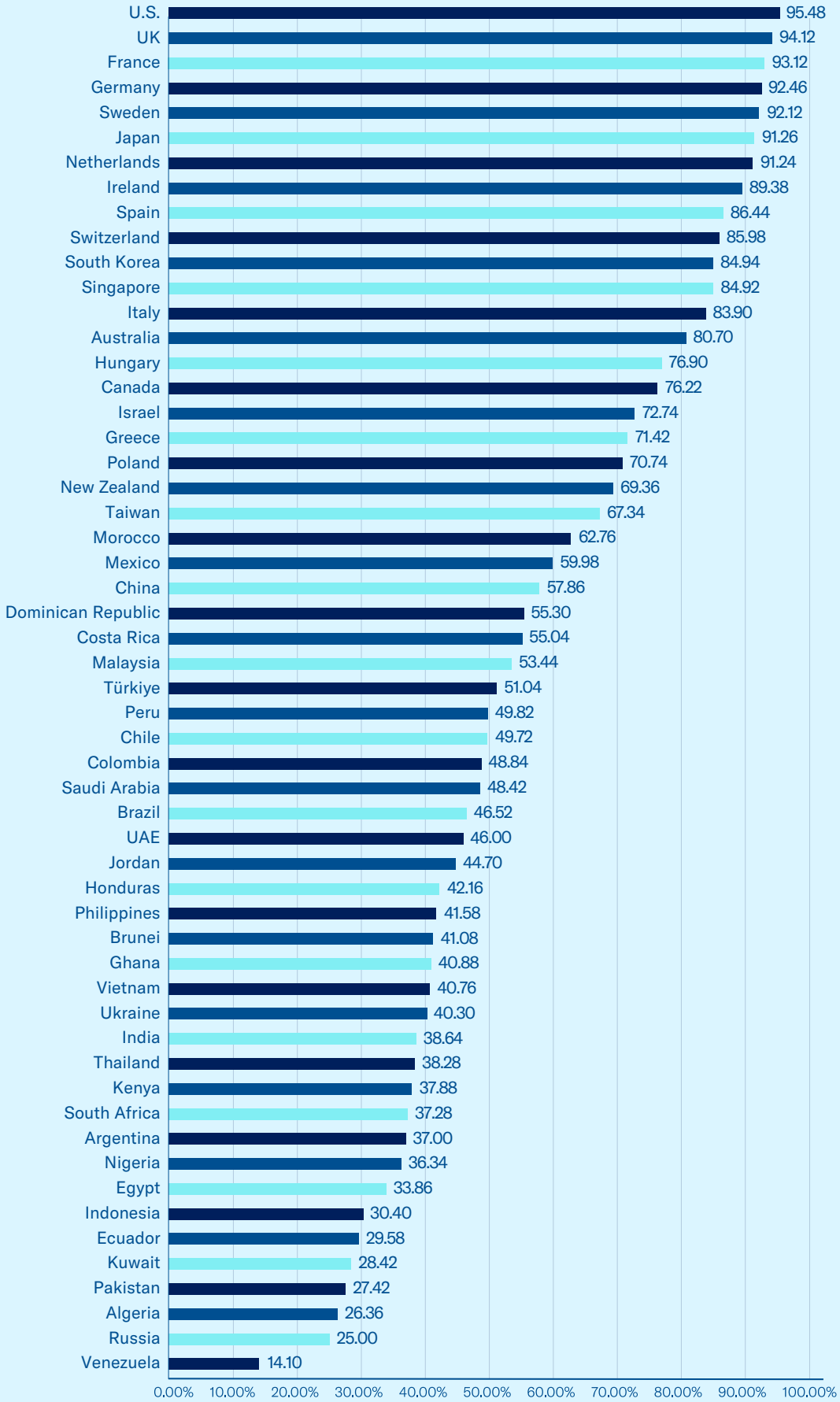


Foreword

As Charles Dicken's wrote in the opening of A Tale of Two Cities, "[i]t was the best of times, it was the worst of times…." That is certainly the state of intellectual property (IP") policy around the globe.

The transformative power of innovation has never been more evident.

People everywhere have more choice than ever before, with an array of technologies at their fingertips to enhance productivity, simplify everyday challenges, and improve the quality of life. We have more medical solutions than any time in history, both to everyday ailments and devasting medical diagnoses. And the rapid growth of new creative content has enriched our lives and expanded our cultural horizons.

Solutions abound to everyday hardships and existential crises, alike, with each new challenge an invitation to innovation that will be critical to advancing human progress.

Day in and day out, society reaps the outsized benefit of these invaluable innovations. Economists quantify these benefits as a "social surplus." While 98% of the value of a new technology benefits the billions of users, the innovator responsible for that technology receives only 2%. That's a value ratio of 50:1.

Intellectual property (IP) is critical to sustaining the innovation ecosystem that propels ongoing progress. IP rights create the legal conditions required for the investment, collaboration, and commercialization needed to improve the human condition.

The U.S. Chamber's International IP Index helps global policymakers assess the strengths and weaknesses of their national ecosystem relative to neighbors and economic competitors. The Index measures how economies empower innovators and creators and whether individual nations and the global marketplace are on the path to shape a brighter future.

While nations like Saudi Arabia, Brazil, and Nigeria have made strides in advancing their IP frameworks, major economies such as the United States and the European Union have remained stagnant, which endangers their continued IP leadership.

On the global stage, we continue to see heated debates around IP waivers through discussions at the World Trade Organization and World Health Organization. There are also continued efforts by India and the Africa Group to undermine IP protections through proposals for mandatory technology transfer of green technology and climate change-related solutions.

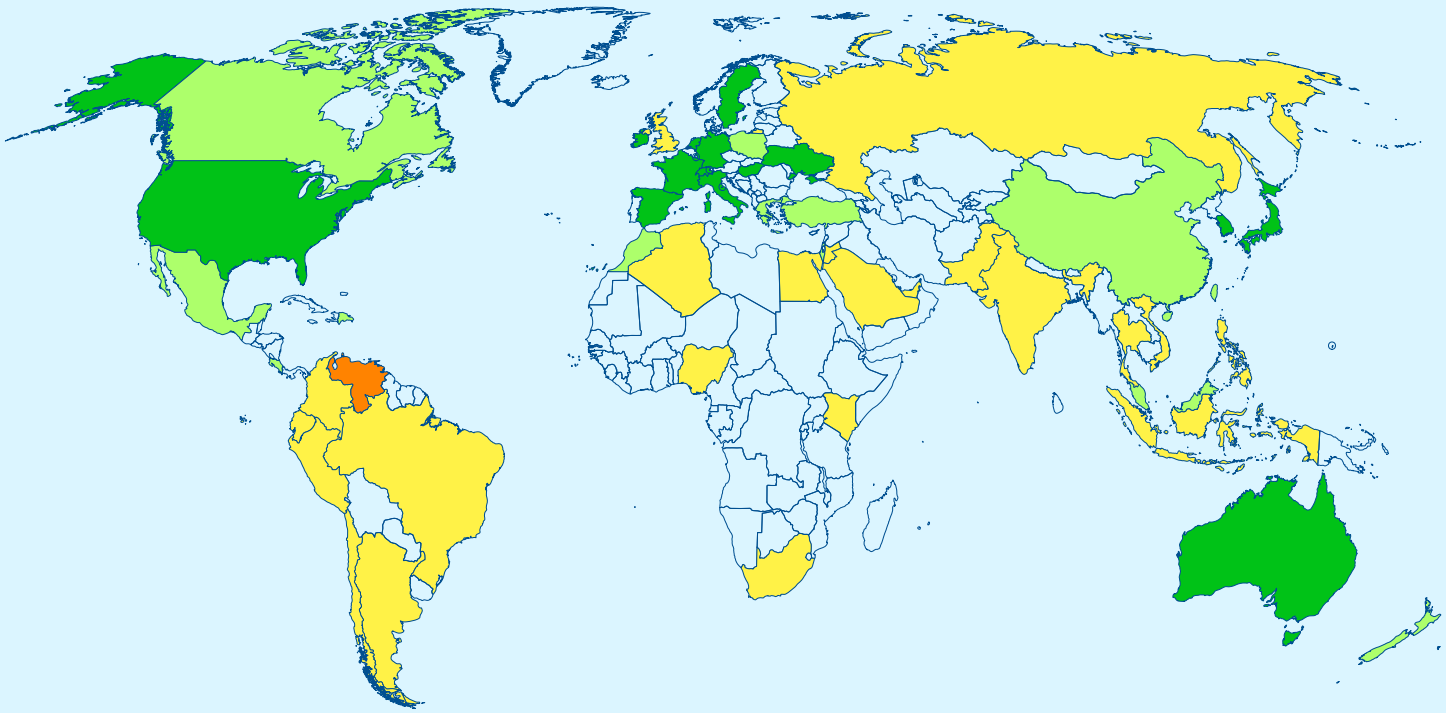
Ironically, those efforts will undercut the business community's efforts to address emerging challenges, from climate change to future pandemics.

IP has helped drive unprecedented global advances over the past fifty years, be it stamping out poverty or improving health. Continued strong IP policies will allow this progress to continue. However, maintaining the status quo or a retreat from IP will cause the innovation engine to sputter, with global consumers suffering the consequences.

Executive Summary

The 12th edition of the International IP Index benchmarks the IP framework in 55 global economies across 50 unique indicators.

The Index not only provides a roadmap for economies seeking to enhance IP-driven innovation and creativity but also sheds light on trends in global IP protection in the last year.



Overall Economy Scores

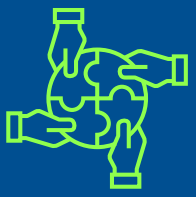
1-25% 26-50% 51-75% 76-100%

Geographic Coverage

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

Key Findings

The overall score improved in 20 economies, creating renewed optimism about the future of global IP policy.



Multilateral organizations have an opportunity to correct course and reaffirm the global commitment to IP, rather than continue to further tolerate counterproductive measures such as IP waivers.

- Saudi Arabia, Brazil, and Nigeria earned the largest improvements in overall score at 6.04%, 4.50%, and 3.00% respectively. These advancements illustrate how economies can make a conscious, policy choice to invest in innovative capacity to help deliver solutions to global challenges.
- Twenty-seven economies' scores remained unchanged. While eight economies overall scores dropped, only Ecuador had a decrease of over 1% reflecting the absence of effective measures to allow border officials to effectively take action against IP-infringing goods.
- There was almost no positive movement among top-ranked economies that have traditionally been global leaders on advancing IP protection, making it incumbent upon the U.S., the EU and others to reassert their global leadership on IP policy.
- While the global public health emergency on covid-19 ended in May 2023, the World Trade Organization (WTO) continues to tirelessly debate the waiver of IP rights for therapeutics and diagnostics. The ongoing waiver debate only ensures that its proponents will be on the sidelines, forced to wait to be recipients of technological solutions, rather than part of the successful ecosystem that creates them. Should WTO members agree to an expansion of the waiver, economies scores will be negatively impacted in the next edition of the Index.
- The World Health Organization's (WHO) draft Pandemic Accord includes calls for further time-bound IP waivers and forced technology transfer while the International Health Regulations likewise propose coercive technology transfer.
- As feared, the effort to undermine IP protections have expanded beyond the life sciences industry, with economies like India and the Africa Group calling for IP waivers and mandatory technology transfer of green technology and climate change solutions.

While developed economies have traditionally had world-class IP systems critical to advancing innovation, many high-income economies continue to consider policy and regulatory proposals which threatens to cede this leadership to foreign competitors.

Economies of all levels of development continue to take steps to combat online piracy, building on positive momentum in recent years.

- In the United States, the Administration released a proposal to expand the use of march-in rights on the basis of price. Coupled with the drug pricing provisions of the Inflation Reduction Act and ongoing uncertainty around patentability, the U.S. continues to undermine the framework needed to sustain the life sciences ecosystem.
- In Europe, the General Pharmaceutical Legislation, Patent Package, and European Health Data Space proposals will limit the availability of regulatory data protection, needlessly expand the ability to grant compulsory licenses, undermine the system for Standard Essential Patent (SEP) licensing and negotiations, and jeopardize trade secrets protection.
- Emerging artificial intelligence policies at the national level must be evaluated in light of pre-existing commitments at the WTO, World Intellectual Property Organization (WIPO) and in free trade agreements, as well as against the important principles articulated by G-7 members.
- The introduction or extended application of dynamic injunctions for protecting copyrighted works online increased in 2023, with Argentina and Brazil joining countries like Canada, India, and Singapore in utilizing some form of dynamic injunctions.
- Additional economies, such as the Philippines, are considering introducing injunctive relief that would include a dynamic element.
- Economies introduced or extended criminal causes of action for copyright infringement. Notably, India enacted criminal sanctions for copyright infringement.

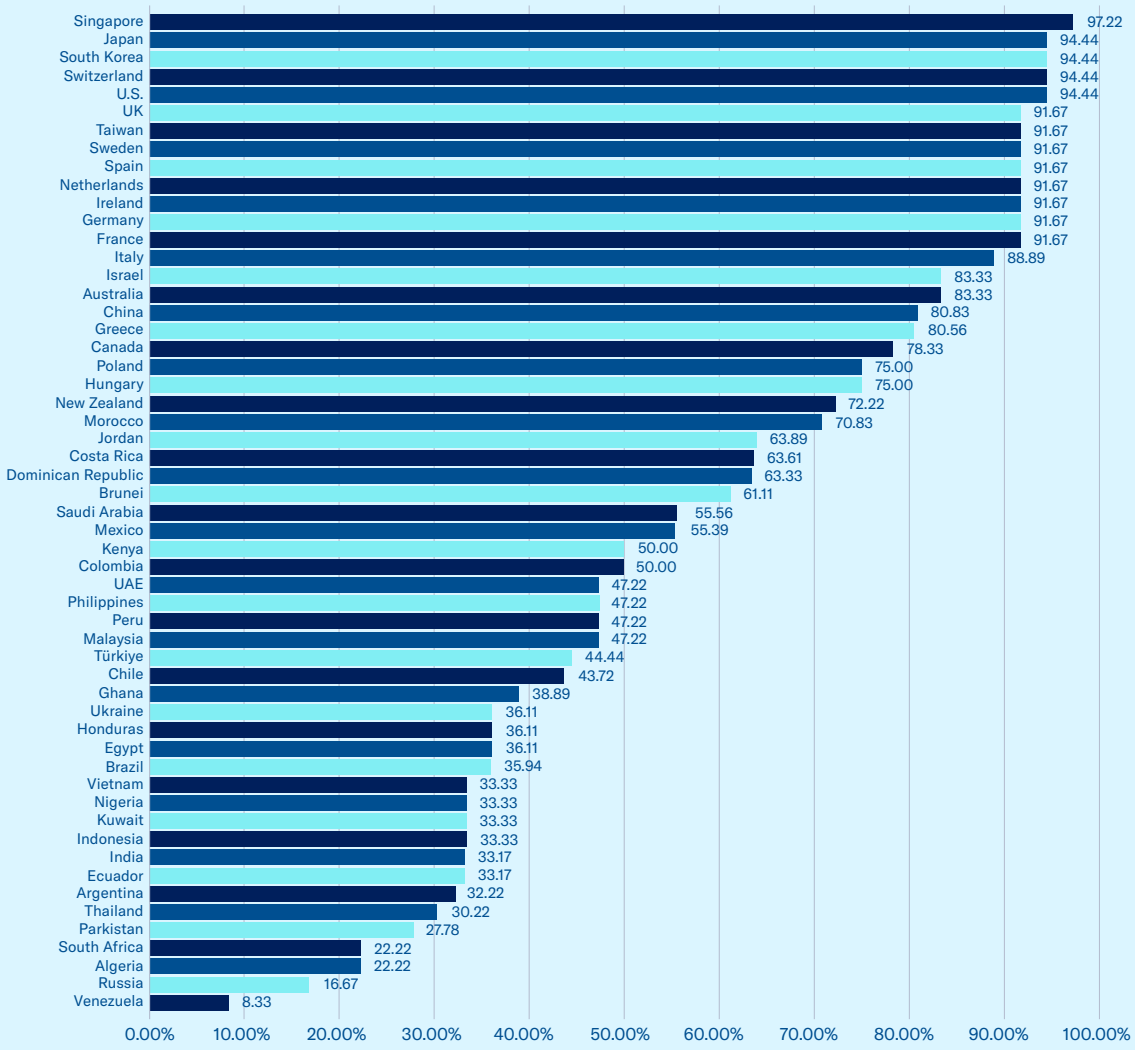
Category-by Category Results

Patents, Related Rights, and Limitations

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

- Draft patent amendments in India will enhance the framework for patent protection by improving existing patent opposition mechanisms and introducing positive changes to the Form 27 requirements to declare a working patent.
- In Pakistan, draft amendments will eliminate the pre-grant opposition in Pakistan, bringing improve certainty to patent rights. However, the proposed legislation also further limits or eliminates the potential patentability of computer-implemented inventions (CIIs) and biopharmaceutical innovation.
- IP holders face continued uncertainty over patents in Brazil. While a Federal Court ruled in favor of a patent term adjustment following an undue delay to the patent grant, the Supreme Court separately ruled that patent rights cannot apply beyond 20 years from initial application, regardless of the time of grant.

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

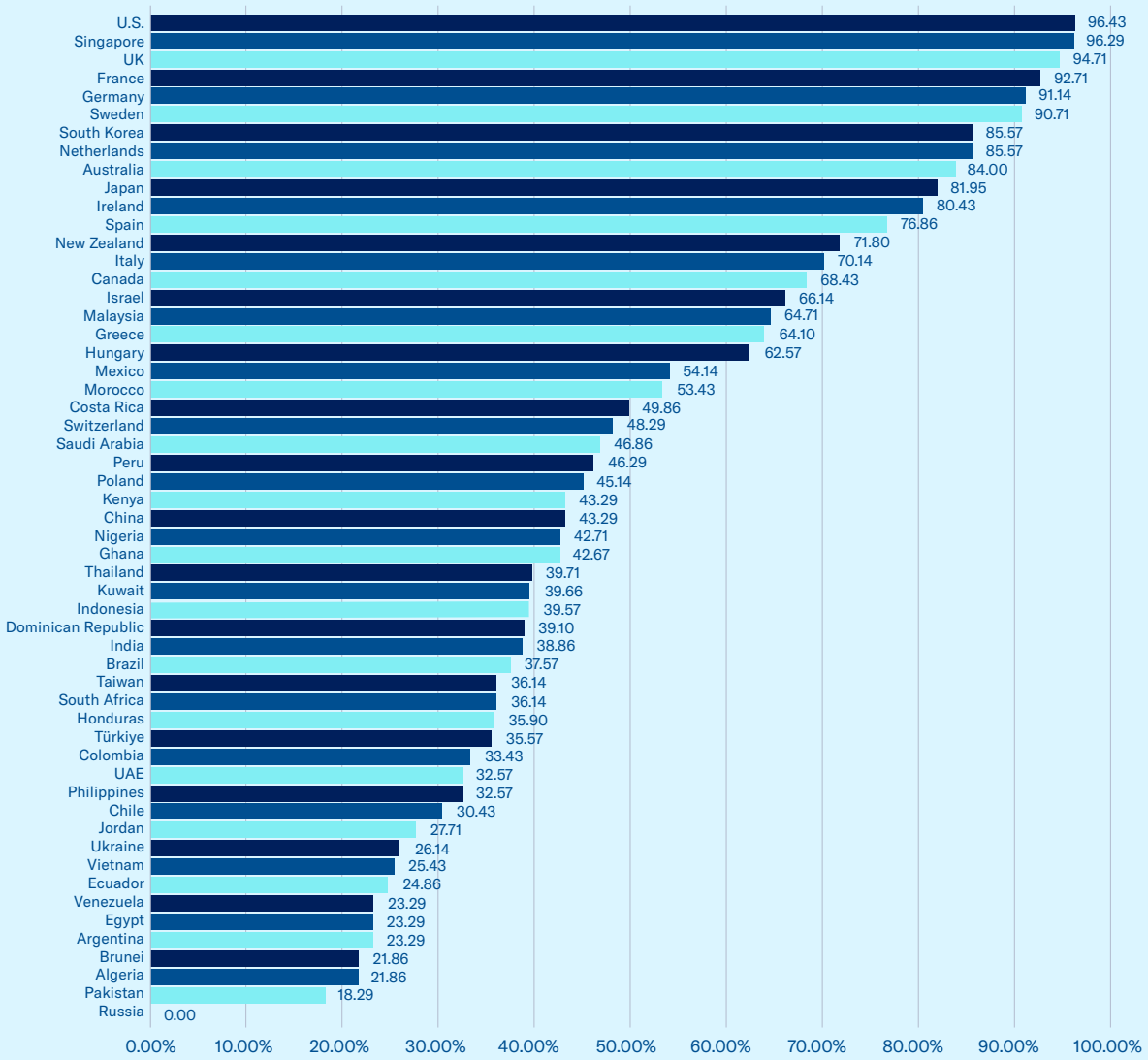


Copyrights, Related Rights, and Limitations

While many Index economies struggle to provide effective copyright protection, the average score on this category improved marginally from 49.70% last year to 50.61% this year in 2023.

- In Brazil, Anatel launched new efforts to locate and disable illegal set-top boxes, which have resulted in the seizure of nearly 1.5 million illegal units.
- Saudi Arabi and Egypt both continued to disable access to copyright-infringement websites, building upon positive momentum in both economies to enhance copyright enforcement.
- Greece's implementation of the EU's Digital Single Market Directive clarified the definition of what constitutes secondary liability for communication to the public of a protected work.
- While Nigeria's new Copyright Act includes new mechanisms to address devices or online platforms with copyright-infringing content, the legislation also creates a new basis to issue compulsory licenses and expands existing educational use exceptions.

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

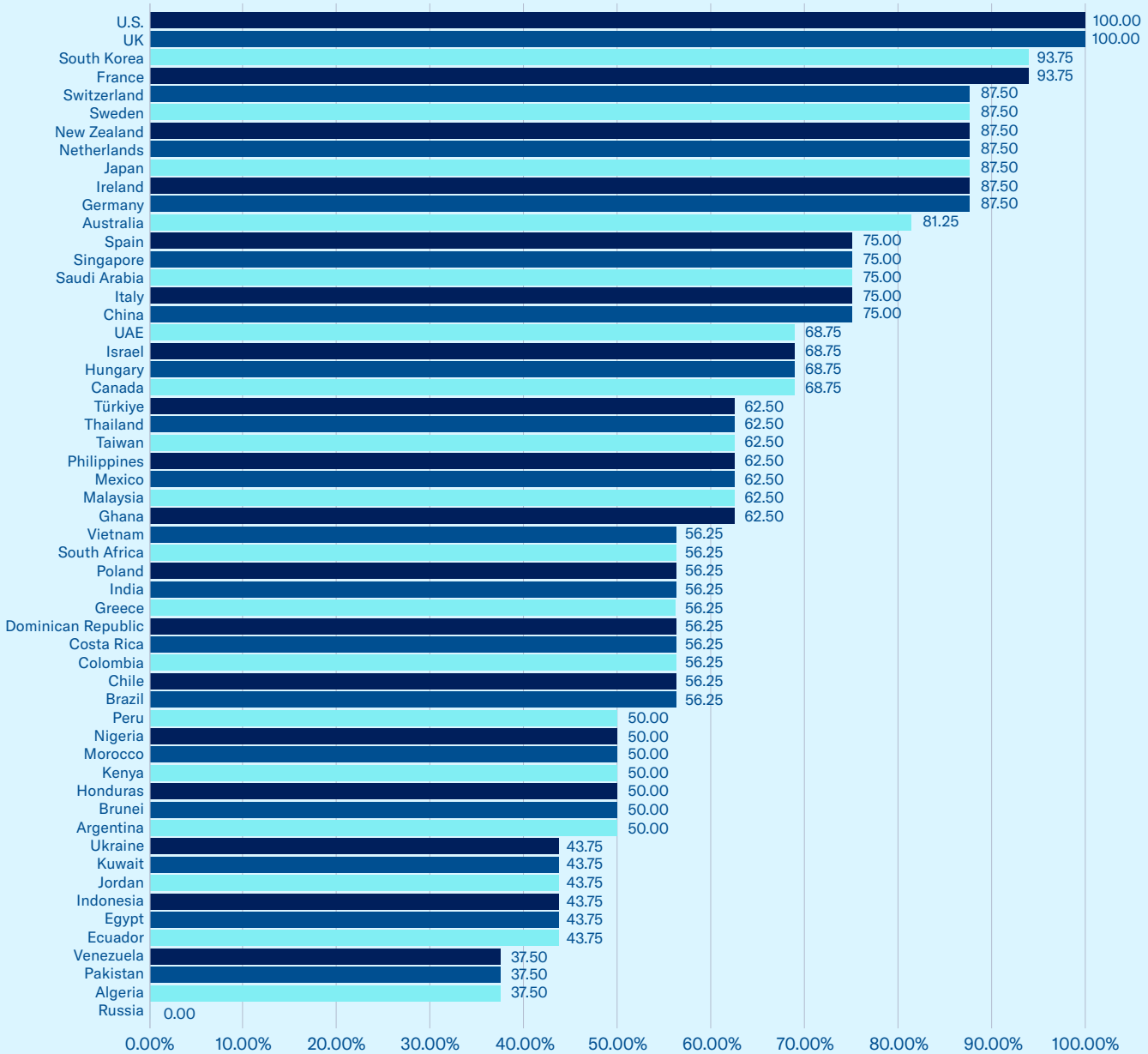


Trademarks, Related Rights, and Limitations

Most economies sampled in the Index offer basic forms of trademark protection, with only 10 of 55 sampled economies failing to score 50% or more on this category. The overall average score in this category increased from 62.39% in the eleventh edition to 62.84% in the twelfth edition.

- The Saudi IP Authority seized more than 12 million trademark and design infringing items and worked with online merchants and intermediaries to take down close to 60,000 e-commerce-related ads or infringing content.
- Taiwan's Supreme Administrative Court issued a potentially precedent setting ruling on what constitutes a well-known mark, marking a potential turning point in Taiwanese jurisprudence and the manner in which administrative law assesses trademark infringement of well-known marks.

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

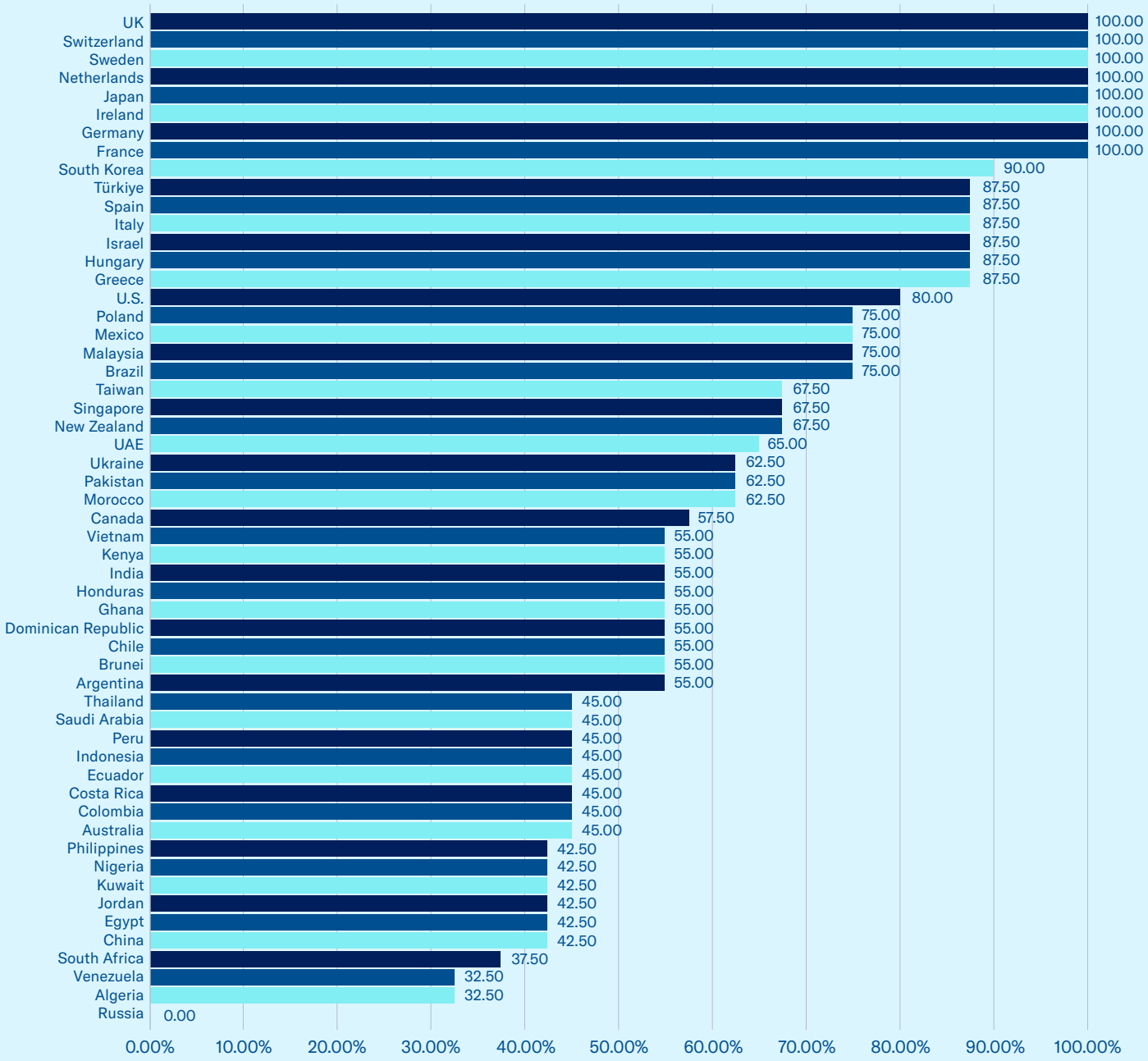


Design Rights, Related Rights, and Limitations

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 64%; up marginally from 63.77% last year.

- Indonesia proposed new amendments to the Design Law to increase of the total term of protection available up to fifteen years.
- The EU proposed changes to the existing legal framework for community designs which updates legal definitions and registration requirements, improves the scope of protection for design rights, and expands the potential exceptions to industrial design protection under a so-called 'repair clause.'

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

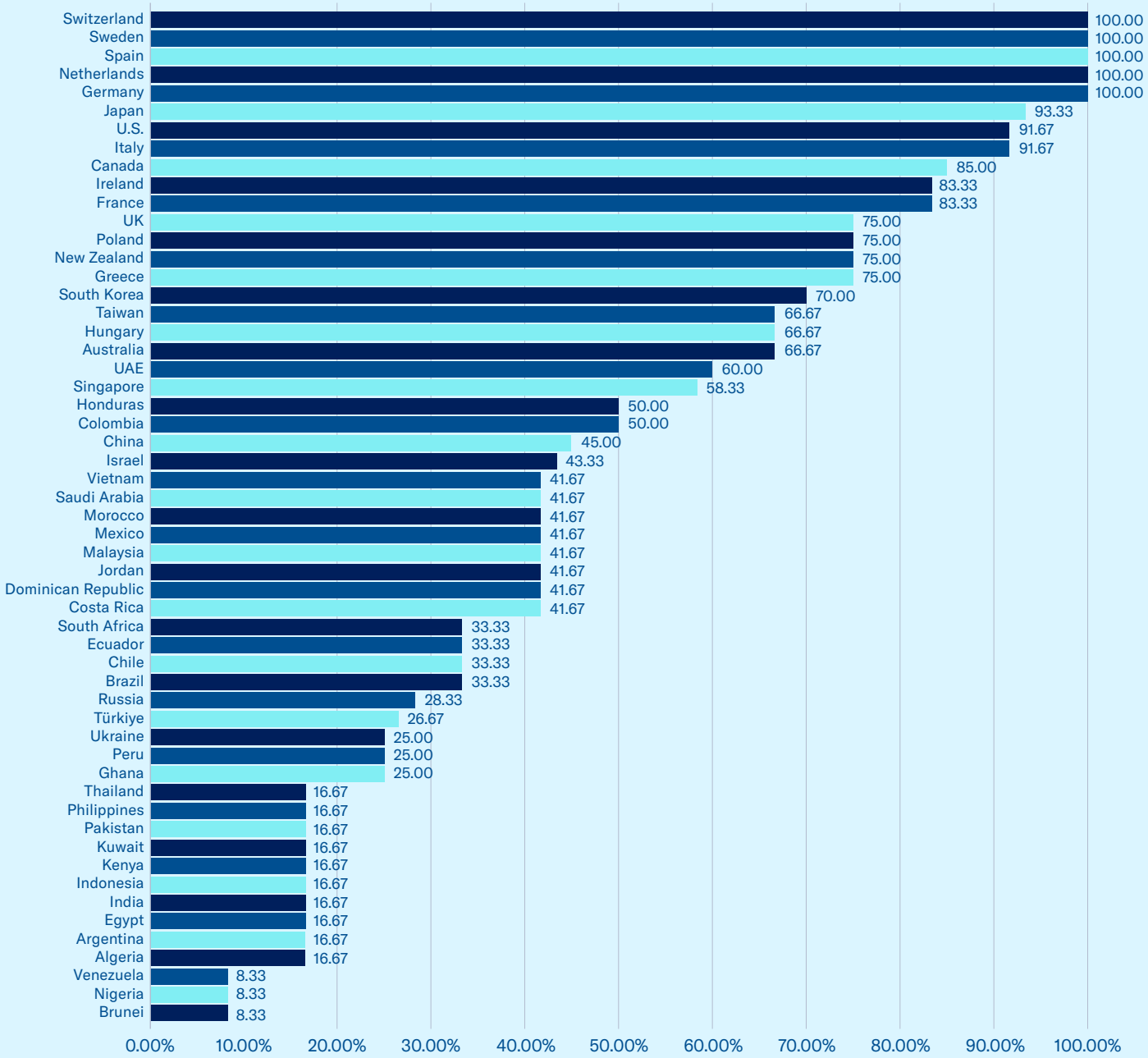


Trade Secrets and the Protection of Confidential Information

Only 23 of the 55 economies included in the Index achieved a score of 50% or more on this category, and 22 economies achieved a score of 33.33% or less. The average score on this category remained the weakest on the Index at 48.97%, unchanged from last year.

- The EU introduced legislation that will reduce the term of regulatory data protection (RDP) and condition the extension of the term of exclusivity on external factors, such as market access.
- The EU also published proposals to create a European Health Data Space (EHDS) that would alter the way confidential and proprietary health data is disseminated and make protected IP and trade secrets subject to secondary use.

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

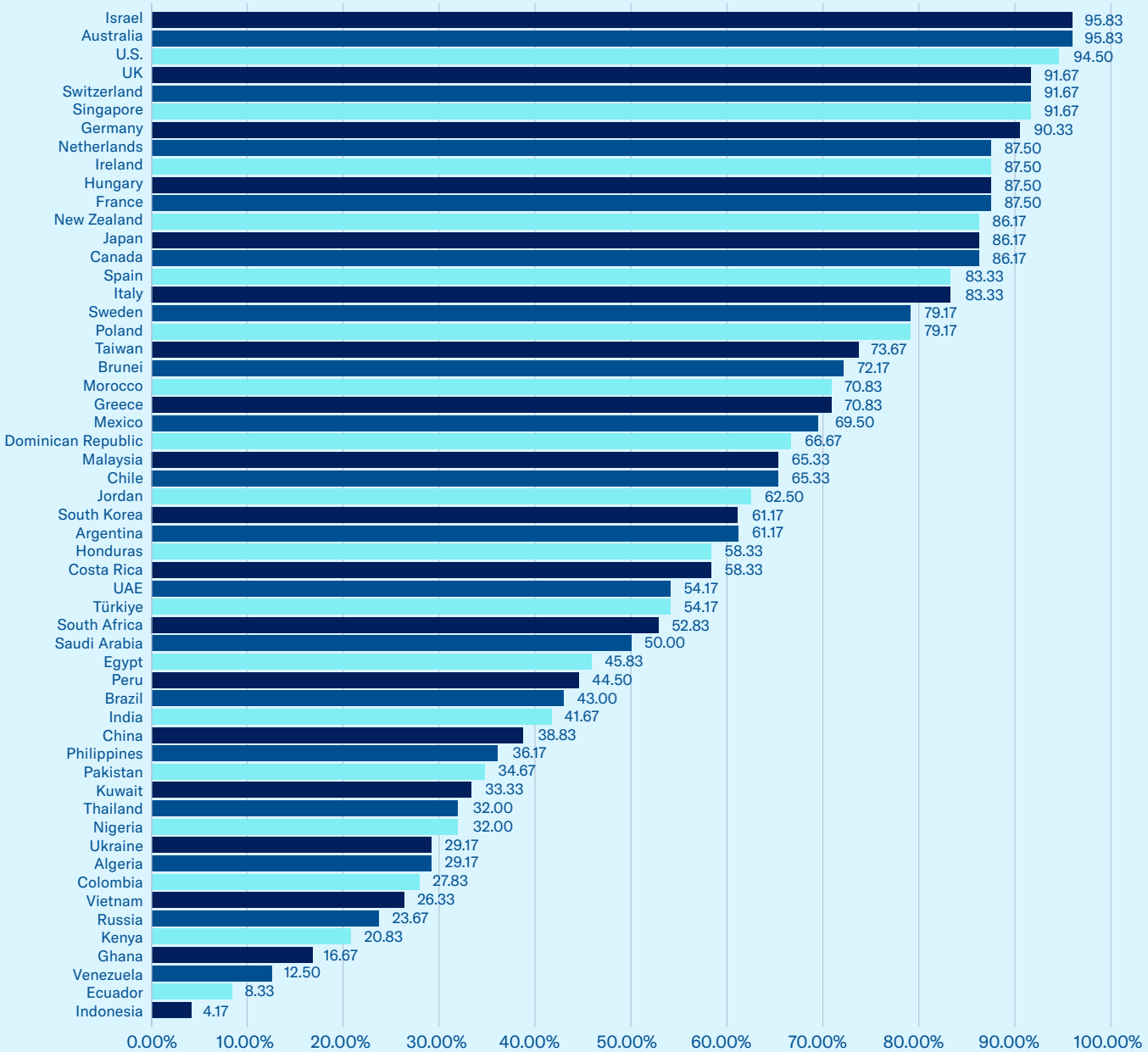


Commercialization of IP Assets

Of the 55 economies sampled, 20 fail to achieve a score of 50% or more with a full thirteen scoring 33.33% or less on the category. The average score on this category was 58.78%.

- In China, new rules that accompany the Anti-Monopoly Law contain broad language and vest considerable discretion with the government to identify and define what constitutes anti-competitive behavior.
- The Turkish Government took steps to address issues with Türkiye's localization policies highlighted in the WTO panel ruling, including the development of new Drug Reimbursement regulations, the termination of relevant import substitution programs, and the opening of reimbursement lists to previously excluded foreign companies.
- Morocco launched a new 'IP Marketplace' to share information on registered IP assets and help facilitate licensing and commercialization activity.

Figure 8: Category 6: Commercialization of IP Assets, % Available Score

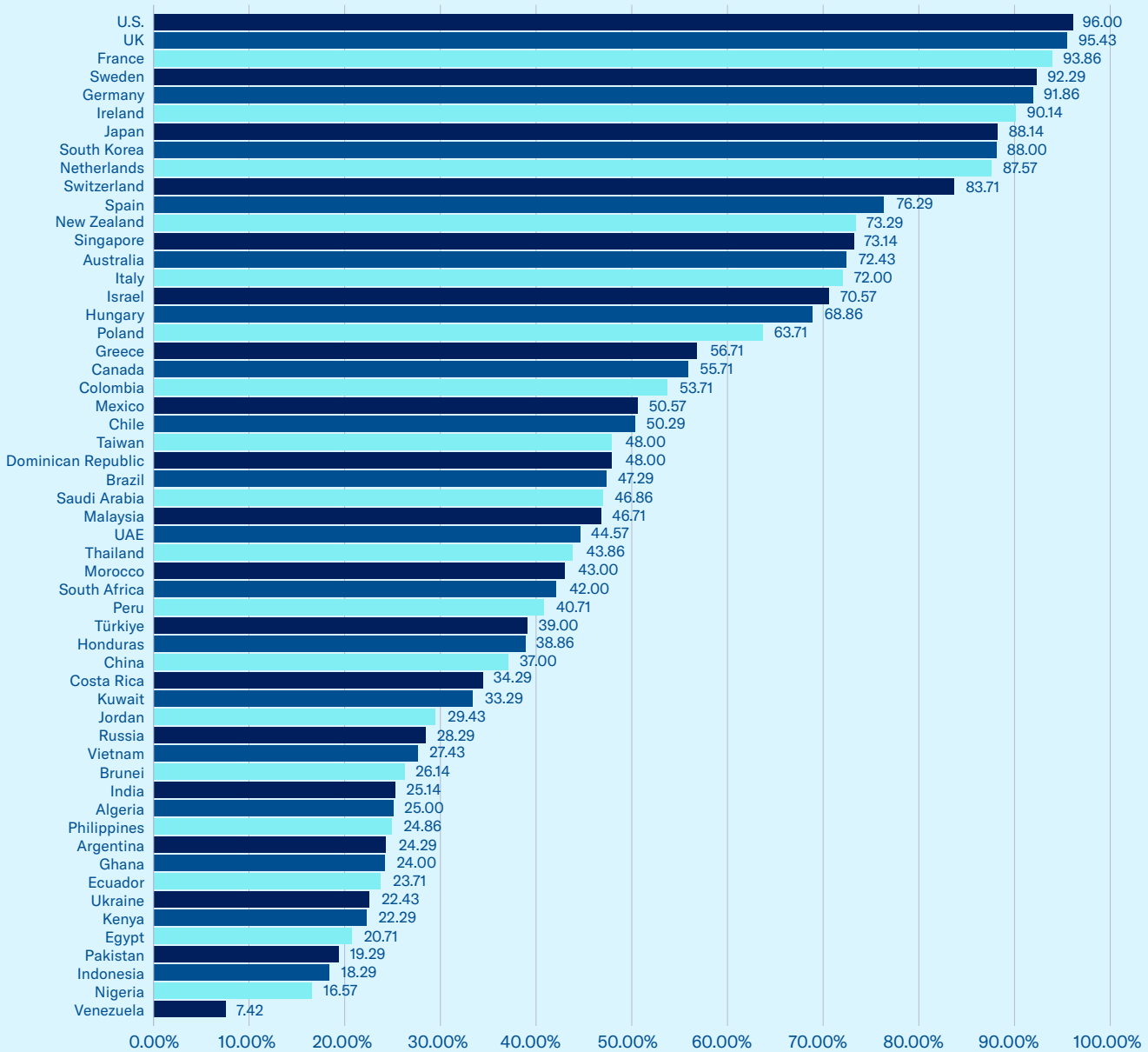


Enforcement

Many Index economies struggle to provide adequate enforcement measures, with only 23 Index economies achieving a score of 50% or more and only 11 economies achieving a score of 75% or more. The average score on this category remains one of the weakest on the Index at 50.24%.

- Dutch law enforcement took decisive action against one of Europe's largest providers of set-top boxes and disabled access to illegal content in hundreds of thousands of set-top boxes across the continent.
- The Dominican Republic established and operationalized a new Inter Ministerial Council on IP that will coordinate IP enforcement across the government.
- Algeria launched a new commercial court which will provide legal expertise on complex areas of commercial law, including IP.

Category 7: Enforcement, % Available Score

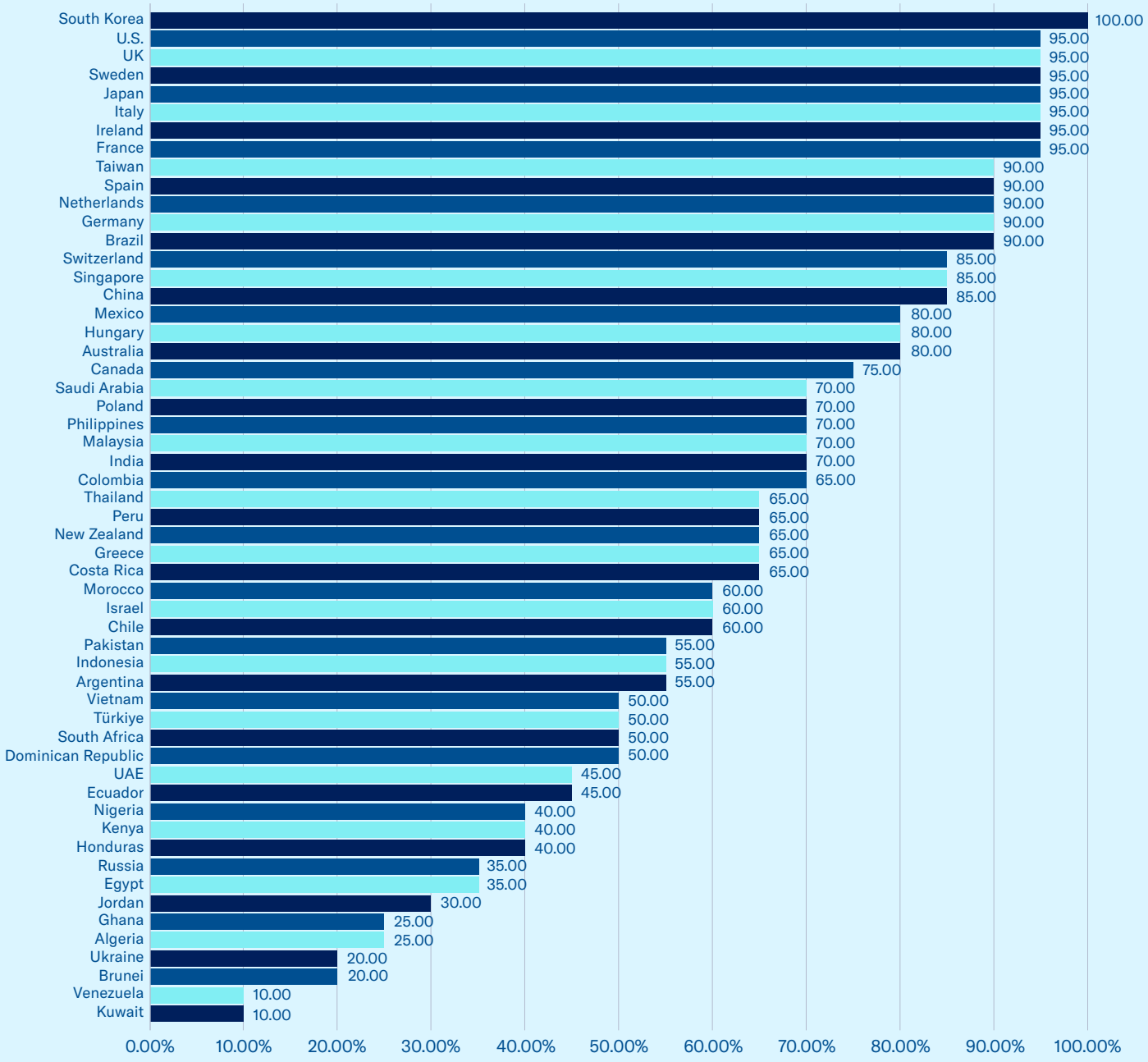


Systemic Efficiency

Only 14 economies failed to achieve a score of 50% or above in this category. Overall, the average score is one of the strongest on the Index, at 63.55%; up from 62.73% last year.

- The Saudi IP Authority continued IP awareness raising activities and improved stakeholder engagement on IP policy through public consultations on a new draft IP Law, the Madrid Protocol, and the WIPO Internet Treaties.
- Kenya joined the World Intellectual Property Organization (WIPO) and the World Economic Forum (WEF)'s "Inventor Assistance Program" (IAP) which provides pro-bono IP legal advice for innovators.
- Costa Rica launched a dedicated IP training and outreach effort focusing exclusively on the needs of entrepreneurs and SMEs.

Category 8: Systemic Efficiency, % Available Score

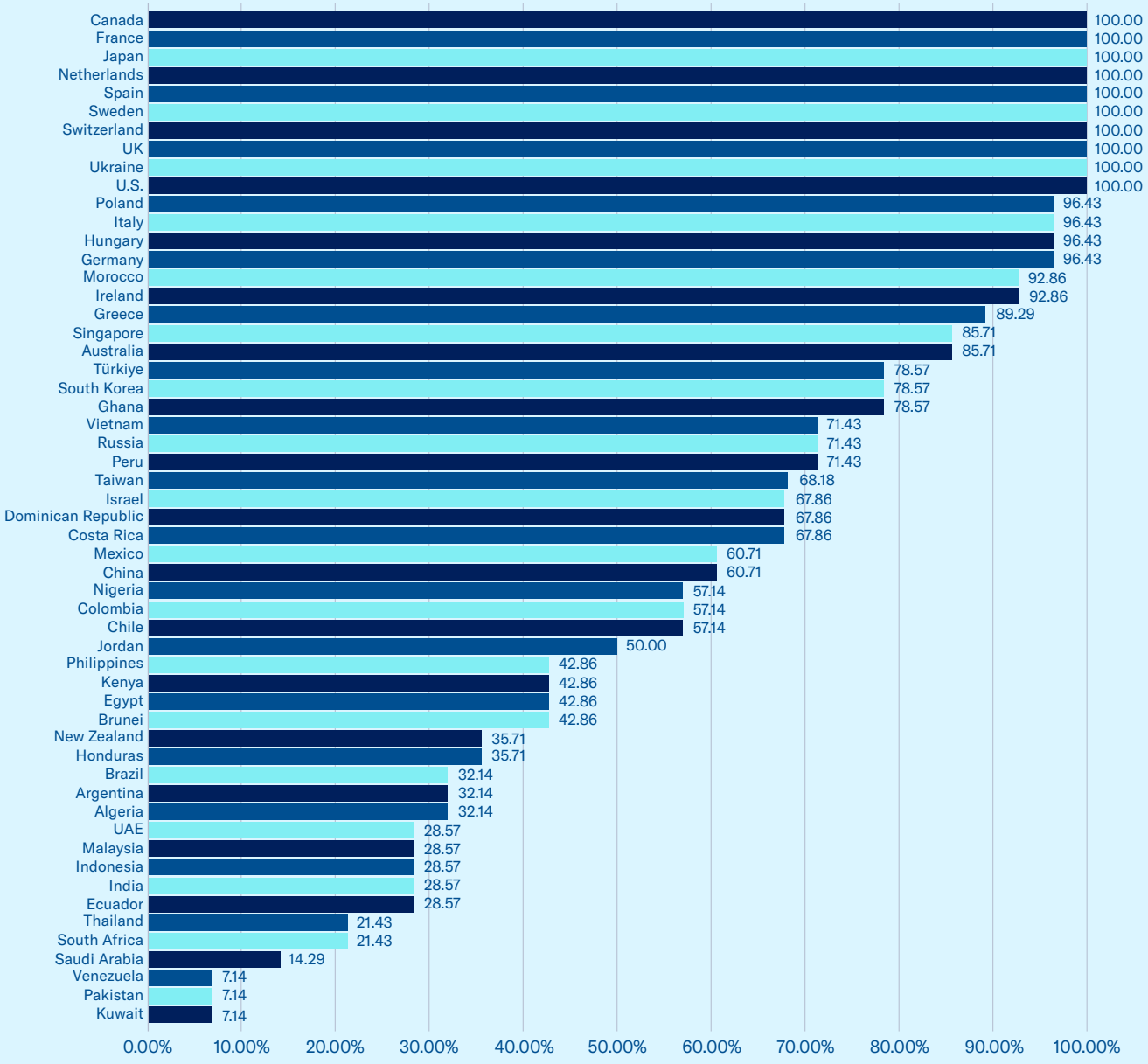


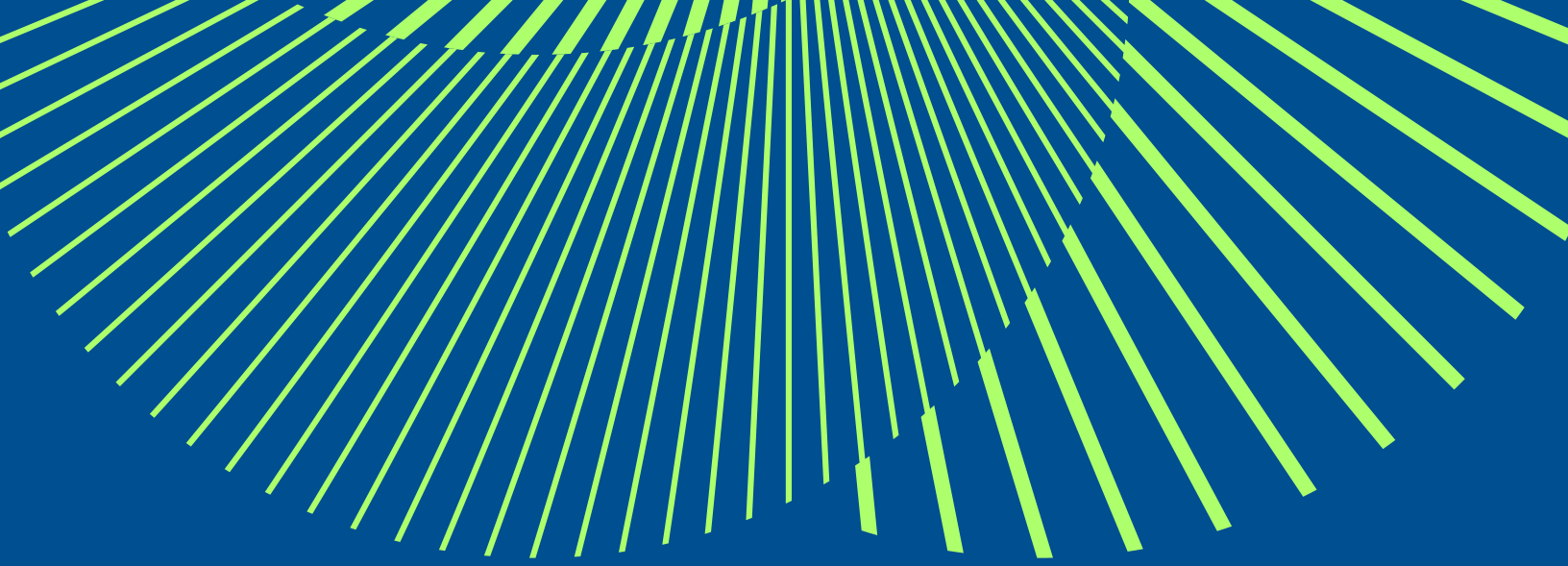
Membership and Ratification of International Treaties

This Index category remains one of the strongest overall with twenty-two economies achieving a score of 75% or more with 14 economies with a score of over 96%. The average score in this category was 62.86%; marginally up from last year's 62.70% average.

- Brazil acceded to the full Hague Agreement including the Geneva Act.
- Thailand is considering new amendments to the Copyright Act to prepare to accede to parts of the WIPO Internet Treaty.
- Many new free trade agreements fail to include comprehensive IP chapters. The New Zealand-European Union Free Trade Agreement does not include any reference to patent rights. Moreover, while the UAE recently concluded four Comprehensive Economic Partnership Agreements which include IP chapters, the substance of the individual IP chapters are limited to rights already defined and specified in TRIPS.

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





Overview of the Twelfth Edition

Now in its twelfth edition, the U.S. Chamber of Commerce's International Intellectual Property (IP) Index continues to provide an important industry perspective on the IP standards that influence both long- and short-term business and investment decisions. The Index is a unique and continuously evolving instrument. Not only does it assess the state of the international IP environment, but it also provides a road map for any economy that wants 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 global economic output, together contributing over 90% of global gross domestic product (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: Twelfth 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			Türkiye	
Thailand			UK	
Vietnam			Ukraine	

Source: World Bank (2023)

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: Twelfth 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
	Türkiye		South Korea
	Venezuela (2020)		Spain
			Sweden
			Switzerland
			UK
			U.S.

Source: World Bank (2023). 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	85.85%
Europe and Central Asia	76.28%
Asia	56.53%
Latin America	44.37%
Africa and Middle East	42.97%

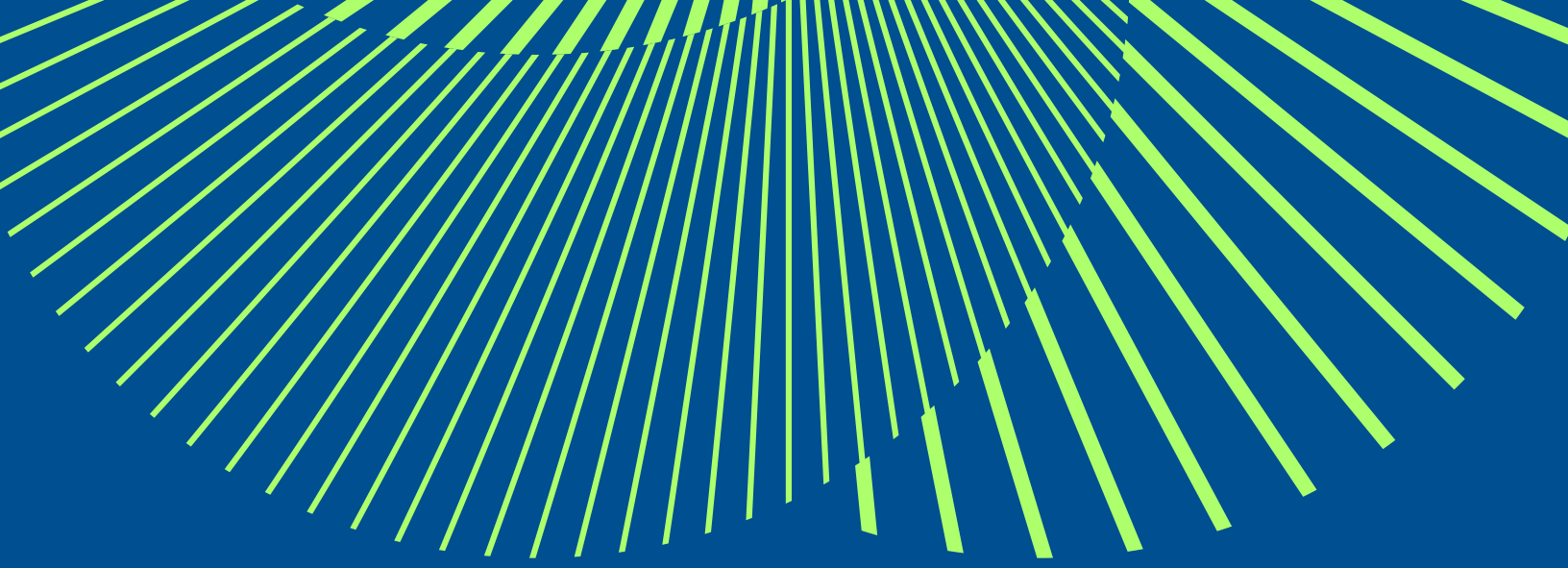
Europe and Central Asia	Overall Score	Regional Ranking
United Kingdom	94.12%	1
France	93.12%	2
Germany	92.46%	3
Sweden	92.12%	4
The Netherlands	91.24%	5
Ireland	89.38%	6
Spain	86.44%	7
Switzerland	85.98%	8
Italy	83.90%	9
Hungary	76.90%	10
Greece	71.42%	11
Poland	70.74%	12
Türkiye	51.04%	13
Ukraine	40.30%	14
Russia	25.00%	15

North America	Overall Score	Regional Ranking
United States	95.48%	1
Canada	76.22%	2

Asia	Overall Score	Regional Ranking
Japan	91.26%	1
South Korea	84.94%	2
Singapore	84.92%	3
Australia	80.70%	4
New Zealand	69.36%	5
Taiwan	67.34%	6
China	57.86%	7
Malaysia	53.44%	8
Phillippines	41.58%	9
Brunei	41.08%	10
Vietnam	40.76%	11
India	38.64%	12
Thailand	38.28%	13
Indonesia	30.40%	14
Pakistan	27.42%	15

Latin America	Overall Score	Regional Ranking
Mexico	59.98%	1
Dominican Republic	55.30%	2
Costa Rica	55.04%	3
Peru	49.82%	4
Chile	49.72%	5
Colombia	48.84%	6
Brazil	46.52%	7
Honduras	42.16%	8
Argentina	37.00%	9
Ecuador	29.58%	10
Venezuela	14.10%	11

Africa and Middle East	Overall Score	Regional Ranking
Israel	72.74%	1
Morocco	62.76%	2
Saudi Arabia	48.42%	3
UAE	46.00%	4
Jordan	44.70%	5
Ghana	40.88%	6
Kenya	37.88%	7
South Africa	37.28%	8
Nigeria	36.34%	9
Egypt	33.86%	10
Kuwait	28.42%	11
Algeria	26.36%	12



The Global IP Environment in 2023—Major Developments, Overall Index Scores, and Category-by-Category Results

International Developments

Yesterday, the #COVID19 Emergency Committee met for the 15th time and recommended to me that I declare an end to the public health emergency of international concern. I have accepted that advice. With great hope I declare COVID-19 over as a global health emergency.

—Dr. Tedros Adhanom Ghebreyesus
WHO Director General, May 5, 2023

Since the onset of the COVID-19 pandemic, a global IP rights architecture developed over several decades has contributed to the rapid availability of lifesaving vaccines and therapies and to a host of other technological solutions that have kept humans safe, connected, and productive to a degree unimaginable in previous health crises. However, over the past three years, those same rights and architecture face serious challenges from governmental and nongovernmental activists who misrepresent the role of IP rights in innovation and the economy. Unfortunately, there is no clearer example of this misrepresentation and disconnection than the ongoing discussion at the World Trade Organization (WTO) on waiving IP rights.

The Evolution of the WTO TRIPS Waiver in 2023

After two years of discussion, the WTO at its Twelfth Ministerial Conference in Geneva in June 2022 approved a waiver of patent rights under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. 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."[2]

The waiver gives members extraordinarily broad latitude in overriding 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 after the first proposal of a waiver, IP rights enabled the development of vaccines, therapeutics, and diagnostics in record time. However, many real barriers inhibited access to these innovative medicines and technologies, including regulatory delays, trade barriers, export restrictions, and last-mile delivery issues. Waiving IP rights will lead to negative long-term policy outcomes without meaningfully addressing these impediments to access and helping those population groups and economies in need of assistance. The way the waiver proposal was framed from the outset, how it has been executed, and the latest proposals for extending it all bear 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.[3] This first proposal would waive almost the entire 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 have been unaffected by this proposal were trademarks, geographical indications, and semiconductors (layout designs). As the Index and others pointed out at the time, these members offered no evidence that IP rights were or would become a barrier to an effective global response to the pandemic. They 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 copyright protection, industrial designs, and trade secrets—or patents for that matter—would have led in any way to a more successful international response to the COVID-19 pandemic.

Although waiver proponents claim that undermining IP rights for complex, hard-to-manufacture medical technologies—including vaccines, treatments, diagnostics, and other related products—will enhance access, waiving IP will not accelerate global production or increase local technical know-how. Instead, such capabilities are cultivated through sustained education and investment over decades, which is precisely what the preexisting system of IP rights has provided in those economies where they have been in place.

Despite the failure of its proponents to demonstrate any benefit from an IP waiver in the first place, the WTO is currently considering an expansion of the waiver to therapeutics and diagnostics. The proposal to extend the 2022 Ministerial Decision and TRIPS waiver was formally introduced by a group of WTO member states in December 2022, many of which had supported the 2020 original waiver proposals.[4] Not only would this proposal extend the existing Ministerial Decision and the waiver of patent rights to related COVID-19 therapeutics and diagnostics, but it would do so for at least five years from the date of the extension and not from the original 2022 Ministerial Decision. Consequently, if approved as currently worded, this waiver extension would run for a longer period than the original Ministerial Decision. At the time of research, the WTO had in 2023 hosted or organized discussions with members and stakeholders on three separate occasions in March, June, and September. Notably, two of these meetings were held after the World Health Organization's (WHO) May announcement that the COVID-19 global health emergency was over.

Although both the initial waiver and its potential expansion aim to enhance the availability of medicines, access to medicines is a complex subject that does not lend itself to generalizing. Access involves many factors such as health system infrastructure, health financing, logistics, transportation networks, proper storage, distribution, and a technical drug regulatory capacity. Within this context, the protection of IP plays a relatively small role. For example, most medicines in the world viewed as essential (as compiled on essential drugs lists by WHO and numerous individual economies) are off patent and are 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, per definition, not an influencing or limiting factor.

In the context of therapeutics and diagnostics, the U.S. International Trade Commission's (USITC) report COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities acknowledges the many real barriers that inhibit access, including slow regulatory approvals, limited government budgets for healthcare expenditures, last-mile issues in lower-middle income countries (LMICs) and low-income countries (LICs), competing healthcare priorities, trade barriers, export restrictions, and issues with customs and border inspections.[5] These challenges have nothing to do with the protection of IP or availability of IP rights.

For diagnostics specifically, the report further notes nonprofit organizations and industry representatives generally agreed that patents did not act as a primary barrier limiting global access to two main types of COVID-19 diagnostic tests.[6]

As noted, the WHO director declared the global health emergency over in May 2023. The global manufacturing and supply of COVID-19 vaccines—with more than 15 billion doses produced—have outstripped global demand for the better part of two years. In fact, in 2022, the International Monetary Fund (IMF), WHO, and WTO all suspended their respective monitoring of the global vaccine supply chain because there was no longer a need to monitor it.[7] Indeed, data from September 2022 archived in the IMF-WHO Vaccine Tracker website suggest that of the 196 economies included in the database, 145 (or 74%) had secured enough vaccine doses to fully vaccinate 70% of their respective populations.[8] As the WTO considers an expansion of the wavier to therapeutics and diagnostics, the USITC report cited rightly notes that "demand has also been impacted by the waning of the pandemic."[9]

Perhaps most tellingly, no WTO Member has made use of the TRIPS waiver to date. Paragraph 5 of the Ministerial Decision includes a requirement that members should 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 late 2023, the TRIPS Council's online database reveals no notifications regarding use of the waiver in 2022 or 2023. This fact has been readily acknowledged by both the WTO and governments around the world. For example, in a March 2023 TRIPS Council meeting, the chair, Lansana Gberie, acknowledged that the council had received no paragraph 5 notifications.[10] The USITC report noted the same fact: "Easing the use of CLs pertaining to COVID-19 vaccines was the primary focus of the 2022 Ministerial Decision; however, as of September 2023, CLs have not been used to access patents pertaining to COVID-19 vaccines."[11]

Given that economies have not used the existing waiver, any expansion would only compound the error of the original waiver, which has set back international IP policymaking for years. As WTO members, international policymakers, and domestic legislators around the world know, the architecture for building a global capacity for both innovation and local production of the products of biopharmaceutical innovation already exists. The ground floor 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 12 years, too many economies have resisted the IP standards embodied in the TRIPS Agreement, which they have viewed as a cost rather than an investment. Consequently, as this Index has quantified for more than a decade, the TRIPS Agreement has never been fully or faithfully implemented by most WTO members. Yet, for economies that want to be on the front lines in devising solutions to the next global health crisis that same IP architecture provides all the tools necessary for full and effective participation in the innovation ecosystem. This enables the allocation of scarce financial resources to risky innovative research & development (R&D), facilitates IP licensing for access to critical know-how, and fosters multidirectional technology transfer through contractual partnerships.

Should WTO members move forward with extending the existing Ministerial Decision to any other products or technologies in 2024, including but not limited to COVID-19–related therapeutics and diagnostics, this would constitute a further weakening of the international IP environment. As such, it would be considered in benchmarking individual economies' scores in upcoming editions of the Index.

Reducing Competitiveness Through Bad Policy: How the EU Has and Continues to Undermine the European Research-Based Biopharmaceutical Industry and International IP Standards

As noted in the Index over the past decade, there continues to be growing uncertainty about the biopharmaceutical IP environment at both the EU level and among member states. Many European and national policymakers understand the industry's strategic value and importance. In its 2020 Pharmaceutical Strategy for Europe, the European Commission recognized the importance of the research-based industry: "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."[12]

The commission is right. 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. Moreover, non-European companies also invest billions of dollars and create thousands of job opportunities in Europe's research-based biopharmaceutical industry. This industry has a long track record of producing lifesaving medical innovations that have been or are currently used by millions of patients, and it is also an engine of economic growth in the EU. Figures from the European Federation of Pharmaceutical Industries and Associations show that in 2021, the European research-based industry directly employed around 865,000 people (with 130,000 in high-skill R&D jobs), invested €44.5 billion in R&D activity, and generated €340 billion in production value.[13] Unfortunately, the strategic value and economic contribution of this industry have, over the past nine years, seldom been recognized in the development of European IP policies.

In 2015, under the overarching initiative to reform and deepen the single market with the purpose of spurring economic growth, the European Commission announced its intention to explore options for recalibrating certain elements of patent term restoration for biopharmaceuticals, or supplementary protection certificates (SPCs). One option for change was to provide European manufacturers of generic drugs and biosimilars with an SPC manufacturing and export exemption (SPC waiver). Although some member states—including Denmark, Sweden, and the United Kingdom (UK)—voted against the measure in the European Council, Regulation 2019/933 has been in force since 2019, and the SPC export exemption is legal and operational in all EU member states. The decision to move ahead with the SPC exemption was a significant blow to biopharmaceutical rightsholders and has weakened the IP environment across the EU. Because of this action, the score for this indicator was reduced by 0.25 for all EU member states in the eighth edition of the Index.

In addition to weakening the SPC system, since 2018, the European Commission has been conducting a regulatory review of the Orphan Regulation and the Pediatric Regulation, which provide special incentives (including IP-based incentives and a defined period of market exclusivity) for products developed for rare diseases and children. In 2020, the commission published an "Inception Impact Assessment" with a view to proposing legislative changes to both regulations.

Orphan drugs are niche treatments for diseases with small patient populations and commercial markets. Since the 1980s, a series of financial and regulatory incentives in the United States (1983), Japan (1993), and the EU (2000) have brought about a sea change in R&D, clinical research, and the development of new products for rare diseases. In the decade before the introduction of special incentives in the United States, only 10 orphan products were approved for market.[14] Since then, more than 575 drugs and biologic products have been developed and approved for treatment of rare diseases.

A clear and strong market exclusivity incentive has played a key role here. In the EU, the 2000 Orphan Regulation provides a 10-year term of marketing exclusivity (potentially expanded by two years or shortened by four years if certain circumstances are met). On the back of these schemes, as well as key pharmacogenomics discoveries that fuelled interest in the development of niche products,[15] the number of orphan drugs developed and authorized for rare diseases has increased exponentially. As of 2017, the regulation has resulted in the following:

- Nearly 2,000 orphan designations approved
- More than 150 orphan medicinal products approved by the European Medicines Agency (EMA) for over 90 rare diseases (up from eight products available in 2000)
- 85% increase in the number of rare diseases for which an orphan designation exists in the EU
- 88% increase in clinical research activity on rare diseases between 2006 and 2016, with the EU-5 countries experiencing a 104% increase during that period.[16]

The data are clear: the Orphan Regulation and its IP rights–based, 10-year market exclusivity incentive have done exactly what they were intended to do: put more orphan medicines on the EU market.

The real challenge facing European policymakers, both regionally and nationally, is to ensure that patients gain meaningful and effective access to these new medicines. Timely and equitable access to orphan medicines is not guaranteed in the EU, and substantial differences exist among members 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 pan-European European Organisation for Rare Diseases (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.[17] The report concluded the following:

> *The full benefits of the EU orphan regulations require optimal synergies between action on Community and on Members 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.*[18]

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 of England, Scotland, and Wales that comprises the UK).[19] 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 the reimbursement decision by the national authority was 23.4 months, nearly two years.[20]
- That 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 National Institute for Health and Care Excellence appraisal was 20.2 months for orphan medicines compared with 12.7 months for nonorphan medicines.

The EU Orphan Regulation has succeeded in promoting research of rare diseases and incentivizing the development of orphan medicinal products, just as 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 the member states' responsibility. As the cited evidence suggests, access to orphan medicinal products is hampered by insufficient reimbursement and long delays, 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—which is what has produced this innovation in the first place—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."[21] 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 health system. Again, within this context, IP rights play no part. The design of a 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 and expenditure containment and do not prioritize patient access to new products and innovation. Proposals for solving the access issue should recognize this fundamental fact. Existing IP incentives are not part of the problem.

Finally, at both the member state EU levels, 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 2020, the Hungarian government introduced an expedited compulsory licensing mechanism for biopharmaceuticals. In a separate development later that year, 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 show the trial was supported by the Hungarian government, the Ministry of Innovation and Technology, through a consortium. A compulsory license was granted by the Hungarian authorities in late 2020. (In a positive development, this involuntary license was annulled by the Hungarian Constitutional Court in a ruling in October 2023. The ruling states that the compulsory licensing process was fundamentally flawed because it unfairly violated the patentee's right to due process and a fair hearing.)

In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. It is difficult to understand the rationale for this Call for Evidence. 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 a pressing need exists for "coordination and harmonization" at the EU level on compulsory licenses but provides no actual evidence that this is the case. 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 international legal grounds for compulsory licensing for medicines.

The chairman's statement accompanying the General Council decision (concerning paragraph 6 of the Doha Declaration) underscores that these provisions are not in any way intended for industrial or commercial objectives and, if used, it is expected that they would be aimed solely at protecting public health.

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. The commission's Call for Evidence asserts that the COVID-19 pandemic shows the need for clearer and more "effective" compulsory licensing mechanisms. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the Call for Evidence.

For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime:

> *In the context of the Union crisis or emergency mechanisms, the Union should therefore have the possibility to rely on compulsory licensing. The activation of a crisis or an emergency mode or the declaration of a crisis or a state of emergency addresses obstacles to free movement of goods, services, and persons in crises and shortages of crisis-relevant goods and services. In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market.*

If anything, the evidence and experience from the COVID-19 pandemic show the complete opposite. For example, as detailed previously, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have proven to be completely unnecessary and ineffective. They address a problem of vaccine shortages that does not exist, and no WTO member has made use of it. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced and sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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.

Fast-Forward to 2023—the European Commission Proposes a New EU Pharmaceutical Legal Framework

In April 2023, the European Commission published a package of proposed legislative changes to almost all facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. The proposed changes would fundamentally weaken the EU's legal framework as it relates to biopharmaceutical IP rights. Specifically, rights related to regulatory data protection (RDP), orphan drugs, and patent protection—through an expansion of existing Bolar exemptions—would be materially weakened.

With respect to RDP, the proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2, which represents a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period or even, under unique circumstances, 12 years. However, the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that any research-based entities will be able to access them. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "released and continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid." Such "conditionality" of IP or regulatory protection establishes a counterproductive precedent as it makes the availability of such protection contingent on factors outside of rightsholders' control.

The commission has not taken into account that biopharmaceutical innovators are not responsible for the procurement, prescribing, and dispensation of medicines and health technologies. Individual EU member states and their respective health systems are in charge of all processes related to "the needs of the patients in the Member States," that is, actual patient access, including pricing and reimbursement, procurement, and, more often than not, prescription and dispensation practices.

The legislation also reduces the market exclusivity period for orphan drugs. As mentioned, the current Orphan Regulation provides a 10-year term of marketing exclusivity. However, orphan status can be withdrawn after six years if designation criteria are no longer met, including if the drug is sufficiently profitable, and exclusivity may be extended by two years if a pediatric investigation plan has been completed when requesting approval. Like the proposed RDP changes, Article 71 of the draft regulation provides a variable set of terms of protection for orphan medicinal products; in this case, the exclusivity periods are 10, 9, and 5 years. Eligibility for the maximum period of 10 years of protection is to be restricted and will be made available only for products that address what is described as a "high unmet medical need." Under Article 70, products will need to provide an "exceptional therapeutic advancement," and the use of the product should result "in a meaningful reduction in disease morbidity or mortality for the relevant patient population." This reduction in eligibility for the maximum period of protection will, per definition, reduce the incentives to invest and develop new products and treatments for patients with rare diseases. Ultimately, it will result in fewer products developed, commercialized, and available to these patient populations.

Finally, the proposal expands existing Bolar exemptions to include health technology assessment and the pricing and reimbursement processes. A Bolar exemption (or exception) allows follow-on applicants to begin the testing and regulatory approval processes for their follow-on products without acquiring consent from the rightsholder, in this case, the market authorization holder of the reference product.

This type of exception originates in the United States and, specifically, the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act). The rationale behind these types of exceptions or exclusivity exemptions is to ensure that there is no undue delay in the market supply of follow-on products once the relevant exclusivity of the reference product expires.

Bolar exceptions are not intended to be used to undermine rightsholders' legitimately granted exclusivity periods. The expansion of the Bolar exemption to include health technology assessment and pricing and reimbursement processes would potentially weaken existing exclusivity periods—including duly granted patent protection—through the premature launch of patent-infringing generics or biosimilars. This would put rightsholders in a position whereby their IP rights are potentially infringed during the period of duly granted exclusivity whether through patent protection or a different IP right.

The Proposed Pharmaceutical Legislation and the Index: Quantifying the Negative Impact on Economies' National IP Environment

The support and adoption of the current proposals to weaken existing biopharmaceutical IP incentives in the EU will have a direct and tangible negative impact on EU member states' national IP environments and corresponding Index score. As currently constructed, the commission's proposals would primarily affect two Index indicators: Indicator 5. Pharmaceutical-related patent enforcement and resolution mechanism and Indicator 25. Regulatory data protection (RDP) term.

Indicator 5 measures 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 or enforcement. If no mechanism is in place, the maximum score that can be achieved is 0.5. Such a score is based on the extent to which *de facto* practices (such as expeditious preliminary injunctive relief) are in place that achieve a similar result.

The European drug regulatory authority, the European Medicines Agency, does not evaluate or adjudicate patent validity or other IP rights–infringing issues before the marketing of a generic or biosimilar product. Instead, rightsholders in all EU member states must seek injunctive relief through a national court of law once a potentially infringing product reaches the market. This is readily available in most EU member states. However, this is a limitation because it does not effectively address the issue of a potentially infringing product being approved for market before sanitary registration and approval, and, consequently, the maximum score that all EU member states have achieved up until now for this indicator has been 0.5.

Indicator 25 measures the term of RDP exclusivity granted to new biopharmaceutical products containing new active ingredients regardless of molecular size and/or complexity. The baseline numerical term used is the existing EU term of 10 years (8+2) of marketing exclusivity. Half (0.5) of the available score is based on the term available for biologics or large molecule compounds. If an economy's relevant RDP legislation or regulation either de jure or *de facto* does not cover such compounds, then the maximum score that can be achieved for this indicator is 0.5.

As mentioned, until now, RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula.

According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to submit bioequivalence studies), and an additional year of protection for new indications of existing products.

This period of protection is not limited to chemical entities and also extends to biologics. Under this formula of data and market exclusivity, the EU's practice has matched that of the Index benchmark, and all EU member states have achieved the maximum available score of 1.00 for this indicator. As Table 3 shows, the latest edition of the Index includes 10 EU member states.

Table 3: EU Member States Included in the Twelfth Edition of the Index

France
Germany
Greece
Hungary
Ireland
Italy
The Netherlands
Poland
Spain
Sweden

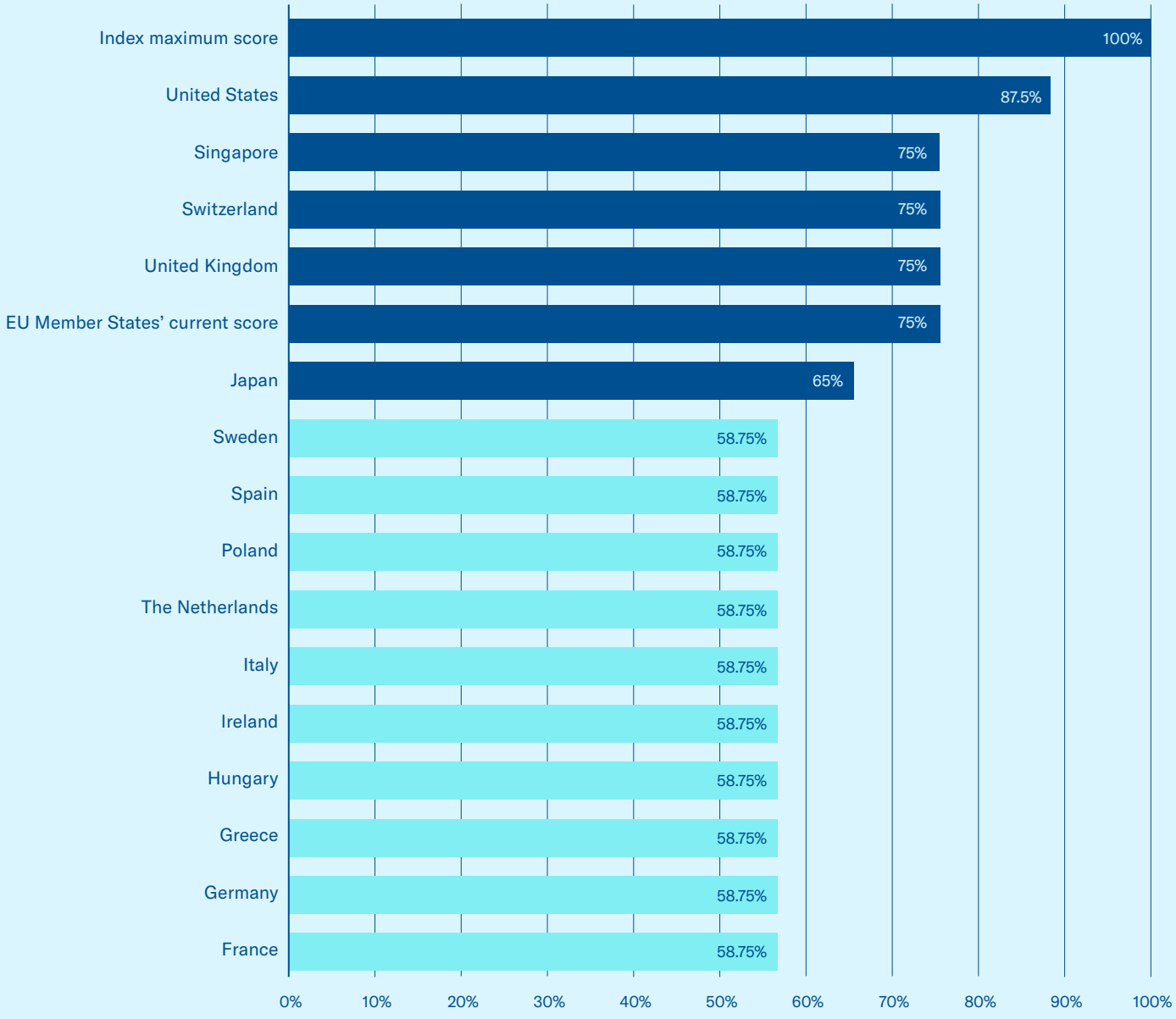
What would the impact of the commission's proposal be on these Index economies' Index scores and specifically the scores for indicators 5 and 25?

As discussed, under the current commission proposals, the effective term of RDP would be reduced from 10 years to 8 years. This would result in a reduction of 0.20 for indicator 25. Similarly, the reduction in effective patent protection for pharmaceuticals due to the expansion of the Bolar exemption will result in a reduction of 0.25 to 0.50 for indicator 5 depending on the implementation in each jurisdiction.

As with all EU legislation, substantial differences can exist among EU member states in how the relevant statute is transposed and/or interpreted in national courts. How such implementation and interpretation take place will determine the total impact of these legislative changes on the national IP environment and accompanying score for this indicator. The estimated score reduction is based on an average score of the midpoint score between a 0.5 reduction and a 0.25 reduction.

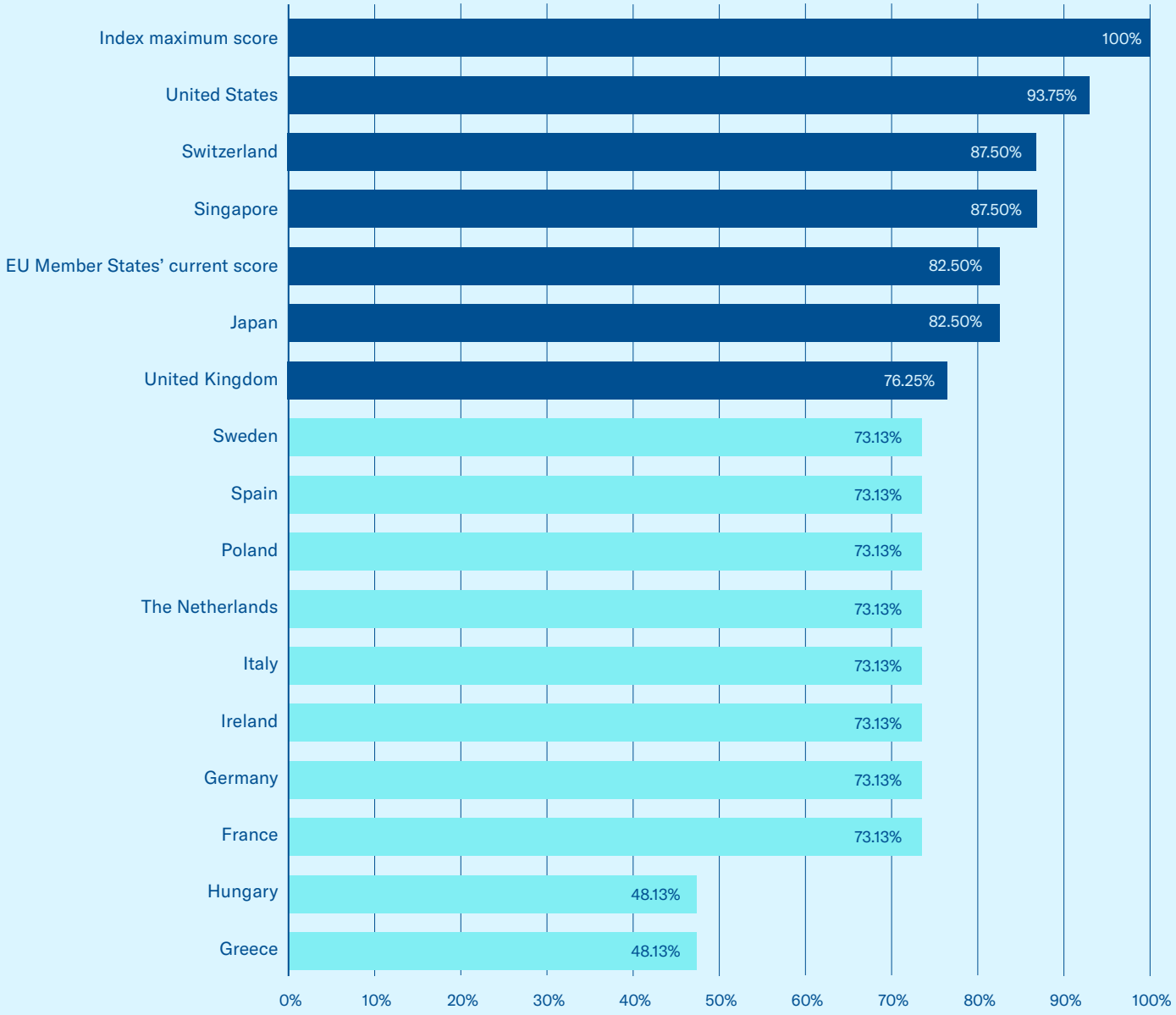
Figure 1 shows the results of this reduction for all 10 EU member states included in the Index.

Figure 1: Current Scores, Indicators 5 and 25, Select Index Economies and EU Member States versus Estimated Score Reduction, EU Member States (Current Scores in Teal; Estimated Reduced Scores in Navy)



It is also possible to broaden this comparative analysis and to estimate the negative impact of the commission's proposal on the total national IP environment as it relates to biopharmaceutical IP rights measured in the Index. This broadens the analysis to include two additional indicators: 6. Legislative criteria and use of compulsory licensing of patented products and technologies and 7. Patent term restoration for pharmaceutical products. Figure 2 shows the results of this reduction for all 10 EU member states included in the Index.

Figure 2: Current Scores; Indicators 5, 6, 7, and 25; Select Index Economies and EU Member States versus Estimated Score Reduction, EU Member States (Current Scores in Navy; Estimated Reduced Scores in Teal)



As Figure 1 shows, the adoption of the commission's proposals as currently drafted would result in a reduction of 16.25% for all EU member states for these two indicators from 75% of the maximum available Index score to 58.75%.

Compared with other Index economies, it would result in the national IP environment in all 10 EU member states for these two indicators becoming weaker than the United States, Singapore, Switzerland, the UK, and Japan.

Currently, all EU member states' score is tied with or higher than all these comparator economies with the exception of the United States.

Similarly, Figure 2 shows that broadening this analysis would result in a negative impact and reduction in all EU member states' score. Currently, the average score for all 10 EU member states for these indicators is 82.50%; this score ranks higher than those for both Japan and the UK. Under the commission's proposals, this would drop to 73.13%, and all EU member states would rank in the bottom below other comparator economies.

Although the General Pharmaceutical Legislation aims to create a 21st-century life sciences landscape that fosters innovation and enhances patient access, the proposed legislation will fundamentally weaken the ecosystem for biopharmaceutical innovation. Over time, such action will hollow out the national IP environment and framework for future biopharmaceutical innovation.

With fewer resources, it stands to reason that biopharmaceutical manufacturers will have less to invest in R&D and will be less likely to develop new biopharmaceutical products and services at the same rate as in the past. The negative effect will be felt most keenly in the EU, which will continue to see rates of biopharmaceutical R&D and clinical research drop. Before the commission moves forward with its reform efforts, it should pause and consider the full ramifications of its proposed policies. The Index will continue to monitor these developments in 2024.

Overall Results and Category-by-Category Scores

Up or down? How have economies fared in this edition of the Index? Table 4 shows the overall results for the twelfth edition of the Index and how they compare to last year's edition.

Table 4: Change in Overall Score, Twelfth Edition versus Eleventh Edition

Economy	Twelfth edition	Eleventh edition	Change in overall score
United States	95.48%	95.48%	0.00%
UK	94.12%	94.14%	–0.02%
France	93.12%	93.12%	0.00%
Germany	92.46%	92.46%	0.00%
Sweden	92.12%	92.14%	–0.02%
Japan	91.26%	91.26%	0.00%
The Netherlands	91.24%	90.70%	0.54%
Ireland	89.38%	89.36%	0.02%
Spain	86.44%	86.44%	0.00%
Switzerland	85.98%	86.00%	–0.02%
South Korea	84.94%	84.44%	0.50%
Singapore	84.92%	84.94%	–0.02%
Italy	83.90%	83.90%	0.00%
Australia	80.70%	80.68%	0.02%
Hungary	76.90%	76.90%	0.00%
Canada	76.22%	75.72%	0.50%
Israel	72.74%	72.72%	0.02%
Greece	71.42%	70.92%	0.50%
Poland	70.74%	70.74%	0.00%
New Zeland	69.36%	69.28%	0.08%
Taiwan	67.34%	66.31%	1.03%
Morocco	62.76%	62.26%	0.50%

Economy	Twelfth edition	Eleventh edition	Change in overall score
Mexico	59.98%	58.98%	1.00%
China	57.86%	57.86%	0.00%
Dominican Republic	55.30%	54.28%	1.02%
Costa Rica	55.04%	54.56%	0.48%
Malaysia	53.44%	53.44%	0.00%
Türkiye	51.04%	51.07%	–0.03%
Peru	49.82%	49.82%	0.00%
Chile	49.72%	49.72%	0.00%
Colombia	48.84%	48.84%	0.00%
Saudi Arabia	48.42%	42.38%	6.04%
Brazil	46.52%	42.02%	4.50%
UAE	46.00%	46.00%	0.00%
Jordan	44.70%	44.70%	0.00%
Honduras	42.16%	42.16%	0.00%
Philippines	41.58%	41.58%	0.00%
Brunei	41.08%	41.08%	0.00%
Ghana	40.88%	40.88%	0.00%
Vietnam	40.76%	40.74%	0.02%
Ukraine	40.30%	39.74%	0.56%
India	38.64%	38.64%	0.00%
Thailand	38.28%	38.28%	0.00%
Kenya	37.88%	37.36%	0.52%
South Africa	37.28%	37.28%	0.00%
Argentina	37.00%	37.00%	0.00%

Economy	Twelfth edition	Eleventh edition	Change in overall score
Nigeria	36.34%	33.34%	3.00%
Egypt	33.86%	32.82%	1.04%
Indonesia	30.40%	30.42%	–0.02%
Ecuador	29.58%	30.68%	–1.10%
Kuwait	28.42%	28.42%	0.00%
Pakistan	27.42%	27.42%	0.00%
Algeria	26.36%	26.36%	0.00%
Russia	25.00%	25.02%	–0.02%
Venezuela	14.10%	14.10%	0.00%

Like last year, in this year's Index, about half of all economies saw their overall scores change. Of the 55 economies included in the eleventh and twelfth editions, this year, there was no score change in 27 economies, 20 economies saw an improvement, and in 8 economies the overall Index score dropped. Most of these changes were movements of less than 1%. This compares to the "big bangs" of recent preceding years—editions 9 and 10—when there was more substantial score movement. However, like last year and all preceding editions of the Index, this does not mean that no meaningful score developments occurred in 2023. On the contrary, three economies—Brazil, Nigeria, and Saudi Arabia—saw score improvements of 4.50%, 6.04% and 3%, respectively. These are substantial and noteworthy improvements, especially for the latter two economies, which have over the course of the Index persisted with substantive reforms to their respective national IP environments.

Since its inception in 2017-2018, the Saudi Authority for Intellectual Property (SAIP) has worked on improving the national IP environment.

As detailed here, SAIP's reform efforts cut across the categories of the Index, with improvements ranging from rightsholders' ability to enforce their rights more effectively to expanding the institutional framework and systemic governance of IP rights and related industries. These improvements are reflected in the Kingdom's overall score increase over the past five years. Before SAIP's reform efforts, Saudi Arabia achieved an overall Index score of 36.60% in the seventh edition of the Index. Today, that score has increased to an overall score of 48.42%. Although this does not mean that rightsholders face no challenges in Saudi Arabia—the overall score remains below 50% of the available score—these are nevertheless real and meaningful improvements to the Saudi national IP environment. The Saudi government and SAIP should be commended for their efforts.

Similarly, Nigeria has over the past five editions of the Index seen its overall Index score improve from 27.62% in the eighth edition of the Index to 36.34% today. This follows targeted reform efforts related to Category 1: Patents, Related Rights, and Limitations; Category 2: Copyrights, Related Rights, and Limitations; and Category 9: Membership and Ratification of International Treaties.

Of the eight economies whose scores dropped, only one, Ecuador, saw a drop of more than 1%. As a result, Ecuador achieves an overall score of 29.58% in this year's Index and is now roughly back to the same level of performance it had five years ago.

However, the lack of large movements in overall scores does not mean that the global IP environment in 2023 stood still. As the following subsections and the individual Economy Overviews in Section 5 detail, a striking number of Index economies put forth policy proposals—both positive and negative—that, if implemented, would amount to substantial overall score changes in coming editions of the Index.

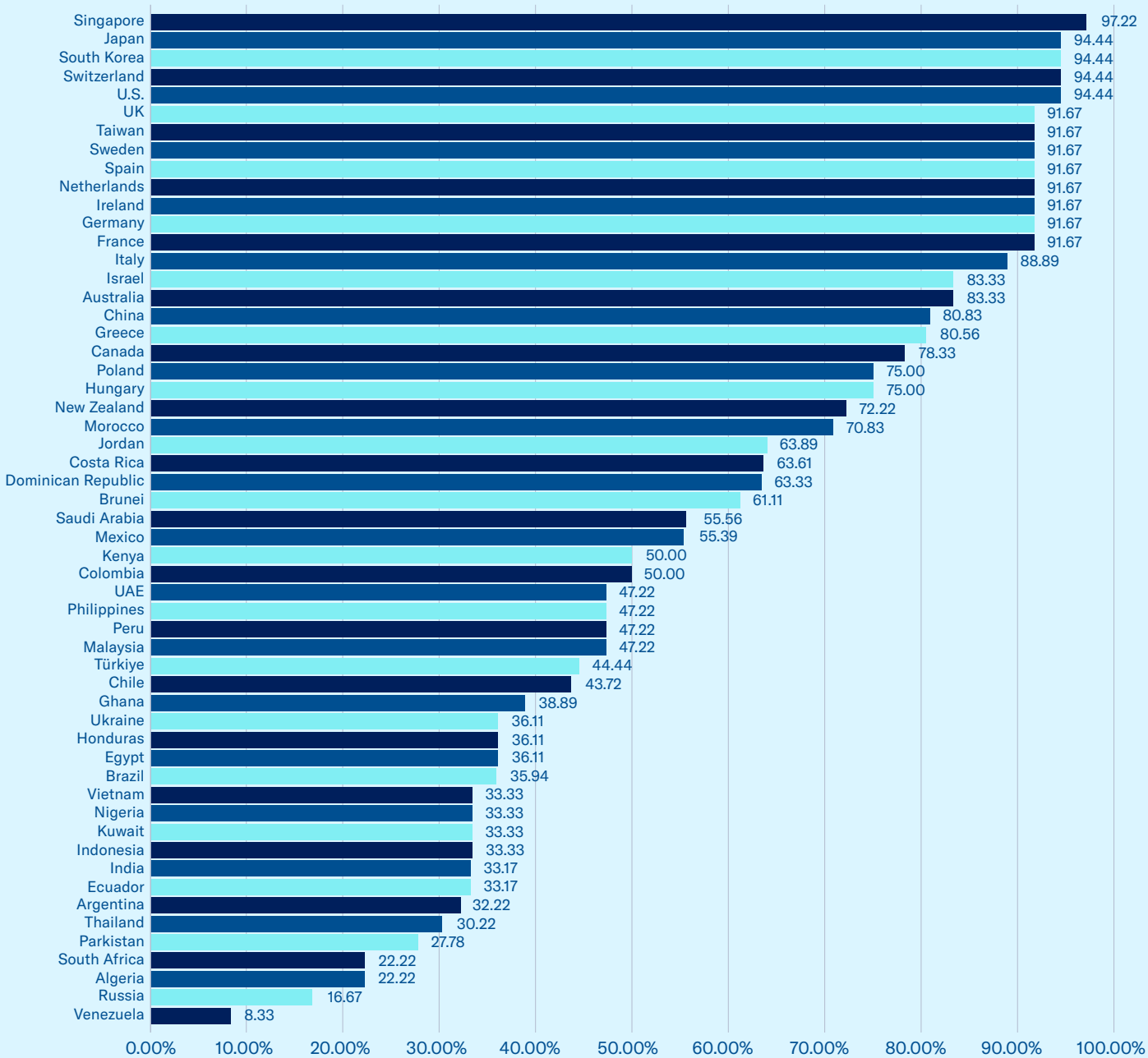
Category 1:

Patents, Related Rights, and Limitations

Figure 3 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 3: 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 achieved a score of 70% or more of the available score, and 31 economies in total achieved a score of 50% or more. The average score in the category is 59.62%, which is the fifth highest-scoring category in the Index. As in years past, Singapore is ranked number one, ahead of Japan, South Korea, Switzerland, and the United States.

As noted in previous editions and detailed in its Economy Overview, 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, which occurs before the specialized Patent Trial and Appeals Board 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 are patentable in the United States. Efforts to address this long-standing problem continued in 2023. Most promisingly, the Patent Eligibility Restoration Act (PERA) and Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL Act) were introduced into the Senate by Senators Tillis and Coons. As discussed with respect to previous iterations of the draft bills, the proposed legislation marks a significant breakthrough on the legislative front. Both drafts address many of the long-standing areas of concern and uncertainty over what constitutes patentable subject matter in the United States as well as the uncertainty and unpredictability caused by the Patent Trial and Appeals Board. At the time of research, the proposed laws had not 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 continued to face many basic challenges in registering and protecting patent-eligible subject matter in 2023. Above all, there has been no resolution with respect to the provision of a TRIPS-compliant minimum term of patent protection. Given the Brazilian Patent and Trademark Office, INPI, has historically had a long backlog of patent applications, Article 40 of 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. In a series of decisions in the spring of 2021, the Brazilian Supreme Court removed this floor. Not only did the court declare that Article 40 was unconstitutional and would no longer be available or applicable, but the court also stated that the ruling should be retroactively applied but only to granted patents in the biopharmaceutical and health-related fields. As noted in the Index since the ruling, the Supreme Court's judgment 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 further weakened Brazil's standards of patent protection, and the selective retroactive application of the ruling to one field of technology and innovation is a violation of Article 27(1) of the TRIPS treaty and established international principles of nondiscrimination. In response to this situation, close to 50 lawsuits have been filed across Brazil with rightsholders from the life sciences and health sector arguing for an extension of a granted patent term because of continued delays in patent prosecution. Unfortunately, these lawsuits have not led to any further clarity on the matter.

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

Discussions on restricting and curtailing patent rights also took place in Pakistan in 2023. In late 2022, the Intellectual Property Organization of Pakistan, IPO-Pakistan, published draft amendments to the Patent Ordinance. These proposed amendments make substantive changes to Pakistan's legal regime for patents, including with respect to patentable subject matter. As noted over the course of the Index, patentability standards in Pakistan have for some time stood outside of international norms, especially with respect to high-tech arts such as computer software and biopharmaceuticals. Unfortunately, under the draft amendments, a revised Section 7 proposes to further limit or eliminate the potential patentability of computer-implemented inventions (CIIs) and biopharmaceutical innovation. Under the existing Patent Ordinance, CIIs were not excluded as such, and the possibility remained to seek patent protection for CIIs. However, the new amendments explicitly exclude "computer programs" as inventions. Given that computer software and CIIs are at the heart of virtually all socioeconomic activity, including desktop PCs, smartphones, artificial intelligence, and the Internet of Things, it is hard to see how eliminating patent eligibility for computer programs will help drive investment and resources into developing new digital and information and communication technology (ICT)-based technologies in Pakistan.

Similarly, a new Subsection (7(4)(f)) related to biopharmaceutical inventions would eliminate the patentability of a "new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance." This would appear to restrict the eligibility of incremental biopharmaceutical innovation, including changes to form and application of a known substance. This is a curious change because incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovation—and the IP rights that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes, for example, insulin and insulin pumps, beta-blockers, ACE inhibitors, contraceptives, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices. It is hard to see how this type of innovation should not be eligible for patent protection. Should these amendments be enacted into law, Pakistan's scores for indicators 2 and 3 will be reduced. In a positive move, the proposed amendments would eliminate Section 23 and the system of pregrant oppositions in Pakistan. Under existing patent statute, an inter partes opposition system is in place that can be triggered within four months after an application is published. If adopted in their current form, amendments to the Patent Ordinance would result in a score rise for indicator 9.

Similarly, as has been detailed for over a decade in the Index, rightsholders in India face many basic challenges in registering and protecting patent-eligible subject matter. Most notably, Indian patent law has in place an additional requirement to patentability that goes beyond the required novelty, inventive step, and industrial applicability requirements.

Under Section 3(d) of the Indian Patent Act, there is an additional "fourth hurdle" regarding inventive step and enhanced efficacy that limits patentability for certain types of pharmaceutical inventions and chemical compounds. Several court cases have established an interpretation of Indian patent law whereby Section 3(d) can be fulfilled only if the patent applicant can show that the subject matter of the patent application has an improved therapeutic efficacy compared with the structurally closest compound as published before the patent application had been filed (regardless of whether a patent application for the earlier compound was filed in India). More broadly, this interpretation and case law also deny patentees with protection that goes substantially beyond what was specifically disclosed in the patent application. Compounds that fall within a chemical formula of a claimed group of compounds in a patent application, but that are not specifically disclosed in the patent, could be regarded as not protected.

Similarly, the environment for protecting CIIs in India has historically been marred by uncertainty. The Patent Act excludes "a mathematical or business method or a computer program per se or algorithms" as patentable subject matter. Equally, old guidance documents, including the Indian patent manual, did not provide clarity on the extent to which CIIs were patentable.

Over the past decade, new patent guidelines have been published. Unfortunately, these were not always consistent, with some more restrictive than others. The latest available document published in 2017, "Guidelines for Examination of Computer Related Inventions (CRIs)," significantly improved the patenting environment for CIIs in India. Unlike previous drafts of the guidelines, there was no requirement for hardware innovation. On this basis, the score for indicator 3 increased by 0.50 in the sixth edition of the Index. Yet, the uncertainty over what CIIs and subject matter remain eligible for patent protection and what constitutes a technical effect within the context of computer software persists. The problem is highlighted by a 2023 court order by the Delhi High Court (Microsoft Technology Licensing, LLC v. The Assistant Controller of Patents and Designs) finding that the Controller General had wholly misunderstood the meaning of Section 3(k) of the Patent Act and wrongly rejected the plaintiff's patent application.

In a separate development, in August 2023, the Controller General opened a public consultation on potential revisions to most of the office's manuals and guideline documents. This includes the existing Patent Manual and biopharmaceutical and CII guidelines. At the time of research, no formal draft proposal had been made available to the public. In an additional and positive development, in August, the Controller General published the "Draft Patents (Amendment), Rules, 2023." The proposed changes include some improvements to the existing opposition mechanisms, including introducing more defined timelines and vesting more discretion with the Controller General as to the "maintainability of the representation" of the opposition.

As noted over the course of the Index, the pregrant patent opposition mechanism in India has long been criticized for adding significantly to the already lengthy patent prosecution timelines, a fact acknowledged by the Prime Minister's Economic Advisory Council (EAC-PM) 2022 report Why India Needs to Urgently Invest in its Patent Ecosystem.

The proposed "Draft Patents (Amendment), Rules" also make changes to Form 27. This requires that patent holders annually provide information on the extent to which a granted patent has been worked by patentees and licensees. As noted in the Index at the time, in 2020, a new Form 27 was introduced. Overall, this was a positive change. The new form removed questions pertaining to licenses and made it possible to file one form for several patents related to the same invention. Still, the form retained questions about the approximate value as either manufactured or imported into India. In a positive move, the 2023 draft changes not only propose to remove any questions related to the approximate value of the patented technology but also clarify that the importation of an invention does not mean that it is "not worked" in India. Both the changes to India's opposition proceedings and Form 27 are important and have the potential to improve India's national IP environment.

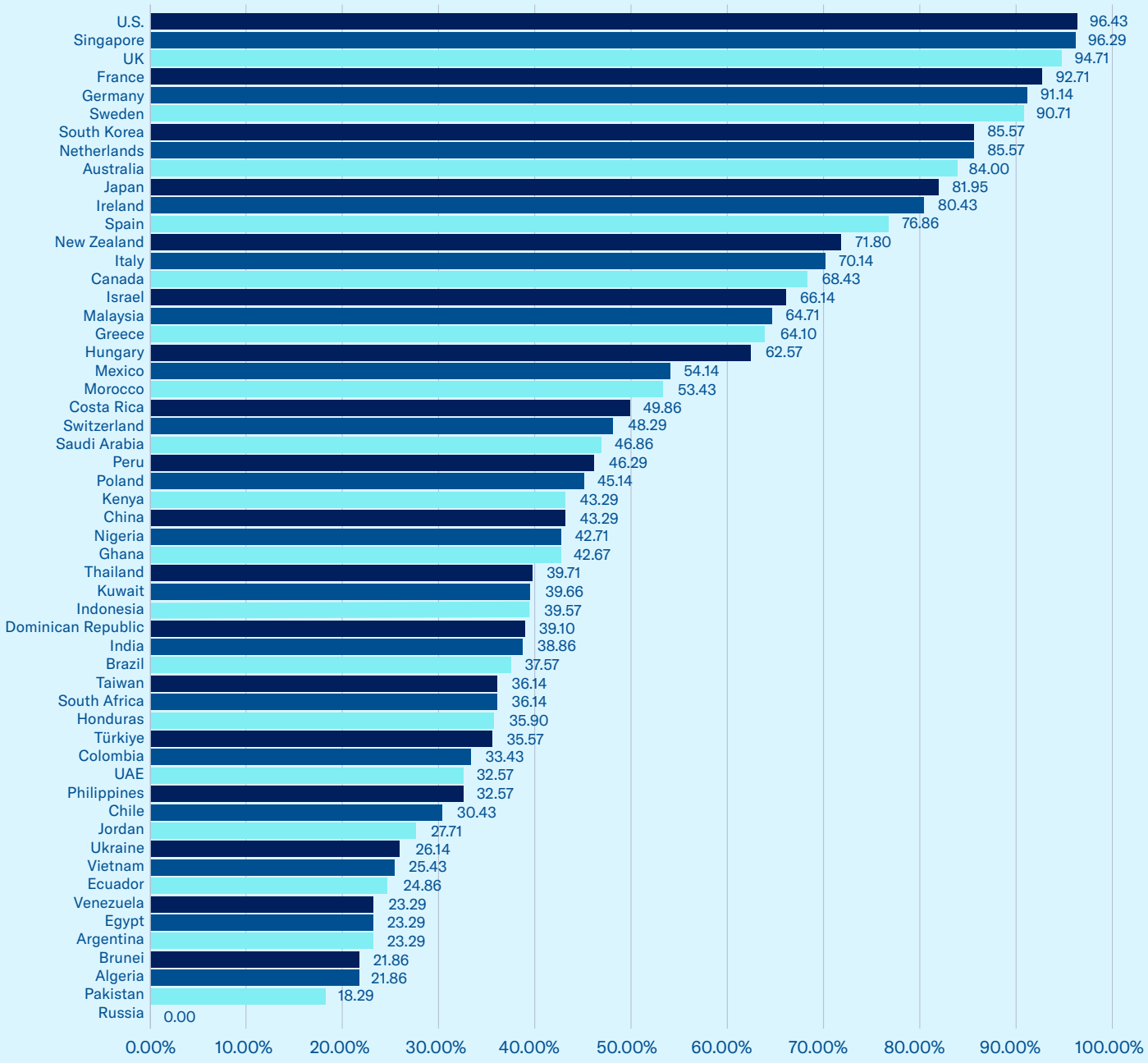
Category 2:

Copyrights, Related Rights, and Limitations

Figure 4 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 4: Category 2: Copyrights, Related Rights, and Limitations, % Available Score



Historically, Index economies have not performed well in Category 2. Although most Index economies continue to score poorly in this category, the average score in this category improved from 49.70% last year to 50.61% in 2023. 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.

As noted in past editions of the Index, one driver of this development is the 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 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. The scale and volume of online infringement have resulted in a growing strain and burden on rightsholders to effectively protect their content and economic rights.

Since the early 2010s, rightsholders have identified and successfully applied injunctive-style relief to combat online infringement. Injunctive-style relief gives rightsholders the option of seeking redress for an infringement of copyright either through a court of law or, administratively, through a government authority. The mechanism can look 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, Canada, and a host of other Index economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online.

These injunctions are often categorized as either static or dynamic. Static injunctions are the most common form. These actions are against a known copyright infringer and seek relief for a specified infringement action. However, 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. Dynamic injunctive relief is an especially important tool for rightsholders of live-streamed content, such as sporting events, concerts, and televised specials.

In welcome news, more Index economies introduced or extended the application of these types of injunctions in 2023.

In May 2023, a federal court in Argentina not only ordered the disabling of access to several copyright infringing websites but also included a dynamic element in the order. The plaintiffs—led by a coalition of international, regional, and domestic rightsholders—specifically requested that the injunction include the ability to update and apply the disabling of access to new websites and URLs as and when they appear.

As noted over the course of the Index, rightsholders have historically faced significant challenges in protecting their copyrighted content in Argentina. The existing legal framework has major gaps, and enforcement remains inadequate. The granting of this court order is potentially of real significance because the judgment not only affirmed the right to injunctive relief online but also included the dynamic element and ability to quickly update the court order without having to restart legal proceedings.

It is hoped that this enforcement route will now be available to rightsholders more broadly and will provide a clear and expeditious path for creators to enforce their rights in Argentina.

Similarly, in Brazil, rightsholders also saw several positive developments with respect to the availability of injunctive relief targeting online piracy. In late 2022, a court in São Paulo ordered the disabling of access to several websites that offered access to infringing materials. This order included a dynamic element. In addition, the Brazilian National Telecommunications Agency, Anatel, launched a dedicated campaign against illicit IPTV set-top boxes. As in many other economies benchmarked in the Index, Brazil has seen an explosion in the growth and use of these physical boxes and the internet-based applications that provide users with copyright infringing content. In February 2023, Anatel announced an "Action Plan to Combat the Use of Clandestine TV Boxes" that gives the agency a dedicated enforcement function to locate and disable these illegal set-top boxes. In September, Anatel announced that it had operationalized a dedicated laboratory and testing site to assist in these efforts. The agency is reportedly targeting both the physical devices and their streaming applications online and had at the time of research seized almost 1.5 million illegal set-top boxes and disabled access to hundreds of illicit access points.

Additionally, in Canada, rightsholders continued to obtain injunctions against online providers of copyright infringing content. In late 2022, the federal court issued another order in relation to illegal streaming of the FIFA World Cup, and in July 2023, the court ordered the disabling of access to the illegal streaming of major league baseball games. Significantly, both these orders included a dynamic element.

Authorities in Saudi Arabia also maintained their commitment to supporting strong enforcement efforts against copyright infringement and online piracy. The national IP office SAIP works directly with rightsholders both as an intermediary, referring cases of infringement to relevant Saudi enforcement authorities, and as an administrative enforcement authority in its own right. Specifically, SAIP has made the disabling of access to copyright infringing content online a major part of its enforcement remit. Historically, the disabling of access to web content, including copyright infringing content, occurred sporadically through the Ministry of Culture and Information. Today, SAIP offers a portal through which rightsholders can directly communicate any suspected online infringement to the Authority, which will then investigate and take enforcement action. This positive work continued in 2023, as the Authority's latest Annual Report of Intellectual Property Enforcement for the Year 2022 shows both the scale and magnitude of the SAIP's enforcement efforts. With respect to copyright enforcement, in 2022, the Authority ordered the disabling of access to close to 1,500 websites and online access points, almost double the number of orders issued in 2021 and five times the number in 2020.

Some notable legislative and policy developments occurred in 2023, including criminal causes of action and greater sanctions for copyright infringement.

As mentioned last year, the pirating of film and audiovisual content through illicit camcording has historically been a major challenge to both domestic and international rightsholders in India. To provide a greater level of deterrence to this type of behavior, in 2019, the Indian government introduced a "Cinematograph (Amendment) Bill.". In 2023, a final bill was enacted. The Cinematograph (Amendment) Bill 2023 includes new language and criminal sanctions on film piracy, including potential imprisonment of up to three years and a substantial fine of up to 5% of the production costs of the infringed motion picture. This is a positive development, and the passing of this bill into law should help address a long-standing issue in India.

Many Index economies also saw developments related to copyright exceptions and limitations related to text and data mining within the context of generative artificial intelligence (AI) and machine learning.

In the United States, both the federal government and Congress have over the past year been working on policy reforms related to AI and machine learning. In October 2023, the White House issued an "Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence." The order cuts across the federal government and provides guidance on the use of AI-based technologies and tools from a security, privacy, and innovation standpoint. With respect to the protection of copyright, the order directs the USPTO, in consultation with the Copyright Office, to issue recommendations to the White House on any necessary executive actions. This includes any actions related to "the scope of protection for works produced using AI and the treatment of copyrighted works in AI training." In a separate development, in August, the Copyright Office issued a "Notice of inquiry request for comments" on the interaction between AI and copyright. Finally, hearings were held throughout the year in both the House of Representatives and Senate on the interaction between generative AI and the protection of copyright.

In the UK, both the British Parliament and government have over the past three years been working on policy reforms related to AI and machine learning. In 2021, the government released a National AI Strategy, a 10-year, cross-government plan of action, and over the past two years, many policy proposals, consultations, hearings, and draft legislation have been published. At the time of research, the UK Intellectual Property Office (UKIPO) was working with the creative sector, researchers, and technologists to develop a voluntary code of practice on copyright and AI.

In the EU, the European Parliament continued its work on the commission's proposed "Artificial Intelligence Act." The Parliament adopted an initial set of amendments in June, and in December 2023, the European Council and Parliament announced a provisional agreement on what a final act would look like. At the time of research, no final text had been published.

In May 2023, the Japanese Agency for Cultural Affairs Copyright Division (part of the Ministry of Education, Culture, Sports, Science and Technology) held a seminar and released a presentation setting out the agency's views on the interaction between copyright protection and the use and application of AI and machine learning. Unfortunately, the presentation and the agency seem to embrace a view of AI application that is almost wholly at the expense of copyright holders. Specifically, it draws a distinction between an "AI development/learning stage" and a "Generation/usage stage." Slides 32 to 38 of the presentation seem to suggest that the use of copyrighted materials—with or without a rightsholder's permission—for "AI development/learning stage" is generally lawful under Section 30(4) of the Japanese Copyright Act and would not infringe copyright. Only slide 39 acknowledges scenarios whereby the learning phase of AI development could potentially harm a rightsholder's copyright and commercial interests. Yet it is not at all clear that, first, such a distinction between a learning/developmental and generative/usage stage of AI-based tools and technologies practically exists and that, second, current Japanese statute would allow the appropriation and use of copyrighted materials under any such scenario.

Article 30(4) allows a narrow set of exceptions to copyright protection for "use in data analysis (meaning the extraction, comparison, classification, or other statistical analysis of the constituent language, sounds, images, or other elemental data from a large number of works or a large volume of other such data…[or] in the course of computer data processing or otherwise exploited in a way that does not involve what is expressed in the work being perceived by the human senses." However, these exceptions are prefaced by such usage being allowed only if it does not "unreasonably prejudice the interests of the copyright owner in light of the nature or purpose of the work or the circumstances of its exploitation." Similarly, this article—and other copyright exceptions defined in the act—do not allow for the unlawful appropriation or access to copyrighted works.

After the agency's seminar and publication of the presentation, a collection of Japanese publishers and rightsholders released a joint public statement calling for more clarity on the interpretation of existing copyright statute and the need for the government to engage rightsholders in this issue.

However, the agency does not appear to differentiate between legal and illegal acquisition of content, essentially turning a blind eye to AI models trained on pirated content. This is concerning for content rightsholders, AI developers, governments, and end users, as developers' use of pirated content could lead to low-quality data points and models as well as hacking, phishing, fraud, and other security issues.

Text and data mining is an important area of future economic activity as advancements 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.

However, this is a new area of copyright law with little in the way of applicable jurisprudence internationally. Given the existing dynamics of the internet and the volume of infringing content available online—much of it made available without rightsholders' permission or even their knowledge—it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can practically enforce their rights in all Index economies. Indeed, in those Index economies that have defined text and data mining exceptions in their copyright laws—including the European Union's Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive) and Section 29A of the UK's Copyright, Designs and Patents Act—the act of copying or communicating for computational analysis can be conducted only for works that have been lawfully obtained or accessed.

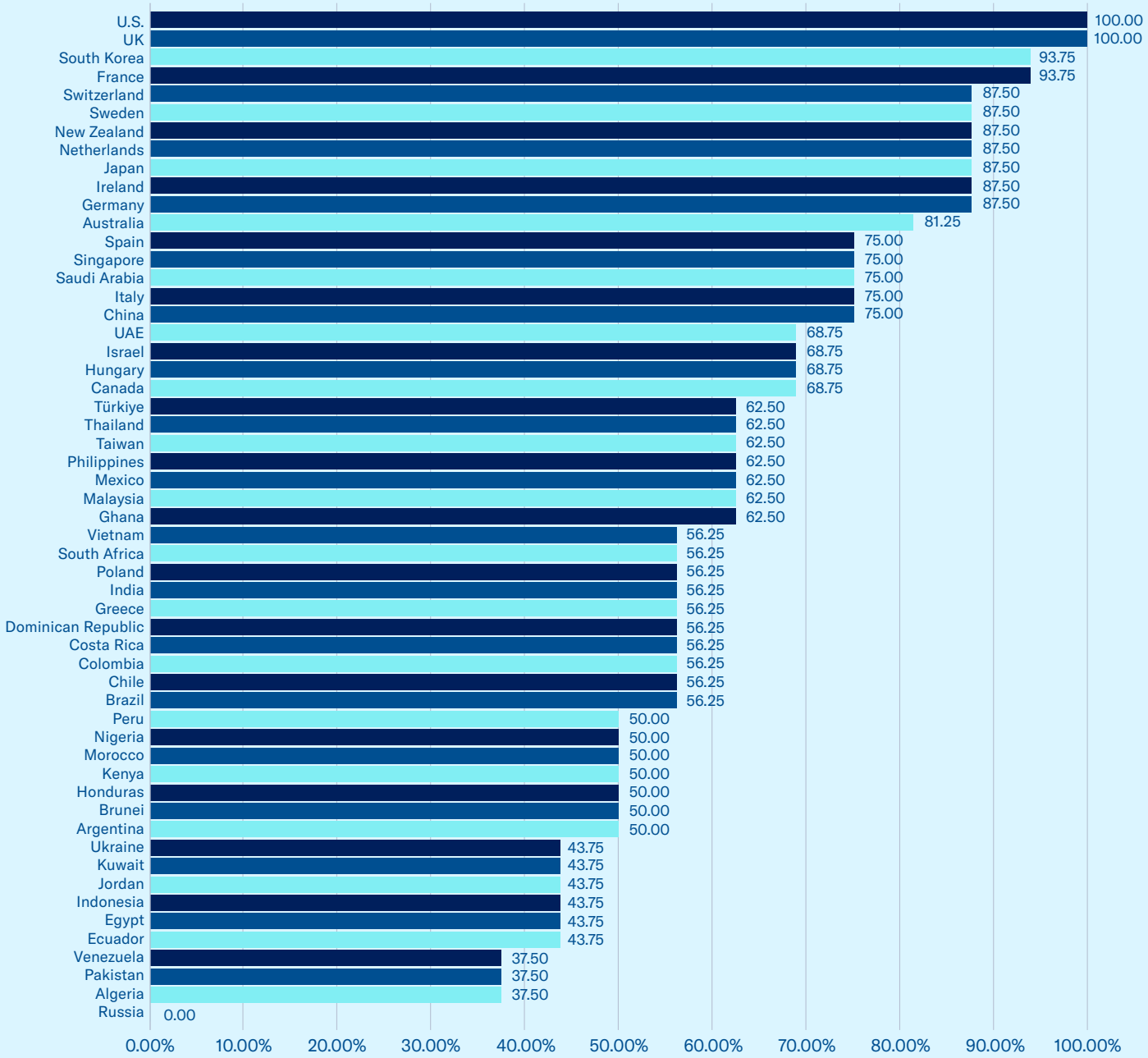
Category 3:

Trademarks, Related Rights, and Limitations

Figure 5 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 5: 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 in this category. As with Category 2: Copyrights, Related Rights, and Limitations, this category of the Index saw an increase in the average score from 62.39% in the eleventh edition to 62.84%.

Just as with the infringement of copyright, 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, in some jurisdictions, relevant legislation, case law, or enforcement practice has established an obligation 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 national IP office SAIP has worked on improving the national IP environment and rightsholders' ability to enforce their trademark and brand rights more effectively in Saudi Arabia. These efforts have continued in 2023. In its Annual Report of Intellectual Property Enforcement, SAIP reported that it had seized more than 12 million trademark and design infringing items, including foodstuffs, clothing and footwear, luxury goods, bags, and leather goods. The Authority received a record 1,100 rightsholder complaints about trademark infringement—a marked increase from the 194 received in 2021. The Authority worked with online merchants and intermediaries and took down close to 60,000 e-commerce–related ads or infringing content. These are significant and sustained actions taken by the Authority and mark another significant step toward improving the enforcement environment as it relates to trademarks and brand rights in the Kingdom.

Some important developments with respect to legal precedent and the interpretation of trademark law also occurred in 2023.

In March 2023, the Grand Chamber of Taiwan's Supreme Administrative Court issued a potentially precedent-setting ruling on what constitutes a well-known mark. (The Grand Chamber of the Supreme Administrative Court is the court of final instance for all disputes relating to administrative law.) The case, between a local company and international goods manufacturer LVMH, hinges on how Article 30(11) of the Trademark Act should be interpreted and, specifically, what defines a well-known mark in Taiwan. As noted over the course of the Index, owners of well-known marks have historically faced a mixed legal environment in Taiwan. Well-known marks are protected under existing statute against dilution and likelihood of confusion, but relevant administrative authorities have taken a varied approach to determining whether a mark is well known or not. Specifically, there has been a tendency to view the meaning of "well known" within the context of the general public as opposed to within a relevant group of users. This was now the issue that the Grand Chamber was tackling. In a unanimous ruling, the Grand Chamber found that in the Trademark Act, related implementing regulations and guidelines were clear that for a well-known trademark to prove its stature, it is sufficient to be known within the relevant group of consumers or businesses and not the general public. The ruling marks a potential turning point in Taiwanese jurisprudence and the manner in which administrative law assesses trademark infringement of well-known marks. Whether this ruling will lead to stronger enforcement against counterfeiting is a separate matter.

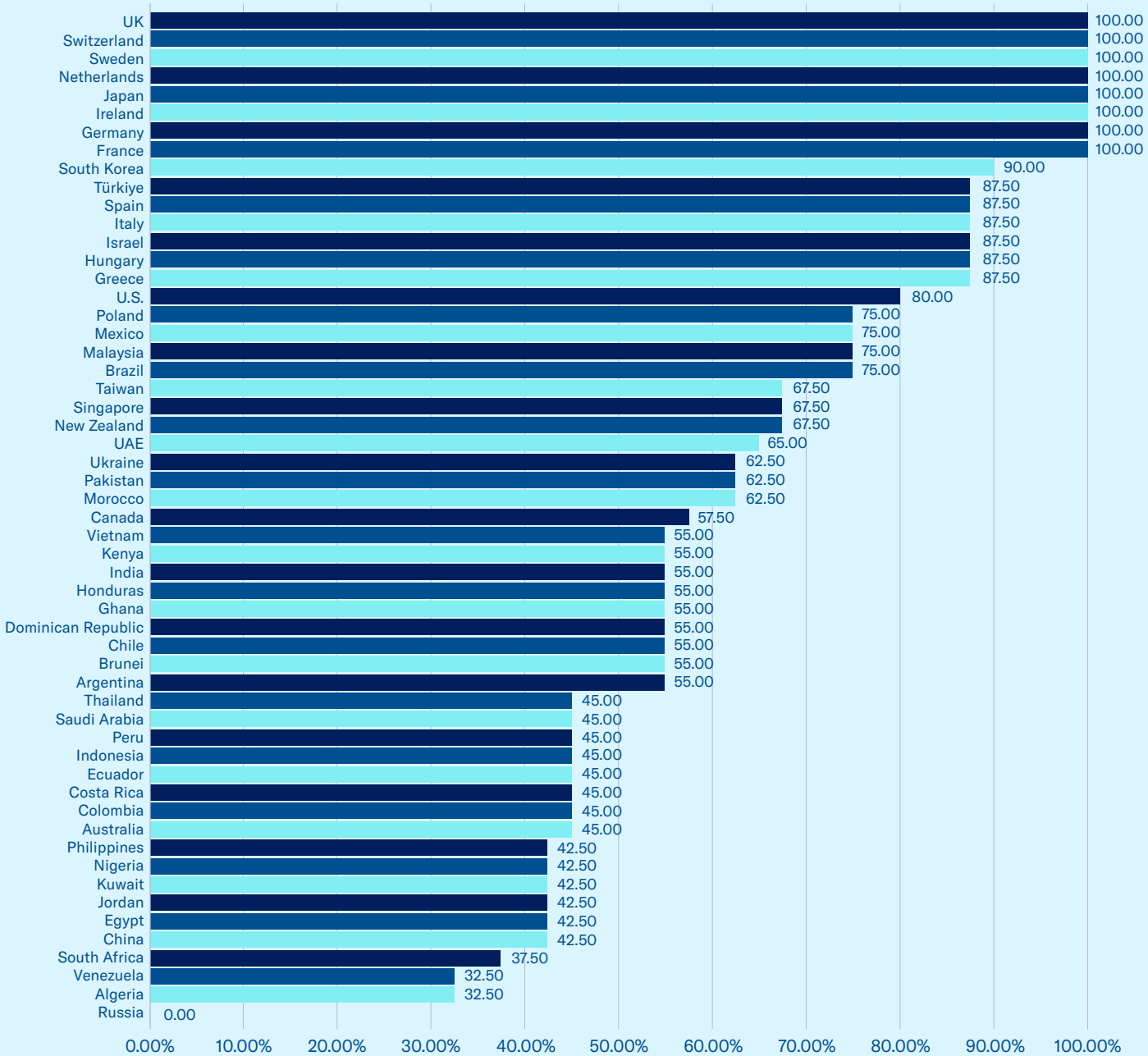
As noted in the Index, with respect to the trade of physical counterfeit goods—including trademark infringing goods—Taiwan has been identified as a central hub for the transshipment of counterfeit goods and the global trade of physical counterfeit goods. For example, in the 2021 publication Global Trade in Fakes: A Worrying Threat, the OECD and the European Union Intellectual Property Office (EUIPO) found that Taiwan was one of the top provenance economies for counterfeit products in the world.

Category 4:

Design Rights, Related Rights, and Limitations

Figure 6 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 6: 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 64%, up marginally from 63.77% last year. Over the past few years, many economies have reformed relevant laws and regulations pertaining to design rights and, in many cases, 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 2023.

As reported in last year's Index, 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. In August 2023, Brazil acceded to the full Hague Agreement, including the Geneva Act.

As noted last year, public reports suggest that the Directorate General of Intellectual Property (DGIP) and the Indonesian government have proposed new amendments to the Design Law, and these include an increase of the total term of protection available up to 15 years. 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. An increase in the term of protection for registered designs will result in a score increase for this indicator. At the time of research, the Indonesian parliament (the People's Consultative Assembly of the Republic of Indonesia) was still examining the bill.

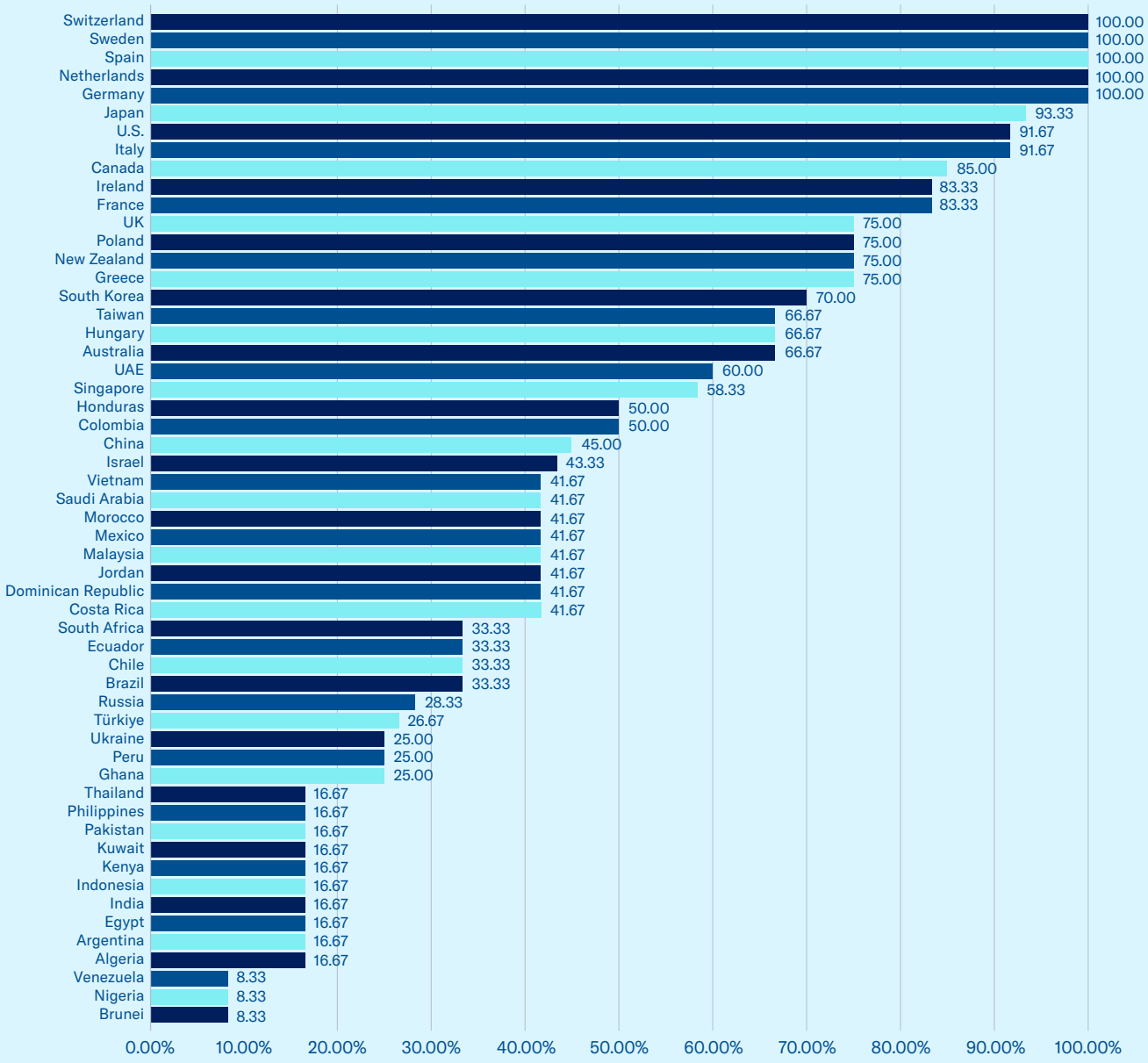
In a separate development, in late 2022, the European Commission proposed changes to the existing legal framework for community designs in the EU. Under a revised directive and regulation on the legal protection of designs, several important changes would be made. To begin with, the draft legislation updates existing legal definitions and registration requirements to better align the legal framework with current and future technological developments. The draft law also improves the scope of protection for design rights, including in relation to potential infringement through 3-D printing. The changes also expand the potential exceptions to industrial design protection under a "repair clause." At the time of research, no finalized legislation had been enacted.

Category 5:

Trade Secrets and the Protection of Confidential Information

Figure 7 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 that measure 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. In total, the category consists of three indicators with a maximum possible score of 3.

Figure 7: 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. And 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.

Overall, only 23 of the 55 economies included in the Index achieved a score of 50% or more on this category. Twenty-two economies achieved a score of 33.33% or less. The average score in this category remained the weakest on the Index at 48.97%, unchanged from last year.

As mentioned, in 2023, the European Commission published a package of proposed legislative changes to not only the EU's RDP regime but to almost all facets related to the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package is almost wholly negative. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window.

Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so convoluted and complex that it is unlikely that many research entities will, in practice, be able to access them. The draft directive also appears to condition the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid." Moving forward with the draft changes to the EU's RDP regime would result in all EU member states included in the Index seeing a score reduction for this indicator.

In addition to these proposed changes affecting the RDP term of protection, the commission has published proposals for the creation of a European Health Data Space (EHDS) and the manner in which confidential and proprietary health data are disseminated in the EU. The purpose of the EHDS is to enable greater access and use of health data, and it constitutes part of the broader policy of building a European Health Union. As part of the EHDS, new "health data access bodies" will be established across the EU. Part of the purpose of these bodies will be to collect relevant health information from what is termed "data holders" and to enable access to these data for "secondary use."

The creation of the EHDS is supported and defined through new primary and secondary legislation. Unfortunately, when drafting the proposal and underlying legislation for the EHDS, the commission seems to have overlooked or ignored several risks. To begin with is the obvious risk to confidential and commercially sensitive information and data.

Significantly, a portion of the health information to be collected and disseminated for secondary use comes from private enterprises and will pertain to proprietary health information, including clinical trial data. Indeed, Article 33(4) states, "Electronic health data entailing protected intellectual property and trade secrets from private enterprises shall be made available for secondary use." [emphasis added.] Yet as the commission well knows, any confidential and proprietary information that is protected by any IP right cannot—as a matter of international, European, and national member state law—be made available to the public outside specific and highly unique circumstances. In fact, confusingly, the next sentence of the draft regulation acknowledges this basic fact and states clearly that such information will not be made available to the public: "Where such data is made available for secondary use, all measures necessary to preserve the confidentiality of IP rights and trade secrets shall be taken." Together the two sentences amount to a gigantic non sequitur. Second, even allowing for the commission's flawed legal logic, it is unclear how these new health data access bodies would be able to separate and define what is protected and confidential information—which is under the cited article not to be disclosed for secondary use—and what is not. Furthermore, given that these bodies will be established in each individual member state—all of which have different standards of public administration and preexisting public transparency and disclosure practices—the practical result is most likely to be that levels and standards of health data disclosure will vary across the EU. Consequently, from a rightsholder's perspective, the protection of proprietary information will depend not necessarily on the underlying EU statute but, instead, on the *de facto* standards and practices used in each individual member state's health data access body in determining what is confidential and protected information and what is not. Under such a scenario, instead of harmonizing access to and the protection of health data, the EHDS will simply produce a postcode lottery across the EU with different standards of disclosure applying in different member states. The result would be that the EHDS would rely not on harmonized EU standards but instead would depend on the individual national capabilities of the new discretion and regulatory authority vested in the health data access bodies.

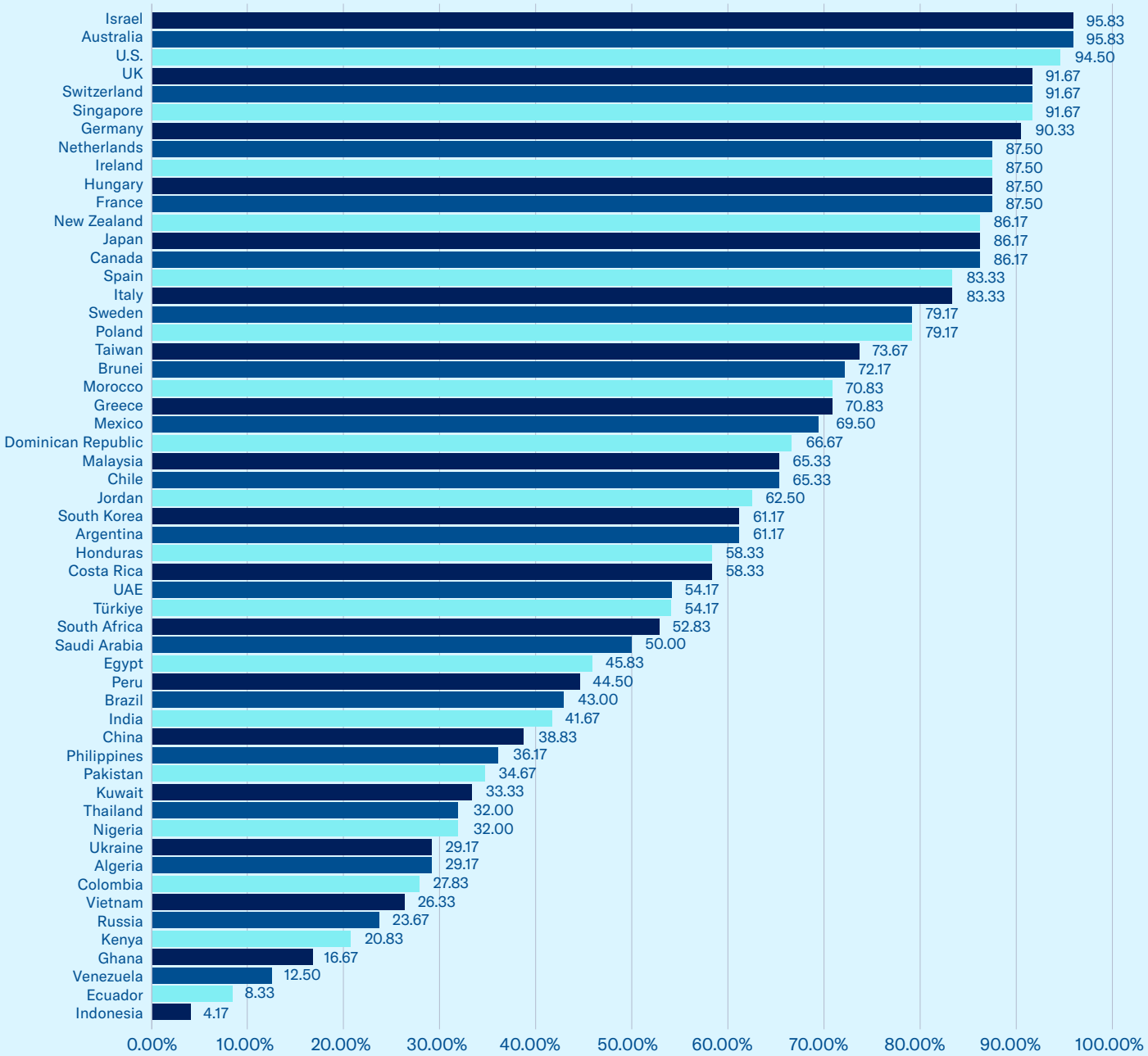
The final risk that the commission also seems to have overlooked is the international ramifications of these disclosure policies. Most economies and legal jurisdictions around the world predicate the protection of proprietary information, including health data and information protected by RDP, on the specific protected information not already being in the public domain. With respect to RDP and the protection of clinical trials and health data submitted during the market authorization process, multinational and international biopharmaceutical manufacturers obtain such protection independently in each legal jurisdiction they wish to operate. Manufacturers must apply separately for marketing authorization in each jurisdiction. A fundamental part of the market authorization approval process in any jurisdiction is the submission of clinical test data proving the safety and efficacy of a given product or technology. However, not all markets are entered into at the same time. Consequently, a product may be launched in some markets many years after it has been approved for sale in others. Yet the product must generally still go through a similar market approval process before being approved. The publication of large volumes of clinical trials and test data submitted as part of a marketing authorization application in one economy or jurisdiction risks putting into the public domain a significant amount of information that may be used by applicants in other jurisdictions as part of new market authorization applications for the same product or technology. Mechanisms (such as RDP) that are contingent on the information submitted in a marketing authorization application not already being publicly available may now—as a result of the EHDS's disclosure of the same or similar information—not be eligible for protection in these jurisdictions. This would be a catastrophic result for international rightsholders.

Category 6:

Commercialization of IP Assets

Figure 8 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 includes barriers to technology transfer, registration and disclosure requirements of licensing agreements, direct government intervention in setting licensing terms, and the existence of tax incentives for the creation and commercialization of IP assets.

Figure 8: Category 6: Commercialization of IP Assets, % Available Score



As has been noted in previous editions of the Index, many of the economies benchmarked in the Index have introduced policies that make it more difficult to access their respective markets or commercialize IP assets. Twenty of the 55 economies 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 58.78%.

In the mid-1980s, the U.S. Congress passed two path-breaking pieces of legislation: the Patent and Trademark Law Amendments Act of 1984 and 1986 (the Bayh-Dole Act) and the Stevenson-Wydler Technology Innovation Act, which was later amended by the Federal Technology Transfer Act of 1986 and the Technology Transfer Commercialization Act in 2003. This legislation attempted to supply federal laboratories (including the National Institutes of Health) and universities using federal funds with the incentives needed to work with industry for the purpose of translating early-stage research into usable products in the marketplace for the benefit of the wider public. The legislation sought to secure these goals through three major changes to the IP system. First, they allowed universities and federally funded bodies to retain ownership of the proprietary knowledge stemming from the research and daily activities of these institutions, including the ability to own patents on their inventions. Second, they encouraged these institutions to become much more proactive and professional in the management and exploitation of their inter partes reviews by creating professional technology transfer offices. Finally, the legislation sought to stimulate the commercial and financial aspects of public-private collaboration, with the intention of creating new businesses (such as spin-off companies) and generating income for the institutions as well as for the researchers.[22]

The importance of the Bayh-Dole framework to U.S. innovation—and especially for the life sciences sector—cannot be overstated. In 2002, the Economist magazine called the law the "most inspired piece of legislation to be enacted in America in the last half-century."

This statement aptly sums up the positive impact the legislation had, and continues to have, on innovation in the United States. Looking at general rates of innovation and commercialization activities, this can be seen in terms of both patenting activity and actual economic impact and output. To begin with, academic research into the effects of the Bayh-Dole framework has found a significant correlation between increased patenting activities at U.S. universities and the act. For example, a 2004 study found that university share of total patenting in the United States increased from 0.69% of total patents at the time of legislation to just under 5% in 1996. Moreover, in a range of 117 industries (including biopharmaceuticals), the difference was from a decrease of 87% in 1969 to an increase of 1,648% in 1996.[23]

The positive impact of Bayh-Dole can also be seen in terms of direct and significant contributions to economic output and employment. For instance, using 25 years of data from the annual Association of University Technology Managers (AUTM) survey, a 2022 study estimating the economic contribution of licensing activity by academic institutions found that in the United States, the contribution of academic licensing to gross industry output ranged from $631 billion to $1.9 trillion (measured in 2012 U.S. dollars).[24] Contributions to GDP were equally significant, estimated at $333 billion to $1 trillion (measured in 2012 U.S. dollars).[25] In addition, this study found that this licensing activity was a major contributor to the American job market, responsible for 2.356 million to 6.499 million person years of employment over the period studied.

Perhaps the most telling statistic is the strong growth in industry-university collaboration and, in effect, the institutionalization of this partnership as the foundation of modern drug development. New technologies and research insights generated at universities and within public research are seldom finished medical products ready to be commercialized. Instead, it often takes years of translational R&D by industry and biopharmaceutical manufacturers to take these technologies and generate a safe and effective medical product.

For example, a decade after Bayh-Dole was passed, the combined campuses of the University of California became the top recipient in the United States of biotechnology patents, a position formally held by Merck.[26] Similarly, looking at licensing income for U.S. universities, not only has this grown exponentially since the mid-1980s, but the life sciences sector is also the predominant source of this income. For example, in 2013, Nature Biotechnology examined licensing income and sector-specific sources of this income for top U.S. universities and research institutes and found that of the $1 billion in total gross licensing income in 2013, over $977 million (97%) came from the life sciences sector.[27] The number was similar with regard to the number of start-ups and licenses executed with most being in the life sciences sector.

More recent data paint a similar picture. Findings from the AUTM survey cited earlier show that most—about 80%—of licensing income to universities and nonprofit institutions, including research hospitals, is derived from the life sciences.[28] Perhaps the most noteworthy example is the $750 million in licensing income the University of Pennsylvania has received through the research of Katalin Karikó and Drew Weissman in the use of mRNA technology in vaccines.[29] In December 2023, the National Institute of Standards and Technology published a "Request for Information" on a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. A primary focus of the Draft is the extent to which the price of a relevant invention can be considered as justifying the federal government's ability to override any existing IP exclusivity. This follows a similar discussion in 2021. In January of that year, the Department of Commerce and the National Institute of Standards Technology requested comments for potential changes to the way federally funded or supported technologies developed are transferred and licensed. Part of the discussion around the proposed rule changes in 2021 related to the issue of "march-in rights." Such rights grant the federal government a mechanism to access a given technology under specific circumstances. Then, as now, these march-in rights are not meant to be used as a lever to reduce the cost of commercialization of a given technology or to abrogate an existing licensing agreement on the basis of cost—an idea that seems to be the focus of this latest request for information. It is vital to all high-tech sectors, industries, and their publicly funded partners that have close partnerships and R&D that the concept of march-in rights not be misconstrued or presented as a basis for introducing price controls with regard to, for example, biopharmaceutical products and technologies. This was never the intention of the underlying legislation. Indeed, should the federal government adopt such a flawed interpretation of Bayh-Dole, it would in all likelihood lead to the complete destruction of the current life sciences R&D ecosystem, which is built around mutually beneficial public-private partnerships.

As detailed in its Economy Overview, rightsholders have over the years faced a growing number of regulatory, procedural barriers and inflexible terms to licensing in China. As discussed in previous editions of the Index, significant positive changes to China's technology transfer and licensing environment occurred in 2019-2020. Most importantly, both the Foreign Investment Law and the Technology Import and Export Regulations and Regulations for the Implementation of the Law of the People's Republic of China on Chinese-Foreign Equity Joint Ventures were changed with many of the most onerous provisions 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 Technology Import/Export Regulations (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 Chapter 20. Notably, 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, regarding 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 for 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 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 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 2022, the European Union filed a request for consultations with China on this issue at the WTO. This was followed by requests from Japan, Canada, and the United States to join these consultations. At the time of research, a dispute panel had been established.

In a separate development, 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. 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 "nonlocal goods" that could, potentially, 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." As detailed last year, just like the underlying legislation, this rule considerably expanded the powers of investigation, punishment, and meaning of what constitutes anticompetitive behavior within the context of the exercise of IP rights. In August 2023, this rule came into effect. Unfortunately, while maintaining some moderate safeguards against potential overreach, the finalized version did not materially improve on the preceding draft. It, too, contains the same broad and vague language on what constitutes anticompetitive behavior within an IP rights context and vests considerable discretion with the anticompetition authorities in identifying and defining such behavior.

In a further development, in June 2023, the State Administration for Market Regulation released draft guidance on antitrust and competition policy within the field of SEPs. This guidance document largely follows in the negative footsteps of both the Anti-Monopoly Law and the "Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition."

As stated last year, 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 Anti-Monopoly Law and accompanying rules—this will result in a sharp score decrease for relevant Index indicators and will negate the positive impact of the Phase I Agreement with the United States. The Index will continue to monitor these developments in 2024.

This is not an isolated trend in China. Unfortunately, many Index economies are considering more interventionist policies that target the SEP licensing and negotiation process.

For example, as discussed in previous editions of the Index, an area of growing interest to Japanese industrial and competition policy has been the centrality of SEPs to future innovation and economic growth. In 2017, the Ministry of Economy, Trade and Industry (METI) issued The Intellectual Property System for the Fourth Industrial Revolution; in 2018, the Japanese Patent Office (JPO) released the Guide to Licensing Negotiations Involving Standard Essential Patents; and in 2022, a new and updated Guide was released together with a stand-alone document titled Good Faith Negotiation Guidelines for Standard Essential Patent Licenses. The initial document had focused on the implementation of two new types of administrative procedures aimed at expediting resolutions and reducing litigation costs in SEP disputes. Under the first procedure, in cases where no agreement between the parties was reached, the amount of royalties would be determined by an administrative committee appointed by the JPO. Under the second pathway for private companies, a dedicated organization would manage the disputes where the parties could not reach an agreement, although the specifics for this process were unclear. As noted in the Index at the time, many rightsholders expressed deep concern over this policy and its potential for direct government intervention and management of this negotiating process.

Subsequent proposals and documents have sought to take a more balanced approach, avoiding direct government intervention, and recognizing that each individual SEP licensing negotiation is shaped by a unique set of facts and legal and commercial circumstances.

In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practice related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through EUIPO are deeply concerning.

SEP-based technologies are central to future innovation and economic growth—in China, Japan, the EU, and globally—and 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 use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

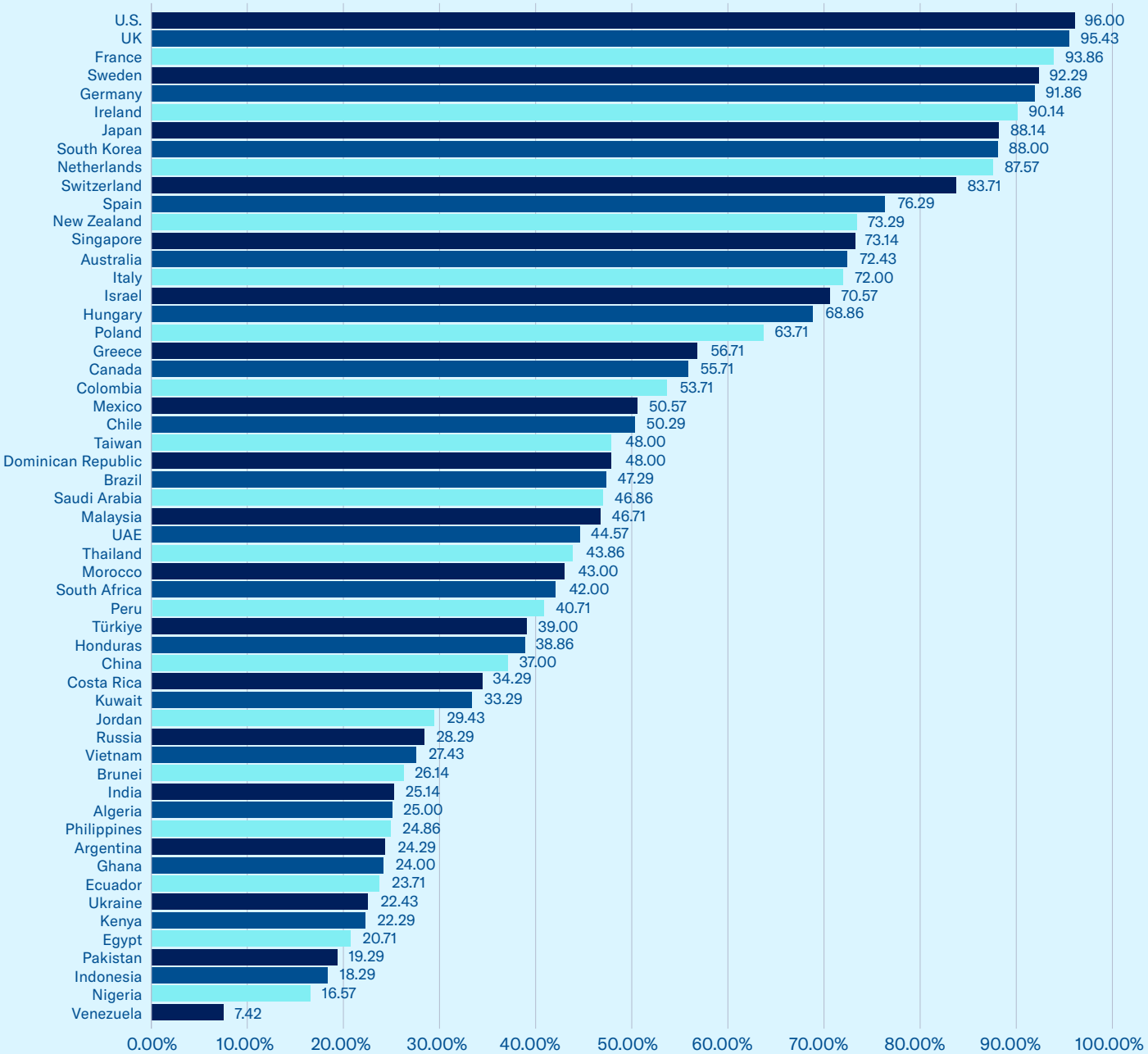
As detailed over the course of the Index, Turkish industrial and economic policy over the past two decades has increasingly been driven by an effort to localize industrial production and R&D. A major part of these efforts has been localization and import substitution policies that actively discriminate against foreign entities and favor domestic Turkish companies. The Turkish government actively uses public procurement policies as a form of incentivizing localization and discriminating against foreign bidders. Many of these localization and discriminatory policies have targeted the research-based biopharmaceutical industry. In 2019, the European Union filed a complaint before the WTO alleging that Türkiye'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 Türkiye 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. An arbitration award was subsequently issued in mid-2022. This award did not materially change the panel's findings. In a subsequent communication to the WTO from the Turkish delegation, Türkiye committed to "implement the recommendations and rulings of the Arbitrators and the Panel in this dispute in a manner that respects its WTO obligations."

As noted last year, both the panel's findings and final arbitration award are significant developments and should mark a positive turning point for affected rightsholders in Türkiye. Throughout the second half of 2022 and in the spring and summer of 2023, Türkiye submitted several notifications on its progress in resolving the issue. Most notably, this included the development of new drug reimbursement regulations, the termination of relevant import substitution programs, and the opening of reimbursement lists to excluded foreign companies.

Category 7:
Enforcement

Figure 9 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 9: Category 7: Enforcement, % Available Score



As in years past, most of the sampled economies in the Index struggle in this category, with only 23 Index economies achieving a score of 50% or more, and only 11 economies achieving a score of 75% or more. The average score in this category remains one of the weakest in the Index at 50.24%, up only marginally from last year's 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 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.

The lack of effective enforcement efforts is a particular problem given the increase in overall levels of global trade. International trade growth has made it possible for even small businesses to reach customers in foreign markets that only a generation ago would have been inaccessible. The result has been a significant increase in the volume and value of global trade. In 1990, the value of world trade in goods was an estimated $3.5 trillion.[30] Today, the value of global trade in goods is over seven times that amount at an estimated $25.05 trillion in 2022. This does not count trade in services, which has grown exponentially over the past two decades.[31]

However, as international trade has increased, so too has the circulation of counterfeit and pirated goods. International efforts to track and measure the scale and circulation of counterfeit and pirated goods have increased over the course of the Index. This work has primarily been driven by the OECD and EUIPO, which have been instrumental in developing new metrics and regular assessments of levels of trade-related counterfeiting.

In 2008, the OECD published The Economic Impact of Counterfeiting and Piracy, which embedded seizure data, customs and industry survey data, and international trade data into an econometric model known as the GTRIC-e that provided an estimation of the magnitude of trade-related physical counterfeiting in aggregate both internationally and within each economy. The study concluded that global physical counterfeiting accounted for some $200 billion in 2005. In 2009, this estimate was updated to account for the growth and changing composition in global trade, thereby increasing the magnitude of global physical counterfeiting to $250 billion.[32] These studies have since been updated with new estimates of the volume of the international trade in counterfeit and pirated goods released in 2013, 2016, 2019, and 2021. These estimates show that the volume and scope of counterfeit and pirated goods are steadily increasing. The latest estimates from 2021 suggest that this aggregated trade was valued at just under $500 billion ($464 billion), or 2.5% of global trade.[33] In addition to measuring the overall volume of trade-related flows of counterfeit and pirated goods, the OECD's and EUIPO's work also allows users to see the world's top provenance economies for counterfeit goods.

Table 5 shows the results of the OECD's and EUIPO's report, which uses the GTRIC-e measure to estimate an economy's propensity to export counterfeit and/or pirated goods.

Table 5: Top 25 Provenance Economies in Terms of Their Propensity to Export Counterfeit Products, GTRIC-e Average 2017-2019 (IP Index Economies Are Highlighted in Bold)[34]

Hong Kong (China)	1.00
Syrian Arab Republic	1.00
China (People's Republic of)	1.00
Türkiye	1.00
Dominican Republic	0.98
Pakistan	0.96
Georgia	0.93
Lebanon	0.87
Senegal	0.83
Afghanistan	0.76
Singapore	0.76
Benin	0.73
UAE	0.72
Morocco	0.69
Cambodia	0.68
Bangladesh	0.66
Curaçao	0.64
Panama	0.62
Tokelau	0.58
Albania	0.58
Serbia	0.55
Paraguay	0.45
India	0.45
Lao People's Democratic Republic	0.44

As Table 5 shows, several economies worldwide have an extremely high likelihood of exporting counterfeit products. Hong Kong (China), Syrian Arab Republic, China (People's Republic of), Türkiye, Dominican Republic, Pakistan, and Georgia all achieved a GTRIC-e score of 0.93 to 1.00. Of these seven economies, more than half are included in the Index. Additional Index economies included in this list are, in order of GTRIC-e score, Singapore, United Arab Emirates (UAE), Morocco, and India. In total, eight Index economies are included in the GTRIC-e top 25.

Of note is that outside of these Index economies, several non-Index economies achieved a relatively high GTRIC-e score and are viewed as having a high propensity to export counterfeit goods, particularly in the Southeast Asia region. This includes Bangladesh, Cambodia, and Laos.

Bangladesh stands out as an interesting and instructive example. For instance, Bangladesh achieved a GTRIC-e score of 0.66 and ranked 16th out of the top 25 economies for counterfeit goods. However, this GTRIC-e rating was significantly higher when examining the destination economies of the exported counterfeit goods. For example, looking at counterfeit goods destined for the EU, Bangladesh achieved a much higher GTRIC-e rating of 0.8316, even higher than Singapore.[35] Looking a little deeper, it is also possible to see how counterfeit rates of particular types of goods from Bangladesh are high, depending on the scale and size of the domestic industry. For example, an examination of the OECD's and EUIPO's data for international trade related to clothing shows that Bangladesh is a major source of counterfeit clothing both in terms of the value of internatioanlly seized goods and the propensity of counterfeit clothing to originate in Bangladesh. For 2017-2019, Bangladesh ranked fifth overall in terms of the total seized value of counterfeit clothing.[36] Similarly, Bangladesh was found to have a GTRIC-e score of 0.32 globally and a score of 0.44 for counterfeit clothing aimed at the EU market.[37]

These important findings have been cited by the U.S. government. For example, in the 2023 Special 301 report, the Office of the U.S. Trade Representative (USTR) referred to the OECD findings stating that the report "identified Bangladesh as one of the top five source economies for counterfeit clothing globally, which stakeholders have also identified as a concern this year."

In positive news, several Index economies have clearly understood the dangers of counterfeit and pirated goods and as a result have increased enforcement resources and have invested in anticounterfeiting and IP rights–infringing activities with respect to criminal enforcement.

For example, the criminal enforcement environment of IP rights in the Netherlands has historically been challenging. Intellectual property infringement is not directly dealt with in criminal law. Instead, related activities and consequences are liable to criminal consequence. For example, acts of counterfeiting that cause threats to public safety are liable to criminal penalties, and similarly, large-scale piracy that causes market distortion can be prosecuted on grounds of unfair competition law. With respect to criminal enforcement related to copyright, this has historically been a serious challenge for rightsholderss in the Netherlands. Levels of piracy have traditionally been high with sites such as the Pirate Bay offering Dutch consumers unimpeded access to copyright infringing content.

As noted in previous editions of the Index, over the past five years, 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 in Category 2: Copyright, Related Rights, and Limitations. Over the past seven 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.

These positive efforts continued in 2023 with Dutch law enforcement taking decisive action against one of Europe's largest providers of illicit digital piracy through set-top or IPTV boxes. As in many other Index economies, the Netherlands 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. Media reports suggest that in May 2023, the Dutch Fiscal Information and Investigation Service, with coordinated support from the European Union Agency for Law Enforcement Cooperation (EUROPOL), raided several sites across the Netherlands, made numerous arrests, and disabled the data center source from which the illegal content was being made available. The successful operation is said to have disabled access to illegal content in hundreds of thousands of set-top boxes around Europe.

Similarly, the past year saw several positive developments in IP enforcement in the Dominican Republic. At the end of 2022, President Abinader issued Decree 776-22, which establishined a new coordinating body on IP policy, the National InterMinisterial Council of Intellectual Property (Consejo Interministerial de Propiedad Intelectual).

As has been noted in previous editions of the Index, rightsholders face significant challenges in enforcing their IP rights in the Dominican Republic. Although many legal standards are in place, *de facto* protection and enforcement remain weak with rates of physical hard-goods piracy and counterfeiting high, particularly for alcohol and optical goods. As noted, the Dominican Republic was one of the Index economies that has an extremely high likelihood of exporting counterfeit products as per the OECD's and EUIPO's GTRIC-e measure. Part of the enforcement problem in the Dominican Republic has historically been a lack of coordination and cooperation among the relevant parts of the government involved in enforcement. No formal mechanism has been in place for interagency coordination of IP enforcement.

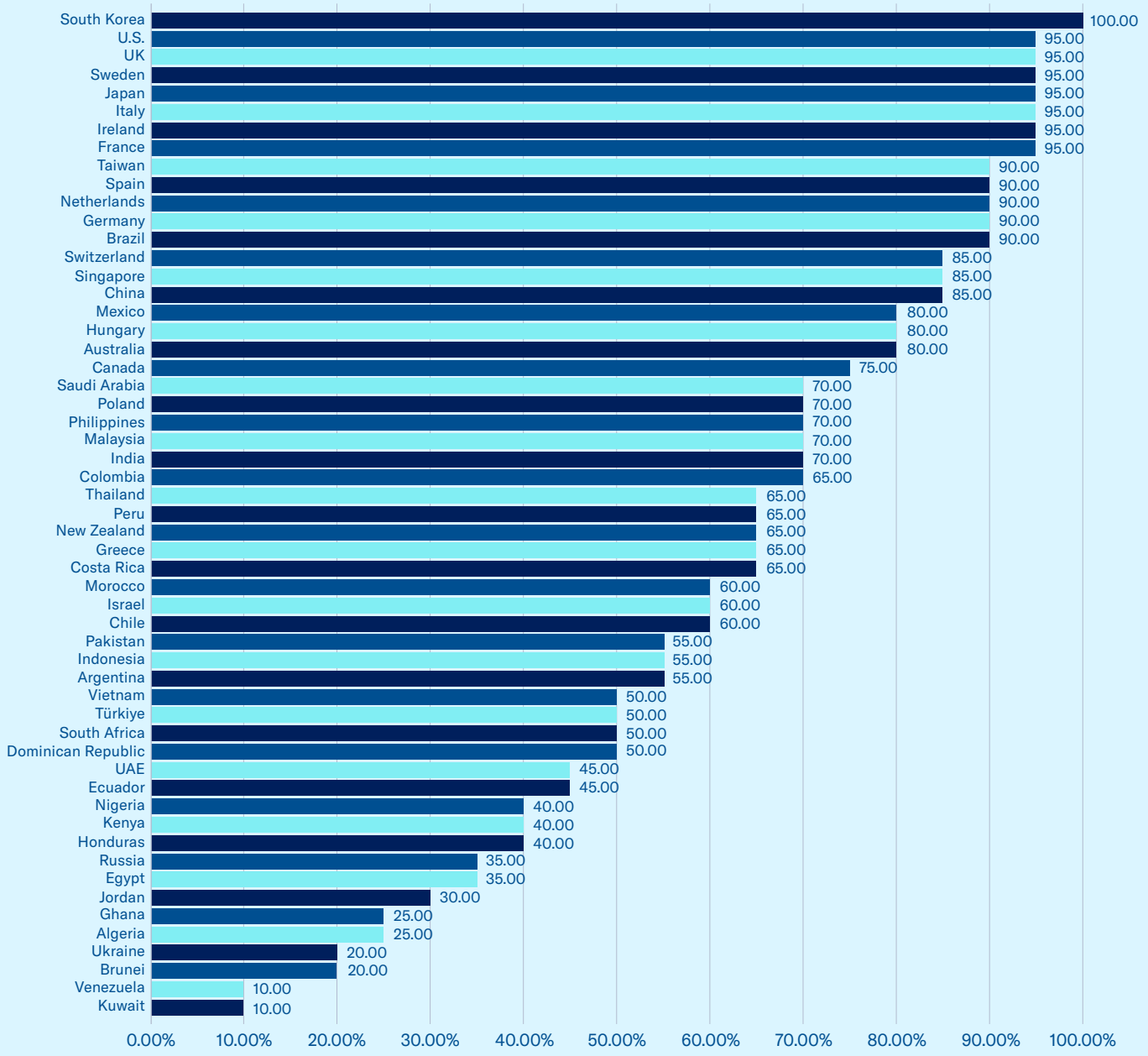
Examples of joint public-private initiatives include the "Campaign against Counterfeiting" (Mesa Presidencial contra el Contrabando), which brings together various agencies and departments from the government with private sector representatives, but this initiative is focused on educational activities and raising awareness, not on the coordination of IP rights enforcement.

Although the new Council of Intellectual Property will work on issues cutting across IP policy, a primary area of emphasis is the coordination of IP enforcement across government. Consequently, its work is an important step in improving the overall IP enforcement environment in the Dominican Republic. Led by the Attorney General's Office and the Ministry of Industry, Commerce and MSMEs, the council includes representatives from all key IP enforcement–related ministries and departments, including Customs, the National Office of Industrial Property, the National Office of Copyright, and the Institute of Telecommunications. The council held its first meeting in February 2023 and, at the time of research, was operational. More broadly, positive developments also occurred in IP enforcement with respect to rates of criminal prosecution. Specifically, statistics published by the Attorney General's Office of Intellectual Property Unit suggest that 2022 saw a notable increase in the prosecution of signal piracy and illicit broadcasting.

Category 8:
Systemic Efficiency

Figure 10 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 the IP law and regulation-making process; 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 an 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 10: Category 8: Systemic Efficiency, % Available Score



As in previous editions, most of the sampled economies in the Index performed well in this category with only 14 economies failing to achieve a score of 50% or above. Indeed, many Index economies outperformed 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 Index 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 63.55%, up from 62.73% last year.

In 2023, these positive efforts continued.

As has been noted across the Index, a key part of Saudi Arabia's national IP office SAIP's work since its inception has been the strengthening of the institutional and systemic features of the Kingdom's national IP environment. In 2023, these efforts continued with respect to both awareness-raising activities and efforts to improve and formalize stakeholder engagement through public consultations. Historically, there has been no formal or statutory requirement that Saudi authorities offer public consultations on proposed legislative and regulatory changes. Public consultations have taken place, but they have varied in length and in substance from ministry to ministry and from topic to topic. However, as noted over the course of the Index, with regards specifically to consultations on changes in IP policy, SAIP has from the outset consistently issued calls for public comments and has sought to actively engage with rightsholders in the Kingdom and internationally. This has continued in 2023 with new consultations issued on a new draft IP law and calls for comments on the Kingdom joining several important international IP treaties, including the Madrid Protocol and the WIPO Internet Treaties.

More broadly, the past few years have seen an increase in efforts by the entire Saudi government to formalize the public consultation process. After the issuing of Cabinet Resolution 476 and as part of the broader transition toward Vision 2030, the National Competitiveness Center now houses an online centralized portal, Istitlaa, where all government issued public consultations can be accessed. This marks another highly positive development: regular consultations with all relevant stakeholders are a prerequisite for developing a world-class national IP environment in line with the highest international standards and practices.

In 2023, positive efforts continued with respect to IP awareness-raising activities in Saudi Arabia. SAIP launched or expanded a range of programs aimed at raising awareness about the positive socioeconomic impact of IP rights and the negative impact of counterfeiting and piracy. Two campaigns and initiatives worth highlighting include the "Intellectual Property Respect Council" (a program targeting IP awareness and outreach activities to businesses) and the "Intellectual Property Respect Officer Initiative" (a program designed to increase awareness and IP rights compliance within the public sector). Both programs were expanded in 2022-2023 with the number of council meetings doubling and more than 100 SAIP officials carrying out awareness-raising and educational activities within public sector entities. In partnership with the Ministry of Education, SAIP also launched a new "Intellectual Property Education Project," which will introduce the concept of IP rights and their value in public education. Finally, the Authority launched a new campaign to promote the socioeconomic value of IP rights and their role in promoting creativity and innovation, "The Game Is Open." Public outreach campaigns such as these have a real and positive impact on the national consciousness and on the respect and appreciation of the value that IP rights bring to society. SAIP and the Saudi government should be commended for their sustained support and expansion of these and their many other educational and awareness-raising efforts.

As many economies focus on rebuilding in the wake of the COVID-19 pandemic, in 2023, many Index economies also expanded efforts to improve incentives for the creation and use of IP assets by SMEs.

For example, up until now, there has been only limited support for the creation and use of IP assets for SMEs by relevant authorities in Kenya and through the regional African Regional Intellectual Property Organization (ARIPO). For example, Kenya's Industrial Property Institute (KIPI), does not provide reduced registration fees or an expedited examination route for SMEs. There has historically been some ad hoc technical assistance provided through various outreach activities, including local workshops at trade fairs, universities, and research institutes, but this assistance has not been aimed specifically at SMEs. Similarly, ARIPO does not provide reduced registration fees for SMEs. The office offers an expedited examination pathway, but this is not specific to or for SMEs. Some technical assistance is available through the ARIPO Academy, but, again, this is directed at students and IP practitioners and not at small businesses. This paucity of SME-specific technical assistance has now changed with Kenya in 2023 joining the "Inventor Assistance Program." Developed by WIPO and the World Economic Forum and launched globally in 2016, the program seeks to match inventors with legal practitioners who provide pro bono legal advice on the technical evaluation and registration process for the IP created.

Similarly, there is a growing recognition in Costa Rica of the importance of SMEs to the creation, dissemination, and commercialization of IP assets. Article 33 of Law 6867 (Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad) provides reduced registration fees for patent applications submitted by individual inventors, universities, public research institutes, and micro and small enterprises.

Historically, no targeted technical assistance or education programs have focused on the creation and commercialization of IP assets for SMEs by the National Registry or other major Costa Rican public institutions. Instead, outreach and technical assistance programs have been more cross-cutting and aimed at academic researchers, research institutes, and SMEs. Alternatively, when these programs targeted SMEs, they did so not within the context of incentivizing the creation of IP assets but more broadly in supporting small business and enterprise. This has now changed. In partnership with WIPO and its WIPO Academy initiative, in late 2022, the National Registry launched a dedicated IP training and outreach effort focused exclusively on the needs of entrepreneurs and SMEs. The inaugural event was held at the University of Costa Rica and was preceded by an outreach campaign targeting local businesses by the National Registry. Training sessions focused on understanding the basics of various forms of IP rights, the registration process, enforcement, IP valuation, and the identification and commercialization of IP assets by small businesses. The National Registry's program is part of a broader effort by the Costa Rican government to partner with WIPO and to boost post-COVID economic growth and development.

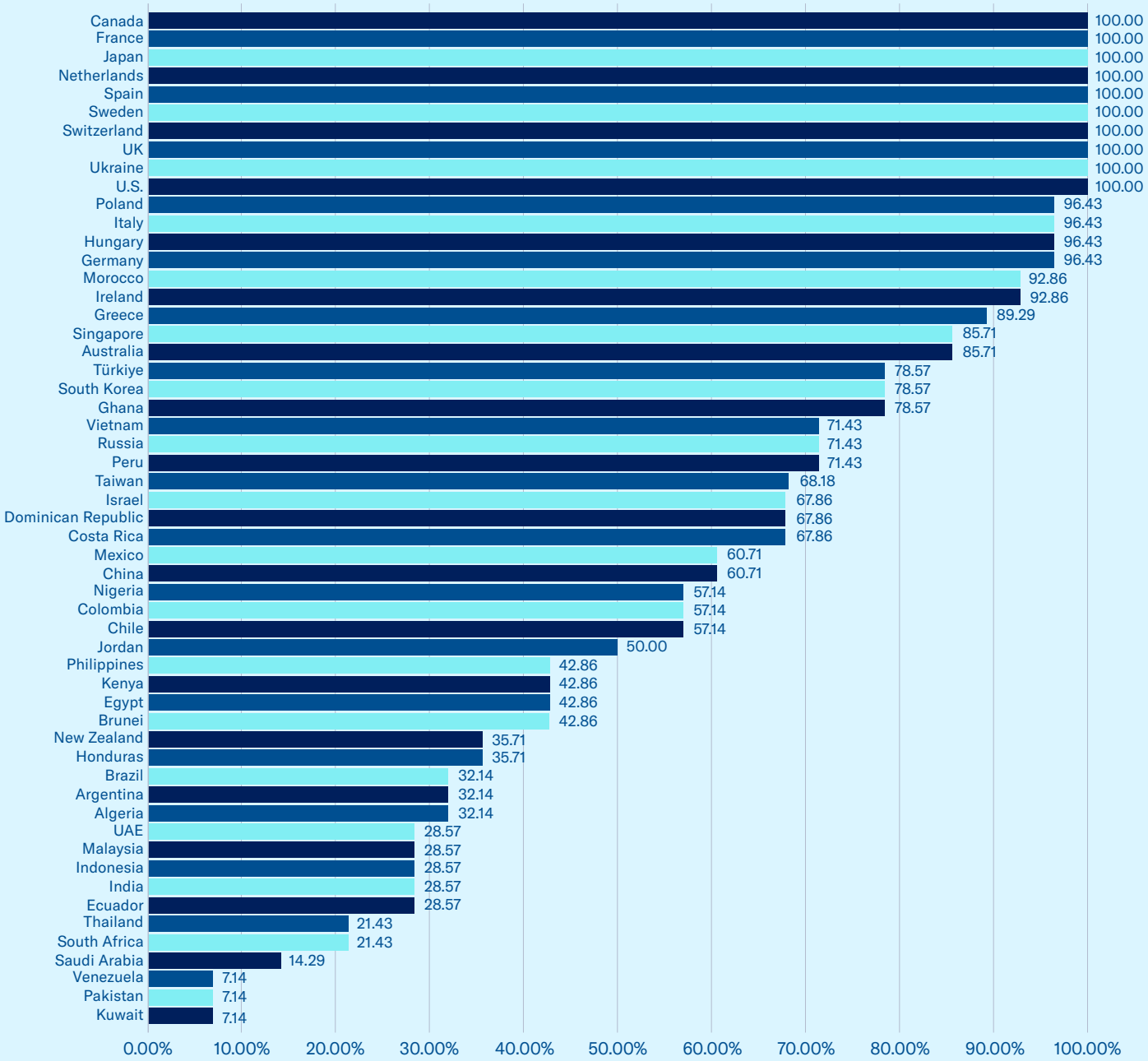
Category 9:

Membership and Ratification of International Treaties

Figure 11 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 11: 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 almost doubled from five to nine. This category remains one of the stronger overall categories in the Index, achieving an average score of 62.86%, marginally up from last year's 62.70% average. Many economies achieved a high score in this category: 22 economies had a score of 75% or more with 14 economies achieving a score of over 96%. Despite this, several notable 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. Notably, Kuwait 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 noted in previous editions of the Index, historically, trade agreements have been fundamental in setting international standards for the protection and enforcement of IP rights. When it entered into force in 1994, the North American Free Trade Agreement (NAFTA) was widely considered to be the first international trade agreement that included specific obligations to protect IP rights. NAFTA included and set the standard in most major areas of IP protection. Many multilateral, plurilateral, and bilateral trade agreements that followed in the quarter century—including the WTO TRIPS Agreement—built on NAFTA's standards and helped raise the international floor for IP protection.

Both the EU and the United States have traditionally been leading advocates for stronger IP standards, with strength measured in terms of the scope, duration, ease of access to, and reliability of the right. In virtually all post-TRIPS free trade agreements (FTAs) concluded by either of the two governments, IP rights and IP standards were central. The benefits have been felt worldwide, with inventors and creators from areas such as the Andes, North Africa, the Middle East, and Asia seeing the positive impact a stronger IP environment has on economic activity, trade, development, and job creation.

Unfortunately, the last half-decade has seen a weakening of both the EU's and United States' commitment to strong IP protection in some of their negotiated FTAs. For example, in 2019, the European Commission and the South American trade bloc Mercosur announced they had reached a trade agreement as part of a wider Association Agreement. Although technically the EU-Mercosur Agreement is a post-TRIPS FTA that contains a separate IP chapter, its IP provisions are notably weaker compared with current international standards and other post-TRIPS agreements concluded by the EU. It is a similar situation in respect of the New Zealand–European Union Free Trade Agreement. In late 2022, the European Commission and government of New Zealand concluded negotiations for a new FTA with the EU. Although this treaty contains some potentially positive features, it does not conform to the standards of a modern post-TRIPS FTA. Curiously, neither the IP chapter nor the rest of the agreement includes any reference to patent rights. Similarly, unlike many other post-TRIPS FTAs, the EU–New Zealand FTA does not contain substantial protections for the life sciences sector. Of note is that the treaty does not refer to 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 a dwindling number of 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.

Similarly, as noted in the Index at the time, the United States-Mexico-Canada Agreement (USMCA) was a significant missed opportunity to elevate IP standards through an FTA with the two largest U.S. trading partners. Although the United States-Mexico-Canada Agreement as originally signed by the parties included many critical 21st-century IP provisions, the text of the final agreement removed or fundamentally altered critical provisions, including those related to biopharmaceutical IP protection and incentives.

This negative trend of weakening IP standards can also be seen in other agreements at both the regional and bilateral levels.

At the regional level, for example, neither the Regional Comprehensive Economic Partnership (RCEP) nor the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) as currently constituted conforms to the modern standards of many other post-TRIPS international trade agreements. Although both treaties include separate IP chapters, neither treaty includes or refers to modern standards of IP protection for important IP-intensive industries, including the life sciences sector and copyright-based industries.

Over the past two years, the UAE has on a bilateral basis concluded several stand-alone Comprehensive Economic Partnership Agreements (CEPAs). At the time of research, four such agreements had been concluded and had come into effect: UAE-India CEPA (2022); UAE-Israel CEPA (2023); UAE-Indonesia CEPA (2023); and UAE-Turkey CEPA (2023). All these CEPAs include a dedicated IP chapter. This is a positive feature of the agreements, and all parties should be commended for recognizing the importance of IP-intensive industries and the centrality of IP rights to future trade and economic development in all economies. Unfortunately, these CEPAs do not conform to the standards of a modern post-TRIPS FTA because the IP chapters do not include substantive IP provisions in line with international best practices and identified in the Index. Indeed, although some variation exists among the individual agreements, much of the substance of the individual IP chapters is linked to rights defined and specified in TRIPS.

When signed in 1994, the TRIPS agreement represented an unprecedented commitment and recognition of minimum global IP standards. But 30 years after the agreement was signed, TRIPS is outdated and no longer represents or includes all the standards and protections that a modern, innovation-based economy needs. In terms of specific features and IP rights missing from these agreements, copyright provisions are relatively limited with no reference to the challenges that the online environment or infringement represents to rightsholders; there is no or limited reference to sector-specific provisions, including biopharmaceutical IP rights such as RDP and patent term restoration; and border measures are either nonexistent or notably weak with, for example, no reference to customs officials' authority to *ex officio* seize and suspend the release of suspected IP-infringing goods, whether intended for the domestic market or in transit.

Economy Overviews

Introduction

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

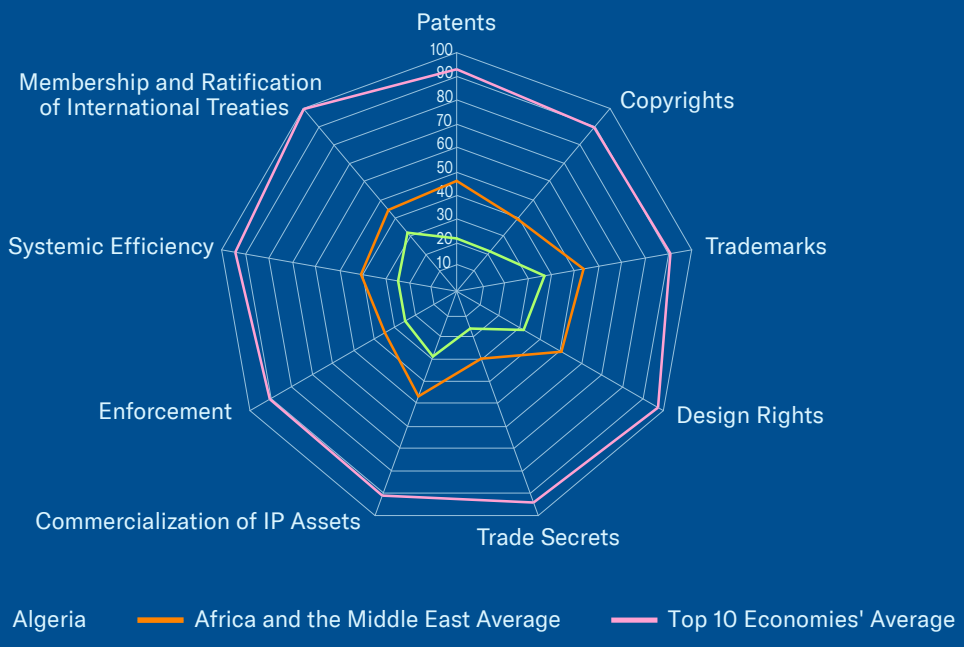
In addition to the total score and overall rank vis-à-vis the other economies included in the Index, each economy overview includes two figures. The first figure displays each economy's performance relative to the top 10 performers in each category of the Index and the regional average for that particular economy.

The second figure displays each economy's overall score compared to the regional average for that particular economy and the top- and bottom-performing economies. Specific challenges, debates, and issues related to the most important recent developments under each category are discussed in more detail in a separate subsection titled "Spotlight on the National IP Environment."

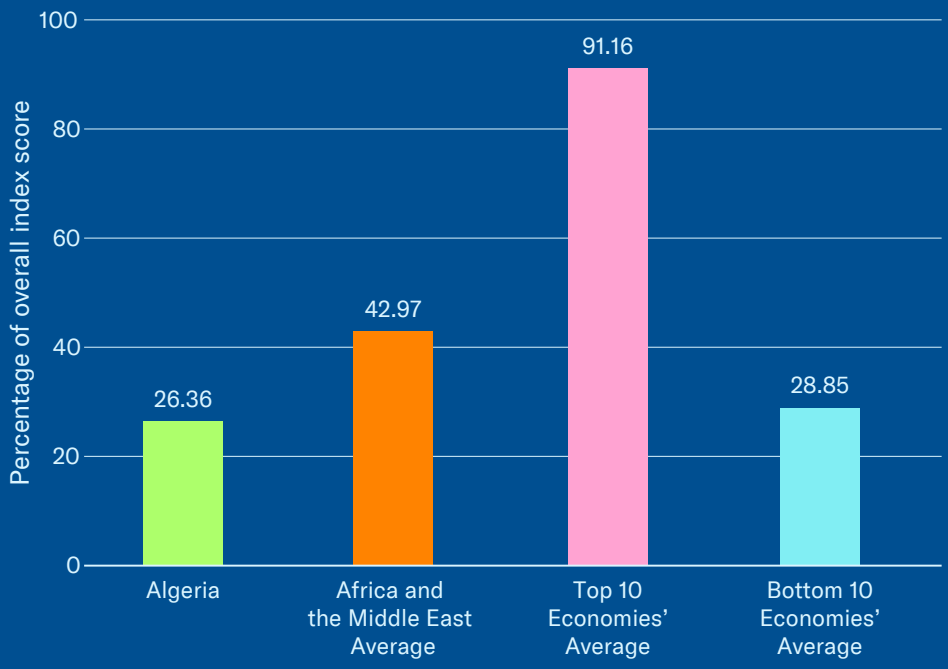
Algeria

Rank
53/55

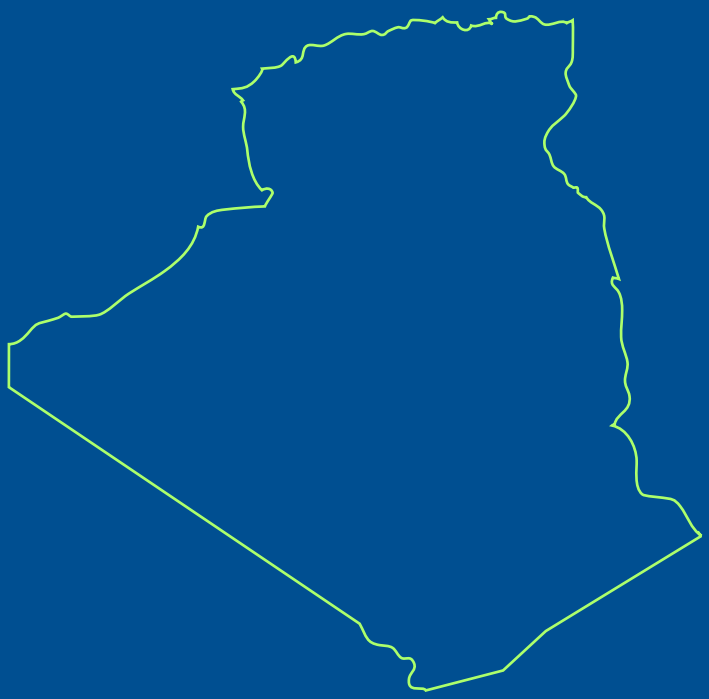
Category Scores



Overall Score in Comparison



Algeria



Key Areas of Strength

- 2022-2023 judicial reforms and introduction of new “specialized commercial courts”
- 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 investments
- A basic framework for IP protection is in place
- Contracting party to the WIPO Internet Treaties, Patent Cooperation Treaty, Patent Law Treaty, and Madrid Protocol

Key Areas of Weakness

- Historically, a difficult localization policy environment with import substitution, bans, and local ownership requirements; the 2021 Finance Law appears to reinstate some of these requirements
- Continued lack of clarity on local ownership requirements for the biopharmaceutical industry
- Weak patenting environment with basic rights missing
- Major holes in the copyright framework; limited coverage and applicability of the existing framework to the online environment
- High rates of piracy
- Not a WTO member or TRIPS signatory

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**2.00**
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.53**
10. Term of protection	0.20
11. Exclusive rights	0.32
12. Injunctive-type relief	0.34
13. Cooperative action against online piracy	1.23
14. Limitations and exceptions	0.50
15. Digital rights management	1.23
16. Government use of licensed software	0.24
Category 3: Trademarks, Related Rights, and Limitations	**1.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.23
19. Exclusive rights, trademarks	0.24
20. Frameworks against online sale of counterfeit goods	1.31
Category 4: Design Rights, Related Rights, and Limitations	**0.65**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
Category 6: Commercialization of IP Assets	**1.75**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.25
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**1.75**
32. Physical counterfeiting rates	0.32
33. Software piracy rates	0.18
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**1.25**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.00
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.00
Category 9: Membership and Ratification of International Treaties	**2.25**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 26.36%

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).

Enforcement

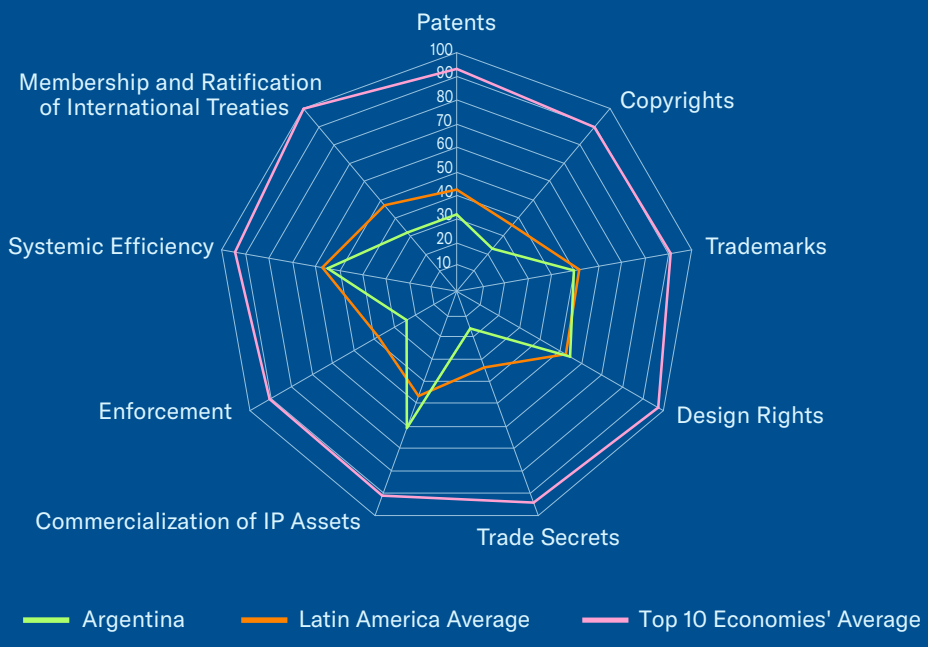
34. Civil and procedural remedies:
Some positive developments occurred in 2022-2023 with respect to the enforcement of IP rights in Algeria. Since January 2023, a system of new commercial courts has been operational in 12 geographic locations across the country. These "specialized commercial courts" are meant to provide legal expertise in complex areas of commercial law, including the protection of intellectual property. The new courts are part of an effort to overhaul and improve the performance of the Algerian judiciary and follows legislative and regulatory changes in the 2022 Investment Law, 2022 Organic Law Relating to Judicial Organization, and executive decrees 23-52 and 23-53 of January 2023.

As has been documented over the course of the Index, IP rightsholders face fundamental difficulties in enforcing their rights and accessing available civil remedies in Algeria. There is a general lack of confidence in the judicial system and a dearth of knowledge of IP rights among the judiciary, and civil proceedings are infrequent. Although there are instances in which damages and redress have been achieved from infringing entities, decisions are often not transparent, and, overall, sentences are nondeterrent. For example, biopharmaceutical patent rightsholders remain unable to effectively enforce their granted exclusivity and patent rights vis-à-vis generic and follow-on manufacturers. Industry reports suggest that in several cases, market authorization has been granted to follow-on products that potentially infringe in force and existing patents. The new commercial courts will hopefully improve the overall technical capacity, expertise, and quality of IP enforcement in Algeria. The Index will continue to monitor these developments in 2024.

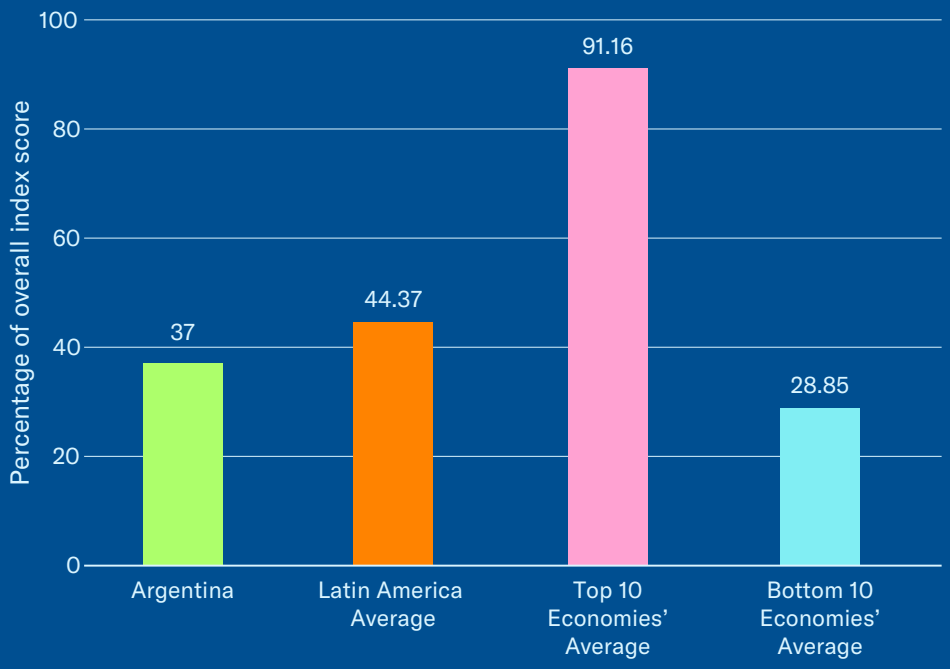
Argentina

Rank
46/55

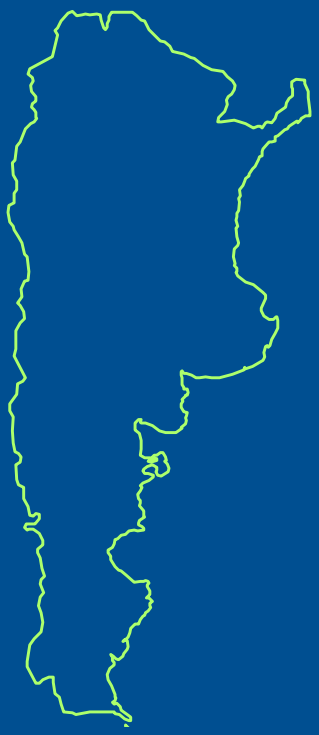
Category Scores



Overall Score in Comparison



Argentina



Key Areas of Strength

- The 2023 copyright infringement injunction against online piracy includes a “dynamic” element
- A basic framework for IP protection is in place
- Pronounced efforts over the past few years have strengthened international cooperation on IP rights, including through PPHs and increased technical cooperation with 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 online, but some important instances of judicial action have occurred
- Persistently high rates of piracy, including physical counterfeiting
- Limited participation in international treaties—has not acceded to the Patent Cooperation Treaty

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

Indicator	Score
Category 6: Commercialization of IP Assets	**3.67**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**1.70**
32. Physical counterfeiting rates	0.37
33. Software piracy rates	0.33
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**2.25**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.25
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 37.02%

Spotlight on the National IP Environment

Past Editions versus Current Score

Argentina's overall score remains unchanged at 37.02% (18.51 out of 50).

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

2. Patentability requirements; 3. Patentability of computer-implemented inventions (CIIs); 8. Membership in a Patent Prosecution Highway (PPH); and 46. Patent Law Treaty and Patent Cooperation Treaty:

As noted over the course of the Index, the patent environment in Argentina remains highly challenging. Patentability restrictions remain a serious and long-standing issue, in particular concerning biopharmaceutical products and processes and CIIs. In violation of TRIPS Article 27, patentability restrictions introduced in 2012 effectively curtailed 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 Institute of Industrial Property (INPI) have also curtailed the protection of biotechnology-based inventions. Similarly, innovators face substantial hurdles obtaining patent protection for CIIs. Section 6 of the Patent Law excludes computer programs from patentability because copyright is referred to as the primary form of protection for CIIs. Although Regulation No. 318/2012 allows CIIs to be patentable under certain conditions, data on patent applications show only a small number of CII applications filed in Argentina. The cost of these legal barriers to the Argentinean economy is substantial in both lost opportunities for domestic innovators and potential foreign direct investment.

For example, the Ministry of Science, Technology and Innovation's annual survey on business R&D (Encuesta sobre I+D del Sector Empresario Argentino) has consistently found that the research-based biopharmaceutical industry and software industry are the largest and most R&D-intensive industries in Argentina. The latest survey, published in May 2023, found that the pharmaceutical industry accounts for 35.6% of total business R&D expenditure, with computer software accounting for a further 13.5%. It is not unreasonable to assume that should rightsholders in these industries be able to better protect their inventions, in line with international standards, their contribution to the Argentinean economy would be even greater.

More broadly, inventors face excessive patent prosecution times and long delays. A substantial backlog of patent applications has existed at INPI for several years; average time to grant for many high-tech arts (including biopharmaceuticals, chemical, and biotech patents) is close to a decade. To alleviate this backlog, INPI has taken some corrective actions over the past few years. 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.

There has also been a concerted effort from INPI to engage in some forms of international patent cooperation and harmonization efforts. For instance, Resolution 56/2016 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 the IP5 Patent Prosecution Highway, INPI has concluded PPHs with the USPTO, JPO, and the Chinese IP office (CNIPA). Unfortunately, a PPH agreement concluded with the United States in 2017, expired in 2020, and has not been renewed. INPI has also deepened its technical cooperation with the European Patent Office (EPO).

In 2016, it signed a memorandum of understanding (MOU) on bilateral cooperation focused on enhancing patent examiners' expertise in the areas of patent procedures, search, and examination. This was followed up in 2018 with a Reinforced Partnership agreement. 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 (PCT) 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.

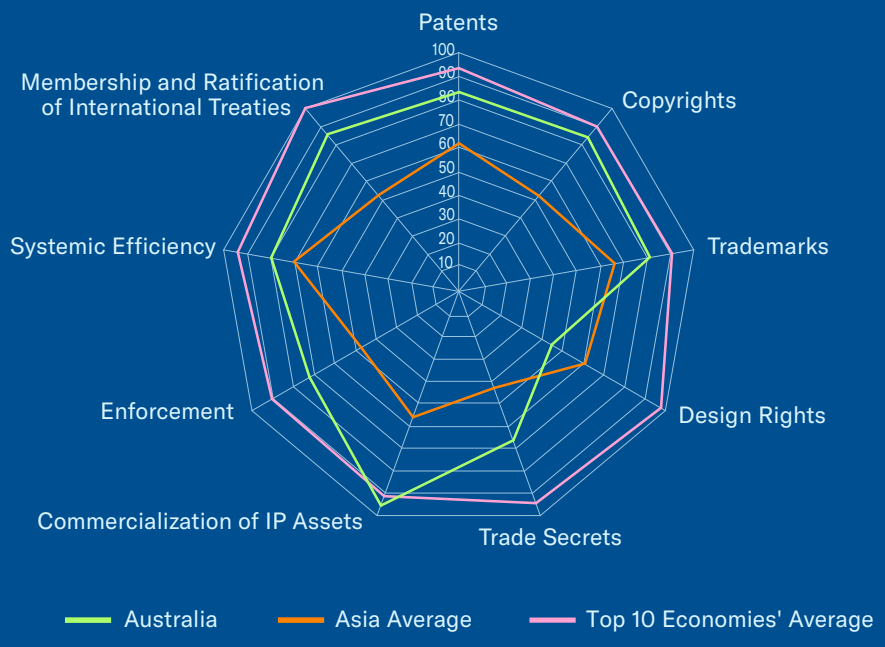
Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online:
Some welcome developments occurred in 2023 with respect to the enforcement of copyright in Argentina. In May, a federal court ordered the disabling of access to several copyright infringing websites and also included a "dynamic" element in the order. The plaintiffs—led by a coalition of international, regional, and domestic rightsholders—specifically requested that the injunction include the ability to update and apply the disabling of access to new websites and URLs as they appear. This type of dynamic injunction effectively addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These types of orders are becoming more commonplace around the world, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, Canada, and the United Kingdom (UK). The granting of this court order is potentially of real significance because the judgment not only affirmed the right to injunctive relief online but also included the dynamic element and ability to quickly update the court order without having to restart legal proceedings. It is hoped that this enforcement route will now be available to rightsholders more broadly and will provide a clear and expeditious path for creators to effectively enforce their rights in Argentina. The Index will monitor these developments in 2024.

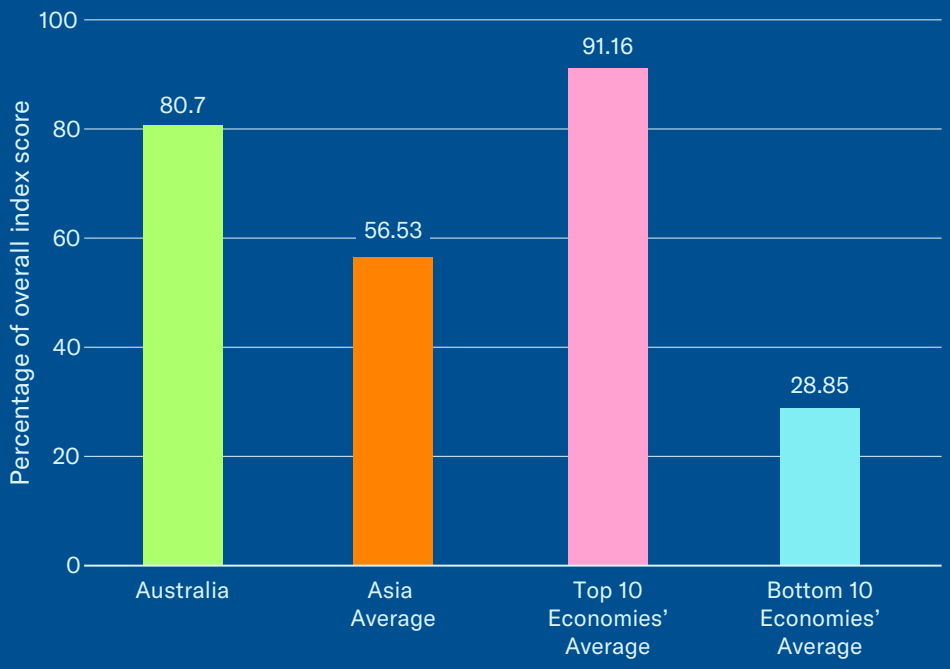
Australia

Rank
14/55

Category Scores



Overall Score in Comparison



Australia

Key Areas of Strength

- Global leader in copyright enforcement in the online space
- Established a system of injunctive relief that permitted the disabling of foreign-hosted infringing websites
- The 2018 National Security Legislation Amendment (Espionage and Foreign Interference) introduces stiff penalties for industrial espionage on behalf of a foreign state entity
- No administrative or regulatory burdens are in place to hinder licensing activity
- The 2019-2020 case law clarified grounds for patentability of biotechnology inventions

Key Areas of Weakness

- The pregrant opposition system causes significant delays to patent grants
- Not a contracting party to the Hague Agreement

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

Indicator	Score
Category 6: Commercialization of IP Assets	**5.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**5.07**
32. Physical counterfeiting rates	0.75
33. Software piracy rates	0.82
34. Civil and precedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**4.00**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 80.70%

Spotlight on the National IP Environment

Past Editions versus Current Score

Australia's overall score has increased from 80.68% (40.34 out of 50) in the eleventh edition of the Index to 80.70% (40.35 out of 50). This reflects a score increase for 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 Australian drug regulatory authority, the Therapeutic Goods Administration (TGA), concluded an 18-month consultation on transparency measures for prescription medicines. As a result of the consultation, the Australian government announced a plan to introduce legislation to create an earlier patent notification framework. The legislation would 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 was listed in the pharmaceutical benefits scheme (PBS). Additionally, the TGA announced it would publish a description of major innovative medicines applications that were under evaluation by the TGA.

As noted in past editions 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 has been published by the TGA or presented to the Australian Parliament since. In March 2023, the TGA published an update on the timetable and implementation plan on a new patent notification framework. Under this proposed framework, first follow-on applicants will be required to notify the rightsholder when an application has been submitted to the TGA but before the agency begins its review process. The introduction of such an early notification requirement in this process would constitute an improvement to Australia's existing patent linkage mechanism. However, it remains unclear when such a scheme will be launched. In its March announcement, the TGA simply stated, "Further information on implementation arrangements will be included on the TGA website in due course." At the time of research, no further details had been made public. The Index will continue to monitor these developments in 2024.

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:
In late 2022, Australia's attorney general announced a "copyright enforcement review." Subsequently, an Issues Paper was released together with a 12-week public consultation.

The purpose of the review is to examine the state of copyright protection in Australia and the extent to which "there is any need to supplement or strengthen existing enforcement mechanisms." At the time of research, the attorney general had not published any final recommendations or conclusions. 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 internet service providers (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 and has demonstrated Australia's leadership in this issue and the ability of rightsholders to effectively address and neutralize the negative impact of online copyright infringement.

In a separate development, the attorney general's department, IP Australia, and the Department of Industry, Science and Resources have all separately and jointly held roundtables and public discussions on the topic of AI, IP rights, and text and data mining. A Ministerial Roundtable was held in early 2023 and was subsequently accompanied by both a discussion paper (Supporting responsible AI) and a full public consultation. Text and data mining 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. However, this is a new area of copyright law with little in the way of applicable jurisprudence either in Australia or internationally. Regardless of how individual Index economies move forward with adapting their legal and governance frameworks for AI-based economic activity and applications, it remains essential that rightsholders can practically enforce their copyright. The Index will continue to monitor these developments in 2024.

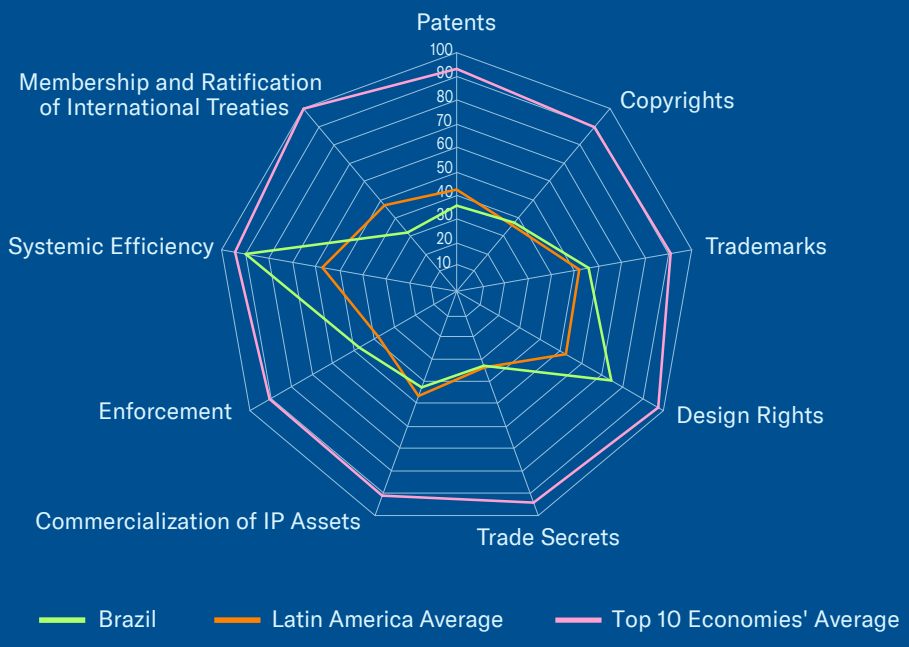
Systemic Efficiency

43. IP-intensive industries, national economic impact analysis:
As noted in past editions of the Index, various parts of the Australian government actively measure and seek to understand the economic contribution and value of IP-intensive industries to the Australian economy. For example, based on WIPO's methodology and study guidelines, Australian public entities have conducted or supported several research reports on the economic contribution of the copyright-based industries to the Australian economy. In addition, the national IP office, IP Australia, has since 2012 had in place an Office of the Chief Economist, which has published and commissioned various sector- and IP rights–specific economic research studies and impact analyses. IP Australia's annual reports also include economic data and analysis explaining the link between economic activity and the use of IP rights by Australian businesses. The latest annual report, released in April 2023, shows the growing importance of IP-intensive industries to the Australian economy. Specifically, the report finds that Australian businesses with IP rights accounted for over a third of the Australian gross domestic product and more than 2.5 million jobs. These substantial figures are in line with similar findings for the United States and the European Union (EU). The Index commends IP Australia for continuing its important work in this field and for setting an example for other Index economies.

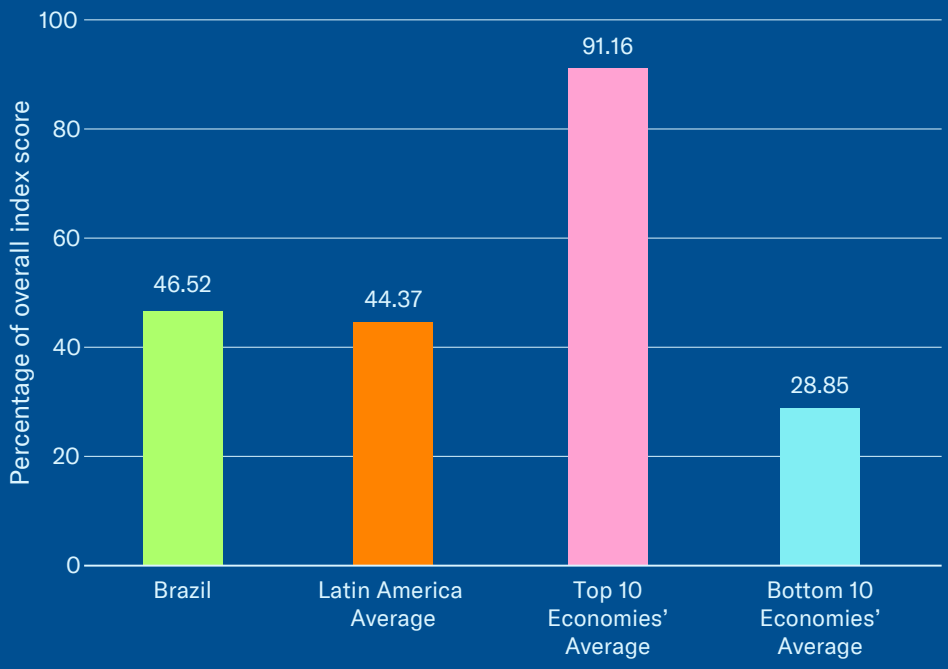
Brazil

Rank
33/55

Category Scores



Overall Score in Comparison



Brazil

Key Areas of Strength

- "Operation Copyright" and "Operation 404 against piracy" continued in full force in 2023; these key enforcement efforts with Brazilian police and international authorities disable access to infringing content online
- Joined the Hague Agreement in 2023
- INPI's 2019 patent backlog plan Plano de Combate ao Backlog de Patentes seeks to eliminate long-standing registration backlogs
- INPI released its first study of IP-intensive industries' national economic impact in Brazil in 2021
- Law No. 14.195/2021 changed Brazil's IP Law so that Brazilian Health Regulatory Agency's (ANVISA) prior consent on patent applications is no longer required

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 remained unaddressed in 2023
- Thousands of patent applications are affected by the Supreme Court ruling
- Compulsory licensing amendments for health emergency broadens existing emergency powers and authority and potentially generates legal uncertainty
- Key life sciences IP rights are missing, including patent term restoration and RDP, and, overall, a challenging patentability environment exists
- Limited participation in international treaties—only a full contracting party to two of nine treaties are included in the Index

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**3.24**
1. Term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.00
4. Plant variety protection	0.74
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**2.63**
10. Term of protection	0.63
11. Exclusive rights	0.50
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.25
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.00**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.00

Indicator	Score
Category 6: Commercialization of IP Assets	**2.58**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.33
Category 7: Enforcement	**3.31**
32. Physical counterfeiting rates	0.53
33. Software piracy rates	0.53
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**4.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**2.25**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

Total: 46.52%

Spotlight on the National IP Environment

Past Editions versus Current Score

Brazil's overall score has increased from 42.02% (21.01 out of 50) in the eleventh edition to 46.52% (23.26). This reflects score increases for indicators 8, 11, 12, and 49.

Patents, Related Rights, and Limitations

2. Patentability requirements and 3. Patentability of computer-implemented inventions (CIIs):
In 2023, rightsholders continued to face many basic challenges in registering and protecting patent-eligible subject matter in Brazil. Above all, there has been no resolution with respect to the provision of a TRIPS-compliant minimum term of patent protection. Given the Brazilian Patent and Trademark Office (INPI) has historically had a backlog of patent applications ranging from 10 to 13 years—depending on the field of technology—the Industrial Property Law had up until 2021 provided innovators in Brazil with a guaranteed minimum term of exclusivity and protection of 10 years from grant for standard patents. Article 40 of the law stated that the term of protection shall "not be less than 10 (ten) years for an invention patent and 7 (seven) years for a utility model patent, beginning on the date of granting, unless the INPI has been prevented from examining the merits of the application by a proven pending judicial dispute or for reasons of force majeure." For years, Article 40 provided rightsholders with a proverbial floor of exclusivity and insurance against INPI's endemic delays. In a series of decisions in the spring of 2021, the Brazilian Supreme Court removed this floor. Not only did the court declare that Article 40 was unconstitutional and would no longer be available or applicable, but it also stated that the ruling should be retroactively applied and only to granted patents in the biopharmaceutical and health-related fields.

As noted over the past few years, the ruling was and remains a grave blow to Brazil's national IP environment, with thousands of biopharmaceutical rightsholders discriminated against and with 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 and retroactive application of the ruling to one field of technology and innovation is a gross violation of Article 27(1) of TRIPS and established international principles of nondiscrimination.

Since this ruling, legislative proposals have been presented in the Brazilian Chamber of Deputies that would provide a period of patent term restoration due to administrative delays during patent examination and prosecution. However, to date, no legislative action has been taken. In response to this situation, close to 50 lawsuits have been filed across Brazil with rightsholders from the life sciences and health sectors arguing for an extension of a granted patent term because of these continued delays in patent prosecution. Unfortunately, these lawsuits have not led to any further clarity on the matter. On the one hand, and in a positive development, a federal court in Rio de Janeiro in April 2023 granted an adjustment of close to one year to the term of a granted patent, finding that there had been undue delay in the granting of the patent. (At the time of research, this case had been appealed by the Brazilian government.) On the other hand, and although the facts of the case and legal issue at hand were different, a Supreme Court panel ruling in January 2023 found that rightsholders did not have the right to extend a patent term of protection beyond 20 years from filing, irrespective of time of grant. The bottom line is that rightsholders continue to face deep uncertainty about whether they will be able to effectively register and protect their innovations in Brazil. The Index continues to urge the Brazilian government and lawmakers to immediately address this issue.

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

As a result of the weakening of the patenting environment and rightsholders' inability to continue to secure even a 10-year minimum period of patent protection—let alone anything close to a TRIPS-defined term of 20 years—Brazil's scores for indicators 2 and 3 were reduced to 0 in the tenth edition of the Index and will remain at zero until this issue is resolved. The Index will continue to monitor these developments in 2024.

8. Membership in a Patent Prosecution Highway (PPH):
As noted over the course of the Index, since 2019, INPI has actively pursued PPH agreements around the world. To date, INPI has signed agreements with all IP5 offices: the Korean Intellectual Property Office, the U.S. Patent and Trademark Office, the Japan Patent Office, the European Patent Office, and the China National Intellectual Property Administration. PPH initiatives and increased cooperation between IP offices are one of the most tangible ways in which the administration and functioning of the international IP system can be improved and harmonized to help inventors and rightsholders. Regrettably, the Brazilian PPH program is hampered by an overall set limit on how many applications INPI can process each year. For 2023, this limit was 800 applications and was reached halfway through the year in July 2023. This is an unfortunate limitation on a program for which such strong demand exists.

Still, to better take account of more economies engaging in bilateral agreements with the IP5, from this edition of the Index onward, all non-IP5 economies will be able to achieve a full score for this indicator if they have equivalent, unrestricted, and separate bilateral PPH agreements in place with all IP5 offices. As a result, Brazil's score for this indicator has increased to 1.

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); and 12. Expeditious injunctive-style relief and disabling of infringing content online:
As noted in previous editions of the Index, rightsholders have for years faced significant challenges in protecting their content and enforcing their copyrights in Brazil. Compared with other Index economies, the legal regime remains underdeveloped, and whether it be through online access or through physical goods, piracy levels remain elevated. Nevertheless, the past few years have seen several dedicated enforcement operations against IP infringing websites, vendors, and suspected criminals. The Brazilian Federal Police launched "Operation Copyright" to tackle copyright piracy in 2019. Similarly, over the past four years, "Operation 404 against Piracy" (Operação 404 contra pirataria) has been operational. Spearheaded by a special police enforcement unit, the Ministry of Justice, and with international support from the U.S. Embassy and UK police, this special enforcement effort has had direct and tangible results. In its first three years of operation, almost 2,000 websites and applications offering copyright infringing content have been shut down, over 100 search and seizure warrants have been issued and executed across 20 Brazilian states, and several arrests have been made. In 2023, these efforts continued with authorities in Brazil and Peru shutting down access to hundreds of infringing websites and online access points.

Rightsholders also saw several positive developments with respect to the availability of injunctive relief targeting online piracy. In late 2022, a court in São Paulo ordered the disabling of access to several websites offering access to infringing materials. This order included a so-called dynamic element. 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.

In addition, the Brazilian National Telecommunications Agency, Anatel, launched a dedicated campaign against illicit IPTV set-top boxes. As in many other economies benchmarked in the Index, Brazil has seen an explosion in the growth and use of these physical boxes and the internet-based applications that provide users with copyright infringing content. Anatel's Action Plan to Combat the Use of Clandestine TV Boxes" was announced in February 2023 and gives the agency a dedicated enforcement function to locate and disable these illegal set-top boxes. In September 2023, Anatel announced that it had operationalized a dedicated laboratory and testing site to assist in these efforts. The agency is reportedly targeting both the physical devices and their streaming applications online and had at the time of this research seized almost 1.5 million illegal set-top boxes and disabled access to hundreds of illicit access points. Together, these positive developments mark a potential turning point for creators and rightsholders in Brazil. As a result, the scores for indicators 11 and 12 have increased by 0.25, respectively. The Index will continue to monitor this activity in 2024.

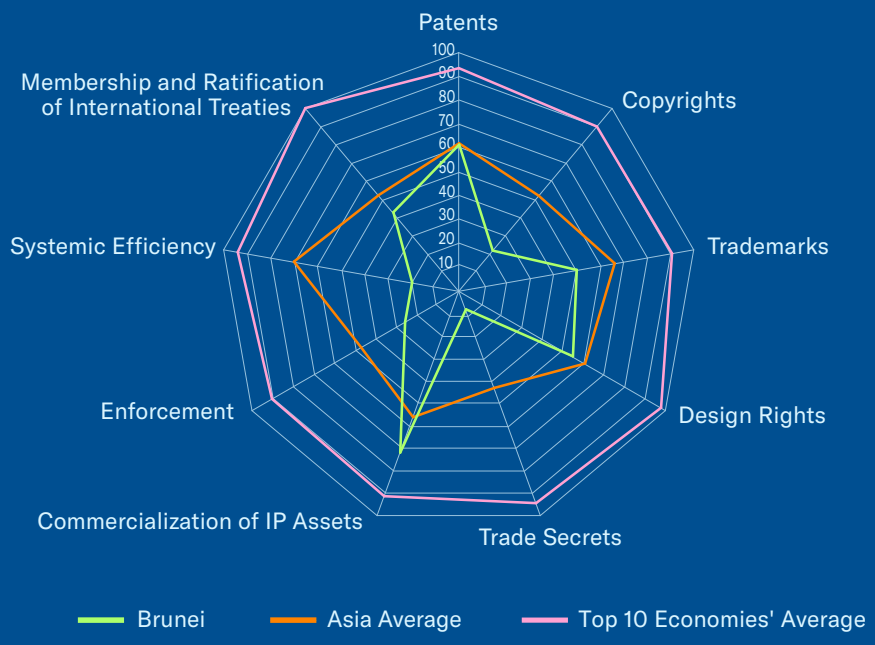
Membership and Ratification of International Treaties

49. The Hague Agreement Concerning the International Registration of Industrial Designs: In August 2023, Brazil acceded to the full Hague Agreement, including the Geneva Act. As a result, the score for this indicator has increased by 1.00.

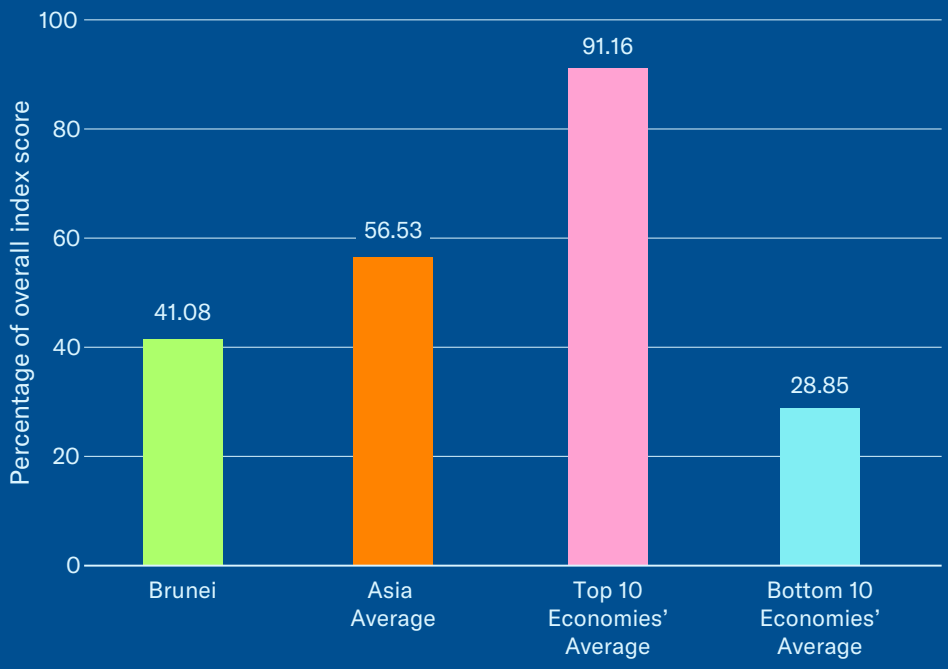
Brunei

Rank
38/55

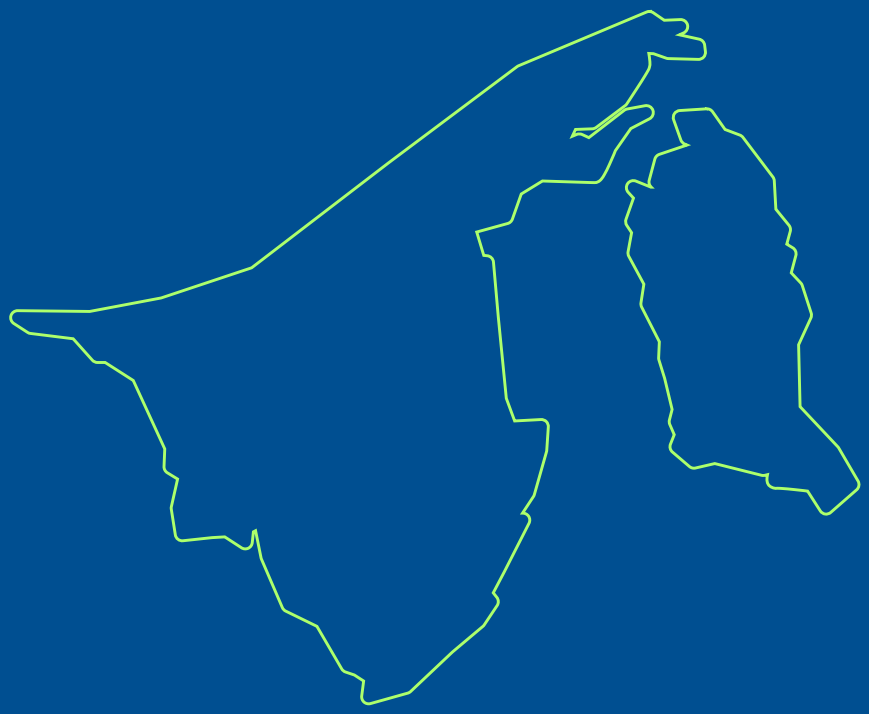
Category Scores



Overall Score in Comparison



Brunei



Key Areas of Strength

- Acceded to the CPTPP in 2023, which has the potential to improve trade secrets protection and the enforcement environment if properly implemented
- Acceded to WIPO Internet Treaties in 2017
- Major IP reforms over the past decade include establishing an IP Office (BruIPO)
- Removed from Special 301 Report
- No fundamental administrative or regulatory barriers are in place for the execution of licensing agreements

Key Areas of Weakness

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

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

Indicator	Score
Category 6: Commercialization of IP Assets	**4.33**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.33
Category 7: Enforcement	**1.83**
32. Physical counterfeiting rates	0.47
33. Software piracy rates	0.36
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.00**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.00
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**3.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

Total: 41.08%

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).

Trade Secrets and the Protection of Confidential Information; Enforcement; and Membership and Ratification of International Treaties

23. Protection of trade secrets (civil remedies); 24. Protection of trade secrets (criminal sanctions); 37. Effective border measures; and 50. Post-TRIPS FTA: In May 2023, Brunei formally ratified the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) with the agreement officially coming into force over the summer. Brunei was the last remaining contracting party not to have formally ratified and acceded to the CPTPP. As has been noted in past editions of the Index, after the withdrawal of the United States from the original Trans-Pacific Partnership (TPP), the CPTPP was fundamentally revised with many parts of the original treaty suspended. With respect to Chapter 18 (Intellectual Property), numerous critical provisions were excluded, including for patentable subject matter; biopharmaceutical-specific IP rights, such as regulatory data protection, copyright protection, and enforcement; and 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 or to any of the other contracting parties included in the Index under Indicator 50. Still, the text of the CPTPP retains some important aspects of the original TPP's IP provisions, including, for example, provisions related to trade secrets and border enforcement.

Specifically, Article 18.78 Trade Secrets requires contracting parties to provide relevant protection in relation to the misappropriation, improper acquisition, use, or disclosure of trade secrets or confidential business information. Subsections 2 and 3 also require contracting parties to provide minimum criminal procedures and penalties.

In Brunei, existing civil and criminal remedies are limited. Statutory law does not provide a defined level of protection or criminal remedies in relation to the misappropriation, improper acquisition, use, or disclosure of trade secrets or confidential business information with civil protection relying on common law. Any potential criminal enforcement would be based on the Penal Code or the Computer Misuse Act. The CPTPP also 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, including against goods in transit, destined for export, and not intended for the domestic market. Article 18.76(5) of the treaty states: "Each Party shall provide that its competent authorities may initiate border measures ex officio with respect to goods under customs control that are: (a) imported; (b) destined for export; or (c) in transit." As with trade secrets and the protection of confidential information, neither current Bruneian trademark nor copyright law provides customs officials with clear ex officio authority to act against goods suspected of IP infringement.

Section 82 of the Trade Marks Act and Sections 109-110 of the Copyright Order require rightsholders 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.

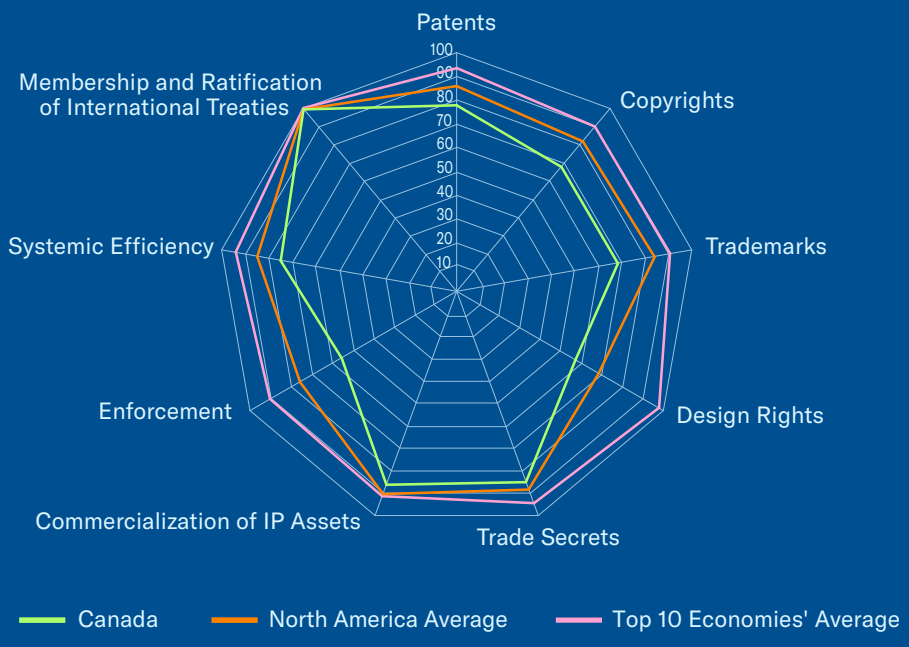
The Copyright Order provides a limited time frame of five years during which customs authorities will treat specified goods as being infringing goods, yet this is available only to published and literary works. Section 109 makes clear that this five-year maximum period is not available for "sound recording or film." Published public guidance by the European Commission suggests that the detention of suspected infringing goods by Bruneian customs authorities is rare. Brunei's accession to the CPTPP is a positive development and has the potential to improve its national IP environment.

Should these referenced provisions of the CPTPP related to trade secrets and border enforcement be incorporated into existing Bruneian statute and practice, this would result in a potential score increase for indicators 23, 24, and 37. The Index will continue to monitor these developments in 2024.

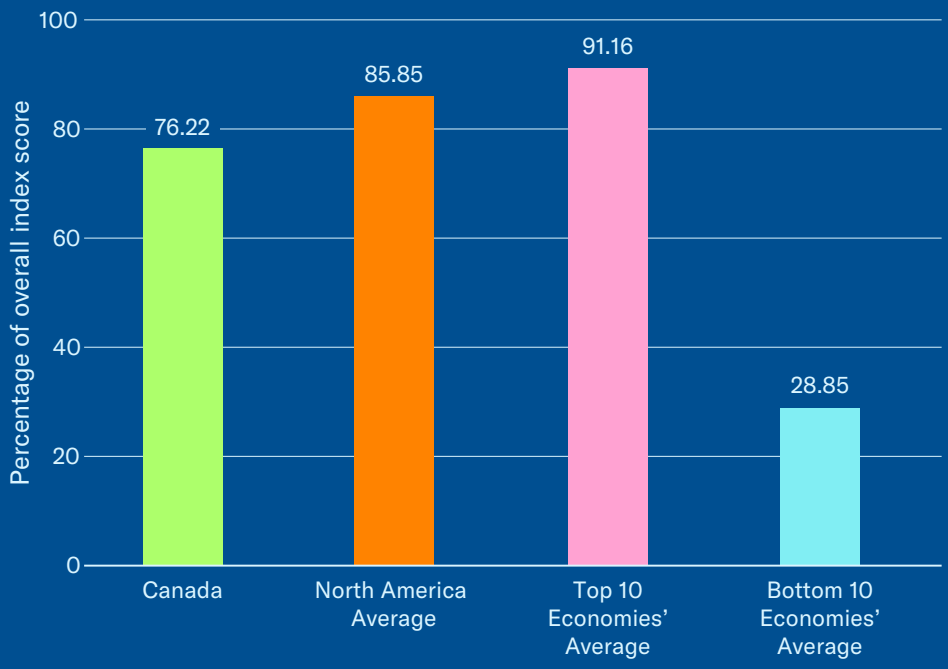
Canada

Rank
16/55

Category Scores



Overall Score in Comparison



Canada

Key Areas of Strength

- Continued issuing of dynamic injunction orders in 2023 further strengthens copyright enforcement in Canada
- The 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
- Comprehensive Economic and Trade Agreement (CETA) legislation is in place in several areas, including patent term restoration
- Significant damages were awarded in a precedent-setting 2017 federal court case with regard to Canada's digital rights management (DRM) provisions

Key Areas of Weakness

- Continued uncertainty about 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…"
- CETA amendments to the Patent Act introducing patent term restoration include 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

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**7.05**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.30
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**4.79**
10. Term of protection	0.79
11. Exclusive rights	0.50
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**2.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.15**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.55**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.80

Indicator	Score
Category 6: Commercialization of IP Assets	**5.17**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**3.90**
32. Physical counterfeiting rates	0.62
33. Software piracy rates	0.78
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**3.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 76.22%

Spotlight on the National IP Environment

Past Editions versus Current Score

Canada's overall score has increased from 75.72% (37.86 out of 50) in the eleventh edition to 76.22% (38.11 out of 50). This reflects a score increase for indicator 12.

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 have been retained and are now in effect. Specifically, the reforms have expanded the size of the basket and have 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 layers of complexity to the pricing and reimbursement process. These changes came into force on July 1, 2022. At the time of research, the PMPRB was still in the process of updating and finalizing a new "Guidance" document; a set of "Interim Guidance" remains in effect.

The direct impact of the Canadian health system's strong focus on cost control has historically been a time lag in new products on the market and patient access. The most recent data show that, on average, it takes 52 months from global launch of a product to reimbursement listing in Canada. Almost two-thirds of this time (34 months) is spent in review after a product has been launched locally. Compared with other OECD peers, many innovative products are not launched or listed in Canada. For example, evidence collected by IQVIA on the availability of new medicines launched in the 10-year period 2012-2021 and published by PhRMA in 2023 shows that of the 460 new medicines launched between 2012 and 2021, Canadian patients had access to only 207, or 45%. This compares to 391 of the 460 products available in the United States (85%).

Older studies confirm that this is a long-term trend and not a more recent phenomenon. For instance, a 2019 study by Innovative Medicines Canada and the Pharmaceutical Research and Manufacturers of America (conducted by Ernst & Young) found that of 243 innovative drugs (new active substance) launched globally between January 2011 and June 2018, only 119 (49%) were launched in Canada. Similarly, a 2016 report conducted by IMS Health Canada, for Innovative Medicines Canada, shows how Canadian patients have access to fewer innovative treatments than do patients in other OECD economies. The study finds that long lags exist between market authorization and inclusion for public reimbursement. On average for the period studied (2010-2014), it took 449 days from market authorization to reimbursement. Looking at access across all Canadian provinces—formulary and reimbursement decisions are taken provincially in Canada—the study finds that only 37% of drugs were reimbursed and available to 80% or more of the population. Gaps in availability were for more advanced treatments, such as cancer medicines and biologic products.

Only 59% of cancer medicines were available to 80% or more of the population. For new biologics, this ratio was even lower at 23%. The changes introduced by the PMPRB's package of regulatory reforms are likely to exacerbate this even further, the result being Canadian patients waiting even longer for access to new and innovative treatments.

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, in 2021, the government 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, Canada's largest provinces—Ontario and Quebec—released new life sciences strategy documents and plans to encourage local biopharmaceutical R&D and innovation. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws. 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 EU, and leading Asian economies. Similarly, recognizing and rewarding innovation in the Canadian health system through adequate pricing and reimbursement policies for biopharmaceuticals would also improve the competitiveness of the Canadian environment and allow innovators—domestic and international—to gain a fair value for their innovation and creativity. The Index will continue to monitor these developments in 2024.

Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online:
In a precedent-setting decision, the federal court in 2022 issued a dynamic injunction order in the case Rogers Media Inc. v. John Doe 1. The order required 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. In a separate development, the Supreme Court of Canada in 2022 denied Teksavvy Solutions Inc.'s 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 once and for all removes any lingering uncertainty about whether injunctive relief and the disabling of access to infringing content through judicial orders are a legally prescribed pathway of enforcement available to Canadian rightsholders. These positive developments have continued over the past year. In late 2022, the federal court issued another order in relation to illegal streaming of the FIFA World Cup, and in July 2023, the court ordered the disabling of access to the illegal streaming of Major League Baseball games. Significantly, both these orders also included a dynamic element. These examples show that rightsholders finally have an effective way of enforcing their copyright online in Canada. As a result of these developments, the score for this indicator has increased by 0.25.

14. Scope of limitations and exceptions to copyrights and related rights:
As has been noted repeatedly in the Index, 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.

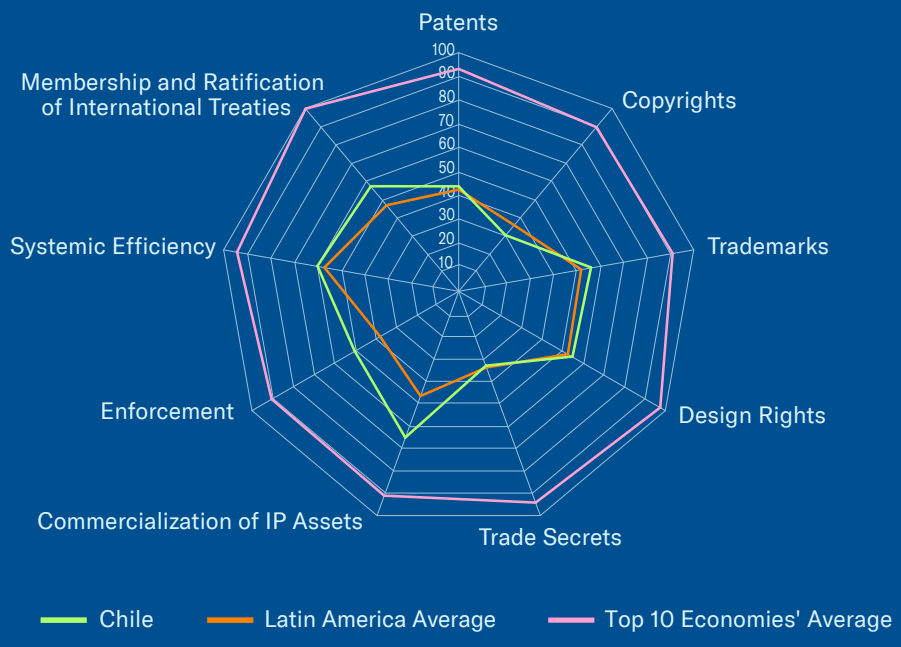
Subsequent statutory reviews of the Copyright Act, parliamentary committee reports, and a 2021 Supreme Court ruling in the long-running case York University v. The Canadian Copyright Licensing Agency ("Access Copyright") have failed to bring any meaningful clarity to Canada's copyright exceptions regime. 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, 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.

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." Unfortunately, the past year has seen no further action. The Index will continue to monitor these developments in 2024.

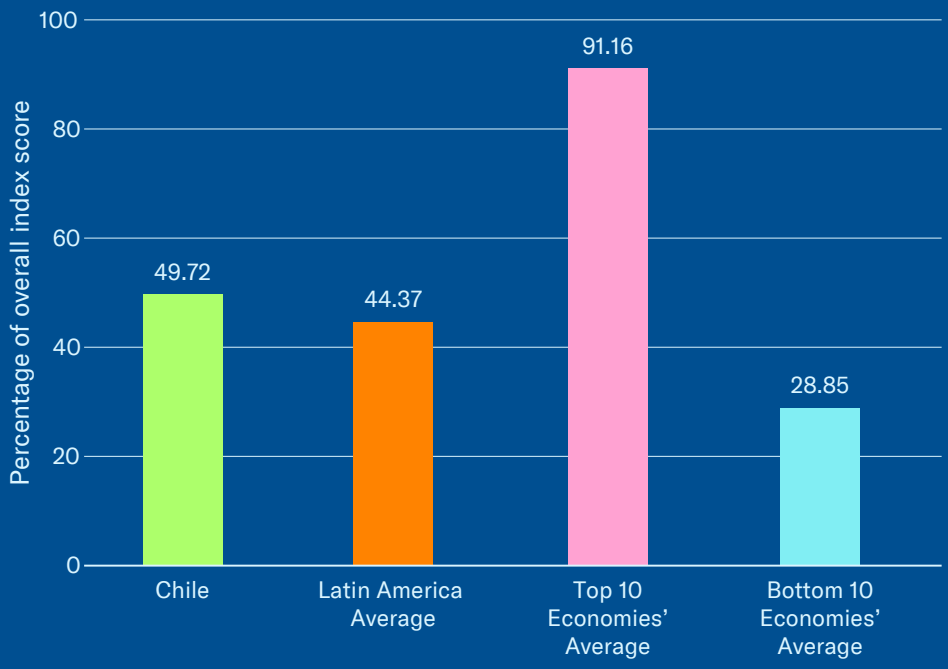
Chile

Rank
30/55

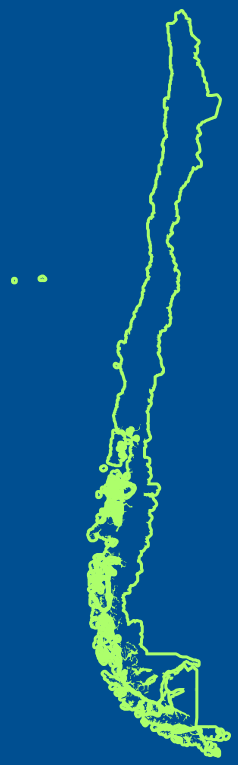
Category Scores



Overall Score in Comparison



Chile



Key Areas of Strength

- Joined the Madrid Protocol in 2022
- IP law amendments (Law 19,309) passed in 2021; extends term of protection for design rights and improves enforcement environment
- Member of Global Patent Prosecution Highway (GPPH) since 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
Category 1: Patents, Related Rights, and Limitations	**3.94**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.00
4. Plant variety protection	0.74
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.70
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.13**
10. Term of protection	0.63
11. Exclusive rights	0.25
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.00
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.00**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**3.92**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	0.75
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**3.52**
32. Physical counterfeiting rates	0.57
33. Software piracy rates	0.45
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**3.00**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**4.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 49.72%

Spotlight on the National IP Environment

Past Editions versus Current Score

Chile's overall score remains unchanged at 49.72% (24.86 out of 50).

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 compulsory license based on cost containment were endorsed by the outgoing government. Also 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 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, which 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 includes 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. Members of the Chilean 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 all products, diagnostics, medical devices, and other medical paraphernalia related to the COVID-19 global pandemic. This resolution 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 prefixing of applicable royalties to a maximum of 5% of the sales price of the licensed product;

and a broad elimination of liability for manufacturers, individuals, and legal entities that violate existing IP rights (including patent rights and trade secrets) for the production or distribution of any "medicines, vaccines, and other technologies subject to patent rights, utility models, undisclosed information, intended to meet public health needs or other public interest within the national territory, in a context of health alert, epidemic or pandemic decreed by the health authority, and that without knowledge of the existence of affected industrial property rights or acting in good faith, violate the provisions of Law No. 19.039." 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 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 2024 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. Individual economies will experience the pandemic's continued health and economic impact differently, with varying levels of severity experienced depending on the individual health and socioeconomic circumstances of that economy.

Undermining incentives and 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 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 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, Chile is obligated 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 19 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 enforcement remains inadequate.

To begin with, Chile's notice-and-takedown procedure does not meet the requirements of its FTA with the United States.

Under current Chilean law, ISPs are required to remove infringing content only if they have "effective knowledge" (meaning that notice must be from a court, not from 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. Regarding 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 respect to TPM and DRM, despite ratification of the WIPO Internet Treaties and the U.S.-Chile FTA, copyright law still only protects against the circumvention of, or interference with, 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. This 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.

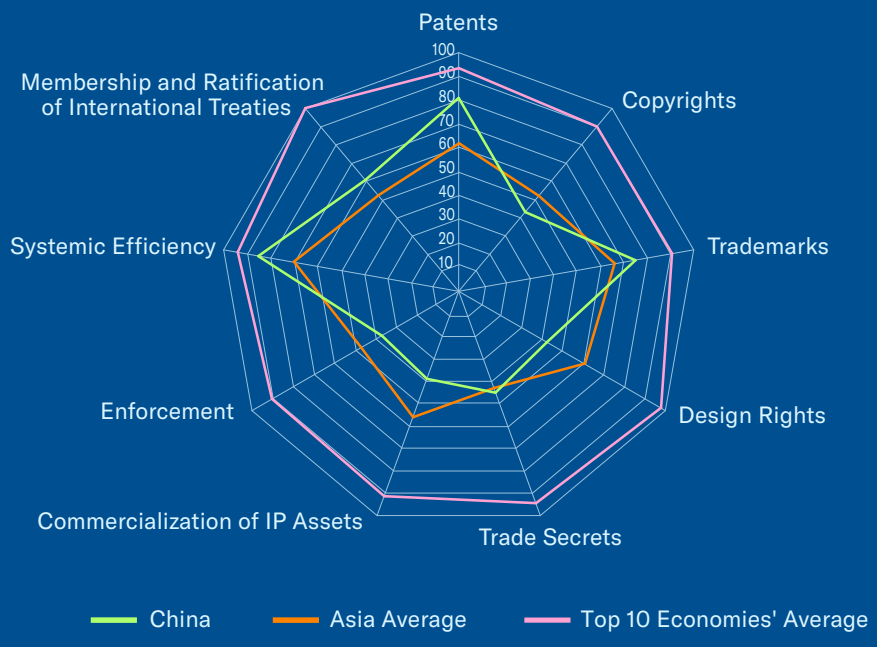
The result is that Chile has, over the course of the Index, maintained high levels of estimated copyright infringement. For example, BSA's estimated rates of the use of unlicensed software suggest that Chile has, since 2011, had a remarkably high rate of software piracy for a high-income OECD member state. The rate has stayed between 55% and 61% over the course of the 12 editions of the Index (in 2018, it was an estimated 55%). This compares with 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%. Although this is 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 (Contra Piratería de Televisión Paga) 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 has 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. Similar results can be seen in more recent surveys. An October 2021 survey sponsored by local rightsholders and conducted by international pollster IPSOS found that 51.5% of those polled had accessed illicit and copyright infringing content within the past six months. Furthermore, almost three-quarters of the survey participants viewed illegal downloading and internet piracy as not constituting a criminal offense.

As the Office of the U.S Trade Representative (USTR) noted in the 2023 Special 301 Report, "It has been over 19 years since the Chile FTA entered into force…[and] it remains important 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 2024.

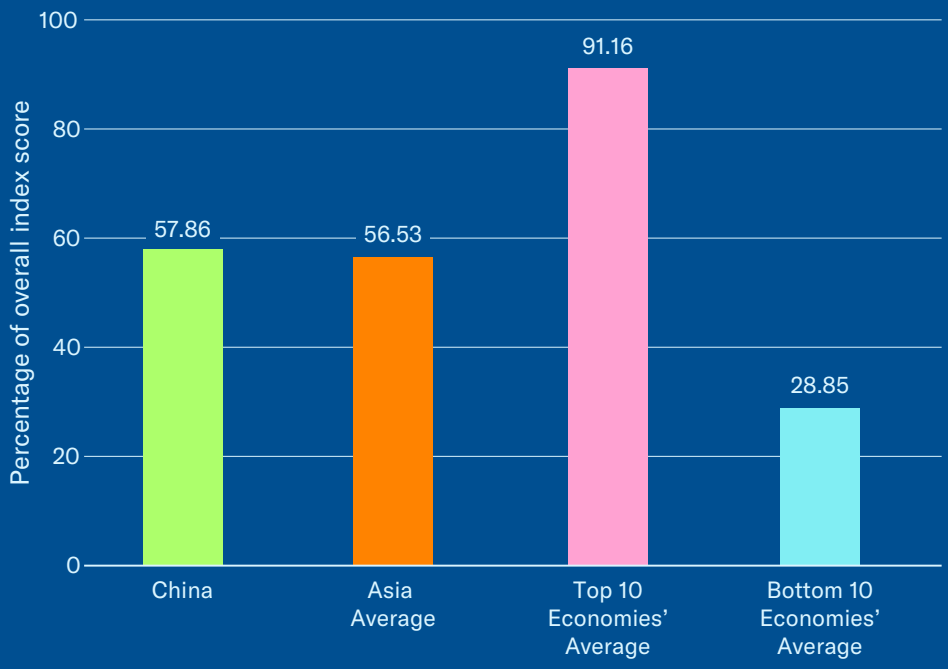
China

Rank
24/55

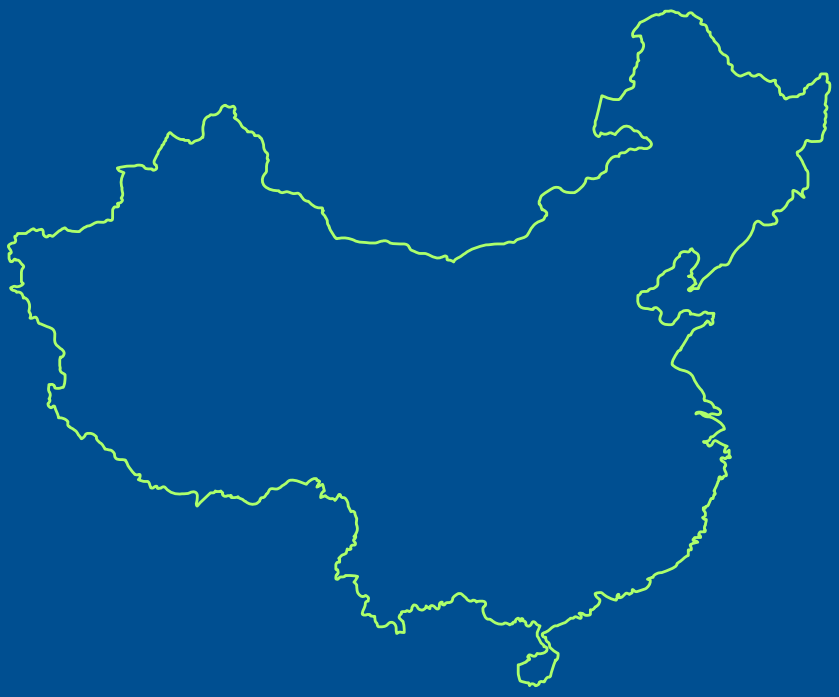
Category Scores



Overall Score in Comparison



China



Key Areas of Strength

- Reform of IP laws after Phase One Agreement with the United States
- The 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
- The 2020 Copyright Law amendments improve the copyright environment
- Positive changes in 2019-2020 regarding tech transfer and licensing through amendments to the Foreign Investment Law and Technology Import and Export Regulations
- The 2019 Trademark Law amendment seeks to address bad-faith filings

Key Areas of Weakness

- Despite positive changes in 2019-2020 regarding technology transfer and licensing, continued challenges exist with respect to technology transfer and the licensing environment for SEPs; growing trend of rightsholders facing global antisuit injunctions and restrictions on their ability to assert infringement claims in legal jurisdictions outside China
- The 2022 Anti-Monopoly Law greatly expands the government's basis for action against anticompetitive behavior and substantially increases fines and penalties; 2023 finalized rules contain not only broad and vague language on what constitutes anticompetitive behavior within an IP rights context but also vest considerable discretion with the anti-competition authorities in identifying and defining such behavior

Key Areas of Strength
(continued)

- The 2019 Anti-Unfair Competition Law amendment seeks to strengthen protection of trade secrets
- Strong efforts to raise awareness and leverage the value of IP rights in academic and private spheres

Key Areas of Weakness
(continued)

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

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

Total: 57.86%

Spotlight on the National IP Environment

Past Editions versus Current Score

China's overall score remains unchanged at 57.86% (28.93 out of 50).

Patents, Related Rights, and Limitations

4. Plant variety protection, term of protection:
In late 2022, the Ministry of Agriculture and Rural Affairs released draft Plant Variety Protection Regulations. In a positive development, these regulations proposed an increase in the term of protection period for plant variety rights from 20 years to 25 years for woody and vine plants and from 15 years to 20 years for other plants. Such an increase would result in a score increase for this indicator. At the time of research, the regulations had not come into effect. The Index will continue to monitor these developments in 2024.

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. After that period, Chinese drug regulatory authorities—the China's National Medical Products Administration (NMPA), formerly China's Food and Drug Authority (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 for this indicator was increased by 0.5. However, the commitment to introducing a linkage regime was not implemented in 2018 and 2019, and China's score for 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 that offers both a potential judicial route of enforcement and administrative enforcement through the China National IP Administration (CNIPA). In 2021, this new regime came into effect with implementing regulations published by NMPA and CNIPA and with 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. Although the 45-day notice period for a rightsholders lodging an objection is rather short, 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.

Over the past two years, dozens of cases have been adjudicated through both the CNIPA route and the judiciary. Of note is that rightsholders have so far in most cases been able to achieve a judgment within the described nine-month waiting period. Nevertheless, these time frames remain tight. Moreover, the research-based biopharmaceutical industry reports that follow-on products continue to receive marketing approval in China even though the reference products remain under patent protection. The Index will continue to monitor these developments in 2024 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 the past two editions of the Index, in 2020, new draft amendments to the Patent Law were passed. Article 42 of these amendments states that a period of term restoration of up to five years for biopharmaceutical products may be made available by relevant Chinese authorities. As of late 2023, 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 such 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 not be made contingent on the first global launch taking place in China.

Instead, as 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 2024.

Trademarks, Related Rights, and Limitations

18. Protection of well-known marks; and 19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks: As noted over the course of the Index, rightsholders have historically faced major challenges protecting their trademarks in China. The infringement of registered trademarks is high, and enforcement is difficult. Bad faith filing applications and trademark squatting remain perennial problems. China has also traditionally had in place a strict well-known mark regime and, as such, required broad geographical coverage and an exceptionally high reputation to exist before protection could be obtained.

As detailed in previous editions of the Index, Chinese policymakers have over the course of the Index sought to address these issues. For example, 2013 amendments (entering into force in 2014) enlarged the basis for filing opposition proceedings, particularly against bad faith applicants. There have also been several important court cases in favor of rightsholders with well-known marks. And in 2019, important changes to primary and secondary legislation to address the long-standing issue of bad faith filing applications and trademark squatting were introduced. New amendments raised fines for bad faith filing applications and sought to further disincentivize and penalize the filing of bad faith applications and trademark squatting. Specifically, the 2019 amendments introduced a lack of use as an absolute ground for opposition and refusal to registration. The law also introduced penalties for filing agents who were viewed as abusing the system and filing applications in bad faith.

Still, despite these reforms, rightsholders have continued to face significant challenges. In 2023, a new package of reforms was introduced, with CNIPA in February releasing draft amendments to the existing Trademark Law. These amendments would more explicitly seek to curtail bad faith filings and weed out nonuse and malicious registrations. The draft amendments also include the ability for well-known mark holders to more effectively cancel and/or transfer registered bad faith marks. These are potentially positive improvements to China's trademark environment. At the time of research, no final legislative package had been published or enacted. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: As detailed in previous editions of the Index, 2019-2020 saw significant positive changes to China's technology transfer and licensing environment. Most importantly, both the Foreign Investment Law and the Technology Import and Export Regulations (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 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 piece of legislation touches on all aspects of civil law, it includes specific provisions related to technology transfer and contract law in a dedicated chapter, Chapter 20. Notably, 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 scores increased for 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 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 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 2022, the EU filed a request for consultations with China on this issue at the WTO. This was followed by requests from Japan, Canada, and the United States to join these consultations. At the time of research, a dispute panel had been established.

In a separate development, 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. 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" that could potentially also apply to foreign producers and promote fairer competition on the Chinese market. With respect to IP rights, Article 68 states that the "Law applies to undertakings' abuse of intellectual property rights to eliminate or restrict competition." The new law was accompanied by several new draft rules, including "Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition." As detailed last year, just like the underlying legislation, this rule considerably expanded the powers of investigation, punishment, and meaning of what constitutes anticompetitive behavior within the context of the exercise of IP rights. In August 2023, this rule came into effect. Unfortunately, while maintaining some moderate safeguards against potential overreach, the finalized version did not materially improve on the preceding draft. It, too, contains the same broad and vague language on what constitutes anticompetitive behavior within an IP rights context and vests considerable discretion with the anticompetition authorities in identifying and defining such behavior.

In a further development, in June 2023, the State Administration for Market Regulation released draft guidance on antitrust and competition policy within the field of SEPs.

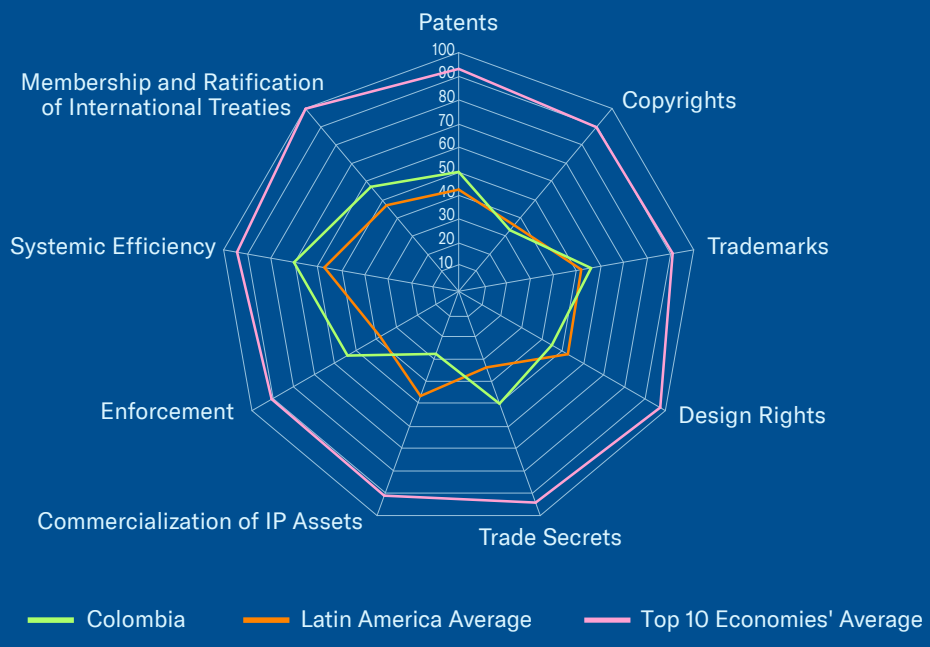
This guidance document largely follows in the negative footsteps of both the Anti-Monopoly Law and the "Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition." SEP-based technologies are central to future innovation and economic growth, both in China and 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 use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to China. This is an evolving field of IP policy and jurisprudence for 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. Unfortunately, neither the Anti-Monopoly Law, the finalized "Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition," nor the latest draft guidance document related to SEPs recognize this basic fact.

As stated last year, 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 Anti-Monopoly Law and accompanying rules—this will result in a sharp score decrease for relevant Index indicators and will negate the positive impact of the Phase I Agreement with the United States. The Index will continue to monitor these developments in 2024.

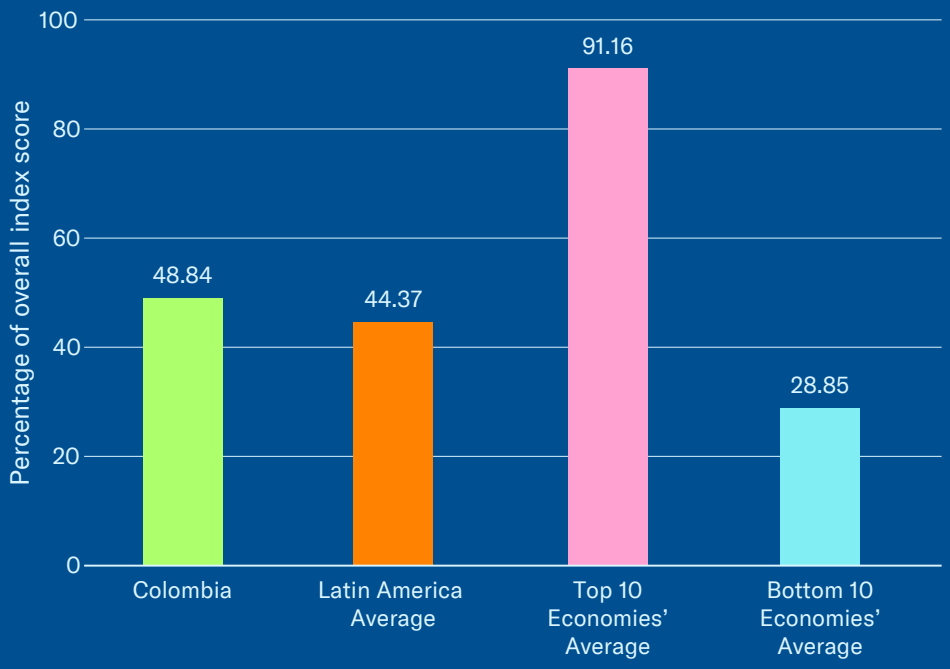
Colombia

Rank
31/55

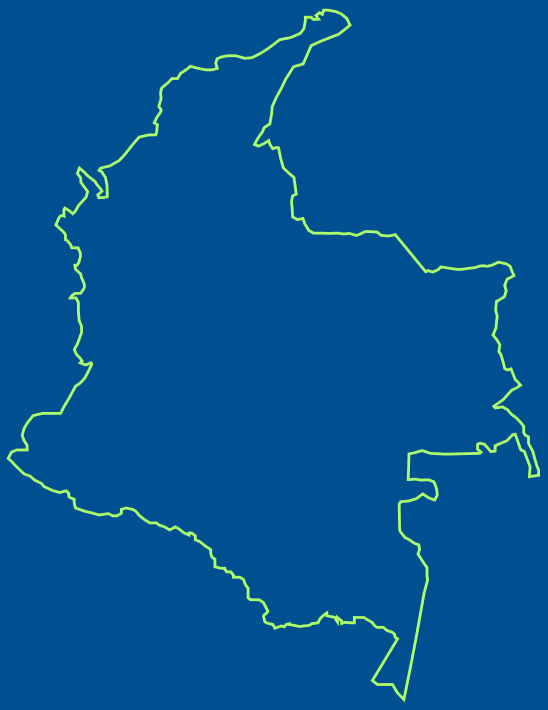
Category Scores



Overall Score in Comparison



Colombia



Key Areas of Strength

- Stronger copyright enforcement efforts through 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) that recognizes the constitutionality of statutory damages for copyright infringement, introduced by 2018 amendments to the Copyright Law
- Targeted incentives are in place for the creation and use of IP assets for SMEs, including reduced filing fees and technical assistance
- Efforts to coordinate interagency IP enforcement and to increase public and stakeholder engagement in IP policymaking and education

Key Areas of Weakness

- The 2023 Ministry of Health Resolution 881 continues policy history of use of compulsory license and public interest declarations to leverage price reductions for biopharmaceuticals
- Substantial barriers are 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
- Uncertainty over the availability of RDP for biopharmaceuticals
- Inadequate and delayed prosecution of and penalties for IP infringement

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**4.50**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.34**
10. Term of protection	0.84
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.50**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**1.67**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**3.76**
32. Physical counterfeiting rates	0.49
33. Software piracy rates	0.52
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**4.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 48.84%

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 May 2023, the Colombian government, led by newly elected President Gustavo Petro, launched a new National Development Plan (Plan Nacional de Desarrollo, PND). Like preceding national plans, the PND sets the major socioeconomic and political goals of the government and current presidential administration for the next few years. The plan includes ambitious goals of transforming Colombia domestically and its role in international affairs. The PND includes a strong emphasis on promoting innovation-based economic activity and the development and growth of knowledge-intensive industries. Legislatively, the plan is outlined through Law 2294/2023, a legislative package touching on virtually all facets of the Colombian economy and society. With respect to IP rights, neither the legislative package nor PND itself included any major reforms. Specifically, Law 2294 does not address any of the long-standing issues detailed over the course of the Index. Patentability standards continue to be outside of international norms, especially for biopharmaceuticals and CIIs; the protection of copyright remains underdeveloped and ill-suited to the challenges of the internet era; and levels of physical and online counterfeit goods remain high but relevant enforcement mechanisms are weak and nondeterrent. Rightsholders also face basic challenges with respect to technology transfer, licensing the use of IP assets, and the commercialization of IP assets. With respect to the latter, Article 170 of Law 2294 appears to expand the government's right of access to new technologies and IP assets developed through public funding. It remains unclear how this modification will affect or improve existing technology transfer mechanisms.

As discussed over the course of the Index, there are already many barriers to effective public-private technology transfer in Colombia. For example, Colombian public sector researchers and university faculty have historically not been allowed to own stock in spin-offs or start-ups. Furthermore, it remains unclear how the new PND will interact with the 2021 National Intellectual Property Policy, CONPES 4062, also drafted and released by the National Planning Department. As detailed last year, the Policy provides a largely positive road map for improving important parts of Colombia's national IP environment. Key areas covered by the Policy and accompanying action items relating to the Index 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. As stated last year, the Colombian government should be commended for taking such a holistic approach to reforming the entire innovation and IP policy ecosystem through this long-term structural reform effort that the National Intellectual Property Policy represents.

As the economic data and analysis in this Index's accompanying Statistical Annex and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for innovation and advanced economic development to take place.

For all economies—emerging and developed alike—what drives innovation, technological advances, and economic development and growth is the creation of new forms of intangible assets and IP. As such, the U.S. Chamber of Commerce and its members stand ready to work with the Colombian government as it moves forward in implementing the National Intellectual Property Policy in 2024 and beyond.

Patent Rights, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In June 2023, the Colombian Ministry of Health and Social Protection (MSPS) issued Resolution 881. The resolution paved the way for an interministerial committee to examine the case for the issuing of a "Declaration of Public Interest" and compulsory license for the HIV/AIDS treatment dolutegravir. The publicly reported basis for launching the Declaration was to respond to the rapid rise in HIV infections in Colombia between 2018 and 2022, caused in part by the influx of Venezuelan migrants according to MSPS. Subsequently, in September 2023, the Interagency Technical Committee (Comité Técnico Interinstitucional, or the "Technical Committee") issued its report recommending that issuance of a compulsory license be declared in the public interest. However, this report limited its issuance to two of the four patents originally identified by the government. MSPS then issued Resolution No. 1579 in October 2023, declaring it to be in the public interest to allow the compulsory licensing for government use of only one of the four patents originally identified. In January 2024, the Superintendent of Industry and Commerce (Superintendencia de Industria y Comercio or SIC) issued a notice setting forth the terms and conditions with respect to the issuance of a compulsory license. After the notice was released, five entities formally submitted applications to SIC to receive the compulsory license, including the MSPS.

As detailed over the course of the Index, up until the mid-2010s, the imposition and discussion of compulsory licensing for biopharmaceuticals had not been a recurring issue in Colombia. To begin with, Article 70 of the 2014-2018 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 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, thus allowing for grounds outside extreme circumstances, including industrial or commercial objectives, to play a role in the issuing of compulsory licenses.

In 2016, the Ministry of Health and the Colombian government actively considered issuing a compulsory license for the oncology drug Glivec on the grounds of high prices. Subsequently, the government issued a "Declaration of Public Interest" via Resolution 2475 and committed to unilaterally reducing the price of Glivec by about 45%. The National Commission of Prices of Medicines and Medical Devices issued Circular No. 3 in 2016, which defines the general pricing methodology applicable to all drugs under a public interest declaration. In contrast to the then existing price setting methodology—whereby the average price is calculated from a group of 17 economies—public interest medicines were to be subject to the lowest price available, including prices of follow-on products. As detailed in the Index at the time, this practice all but nullified any existing IP protection and was highly questionable given Colombia's obligations under TRIPS and the U.S.-Colombia Trade Promotion Agreement.

Shortly after the issuance of Circular No. 3, the National Pricing Commission issued Circular No. 4, which set the price of Glivec at about 44% of its former price. Subsequently, in 2017, the government issued Decree No. 670, which regulates the use of the public interest measure. The decree requires that any public interest declaration 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 late 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 but instead identified the whole class of products.

In 2020, Decree 476 was issued by the 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 COVID19." Although not legally a compulsory license, it has the same practical impact of eliminating rightsholders' ability to freely use a granted exclusivity.

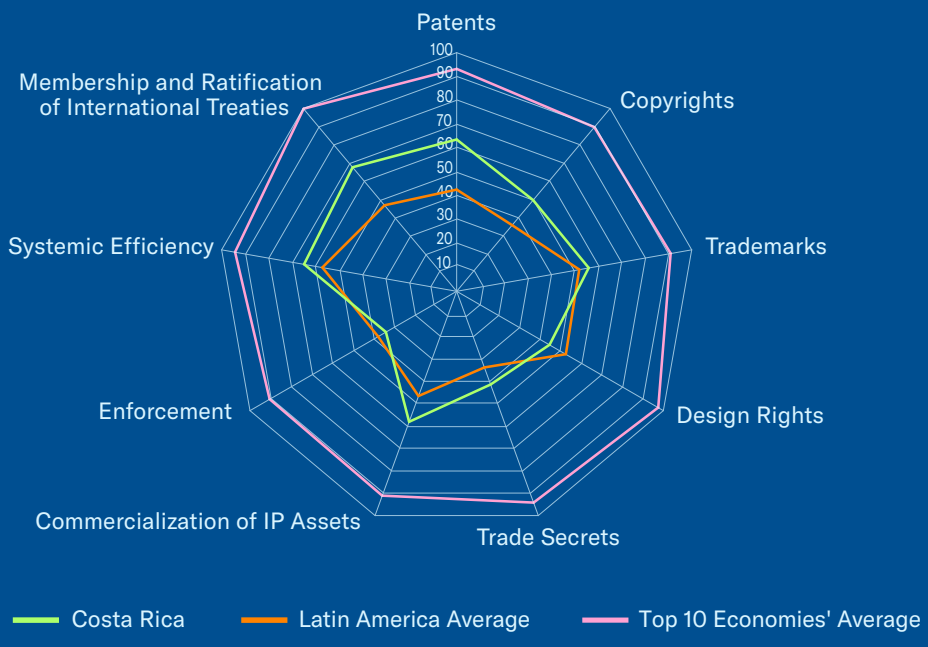
The same logic is present in a legislative proposal introduced in the Colombian Senate, Bill 372, on Pharmaceutical Safety. The proposed legislation seeks to address the manifold biopharmaceutical challenges posed by the COVID-19 pandemic. Although the draft bill seeks to address the complex issue of securing biopharmaceuticals and medical supplies amid 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 all IP rights through executive fiat.

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" 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 2024.

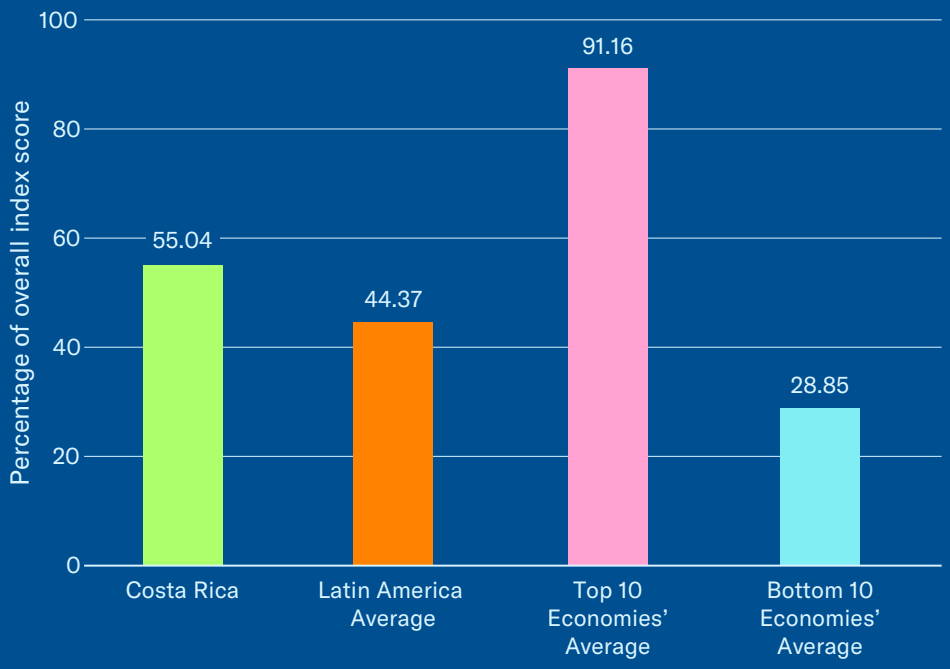
Costa Rica

Rank
26/55

Category Scores



Overall Score in Comparison



Costa Rica

Key Areas of Strength

- Launch of IP technical assistance programs for SMEs in 2023
- Implementation of software management tools for the public sector addresses the long-standing issue of unlicensed software use
- Expanded support for awareness raising and IP rights educational activities in 2020
- Member of the regional Forum for the Progress and Integration of South America (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 a significant lack of implementation of the online copyright regime
- Gaps exist in effectiveness of life sciences IP rights
- The system of enforcement of IP rights is slow and lacks effectiveness
- Inadequate penalties for IP infringement

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

Indicator	Score
Category 6: Commercialization of IP Assets	**3.50**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**2.40**
32. Physical counterfeiting rates	0.48
33. Software piracy rates	0.42
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.50
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**3.25**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**4.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 55.04%

Spotlight on the National IP Environment

Past Editions versus Current Score

Costa Rica's overall score has increased from 54.56% (27.28 out of 50) in the eleventh edition to 55.04% (27.52 out of 50). This reflects a score increase for indicator 42 and a decrease for indicator 32.

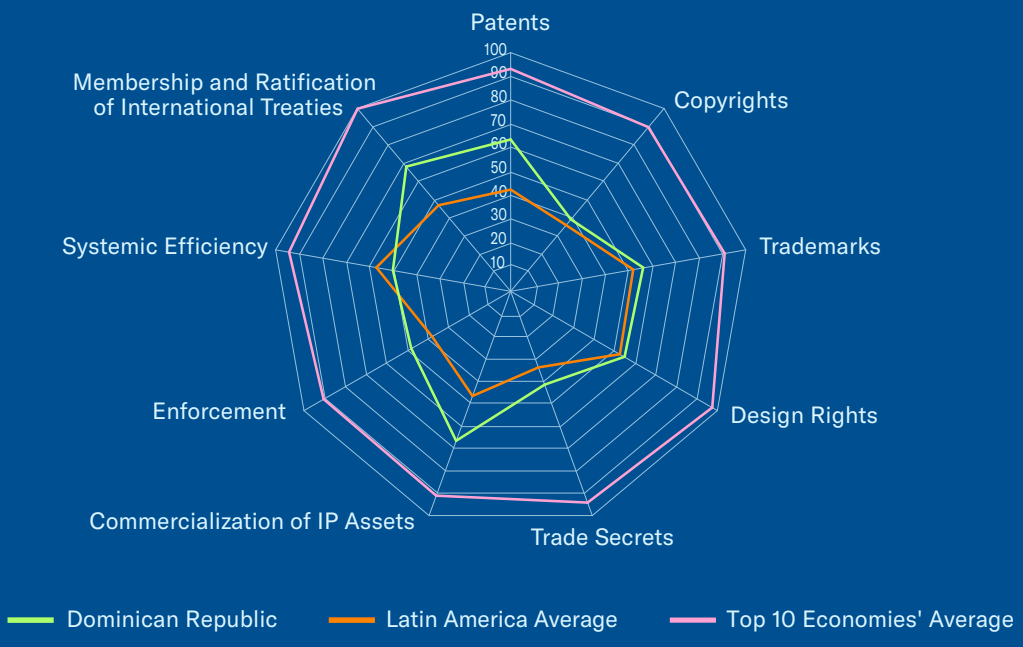
Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs:
As noted in previous editions of the Index, there is a growing recognition in Costa Rica of the importance of SMEs to the creation, dissemination, and commercialization of IP assets. Article 33 of Law 6867 (Ley de Patentes de Invención, Dibujos y Modelos Industriales y Modelos de Utilidad) provides reduced registration fees for patent applications submitted by individual inventors, universities, public research institutes, and micro and small enterprises. Historically, there has been no targeted technical assistance or education programs on the creation and commercialization of IP assets for SMEs by the National Registry or other major Costa Rican public institutions. Instead, outreach and technical assistance programs have been more cross-cutting and aimed at academic researchers, research institutes, and SMEs. Alternatively, when these programs targeted SMEs, they did so not within the context of incentivizing the creation of IP assets but more broadly in supporting small business and enterprise.
This has now changed. In partnership with WIPO and its WIPO Academy initiative, in late 2022, the National Registry launched a dedicated IP training and outreach effort focused exclusively on the needs of entrepreneurs and SMEs.
The inaugural event was held at the University of Costa Rica and was preceded by a National Registry outreach campaign targeting local businesses. Training sessions focused on understanding the basics of various forms of IP rights, the registration process, enforcement, IP valuation, and the identification and commercialization of IP assets by small businesses. The National Registry's program is part of a broader effort by the Costa Rican government to partner with WIPO and to boost post-COVID economic growth and development. As a result of these positive efforts, the score for this indicator has increased by 0.25.

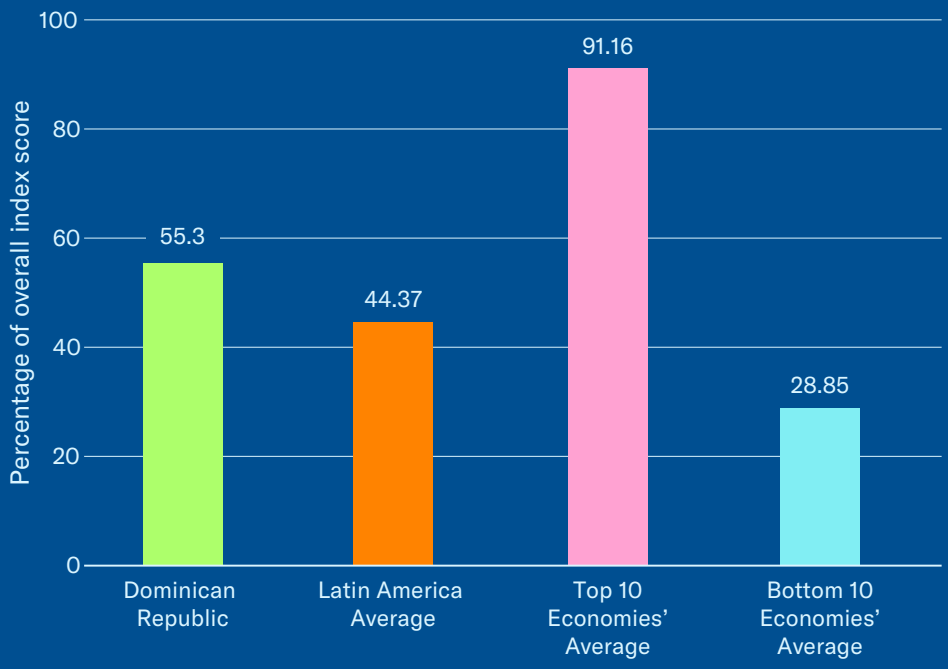
Dominican Republic

Rank
25/55

Category Scores



Overall Score in Comparison



Dominican Republic

Key Areas of Strength

- Launch of a new IP enforcement coordinating body, the National Inter_Ministerial Council of Intellectual Property in 2023
- Dominican Republic–Central America Free Trade Agreement (CAFTA) membership fundamentally improved the national IP environment
- Member of PROSUR regional PPH
- Plant variety protection is in place
- No evidence of active government intervention in technology transfer or licensing
- Fairly strong legal requirements and administrative practices for public consultations

Key Areas of Weakness

- Patentability standards are outside international norms—no second-use claims for biopharmaceuticals and virtually no patent protection for CIIs
- RDP term not granted although required by law
- Enforcement of copyright is highly challenging and is one of the main reasons the Dominican Republic has remained on USTR's 301 Watch List for years
- Infringement of copyright through signal piracy and online and web-based streaming is highly pervasive and constitutes a major source of illegal content not effectively addressed by the 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
Category 1: Patents, Related Rights, and Limitations	**5.70**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.70
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**2.74**
10. Term of protection	0.74
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**4.00**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**3.36**
32. Physical counterfeiting rates	0.36
33. Software piracy rates	0.25
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**2.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**4.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 55.30%

Spotlight on the National IP Environment

Past Editions versus Current Score

The Dominican Republic's overall score has increased from 54.28% (27.14 out of 50) in the eleventh edition to 55.30% (27.65 out of 50). This reflects score increases for indicators 32 and 39.

Enforcement and Systemic Efficiency

36. Criminal standards including minimum imprisonment and minimum fines; and
39. Coordination of IP rights enforcement:
2022-2023 saw several positive developments on IP enforcement in the Dominican Republic. At the end of 2022, President Abinader issued Decree 776-22 establishing a new coordinating body on IP policy, the National Inter_Ministerial Council of Intellectual Property (Consejo Interministerial de Propiedad Intelectual). As has been noted in previous editions of the Index, rightsholders face significant challenges in enforcing their IP rights in the Dominican Republic. Although many legal standards are in place, de facto protection and enforcement remain weak with rates of physical hard-goods piracy and counterfeiting high, particularly for alcohol and optical goods. Part of the enforcement problem in the Dominican Republic has historically been a lack of coordination and cooperation between the relevant parts of the government involved in enforcement. No formal mechanism has been in place for interagency coordination of IP enforcement. There have been examples of joint public-private initiatives, including the "Campaign against Counterfeiting" (Mesa Presidencial contra el Contrabando), which brings together various agencies and departments from the government with representatives from the private sector, but this is an initiative focused on educational activities and awareness raising, not on the coordination of IP rights enforcement.

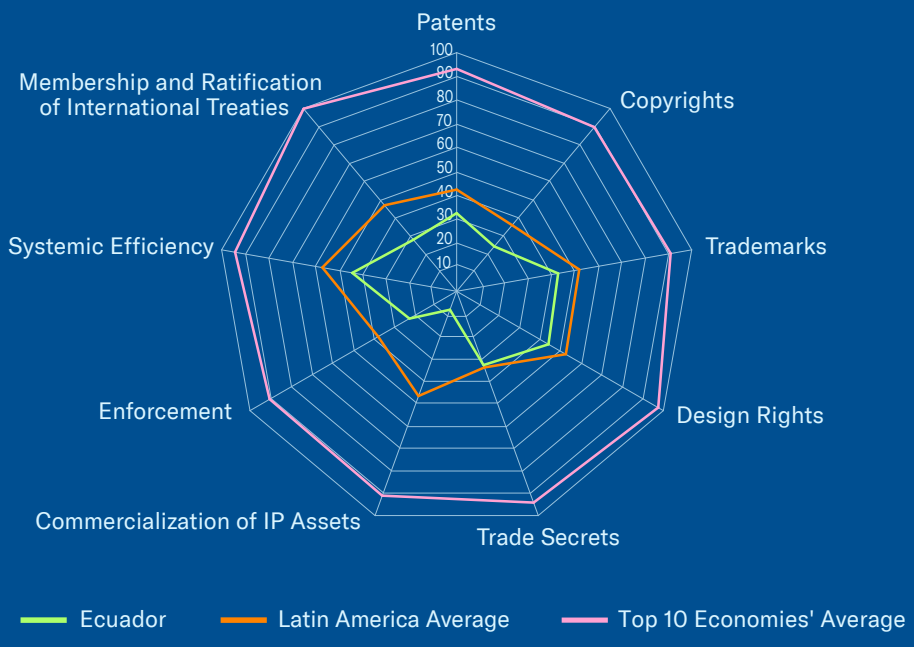
Although the new council will work on issues cutting across IP policy, a primary area of emphasis is the coordination of IP enforcement across government. Consequently, its work is an important step in improving the overall IP enforcement environment in the Dominican Republic. Led by the Attorney General's Office and the Ministry of Industry, Commerce and MSMEs, the council includes representatives from all key IP enforcement-related ministries and departments including Customs, the National Office of Industrial Property, the National Office of Copyright, and the Institute of Telecommunications. The council held its first meeting in February 2023 and, at the time of this research, was operational. As a result of the establishment of the council, the score for indicator 39 has increased by 0.50.

More broadly, there were also positive developments in IP enforcement with respect to rates of criminal prosecution. Specifically, statistics published by the Attorney General's Office Intellectual Property Unit suggest that 2022 saw a notable increase in the prosecution of signal piracy and illicit broadcasting. In 2022, 69 requests were made for preliminary judicial measures versus 25 in 2021. As has been noted repeatedly in the Index, the infringement of copyright through signal piracy and online and web-based streaming is highly pervasive and constitutes a major source of illegal content in the Dominican Republic. Authorities in the Dominican Republic have repeatedly made a commitment to better enforce copyright and to address this issue but have thus far failed to do so. Such a commitment was, for example, made in a side letter between the United States and the Dominican Republic in 2004 during the conclusion of the Dominican Republic–Central America Free Trade Agreement. The USTR has repeatedly stated its concern with the lack of action on signal piracy and copyright infringement. The increase in rates of criminal prosecution is a positive development that, if continued, will lead to an improved national IP environment in the Dominican Republic and a score increase for indicator 36.

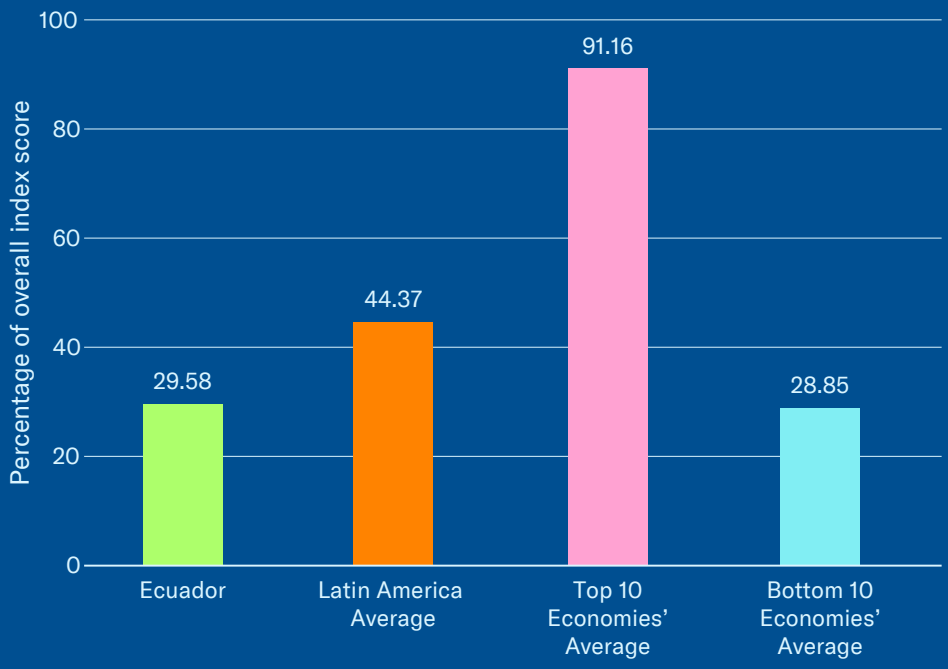
Ecuador

Rank
50/55

Category Scores



Overall Score in Comparison



Ecuador

Key Areas of Strength

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

Indicator	Score
Category 6: Commercialization of IP Assets	**0.50**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.25
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**1.66**
32. Physical counterfeiting rates	0.34
33. Software piracy rates	0.32
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**2.25**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.50

Total: 29.58%

Spotlight on the National IP Environment

Past Editions versus Current Score

Ecuador's overall score decreased from 30.68% (15.34 out of 50) in the eleventh edition to 29.58% (14.79 out of 50). This reflects score decreases for indicators 32 and 37.

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; 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 copyrighted content in Ecuador. The existing legal framework has major gaps, and enforcement remains inadequate. This remained unchanged in 2023.

In February, a new law was enacted to incentivize the creation, dissemination, and use of digital and audiovisual products and services, the Law for Digital and Audiovisual Transformation (Ley Orgánica para la Transformación Digital y Audiovisual). The law rightly points to the importance of the digital revolution to future economic growth and development and centrality of the audiovisual sector to the creative economy. Unfortunately, the law does not acknowledge or refer to the protection of IP rights, and IP policy does not seem to be part of its remit.

As the economic data and analysis in this Index's accompanying Statistical Annex and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for creativity and digital economic development to take place.

For all economies—emerging and developed alike—what drives creativity, technological advances, and economic development and growth is the creation of new forms of intangible assets and IP. Yet Ecuador still lacks many fundamental rights and incentives. Instead, the past eight years have seen a substantial deterioration in the national IP environment.

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 law's provisions conflicted with Ecuador's old Intellectual Property Law and its international treaty obligations, including the TRIPS agreement and the EU'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 with regard to statutory exceptions to copyright.
The Codigo Ingenios introduced several substantial changes in both the number and extent of exceptions and limitations. The number of defined statutory exceptions was increased substantially with Article 212 defining 29 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 Codigo 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. Unfortunately, these regulations did not effectively address the underlying legislation's deficiencies.

The USTR has 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.

More broadly, Ecuador has over the past decade acted to decriminalize IP infringement. The 2013 amendments to the Intellectual Property Law removed criminal penalties and sanctions for copyright and trademark infringement altogether. 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 (AlianzaContra la Piratería de Televisión Paga en América Latina) 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 Codigo 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. Over the past few years, SENADI has ordered the disabling of access to several websites hosting infringing and unlicensed content. The first order came in 2019 after 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 at the time, this was a positive development that resulted in a score increase for indicator 12. It was hoped that this administrative enforcement route would become more readily available to rightsholders 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 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. They have proven to be effective in reducing the availability of copyright infringing content.

As 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.

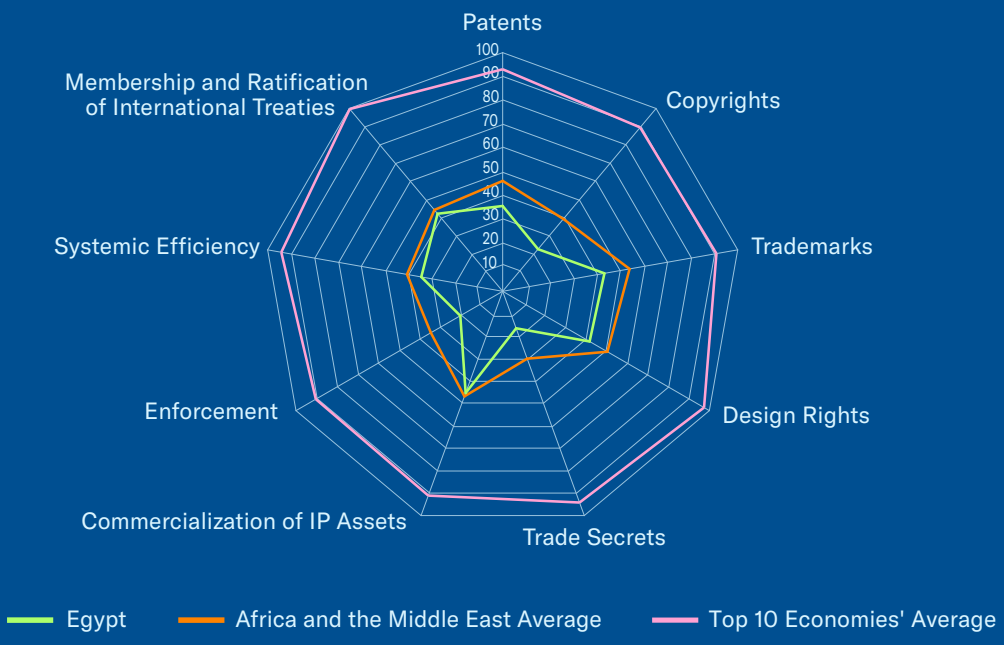
Enforcement

37. Effective border measures:
Before 2016 and the enactment of the Código Ingenios, Ecuadorian border officials not only had the power to seize suspected IP infringing goods but were legally obliged and compelled to do so with failure to act constituting a potential offense. Article 342 of the Intellectual Property Law 2006_13 stated, "The Ecuadorian Customs Corporation and all those that have control over the entry or exit of goods into or from Ecuador shall be obliged to prevent the entry or export of goods that in any way infringe intellectual property rights. Where, at the request of an interested party, they do not prevent the entry or export of such goods, they shall be considered accessories to the offense committed, without prejudice to the relevant administrative penalty." This right to act was granted through both a rightsholder notification process and through ex officio powers. Article 575 of the Código Ingenios and Articles 458-465 of the 2020 Implementing Regulations removed this right of action from customs officials and instead transferred both the notification process and ex officio authority to the national IP office SENADI. IP infringing counterfeit and pirated goods poses a threat to the health and safety of consumers in Ecuador and around the world. Counterfeit and pirated goods jeopardize consumer health and often pose a serious safety risk: counterfeit toys contain hazardous and prohibited chemicals and detachable small parts, counterfeit medicines pose a direct risk to the health and safety of patients around the world, and counterfeit microchips for civilian aircrafts endanger air passengers. Counterfeit and pirated products are also a drag on national economies, as they are, per definition, the result of criminal and black-market trading activity. As a result, they deprive governments of legitimate tax revenue and undermine legitimate markets for innovators and creators everywhere. The OECD and EUIPO estimated in 2021 that global physical counterfeiting accounted for some $464 billion or 2.5% of global trade, more than double an estimated $200 billion in 2005. National customs officers are the first line of defense against this menace, and it is essential that they be able to act expeditiously and effectively against suspected IP-infringing goods. As Ecuadorian customs and border officials continue to lack this power of action, the score for this indicator has been reduced to 0.

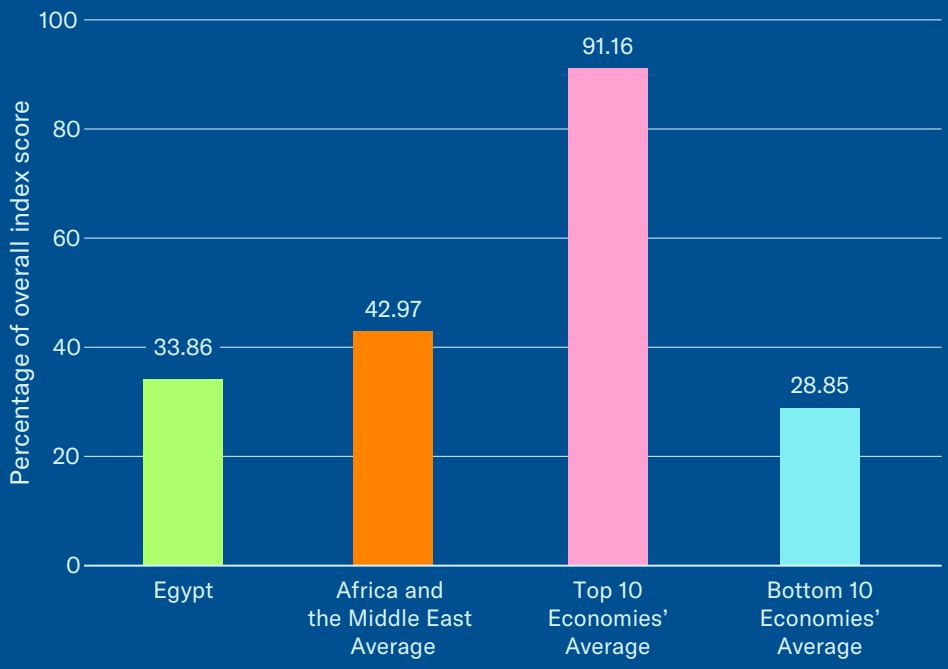
Egypt

Rank
48/55

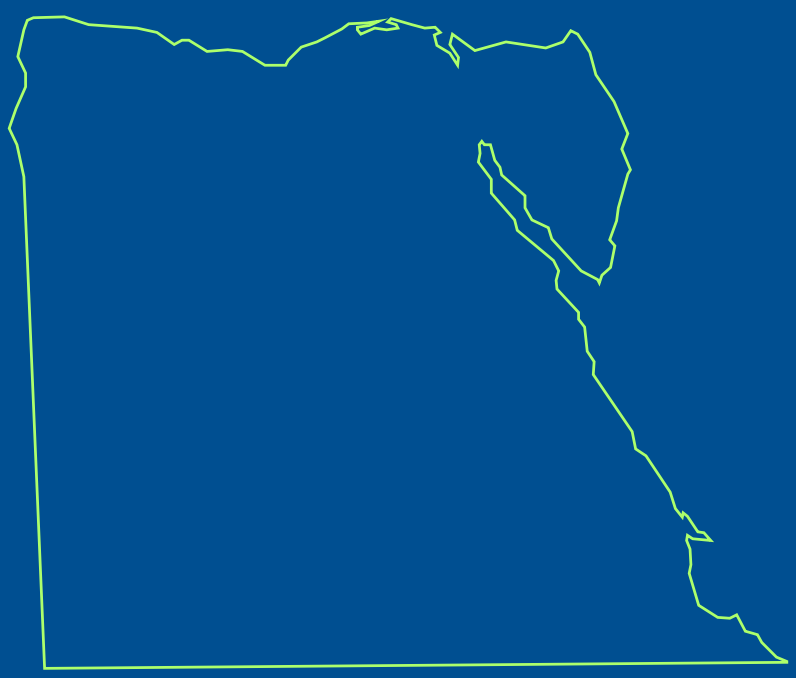
Category Scores



Overall Score in Comparison



Egypt



Key Areas of Strength

- Increased copyright enforcement in 2023
- Egypt joined the 1991 International Convention for the Protection of New Varieties of Plants (UPOV) agreement in 2020
- Since 2015, a PPH has been in place with the JPO
- Relative freedom to patent CIIs and support from government agencies
- Relatively strong push from the government to raise awareness of counterfeit products, particularly medicines

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 with regard to protection of content online
- High levels of piracy—BSA estimated a 59% software piracy rate
- Challenging enforcement environment and a lack of border measures

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**3.25**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**1.63**
10. Term of protection	0.38
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.25
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
Category 6: Commercialization of IP Assets	**2.75**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**1.45**
32. Physical counterfeiting rates	0.29
33. Software piracy rates	0.41
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.50
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**3.00**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

Total: 33.86%

Spotlight on the National IP Environment

Past Editions versus Current Score

Egypt's overall score has increased from 32.82% (16.41 out of 50) in the eleventh edition to 33.86% (16.93 out of 50). This reflects score increases on indicators 12, 32 and 36.

Area of Note

In a positive development, a new Egyptian national IP office was established under law in August 2023. The Egyptian Intellectual Property Authority came into being through Law 163 and was expected to be operational in 2024. The Index will continue to monitor these developments in 2024.

Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism:
As noted over the course of the Index, no mechanism links the market authorization of a follow-on biopharmaceutical product with the exclusivity status of the reference product. Industry reports suggest that, over the past decade, several follow-on products have been granted market authorization by the health authorities even though the reference product is under patent protection. 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 case.

Egypt is ranked low on international indices pertaining to the ability to seek legal judicial redress. In the 2019 edition of the World Bank's Doing Business report, Egypt ranked 160th in the category "Enforcing Contracts" and 101st for "Resolving Insolvency."

It takes, on average, 1,010 days to enforce a contract—over 2.5 years—and at a cost of over 25% of the claim value. This has remained unchanged for the past 15 years. Given the difficulties in enforcing IP rights through the Egyptian court system, the lack of a linkage mechanism means rightsholders have a limited ability to protect and defend their IP from infringement. This issue remained unresolved in 2023.

Copyrights, Related Rights, and Limitations; and Enforcement

12. Expeditious injunctive-style relief and disabling of infringing content online; and 36. Criminal standards including minimum imprisonment and minimum fines:
Rightsholders have historically faced significant challenges in protecting their content in Egypt. The existing legal copyright framework has major gaps, and enforcement remains inadequate. Egypt's copyright law (Book 3 of Law 82) provides standard exclusive rights only for traditional, physical media and no specific remedies or rights in an online or digital context. 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, but this is carried out on an ad hoc basis; there is no established mechanism or pathway (judicial or administrative) that rightsholders can use to combat online copyright infringement.

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. Similarly, the U.S. government has for years highlighted the high prevalence of copyright piracy, including signal piracy, in Egypt. In this respect, it is noteworthy that the past 2 years have seen some positive enforcement developments.

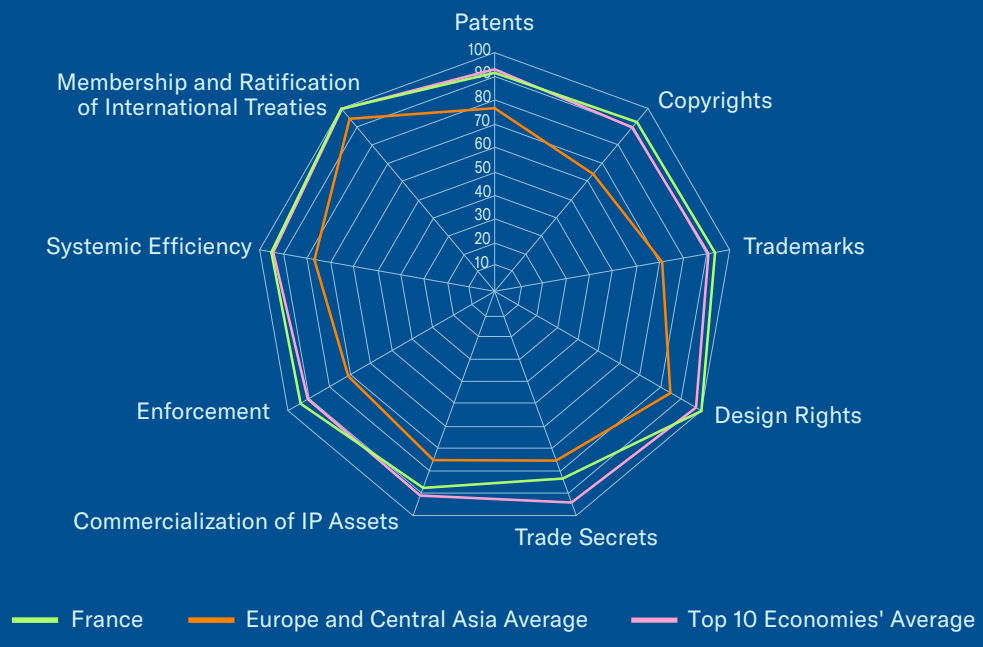
As noted in last year's Index, in 2022, an international rightsholders' coalition, the Alliance for Creativity and Entertainment, announced that, together with local Egyptian law enforcement, it had disabled access to a significant source of pirated sports content in Egypt. Several streaming sites were reported to have been disabled, domain names were seized, and arrests were made. These positive efforts continued in 2023. Additional websites have been taken down, arrests have been made, and the level of criminal enforcement against copyright piracy has increased. In February, access to the MyCima and Shahed4U websites were disabled, and in June, the same happened with Movizland. As a result of these positive efforts, the score for indicators 12 and 36 have increased by 0.25, respectively.

37. Effective border measures:
The right to take ex officio action against suspected IP-infringing goods is not explicitly provided by Customs Law or the 2005 "Executive Regulation to Implement Import and Export Law" (No. 770/2005). Furthermore, Egyptian customs authorities do not use a centralized recording system. Existing procedures require rightsholders to notify customs in advance of specific suspected shipments and to provide evidence of infringement of their IP rights. Local legal analysis suggests that border measures do not extend to goods in transit; Egyptian IP law relates only to goods intended for the Egyptian market. This has not changed over the course of the Index. The lack of adequate border enforcement has resulted in Egypt being a central international transit point and source of illicit goods. Using global customs data, the OECD and 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, footwear, and jewelry.

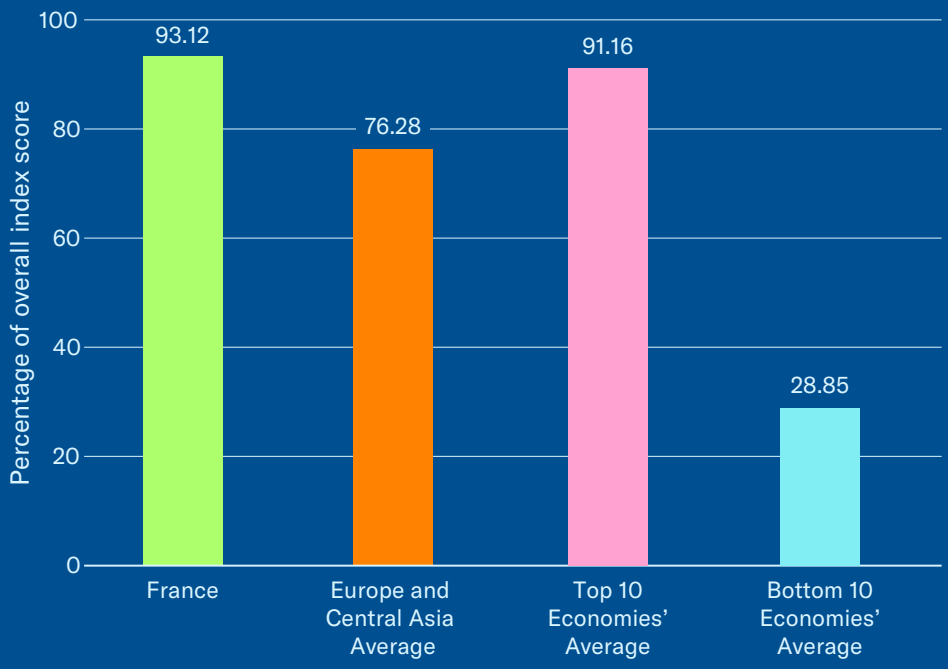
France

Rank
3/55

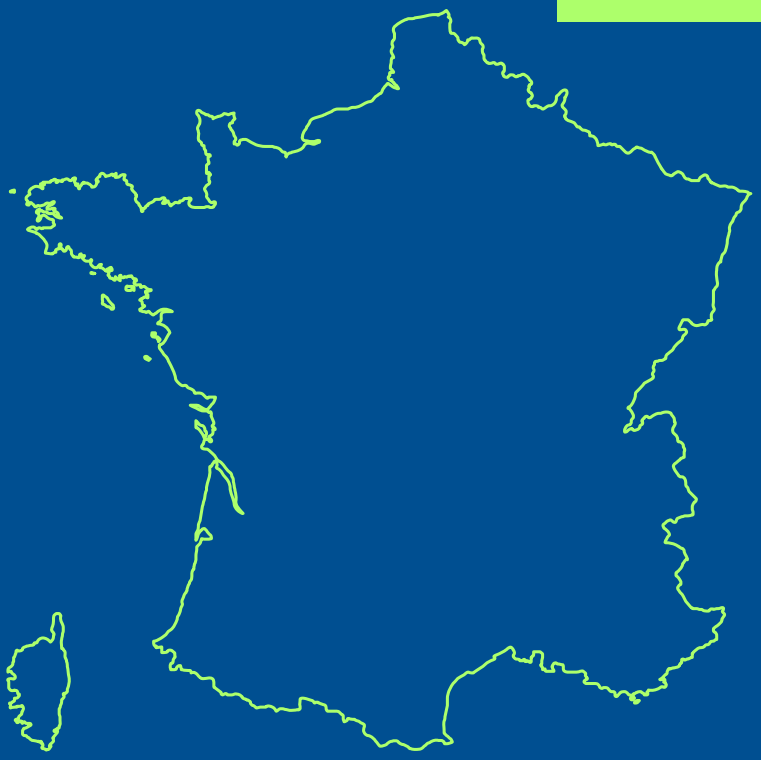
Category Scores



Overall Score in Comparison



France



Key Areas of Strength

- Under Law 2021-1382, copyright enforcement powers have been expanded to allow French Copyright Authority (HADOPI) to take quicker action against mirror sites; establish a black list of repeat infringing hosts and websites; expedite disabling of access after a 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

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for new EU compulsory licensing regime
- 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
Category 1: Patents, Related Rights, and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**6.49**
10. Term of protection	0.74
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.75**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.75
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.50**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**5.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**6.57**
32. Physical counterfeiting rates	0.89
33. Software piracy rates	0.68
34. Civil and precedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 93.12%

Spotlight on the National IP Environment

Past Editions versus Current Score

France's overall score remains unchanged at 93.12% (46.56 out of 50).

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. The commission posits in the "Call for Evidence" that a pressing need exists 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have never been used. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 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. 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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023, the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU. Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite.

Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allowed companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines.

Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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 health system. Within this context, IP rights play no part. The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including France, seeing a 0.20 score reduction for this indicator . The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination."

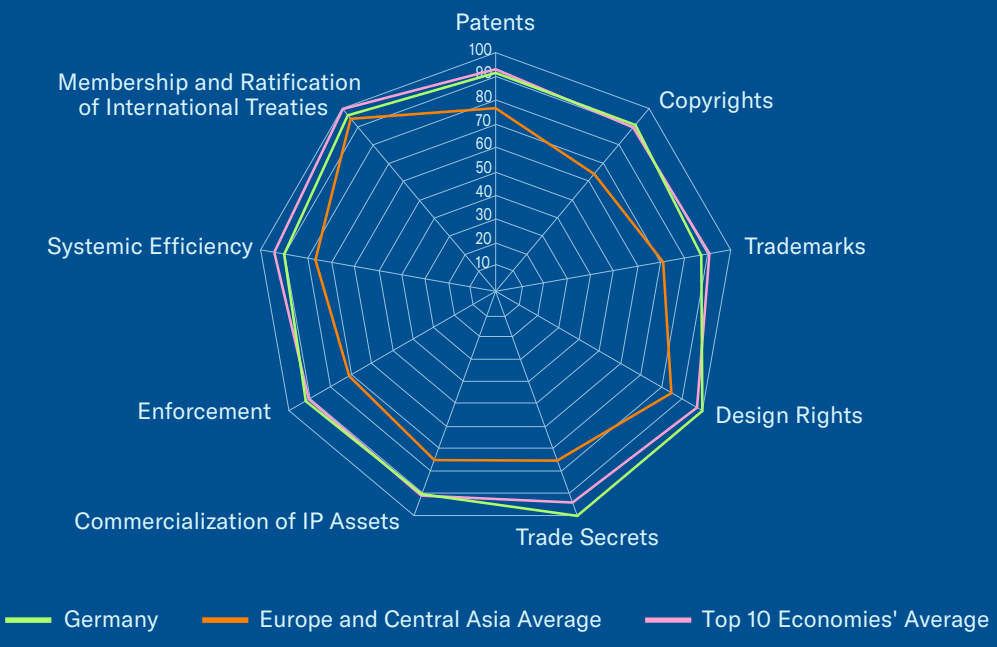
The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

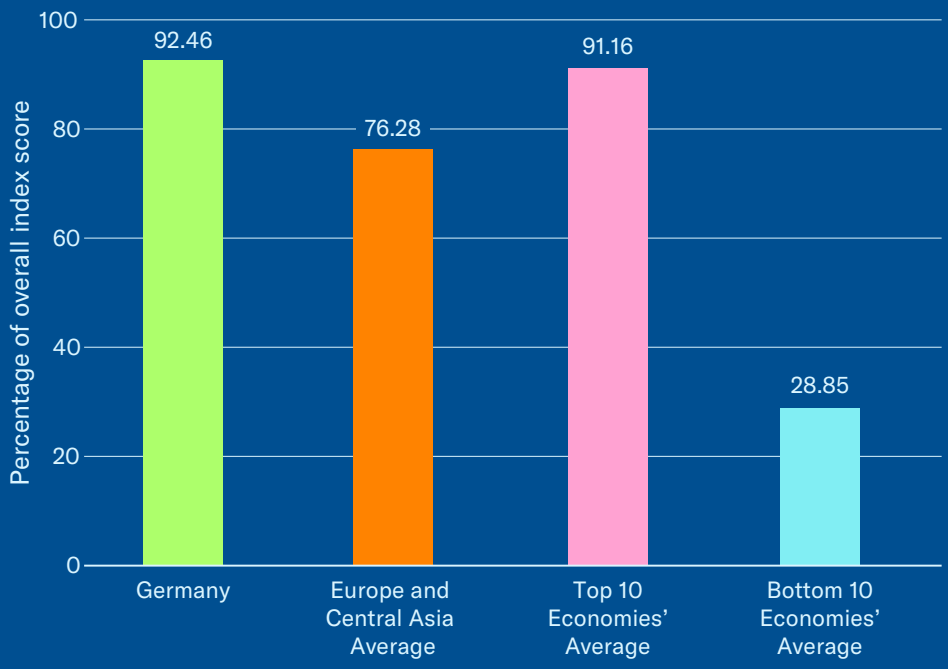
Germany

Rank
4/55

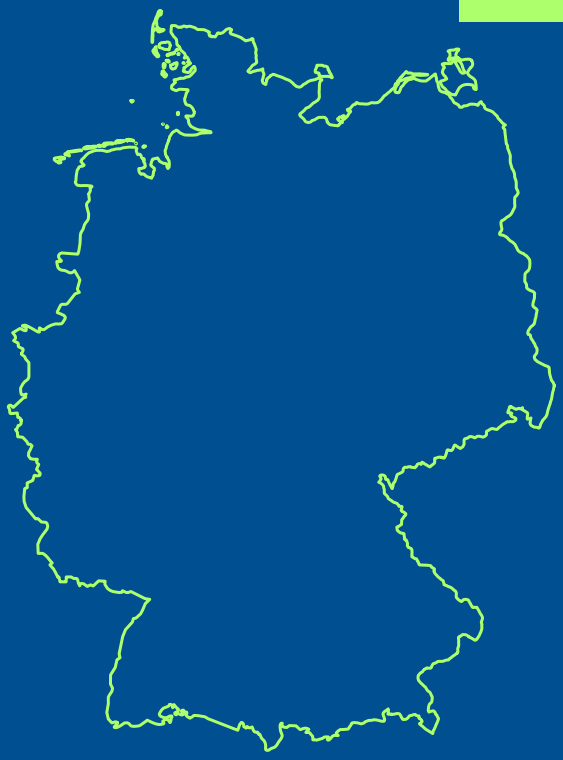
Category Scores



Overall Score in Comparison



Germany



Key Areas of Strength

- Additional R&D tax credits introduced in 2020
- Advanced and sophisticated national IP environment
- Sector-specific IP rights are in place
- Membership in all major international PPH tracks through the national patent office and EPO

Key Areas of Weakness

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for new EU compulsory licensing regime
- 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
Category 1: Patents, Related Rights, and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**6.38**
10. Term of protection	0.63
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.75
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**5.42**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**6.43**
32. Physical counterfeiting rates	0.88
33. Software piracy rates	0.80
34. Civil and precedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 92.46%

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

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. The commission posits in the "Call for Evidence" that a pressing need exists 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have never been used. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 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.

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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023, the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU.

Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allowed companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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 health system. Within this context, IP rights play no part. The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including Germany, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

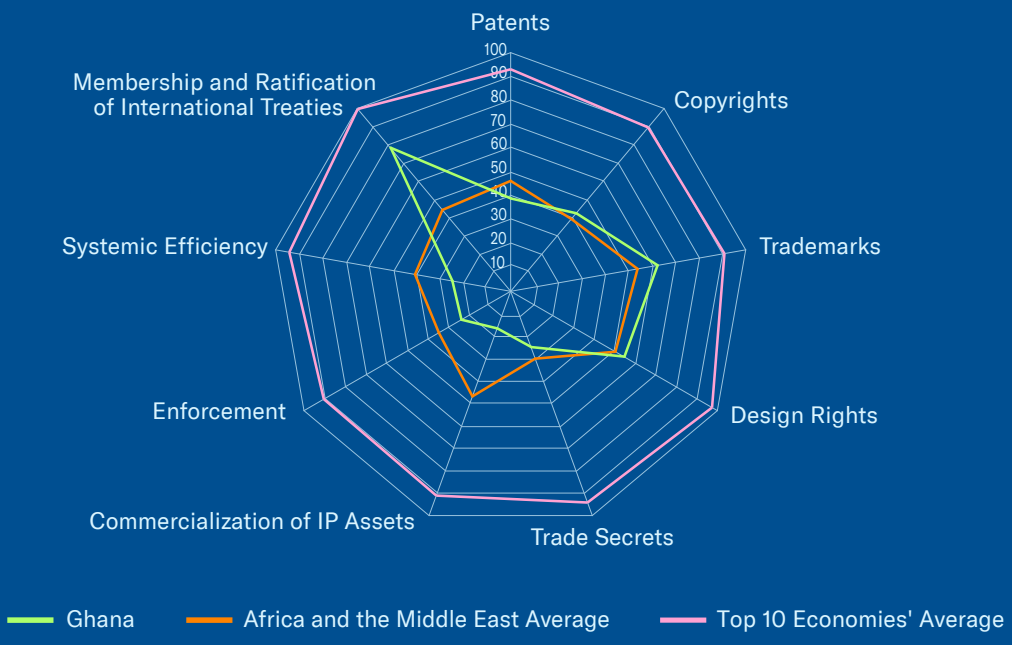
27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

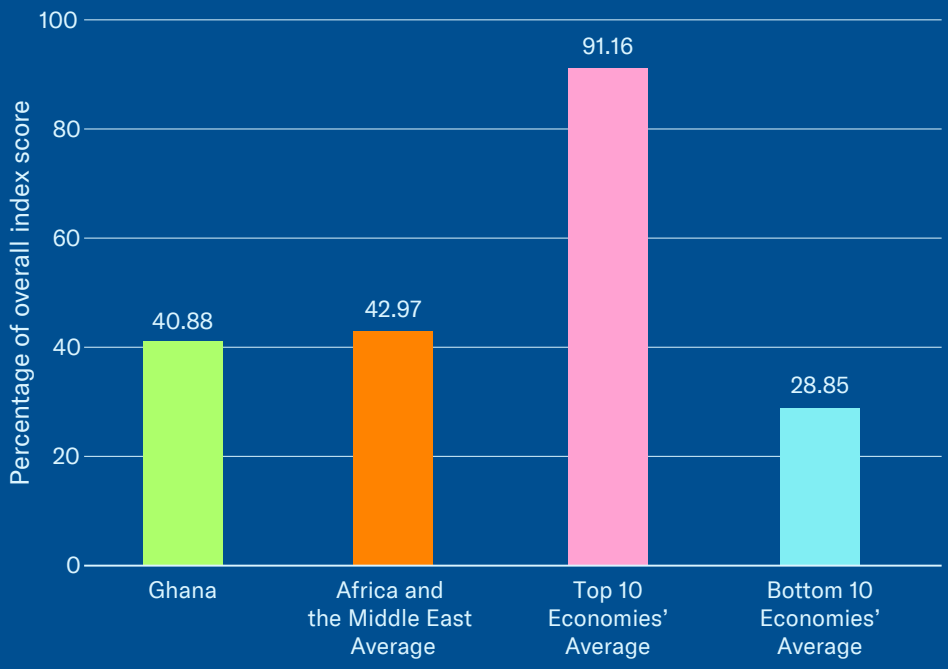
Ghana

Rank
39/55

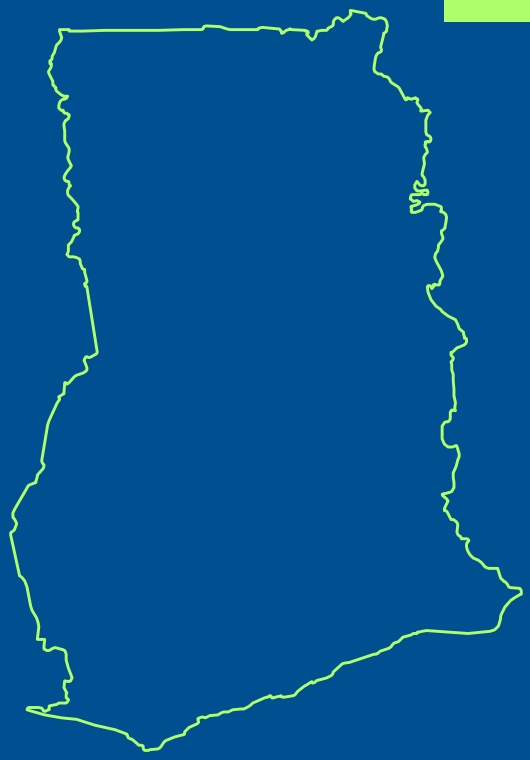
Category Scores



Overall Score in Comparison



Ghana



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 CIIs)
- New Plant Variety Protection Act 2020
- The Electronic Transactions Act 2008 includes a 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
Category 1: Patents, Related Rights, and Limitations	**3.50**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**2.99**
10. Term of protection	0.74
11. Exclusive rights	0.50
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.75**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
Category 6: Commercialization of IP Assets	**1.00**
26. Barriers to market access	0.50
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	0.50
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**1.44**
32. Physical counterfeiting rates	0.44
33. Software piracy rates	NA
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.25**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**5.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

Total: 40.88%

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).

Area of Note

Following the 46th Session of the Administrative Council of the African Regional Intellectual Property Organization (ARIPO) in late 2022, changes to both the Harare Protocol on Patents and Industrial Design and the Banjul Protocol on Marks took effect in 2023. Although not materially affecting the national IP environment in Ghana, some of these changes are nevertheless important to rightsholders both in Ghana and internationally. To begin with, the term of protection of industrial design was increased from a total period of 10 years to 15 years; this matches the current term of protection (including renewals) in Ghana under the Industrial Designs Act. The reforms also introduced a new Section 2 in the Harare Protocol, which formalizes how pregrant, third-party observations can be submitted. Rule 19 of the regulations now defines the process whereby such observations can be submitted and formalizes the procedure. A formalized route for the submission of third-party observations is available in most leading jurisdictions, and the process within ARIPO is now better aligned with other major IP offices and international best practices.

Enforcement

37. Effective border measures:
Ghana's legal framework related to border measures consists of two layers of laws and regulations: (1) domestic Ghanian laws and (2) regional commitments as a member of the Economic Community of West African States, which has its own regional customs code. Under current domestic Ghanian legislation, customs officials are provided with only a partial ex officio authority to act against goods suspected of infringing on IP rights. Neither the Copyright Act, Trademark Act, nor Customs Act specify an explicit ex officio authority in relation to goods destined for the domestic market or for transshipment or in transit. Instead, under Section 26 of the Copyright Act, a more partial form of ex officio authority is provided in the sense that the act obliges customs officials to act proactively against suspected pirated audiovisual goods. Specifically, it states the following: "An officer of the Customs, Excise and Preventive Service shall, unless satisfied that an imported sound recording or other copyright work is not a pirated product, not permit the importation of the copyright work without written clearance from the right owner of the work and the Copyright Office."

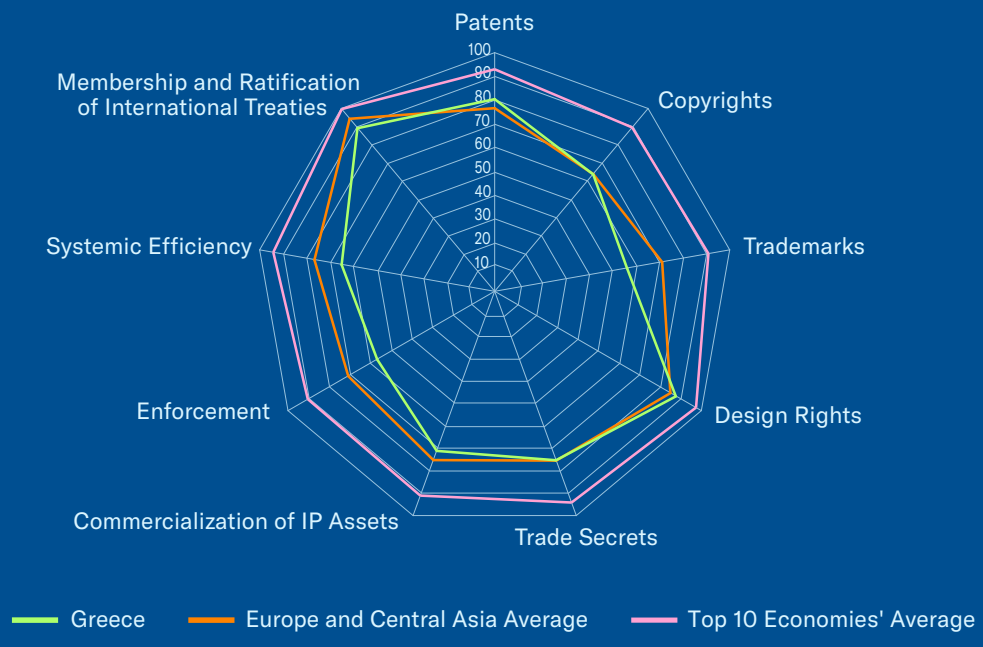
The Trademark Act provides for a notification system whereby rightsholders can notify the Customs Authority of any suspected goods. The Customs Act provides only a general right of action under Sections 112-120. Under these sections, officers may seize "un-customed, prohibited or restricted goods" discovered in the course of duty. Prohibited goods under the act are defined as "goods whose importation or exportation is prohibited by law." With respect to Ghana's regional commitments, no explicit ex officio authority is provided under the Economic Community of West African States Customs Code.

Counterfeit and IP-infringing goods are widely available in Ghana. A 2019 OECD case study of counterfeiting in Ghana found that it "has a high prevalence of counterfeit, pirated and substandard goods." The study noted problem areas with respect to medicines and the high availability of counterfeit, substandard, and unregistered medicines, which together were estimated by the Ghana FDA to constitute around 20% to 30% of the total market. The study also noted the high prevalence of counterfeit consumer goods, textiles, copyright-infringing goods, and electronics. Other sources confirm these reports with, for example, the U.S. State Department in its annual Investment Climate report for Ghana stating that IP rights "enforcement remains weak, and piracy of intellectual property continues." The past few years have also seen an increase in counterfeit goods exported from Ghana. For example, in the 2021 OECD and EUIPO report, Illicit Trade Global Trade in Fakes, A Worrying Threat, Ghana is listed as a growing source of counterfeit leather articles and handbags, footwear, jewelry, and clothing.

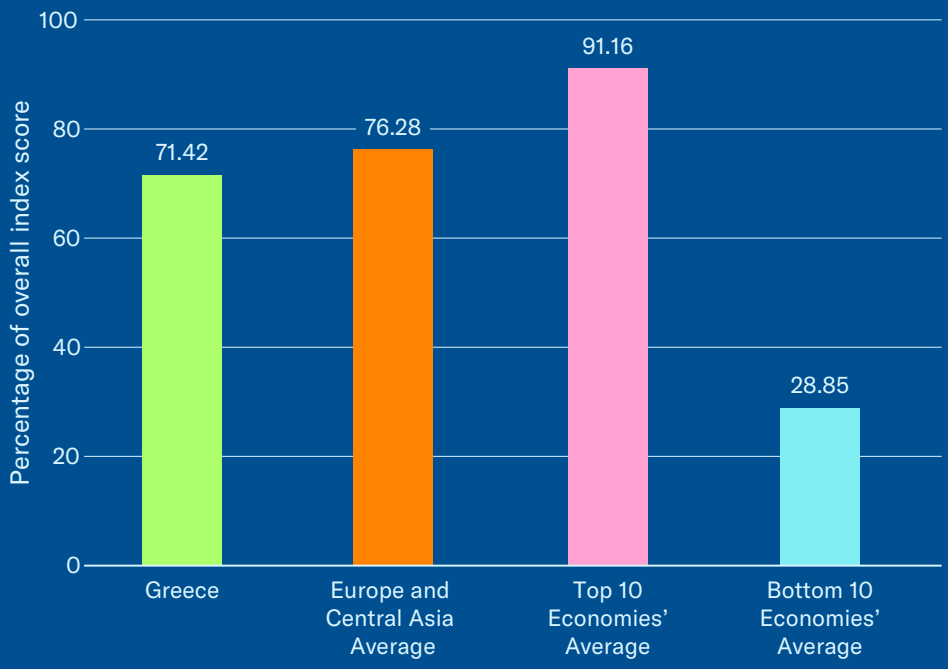
Greece

Rank
18/55

Category Scores



Overall Score in Comparison



Greece

Key Areas of Strength

- 2023 transposition of CDSM Directive into Greek law through Law 4996/2022
- Continued strong efforts on copyright enforcement through administrative relief and disabling of infringing websites, including introduction of dynamic injunctions
- Relatively strong national IP environment; Greece benefits from EU membership and from being a contracting party to the European Patent Convention
- Many sector-specific IP rights are in place

Key Areas of Weakness

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for new EU compulsory licensing regime
- The 2019 changes to the compulsory licensing regime are out of line with international standards; introduces price considerations as a basis for issuing license
- Historically, Greece has been home to high levels of online piracy

Key Areas of Strength
(continued)

- Membership in all major international PPH tracks through the EPO

Key Areas of Weakness
(continued)

- BSA's estimated rates of the use of unlicensed software suggest that Greece has since 2011 had a remarkably high rate of software piracy for an EU and OECD member state
- The software piracy rate has consistently stayed between 61% and 63% (in 2018, it was an estimated 61%) compared with 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
Category 1: Patents, Related Rights, and Limitations	**7.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**4.49**
10. Term of protection	0.74
11. Exclusive rights	0.50
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	0.75
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.25**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**4.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**3.97**
32. Physical counterfeiting rates	0.58
33. Software piracy rates	0.39
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**3.25**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.25**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 71.42%

Spotlight on the National IP Environment

Past Editions versus Current Score

Greece's overall score has increased from 70.92% (35.46 out of 50) in the eleventh edition to 71.42% (35.71). This reflects a score increase for indicator 13.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. It is difficult to understand the rationale for this "Call for Evidence." Each individual EU member state has national laws in place that address compulsory licensing in line with the member state's World Trade Organization (WTO) commitments. The commission posits in the "Call for Evidence" that a pressing need exists for "coordination and harmonization" at the EU level for 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, as detailed above, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have proven to be completely unnecessary and ineffective. It addresses a problem of vaccine shortages that does not exist, and no WTO member has made use of it. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 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. 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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

Copyrights, Related Rights, and Limitations

13. Availability of frameworks that promote cooperative action against online piracy:
As detailed in previous editions of the Index, Greece has for the past four 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). Law 4996/2022 was enacted in late 2022 and is now in force. The law broadly follows the scope of the underlying directive, particularly with regard to responsibilities and requirements under Article 17. Although it maintains existing exceptions and limitations provided under Greek and European copyright law and jurisprudence, the law strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. The law 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 for this indicator has increased by 0.25

14. Scope of limitations and exceptions to copyrights and related rights:
The transposition of the CDSM Directive into Greek copyright law through Law 4996/2022 also included changes to the existing copyright exceptions regime. First, the new law includes a new set of defined digital exceptions for teaching and educational instruction. These exceptions are similar to the existing exceptions regime under Articles 18-28 of Law 2121/1993, which make clear reference to both the Berne Convention and relevant EU law stating that the exceptions and restrictions outlined in the law should be "applied only in certain special cases which do not conflict with a normal exploitation of the work or other subject-matter and do not affect unreasonably the legitimate interests of the rightholder."

Second, like the underlying directive, Law 4996 includes new exceptions to copyright for text and data mining. These exceptions largely mirror the provisions of the CDSM. Text and data mining 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. The CDSM and Law 4996 both retain an option for rightsholders to expressly disallow the use of their content for text and data mining purposes unless conducted for the purposes of nonprofit scientific research. Similarly, both laws state clearly that text and data mining analysis can be conducted only for works that have been lawfully obtained or accessed. This is a new area of copyright law with little in the way of applicable jurisprudence. It is essential that rightsholders be able to practically enforce their rights and that the mandatory exception for scientific research be accessible only to bona fide research institutions as defined in the CDSM both in Greece and in the wider EU.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023, the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU. Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond.

For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allowed companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies.

Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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 health system. Within this context IP rights play no part.

The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including Greece, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination."

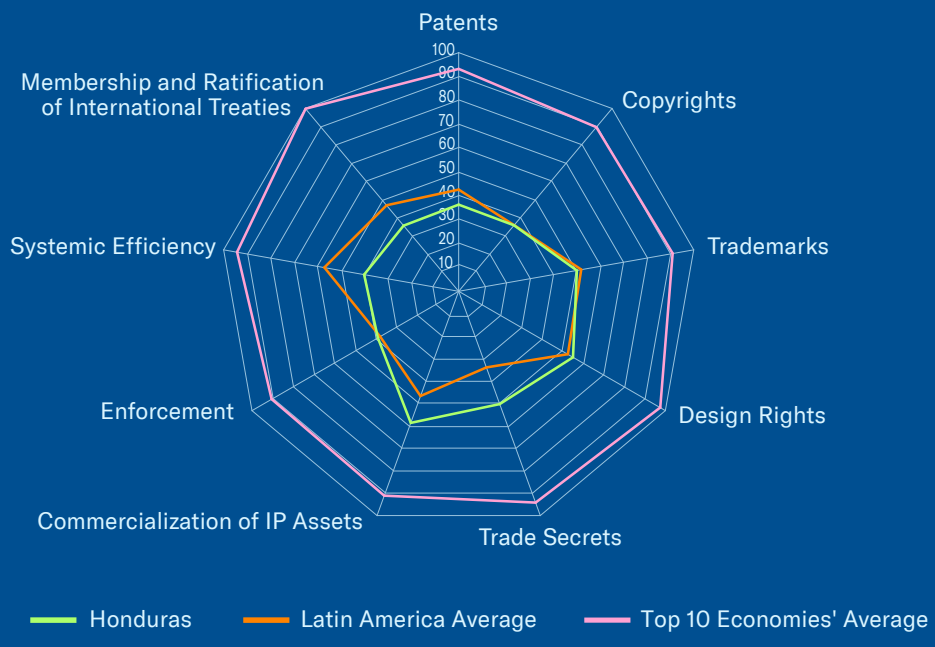
The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

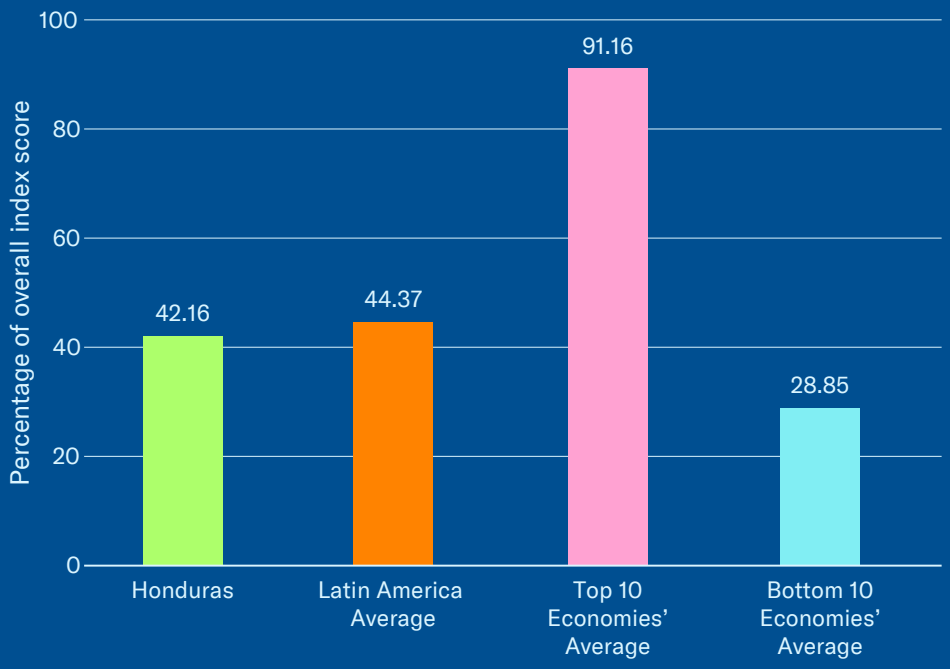
Honduras

Rank
36/55

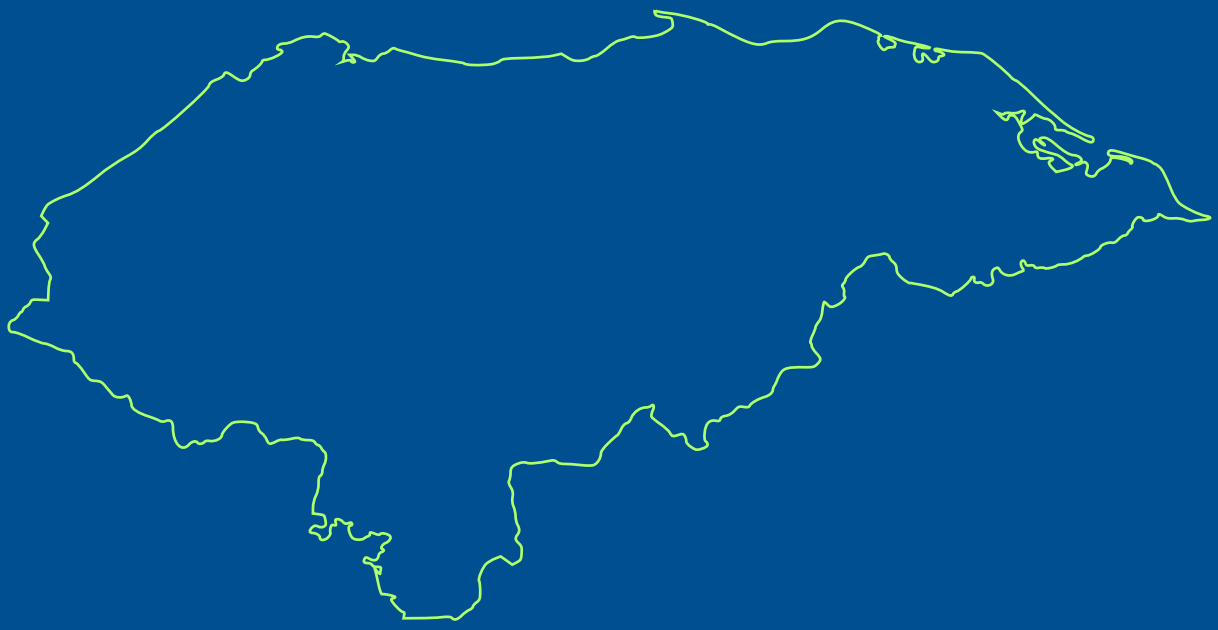
Category Scores



Overall Score in Comparison



Honduras



Key Areas of Strength

- CAFTA membership fundamentally improved the national IP environment
- Plant variety protection is in place
- No evidence of active government intervention in technology transfer or licensing

Key Areas of Weakness

- Patentability standards outside international norms; key problem areas include second-use claims for biopharmaceuticals and patent protection for CIIs
- Uncertainty about access to a statutory period of RDP: 2018 implementing regulations (Acuerdo No. 024-2018) provide a broad basis for overriding exclusivity
- Challenging enforcement environment, particularly for online and digital content
- Infringement of copyright through signal piracy and 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 Latin American region at 75%
- Signal piracy and theft are among the highest in Latin America: the total pirated or unreported market in Honduras is estimated at 50% of the total number of potential end users

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**3.25**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.51**
10. Term of protection	0.76
11. Exclusive rights	0.25
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.50**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**3.50**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**2.72**
32. Physical counterfeiting rates	0.47
33. Software piracy rates	0.25
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.00**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.00
Category 9: Membership and Ratification of International Treaties	**2.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 42.16%

Spotlight on the National IP Environment

Past Editions versus Current Score

Honduras' overall score remains unchanged at 42.16% (21.08 out of 50).

Patents, Related Rights, and Limitations

8. Membership in a Patent Prosecution Highway (PPH):
Honduras is not a member of the Global Patent Prosecution Highway, the IP5 Patent Prosecution Highway, or a regional patent prosecution highway, such as the Latin American Regional Cooperation System on Industrial Property, PROSUR. Similarly, Honduras does not have any bilateral PPH agreements in place. PPH initiatives and increased cooperation among IP offices are the most tangible ways in which the administration and functioning of the international IP system can be improved and harmonized to help inventors and rightsholders.

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); and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation:
As noted in previous editions of the Index, like in many parts of Central America and the Caribbean, satellite and cable signal piracy in Honduras is high and has remained so for years. In 2019, the Latin American industry association ALIANZA (AlianzaContra la Piratería de Televisión Paga en América Latina) 2019 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 Honduras was an estimated 50% of the total number of potential end users. Of the 19 Latin American economies sampled, Honduras' estimated rate of signal piracy was virtually the same as the top three signal piracy markets of Nicaragua (52%), Guatemala (51%), and Bolivia (51%) and double the estimated pirated rate in Argentina and Brazil. This remained the case in 2023.

Although Honduras was not included on this year's watch list, the USTR noted in the 2023 Special 301 Report that "Honduras has one of the highest rates of signal piracy in Latin America and the Caribbean, with lack of enforcement being an ongoing problem. There are also concerns that a major cable provider in the country offers unlicensed programming, is using that pirated content to expand its market share, and is now moving to illegal streaming as well." Both the U.S. government and affected rightsholders have highlighted this issue and have engaged with the government of Honduras for years. For example, in 2016, the USTR and the government of Honduras agreed on an "Intellectual Property Work Plan." This followed an Out-of-Cycle review in 2015. The Index will continue to monitor these developments in 2024.

16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software:
The government of Honduras has for years been in the process of building a centralized ICT policy framework, including for software usage and procurement. A 2014-2015 review of ICT usage and capabilities with the view of developing a stronger cross-governmental e-government capacity (Plan Maestro del Gobierno Digital para la República de Honduras) found a basic lack of planning and capacity across the entire central government with respect to all facets of ICT procurement, usage, and development, including for software licenses.

In a survey of all major central government departments, the review found that most were lacking in their overall ICT capacities. For example, within the review of the Secretariat of Infrastructure and Public Services, the study found that although the Secretariat kept a central database of ICT equipment and software, licenses and equipment were not updated or properly renewed. The 2020 Decree PCM-086 on E-Government refers to software licensing, but this is in the context of preferences for open-source software and not software asset management or licensing procedures.

Parts of the central government have procurement and software licensing policies in place. For example, since 2003, the Supreme Court and Judiciary have had in place an "Infotechnology Directorate," which is charged with handling all procurement and administration of ICT goods and services. Part of these guidelines and the description of this directorate include the acquisition of licensed software. This lacunae in domestic policies stand in contrast to Honduras' clear commitments under the Dominican Republic–Central America Free Trade Agreement (CAFTA-DR). Article 15.5(9) of CAFTA-DR includes a commitment to ensure central government compliance with using licensed software and actively managing its software assets "in order to confirm that all agencies at the central level of government use computer software only as authorized, each Party shall issue appropriate laws, orders, regulations, or decrees to actively regulate the acquisition and management of software for such use. These measures may take the form of procedures such as preparing and maintaining inventories of software on agency computers and inventories of software licenses."

Honduras should look to the positive effort its neighbor and fellow CAFTA-DR contracting party Costa Rica has put into addressing this issue.

In Costa Rica, the 2012 Executive Decree No. 37549-JP states that all central government ministry and agencies have an obligation to ensure that any and all software used in ICT systems should be fully licensed, whether proprietary or open source. Since 2019-2020, the National Registry Office has provided an automated registration, compliance, and software asset management platform, El Sistema de Legalización de Software. This web portal allows all ministries and relevant government agencies to file annual software audits, inventories, and proof of licensing compliance electronically and provides the registry with a centralized platform to store and process all data and information.

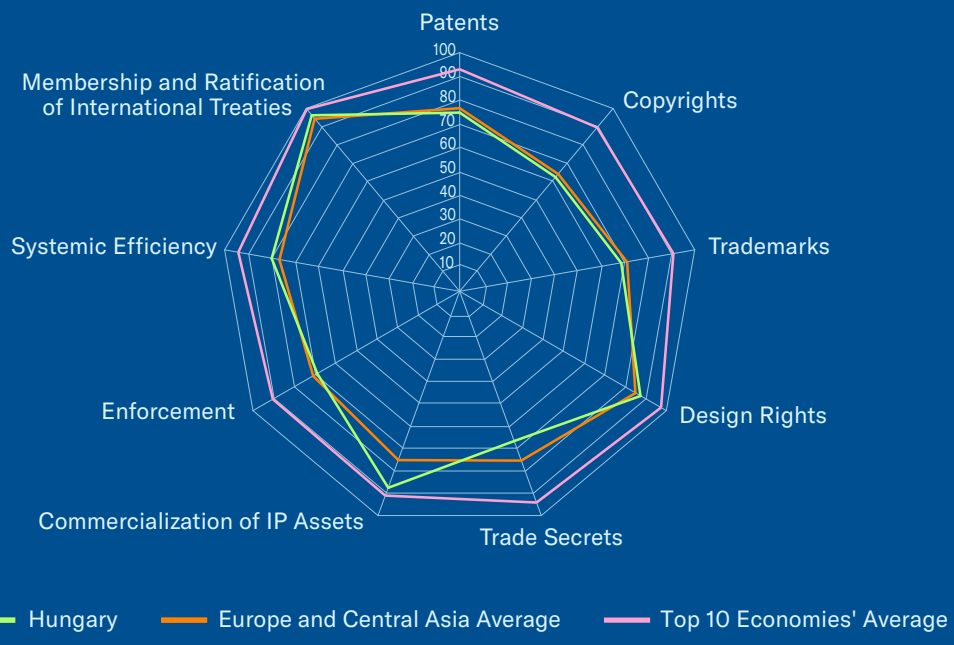
Membership and Ratification of International Treaties

Honduras' score for this Index category remains unchanged at 2.50, or 35.71% of the total available score. Honduras has not become a contracting party, nor has it acceded to any of the IP treaties included in the Index over the past three editions. Being a contracting party to key international IP treaties reflects an economy's broader participation in the international IP community and its embrace of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy chooses to both participate in the international IP system and adhere to established standards and best practices. Honduras is a contracting party to the WIPO Internet Treaties and the Patent Cooperation Treaty. Honduras 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 on Trademarks; the Patent Law Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; the Convention on Cybercrime; or the Hague Agreement Concerning the International Registration of Industrial Designs. Honduras concluded a post-TRIPS FTA with substantial IP provisions in 2006 with the coming into effect of the CAFTA-DR.

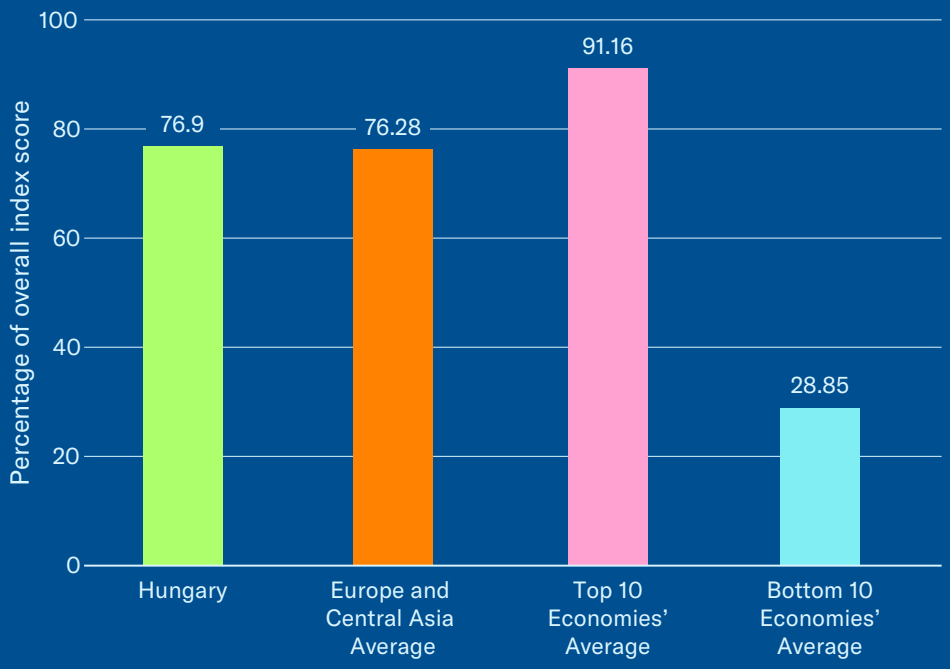
Hungary

Rank
15/55

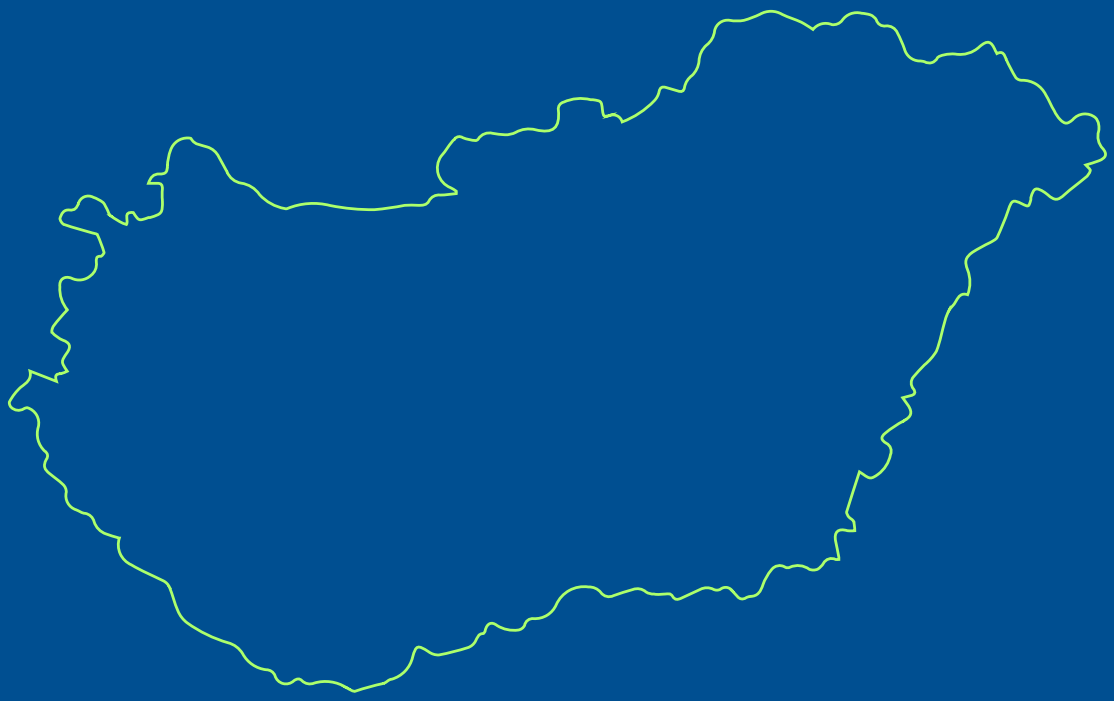
Category Scores



Overall Score in Comparison



Hungary



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

Key Areas of Weakness

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for new EU compulsory licensing regime
- 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 with regard to online and digital content
- Consultation mechanisms are in place, but the time offered to make submissions is relatively short

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**6.75**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	0.75
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**4.38**
10. Term of protection	0.63
11. Exclusive rights	0.50
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	0.75
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.00**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**5.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**4.82**
32. Physical counterfeiting rates	0.68
33. Software piracy rates	0.64
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.00**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 76.90%

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 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. The commission posits in the "Call for Evidence" that a pressing need exists 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have never been used. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 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.

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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023, the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU.

Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allowed companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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 health system. Within this context, IP rights play no part.

The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including Hungary, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

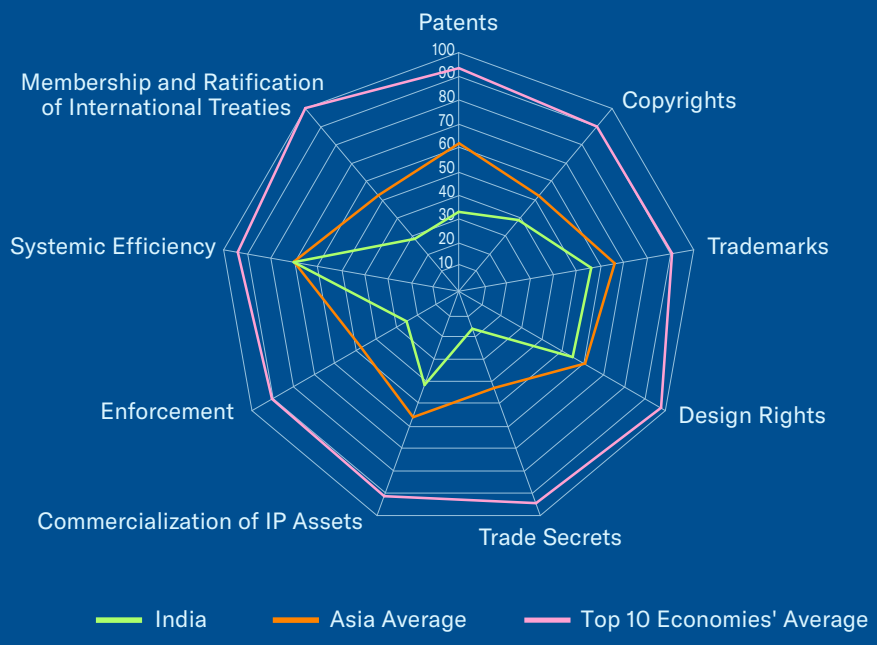
27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

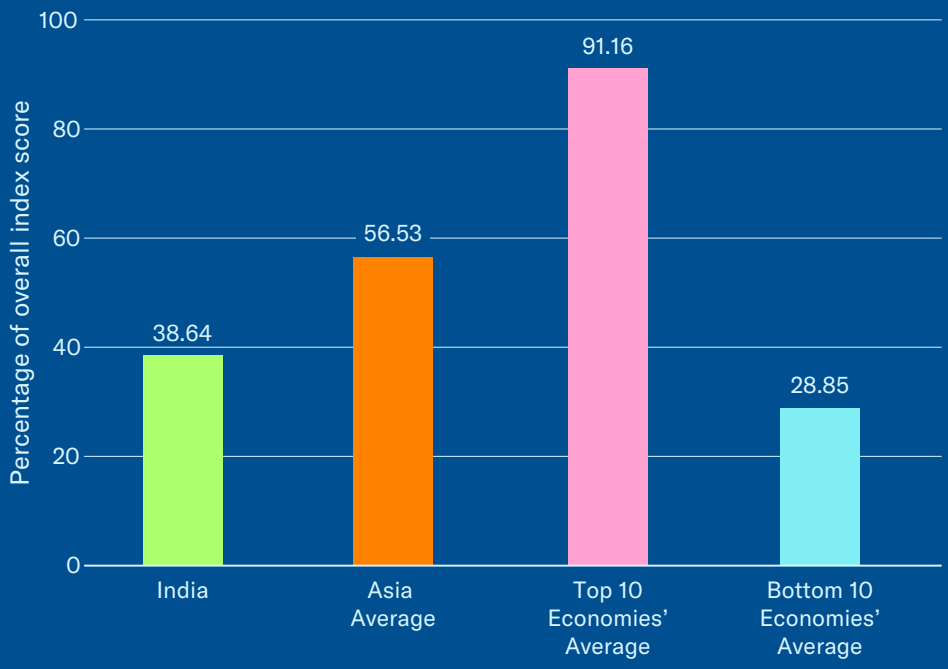
India

Rank
42/55

Category Scores



Overall Score in Comparison



India

Key Areas of Strength

- Cinematograph (Amendment) Bill 2023 includes new language and criminal sanctions on film piracy
- 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

Key Areas of Weakness

- The 2021 dissolution of the Intellectual Property Appellate Board combined with the long-standing issue of an under resourced and overstretched judiciary raises serious concerns about rightsholders’ ability to enforce their IP rights in India and to resolve IP-related disputes
- Barriers to licensing and technology transfer, including strict registration requirements
- Limited framework for the protection of biopharmaceutical IP rights
- Patentability requirements are outside international standards

Key Areas of Strength
(continued)

- Global leader in 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
(continued)

- No RDP or patent term restoration for biopharmaceuticals is available
- Lengthy pregrant opposition proceedings
- Previously used compulsory licensing for commercial and nonemergency situations
- Limited participation in international treaties

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

Indicator	Score
Category 6: Commercialization of IP Assets	**2.50**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**1.76**
32. Physical counterfeiting rates	0.34
33. Software piracy rates	0.42
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 38.64%

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 3. Patentability of computer-implemented inventions (CIIs):
As has been noted in previous editions of the Index, rightsholders in India face many basic challenges in registering and protecting patent-eligible subject matter. To begin with, Indian patent law has in place an additional requirement to patentability that goes beyond the required novelty, inventive step, and industrial applicability requirements. Under Section 3(d) of the Indian Patent Act, there is an additional "fourth hurdle" regarding the inventive step and enhanced efficacy that limits patentability for certain types of pharmaceutical inventions and chemical compounds. Several court cases have established an interpretation of Indian patent law whereby Section 3(d) can be fulfilled only if the patent applicant can show that the subject matter of the patent application has an improved therapeutic efficacy compared with the structurally closest compound as published before the patent application had been filed (regardless of whether a patent application on the earlier compound was filed in India). More broadly, this interpretation and case law also deny patentees with protection that goes substantially beyond what was specifically disclosed in the patent application; compounds that fall within a chemical formula of a claimed group of compounds in a patent application, but that are not specifically disclosed in the patent, could be regarded as not protected. Similarly, the environment for protecting CIIs in India has historically been marred by uncertainty. The Patent Act excludes "a mathematical or business method or a computer program per se or algorithms" as patentable subject matter. Equally, old guidance documents, including the Indian patent manual, did not provide clarity on the extent to which CIIs were patentable.

Over the past decade, new patent guidelines have been published. Unfortunately, these were not always consistent; some were more restrictive than others. The latest available document, published in 2017, "Guidelines for Examination of Computer-Related Inventions (CRIs)," significantly improved the patenting environment for CIIs in India. Unlike previous drafts of the guidelines, there was no requirement for hardware innovation. On this basis, the score for indicator 3 increased by 0.50 in the sixth edition of the Index. Yet the uncertainty over what subject matter remains eligible for patent protection and what constitutes a technical effect within the context of computer software persists. The problem is highlighted by a 2023 court order by the Delhi High Court (Microsoft Technology Licensing, LLC v. The Assistant Controller of Patents and Designs), which found that the Controller General had wholly misunderstood the meaning of Section 3(k) of the Patent Act and had wrongly rejected the plaintiff's patent application. In August 2023, the Controller General opened a public consultation on potential revisions to most of the office's manuals and guideline documents. This includes the existing patent manual and biopharmaceutical and CII guidelines. At the time of research, no formal draft proposal had been made available to the public. The Index will continue to monitor these developments in 2024.

9. Patent opposition:
As noted in last year's Index, the past few years have seen the Indian government take steps to improve its national IP environment, including in relation to the processing of patent applications in a timelier manner. Since 2016's National Intellectual Property Rights Policy, considerable energy has been put into decreasing pendency rates for patent and trademark applications. More staff have been hired and resources invested into modernizing and improving the administrative capacities of the Office of the Controller General of Patents, Designs, and Trademarks. Although these efforts have resulted in some improvement, rightsholders still face substantial delays and processing times for patent and trademark applications. Recognizing this issue, in 2022, the Prime Minister's Economic Advisory Council (EAC-PM) issued the report Why India Needs to Urgently Invest in Its Patent Ecosystem. The report rightly recognizes the centrality of IP rights to modern economic development: "An evolved Intellectual Property Rights regime is the basic requirement for a knowledge-based economy. Technological innovation and scientific research require a robust patenting system. India is seeing a surge in start-ups and unicorns, and an efficient IPR system is an essential prerequisite for a healthy startup ecosystem."

This view echoes the sentiments expressed in 2021 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 among 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 improvements have been made in decreasing processing time and pendency rates, but, overall, India's performance is behind that of other major economies. Specifically, the EAC-PM report points to the need for additional examiners, investments, and a clear delineation of processing time frames and deadlines. As noted in last year's Index, it is especially welcome news that the report acknowledged the detrimental impact the current opposition system has on patent processing times.

Section 25 of the Patents Act outlines the procedures and requirements for initiating opposition proceedings. The law provides for both pre- and postgrant oppositions. The procedures are similar; the key difference is that pregrant opposition can be initiated by "any person," whereas postgrant opposition must be initiated by an interested party. The pregrant opposition mechanism in India has long been criticized for adding significantly to the already lengthy patent prosecution timelines. In 2023, the EAC-PM report's suggestion to clearly define timelines during patent prosecution, including for opposition proceedings, has been followed up with action by the Controller General. In August 2023, the "Draft Patents (Amendment), Rules, 2023" were published. The proposed changes include some improvements to the existing opposition mechanisms, including introducing more defined timelines and vesting more discretion with the Controller General regarding the "maintainability of the representation" of the opposition.

In a separate development, the proposed amendments also make changes to Form 27. This requires that patent holders annually provide information on the extent to which a granted patent has been worked by patentees and licensees. As noted in the Index, in 2020 a new Form 27 was introduced. This was, overall, a positive change. The new form removed questions pertaining to licenses and made it possible to file one form for several patents related to the same invention. Still, the form retained questions about the approximate value as either manufactured or imported into India.

In a positive move, the 2023 changes not only propose to remove any questions related to the approximate value of the patented technology but also clarify that the importation of an invention does not, in itself, mean that it is "not worked" in India. These proposed reforms are important and have the potential to improve India's national IP environment. The Index will continue to monitor these developments in 2024.

Copyrights, Related Rights, and Limitations; and Enforcement

11. Legal measures that provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); and 36. Criminal standards, including minimum imprisonment and minimum fines:
As mentioned in last year's Index, the pirating of film and audiovisual content through illicit video recording has historically been a major challenge to both domestic and international rightsholders in India. To provide a greater level of deterrence to this type of behavior, the Indian government introduced a Cinematograph (Amendment) Bill in 2019. In 2023, a final bill was enacted. The Cinematograph (Amendment) Bill 2023 includes new language and criminal sanctions on film piracy, including potential imprisonment of up to three years and a substantial fine of up to 5% of the production costs of the infringed motion picture. This is a positive development, and the passing of this bill into law should help address a long-standing issue in India. In 2023, the Jan Vishwas (Amendment of Provisions) Bill was enacted. The legislation introduces changes to criminal sanctions in more than 40 pieces of legislation, including the Copyright Act. Specifically, Section 68 of the act related to the making of false statements to law enforcement has been eliminated. It is unclear why the Indian government saw the need to decriminalize this activity. The Index will continue to monitor these developments in 2024.

12. Expeditious injunctive-style relief and disabling of infringing content online:
As the Index has detailed, in what is otherwise a challenging copyright environment in India, a positive trend has emerged over the past decade with rightsholders increasingly being able to defend and enforce their copyrights through injunctive relief. Since 2019, Indian courts have also begun to issue "dynamic" injunctions. Such injunctions address the issue of mirror sites and disabled infringing content making its way back into the public domain by simply being moved to a different access point online. These positive efforts continued in 2023. In January, the Delhi High Court ordered the disabling of access to "stream-ripping" websites and access points. This marked the first time in India an order had been issued targeting this type of infringement. And in August, the same court issued a dynamic injunction against the infringement of audiovisual content that also includes future creation and copyrighted work. The August injunction also marks the first time such an injunction has been issued in India. This judicial route of injunctive-style relief now offers rightsholders an effective and meaningful way of combating copyright infringement in India. The Index will continue to monitor these developments in 2024.

13. Availability of frameworks that promote cooperative action against online piracy:
As mentioned last year, in 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. In late 2022, these rules were finalized. (Additional changes were announced in April 2023 expanding the remit of the rules to include online gaming.)

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 reference IP rights and copyright specifically. Under Section 3(b), intermediaries are obliged to not only inform users of each intermediary's 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 "make reasonable efforts" to ensure compliance with those terms of use. As noted last year, 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 to the expeditious removal of infringing material only upon notification.

In the Copyright Act and amendments introduced in 2012, the burden on intermediaries is even less pronounced; any removal is 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 in Shreya Singal v. Union of India. In a case primarily centered 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 about the potentially infringing nature of a piece of information referred to in the notice. Rather, the court found 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."

In part, the court stated that its reasoning relied on what was deemed to be practical for internet intermediaries and also what has been established as international best practices, arguing that "it would be very difficult for intermediaries like Google, Facebook, etc. to act when millions of requests are made and the intermediary is then to judge as to which of such requests are legitimate and which are not. We have been informed that in other countries worldwide this view has gained acceptance, Argentina being in the forefront." One solution could be the wholesale replacement of the Information Technology Act with a new Digital India Act. This would provide an opportunity to develop a modern system of copyright enforcement for the internet that is fit for the 21st century. Proposals for a new cross-cutting law were published by the Ministry of Electronics and Information Technology in September 2023. At the time of research, no formal draft bill had been made public. The Index will continue to monitor these developments in 2024.

Membership and Ratification of International Treaties

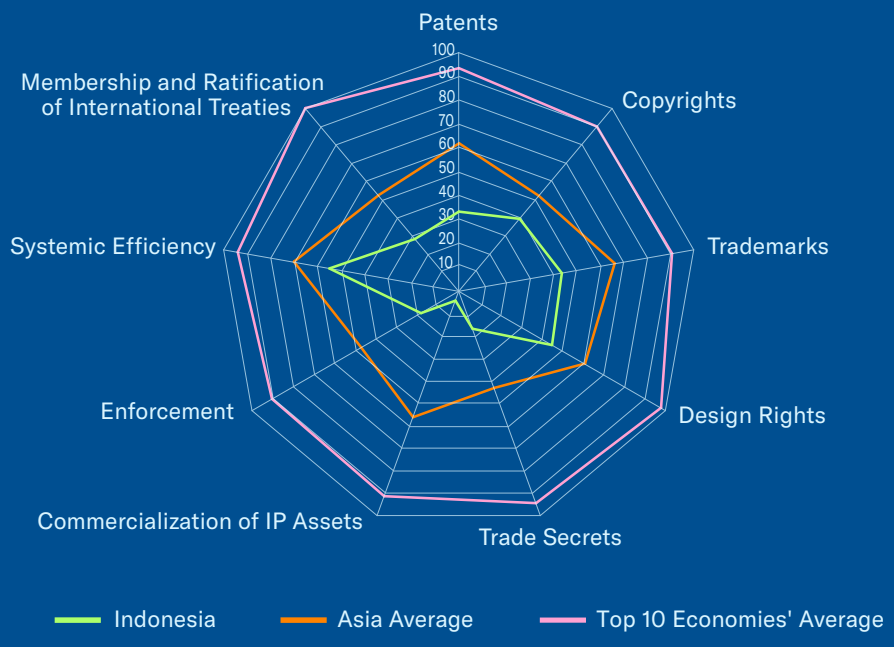
Being a contracting party to key international IP treaties reflects an economy's broader participation in the international IP community and its embrace of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adhere to established standards and best practices. India's score for this category of the Index has increased from 0 in the first edition of the Index to 2, or 28.57% of the total available score. This is notably less than other BRIC economies, including China and Russia. Overall, India is a contracting party and has acceded to the WIPO Internet treaties, the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, and the Patent Cooperation Treaty. India is not a contracting party to the Patent Law Treaty; the Singapore Treaty on the Law of Trademarks; the International Convention for the Protection of New Varieties of Plants, Act of 1991; the Convention on Cybercrime, 2001; or the Hague Agreement Concerning the International Registration of Industrial Designs.

49. The Hague Agreement Concerning the International Registration of Industrial Designs: In a positive development, in August 2023, the Controller General issued a call for public feedback on India potentially becoming a contracting party to several international IP treaties, including the Hague Agreement and Geneva Act. India's accession to the Hague Agreement would be a positive development and would result in a score increase for this indicator.

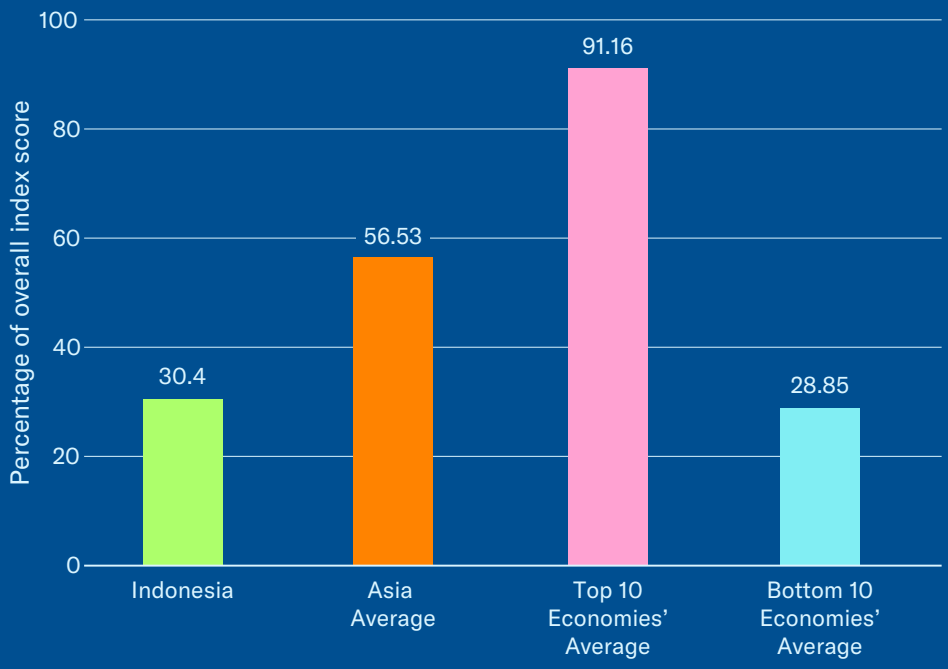
Indonesia

Rank
49/55

Category Scores



Overall Score in Comparison



Indonesia

Key Areas of Strength

- The Omnibus Job Creation Bill modifies general technology transfer and the localization requirement of the 2016 Patent Act to include importation
- Continued strong efforts made by the Directorate General of Intellectual Property to improve enforcement environment
- PPH is in place with JPO
- Administrative relief is available for copyright infringement online

Key Areas of Weakness

- A government-use license was issued in 2021 for patents related to COVID-19 treatment
- History of using compulsory licensing for commercial and nonemergency situations; the 2018-2019 regulations go far beyond the stated goals and circumstances for the issuing of compulsory licenses under the TRIPS Agreement
- The 2020 Presidential Regulation, Number 77, further expands compulsory licensing and emergency use provisions

Key Areas of Strength
(continued)

- Good cabinet-level coordination and a coordinating framework for IP enforcement exist

Key Areas of Weakness
(continued)

- Significant barriers are in place for licensing and commercialization of IP assets, including technology transfer
- Biopharmaceutical patentability standards are outside international norms
- The challenging copyright environment has high levels of piracy because 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 active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.77**
10. Term of protection	0.52
11. Exclusive rights	0.25
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

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

Total: 30.42%

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 and several negative legislative developments over the past eight years. In 2016, the Indonesian Parliament passed a new wide-ranging patent law (Law 13 2016). Although the law aimed to strengthen Indonesia's innovation infrastructure and to encourage more high-tech economic development through the creation and use of new technologies, overall, it did not improve what was already a challenging patenting environment. Article 4 inserted a new heightened efficacy requirement targeting biopharmaceutical products and outlawed second-use claims. Article 167 allowed the parallel importation of follow-on products under patent protection in Indonesia but approved for consumption in other markets. Article 20 of the law made the granting of a patent conditional on localizing manufacturing and/or R&D in Indonesia. In 2018, long-awaited patent regulations provided the possibility of indefinitely postponing these requirements. However, instead of revised regulations, the Indonesian government proposed fresh amendments to the Patent Act in 2020. In a reversal from its previous stance, the proposed amendments—as part of a sprawling legislative package, the Omnibus Job Creation Bill (Undang-Undang (RUU) Omnibus Cipta Kerja)—simply deleted Article 20 of the 2016 Patent Act. Although the removal of this article would have been a positive step, in late 2021, the Indonesian Constitutional Court ruled that the Omnibus Bill was unconstitutional. The court order gave the government two years to remedy these flaws.

In early 2023, the Indonesian parliament approved a new version of the Omnibus package—Government Regulation in lieu of Law No. 2 of 2022 on Job Creation. Article 107(2) related to the working of a patent in Indonesia remains unchanged in this version of the law. This remains a net positive. However, after the enactment of this second version of the Omnibus law, several new petitions were filed with the Constitutional Court arguing the law's enactment did not follow due process and was unconstitutional. At the time of research, it was unclear whether any of these challenges would be successful.
In a separate development, the Indonesian House of Representatives continued to consider an additional bill amending the patent law. The Index will continue to monitor these developments in 2024.

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, HIV drugs, and, most recently, treatments related to COVID-19. These licenses allow the government to exploit existing patent-protected products in the event of threats to national security or an urgent public need. The 2016 amendments to the Patent Act included changes with respect to compulsory licensing, 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 2021, the government issued a government use license for patents related to remdesivir—Gilead Sciences' COVID-19 treatment. Although the license cited the urgent need to access the medicine, the rightsholder in question reported that there was no evidence of existing IP rights or supply being a barrier to accessing remdesivir in Indonesia.

The focus on compulsory licensing as public health policy continued in 2023. In August, the Health Omnibus Law was enacted (Law No. 17). The law repeals and replaces much of the underlying legal framework for the provision of health care services and products, including with respect to biopharmaceuticals and medical devices. With respect to involuntary licensing, Articles 314 and 326 of the law reiterate the government's responsibility, and right, to override patent protection through the use of compulsory licenses to "ensure the sustainability of the supply chain." TRIPS Article 31, including 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), forms 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. The new Health Omnibus Law also strengthens the long-standing drive to localize biopharmaceutical production.

As detailed across the Index, Indonesian industrial and economic policy has historically centered on mandatory localization, widespread protectionism, and limiting foreign entities' access to its market. Although the 2020 Omnibus Law and subsequent legislative packages have introduced substantial reforms and a liberalization of the foreign investment environment, much of this localization drive is still in place for the life sciences sector and has now been strengthened through the new Health Omnibus Law.

These developments further weaken what was already a highly challenging national IP environment for biopharmaceutical rightsholders. Developing new medicines is a long-term, high-risk, resource-intensive process. 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. Undermining the IP framework through the use of compulsory licensing and the overriding of IP rights is counterproductive. Over time, such action will hollow out the national IP environment and the enabling environment 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. As noted last year, reports suggest that the Directorate General of Intellectual Property (DGIP) and the government have proposed new amendments to the Design Law, and these 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 for this indicator. At the time of research, the Indonesian parliament (the People's Consultative Assembly of the Republic of Indonesia) was still examining the bill. The Index will continue to monitor these developments in 2024.

Enforcement

As discussed in previous editions of the Index, in what is otherwise a highly challenging environment for the enforcement of all major IP rights, the DGIP continues to work on improving the enforcement environment. In 2021, several new initiatives were launched and announced. This includes increased anticounterfeiting activity at shopping malls and direct cooperation with international rightsholders and law enforcement, including the FBI; a dedicated interagency taskforce tasked with coordinating enforcement leading to the removal of Indonesia from the USTR's Priority Watch List; a dedicated anticopyright piracy team within the IP office; and 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.

Similarly, some of these new policies were applied in 2022. Specifically, the interagency task force—named the Intellectual Property Operations Task Force—was launched. Like the existing National IP Task Force (established under Presidential Decree No. 4 of 2006), the IP Ops task force includes representatives from across the government. There was also increased activity with respect to the inspection of shopping malls and a program of certifying legitimate physical and online places of commerce. These positive efforts continued in 2023. In January, a new Ministerial Regulation ("On the Management of Criminal Investigations in the Field of Intellectual Property") was published. The regulation outlines the process to be followed by the DGIP and related authorities in the investigation of IP crimes. The DGIP was also reported to be negotiating a memorandum of understanding on combating online counterfeiting with some of Indonesia's major e-commerce platforms. The DGIP and its leadership team should be commended for 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 2024.

Membership and Ratification of International Treaties

Being a contracting party to key international IP treaties reflects an economy's broader participation in the international IP community and its embrace of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy chooses to both participate in the international IP system and adhere to established standards and best practices. Indonesia's score in this category of the Index has increased from 1 (or 25.00%) in the second edition of the Index (the first year Indonesia was included) to 2, or 28.57% of the total available score. This is notably less than other major emerging economies. Overall, Indonesia is a contracting party and has acceded to the WIPO Internet treaties, the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, and the Patent Cooperation Treaty. Indonesia is not a contracting party to the Patent Law Treaty; the Singapore Treaty on the Law of Trademarks; the International Convention for the Protection of New Varieties of Plants, Act of 1991; the Convention on Cybercrime, 2001; or the Hague Agreement Concerning the International Registration of Industrial Designs.

50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices:
As a member of Association of Southeast Asian Nations (ASEAN), Indonesia is a contracting party to several post-TRIPS FTAs, including bilaterally with Japan, South Korea, and India and plurilaterally through the Regional Comprehensive Economic Partnership (RCEP). (The latter was ratified by Indonesia in late 2022 and entered into force in 2023.) However, none of these treaties include "substantive IP provisions and chapters in line with international best practices" as defined under this indicator. For example, the most recent 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 or copyright-based industries, and no score has been allocated to Indonesia under indicator 50.

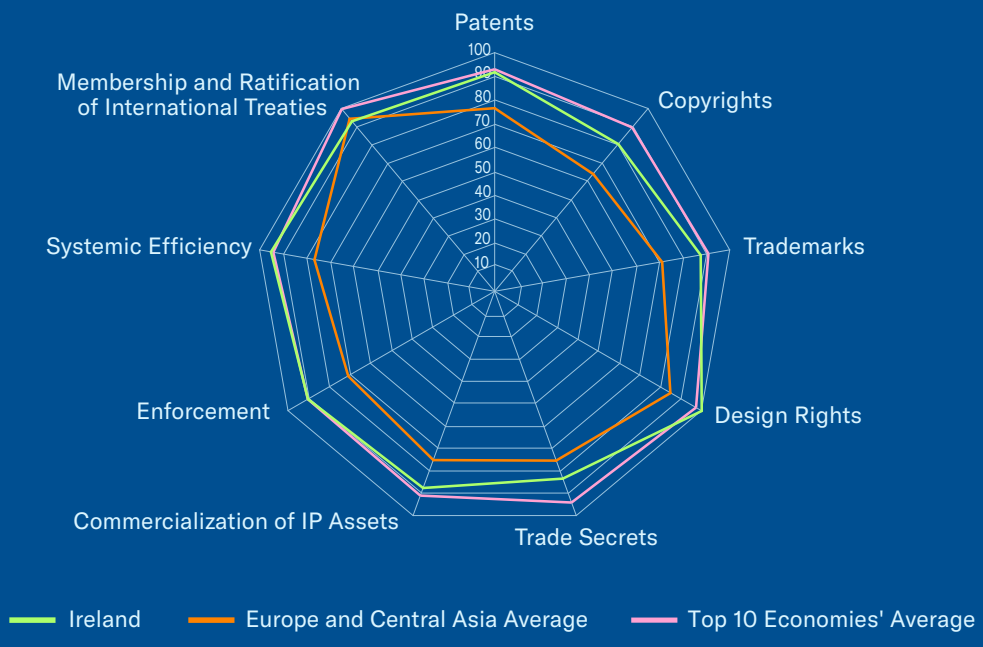
Similarly, Indonesia has not concluded any bilateral post-TRIPS FTAs with substantial IP provisions. For example, the 2019 Indonesia Australia Comprehensive Economic Partnership Agreement (CEPA) does not include any substantive provisions related to the protection of IP. In 2023, Indonesia concluded a CEPA with the United Arab Emirates (UAE). This agreement includes a dedicated IP chapter (chapter 12). This is a positive feature of the agreement; both the UAE and Indonesia should be commended for recognizing the importance of IP-intensive industries and the centrality of IP rights to future trade and economic development in all economies. However, the CEPA does not conform to the standards of a modern post-TRIPS FTA because the IP chapter does not include substantive IP provisions in line with international best practices and identified in the Index. Instead, much of the IP chapter is linked to rights defined and specified in TRIPS. When signed in 1994, the TRIPS Agreement represented an unprecedented commitment and recognition of minimum global IP standards. But 30 years after TRIPS was signed, the agreement is outdated and no longer represents or includes all the standards and protections that a modern, innovation-based economy needs.

Specific features and IP rights missing from these agreements include copyright provisions that are relatively limited with no reference to the challenges that the online environment or infringement represents to rightsholders; no reference to sector-specific provisions, including biopharmaceutical IP rights such as RDP and patent term restoration; and weak enforcement measures, for example, no reference to customs officials' authority to ex officio seize and suspend the release of suspected IP-infringing goods whether intended for the domestic market or in transit. As such, no score has been allocated to Indonesia under indicator 50.

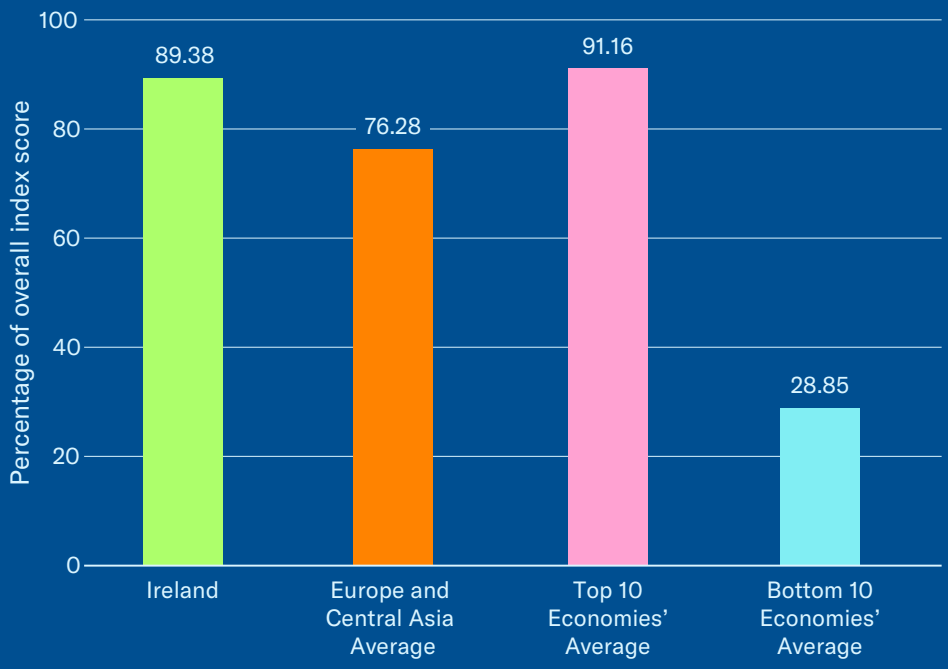
Ireland

Rank
8/55

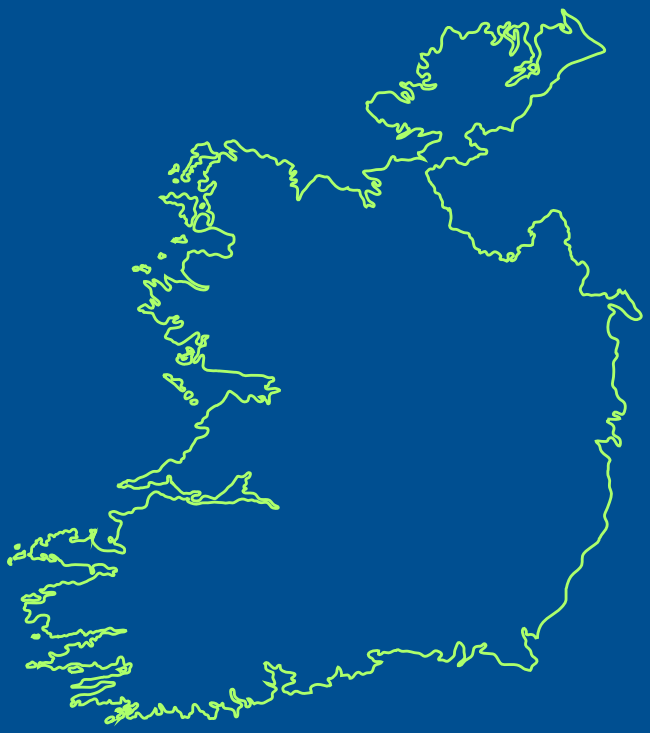
Category Scores



Overall Score in Comparison



Ireland



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

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for new EU compulsory licensing regime
- 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
Category 1: Patents, Related Rights, and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**5.63**
10. Term of protection	0.63
11. Exclusive rights	0.75
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.75
15. Digital rights management	0.75
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.50**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**5.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**6.31**
32. Physical counterfeiting rates	0.85
33. Software piracy rates	0.71
34. Civil and precedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 89.38%

Spotlight on the National IP Environment

Past Editions versus Current Score

Ireland's overall score has increased from 89.36% (44.68 out of 50) in the eleventh edition to 89.38% (44.69 out of 50). This reflects a score increase for indicator 32.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. The commission posits in the "Call for Evidence" that a pressing need exists 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have never been used. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 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.

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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023 the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU.

Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years the EU to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allowed companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access.

For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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 health system. Within this context, IP rights play no part.

The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including Ireland, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU.

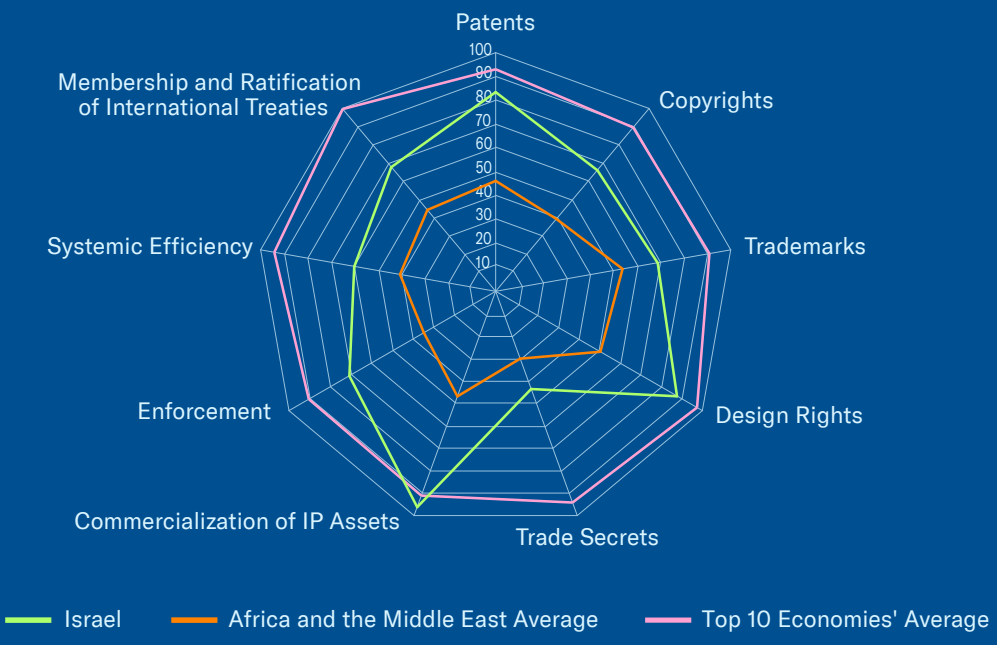
This is an evolving field of IP policy and jurisprudence for subject matter that is deeply complex. Each licensing negotiation is unique and should not be subject to prescriptive government action or intervention, whether through direct or indirect pressure. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

31. Tax incentives for the creation of IP assets: Irish tax law provides both a generous R&D tax credit and IP-specific tax incentives in the form of a "Knowledge Development Box" (KDB). The R&D incentive consists of a 25% tax credit on qualifying expenditures for large entities and 30% for small and micro entities. The KDB historically provided a 50% relief on Irish corporation tax, which, up until 2023, resulted in an effective rate of 6.25% on qualifying income derived from specified IP assets. As part of Ireland's commitments made under the OECD's Base Erosion and Profit Shifting project and 2021 agreement to a global minimum effective rate of corporate tax of 15%, the Finance Bill 2022 raised the effective KDB rate from 6.25% to 10% by lowering the relevant deduction from 50% to 20% on qualifying income. The net value of the R&D tax credit was also reduced. At the time of research, it was not clear how, or if, the Irish government would seek to ameliorate these changes through additional changes to the tax code. The Index will continue to monitor these developments in 2024.

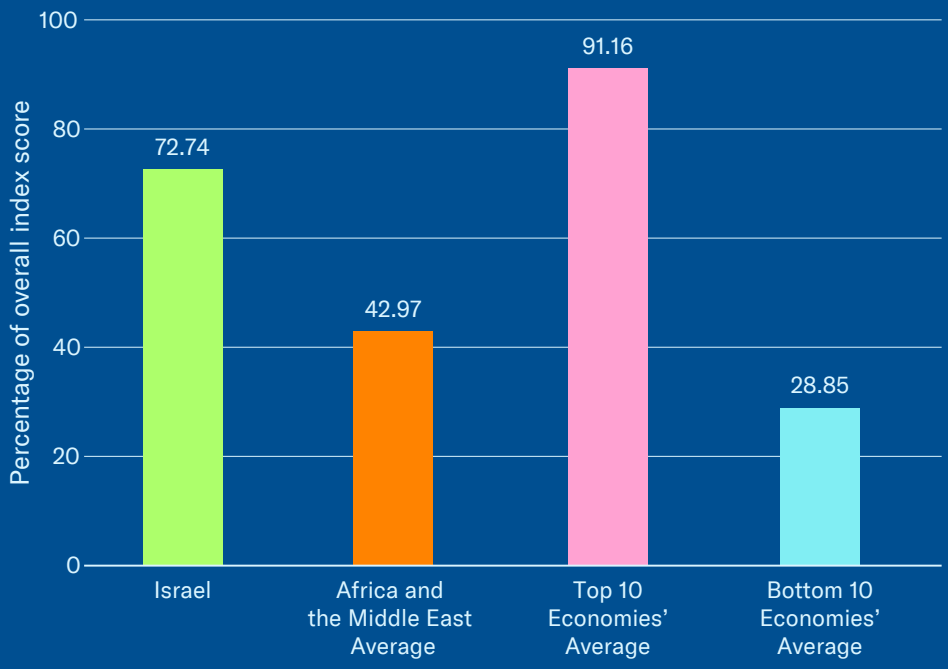
Israel

Rank
17/55

Category Scores



Overall Score in Comparison



Israel

Key Areas of Strength

- The 2019 copyright amendments strengthened enforcement against online infringement and introduced the possibility of injunctive-style relief
- Global leader in technology transfer and international licensing activity—no administrative or regulatory barriers are in place
- Generous R&D and IP-specific tax incentives are in place
- The Israeli Patent Office is an active participant in all major PPH tracks

Key Areas of Weakness

- The 2021 proposed amendments to Patent Law introduce a manufacturing, export, and stockpiling exemption to the current patent term restoration regime
- A compulsory license was issued in response to the COVID-19 pandemic
- Current pregrant patent opposition proceedings are characterized by long delays to patent prosecution
- The extent to which current RDP applies to large molecule products is unclear

Key Areas of Strength
(continued)

- Life sciences IP rights reform efforts have considerably strengthened Israel's IP environment
- An industrial design law was passed in 2017
- Joined the Hague Agreement in 2019

Key Areas of Weakness
(continued)

- More limited participation in international treaties than other high-income OECD economies

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

Indicator	Score
Category 6: Commercialization of IP Assets	**5.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**4.94**
32. Physical counterfeiting rates	0.71
33. Software piracy rates	0.73
34. Civil and precedural remedies	0.75
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.00**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**4.75**
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

Total: 72.74%

Spotlight on the National IP Environment

Past Editions versus Current Score

Israel's overall score has increased from 72.72% (36.36 out of 50) in the eleventh edition to 72.74% (36.37 out of 50). This reflects a score increase for indicator 32.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing 7. Patent term restoration for pharmaceutical products:
Up until 2014, Israel did not offer patent restoration for pharmaceutical products. In 2014, after 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 2020, Ukraine introduced a similar set of provisions, and now Israel has done the same. 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 that seek 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. After the IP policy reform efforts, biopharmaceutical foreign direct investment in Israel surged, growing over 250% in the five-year period after the reforms. As importantly, the IP reforms did not have a negative impact on the domestic generics industry. Contrary to common perceptions and perceived wisdom, providing a supportive environment for innovative activities in the life sciences (including a robust IP regime) has not hurt Israel's generic drugs industry, including its national champion Teva.

Israel has fought hard to strengthen its national IP environment over the past 10 years. 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 for this indicator has changed. This indicator now consists of two distinct variables: 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 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 based on 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 for this indicator will be reduced from 1 to 0.75.

9. Patent opposition:
Israeli patent law provides for a pregrant 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 it is 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, the Ministry of Justice and the Patent Office have held two public consultations and proposed regulatory amendments in 2021. 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. Other patent offices around the world have recognized the need for shortening the time allocated for opposition procedures. For example, in 2016, the EPO instituted the "Early Certainty" initiative, which aimed to cut opposition timelines to 15 months. Statistics published by the EPO in 2020 suggest that this has been achieved with opposition proceedings taking, on average, 15.7 months. 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 pregrant system imposes on inventors and Israeli consumers. Instituting such changes would result in a score increase for this indicator. The Index will continue to monitor these developments in 2024.

Membership and Ratification of International Treaties

Being a contracting party to key international IP treaties reflects an economy's broader participation in the international IP community and its embrace 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 1, or 25%, in the fourth edition of the Index (the first year Israel was included) to 4.75, or 67.86% of the total available score. Although higher than that of some other high-income economies, such as New Zealand and the UAE, Israel's score is notably lower than that of many other OECD economies. Virtually all EU member states, Japan, the United States, and Canada achieve a score of 90% or more in 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.

50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices:
Israel is a contracting party to several post-TRIPS bilateral and plurilateral FTAs. This includes full FTAs and economic partnership agreements with Ukraine, Colombia, 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 Free Trade Agreement—they do not conform to the modern IP standards of other post-TRIPS international trade agreements.

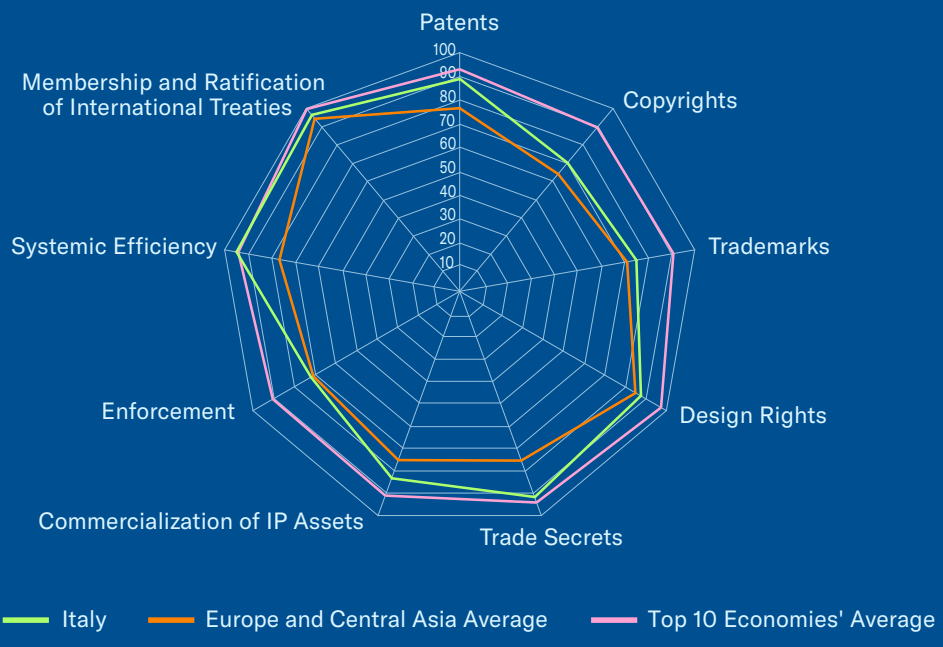
In 2022, the government of Israel and the UAE announced a new free trade agreement, the Comprehensive Economic Partnership Agreement. This follows the historic Abraham Accords Peace Agreement of 2020, which established diplomatic relations between Israel and the UAE. This economic partnership came into effect in 2023. Like the Canada-Israel Free Trade Agreement, the new UAE-Israel partnership includes a dedicated IP chapter, Chapter 11. This is a positive feature of the agreement, and both parties should be commended for recognizing the importance of IP-intensive industries and the centrality of IP rights to future trade and economic development in both Israel and the UAE. Unfortunately, the UAE-Israel partnership does not conform to the standards of a modern post-TRIPS FTA. Specifically, the IP chapter does not include substantive IP provisions in line with international best practices and identified in the Index. Indeed, much of the chapter is linked to rights defined and specified in TRIPS.

When signed in 1994, the TRIPS Agreement represented an unprecedented commitment and recognition of minimum global IP standards. But 30 years after TRIPS was signed, the agreement is outdated and no longer represents or includes all the standards and protections that a modern, innovation-based economy needs. In terms of specific feature and IP rights missing, copyright provisions are relatively limited with no reference to the challenges that the online environment or infringement represents to rightsholders; there is no reference to sector-specific provisions, including biopharmaceutical IP rights such as RDP and patent term restoration; and border measures are notably weak with Article 11.31 making no reference to customs officials authority to ex officio seize and suspend the release of suspected IP-infringing goods whether intended for the domestic market or in transit. As such, despite the obvious geopolitical and geoeconomic benefits to a volatile region, from an IP perspective and the standpoint of the Index, the UAE-Israel Comprehensive Economic Partnership Agreement stands as a missed opportunity with no score allocated under indicator 50.

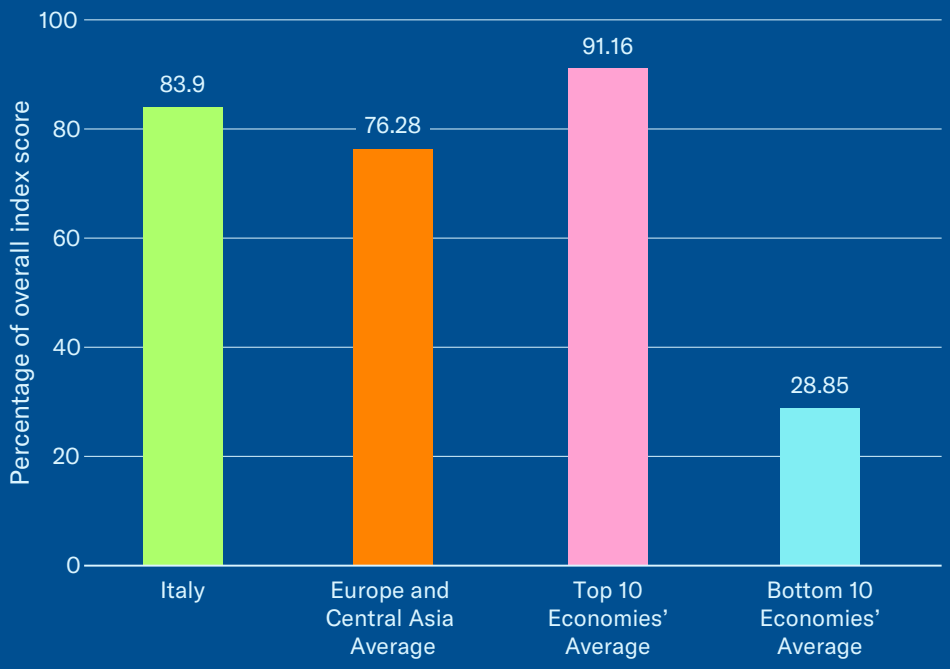
Italy

Rank
13/55

Category Scores



Overall Score in Comparison



Italy

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 are in place
- Fairly advanced national IP framework
- Major life sciences IP rights are in place
- Administrative and judicial mechanisms address online copyright infringement
- Public consultation during policy formation and efforts to raise awareness of IP importance are present

Key Areas of Weakness

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for new EU compulsory licensing regime
- 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
Category 1: Patents, Related Rights, and Limitations	**8.00**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**4.91**
10. Term of protection	0.66
11. Exclusive rights	0.50
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.75**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**5.00**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**5.04**
32. Physical counterfeiting rates	0.72
33. Software piracy rates	0.57
34. Civil and precedural remedies	0.75
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**6.75**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 83.90%

Spotlight on the National IP Environment

Past Editions versus Current Score

Italy's overall score remains unchanged at 83.90% (41.95 out of 50).

Area of Note

As noted in last year's Index, as part of its national response to the launch of the European Commission's "Action Plan on Intellectual Property," the Italian government is reforming 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 2021-2023. Part of this plan includes legislative changes to the Industrial Property Code (IPC). In July 2023, these proposed amendments were enacted, and a new updated IPC came into effect. In addition to seeking to promote greater digitization and simplification of the Italian Patent and Trademark Office's (UIBM) work, the new code makes important changes to existing patent law and technology transfer regulations. With respect to patent protection, Article 59 of the IPC has been revised to ensure that, with the entry into force of the European unitary patent, patents with a unitary effect can coexist with registered Italian patents for the same invention. Articles 65 and 65bis clarify ownership and commercialization opportunities for IP assets and new technologies developed from research conducted at universities and other public institutions.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. The commission posits in the "Call for Evidence" that a pressing need exists 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have never been used. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 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. 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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023, the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU.

Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allowed companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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. Within this context IP rights play no part.

The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including Italy, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

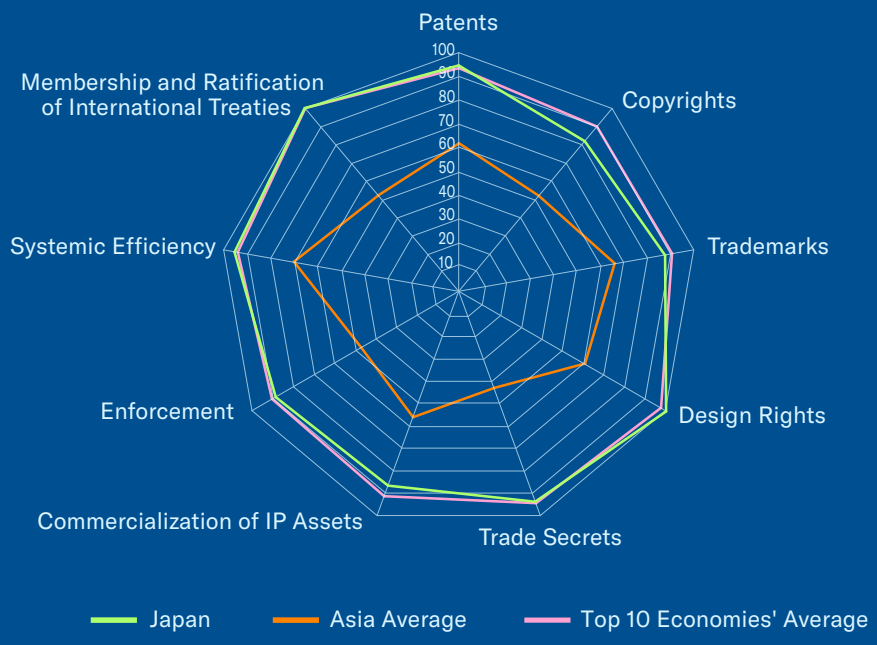
SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU.

This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

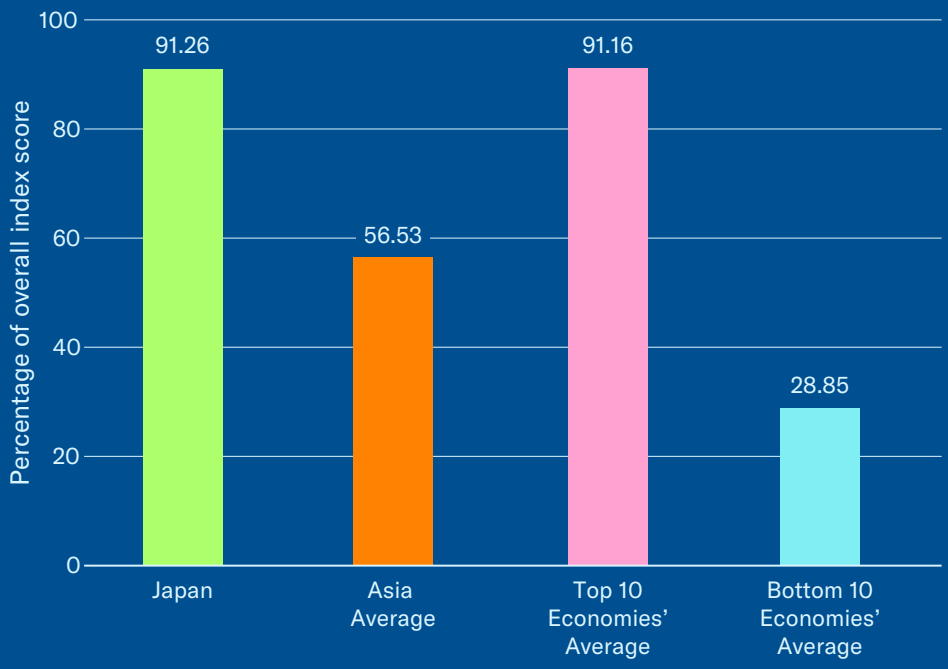
Japan

Rank
6/55

Category Scores



Overall Score in Comparison



Japan

Key Areas of Strength

- Continued strong copyright enforcement efforts
- 2020 amendments to the Copyright Act continue to strengthen the copyright environment
- The Design Act amendments came into effect in 2020 and increase the 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

Key Areas of Weakness

- Concerns about 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 are in place, such as a patent box regime
- Remedies against online copyright infringement remain underdeveloped compared to other OECD economies

Key Areas of Strength
(continued)

- 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 is in place with relevant IP rights and protection available for all major IP rights categories

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

Indicator	Score
Category 6: Commercialization of IP Assets	**5.17**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**6.17**
32. Physical counterfeiting rates	0.83
33. Software piracy rates	0.84
34. Civil and precedural remedies	0.75
35. Pre-established damages	0.75
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 91.26%

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).

Copyrights, Related Rights, and Limitations

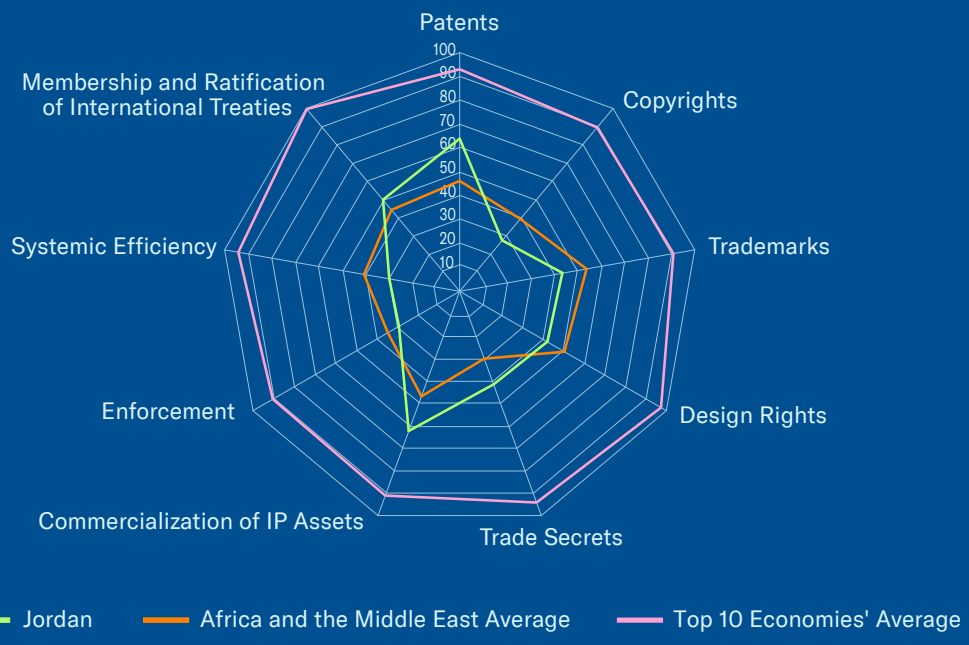
14. Scope of limitations and exceptions to copyrights and related rights:
Agency for Cultural Affairs Copyright Division (part of the Ministry of Education, Culture, Sports, Science and Technology) held a seminar and released a presentation of the agency's views on the interaction between copyright protection and the use and application of AI and machine learning. Text and data mining is an important area of future economic activity because 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. However, this is a new area of copyright law with little in the way of applicable jurisprudence either in Japan or internationally. The presentation and the agency seem to embrace a view of AI application that is almost wholly at the expense of copyright holders. Specifically, it draws a distinction between what is termed an "AI development/learning stage" and a "Generation/usage stage." Slides 32-38 of the presentation seem to suggest that the use of copyrighted materials—with or without a rightsholder's permission—for the "AI development/learning stage" is generally lawful under Section 30(4) of the Japanese Copyright Act and would not infringe copyright. Only slide 39 acknowledges scenarios whereby the learning phase of AI development could potentially harm a rightsholder's copyright and commercial interests. Yet it is not at all clear that, first, such a distinction between a learning/developmental stage and a generative/usage stage of AI-based tools and technologies exists and, second, that current Japanese statute would allow the appropriation and use of copyrighted materials under any such scenario.

Article 30(4) allows a narrow set of exceptions to copyright protection for "use in data analysis (meaning the extraction, comparison, classification, or other statistical analysis of the constituent language, sounds, images, or other elemental data from a large number of works or a large volume of other such data…[or] in the course of computer data processing or otherwise exploited in a way that does not involve what is expressed in the work being perceived by the human senses." However, these exceptions are prefaced by such usage only being allowed if it does not "unreasonably prejudice the interests of the copyright owner in light of the nature or purpose of the work or the circumstances of its exploitation." Similarly, this article—and other copyright exceptions defined in the act—do not allow for the unlawful appropriation or access to copyrighted works. After the agency's seminar and publication of the presentation, a collection of Japanese publishers and rightsholders released a joint public statement calling for more clarity on the interpretation of existing copyright statute and the need for the government to engage rightsholders in this issue. Most concerningly, however, is the agency does not appear to differentiate between legal and illegal acquisition of content, essentially turning a blind eye to AI models trained on pirated content. This presents significant risks for content rightsholders, AI developers, governments, and end users alike, as developers' use of pirated content could lead to low-quality data points and models, as well as hacking, phishing, fraud, and other security issues. The Index will monitor these developments in 2024.

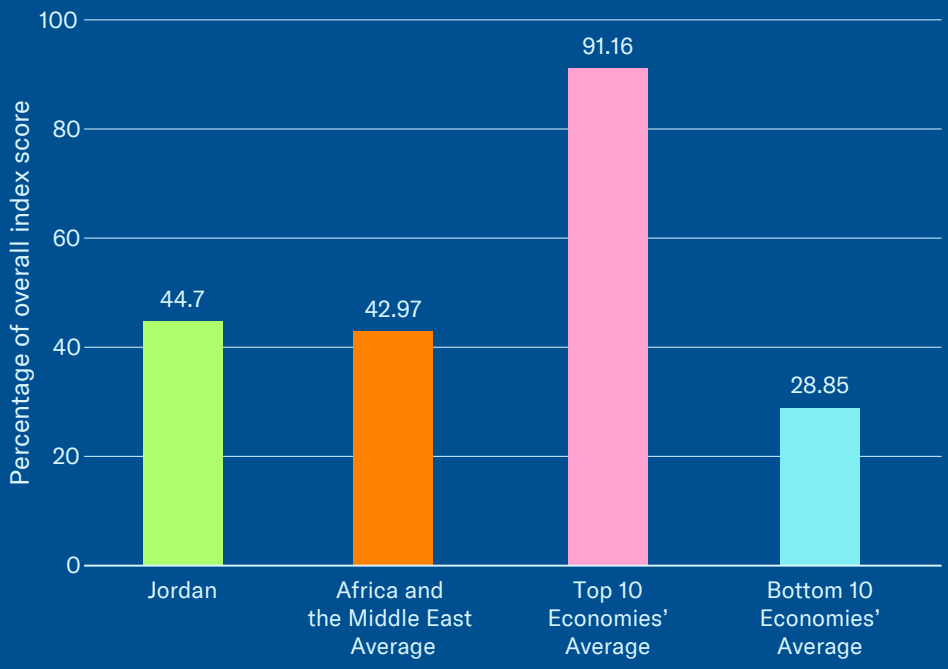
Jordan

Rank
35/55

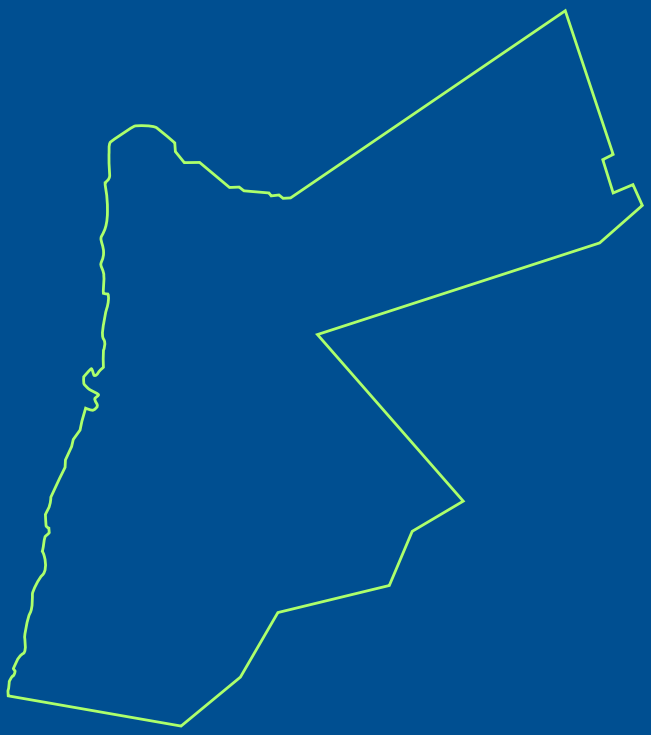
Category Scores



Overall Score in Comparison



Jordan



Key Areas of Strength

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

Key Areas of Weakness

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

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

Indicator	Score
Category 6: Commercialization of IP Assets	**3.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.25
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**2.06**
32. Physical counterfeiting rates	0.36
33. Software piracy rates	0.45
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.50**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**3.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 44.70%

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; Enforcement

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; and 36. Criminal standards including minimum imprisonment and minimum fines:
As noted in previous editions of the Index, copyright infringement through set-top boxes and illicit streaming devices is becoming more widespread throughout Jordan and many other Index economies in the Middle East and North Africa region. The USTR in both the Review of Notorious Markets for Counterfeiting and Piracy and Special 301 Report have included reference to a Jordanian entity called "Spider" that sells pirate set-top boxes and streaming devices. Industry reports suggest that in addition to Spider, several other Jordan-based organizations specialize in the circulation of these devices. The Jordanian Copyright Act provides only basic exclusive rights and does not include specific reference to the internet or mechanisms that address online infringement. No notice-and-takedown system is in place, and no established mechanism exists for gaining injunctive-style relief within the context of copyright infringement.

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. Still, the scale of both physical and online copyright infringement is substantial, and consistent enforcement efforts are lacking.

In this respect, 2022-2023 saw some positive developments. Specifically, at the end of 2022 and beginning of 2023, the Qatari multinational network of sports channels, beIN Sports, announced that, working together with the relevant Jordanian authorities, a series of raids against a branch of retailers selling pirate set-top boxes and streaming devices was carried out. The Jordanian Media Commission was also reported to have ordered the disabling of access to 77 websites that provide illegal access to beIN broadcasting sporting events. Considering the many enforcement challenges in Jordan, these limited efforts are significant developments. Advancing this to develop the means for widespread availability of a defined and copyright-specific mechanism of injunctive-style relief and the option of ISPs disabling access to illegal content through orders from the Media Commission would be an important development.

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. These efforts are frequently used against the most egregious and sophisticated offenders who often profit from illegal activities. Many of these economies are also introducing "dynamic" injunctions. Such an injunction addresses the issue of mirror sites and infringing content that is simply being moved to a different online location. These types of dynamic injunction orders are becoming more commonplace. They have proven to be effective in reducing the availability of copyright infringing content within these jurisdictions. The Media Commission's latest available annual report published in 2021 suggests that only a handful of complaints filed with the commission since 2016 have been related to IP infringement. The Index will continue to monitor this activity in 2024.

Systemic Efficiency

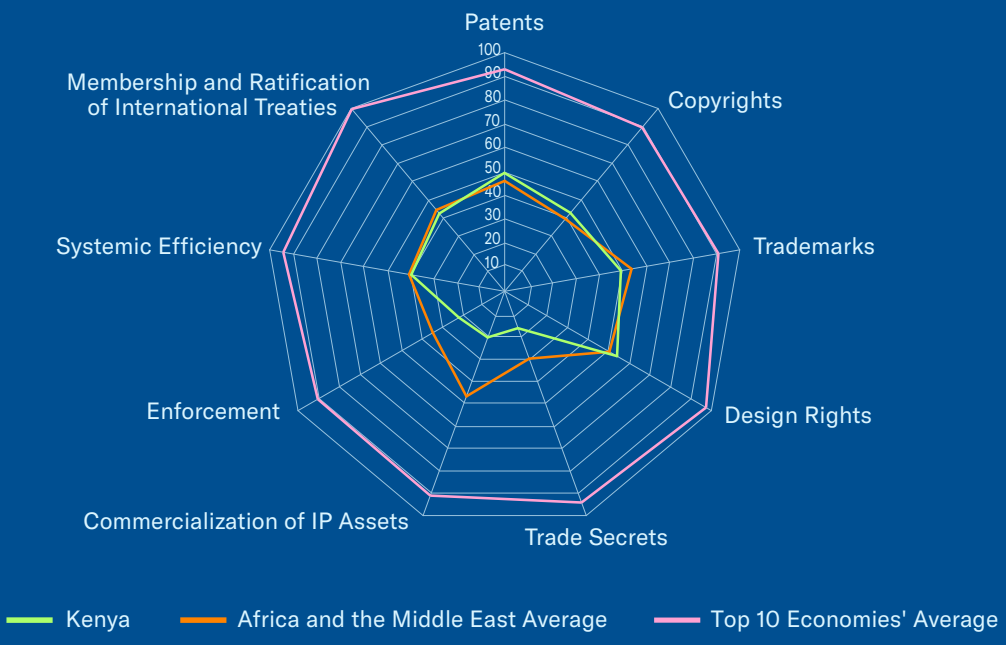
40. Consultation with stakeholders during IP policy formation:
Historically, there has been a degree of uncertainty about the extent to which the government of Jordan and its individual ministries and agencies offer public consultations on proposed legislative and regulatory changes for both IP-related and broader legislation. Individual government agencies regularly share draft regulations and rules with the public and/or solicit input through public consultations, but this historically has not been the norm or consistently required across government practices. In a positive development, this may now be changing. As part of a set of structural economic and political reforms aimed at reforming the Jordanian economy and improving public administration, the Deputy Prime Minister for Economic Affairs and Minister of State for Public Sector Modernization, Nasser Shraideh, announced in May 2023 the publication of a new Impact Assessment Policy Guide developed together with the World Bank. The purpose of the Guide is to give ministries and government agencies a step-by-step road map of the policy development process.

The Guide places a strong emphasis on the importance of public consultations to the policy development process. It describes consultations as a "major tool for producing high quality, credible and transparent" policies and laws. This is a potentially important development; regular consultations with all relevant stakeholders are a prerequisite for developing sound public policy and for promoting good governance for Jordan's national IP environment and beyond. A more formalized and consistently applied public consultation process will also result in a score increase for this indicator. The Index will continue to monitor these developments in 2024.

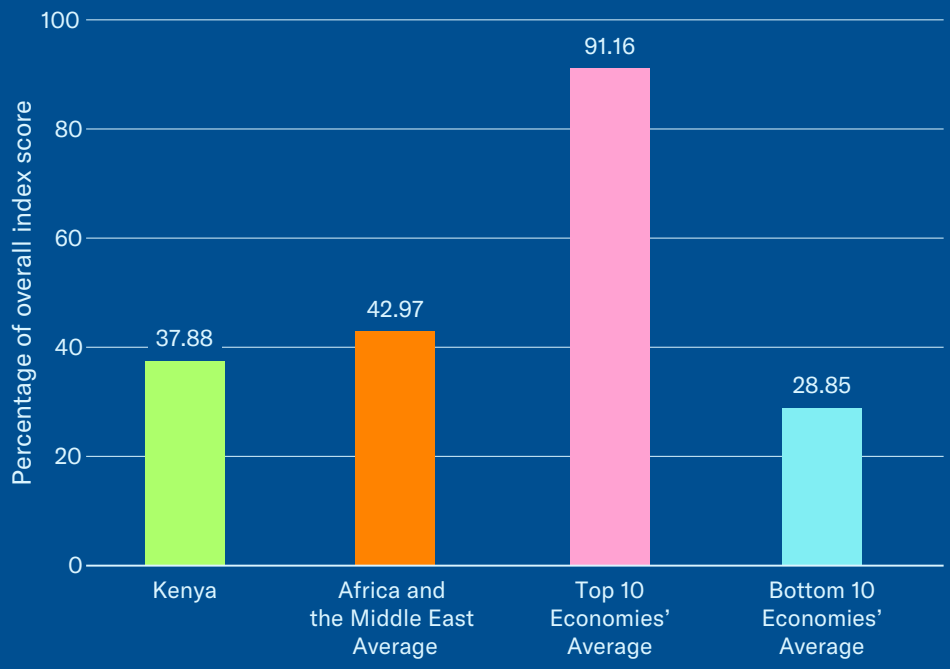
Kenya

Rank
44/55

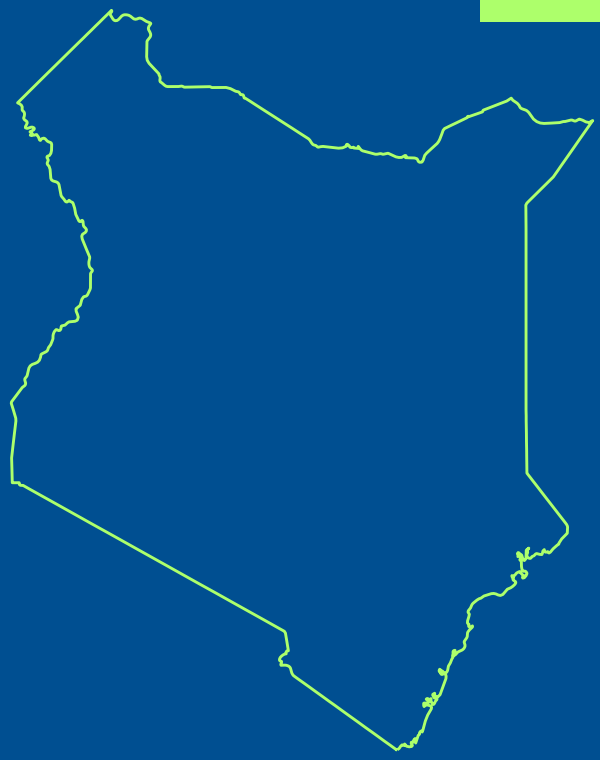
Category Scores



Overall Score in Comparison



Kenya



Key Areas of Strength

- The 2021 Anti-Counterfeit Amendment Regulations allow rightsholders to register their rights with the Anti-Counterfeit Authority
- The 2020 Anti-Counterfeit Act amendments strengthen enforcement powers
- The 2019 copyright amendments strengthen protection of copyright in Kenya
- A basic IP framework is in place, including several sector-specific rights
- Dedicated IP bodies and enforcement agencies

Key Areas of Weakness

- Data Protection (General) Regulations 2021 do not provide clarity on potential data localization requirements under the 2019 Data Protection Act
- The draft IP Bill would combine IP authorities under one office; it is unclear whether each section would have enough resources and staff
- Barriers are in place for licensing and technology transfer
- No R&D or IP-specific tax incentives are in place

Key Areas of Strength
(continued)

- Recent efforts to improve knowledge and frameworks for proper use and commercialization of IP assets

Key Areas of Weakness
(continued)

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

Indicator	Score
Category 6: Commercialization of IP Assets	**1.25**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**1.56**
32. Physical counterfeiting rates	0.30
33. Software piracy rates	0.26
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**2.00**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**3.00**
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 37.88%

Spotlight on the National IP Environment

Past Editions versus Current Score

Kenya's overall score has increased from 37.36% (18.68 out of 50) in the eleventh edition to 37.88% (18.94 out of 50). This reflects score increases for indicators 32 and 42.

Area of Note

After the 46th Session of the Administrative Council of the African Regional Intellectual Property Organization (ARIPO) in late 2022, changes to both the Harare Protocol on Patents and Industrial Design and the Banjul Protocol on Marks took effect in 2023. Although not materially affecting the national IP environment in Kenya, some of these changes are nevertheless important to rightsholders both in Kenya and internationally. To begin with, the term of protection of industrial design was increased from a total period of 10 years to 15 years; this matches the current term of protection (including renewals) in Kenya under the Industrial Property Act. The reforms also introduced a new Section 2 in the Harare Protocol, which formalizes how pregrant, third-party observations can be submitted. Rule 19 of the regulations now defines the process whereby such observations can be submitted and formalizes the procedure. A formalized route for the submission of third-party observations is available in most leading jurisdictions, and the process within ARIPO is now better aligned with other major IP offices.

Patents, Related Rights, and Limitations

3. Patentability of computer-implemented inventions (CIIs):
In the second half of 2022, Kenyans elected a new government under the leadership of President William Ruto. A key part of the new government's economic reforms—the "Bottom-Up Economic Transformation Agenda" —is a redoubling of Kenya's efforts to expand its digital infrastructure and economic growth from the ICT-based industries. In 2022, the Ministry of Information, Communication, and the Digital Economy released the Kenya National Digital Master Plan 2022–2032. The Plan builds on previous efforts, including the National ICT Policy and Digital Economy Blueprint. In a welcome development, the Plan includes specific reference to the protection of ICT-based technologies and computer software. Under Annex A1.5 Policy, Legal & Regulatory Framework and A4.5 Policy, Legal & Regulatory Framework, the inclusion, and identification of computer software as an IP asset within the Industrial Property Act is listed as a key performance indicator and metric. This is a positive development because there has historically been a degree of uncertainty regarding the patentability of software and/or CIIs in Kenya.

Both the Industrial Property Act and Kenya Industrial Property Institute's (KIPI) Guideline for the Examination of Patents, Utility Models, and Industrial Designs are silent on the patentability of CIIs. Section 21(3) the Industrial Property Act excludes as patentable subject matter "discoveries, scientific theories and mathematical methods… schemes, rules or methods for doing business, performing purely mental acts or playing games… [and the] mere presentation of information." The Guideline simply states that "methods of doing business" is an exclusion of importance. Methods of bookkeeping and trading stocks and shares are generally not patentable.

Kenya is also a member of the African Regional Intellectual Property Organization (ARIPO) and a contracting party to the Harare Protocol on Patents and Industrial Designs. The protocol, subsequent amendments, and patentability guidelines issued by the ARIPO (Guidelines for Examination at the ARIPO Office) are also not clear about the patentability of software or CIIs. On the one hand, Section 3, paragraph 10(h) of the Harare Protocol explicitly excludes "programs for computers." Conversely, ARIPO's examination Guidelines state quite clearly that CIIs may be granted if there is a clear technical effect and a contribution to the prior art. However, patent statistics housed by WIPO for Kenya and ARIPO suggest that only a small number of patent applications (patent publications by technology) were under the categories "Computer technology" and "IT methods for management."

Data for Kenya are available only for the years 1980-1989. During this period, four patent applications were published under the categories "Computer Technology" and "IT Methods for Management." This compares with 959 total applications during this period. Although the paucity of the data and limited time covered make it difficult to draw any firm conclusions, regional data for ARIPO suggest that CIIs and ICT-related patents are relatively few. Between 1980 and 2017, 320 patent applications were published under the categories "Computer Technology" and "IT Methods for Management." This compares with 10,421 total applications during this time, or 3.07% of the total number of applications published. Statistics for the number of patents granted are not available by technology for Kenya or ARIPO. However, in most jurisdictions, not all patents published are granted. A revised Industrial Property Act and accompanying patent examination guidelines that provide clarity on the patentability of computer software and/or CIIs would mark a substantial improvement in Kenya's national IP environment. The full implementation and application of such a revised law and practice would also result in a score increase for indicator 3. The Index will continue to monitor these developments in 2024.

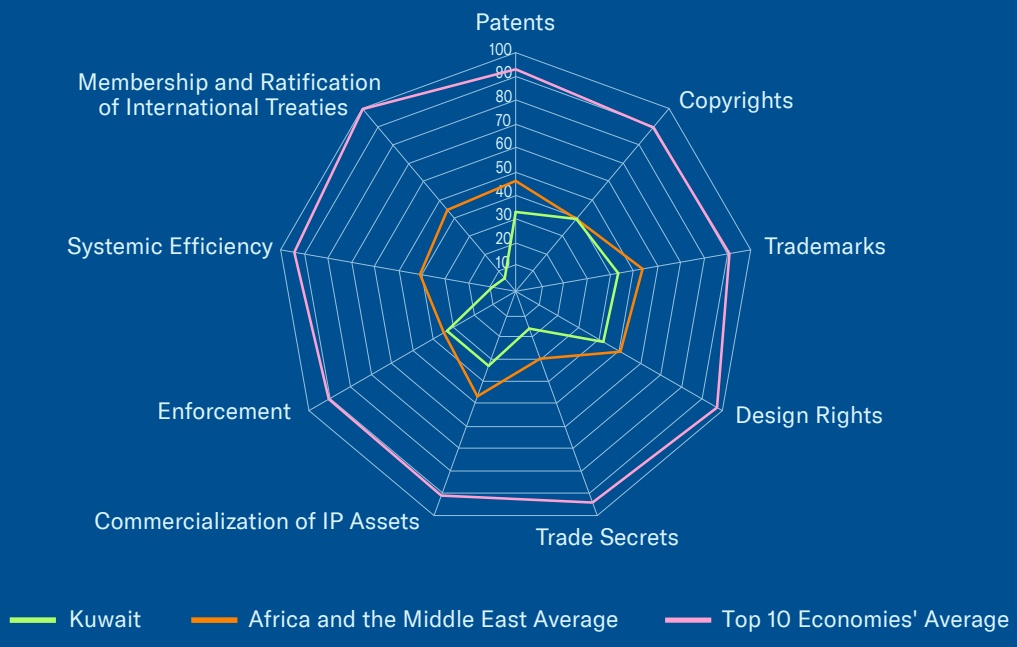
Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs:
Up until now, there has been only limited support for the creation and use of IP assets for SMEs by relevant authorities in Kenya and through ARIPO. For example, KIPI does not provide reduced registration fees or an expedited examination route for SMEs. Some ad hoc technical assistance has historically been provided through various outreach activities, including local workshops at trade fairs, universities, and research institutes, but this assistance has not been aimed specifically at SMEs. Similarly, ARIPO does not provide reduced registration fees for SMEs. The office offers an expedited examination pathway, but this is not specific to or for SMEs. Some technical assistance is available through the ARIPO Academy, but, again, this is directed at students and IP practitioners and not at small businesses. Specifically, the academy offers a master's degree in partnership with three separate academic institutions and WIPO in Zimbabwe, Ghana, and Tanzania. This paucity of SME-specific technical assistance changed in 2023 with Kenya joining the Inventor Assistance Program. Developed by WIPO and the World Economic Forum and launched globally in 2016, the program seeks to match inventors with legal practitioners who provide pro bono legal advice on the technical evaluation and registration process for the IP created. As a result of this positive activity, the score for this indicator has increased by 0.25.

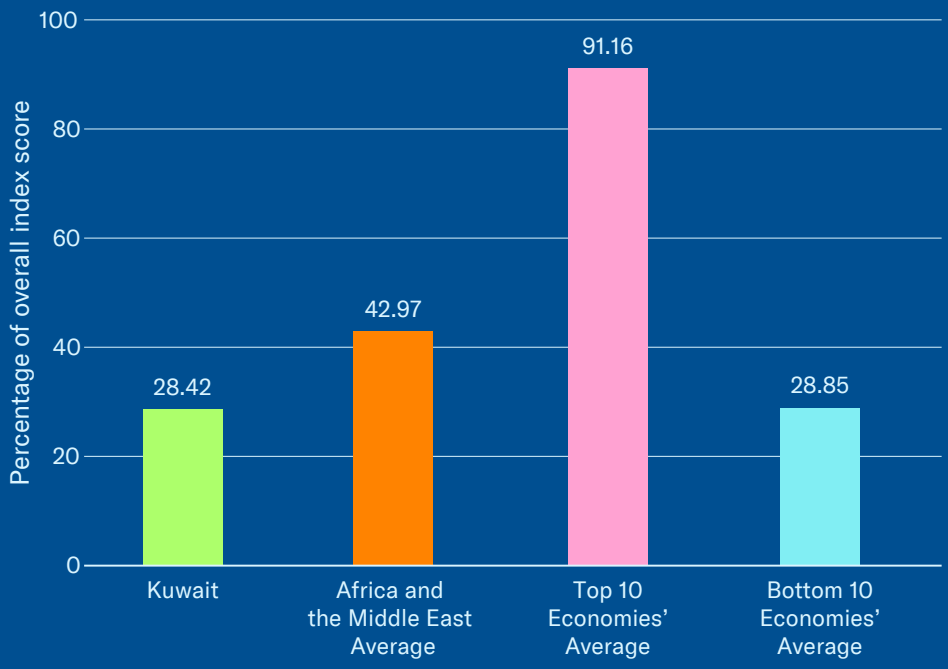
Kuwait

Rank
51/55

Category Scores



Overall Score in Comparison



Kuwait

Key Areas of Strength

- A new administrative copyright enforcement option was made available in 2022 through the National Library
- A basic IP framework is in place
- Participates in regional patent and trademark harmonization efforts through Gulf Cooperation Council (GCC)

Key Areas of Weakness

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

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**3.00**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.25
4. Plant variety protection	0.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.78**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**1.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.25
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
Category 6: Commercialization of IP Assets	**2.00**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**2.33**
32. Physical counterfeiting rates	0.40
33. Software piracy rates	0.43
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**0.50**
39. Coordination of IP rights enforcement	0.00
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.00
Category 9: Membership and Ratification of International Treaties	**0.50**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 28.42%

Spotlight on the National IP Environment

Past Editions versus Current Score

Kuwait's overall score remains unchanged at 28.42% (14.21 out of 50).

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

12. Expeditious injunctive-style relief and disabling of infringing content online; 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 noted in previous editions of the Index, the IP enforcement environment in Kuwait has historically been difficult. Although civil remedies, including injunctive relief, the suspension of alleged infringing activities, and the seizure of infringing materials and goods, are available in law for most major IP rights, active enforcement has been lacking. Estimated rates of software piracy have essentially stood still since 2011; the latest estimates from BSA published in 2018 indicated that 57% of software in Kuwait was unlicensed. This is virtually unchanged since 2011 when the estimated rate was 59%. As one of the most developed economies in the Middle East region with one of the highest per capita incomes in the world, this figure stands out. Saudi Arabia and Qatar both have estimated rates of unlicensed software at 47% and the UAE at 32%—all substantially lower than those of Kuwait. Similarly, the lack of enforcement against counterfeit and hard goods piracy was one of the chief reasons Kuwait was, up until 2022, included on the USTR's Special 301 Watch List. Nevertheless, the past few years have seen some improvements to the national IP environment.

As noted in the Index at the time, in 2019, a new copyright law, Law 75 on Copyright and Related Rights, was enacted. This made some important changes to Kuwait's copyright regime with potential new avenues of copyright 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 has, since these amendments took effect, offered rightsholders the option of filing copyright infringement complaints directly through an online portal.

This administrative enforcement option comes on top of a preexisting mechanism through the Communications and Information Technology Authority (CITRA). Since 2014-2015, new laws related to telecommunications and cybercrime have invested vast powers in CITRA to oversee and regulate the online space. These laws have also included some reference to the protection of copyright. For example, 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 late 2022, these powers of administrative enforcement were extended to other IP rights, including trademarks.

Like the National Library, today the Ministry of Commerce and Industry offers rightsholders the ability to submit infringement complaints directly through their website. However, it remains unclear the extent to which these enforcement powers are related to the sale of counterfeit and trademark infringing goods online or only in a physical marketplace. There has historically been no legally defined notification system aimed at allowing rightsholders to request the removal of trademark infringing content online. Neither the Trademark Law, the Electronic Transactions Law, nor the Cybercrime Law includes specified remedies for trademark infringement. As mentioned with respect to the disabling of websites hosting copyright infringing material, CITRA has a broad mandate to disable any web content that "contradicts [the] public interest" and has a designated web portal for such requests. Should rightsholders be able to enforce their trademark rights more effectively through the Ministry of Commerce and Industry's new online complaints portal, this would be a positive development and would result in a potential score increase for indicator 20. The Index will continue to monitor these developments in 2024.

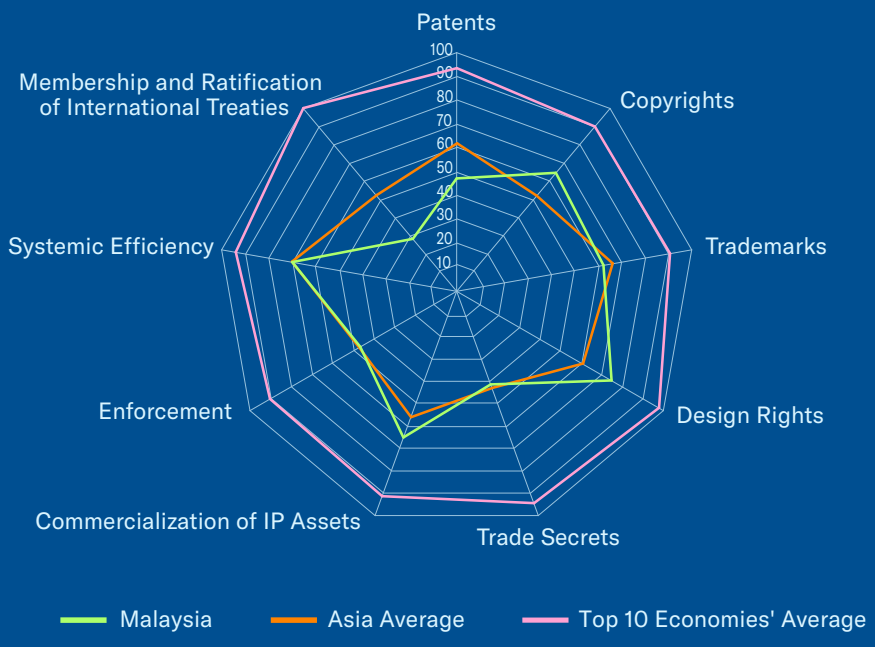
Membership and Ratification of International Treaties

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

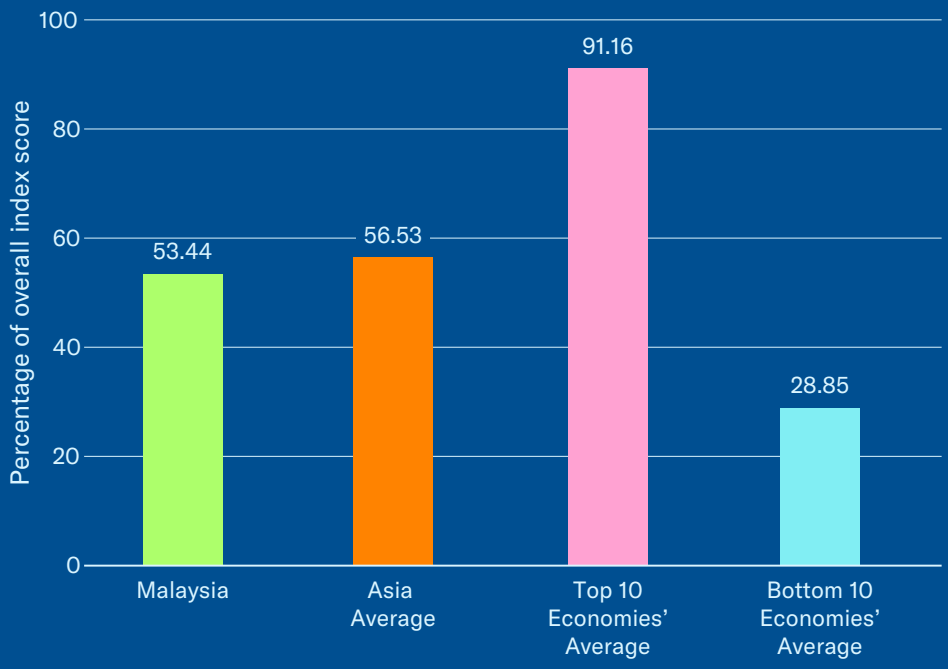
Malaysia

Rank
27/55

Category Scores



Overall Score in Comparison



Malaysia

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
- The 2022 amendments to the Patent Act now provide a defined pathway of postgrant opposition proceedings
- The 2020 Trademark Act amendments strengthen the enforcement environment
- Generous R&D and IP-specific tax incentives are in place

Key Areas of Weakness

- A government-use license (the equivalent of a compulsory license) was 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

Key Areas of Strength
(continued)

- The Intellectual Property Corporation of Malaysia (MyIPO) 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

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**4.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	0.25
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**4.53**
10. Term of protection	0.53
11. Exclusive rights	0.75
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	0.50
15. Digital rights management	0.75
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**3.92**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**3.27**
32. Physical counterfeiting rates	0.53
33. Software piracy rates	0.49
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.75
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 53.44%

Spotlight on the National IP Environment

Past Editions versus Current Score

Malaysia's overall score remains unchanged at 53.44% (26.72 out of 50).

Copyrights, Related Rights, and Limitations; and Enforcement

11. Legal measures that 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:
In 2023, Malaysian authorities continued with their strong enforcement efforts against online piracy and, specifically, the sale and distribution of illicit set-top boxes used to access and stream illegal content. Several prosecutions took place with both the IP High Court and several magistrates courts handing down criminal sentences. As in many other Index economies, there has been an explosion in the growth and use of internet-based applications that provide infringing content to set-top boxes in Malaysia. 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.

As noted over the past several editions of the Index, Malaysian rightsholders and policymakers have acted forcefully in response with injunctive-style relief and the disabling of access to infringing content playing a key part in the government's response. 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, 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. 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 $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. The Index commends these positive actions and will continue to monitor these developments in 2024.

Trade Secrets and the Protection of Confidential Information; Enforcement; and Membership and Ratification of International Treaties

23. Protection of trade secrets (civil remedies); 24. Protection of trade secrets (criminal sanctions); 37. Effective border measures; and 50. Post-TRIPS FTA:
In November 2022, Malaysia formally ratified the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), and the agreement officially came into force. As noted in past editions of the Index, after the withdrawal of the United States from the original Trans-Pacific Partnership (TPP), the CPTPP was fundamentally revised and many parts of the original treaty were suspended.

With respect to Chapter 18 (Intellectual Property), numerous critical provisions were excluded, including for patentable subject matter, biopharmaceutical-specific IP rights such as regulatory data protection, copyright protection and enforcement, and 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 Malaysia or to any of the other contracting parties included in the Index under indicator 50. (Separately, Malaysia and the EU concluded and signed a Partnership and Cooperation Agreement in December 2022. This agreement includes a reference to IP rights but does not constitute a new FTA.) Still, the text of the CPTPP retains important aspects of the original TPP's IP provisions, including, for example, provisions related to trade secrets and border enforcement. Specifically, Article 18.78 Trade Secrets requires contracting parties to provide relevant protection in relation to the misappropriation, improper acquisition, use, or disclosure of trade secrets or confidential business information. Subsections 2 and 3 also require contracting parties to provide minimum criminal procedures and penalties.

In Malaysia, existing civil and criminal remedies are limited and based largely on common law. Statutory law does not provide a defined level of protection or criminal remedies in relation to the misappropriation, improper acquisition, use, or disclosure of trade secrets or confidential business information. Any potential criminal enforcement, for instance, would be based on either existing criminal statute—which relates primarily to physical tangible property—or the Computer Crimes Act, but this pertains solely to data that are housed or processed on a computer. Penalties under the latter are up to five years' imprisonment and/or a fine of up to $10,000.

The CPTPP also 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. This includes against goods in transit, destined for export, and not intended for the domestic market. Article 18.76(5) of the treaty states, "Each Party shall provide that its competent authorities may initiate border measures ex officio with respect to goods under customs control that are: (a) imported; (b) destined for export; or (c) in transit."

Under the Trademark Act, the Royal Malaysian Customs Department (RMC) has ex officio powers to act against suspected infringing goods. Section 70(o) states explicitly that "any authorised officer may detain or suspend the release of goods which, based on prima facie evidence that he has acquired, are counterfeit trade mark goods."

Unfortunately, this ex officio power does not extend to goods in transit. In fact, any border enforcement action against goods in transit has historically been marred by a degree of uncertainty. To begin with, Section s70d(8) of the Trademark Act excludes seizure of goods in transit: "Where an authorised officer has been notified by the Registrar, he shall take the necessary action to prohibit any person from importing goods identified in the notice, not being goods in transit, and shall seize and detain the identified goods."

There has also been the added dimension of free trade zones and, specifically in Malaysia, the interaction between the Free Zones Act and relevant IP rights legislation. In many economies, not just Malaysia, goods in transit and goods passing through free trade zones are generally not subject to detainment and seizure.

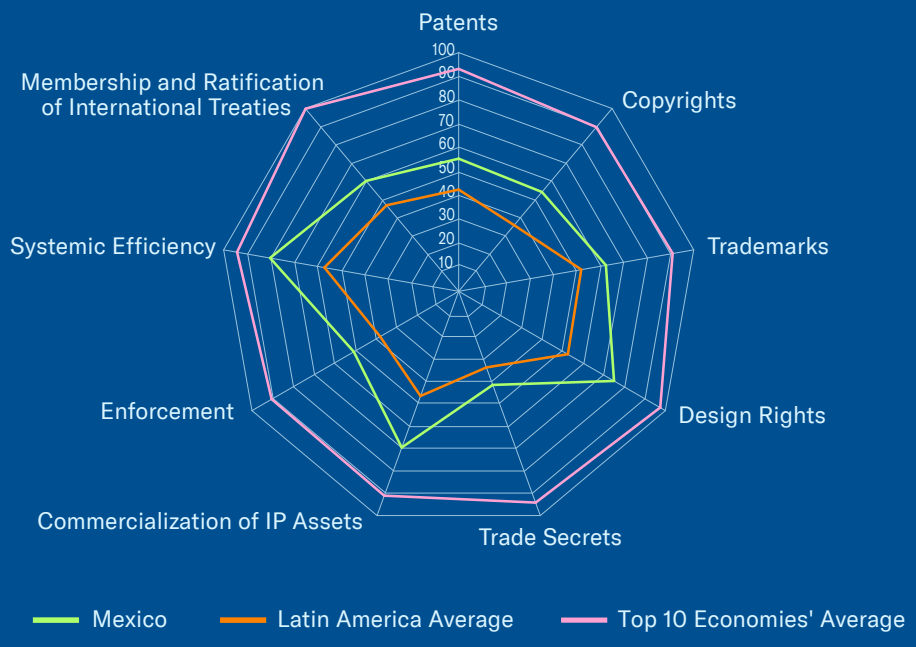
On a positive note, and as noted in the Index in 2019, the Malaysian High Court in the same year issued a final decision in a long running trademark infringement case between Phillip Morris and an Egyptian tobacco manufacturer (Philip Morris Brands Sari v Goodness For Import and Export & Ors). The decision placed perpetual mandatory injunctions for the trademark infringement and passing off and ordered the RMC to destroy the infringing products at the owner's expense. Most importantly, the case provided a strong precedent for the RMC to continue to take action against suspected infringing goods even if they were in transit. In closing, the judgment stated, "This judgment sends a clear message that Malaysian ports, airports and territory cannot be used to transit goods by any mode which infringe Malaysian registered trade marks or which constitute the subject matter of a tort of passing off (actionable in Malaysia)." Unfortunately, it is not clear that there has been a notable increase in ex officio action against counterfeit goods in transit in the intervening years.

The U.S. State Department in its 2023 Investment Climate Statement noted that "there are concerns that the RMC is not always effectively identifying counterfeit goods in transit." Should these referenced provisions of the CPTPP related to trade secrets and border enforcement be incorporated into existing Malaysian statute and practice, this would result in increased scores for indicators 23, 24, and 37. The Index will continue to monitor these developments in 2024.

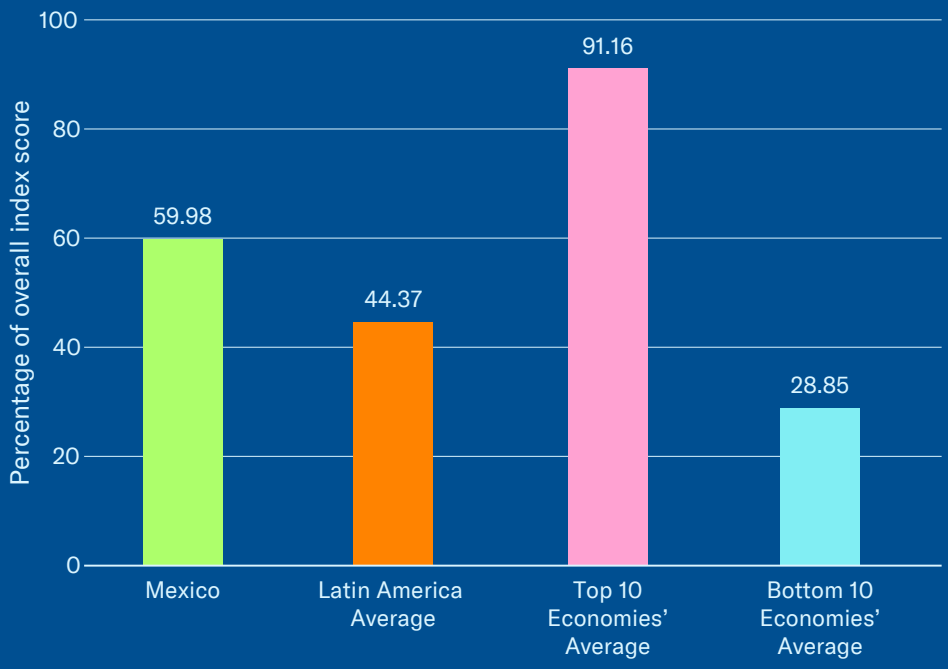
Mexico

Rank
23/55

Category Scores



Overall Score in Comparison



Mexico

Key Areas of Strength

- 2021 publication of an IMPI study on the economic impact of IP-intensive industries in Mexico: analysis conducted with EUIPO and modeled on EPO and USPTO studies
- The 2020 amendments to the Industrial Property Law implement some provisions of the USMCA
- The 2020 amendments to the Federal Law on Copyright implement many provisions of USMCA
- The term of protection for industrial design rights has been extended to 25 years

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
- USMCA patent obligations are not fully met, most notably requirements for an effective pharmaceutical-related patent enforcement and resolution mechanism

Key Areas of Strength
(continued)

- Efforts have been made to ease the ability to commercialize IP assets and to develop public-private partnerships, particularly for public research organizations and universities
- A dedicated endeavor is in place to streamline the IP review process and criminal justice system and to harmonize them to international standards
- Efforts have been made to increase awareness of the importance of IP rights

Key Areas of Weakness
(continued)

- Unclear amendments regarding copyright protections and enforcement, possibly in violation of USMCA obligations

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**4.99**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.00
4. Plant variety protection	0.74
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**3.79**
10. Term of protection	0.79
11. Exclusive rights	0.50
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.25

Indicator	Score
Category 6: Commercialization of IP Assets	**4.17**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incenstives 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 precedural remedies	0.50
35. Pre-established damages	1.00
36. Criminal standards	0.75
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**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, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 59.98%

Spotlight on the National IP Environment

Past Editions versus Current Score

Mexico's overall score has increased from 58.98% (29.49 out of 50) in the eleventh edition to 59.98% (29.99 out of 50). This reflects a score increase for indicator 8.

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; rather, some have compounded the existing deficiencies.

In 2019, the Mexican Senate proposed modifications to the Health Law. Under the proposed system, only one patent could be listed per each new chemical entity, and patents for biologics would not be considered. If adopted, this reform would be a highly negative move by the Mexican authorities that would further devalue the existing linkage regime and rightsholders' ability to enforce their patents.

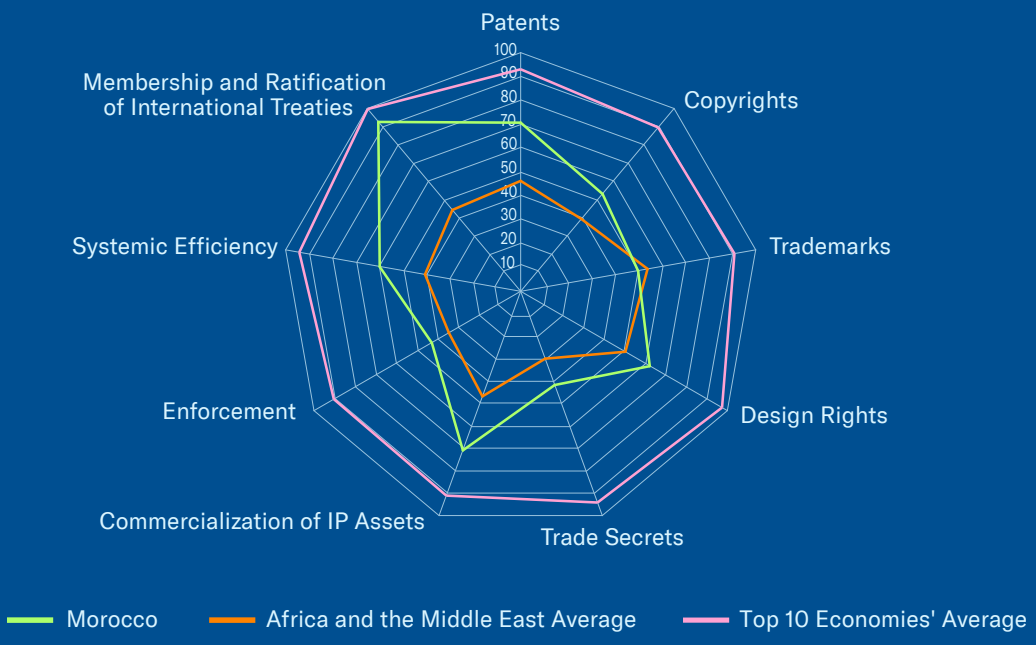
Mexico is, through the USMCA, bound to introduce a more comprehensive and practical system of biopharmaceutical patent enforcement. Article 20.50 of the USMCA provides a clear requirement that the contracting parties provide "a system to provide notice to a patent holder or to allow for a patent holder 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 related to the existing linkage regime. Transitional paragraph (5) of the law simply states that the Mexican Institute of Industrial Property (IMPI) shall "participate" with the Federal Commission for the Protection against Sanitary

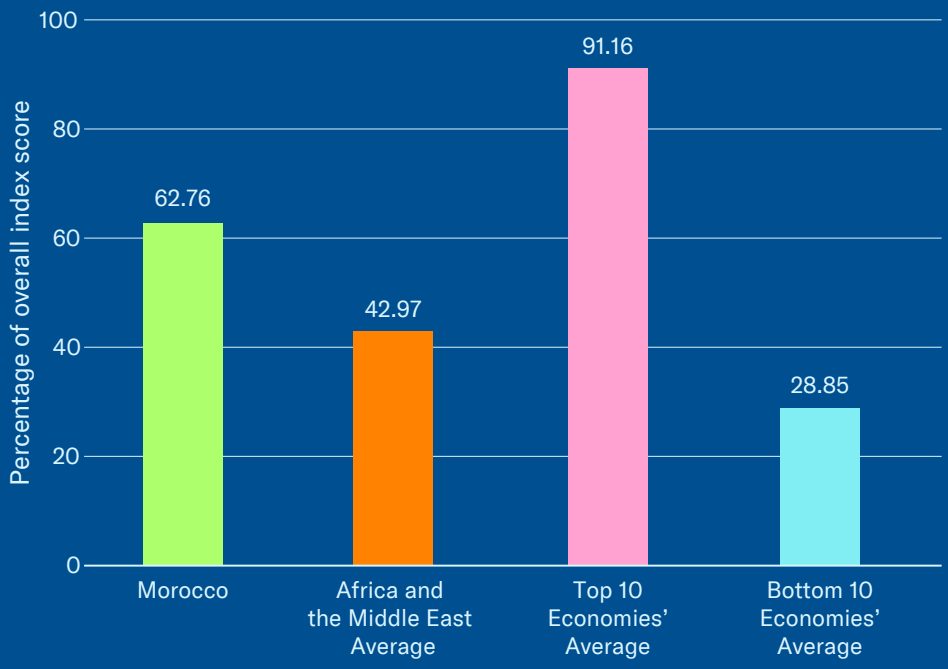
Morocco

Rank
22/55

Category Scores



Overall Score in Comparison



Morocco

Key Areas of Strength

- 2022 accession to Singapore Treaty and Geneva Act (part of Hague Agreement)
- Fairly well-developed national IP system—highest-performing middle income economy in the Index
- Strong protection for patents and related rights
- The U.S.-Morocco FTA and agreements with the EU have encouraged Morocco to strengthen its IP environment and related standards
- PPH is in place with Spain
- The Moroccan IP Office (OMPIC) offers validation of all EPO-registered patents

Key Areas of Weakness

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

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

Indicator	Score
Category 6: Commercialization of IP Assets	**4.25**
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	0.75
31. Tax incenstives 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 precedural remedies	0.25
35. Pre-established damages	0.50
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**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, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 62.76%

Spotlight on the National IP Environment

Past Editions versus Current Score

Morocco's overall score has increased from 62.26% (31.13 out of 50) in the eleventh edition to 62.76% (31.38 out of 50). This reflects a score increase for indicator 30.

Patents, Related Rights, and Limitations

8. Membership in the Patent Prosecution Highway (PPH):
Although Morocco is not a member of the Global Patent Prosecution Highway or the IP5 PPH, the Moroccan Office of Industrial and Commercial Property (OMPIC) has, since 2016, had a PPH agreement in place with the Spanish Patent and Trademark Office—the PPH-Moittainai pilot program. In 2021, another PPH was added with the announcement of an agreement between OMPIC and the JPO. In addition, since 2015, the OMPIC has also offered a validation service of EPO-issued patents. Under this agreement between the EPO and the OMPIC, all qualifying patents filed directly with the EPO or through the PCT route in Europe are eligible for registration in Morocco. Patent applicants can designate Morocco together with EU countries, and EPO patents have the same legal effect as a national patent and are thus subject to Moroccan law. The number of European patent applications designating Morocco has doubled since 2015 to reach an average of about 2,000 applications a year. These positive efforts continued in 2023. In April, the OMPIC announced that a new PPH had been agreed with the USPTO. The agreement is initially on a pilot basis. PPH initiatives and increased cooperation among IP offices—like the patent validation scheme described earlier with the EPO—are a tangible way in which the administration and functioning of the international IP system can be improved and harmonized to help inventors and rightsholders.

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 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:
Some important developments occurred in 2022 and 2023 with respect to the protection of copyrighted content in Morocco. To begin with, a series of amendments to existing copyright statute were passed and promulgated in 2022-2023. The amendments build on a reform package that was introduced in the Moroccan Parliament in 2020.

As mentioned in the Index at the time, the government's recognition of the need to modernize the copyright framework is commendable. The creative industries are an engine for economic growth and development, especially in emerging markets such as Morocco. With the right legal framework in place and the active enforcement of copyright laws, domestic creators and innovators can flourish. The 2022-2023 amendments make changes to Law 66-19 and Law 25-19. Many of these changes seem inspired by EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive). For example, the amendments introduce a new two-year digital right for press publishers and the use of their content online. Similarly, new responsibilities are placed on both internet service providers and providers of "internet content sharing services." Moreover, the Moroccan Copyright Office, Bureau Marocain du Droit d'Auteur, was extensively reorganized and granted both greater powers of enforcement and representation.

As has been noted in previous editions of the Index, Morocco already had a strong statutory copyright framework in place. Article 10 of the Law on Copyright and Related Rights provides definitions of exclusive rights of exploitation, and standard civil remedies are available. Furthermore, Article 65.12 provides the possibility of seeking an injunction and a court order for the disabling of access to infringing content with respect to foreign hosts, and Law 34-2005 amended Article 60 and introduced a notice-and-takedown regime.

Moroccan law also has in place robust provisions related to digital rights management and technological protection measures. The 2005 copyright amendments made acts of circumvention and related activities (including manufacturing, sale, importation, offering for sale and distribution to the public) infringements of copyright. It remains unclear how the 2022-2023 legislative changes will interact with some of this preexisting legal framework. For example, under the revised Law 25-19, the Moroccan Copyright Office seems to have been granted sole rights of representation and enforcement of copyright throughout Morocco. Likewise, under Article 4, all rightsholders appear to be required to register and assign the protection of their copyrights to the Office. This stands in contrast to the provisions of Article 60 of Law 2-00. Nevertheless, the expansion of the Office's enforcement powers is a positive feature of the legislation and will hopefully result in stronger and more sustained levels of copyright enforcement.

As discussed in previous editions of the Index, a key challenge for rightsholders in Morocco has long been the lack of effective enforcement and application of the existing legal framework. Levels of copyright infringement remain high. For example, estimated levels of software piracy in Morocco have for over a decade been consistently high. The latest estimates from the BSA from 2018 estimated the overall level of software piracy at 64%.

This is largely unchanged from 2009 when the level of unlicensed software used was 66%. This is substantially higher than the 56% average in the Middle East and African region. Furthermore, historically, rightsholders in North Africa and Morocco have faced significant problems with satellite decoding and broadcasting signal piracy. Decoders have been readily available and used across North Africa to illegally access copyrighted content. In 2011, the French satellite and content provider Canal+ withdrew from the Moroccan and Algerian markets citing widespread piracy as the main reason.

The latest trend has seen a migration from physical decoders and satellite piracy to the use of set-top boxes and the accessing of infringing content over the internet through streaming. For example, the USTR in its 2023 Special 301 Report referred to Morocco as an economy with "notable levels of piracy through ISDs and illicit IPTV apps" as reported by stakeholders. In response to this trend, the past few years have seen an uptick in enforcement activity. In 2021, an international rightsholders' coalition, the Alliance for Creativity and Entertainment, announced that it had successfully disabled access to a significant source of pirated content in Morocco and North Africa, Electro TV Sat. The provider sold illicit streaming devices and illegal access to thousands of television channels, film, and audiovisual content, including French-speaking content created and supported by Canal+. As noted in the Index at the time, this was a positive development for both domestic Moroccan creators and international rightsholders. Similarly, in late 2022—just a few weeks before the 2022 FIFA World Cup—the Alliance reported that it had successfully disabled access to two major sports piracy platforms in Morocco, livekoora.online and yalla-shoot-new.tv. However, as with the previous enforcement efforts, it remains unclear the extent to which Moroccan authorities actively participated in this action. The Index will monitor the extent to which the changes to Morocco's copyright laws improve the enforcement environment in 2024.

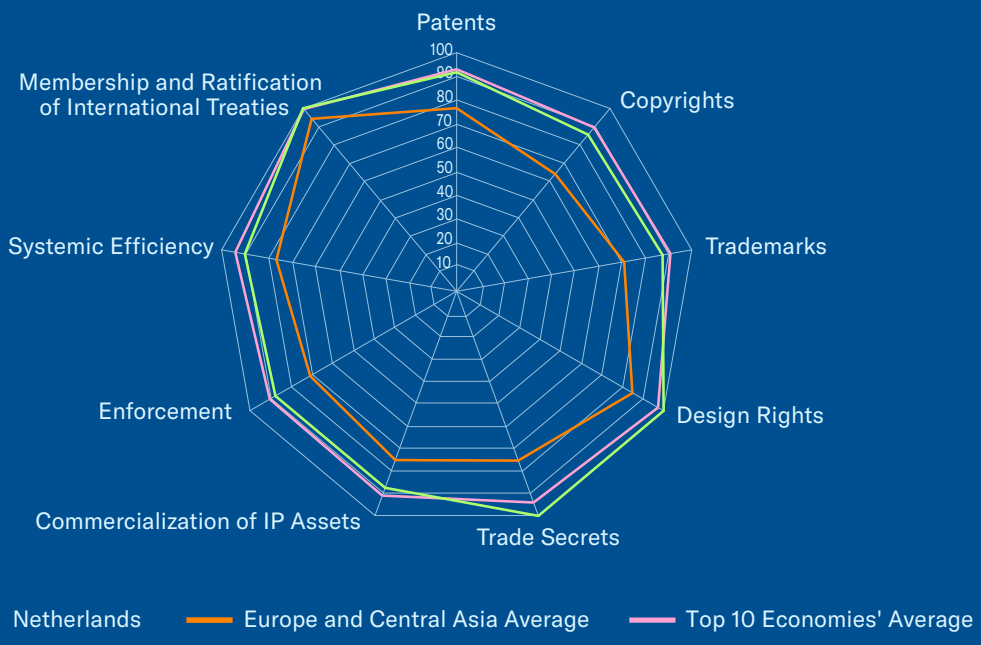
Commercialization of IP Assets and Market Access

30. IP as an economic asset:
The Office has a pronounced and consistent focus in its work to promote the development and commercialization of IP assets and to promote technology transfer in Morocco. As mentioned in last year's Index, in 2022, OMPIC sponsored the establishment of two new university tech transfer offices, and the Office also launched two new technical assistance programs aiming to provide businesses with an in-depth review of existing IP assets and protections and tailored guidance on existing prior art, the patenting process, and key industrial technology trends. These programs seek to provide additional technical assistance and support for the registration and commercialization of IP assets by academic researchers, research institutes, and SMEs. These positive efforts continued in 2023. In March, the Office announced the creation of an "IP Marketplace" online platform. The purpose of the platform is to provide an accessible information hub on existing registered IP assets and technologies and to facilitate licensing and commercialization activities by connecting licensees and licensors. In partnership with the Moroccan Association of Exporters, the Office also announced a dedicated educational and awareness campaign on IP as an economic asset for Moroccan exporters. As a result of these efforts, the score for indicator 30 has increased by 0.25.

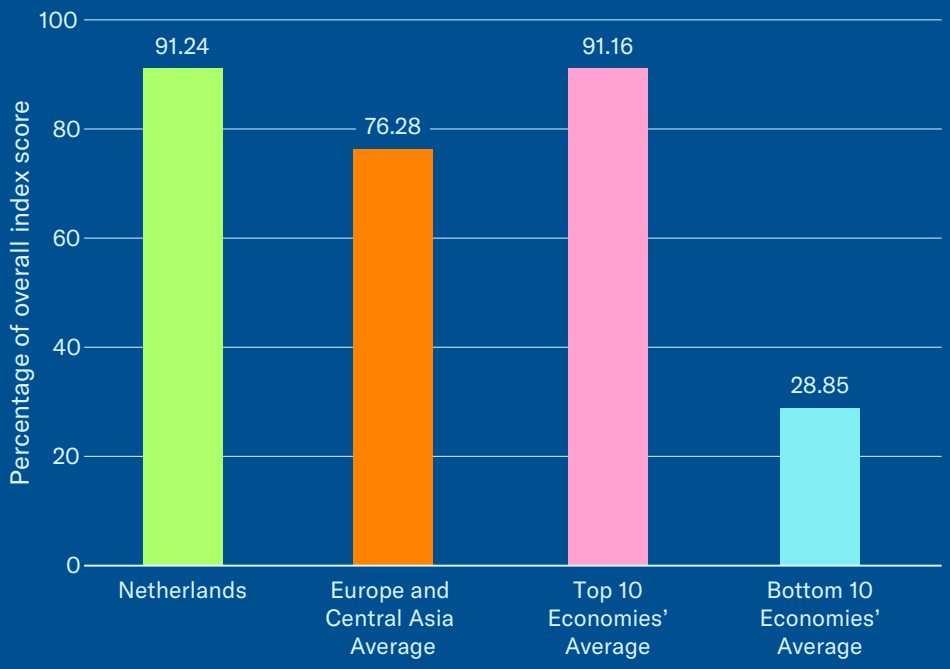
The Netherlands

Rank
7/55

Category Scores



Overall Score in Comparison



The Netherlands

Key Areas of Strength

- Continued leader in copyright enforcement—private-public initiatives led by the national copyright foundation BREIN and the Dutch government
- The 2018 transposition of the EU Trade Secrets Directive improves the Dutch trade secret environment
- Generous R&D and IP-specific tax incentives are in place
- Advanced and sophisticated national IP environment
- Sector-specific IP rights are in place
- Membership in all major international PPH tracks through EPO

Key Areas of Weakness

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for a new EU compulsory licensing regime
- Registration requirements are in place for licensing agreements
- Regulation 2019/933 and the existing SPC exemption for exports of biopharmaceuticals pose significant risk to Netherland's and the EU's research and IP-based biopharma industry
- Proposals explore the use of compulsory licensing for medicines whose price is deemed excessive and is outside international norms

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**5.99**
10. Term of protection	0.74
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.75
15. Digital rights management	0.75
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**5.25**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**6.13**
32. Physical counterfeiting rates	0.85
33. Software piracy rates	0.78
34. Civil and precedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.50**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 91.24%

Spotlight on the National IP Environment

Past Editions versus Current Score

The Netherlands' overall score has increased from 90.70% (45.35 out of 50) in the eleventh edition to 91.24 (45.62 out of 50). This reflects score increases for indicators 32 and 36.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. The commission posits in the "Call for Evidence" that a pressing need exists 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licencing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have never been used. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 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.

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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023 the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU.

Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allowed companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft Directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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. Within this context, IP rights play no part.

The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including the Netherlands, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

Enforcement

36. Criminal standards, including minimum imprisonment and minimum fines:
The criminal enforcement environment of IP rights in the Netherlands has historically been challenging. Intellectual property infringement is not directly dealt with in criminal law. Instead, related activities and consequences are liable to criminal consequence. For example, acts of counterfeiting that cause threats to public safety are liable to criminal penalties and, similarly, large-scale piracy that causes market distortion can be prosecuted on grounds of unfair competition law. With respect to criminal enforcement related to copyright, this has historically been a serious challenge for rightsholders in the Netherlands. Levels of piracy have traditionally been high with sites such as the Pirate Bay, which offers Dutch consumers unimpeded access to copyright infringing content.

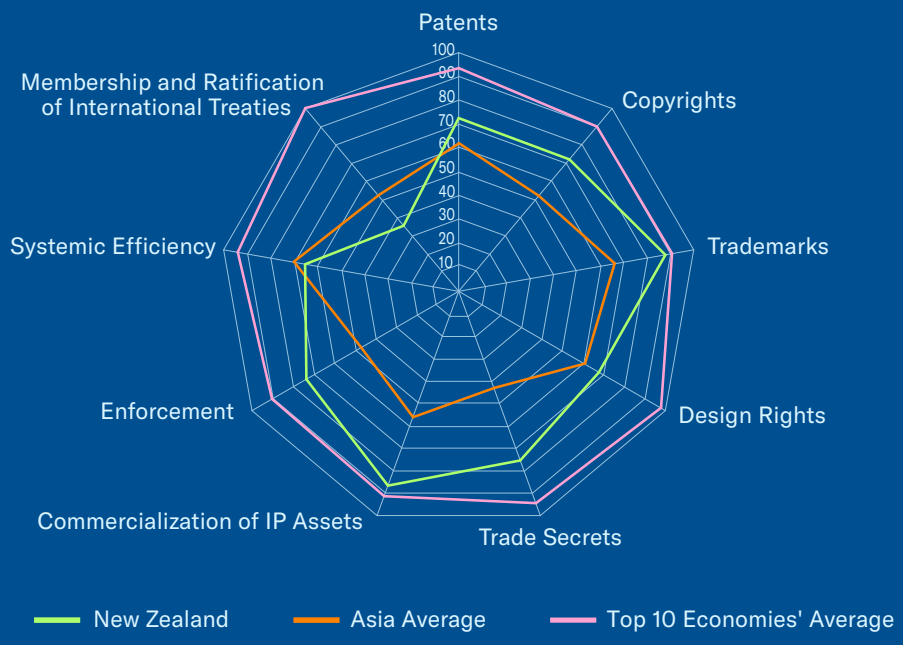
As noted in previous editions of the Index, over the past half decade, the Netherlands and EU have introduced and implemented a range of new mechanisms and powers to help combat online infringement. The positive impact of these efforts can be seen in the Netherlands' score change in Category 2: Copyright, Related Rights, and Limitations. Over the past seven 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. These positive efforts continued in 2023 with Dutch law enforcement taking decisive action against one of Europe's largest providers of illicit digital piracy through so-called set-top or IPTV boxes.

As in many other Index economies, the Netherlands 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. Media reports suggest that in May, the Dutch Fiscal Information and Investigation Service, with support from Europol, in a coordinated effort raided several sites across the Netherlands, made numerous arrests, and disabled the data center source from which the illegal content was made available. The successful operation is said to have disabled access to illegal content in hundreds of thousands of set-top boxes around Europe. As a result of these positive actions, the score for this indicator has increased by 0.25.

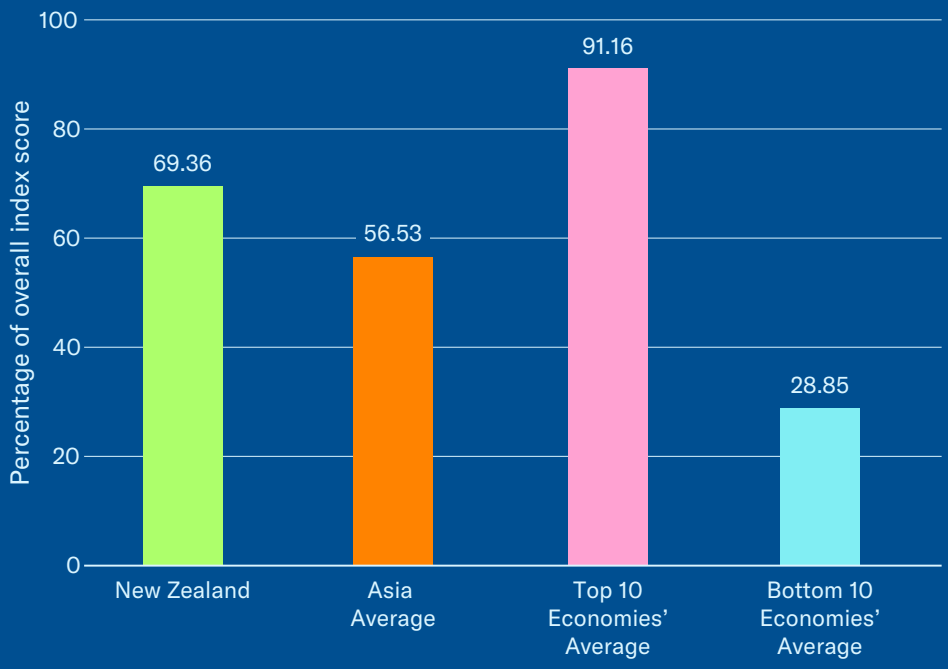
New Zealand

Rank
20/55

Category Scores



Overall Score in Comparison



New Zealand

Key Areas of Strength

- The New Plant Variety Rights Act improves the term of protection for the Index standard
- R&D tax incentives were passed in 2019
- Legislative amendments after the ratification of the CPTPP provide border officials with clear ex officio authority
- A sophisticated national IP environment has strengths across most categories of the Index
- No significant barriers to or restrictions on licensing activity and technology transfer

Key Areas of Weakness

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

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**6.50**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**5.03**
10. Term of protection	0.53
11. Exclusive rights	0.75
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	0.75
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.35**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.25**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**5.17**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**5.13**
32. Physical counterfeiting rates	0.79
33. Software piracy rates	0.84
34. Civil and precedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.25**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**2.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 69.36%

Spotlight on the National IP Environment

Past Editions versus Current Score

New Zealand's overall score has increased from 69.28% (34.64 out of 50) in the eleventh edition to 69.36% (34.68 out of 50). This reflects a score increase for indicator 4.

Patents, Related Rights, and Limitations

4. Plant variety protection, term of protection:
In November 2022, the New Zealand Parliament passed a new law for the protection of plant varieties, the Plant Variety Rights Act. Under Section 19, the term of protection has been extended to 25 years for a "woody plant or its rootstock" and 20 years for all other varieties. As a result, the score for this indicator has been increased to 1.

Copyrights, Related Rights, and Limitations

10. Copyright (and related rights) term of protection; and 12. Expeditious disabling of infringing content online:
As detailed last year, in 2022, New Zealand and the UK agreed on a new comprehensive trade agreement. This was followed up in July with an announcement that the European Commission and the government of New Zealand had concluded negotiations for a separate FTA with the EU. At the time of research last year, the terms of that agreement were still to be finalized, and the full text had not been published. Now the full agreement has been made available to the public and can be evaluated in this year's Index. For full details, see the following discussion under indicator 50.

Both these FTAs are wide-ranging and include separate and distinct chapters dedicated to the protection of IP. With respect to the protection of copyright, both agreements include some potentially positive changes to New Zealand's copyright environment. First, both would align the current headline term of copyright protection with European and British standards. Specifically, they would provide a term of protection of an author's life plus 70 years. For anonymous works 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 some time. As mentioned last year, under the terms of the UK-New Zealand Agreement, this has been pushed back for 15 years. Article 17.48(10) of the agreement states, "The obligations in this Article [term extension] shall only commence applying 15 years after the date of entry into force of this Agreement."

Similarly, the EU–New Zealand Agreement postpones the implementation of this term extension for four years. Article 18.13, footnote 1, states, "If on the date of entry into force of this Agreement a Party's laws and regulations do not provide for the terms of protection set out in this Article, this Article shall apply only as of the date such laws and regulations enter into effect in that Party and in any case no later than four years after the date of entry into force of this Agreement." This is surprising and disappointing because it is not clear why the postponement is needed in the first place. 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 will result in a score increase for indicator 10.

As discussed last year, the New Zealand–UK 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, "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 online service provider (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." As mentioned last year, the implementation of this right into New Zealand statute would be a notable achievement and would result in a score increase for indicator 12.

As detailed over the course of the Index, 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. Recognizing the difficulties creators and rightsholders face today due to online infringement and the lack of effective enforcement mechanisms in New Zealand, MBIE said, "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 implementing law enacted by Parliament in November 2022, the United Kingdom Free Trade Agreement Legislation Act, does 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 implementing law is not amended to include such an elemental part of the trade agreement's IP chapter. The Index will continue to monitor these developments in 2024.

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:

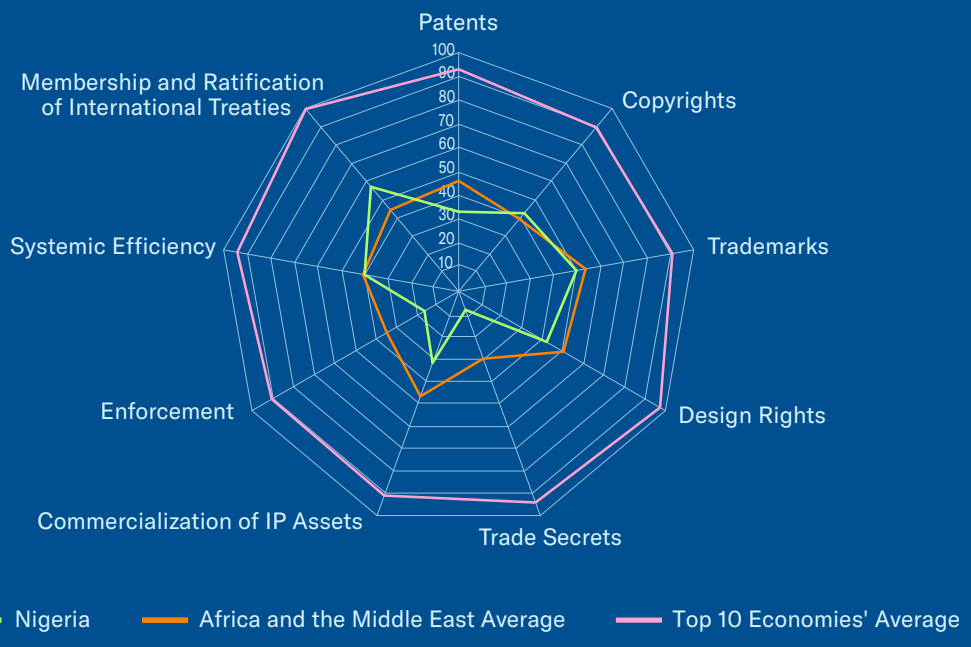
As mentioned, in 2022, the European Commission and the government of New Zealand concluded negotiations for a new FTA with the EU. Although this treaty contains some potentially positive changes to New Zealand's national IP environment, it does not conform to the standards of a modern post-TRIPS FTA. Curiously, neither the IP chapter nor the rest of the agreement includes any reference to patent rights. Similarly, unlike many other post-TRIPS FTAs, the EU–New Zealand FTA does not contain substantial protections for the life sciences sector. Notably, the treaty does not refer to 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 a dwindling number of 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 EU, a maximum five-year term of restoration is provided through the system of supplementary protection certificates (SPCs) and has been in place for decades. Likewise, the FTA's provisions related to regulatory data protection do not recognize current international best practices and provide only a five-year term of protection. This mirrors Section 23B of the New Zealand Medicines Act, which provides protection for submitted clinical test data for a period of five years. As noted in previous editions of the Index, this is significantly shorter than the baseline term (that of the EU) used in this Index and the term in place in most other high-income OECD economies.

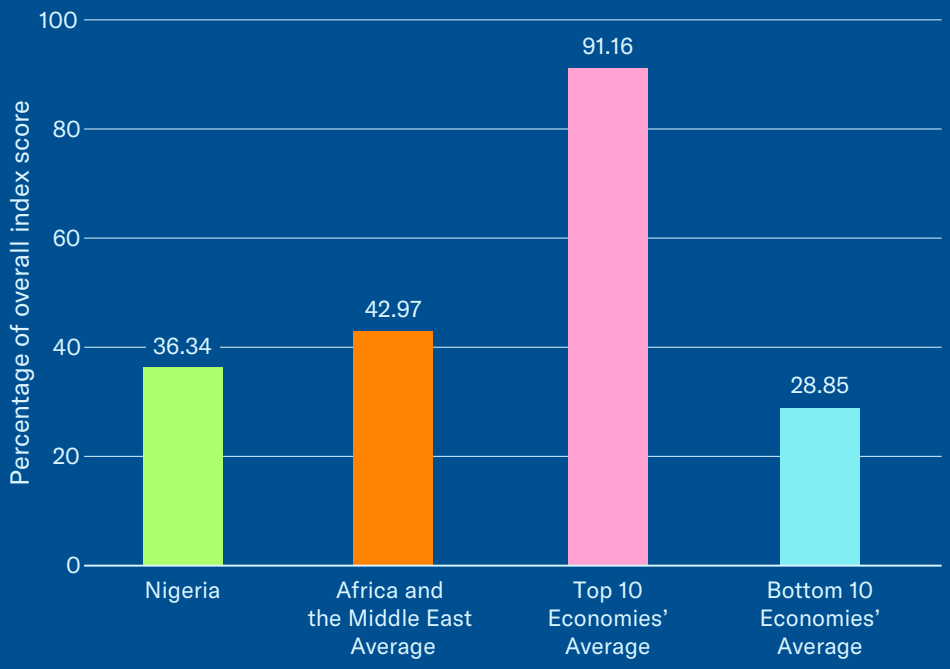
Nigeria

Rank
47/55

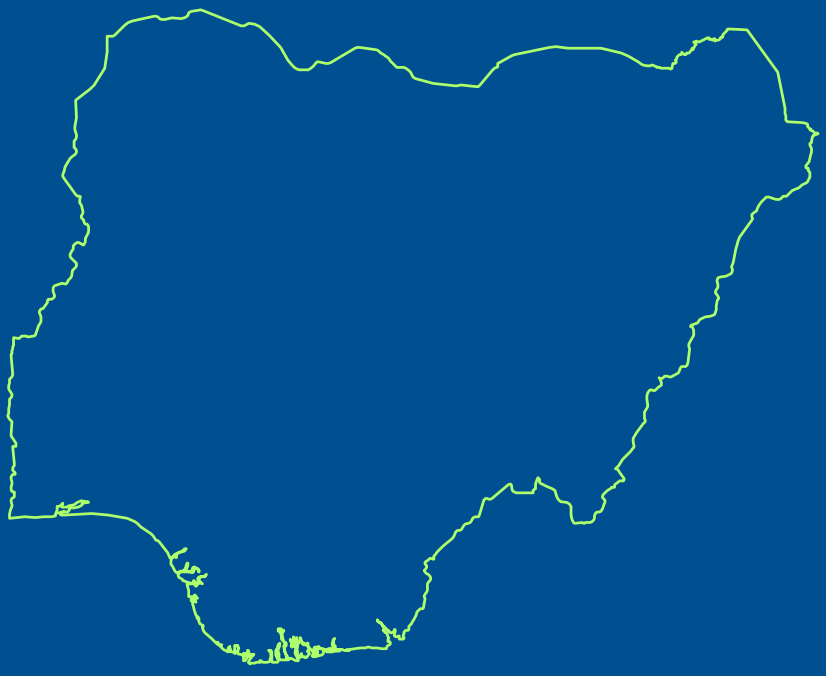
Category Scores



Overall Score in Comparison



Nigeria



Key Areas of Strength

- The 2023 new Copyright Act improves Nigeria's national IP environment
- Joined the Convention on Cybercrime in 2022
- Joined the Plant Variety Protection Act in 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 is estimated at 80% by BSA
- Localization barriers and restrictions regarding technology transfer and licensing activities intensified in 2020
- National Office for Technology Acquisition and Promotion (NOTAP) oversees all technology transfer and licensing between Nigerian entities and foreign licensors and has the power to evaluate and approve or disapprove technology transfer agreements, including evaluating royalty amounts

Indicator	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	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**2.99**
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	0.25
15. Digital rights management	0.50
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.25**
23. Protection of trade secrets (civil remedies)	0.00
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
Category 6: Commercialization of IP Assets	**1.92**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.00
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incenstives 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 precedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**2.00**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**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, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 36.34%

Spotlight on the National IP Environment

Past Editions versus Current Score

Nigeria's overall score has increased from 33.34% (16.67 out of 50) in the eleventh edition to 36.34% (18.17 out of 50). This reflects score increases for indicators 11, 12, 13, and 15.

Area of Note

At the end of 2022, the Nigerian government and WIPO held several meetings on launching a new National IP Policy and Strategy. In September, the local WIPO office, government representatives and a group of academics and local consultants held a meeting to present the results of the draft National IP Policy and Strategy. In conjunction with this meeting, the then Attorney General and Minister of Justice Abubakar Malami stated in local media that the government was committed to modernizing the Nigerian national IP system, including considering legislative changes to existing patent, design, and trademark laws. At the time of research, no final Policy or Strategy document had been published, and it was unclear the extent to which the incoming government, led by President Tinubu, would adopt the document in its current form. 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 Nigerian government and National Assembly pursue a program of national IP rights reforms, we encourage them to use the Index findings and accompanying Statistical Annex as a guide in 2024 and beyond.

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 15. Technological Protection Measures (TPM) and Digital rights management (DRM) legislation: As noted in previous editions of the Index, the Nigerian Copyright Commission (NCC) has for the past decade sought to amend and update the Copyright Act. In 2022-2023, the National Assembly passed the Copyright Act, 2022, and the then-President Buhari signed the bill into law. Although not perfect, overall, this new act provides a much-needed update to Nigeria's copyright environment. The 2004 Copyright Act provided rightsholders with only general and basic exclusive rights and contained only limited references to the online space. For example, no provision in the act or other relevant legislation (including the 2015 Cybercrimes Act) instituted a notice-and-takedown mechanism, injunctive-style relief, or copyright-specific TPM and DRM provisions.

Part 3, Section 11 of the 2008 Guidelines for the Provision of Internet Service, published by the NCC, provided 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 because they do not carry the force of statutory law.

Similarly, although the Cybercrimes Act contains language that makes it an offense to use or make available any "devices primarily designed to overcome security measures in any computer, computer system or network," these provisions are not specific to copyright, and no evidence shows they have actively been used to counter copyright piracy. These legal shortcomings have now been largely rectified in the new Copyright Act.

Articles 48-52 provide explicit provisions related to the use, sale, manufacture, and distribution of circumvention devices used to infringe copyright and the disabling of any rights management information or tools. Articles 54-60 outline a notice-and-takedown regime that requires relevant service providers to act expeditiously upon receiving a complaint of potential copyright infringement.

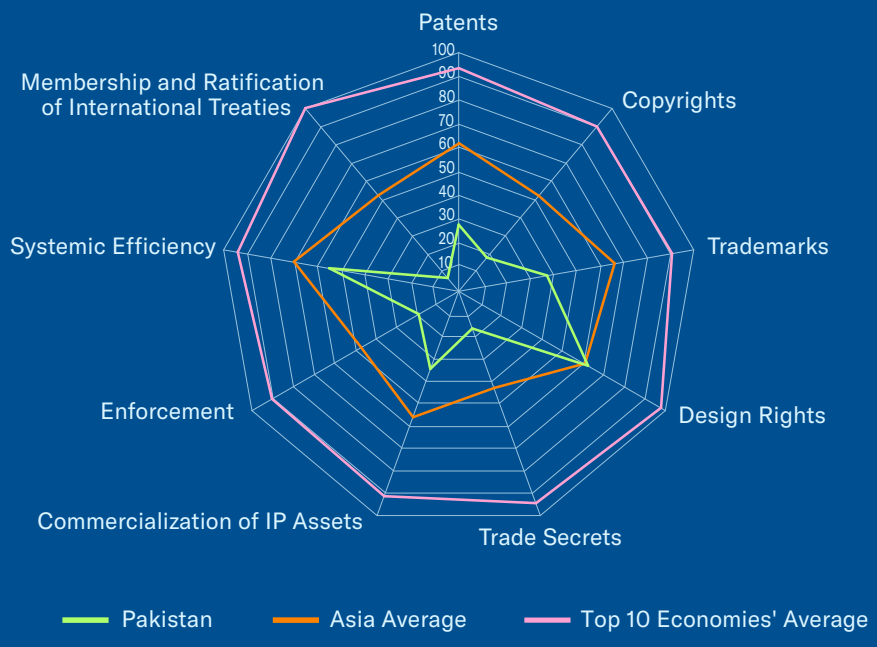
Finally, Article 61 provides an injunctive-style administrative relief mechanism by granting the NCC authority to order the disabling of access to infringing content online. Together, these changes to Nigeria's copyright law constitute a major improvement and step forward. As a result, the scores for indicators 11, 12, 13, and 15 have increased.

Unfortunately, the new Copyright Act also includes some notable negative changes. Specifically, Section 35 inserts a new basis of "rectifying the abuse of a dominant market position or to promote public interest" for the issuing of a compulsory license. It is unclear how this power vested in the NCC will be exercised or for what purpose. Furthermore, the act not only retains preexisting broad personal and educational use exceptions to copyright but also adds to these by inserting a new "non-commercial research and private study" exception. The Index will monitor the application of the new Copyright Act in 2024 and beyond.

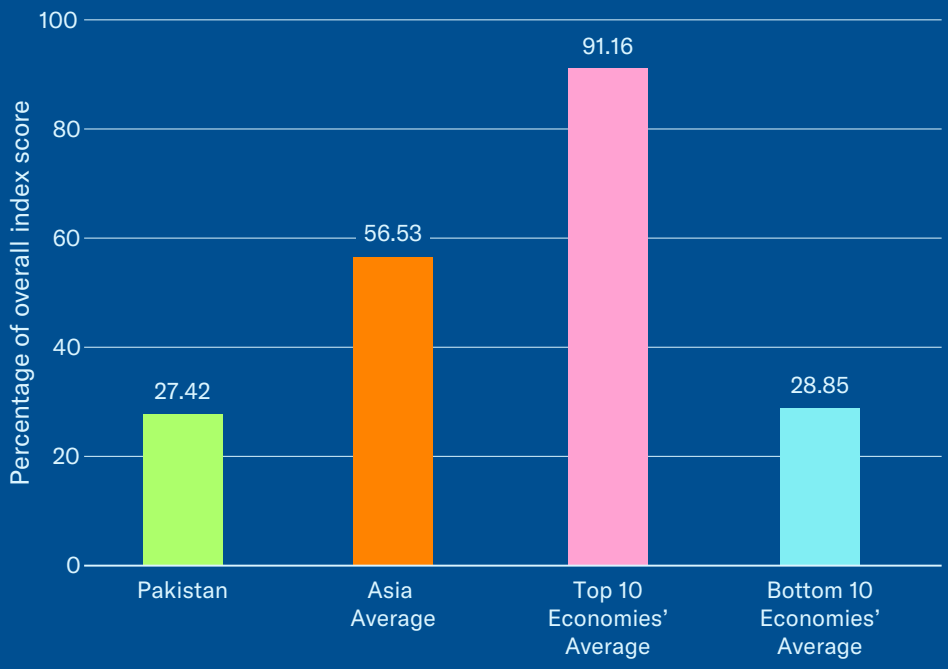
Pakistan

Rank
52/55

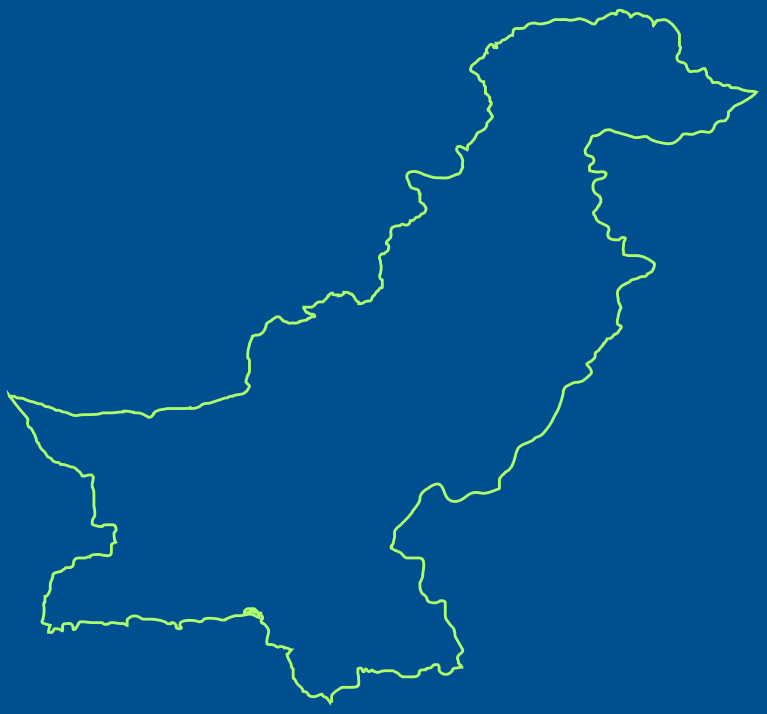
Category Scores



Overall Score in Comparison



Pakistan



Key Areas of Strength

- 2021 accession to Madrid Protocol
- Basic IP laws and legal framework are in place
- Introduction of specialized IP courts and capacity building
- Greater efforts made in public education, modernization of IP laws, and enhancing coordination among enforcement agencies

Key Areas of Weakness

- Limited sector-specific IP protections are available
- Significant discrepancy between IP rights in law and level of practical enforcement
- Enforcement is often arbitrary and nondeterrent (although efforts to improve are underway)
- High counterfeiting and piracy rates—latest BSA estimates put software piracy at 83%
- Punitive changes to the Patent Ordinance under consideration would exclude protections for CIIs and new-form biopharmaceuticals

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

Indicator	Score
Category 6: Commercialization of IP Assets	**2.08**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.33
Category 7: Enforcement	**1.35**
32. Physical counterfeiting rates	0.18
33. Software piracy rates	0.17
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.75**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**0.50**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 27.42%

Spotlight on the National IP Environment

Past Editions versus Current Score

Pakistan's overall score remains unchanged at 27.42% (13.71 out of 50).

Patents, Related Rights, and Limitations

2. Patentability requirements; and 3. Patentability of computer-implemented inventions (CIIs):
In late 2022, the Intellectual Property Organization of Pakistan (IPO-Pakistan) published draft amendments to the Patent Ordinance. These proposed amendments make substantive changes to Pakistan's legal regime for patents, including with respect to patentable subject matter. As noted over the course of the Index, patentability standards in Pakistan have stood outside of international norms, especially with respect to high-tech arts, including computer software and biopharmaceuticals. Unfortunately, under the draft amendments, a revised Section 7 proposes to further limit or eliminate the potential patentability of CIIs and biopharmaceutical innovation. Under the existing Patent Ordinance, CIIs were not excluded and there remained the possibility to seek necessary patent protection. However, the new amendments explicitly exclude "computer programs" as inventions. Given the fact that computer software and CIIs are at the heart of virtually all socioeconomic activity—desktop computers, smartphones, artificial intelligence, the Internet of Things—it is hard to see how eliminating patent eligibility for computer programs will help drive investment and resources into developing new digital and ICT-based technologies in Pakistan.

Similarly, a new Subsection (7(4)(f)) related to biopharmaceutical inventions would eliminate the patentability of a "new form or new property of a known substance which does not result in the enhancement of the known efficacy of that substance."

This would appear to restrict the eligibility of incremental biopharmaceutical innovation, including changes to the form and application of a known substance. This is a curious change because incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally improved or altered therapies frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovation—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin and insulin pumps, beta-blockers, ACE inhibitors, contraceptives, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices.

The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared with its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals both had serious side effects and were combination therapies that required the consumption of large volumes of medication several times per day. Side effects included gastrointestinal discomfort, severe nausea, loss of taste, skin problems, and nerve injury. The development of the second generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still, treatment centered on the administration and consumption of several medicines per day.

It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require that the patient take only a single pill once daily. This new ease of medication has led to increased adherence, which has, in turn, increased efficacy significantly with little to no significant change in lifestyle. This allows patients to live socioeconomically productive lives with what had been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a health system. It is hard to see how this type of innovation should not be eligible for patent protection. Should these amendments be enacted into law, the score for indicators 2 and 3 will be reduced. The Index will monitor these developments in 2024.

9. Patent opposition:
In a positive development, the proposed amendments to the Patent Ordinance published by IPO-Pakistan would eliminate Section 23 and the system of pregrant oppositions. Under existing patent statute, an inter-partes opposition system is in place that can be triggered within four months after an application is published. If adopted in their current form, amendments to the Patent Ordinance would result in a score rise for indicator 9.

Copyrights, Related Rights, and Limitations; Enforcement

15. Technological protection measures (TPM) and digital rights management (DRM) legislation; and 36. Criminal standards including minimum imprisonment and minimum fines:
In late 2022, IPO-Pakistan published draft amendments to the Copyright Ordinance. As noted over the course of the Index, Pakistan's Copyright Ordinance provides a basic legal framework that remains underdeveloped and ill-suited to the challenges of the internet era. Levels of copyright piracy and counterfeit goods remain high, whereas relevant enforcement mechanisms are weak and nondeterrent. Although the proposed amendments do not include a notice-and-takedown notification system for online piracy or an injunctive-style relief option whereby through a court of law or administrative mechanism rightsholders can directly request the disabling of access to infringing content, the proposed amendments include new provisions related to TPM and DRM.

Up until now, Pakistan copyright law has had no legal definitions or provisions related to the use of circumvention devices and the overriding or disabling of TPMs or DRMs. Some provisions of the Cyber Crime Act and Prevention of Electronic Crimes Act could potentially be applied within the context of copyright, but these are broad based, and they are not defined or structured in a way to apply to circumvention devices or copyright infringement. New Sections 56A and 56B would remedy this and would provide legal definitions and remedies for the violation of TPMs and DRMs within Pakistani copyright law. As the IPO-Pakistan and Pakistani legislature work on these amendments, it is important that these new provisions extend not only to the use of circumvention devices but also to the distribution, offering for sale, distribution, and importation of such devices.

Another positive feature of the draft amendments is the increase in criminal penalties. Specifically, draft Sections 66A-70A and 70B provide both higher minimum sentences and tougher punishment for repeat offenders. Should these amendments be enacted into law, the score for indicators 15 and 36 would potentially increase. The Index will monitor these developments in 2024.

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

19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks; and 45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks:
In 2021, WIPO announced that Pakistan had acceded to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. As noted at the time in the Index, Pakistan's accession to the Madrid Protocol was a positive development that resulted in a score increase for indicator 45. In August 2023, the National Assembly passed and President Alvi signed into law the Trademarks (Amendment) Act 2023. The act includes several important administrative changes to the trademark registration process and specifically codifies Pakistan's commitments under the Madrid Protocol. The amendments also vest more administrative authority with the IP Tribunal, a division of IPO-Pakistan. The Index will continue to monitor these developments in 2024.

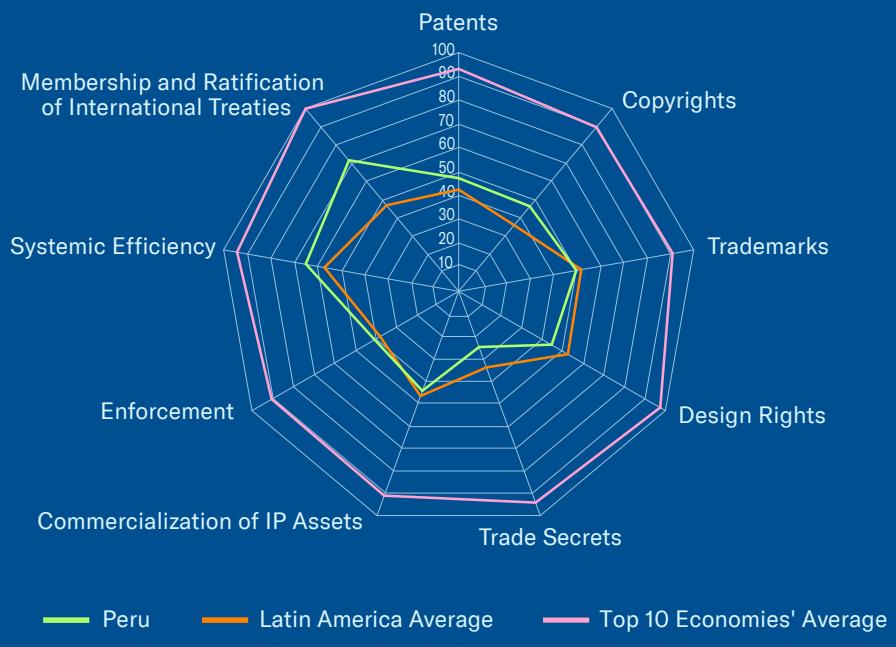
Systemic Efficiency

40. Consultation with stakeholders during IP policy formation:
Historically, a degree of uncertainty has existed about the extent to which the government of Pakistan and its individual ministries and agencies offer public consultations on proposed legislative and regulatory changes. Draft laws and regulations are not always or consistently published and made available for public comment, and no consistent process or time frame has been applied to receiving public comments. Individual government agencies regularly share draft regulations and rules with the public and solicit input through public consultations, but this has historically not been the norm or consistently required across government ministries and agencies. The result is that different ministries and agencies apply different standards and methods in consulting with key stakeholders.

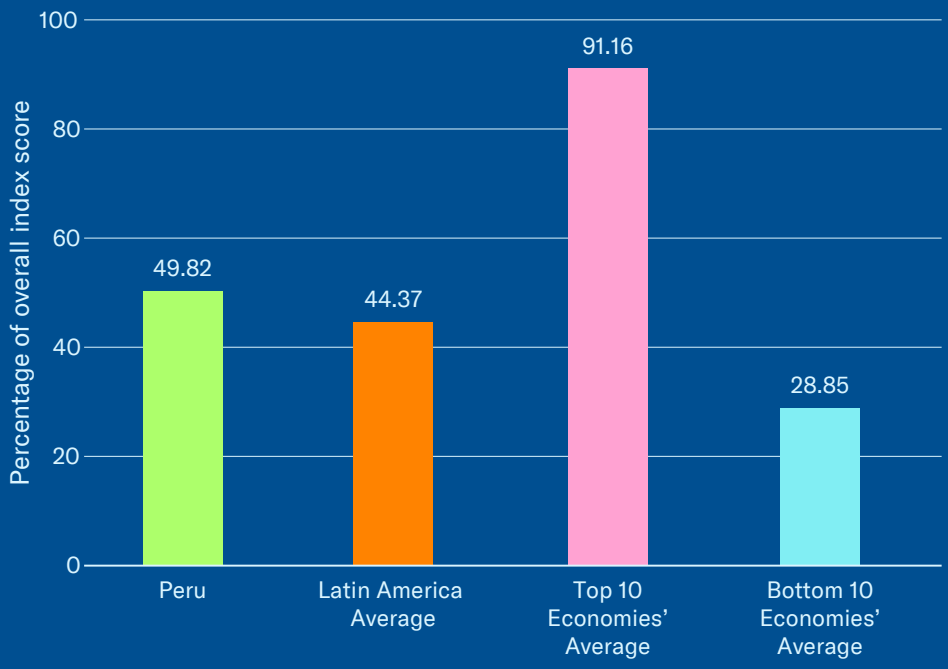
Peru

Rank
29/55

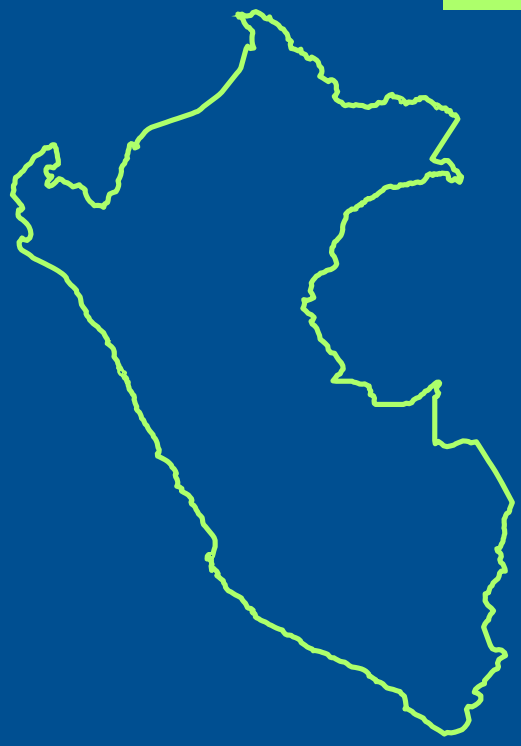
Category Scores



Overall Score in Comparison



Peru



Key Areas of Strength

- Continued injunctive-style relief and copyright enforcement by the national IP office INDECOPI in 2023
- The 2021 Decree 063-2021 strengthens public consultation and stakeholder participation in the lawmaking and regulatory process
- INDECOPI support for SMEs strengthened in 2021, which created new technical assistance and IP asset identification programs
- In 2019, Peru joined the Global Patent Prosecution Highway
- INDECOPI continued suspending access to copyright infringing websites

Key Areas of Weakness

- Compulsory license is actively considered for biopharmaceuticals based on cost
- Administrative and regulatory barriers to 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

Key Areas of Strength
(continued)

- Basic IP protections are available
- Border measures are provided for in legislation
- Efforts made to coordinate IP rights enforcement across government agencies and to raise awareness of the importance of IP protection

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**4.25**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**3.24**
10. Term of protection	0.74
11. Exclusive rights	0.50
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.75**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.25

Indicator	Score
Category 6: Commercialization of IP Assets	**2.67**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**2.85**
32. Physical counterfeiting rates	0.47
33. Software piracy rates	0.38
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.25**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**5.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 49.82%

Spotlight on the National IP Environment

Past Editions versus Current Score

Peru's overall score remains unchanged at 49.82% (24.91 out of 50).

Copyrights, Related Rights, and Limitations

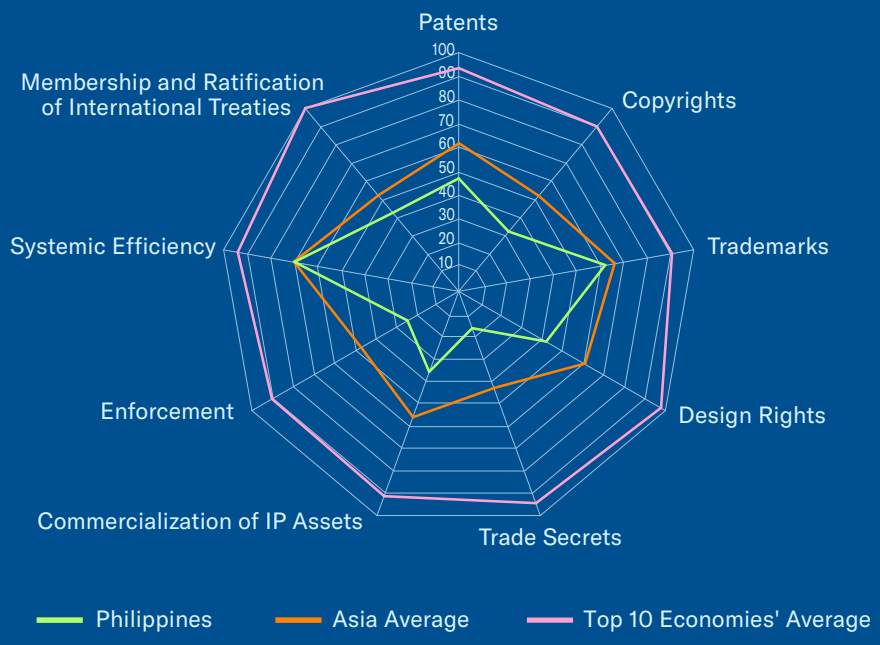
11. Legal measures that provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy:
In 2023, Peru's national IP authority, INDECOPI, continued to clamp down on online copyright piracy. In late 2022, the authority ordered that 51 websites offering illegal access to the FIFA World Cup be shut down. And in March 2023, INDECOPI took part in what has become a multinational effort to disable copyright piracy across Latin America, Operation 404. First initiated in Brazil in 2020 and 2021, Operação 404 contra pirataria is spearheaded in Brazil by a special police enforcement unit (SEOPI) and the Ministry of Justice. The operation has also received international support from the U.S. Embassy in Brasilia and UK law enforcement. In its first three years of operation, hundreds of websites and applications offering copyright infringing content have been shut down, over 50 search and seizure warrants issued and executed across 20 Brazilian states, and several arrests have been made. In 2023, these efforts continued with authorities in Brazil and Peru shutting down access to hundreds of infringing websites and online access points. In Peru, these efforts were, again led by INDECOPI, and resulted in the disabling of 69 websites. The Index commends the government of Peru and INDECOPI for their continued strong efforts and regional leadership on this issue.

Unfortunately, this positive activity has not been matched in legislative reform. Most notably, despite its obligation to do so under Article 29(b)(ix) of the U.S.-Peru Free Trade Agreement, Peru has yet to introduce a notice-and-takedown mechanism to effectively combat infringing content online. Reform proposals have been put forth over the years, for example, in the various iterations of the "General Internet Law,'" Proyecto de Ley nº 00878/2021-CR. Ley General de Internet. However, in the 14 years since the agreement came into force, Peru is still no closer to a functioning notice-and-takedown mechanism. It remains imperative that Peru introduce a legislative framework that gives rightsholders the legal certainty and ability to practically enforce their rights through a well-defined and structured mechanism. The introduction of such a system and the continued support and ability of INDECOPI to carry out its enforcement activity would result in further score increases in Category 2: Copyrights, Related Rights, and Limitations. As noted, 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 primarily due to INDECOPI's sustained effort to disable access to infringing content. The Index will continue to monitor these developments in 2024.

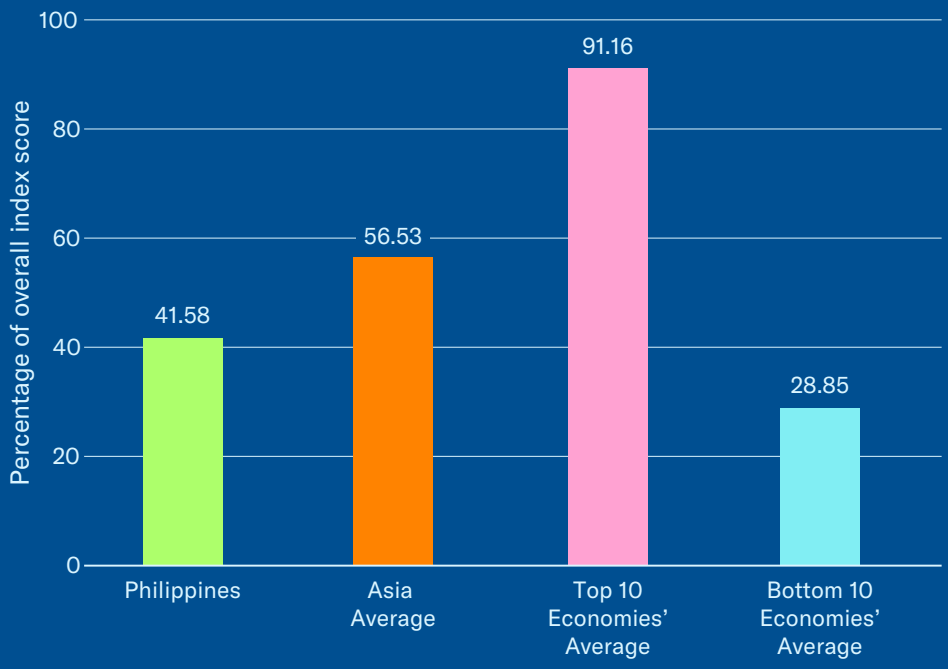
Philippines

Rank
37/55

Category Scores



Overall Score in Comparison



Philippines

Key Areas of Strength

- IPOPHL continued stronger IP enforcement efforts online in 2022
- Draft amendments to the IP Code would strengthen the IP environment
- R&D tax incentives are in place
- Most basic IP rights are provided for in existing legislation
- Growing specialization and capacity building, such as in administrative IP courts

Key Areas of Weakness

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

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**4.25**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**2.28**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**0.85**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
Category 6: Commercialization of IP Assets	**2.17**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**1.74**
32. Physical counterfeiting rates	0.38
33. Software piracy rates	0.36
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**3.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 41.58%

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).

Area of Note

In July 2023, the National Economic and Development Authority published the National Innovation Agenda and Strategy Document (NIASD), a 10-year plan outlining the government's major policy objectives with respect to national innovation and related fields, including IP rights. The NIASD is an ambitious flagship document seeking to "transform the country into a Smart and Innovative Philippines that is productive, resilient, sustainable, and inclusive." With respect to IP policy, the NIASD will seek to strengthen existing technical assistance for small businesses and to promote technology transfer and the development and commercialization of IP assets.

As the economic data and analysis in this Index's accompanying Statistical Annex and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for innovation and advanced economic development to take place. For all economies—emerging and developed alike—what drives innovation, technological advances, and economic development and growth is the creation of new forms of intangible assets and IP. Covering 50 indicators across nine 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 National Economic and Development Authority and the government of Philippines pursue a program of national IP rights reforms, we encourage them to use the Index findings and accompanying Statistical Annex as a guide in 2024 and beyond.

Copyrights, Related Rights, and Limitations

12. Expeditious disabling of infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy: In 2023, the Philippines came closer to adopting more effective mechanisms to fight online copyright infringement. In the spring, the House of Representatives passed Bill HB 7600, a set of amendments to the Philippines' main IP law, the IP Code. The centerpiece of the bill is an amended Section 216. This amendment would grant the Intellectual Property Office of the Philippines (IPOPHIL) the administrative power to order the disabling of access to infringing content online. Under the proposed system, rightsholders (defined as "eligible parties") would contact IPOPHIL directly and file a complaint asking for the disabling of access to the alleged infringing online activity. IPOPHIL would then review the application and, if deemed legitimate, would contact the responsible party and/or give due notice of the pending enforcement action, and within five days of giving such notice order the disabling to take place via a domestic ISP.

The draft legislation includes a "dynamic element." This gives IPOPHIL the ability to update the order as and when new infringing activities move from one online location to another. The ability to update the order on a dynamic basis is significant. This type of dynamic injunction order effectively 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 orders have become more commonplace around the world, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, and the UK. At the time of research, the Senate was reviewing the legislation, and no final law had been passed. Should this draft legislation be enacted, it would result in score increases for indicators 12 and 13. The Index will continue to monitor these developments in 2024.

Enforcement; and Membership and Ratification of International Treaties

37. Effective border measures; and 50. Post-TRIPS FTA:
On June 2, 2023, the Regional Comprehensive Economic Partnership (RCEP) agreement entered into force in the Philippines. This follows formal ratification by the executive branch and concurrence by the Senate in Resolution 42. As noted in previous editions of the Index, 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 or copyright-based industries—and no score has been allocated to Philippines under indicator 50. 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, it should also be noted that 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.

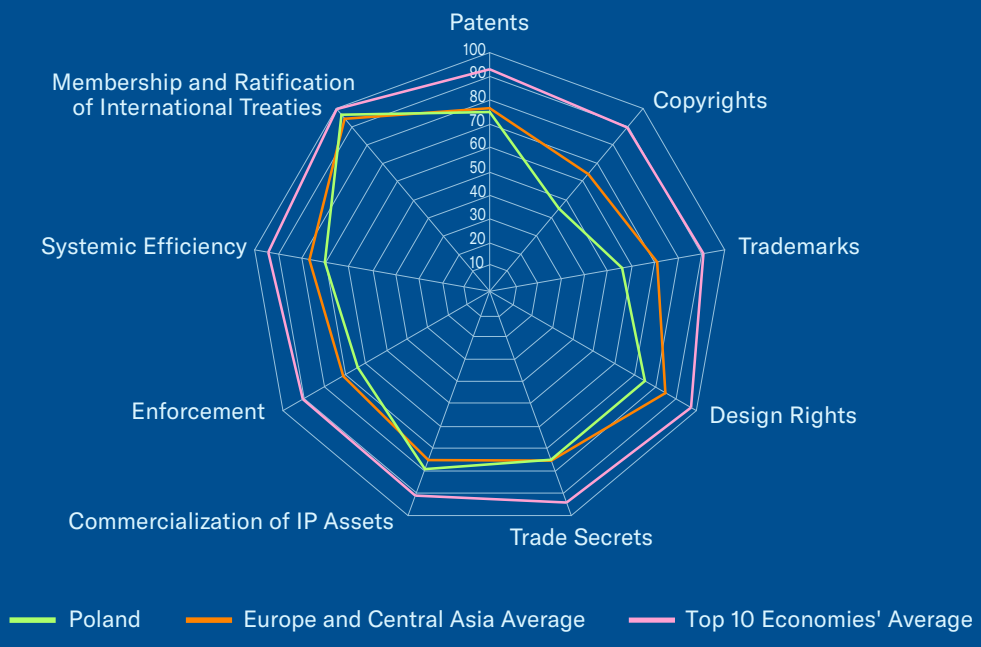
The order offers the possibility for IP rightsholders who have not registered their relevant IP rights to request seizure action to be taken, but this is to be allowed only in "meritorious cases" and in ports outside of Manilla. The order also allows, but does not require, that customs officials carry out "random checks." But this does not amount to or define itself as an ex officio authority or duty. Subsequent orders have not expanded or further defined this power in relation to goods intended for the domestic Filipino market or in transit.

In Resolution 42, the Senate outlined key policy areas it expected the executive branch to actively engage in as a result of the RCEP coming into force. This did not include any specific reference to IP rights policy generally or to the enforcement of IP rights by customs officials. Should this provision of the RCEP agreement be incorporated into existing Filipino statute and practice, it would result in a score increase for indicator 37. The Index will continue to monitor these developments in 2024.

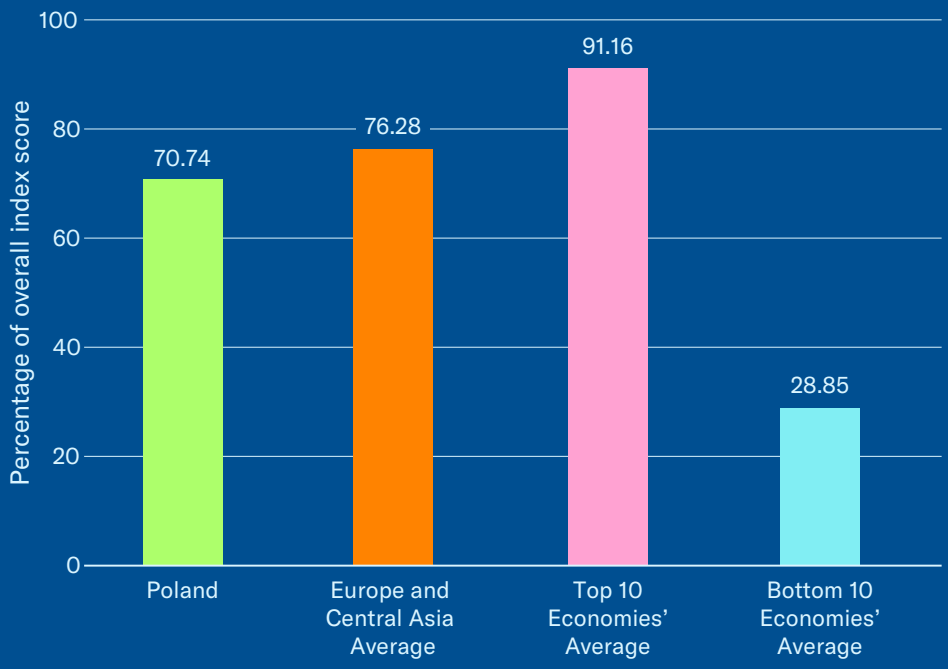
Poland

Rank
19/55

Category Scores



Overall Score in Comparison



Poland

Key Areas of Strength

- R&D tax incentives are in place
- The 2018 transposition of EU Trade Secrets Directive harmonized Polish trade secret law with EU standards
- The legal framework for IP protection is largely aligned with EU standards

Key Areas of Weakness

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for new EU compulsory licensing regime
- 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 active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**3.16**
10. Term of protection	0.66
11. Exclusive rights	0.25
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	0.25
15. Digital rights management	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.50**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**2.25**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

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

Total: 70.74%

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).

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. The commission posits in the "Call for Evidence" that a pressing need exists 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have never been used. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 threaten the very foundation of the EU's position as a global leader in innovation and high-tech industries including biopharmaceuticals.

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.

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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

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 significant 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 take-down 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. 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, Poland remained one of a handful of EU member states that had not transposed the CDSM Directive. In early 2023, the European Commission was reported to have referred these members, including Poland, to the Court of Justice for their delay in implementing the directive. The Index will continue to monitor these developments in 2024.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term:
RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023, the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs.

Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU. Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allows companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access.

For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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. Within this context, IP rights play no part.

The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including Poland, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

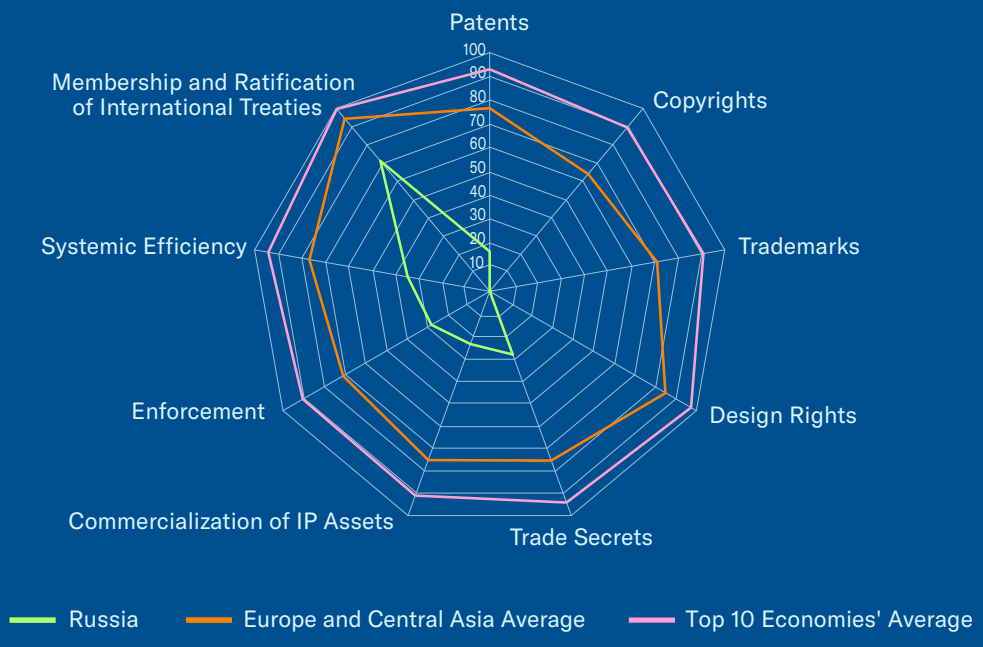
Enforcement

34. Civil and procedural remedies: In 2023, important changes were made to the Polish Code of Civil Procedure, including with respect to the enforcement of IP rights. Most importantly, when seeking an injunction against alleged infringement, rightsholders must inform the presiding court whether any invalidation proceeding of the right in question is currently being pursued or has been in the past. It will also no longer be possible to seek an injunction more than six months after a rightsholder learns of a potential infringement. Finally, the amendments establish that, in most cases, all parties—including an alleged infringer—must be heard by the presiding court before a decision is issued. Some exceptions are in place for cases with extreme urgency. It remains unclear if these changes will have any material impact on rightsholders' ability to seek effective civil redress through Poland's judiciary. The Index will continue to monitor these developments in 2024.

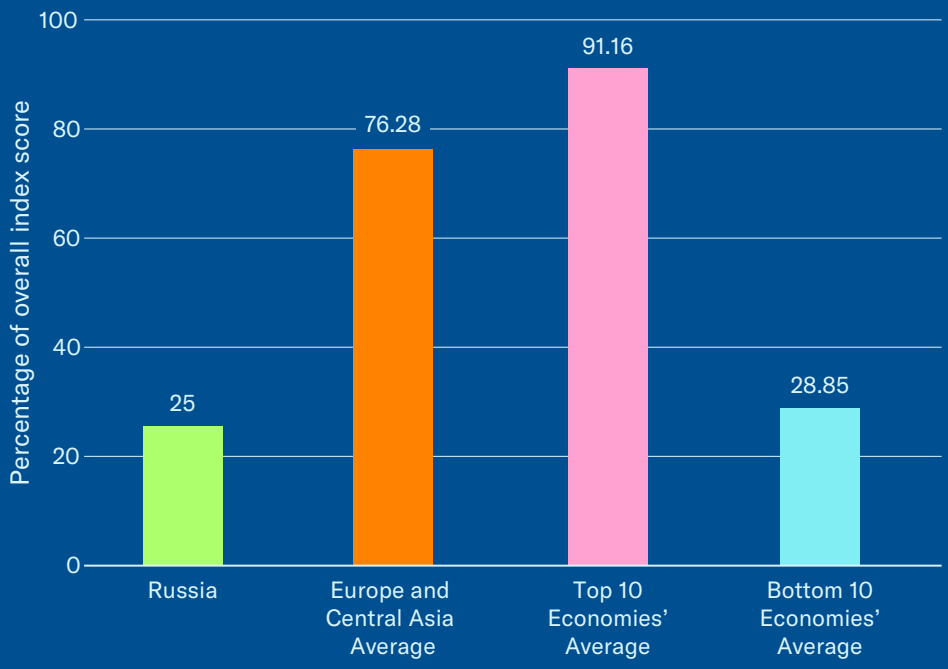
Russia

Rank
54/55

Category Scores



Overall Score in Comparison



Russia

Key Areas of Strength

- The past few years have seen new copyright laws passed that strengthen rightsholders' ability to request the disabling of access to infringing material online
- Federal Service for Intellectual Property (ROSPATENT) has in place numerous PPHs and is a full participant in the GPPH

Key Areas of Weakness

- The 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 exists about 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

Russia

Key Areas of Strength
(continued)

- Full participant in international IP treaties benchmarked in the Index

Key Areas of Weakness
(continued)

- 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 the existing basis for action
- Administrative and regulatory barriers to licensing activities, including direct government intervention
- Increasingly punitive localization requirements targeting information and communication technology (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
Category 1: Patents, Related Rights, and Limitations	**1.50**
1. Term of protection	0.00
2. Patentability requirements	0.00
3. Patentability of CIIs	0.00
4. Plant variety protection	0.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.50
Category 2: Copyrights, Related Rights, and Limitations	**0.00**
10. Term of protection	0.00
11. Exclusive rights	0.00
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.00
15. Digital rights management	0.00
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**0.00**
17. Term of protection	0.00
18. Protection of well-known marks	0.00
19. Exclusive rights, trademarks	0.00
20. Frameworks against online sale of counterfeit goods	0.00
Category 4: Design Rights, Related Rights, and Limitations	**0.00**
21. Industrial design term of protection	0.00
22. Exclusive rights, industrial design rights	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	**0.85**
23. Protection of trade secrets (civil remedies)	0.00
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.60

Indicator	Score
Category 6: Commercialization of IP Assets	**1.42**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.25
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**1.98**
32. Physical counterfeiting rates	0.35
33. Software piracy rates	0.38
34. Civil and precedural remedies	0.00
35. Pre-established damages	0.00
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**1.75**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**5.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

Total: 25.00%

Spotlight on the National IP Environment

Past Editions versus Current Score

Russia's overall score has decreased from 25.02% (12.51 out of 50) in the eleventh edition to 25.00% (12.50 out of 50). This reflects a score decrease for indicator 32.

Area of Note

As noted in last year's Index, over the course of 2022, the Russian government 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 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 placed in Russian rubles.

Decree 299 targets potential royalty payments to rightsholders for compulsory licenses. 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 over the course 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 protection.

In 2023, further proposals were presented in the Duma for introducing a compulsory licensing regime specifically targeting copyrighted and audiovisual content. Similarly, one of the central features of the strategic cross-cutting industrial-economic policy document Technology 2030—approved by Prime Minister Mishustin in late 2022—is the use of involuntary tools to access innovative technologies and IP assets. The document, which lays out a long-term plan for achieving "technological sovereignty" and parity with the West, specifically identifies the use of involuntary licensing mechanisms of "unused results of intellectual activity, the exclusive rights to which belong to rightsholders from unfriendly countries" as one of the pillars on which Russian future technological development can be achieved.

More broadly, in 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."

President Putin also signed into law amendments to Article 18 of the law through Federal Law No. 213-FZ. These amendments 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."

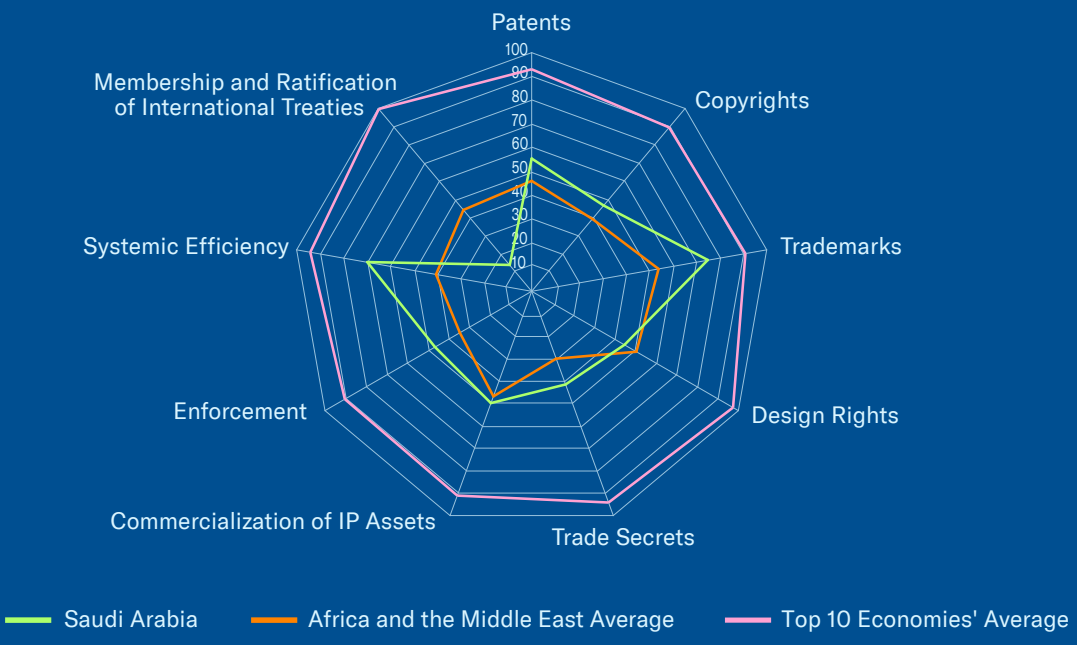
At the end of March 2023, the government issued Resolution 506 (signed by Prime Minister Mishustin). This resolution appears to limit the suspension of protection under the Civil Code Part IV to Articles 1359(6) and 1487, both of which relate specifically to parallel imports and Russia's preexisting 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 can be revoked or altered at any time. Subsequent government announcements clarified the goods that are subject to the parallel importation regime. This list is subject to variation. Changes have taken place over the course of 2022 and 2023, and the list has consistently included a broad range of consumer goods products, medical goods, automotive parts, electronics, and other staple goods. Press reports suggest that the list has expanded in 2023 with both luxury goods added and an increasing number of automotive manufacturers. The estimated value of parallel imports for 2022 was over $20 billion and growing. The net result is continued deep and abiding uncertainty about the extent to which rightsholders will, in practice, at any point in the future be able to use 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 for indicators 1, 2, 3, 4, 7, 10, 11, 12, 13, 15, 17, 18, 19, 21, 22, 23, 27, 34, and 35 were reduced to 0 last year. No positive changes to Russia's national IP environment occurred in 2023, and these reductions remain in place. The Index will continue to monitor these developments in 2024.

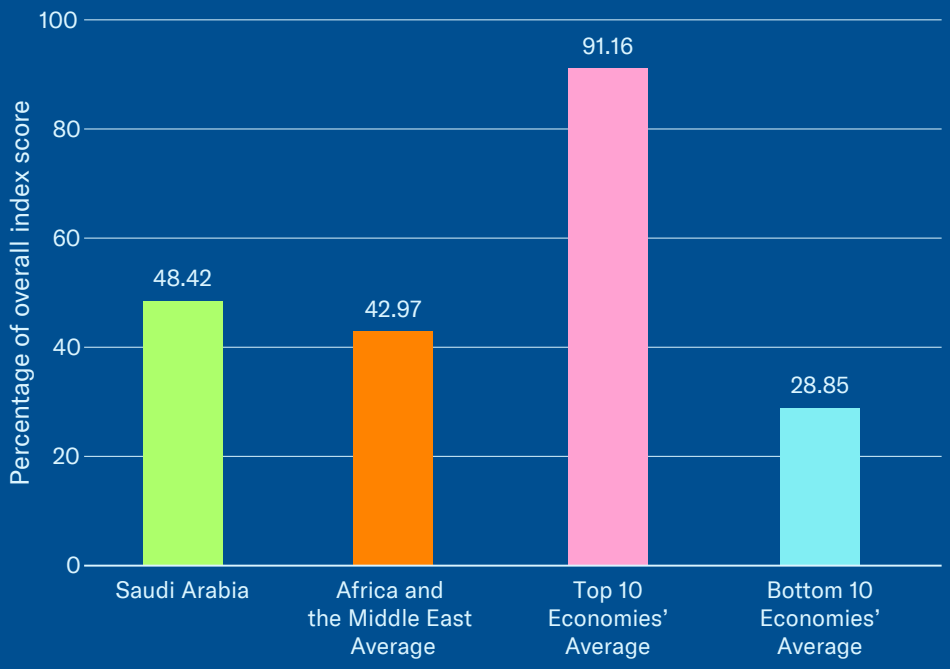
Saudi Arabia

Rank
32/55

Category Scores



Overall Score in Comparison



Saudi Arabia

Key Areas of Strength

- The Saudi IP authority (SAIP) continues to assume leadership on IP policy and enforcement; a marked increase in online copyright and trademark enforcement occurred in 2022-2023
- SAIP has put in place an ambitious reform agenda and is revamping the administration of the Kingdom's national IP environment; continued positive efforts occurred in 2023
- SAIP is leading and coordinating IP enforcement on the 2021 National Committee for the Enforcement of Intellectual Property Rights

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 related to protection online
- Increasing number of localization requirements
- Industry reports of a lack of practical availability of RDP—indirect reliance has been allowed when reviewing follow-on products

Key Areas of Strength
(continued)

- Multiple PPHs joined 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 is in place for customs officials

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**5.00**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.75
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**3.28**
10. Term of protection	0.53
11. Exclusive rights	0.50
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.75
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**3.00**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**3.28**
32. Physical counterfeiting rates	0.50
33. Software piracy rates	0.53
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.50**
39. Coordination of IP rights enforcement	1.00
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	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**1.00**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 48.42%

Spotlight on the National IP Environment

Past Editions versus Current Score

Saudi Arabia's overall score has increased from 42.38% (21.19 out of 50) in the eleventh edition to 48.42% (24.21out of 50). This reflects score increases for indicators 8, 12, 15, 18, 19, 20, 22, 32, 35, 40, and 41.

Area of Note

In April, the national IP office, the Saudi Authority for Intellectual Property (SAIP), released a draft version of an overarching Intellectual Property Law. The draft law covers all major IP rights in the Kingdom. It does not provide new legal definitions or requirements to the existing specialized statute; rather, the draft law aims to complement the existing legal framework and to achieve "consistency and harmony between specialized systems…enhancing clarity and transparency in procedures related to intellectual property." Notably, strong emphasis is placed on promoting the identification, development, and use of IP assets by public sector entities and supported organizations. Chapter 4 of the law requires such entities to identify and use IP policies in their day-to-day operations. The law also refers to the role that AI will play in the development of new technologies and products; the draft law states that ownership of a patent right can be granted to only a "natural person." At the time of research, no final version had been published or any further action taken. The Index will monitor these developments in 2024.

Patents, Related Rights, and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism:
As noted in last year's Index, in 2022, the Saudi Food and Drug Authority (SFDA), 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 Saudi FDA when registering a follow-on drug application. The procedure states that follow-on applicants must submit a statement (Annex 1) stating that the follow-on application does not infringe on 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 procedure is a positive move by the SFDA. 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 time 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 because 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 noninfringement 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 2024.

8. Membership in a Patent Prosecution Highway (PPH):
As noted over the course of the Index, since 2019, SAIP has actively pursued PPH agreements around the world. To date, the Authority has signed agreements with all IP5 offices: the Korean Intellectual Property Office (KIPO), the United States Patent and Trademark Office (USPTO), the Japan Patent Office (JPO), the European Patent Office (EPO), and the China National Intellectual Property Administration (CNIPA). PPH initiatives and increased cooperation among IP offices are a tangible way in which the administration and functioning of the international IP system can be improved and harmonized to help inventors and rightsholders.

To better take account of the increasing number of economies that engage in bilateral agreements with the IP5, from this edition of the Index onward, all non-IP5 economies will be able to achieve a full score for this indicator if they have equivalent, unrestricted, separate, and bilateral PPH agreements in place with all IP5 offices. As a result, Saudi Arabia's score for this indicator has increased to 1.

Copyrights, Related Rights, and Limitations

12. Expeditious disabling of infringing content online; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation:
Since its inception in 2017-2018, SAIP has worked to improve the national IP environment and rightsholders' ability to enforce their copyrights more effectively. The Authority works directly with rightsholders both as an intermediary, referring cases of infringement to relevant Saudi enforcement authorities, and as an administrative enforcement authority. Specifically, SAIP has made the disabling of access to copyright infringing content a major part of its enforcement remit.

Historically, the disabling of access to web content, including copyright infringing content, occurred sporadically through the Ministry of Culture and Information. Today, SAIP offers a portal through which rightsholders can directly communicate any suspected online infringement to the Authority, which will then investigate and take enforcement action. This positive worked continued in 2023.

The Authority's latest Annual Report of Intellectual Property Enforcement for the Year 2022 shows both the scale and magnitude of the SAIP's enforcement efforts. With respect to copyright enforcement, in 2022, the Authority ordered the disabling of access to close to 1,500 websites and online access points.

This was almost double the number of orders issued in 2021 and five times the number in 2020. Much of this copyright infringing content consisted of illicit streaming of TPM and DRM protected live sports and audiovisual content.

In addition to its strong enforcement activity online, SAIP acted against the sale of physical copyright infringing goods in brick-and-mortar stores. The Authority has developed and expanded a "mystery shopper" program as an intelligence gathering tool all around the Kingdom and as a basis for subsequent law enforcement action. In 2022, SAIP carried out almost 1,500 such visits. The Index commends SAIP and the Saudi government for their continued regional leadership on this issue. This is yet another positive step taken by SAIP to offer rightsholders a more effective and practical route of copyright enforcement in Saudi Arabia. As a result of these continued positive efforts, the scores for indicators 12 and 15 have increased by 0.25, respectively.

Trademarks, Related Rights, and Limitations; and Design Rights, Related Rights, and Limitations

18. Protection of well-known marks; 19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks; 20. Availability of frameworks that promote action against online sale of counterfeit goods; and 22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights:
SAIP's strong enforcement efforts described previously have not been confined to copyright infringing goods; the Authority has an equally well-developed and growing capability to enforce trademarks and design rights. In 2022, SAIP reported that it had seized more than 12 million trademark and design infringing items, including foodstuffs, clothing and footwear, luxury goods, bags, and leather goods.

The Authority received a record 1,100 rightsholder complaints about trademark infringement, a marked increase from the 194 received in 2021. SAIP's "mystery shopper" program is not exclusive to copyright infringement but includes other IP rights, such as trademark and design infringement. The authority worked with online merchants and intermediaries and took down close to 60,000 e-commerce–related ads or infringing content. These are significant and sustained actions taken by the Authority, and they mark another significant step toward improving the enforcement environment as it relates to trademarks and design rights in the Kingdom. As a result of these positive actions, the scores for indicators 18, 19, 20, and 22 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 "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 commended 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 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 "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 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 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 2022, SAIP and SFDA reportedly released a statement reaffirming their support for the availability of regulatory data protection in the Kingdom. In its 2022 Investment Climate Statement, the U.S. State Department noted the publication of this statement and, through it, SAIP's "commitment to regulatory data protection." The Index will continue to monitor these developments in 2024.

Enforcement

35. Preestablished damages and/or mechanisms for determining the amount of damages generated by infringement:
No statutorily defined preestablished or statutory damages exist for most major IP rights, and, historically, rightsholders have had difficulty being awarded substantial and deterrent damages. However, that may now change. For the past two to three years, SAIP has published the judgments reached by standing committees related to copyright and patent infringement (the "Committee for Review of Violations of the Copyright Protection System" and the "Committee for Consideration of Patent Claims"). This suggests that, first, the number of cases considered has increased, and, second, damages are more consistently awarded. For example, in 2022, the Committee for Review of Violations of the Copyright Protection System issued decisions in 175 cases—up by 16% compared with 2021—and issued fines and damages of close to $400,000. As a result, the score for this indicator has increased by 0.25.

Systemic Efficiency

40. Consultation with stakeholders during IP policy formation:
Historically, there has been no formal or statutory requirement that Saudi authorities offer public consultations on proposed legislative and regulatory changes. Public consultations have taken place, but they have varied in length and in substance from ministry to ministry and from topic to topic. As the U.S. Department of State noted in the 2023 Investment Climate Statement, "Stakeholder consultation on regulatory issues is inconsistent. Some Saudi organizations are diligent in consulting businesses affected by the regulatory process, while others tend to issue regulations with no consultation at all. Proposed laws and regulations are not always published in draft form for public comment…[and] the processes and procedures for stakeholder consultation remain generally opaque and are not codified in law or regulations."

However, as noted over the course of the Index, with regard specifically to consultations on changes in IP policy, SAIP has from the outset consistently issued calls for public comments and has sought to actively engage with rightsholders in the Kingdom and internationally. This has continued in 2023 with new consultations issued on a new draft IP Law (see previous discussion) and calls for comments on the Kingdom joining several important international IP treaties, including the Madrid Protocol and the WIPO Internet Treaties. More broadly, the entire Saudi government has increased efforts to formalize the public consultation process over the past few years. Following the issuing of Cabinet Resolution 476 and as part of the broader transition toward Vision 2030, the National Competitiveness Center now houses an online centralized portal, Istitlaa, where all government-issued public consultations can be accessed. This marks another highly positive development: regular consultations with all relevant stakeholders are a prerequisite for developing a world-class national IP environment in line with the highest international standards and practices. As a result, the score for this indicator has increased by 0.25.

41. Educational campaigns and awareness raising: Historically, awareness-raising activities in Saudi Arabia have primarily taken place through the King Abdulaziz City for Science and Technology and have focused on patents and technology transfer. There have been examples of past awareness-raising efforts on other IP rights or themes through various Saudi government agencies (e.g., software piracy and a 2012 "General Administration Copyright Workshop" in 2013 and the "Annual Government Officials Conference on Copyright Protection in Arab Countries" held in Riyadh) but, overall, there has been limited activity in relation to other IP rights or key themes such as counterfeiting or the value of IP and knowledge-based assets to the Saudi economy.

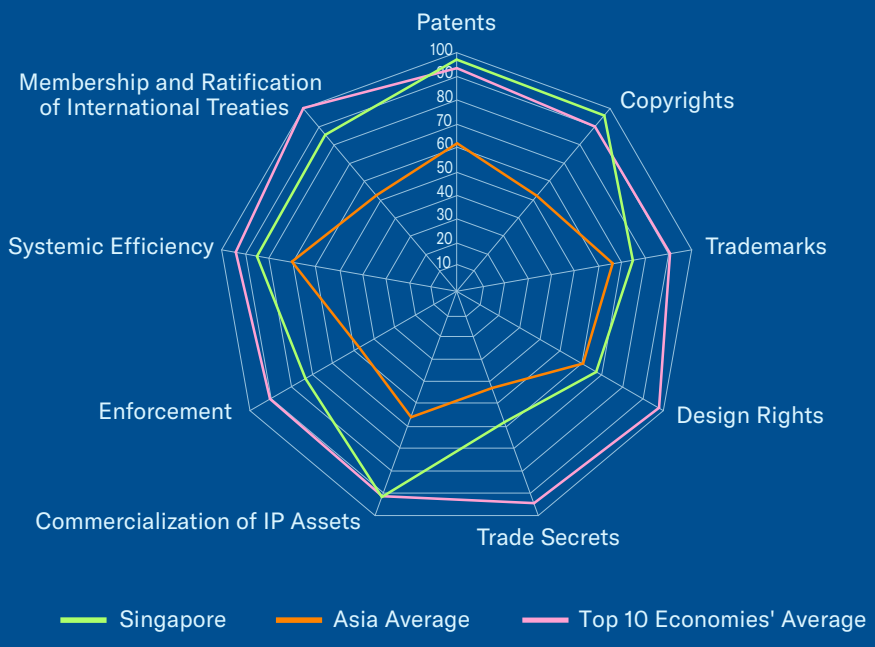
However, in 2019, SAIP launched and has since sustained several important and high-profile awareness-raising campaigns aimed at reaching the public. These include a general cross-sectoral campaign titled "I Respect Intellectual Property Rights," the copyright-related campaigns "Own Your Drawing" and "Acquire Your Idea," and a special initiative targeting IP and sports called "Reach for Gold: IP and Sports," which includes a partnership with the Saudi soccer league. SAIP has also supported an "Intellectual Property Pioneers' Program," an initiative targeting university graduates with technical training. These positive efforts have continued in 2023. SAIP has launched or expanded a range of programs aimed at raising awareness about the positive socioeconomic impact of IP rights and the negative impact of counterfeiting and piracy. Two campaigns and initiatives worth highlighting are the "Intellectual Property Respect Council" (a program targeting IP awareness and outreach activities to businesses) and the "Intellectual Property Respect Officer Initiative" (a program designed to increase awareness and IP rights compliance within the public sector). Both programs were expanded in 2022 with the number of council meetings doubling and more than 100 SAIP officials carrying out awareness-raising and educational activities within public sector entities.

In partnership with the Ministry of Education, SAIP also launched a new "Intellectual Property Education Project," which will introduce the concept of IP rights and their value in public education. Finally, the Authority launched a new campaign called "The Game Is Open" to promote the socioeconomic value of IP rights and their role in promoting creativity and innovation. Public outreach campaigns such as these have a real and positive impact on the national consciousness and highlight the value that IP rights bring to society. SAIP and the Saudi government should be commended for their sustained support and expansion of these and their many other educational and awareness-raising efforts. As a result of these positive efforts, the score for this indicator has increased by 0.5.

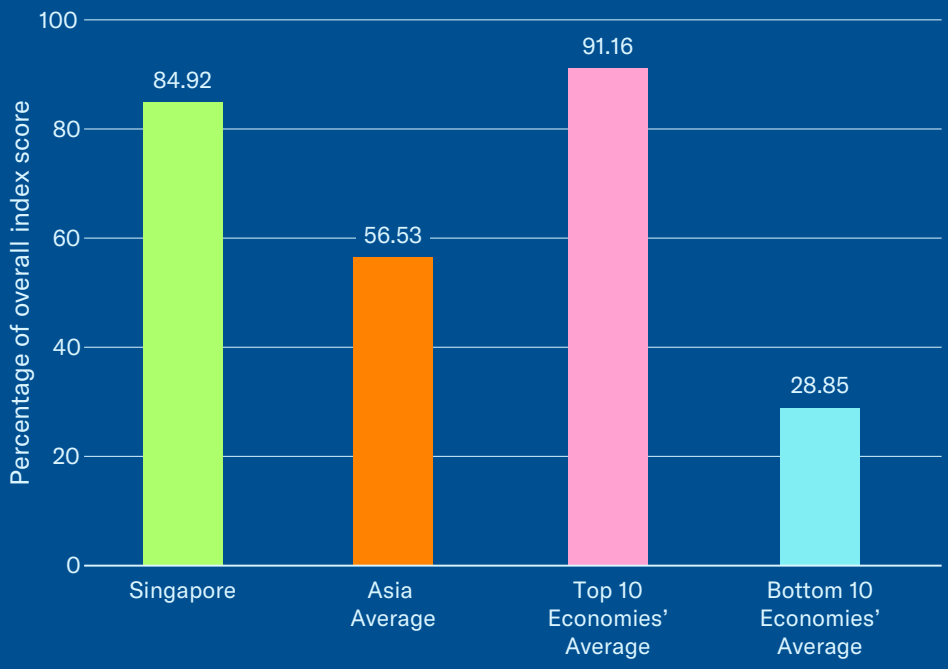
Singapore

Rank
12/55

Category Scores



Overall Score in Comparison



Singapore

Key Areas of Strength

- The 2021 Copyright Act contains substantial liability provisions related to the sale and distribution of set-top boxes
- Implementation of an R&D and IP tax incentives scheme in 2019
- An advanced national IP framework is in place
- Global leader in online copyright enforcement—continued strong efforts in 2022
- Singapore is an active participant in efforts to accelerate patent prosecution; Ministry of Law and the Intellectual Property Office of Singapore (IPOS) has several PPHs in place and is a member of the GPPH

Key Areas of Weakness

- The 2021 Copyright Act expanded the existing copyright exceptions regime
- Estimated software piracy has decreased from 35% in 2009 to 27% today, but it is still high for a developed high-income economy
- Lack of transparency and data on customs seizures of IP-infringing goods

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**8.75**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	1.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**6.74**
10. Term of protection	0.74
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.35**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**1.75**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**5.50**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**5.12**
32. Physical counterfeiting rates	0.64
33. Software piracy rates	0.73
34. Civil and precedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	0.75
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**4.25**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**6.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 84.92%

Spotlight on the National IP Environment

Past Editions versus Current Score

Singapore's overall score has decreased from 84.94% (42.47 out of 50) in the eleventh edition to 84.92% (42.46 out of 50). This reflects a score decrease for indicator 32.

Copyrights, Related Rights, and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:
As discussed in the past two editions of the Index, the 2021 changes to the Copyright Act included significant changes to Singapore's copyright limitations and exceptions regime. Conceptually, the new act changed the regime from a "fair dealing" framework to one of "fair use." As noted at the time, in a negative development, a new Section 204 broadened existing educational exceptions to include digital materials found online. Under the amended law, educational institutions and students are now, as a rule, able to use any and all materials found on the internet without seeking 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 expanded exception will lead to the 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 in place in the sense that works on the internet can be circulated only through the network that is operated by or through an educational institution and in which access is limited to staff and students.

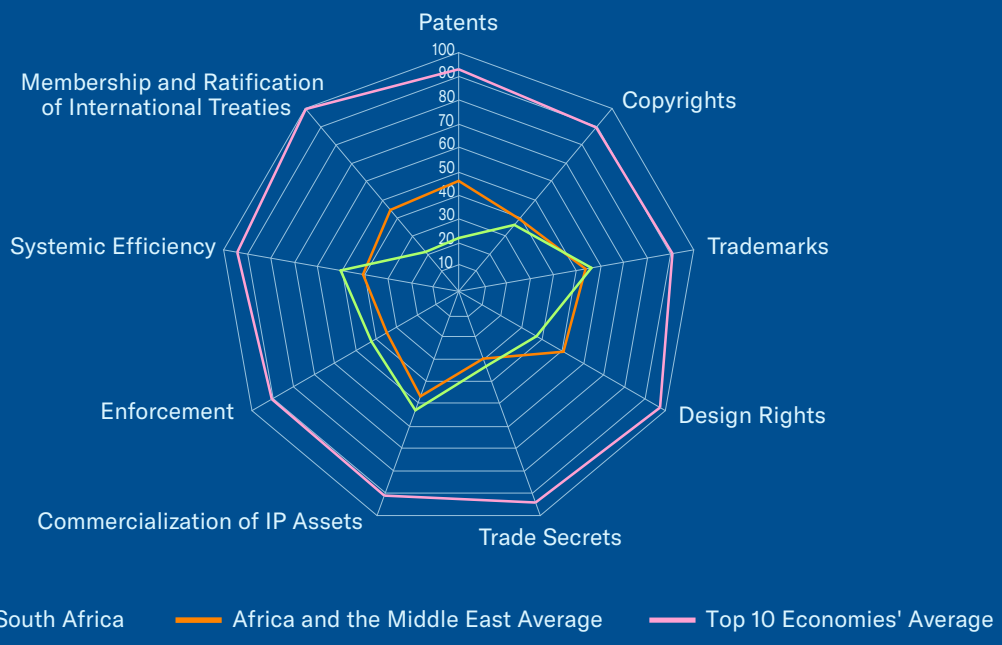
Still, as the Index pointed out at the time, it remains unclear how effective the limitations on this usage would be in practice. This remained the case in 2023.

The act also includes a clarification on the extent to which text and data mining is allowed for research purposes (called "computational data analysis"). Text and data mining is an important area of future economic activity. Advances in computational power and new technological advancements in AI and machine learning allow for scientific breakthroughs and innovation to take place through the analysis of large volumes of data and information. However, this is a new area of copyright law with little in the way of applicable jurisprudence either in Singapore or internationally. Like similar exceptions introduced in other jurisdictions—including the European Union's Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive)—under Section 244(2)(d) of the act, copying or communicating for computational analysis can be carried out only for works that have been lawfully obtained or accessed. Given the existing dynamics of the internet and the volume of infringing content available online—again, much of it made available without rightsholders' permission or even their knowledge—it is essential that this safeguard be adhered to and that rightsholders be able to practically enforce their rights. The Index will continue to monitor these developments in 2024.

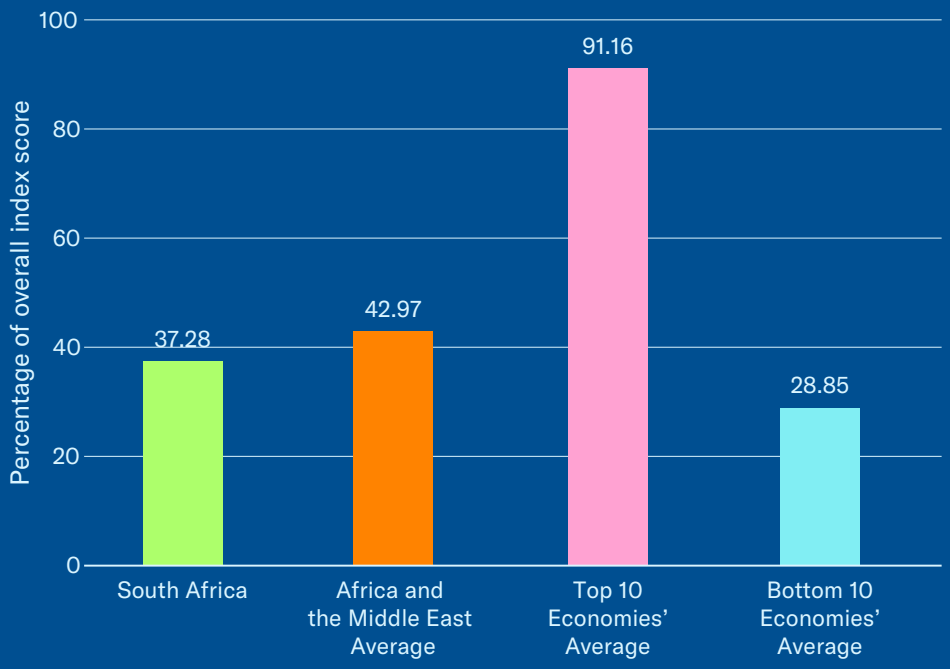
South Africa

Rank
45/55

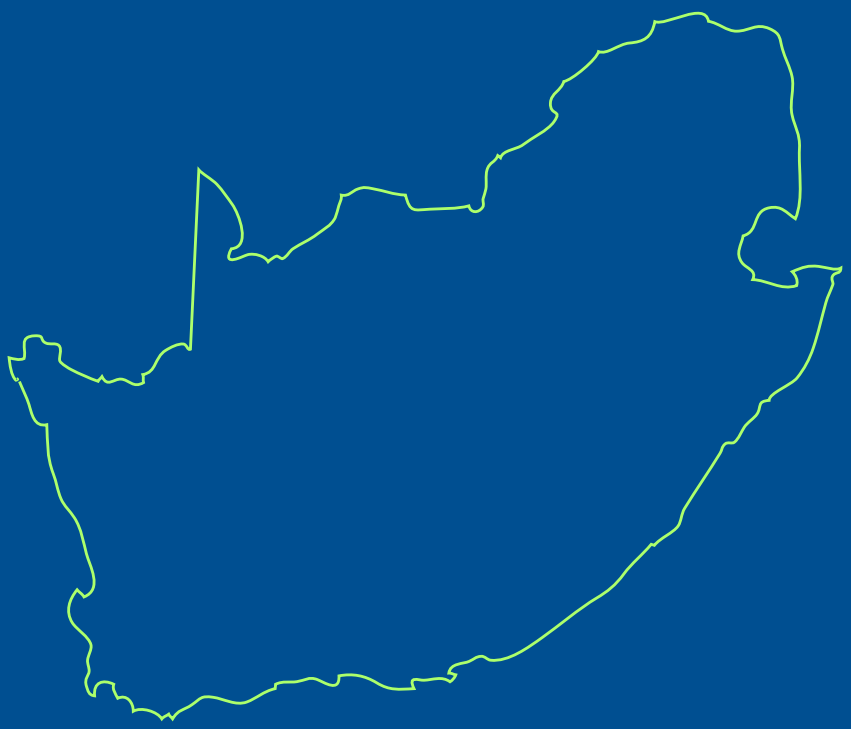
Category Scores



Overall Score in Comparison



South Africa



Key Areas of Strength

- The 2021 Cyber Crime Act strengthens potential criminal sanctions for the misappropriation and illicit accessing of trade secrets and confidential information
- Basic IP framework is 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; the focus is not on the innovation and development of new IP in South Africa but on the use of existing developed IP through compulsory licenses, parallel imports, and restricting patentability of pharmaceuticals
- Proposed copyright amendments create uncertainty for rightsholders through expansive "fair use" definitions
- Major gaps in laws and enforcement exist across all categories of the Index

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

Indicator	Score
Category 6: Commercialization of IP Assets	**3.17**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**2.94**
32. Physical counterfeiting rates	0.51
33. Software piracy rates	0.68
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.50**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**1.50**
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 37.28%

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

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. Just as for the rest of the world, the ICT and internet revolutions are fundamentally changing how South Africans interact socially and economically. In virtually all sectors, industries, and businesses, digital and mobile technologies shape economic interaction today. 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. Having an effective and modern copyright regime that encourages innovation and creativity is critical to making the most of the socioeconomic opportunities that these deep structural changes to human behavior offer. Given the size and breadth of the creative sector in South Africa, with the right IP-based incentives in place, the copyright industries could become an even more powerful source of economic growth and development.

Unfortunately, the draft amendments do not fundamentally address the current shortcomings in South Africa's copyright regime. Instead, they add more uncertainty and potential difficulties for rightsholders. Most notably, the draft amendments have been consistent in their aim to introduce a new, more expansive system of exceptions and limitations to copyright. For many years, there has been a lack of clarity in South Africa on what constitutes infringement of copyright and what is fair reproduction and use, with no relevant full definition in the current Copyright Act and only limited case law. All the draft copyright amendments have expanded the current exceptions regime.

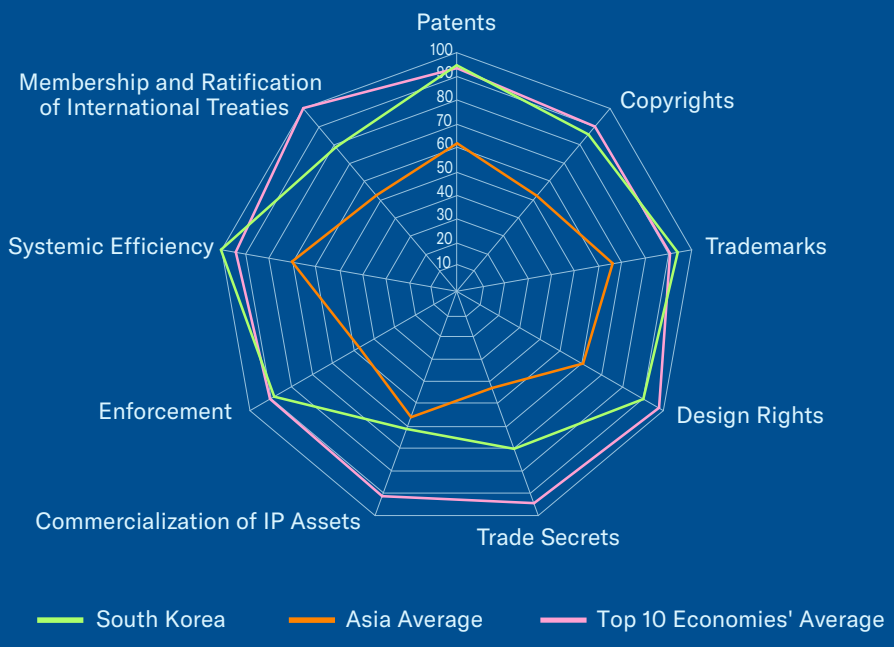
The latest drafts have introduced a new general doctrine of "fair use" exceptions to all copyrighted work as well as several remarkably broad statutory exceptions and limitations, particularly for educational use. Exceptions and limitations to copyright should be considered against the three-step test embodied in the Berne Convention and the WTO TRIPS Agreement. Yet, as noted by the 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 exist only 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 to fundamentally strengthen rightsholders' ability to more effectively enforce their rights or address the growing issue of online piracy. Of note is that the draft legislation still does not include additional enforcement measures such as the disabling of access through an injunctive-style relief program.

The 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, Canada, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies have also introduced "dynamic" injunctions. Such injunctions address the issue of mirror sites and disable infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders have become more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, the UK, and Canada. The Index will continue to monitor these developments in 2024.

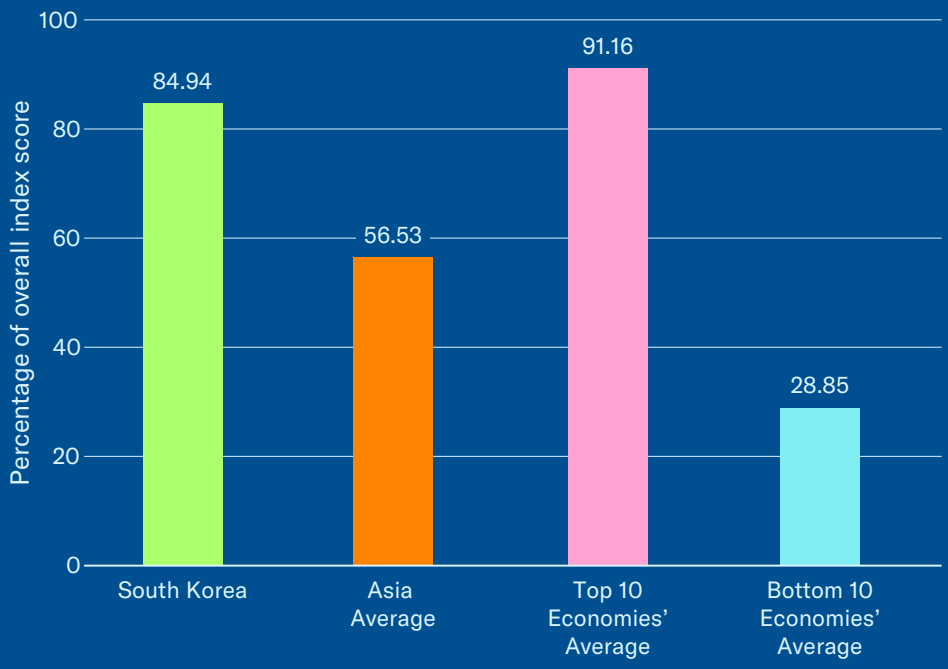
South Korea

Rank
11/55

Category Scores



Overall Score in Comparison



South Korea

Key Areas of Strength

- Over the past decade, South Korea has taken an increasingly active stance toward combating online piracy; this 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 economic activity
- Amendments to the Unfair Competition Prevention and Trade Secret Protection Act in 2020 strengthened criminal sanctions
- 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

Key Areas of Weakness

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

Key Areas of Strength
(continued)

- Patenting standards are in line with international best practices
- A relatively robust legal framework for trademark and design protection is in place
- Membership in Global PPH and IP5 and the new postgrant 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

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

Indicator	Score
Category 6: Commercialization of IP Assets	**3.67**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**6.16**
32. Physical counterfeiting rates	0.73
33. Software piracy rates	0.68
34. Civil and precedural remedies	0.75
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**5.00**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**5.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 84.94%

Spotlight on the National IP Environment

Past Editions versus Current Score

South Korea's overall score has increased from 84.44% (42.22 out of 50) in the eleventh edition to 84.94% (42.47 out of 50). This reflects a score increase for indicator 26.

Copyrights, Related Rights, and Limitations

As has been highlighted over the course of the Index, over the past 15 years, 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 Communications 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. 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 (P2P) sites after three instances of disabling a 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 continued to be substantial and valued at over $12 billion in exports in 2019.

Nevertheless, as the demand for Korean creative content continues to grow, so have levels of infringement both in Korea and abroad. In response to this increase in illicit content, a new antipiracy initiative targeting the infringement of "K-Content" was launched in 2023. Although the effort is led by the Ministry of Culture, Sports, and Tourism, this is an all-of-government effort and will involve the Ministry of Science and ICT, the Ministry of Foreign Affairs, the Ministry of Justice, and the KCC. The initiative is built around increasing domestic enforcement through swifter disabling of access to websites and online access points that provide or enable infringement (primarily through the KCC's administrative enforcement program but also through the Ministry of Justice and national police); increasing international cooperation and enforcement (chiefly through INTERPOL and U.S. law enforcement); and the launch of new awareness-raising and educational efforts on the importance of copyright protection in Korea. As these recent efforts show, Korea continues to stand as an example to Southeast Asia and emerging markets around the world of what strong and consistent copyright protection can achieve in terms of stimulating innovation, cultural production, and economic activity. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

26. Barriers to market access:
As noted over the course of the Index, Korea has historically imposed restrictions on digital trade and, specifically, on the cross-border transfer of data. Although the 2011 Personal Information Protection Act (PIPA) has technically allowed cross-border data transfers, the conditions for consent and disclosure requirements have been high. Local storage requirements for the public sector have also been in place under the 2015 Promotion of Cloud Computing and Protection of Users Act and the Cloud Security Assurance Program. These cloud storage restrictions have effectively meant that non-Korean entities have been de facto unable to participate in the Korean government's recently announced full digital migration. Further sector-specific data transfer and storage restrictions have also been in place for financial services, satellite mapping, and payment services.

In a positive move, the PIPA was amended in early 2023 with the new law and implementing regulations taking effect in September. These changes now make it less onerous for cross-border transfers to take place by expanding the situations whereby a data subject's explicit consent is not required, and a cross-border transfer is permissible.

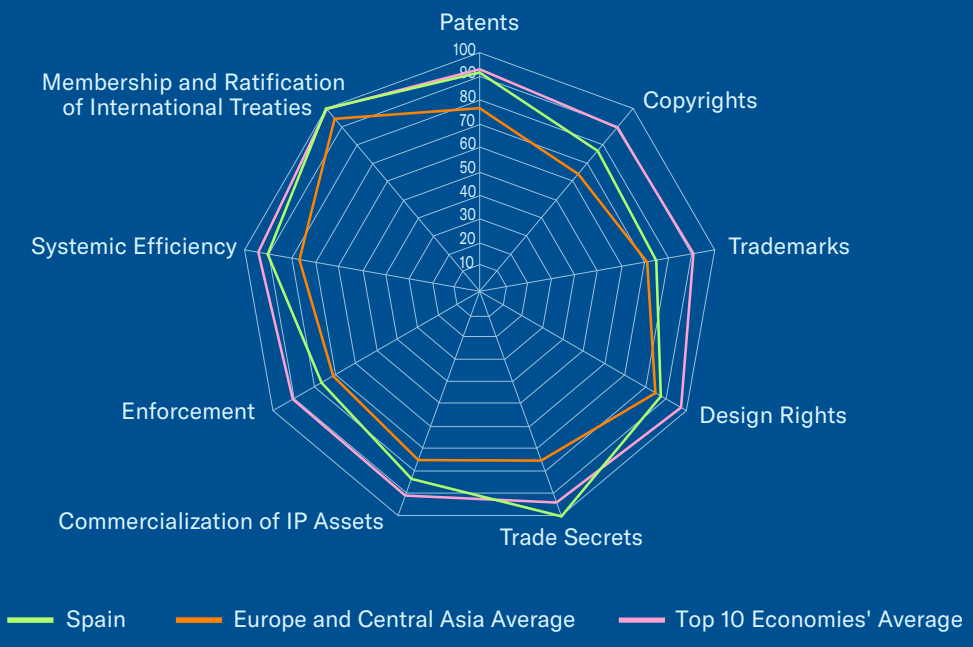
The ICT and internet revolutions have fundamentally changed how consumers interact socially and economically. In virtually all industries, data and digital technologies shape business and economic interaction today. These technologies allow companies across all business sectors and public and private research organizations to collect and use greater levels of data and information than ever before.

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, it is possible 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 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 must be formulated accordingly. As a result of the positive amendments to the PIPA, the score for this indicator has increased by 0.25.

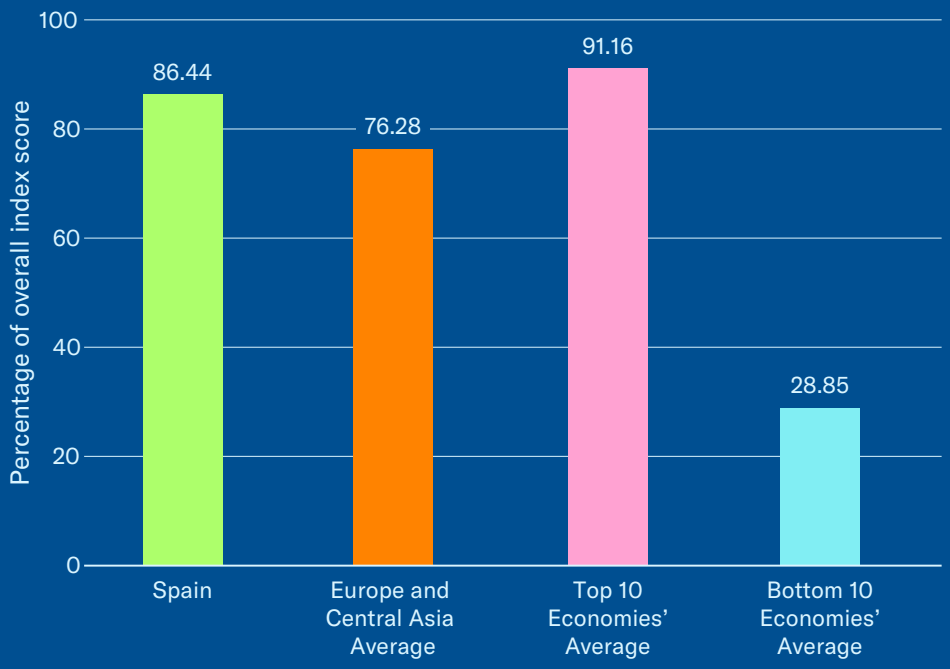
Spain

Rank
9/55

Category Scores



Overall Score in Comparison



Spain

Key Areas of Strength

- The Royal Decree-Law 24/2021 transposed EU Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive)
- The 2021 Protocol to Strengthen the Protection of Intellectual Property Rights further strengthens Spanish enforcement efforts
- The 2019 trade secret law is operational; the Business Secrets Act was entered into force in March 2019
- Stronger copyright enforcement measures are in place through Royal Decree Law 2/2018—continued enforcement efforts through the Ministry of Culture

Key Areas of Weakness

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights including RDP
- 2023 proposal for new EU compulsory licensing regime
- 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 with those of other EU economies; software piracy is estimated at 42%

Key Areas of Strength
(continued)

- As an EU member state, Spain has an advanced IP system in place
- Sector-specific rights are in place and enforced
- Efforts made 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 exist

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**5.38**
10. Term of protection	0.63
11. Exclusive rights	0.75
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.75
15. Digital rights management	0.75
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.75**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**5.00**
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**5.34**
32. Physical counterfeiting rates	0.76
33. Software piracy rates	0.58
34. Civil and precedural remedies	0.75
35. Pre-established damages	0.50
36. Criminal standards	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 86.44%

Spotlight on the National IP Environment

Past Editions versus Current Score

Spain's overall score remains unchanged at 86.44% (43.22 out of 50).

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime: "In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision has never been used. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 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.

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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term
RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023 the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU.

Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allows companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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 health system. Within this context IP rights play no part.

The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including Spain, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

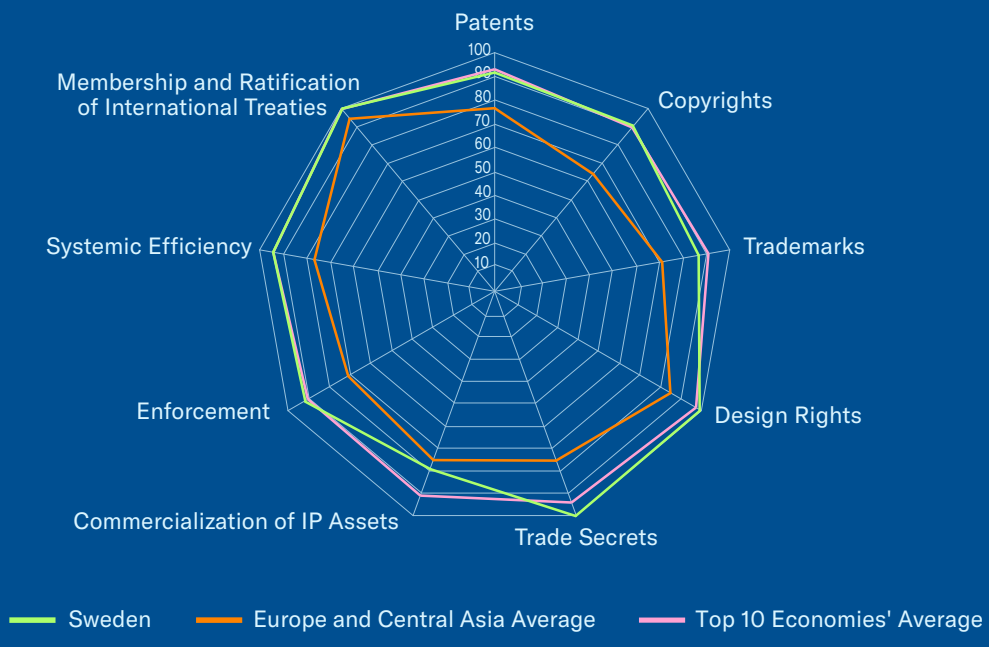
27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

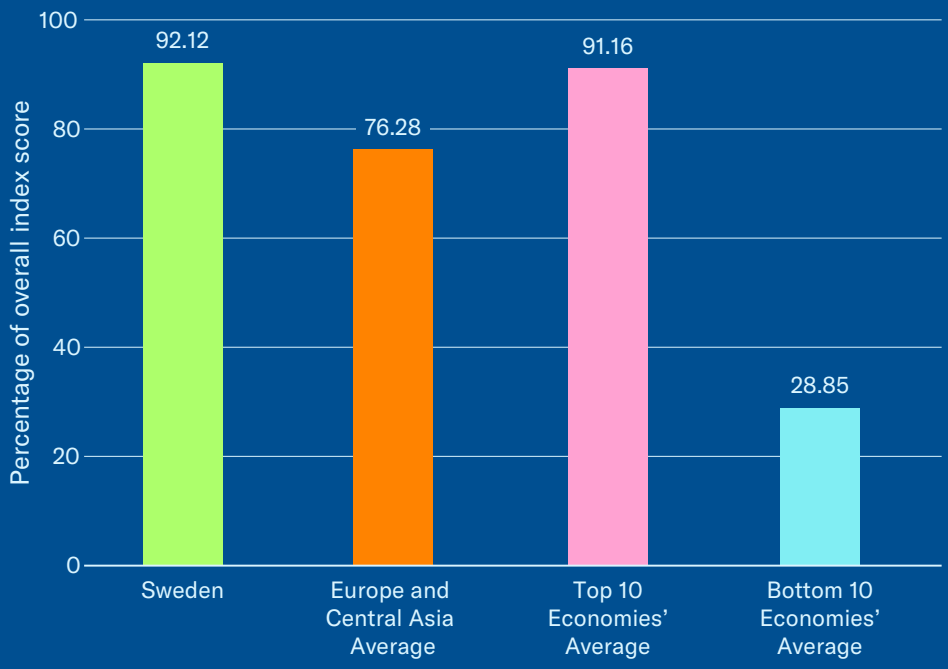
Sweden

Rank
5/55

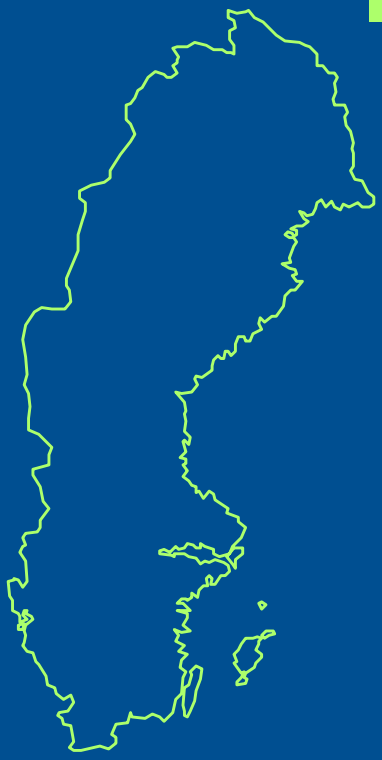
Category Scores



Overall Score in Comparison



Sweden



Key Areas of Strength

- 2021 accession to the 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 about under what circumstances Swedish ISPs and internet mediators will be ordered to disable access to infringing content

Key Areas of Weakness

- The 2023 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP
- 2023 proposal for new EU compulsory licensing regime
- 2023 proposal for new EU compulsory licensing regime
- No R&D or IP-specific tax incentives are in place
- Regulation 2019/933 and the 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
Category 1: Patents, Related Rights, and Limitations	**8.25**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights, Related Rights, and Limitations	**6.35**
10. Term of protection	0.60
11. Exclusive rights	1.00
12. Injunctive-type relief	1.00
13. Cooperative action against online piracy	0.75
14. Limitations and exceptions	1.00
15. Digital rights management	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks, Related Rights, and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

Indicator	Score
Category 6: Commercialization of IP Assets	**4.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**6.46**
32. Physical counterfeiting rates	0.90
33. Software piracy rates	0.81
34. Civil and precedural remedies	0.75
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 92.12%

Spotlight on the National IP Environment

Past Editions versus Current Score

Sweden's overall score has decreased from 92.14% (46.07 out of 50) in the eleventh edition to 92.12% (46.06 out of 50). This reflects a score decrease for indicator 32.

Patents, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2022, the European Commission issued a "Call for Evidence" on the current compulsory licensing regime across the EU. It is difficult to understand the rationale for this "Call for Evidence." Each individual EU member state has national laws in place that address compulsory licensing in line with the member state's World Trade Organization (WTO) commitments. The commission posits in the "Call for Evidence" that a pressing need exists 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. This was followed up with a proposal for new EU legislation in April 2023. Unfortunately, the proposed regulation is based on the same flawed logic as the "Call for Evidence." For example, the preamble of the draft regulation explains the rationale and need for an EU-wide compulsory licensing regime:
"In cases where access to crisis-relevant products and processes protected by a patent cannot be achieved through voluntary cooperation, compulsory licensing can help in lifting any patent-related barriers and thus ensure the supply of products or services needed to confront an ongoing crisis or emergency. It is therefore important that, in the context of said crisis mechanisms, the Union can rely on an efficient and effective compulsory licensing scheme at Union level, which is uniformly applicable within the Union. This would guarantee a functioning internal market, ensuring the supply and the free movement of crisis-critical products subject to compulsory licensing in the internal market."

But if anything, the actual evidence and experience from the COVID-19 pandemic show the complete opposite. For example, as detailed previously, the much-discussed TRIPS waiver and subsequent 2022 WTO Ministerial Decision have proven to be completely unnecessary and ineffective. It addresses a problem of vaccine shortages that does not exist, and no WTO member has made use of it. Similarly, only one compulsory license was issued during the pandemic by the Israeli government to specifically address a perceived shortage of medicines, but the generic product was never distributed to Israeli patients with COVID-19.

Much like the WTO's TRIPS waiver, the European Commission's fascination with expanding involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism does not seem to be based on actual 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 developing economies with underdeveloped health systems and limited financial resources, not the European Commission or high-income EU member states with advanced sophisticated health systems. The issuing of a compulsory license undermines the basic idea of the protection and sanctity of property rights, including IP rights in place to protect and incentivize 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 threaten the very foundation of the EU's position as a global leader in innovation and high-tech industries including biopharmaceuticals.

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. 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, these measures could subsequently be applied to the procurement of medical devices, software, trains, automobiles, or any other high-tech product that the public sector purchases.

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, Sweden has for the past four 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). A first draft of the implementing law was published in late 2021 by the Ministry of Justice, and in late 2022, a final draft was enacted by the Swedish Parliament and is now in force (SFS 2022:1712). The law broadly follows the scope of the underlying directive, particularly with regard to 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.

14. Scope of limitations and exceptions to copyrights and related rights:
The transposition of the CDSM Directive into Swedish copyright law also included changes to the existing copyright exceptions regime. Like the underlying directive, the amendments include new exceptions to copyright for text and data mining. These exceptions largely mirror the provisions of the CDSM. Text and data mining 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. The CDSM and Swedish amendments both retain an option for rightsholders to expressly disallow the use of their content for text and data mining purposes unless carried out for the purposes of nonprofit scientific research. Similarly, both laws state clearly that text and data mining analysis can be conducted only for works that have been lawfully obtained or accessed. This is a new area of copyright law with little in the way of applicable jurisprudence. It is essential that rightsholders be able to practically enforce their rights and that the mandatory exception for scientific research be accessible only to bona fide research institutions as defined in the CDSM both in Sweden and in the wider EU.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term:
RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU's RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula.

According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU member states have achieved the maximum available score of 1 for this indicator.

As discussed in more detail in Section 4, in 2023, the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs. Unfortunately, this reform package includes many negative provisions that will underpin the framework that facilitated the growth of a robust life sciences ecosystem in the EU. Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, the proposed legislative changes will likely do the opposite. Indeed, the proposed legislative package builds on efforts over the past 10 years to undermine the IP infrastructure needed for the biopharmaceutical industry to flourish both in Europe and beyond. For example, in 2019, the supplementary protection certificate (SPC) manufacturing and export exemption allows companies to manufacture generic and biosimilar products in Europe during the SPC period for export to third (non-EU) countries and to stockpile during the last six months of the validity of the SPC for the domestic market. As noted over the course of the Index, it is unclear what material benefits to the EU the introduction of this exemption has had, including in additional jobs within the generics industry.

The European Commission is further undermining the framework for life sciences innovation with the proposed changes to the EU's RDP regime. The proposed revised directive would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being "continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid."

Each member state, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU member states and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, 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 health system. Within this context, IP rights play no part.

The bottom line is that, just as with the SPC exemption, the European Commission's proposed reform package will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist. Moving forward with the draft changes to the EU's RDP regime would result in EU member states, including Sweden, seeing a 0.20 score reduction for this indicator. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

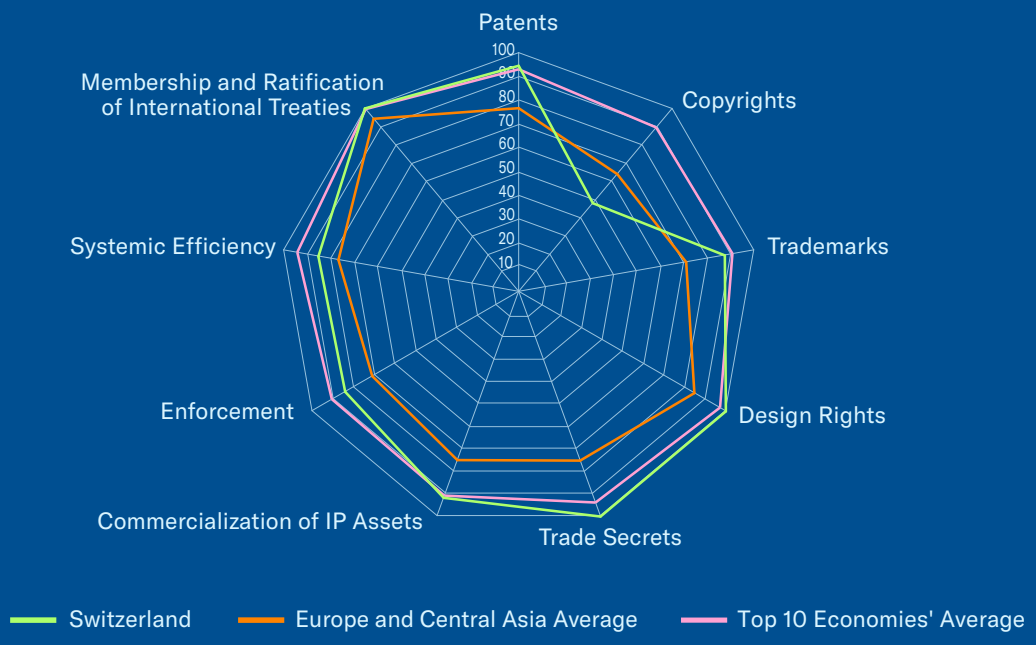
27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: In 2023, the European Commission proposed wide-ranging reforms to the SEP negotiation process in the EU. In April, the commission released a draft regulation that would significantly change current practices related to SEPs and licensing negotiations. Specifically, the proposal would establish EUIPO as an SEP "competence center" tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of "royalty determination." The draft regulation would also require SEP holders to register their essential patents with EUIPO; a failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration. Like the proposals in Japan described above, this centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO is deeply concerning.

SEP-based technologies are central to future innovation and economic growth in China, Japan, the EU and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, artificial intelligence, robotics, and 3-D printing—will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies are likely to result in an even greater use of SEPs and 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 (FRAND) licensing terms are not new, nor are they unique to the EU. This is an evolving field of IP policy and jurisprudence for 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. As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority.

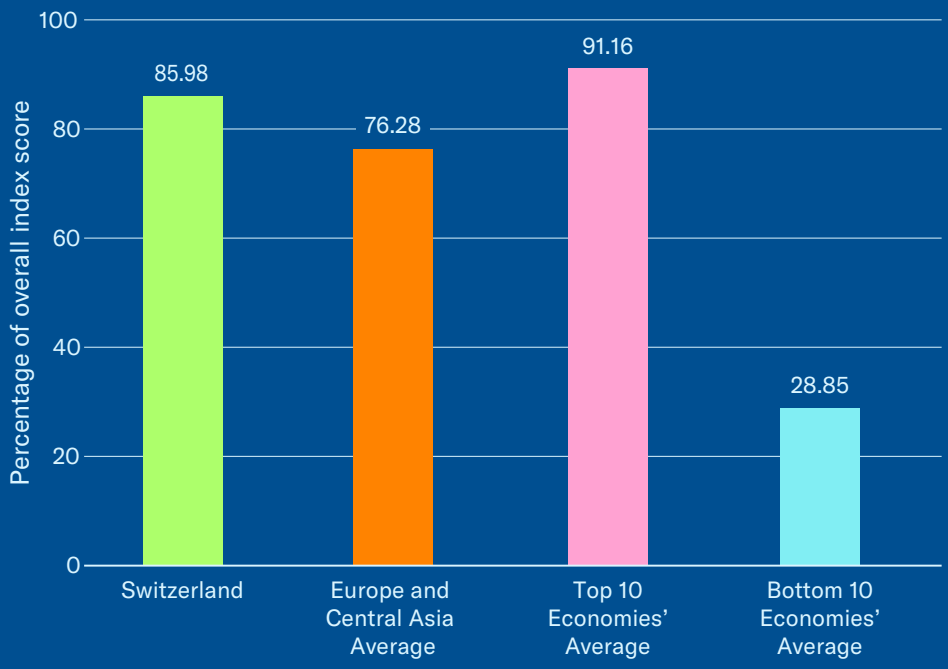
Switzerland

Rank
10/55

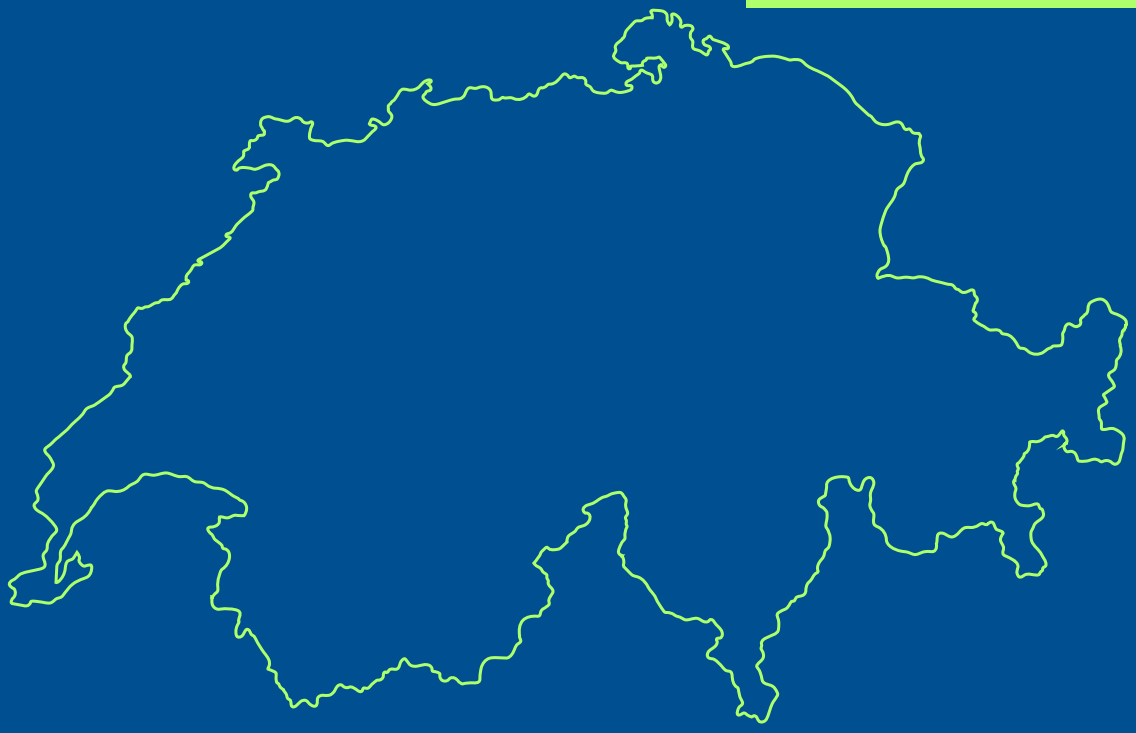
Category Scores



Overall Score in Comparison



Switzerland



Key Areas of Strength

- R&D and IP tax incentives have been in place since 2019
- Strong and sophisticated national IP environment
- Strong patent rights and enforcement environment
- Switzerland is a founding member of EPO and a full participant in PPH initiatives

Key Areas of Weakness

- The 2020 copyright law amendments only partially address 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 exist in enforcement and prosecution of online copyright infringement

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

Indicator	Score
Category 6: Commercialization of IP Assets	**5.50**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**5.86**
32. Physical counterfeiting rates	0.82
33. Software piracy rates	0.79
34. Civil and precedural remedies	0.75
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.25**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 85.98%

Spotlight on the National IP Environment

Past Editions versus Current Score

Switzerland's overall score has decreased from 86.00% (43.00 out of 50) in the eleventh edition to 85.98% (42.99 out of 50). This reflects a score decrease for indicator 32.

Patents, Related Rights, and Limitations

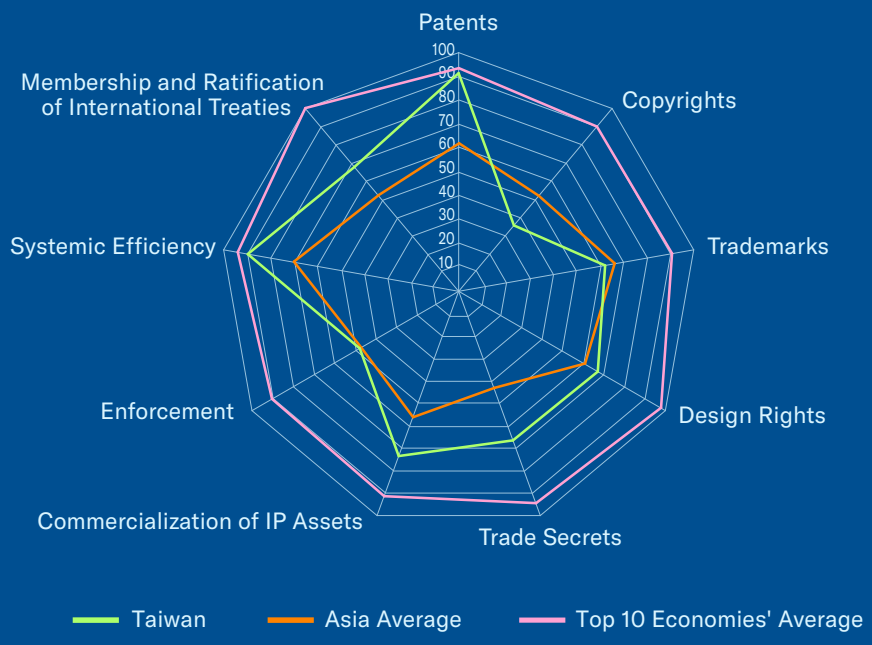
2. Patentability requirements; and 9. Patent opposition:
In late 2022, the Swiss Federal Council published draft amendments to the Patent Law. The proposed amendments are built on proposals first developed by the Federal Institute of Intellectual Property and shared with the public in 2019-2020. Originally, the proposed changes would have had only a relatively minor impact on the Swiss patent system. For example, the reforms would introduce a new utility model option as well as some procedural changes to the existing patent opposition system, first introduced in 2008. The current draft amendments differ substantially and go much further than the original proposal. Although the proposal introduces the possibility of a full examination upon request, from the Index's perspective, the most important part of the proposal is the abolition of the existing opposition system for national applications (Switzerland is a founding member of the European Patent Convention, and the majority of patent activity takes place via the EPO) and replacing it with a new system whereby granted patents could be opposed via the court system and specifically the Federal Patent Court.

All national IP systems should seek to ensure that granted patents are in line with well-established international standards of novelty, inventive step, and industrial applicability. When disputes over validity arise, resolution mechanisms should be readily available and should allow all parties to be heard fairly and impartially in a quick and cost-efficient manner. Unfortunately, in many jurisdictions, existing avenues of patent opposition and invalidity are frequently abused for commercial purposes to delay patent prosecution and limit competition. Local legal analysis suggests that under the proposed amendments, the Swiss opposition procedure would potentially allow such an opportunity for abuse. Specifically, any filed opposition would automatically result in the exclusivity status of the granted patent being suspended. Given the time it invariably takes for any opposition proceeding to run its course, this places a rightsholder in a highly precarious position for an extended period. Although the proposed legislation includes some potential limitations—chiefly through which third parties may lodge an opposition—overall, this loophole seems both unnecessary and highly damaging to rightsholders' legitimate interests. The Index will monitor these developments in 2024.

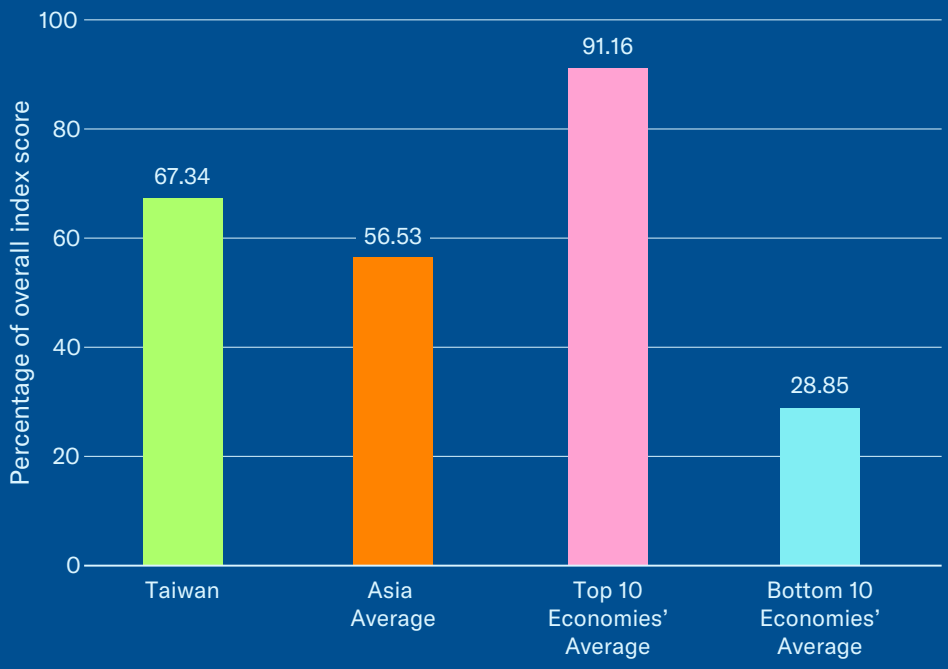
Taiwan

Rank
21/55

Category Scores



Overall Score in Comparison



Taiwan

Key Areas of Strength

- Continued strong support exists for SMEs to develop IP assets through the TIPO fast-track examination procedure and expanded technical assistance
- Amendments to the trade secrets law improved the IP environment in 2020
- The pharmaceutical linkage regime is operational and strengthens protection and enforcement of biopharmaceutical IP rights
- The term of protection for industrial design rights has been extended from 12 to 15 years
- The patent framework is in line with international standards
- Although it faces 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 exist in the digital copyright regime, and the 2022 Copyright Act amendments do not fundamentally address this
- The new Copyright Act introduces an unprecedentedly broad exceptions regime related to educational, personal use, and nonprofit copyright exceptions
- Relatively high rates of online piracy and physical counterfeiting exist

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

Indicator	Score
Category 6: Commercialization of IP Assets	**4.42**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**3.36**
32. Physical counterfeiting rates	0.45
33. Software piracy rates	0.66
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**4.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Membership and Ratification of International Treaties	**3.75**
44. WIPO Internet Treaties	0.75
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.50
50. Post-TRIPS FTA	0.00

Total: 67.34%

Spotlight on the National IP Environment

Past Editions versus Current Score

Taiwan's overall score has increased from 66.31% (32.16 out of 48.50) in the eleventh edition to 67.34% (32.66 out of 48.50). This reflects a score increase for indicator 42.

Patents, Related Rights, and Limitations

7. Patent term restoration for pharmaceutical products:
In a positive feature of Taiwan's national IP environment, Section 53 of the Patent Act provides a clear and unambiguous five-year maximum period of patent term restoration for pharmaceuticals or agrochemicals. Rightsholders report that since 2018, uncertainty surrounds how current regulatory practices recognize and assess the period of exclusivity to be restored. Specifically, current Patent Examination Guidelines no longer align with international best practices. The Index will continue to monitor these developments in 2024.

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; 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, Taiwan has been in the process of amending its copyright laws for close to a decade. Recent years have seen an acceleration in these efforts. The 2019 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 of imprisonment and/or a fine. In 2020-2022, this piecemeal reform effort continued with the Taiwanese Intellectual Property Office (TIPO) releasing for public comment a new batch of draft amendments and a finalized draft Copyright Act approved by the Executive Yuan and submitted to the Legislative Yuan. As noted last year, although some provisions strengthen the enforcement framework, overall, these amendments do not fundamentally change the dynamics of copyright enforcement and online piracy in Taiwan. To begin with, the most far-reaching changes relate to the exceptions and limitations regime. Under revised Articles 44-63 and 65, the amendments introduce 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 rightsholders' ability to exploit their work.

This amended exceptions regime also affects Taiwan's legal regime related to TPM protection. Specifically, Article 80 (9) allows the circumvention of technological protection measures if it is done in accordance with or fulfillment of 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 appears that the circumvention of TPM and DRM protection in Taiwan would be lawful if carried out 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. More broadly, these amendments do not effectively address the long-standing challenges rightsholders face in Taiwan. As documented in the Index, Taiwan continues to lack many of the fundamental building blocks for effective copyright enforcement. Specifically, although Article 100 includes digital piracy as an actionable criminal offense not requiring a formal complaint—provided certain thresholds of estimated economic damage are met—the act does not include a defined and copyright-specific mechanism of injunctive-style relief and the option of ISPs disabling 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, Canada, 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 have also introduced "dynamic" injunctions. Such injunctions address the issue of mirror sites and disable infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders have become 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.

In a separate and positive development the successful prosecution and sentencing of a major online piracy network occurred in 2023. In April, two defendants were sentenced to 18 months in prison for running the "8maple" network, a series of online access points that provide access to copyright infringing content. The sentencing follows a successful public-private partnership between a coalition of rightsholders and local law enforcement. The Index will continue to monitor Taiwan's efforts to improve its copyright environment in 2024.

Trademarks, Related Rights, and Limitations

18. Protection of well-known marks:
In March 2023, the Grand Chamber of Taiwan's Supreme Administrative Court issued a potentially precedent-setting ruling on what constitutes a well-known mark. (The Grand Chamber of the Supreme Administrative Court is the court of final instance for all disputes relating to administrative law.) The case, between a local company and international goods manufacturer LVMH, hinges on how Article 30(11) of the Trademark Act should be interpreted and, specifically, what defines a well-known mark in Taiwan.

As noted over the course of the Index, owners of well-known marks have historically faced a mixed legal environment in Taiwan. For example, 2015 amendments to the Fair Trade Act weakened the legal basis for protection of unregistered well-known marks (although protection is still afforded under the Trademark Act). Specifically, the revised law did not protect against the dilution of unregistered well-known marks. Protection of unregistered marks was provided against only same or similar marks but not against marks that may cause likelihood of confusion. With respect to registered well-known marks, they are protected under existing statute against dilution and likelihood of confusion, but relevant administrative authorities have taken a varied approach to determining whether a mark is well known.

Specifically, there has been a tendency to view the meaning of "well known" within the context of the public as opposed to within a relevant group of users. This was the issue that the Grand Chamber was tackling. In a unanimous ruling, the Grand Chamber found that the Trademark Act and related implementing regulations and guidelines were clear that for a well-known trademark to prove its stature, it is sufficient to be known within the relevant group of consumers or businesses and not the public. The ruling marks a potential turning point in Taiwanese jurisprudence and the manner in which administrative law assesses trademark infringement of well-known marks. Whether this ruling will lead to stronger enforcement against counterfeiting is a separate matter.

As noted in the Index, with respect to the trade in physical counterfeit goods, including trademark infringing goods, Taiwan has been identified as a central hub for the transshipment of counterfeit goods and the global trade of physical counterfeit goods. For example, the OECD and EUIPO in the 2021 publication Global Trade in Fakes: A Worrying Threat found that Taiwan was one of the top provenance economies for counterfeit products in the world. The Index will continue to monitor these developments in 2024.

Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs:
As has been noted over the course of the Index, Taiwan is one of the regional leaders in technology development, transfer, and IP commercialization activities. The Basic Law on Science and Technology introduced in 1999 establishes a Bayh-Dole style framework for tech transfer such that publicly funded IP rights and technologies are fully owned by public institutions. Taiwanese universities and research institutes are known for strong patenting rates and for generating substantial income from royalties and license fees. Significant resources are dedicated to training IP management and commercialization for universities and SMEs.

Since 2005, the Taiwan Intellectual Property Training Academy (TIPA), led by TIPO and the National Taiwan University, has provided training to IP professionals at several universities across Taiwan. TIPA targets SMEs and R&D institutions as well as academic, technology transfer, and legal professionals. Courses include IP management practice and commercialization strategies for all major types of IP rights. IP awareness classes are organized by TIPO and held at individual SMEs' locations and at industrial parks. In terms of direct support, TIPO offers reduced fees and technical assistance to SMEs through various programs, including for patent commercialization, the "SME IP Zone," and bespoke consulting services for the identification and registration of IP assets. To help inventors expand overseas, TIPO has created a new dedicated consulting service for SMEs to help them apply for patent registration outside of Taiwan in foreign jurisdictions. These efforts have been expanded considerably over the past three years and in response to the COVID-19 pandemic. In the past year, TIPO has organized training and educational courses for R&D personnel, SMEs, and start-ups on IP registration; IP asset management; global patent searches (including the use of TIPO's own database of international patenting activity, the "Industrial Patent Knowledge Platform"); patent portfolio management; and one-on-one consulting services for start-ups. Finally, in 2021, TIPO launched a fast-track examination program for patent applications submitted by start-ups, the "Positive Patent Examination Pilot Program for Startup Companies." At the time of research, this program was still in operation. As a result of these positive efforts, the score for this indicator has increased by 0.5.

Membership and Ratification of International Treaties

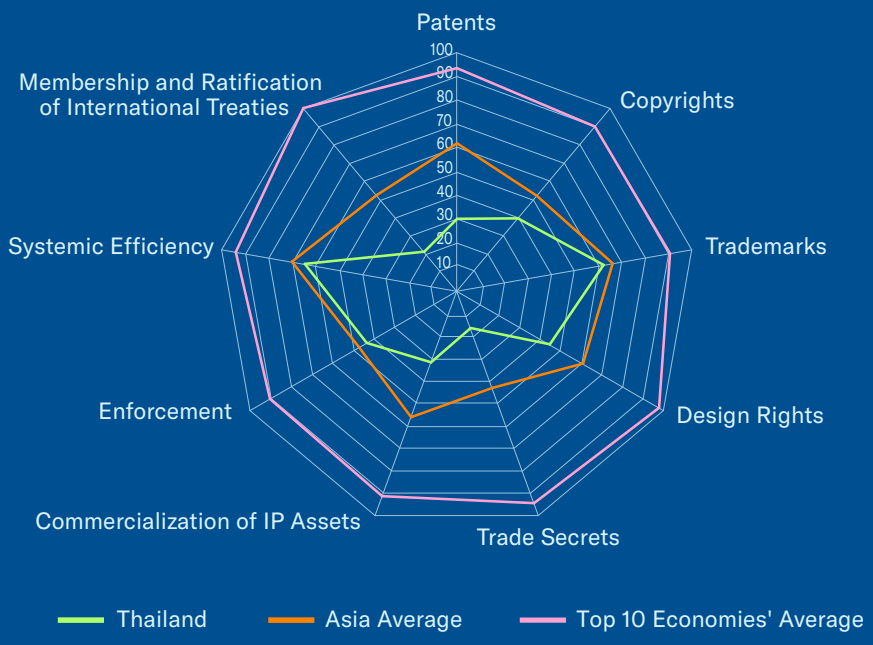
Taiwan is a full member of the WTO but is not eligible for membership in the United Nations or affiliated institutions, including WIPO. Taiwan is therefore unable to join and become a contracting party to any WIPO-administered treaty. Taking into consideration these political hurdles to Taiwan becoming a contracting party to many of the treaties included in the Index, Taiwan has since the fifth edition of the Index not been scored on whether it is a signatory to and has acceded to these treaties. Instead, the Index has measured the extent to which core elements of the treaties included in the Index are present in equivalent Taiwanese domestic legislation. This is, however, not possible to do with all the treaties included in the Index.

For example, those treaties whose primary goal is to establish and harmonize administrative and operational procedures for the international registration of IP rights cannot be wholly scored for Taiwan. Such treaties measured in the Index include the Patent Cooperation Treaty, the 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, not 7. Overall, Taiwan's maximum available score in the Index is 48.5, not 50.

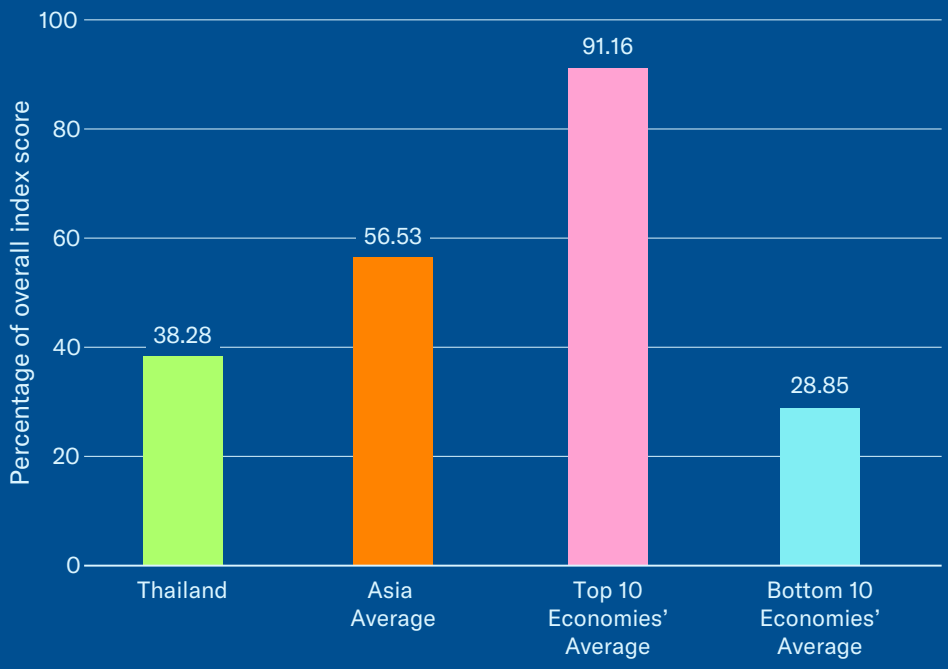
Thailand

Rank
43/55

Category Scores



Overall Score in Comparison



Thailand

Key Areas of Strength

- The 2022 Copyright Act amendments introduced a notice-and-takedown scheme and additional remedies for the circumvention of technological protection measures, including the manufacture, sale, rental, or importation of circumvention devices
- The 2022 Thailand Research and Innovation Utilization Promotion Act improves technology transfer environment
- An injunctive-style relief mechanism under the Computer Crime Act was used against trademark infringement in 2020
- Higher damages were awarded in IP -infringement proceedings in 2019 and 2020

Key Areas of Weakness

- Inadequate patent protection and gaps in patentability for high-tech arts, including life sciences and CIIs
- 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 is estimated at 64%

Key Areas of Strength
(continued)

- The Customs Act amendments have resulted in greater anticounterfeiting 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; this was driven by stronger enforcement and coordination within the Thai government
- A basic level of protection and registration system is in place for copyrights, trademarks, and designs

Key Areas of Weakness
(continued)

- Limited participation in international treaties

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**2.72**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.25
4. Plant variety protection	0.72
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.00
Category 2: Copyrights, Related Rights, and Limitations	**2.78**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.50
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. Digital rights management	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks, Related Rights, and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.75
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**0.50**
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
Category 6: Commercialization of IP Assets	**1.92**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**3.07**
32. Physical counterfeiting rates	0.48
33. Software piracy rates	0.34
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**3.25**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**1.50**
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 38.28%

Spotlight on the National IP Environment

Past Editions versus Current Score

Thailand's overall score remains unchanged at 38.28% (19.14 out of 50).

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 noted in last year's Index, in 2022, a new and updated Copyright Act was enacted. Key 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. It also provides 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 would conduct a preliminary investigation and then pass 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 did not provide timely redress. 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 strengthened existing protection mechanisms for TPM and DRM. As noted last year, these are substantive legal improvements, and the scores for indicators 13 and 15 were increased. These positive efforts continued in 2023 with Thailand considering a further set of amendments to the Copyright Act. These amendments seek to update the act in preparation of Thailand acceding to the WIPO Performances and Phonograms Treaty. At the time of research, no new law had been enacted. The Index will continue to monitor these developments in 2024.

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, the availability of physical counterfeit goods is high in Thailand, and as e-commerce grows, much of the counterfeit trade is moving online.

The past four years have seen major developments with respect to online enforcement against counterfeit goods. In 2019, the Thai government, through the national IP office, the DIP, held consultations with some of the major e-commerce platforms to discuss tools and procedures to tackle online infringement and the sale of counterfeit goods more effectively. The same year, DIP held a workshop for 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.

These positive developments continued in 2020 with what could perhaps be a precedent-setting application of an injunctive-style relief mechanism introduced in the 2016 Computer Crime Act. Up until 2020, copyright holders had exclusively used this mechanism. This has now changed with both the Ministry of Digital Economy and Society (MDES) and a relevant court approving and ordering the disabling of access to several websites based on infringement of trademark rights. As noted in the Index at the time, the decision marks a new potential pathway whereby rightsholders can more effectively enforce their trademarks online.

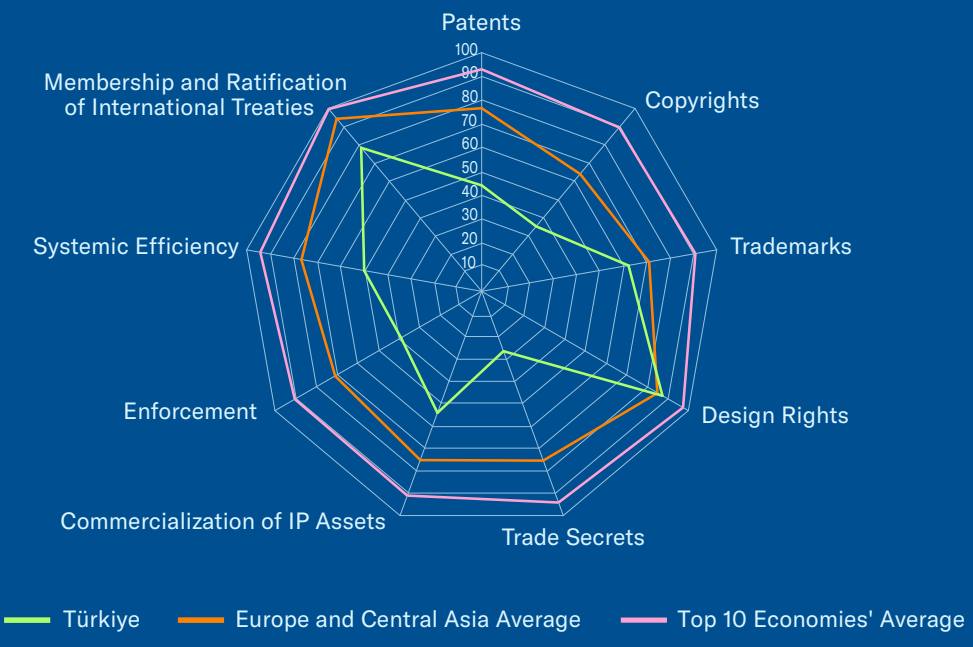
In 2021, the Deputy Prime Minister presided over the signing of a Memorandum of Understanding (MOU) among rightsholders, online retailers, and the Thai government. The purpose of the MOU is to facilitate stronger cooperation among online retailers, rightsholders, and relevant government ministries and agencies in eliminating counterfeiting and enforcing IP rights. Government sources suggest that the MOU is facilitating greater cooperation among the signatories and has increased enforcement efforts against counterfeit goods available online.

These positive efforts continued in 2023. Enforcement statistics published by the DIP show how the Royal Thai Police, Department of Special Investigation, and the Department of Customs continue to actively enforce IP rights and take action against hard goods piracy. The Index commends the Thai government and DIP for their leading role in these positive developments.

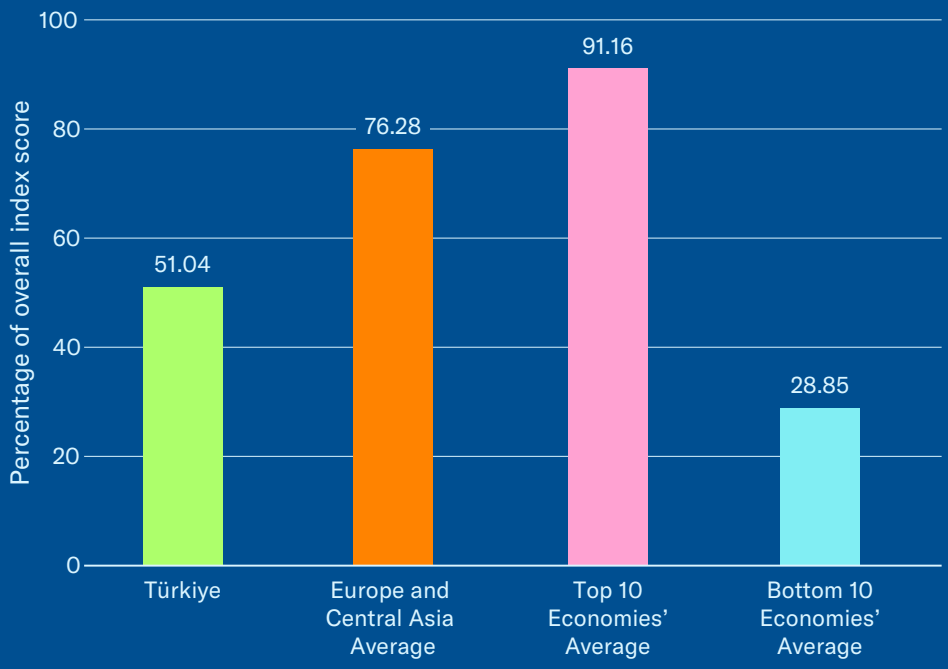
Türkiye

Rank
28/55

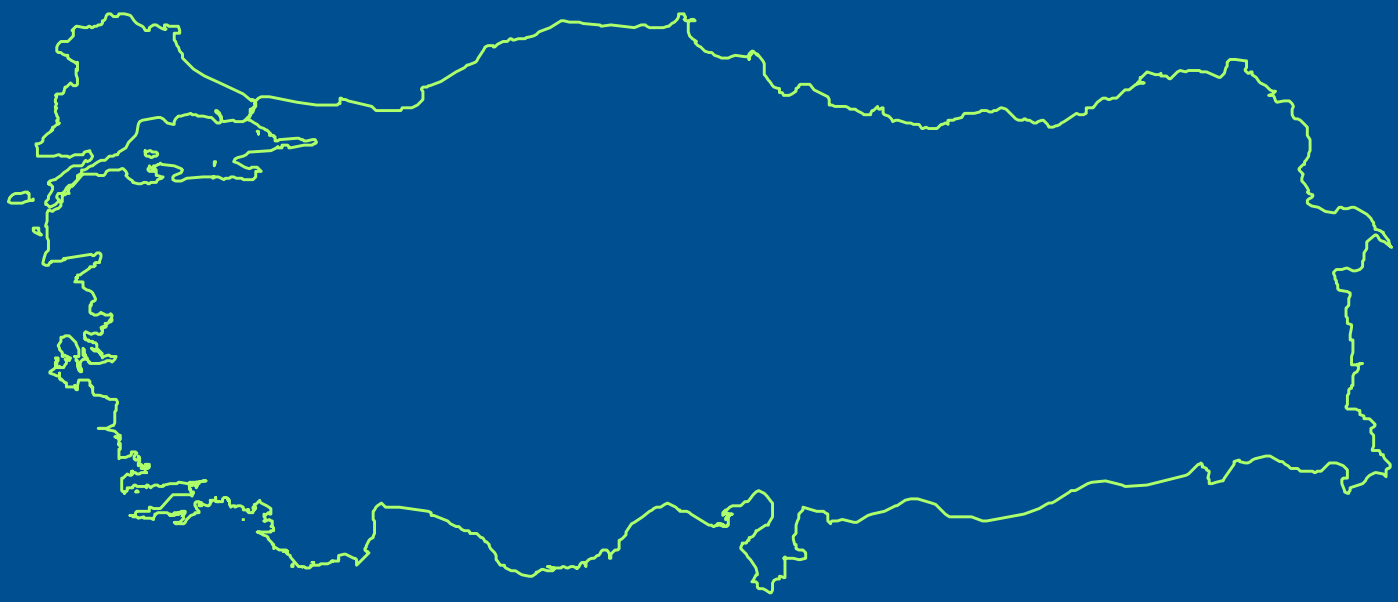
Category Scores



Overall Score in Comparison



Türkiye



Key Areas of Strength

- 2023 reforms of the biopharmaceutical localization environment following the WTO ruling
- Türkiye has sought to align its national IP environment with EU standards in recent years
- Active promotion of the importance of IP protection and its 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 have become a more prominent part of industrial and economic policy targeting high-tech sectors
- RDP is not granted to biologics
- Key gaps persist in the copyright environment and in 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 latest BSA estimates

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

Indicator	Score
Category 6: Commercialization of IP Assets	**3.25**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**2.73**
32. Physical counterfeiting rates	0.29
33. Software piracy rates	0.44
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**2.50**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**5.50**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	0.00

Total: 51.04%

Spotlight on the National IP Environment

Past Editions versus Current Score

Türkiye's overall score has decreased from 51.07% (25.53 out of 50) in the eleventh edition to 51.04% (25.52 out of 50). This reflects a score decrease for indicator 32.

Commercialization of IP Assets and Market Access

26. Barriers to market access:
As detailed over the course of the Index, Turkish industrial and economic policy over the past two decades has increasingly been driven by an effort to localize industrial production and R&D. A major part of these efforts has been localization and import substitution policies that actively discriminate against foreign entities and favor domestic Turkish companies. The Turkish government actively uses public procurement policies as a form of incentivizing localization and discriminating against foreign bidders.

Since 2002, under Article 63 of the Procurement Law, domestically manufactured products are afforded a 15% price advantage in tenders. For several years, some uncertainty surrounded what constituted a "local" product. In 2014, the threshold for being considered a local product was explicitly defined and raised as part of Decree 2014/35. To obtain a "Domestic Goods Certificate," and in so doing qualify for the price preference, all companies operating in Türkiye, including foreign firms, must make domestic investments of at least 51% of the contract value. This investment must include major parts of the production process and not just the final stages. Also, any certificate applicants operating under a joint venture must comprise only domestic partners. Furthermore, since 2015, all government ministries can apply "Industrial Cooperation" (civil offset) clauses for public procurement contracts.

Many of these localization and discriminatory policies have targeted the research-based biopharmaceutical and ICT industries.

With regard to the ICT sector, Turkish laws place onerous requirements (including local data storage) on ICT companies and digital service providers. Sector-specific data storage requirements are in place for payment service providers and banking and financial services institutions. Although cross-border transfers are technically allowed under the Law on the Protection of Personal Data, such transfers can take place only after explicit consent has been obtained from the data subject or after the country to which data are transferred provides an equivalent level of protection as in Türkiye.

As with other localization measures, the requirements for data providers have intensified in the past few years. In 2020, the Turkish Parliament passed amendments to Law No. 5651 (the Regulation of Internet Broadcasts and Prevention of Crimes Committed through Such Broadcasts). These amendments require social media service providers with over 1 million visits per day to store any user data locally in Türkiye, appoint a legal representative in Türkiye, and report regularly on their activities and requirements under these amendments. Noncompliance is potentially subject to substantial fines. Additional requirements were introduced in late 2022 through Law No. 7418, the Amendment of Press Law and Certain Laws.

With respect to the biopharmaceutical sector, in 2014, the Turkish Prime Minister presented the objectives of covering 60% of national demand for pharmaceuticals and 20% for medical devices with local production, as well as increasing clinical research by 25%. In 2016, the Turkish Medicines and Medical Devices Agency began to implement an import substitution plan whereby drugs that have at least one local generic or therapeutic equivalent are required to localize their production or be excluded from public reimbursement.

An Import and Transfer Commission was set up to manage the process and to evaluate drug producers' commitments. Industry reports suggest that close to 200 products were delisted in 2018, of which 71 medicines were identified and delisted from reimbursement in early 2018 by the Turkish Social Security Institution.

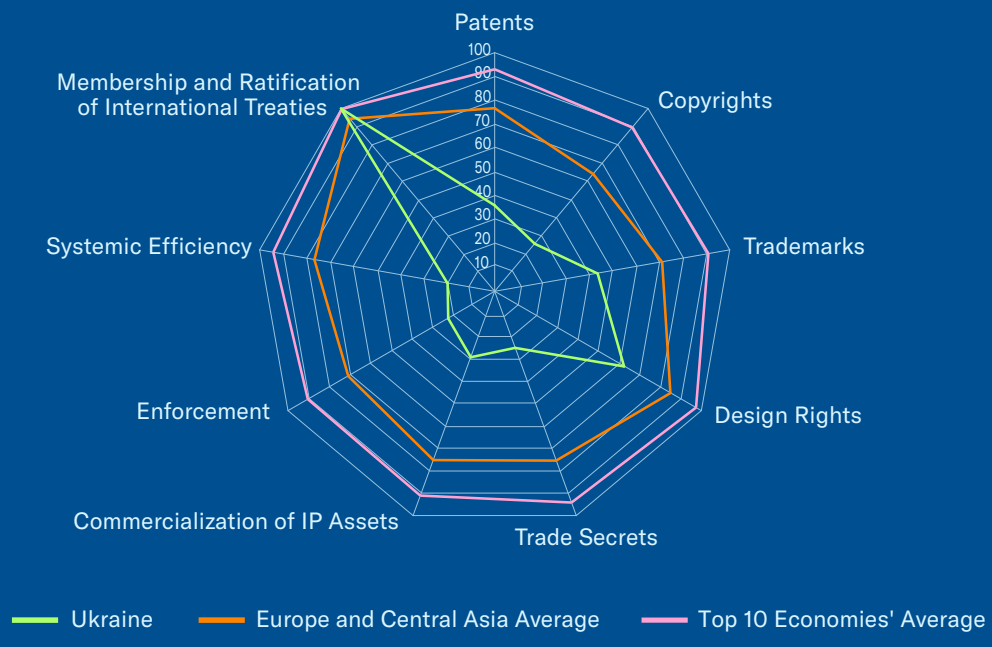
In 2019, the European Union filed a complaint before the WTO alleging that Türkiye's localization policies were in violation of fundamental provisions of the General Agreement on Tariffs and Trade (GATT), Agreement on Trade-Related Investment Measures (TRIMS), TRIPS, and Subsidies and Countervailing 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 Türkiye 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. An arbitration award was subsequently issued in mid-2022. This award did not materially change the panel's findings. In a subsequent communication to the WTO from the Turkish delegation, Türkiye committed to "implement the recommendations and rulings of the Arbitrators and the Panel in this dispute in a manner that respects its WTO obligations." As noted last year, both the panel's findings and the final arbitration award are significant developments and should mark a positive turning point for affected rightsholders in Türkiye.

Throughout the second half of 2022 and in the spring and summer of 2023, Türkiye submitted several notifications on its progress in resolving the issue. Most notably, this included the development of new Drug Reimbursement regulations, the termination of relevant import substitution programs, and the opening of reimbursement lists to excluded foreign companies. Once these policies take full effect and rightsholders are once again able to access the Turkish market fully and freely on a nondiscriminatory basis, the score on this indicator will be increased. The Index will continue to monitor these developments in 2024.

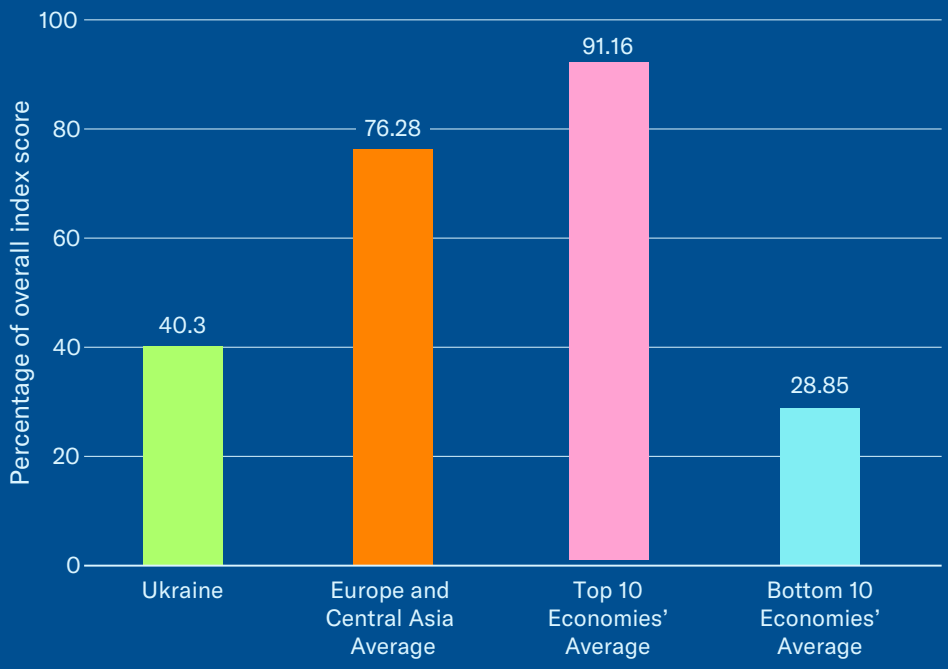
Ukraine

Rank
41/55

Category Scores



Overall Score in Comparison



Ukraine

Key Areas of Strength

- The 2020 amendments to the law on design rights extends the term of protection to 25 years
- Growing body of case law on protection of trade secrets
- Amendments to the Customs Code strengthen enforcement capacity
- Efforts made to align IP legislation to EU standards and implement Deep and Comprehensive Free Trade Area (DCFTA)
- New first instance Court for IP matters (the High Court), set up in 2017, should help improve consistency and expertise within the judiciary

Key Areas of Weakness

- The 2020 amendments to the Law on Protection of Rights to Inventions and Utility Models weaken the national IP environment, especially in relation to life sciences
- The 2020 amendments restrict patentability of biopharmaceutical inventions and introduce an export exemption for products under patent term restoration (modeled on EU's Regulation 2019/933)
- Major gaps exist across all categories of the Index—both a lack of relevant IP laws and weak enforcement
- BSA's latest estimates show an 80% software piracy rate; continued lack of effective effort to reduce the use of unlicensed software by the public sector

Ukraine

Key Areas of Strength
(continued)

- Contracting party to all international IP treaties included in the Index

Key Areas of Weakness
(continued)

- High rates of physical counterfeiting—key transit point for counterfeiting entering EU
- Gaps exist in customs activities; notable lack of effective procedures for the destruction of counterfeits

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

Indicator	Score
Category 6: Commercialization of IP Assets	**1.75**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	0.00
Category 7: Enforcement	**1.57**
32. Physical counterfeiting rates	0.37
33. Software piracy rates	0.20
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**1.00**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 40.30%

Spotlight on the National IP Environment

Past Editions versus Current Score

Ukraine's overall score has increased from 39.74% (19.87 out of 50) in the eleventh edition to 40.30% (20.15 out of 50). This reflects score increases for indicators 32 and 35.

Area of Note

Russia's military invasion of Ukraine continued in 2023. At the time of research, Ukraine continued to be under a state of martial law and mass mobilization. Despite these difficulties, the government of Ukraine and the ministries and agencies that make up the Ukrainian state continued to function. This includes the national IP authorities, which in 2023 sought to resume full operations. The IP Office also deepened its existing partnerships and cooperation agreements with several EU member states and European institutions, including EPO and EUIPO. This is part of Ukraine's ongoing efforts to strengthen political and institutional ties with the EU after the granting of official candidate status for EU membership in mid-2022. In late 2022, the EU and Ukraine agreed on a new "Priority Action Plan" for the EU-Ukraine Deep and Comprehensive Free Trade Area. Finally, as outlined here, several important legislative amendments were passed by the Ukrainian Parliament and signed into law by President Zelensky. The Index commends the government of Ukraine and the IP Office for its positive work under such trying circumstances.

Enforcement

34. Civil and procedural remedies; and 35. Preestablished damages and/or mechanisms for determining the amount of damages generated by infringement:
As has been documented over the course of the Index, rightsholders face fundamental difficulties in enforcing their rights and accessing available civil remedies in Ukraine. There is a general lack of confidence in the judicial system and a dearth of knowledge of IP rights among the judiciary, and civil prosecutions are infrequent. Although in the past damages had been successfully claimed from infringing companies, decisions are often not transparent, and overall sentences have been nondeterrent. Furthermore, before the Russian invasion, Ukraine had some of the world's highest estimated levels of both hard goods and online piracy in the world.

As noted in the Index, Ukraine has historically been a global transit point for counterfeit goods. Using global customs data, the OECD and EUIPO found in the 2021 Global Trade in Fakes: A Worrying Threat, Illicit Trade that Ukraine was a key transit point for redistributing counterfeit products aimed at the EU market. The Ukrainian government has over the course of the Index attempted to improve civil provisions and rightsholders' ability to enforce their IP rights. In 2016, the Cyber Police Department, in a joint operation with U.S. and UK enforcement, shut down the second most popular torrent website worldwide, which was run in Ukraine. In addition, the department took down one of the country's major pirate movie websites. Also in 2016, the National Police signed an MOU with the media community launching a joint antipiracy initiative based on technical assistance and information exchange.

In 2017, a first-instance court for IP matters (the High Court) was announced. After years of delay, the specialized IP court finally began operating in 2020.

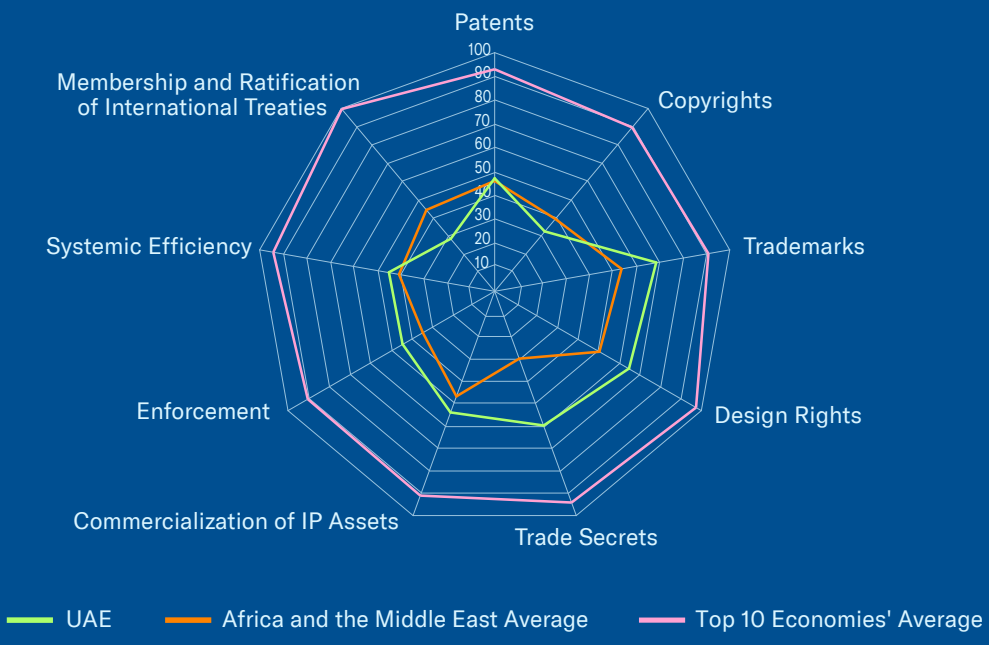
These positive efforts continued in 2023. In March, the Ukrainian Parliament, the Verkhovna Rada, passed Law 6,464 "on making changes to some legislative acts of Ukraine regarding strengthening the protection of intellectual property rights." President Zelensky signed the bill into law in April.

The amendments strengthen existing civil remedies related to IP infringement and, in particular, with respect to the circulation of infringing goods and the manner in which damages are assessed and awarded. As a result of these positive changes, the score for indicator 35 has increased by 0.25.

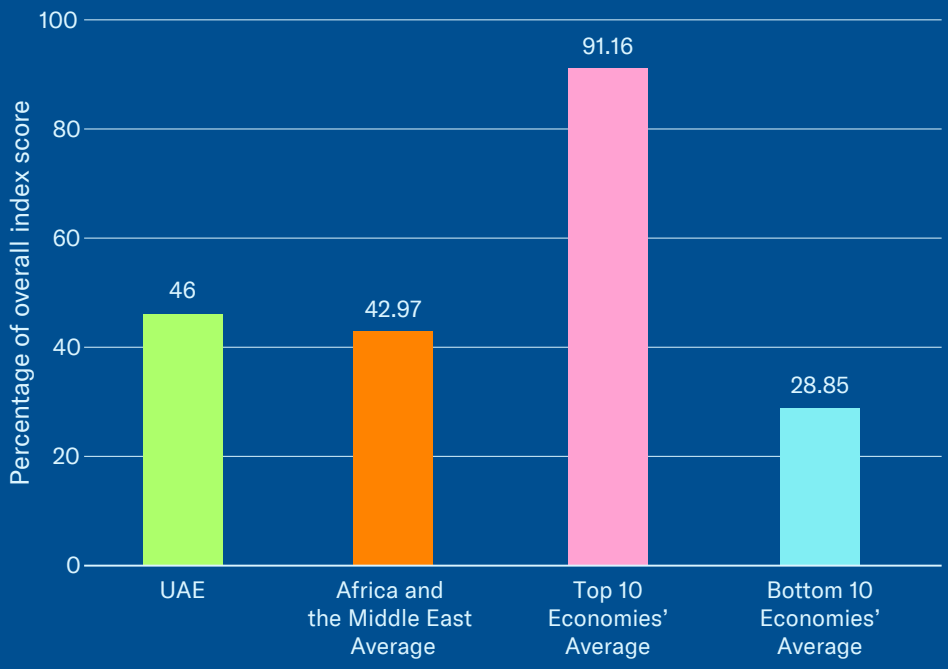
United Arab Emirates

Rank
34/55

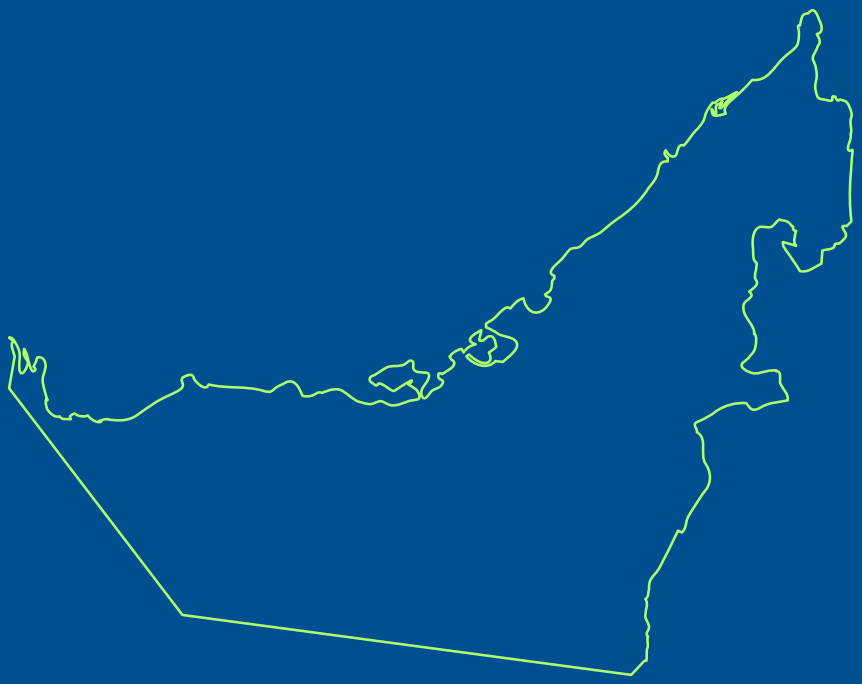
Category Scores



Overall Score in Comparison



United Arab Emirates



Key Areas of Strength

- The term of protection for design rights was extended in 2021
- Acceded to the Madrid Protocol in 2021
- The 2021 Trademark Law improves the environment for well-known marks and raises potential damages
- The 2021 Trademark Law provides stronger border measures against counterfeit goods
- Defined RDP term introduced in 2020

Key Areas of Weakness

- The 2022 Copyright Law and implementing Cabinet Decision No. 47/2022 do not fundamentally change the legal dynamic in the UAE; no notice-and-takedown mechanism or a defined and copyright-specific mechanism of injunctive-style relief is in place
- The 2022 Executive Regulations for Industrial Property Law (Federal Law 11) do not clarify under what circumstances a compulsory license may be issued
- The RDP term contains a potential exception establishing a compulsory license (Article 5) that is potentially out of step with its international obligations

Key Areas of Strength
(continued)

- The Foreign Direct Investment Law offers the possibility of 100% foreign ownership, which grants foreign investors a potential exemption from the requirement of having an Emirati partner hold a minimum of 51% of a company's shares
- Basic IP protections are in place
- Enhanced anticounterfeiting efforts include criminal penalties
- Awareness-raising and capacity building efforts highlight the importance and value of IP rights

Key Areas of Weakness
(continued)

- Deep uncertainty surrounds protection for biopharmaceutical patents because no action has been taken on the 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 exist in customs measures and civil remedies for infringement
- Limited participation in international treaties

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**4.25**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.00
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**2.28**
10. Term of protection	0.53
11. Exclusive rights	0.50
12. Injunctive-type relief	0.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. Digital rights management	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.75**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**1.30**
21. Industrial design term of protection	0.80
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.80**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.80

Indicator	Score
Category 6: Commercialization of IP Assets	**3.25**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**3.12**
32. Physical counterfeiting rates	0.44
33. Software piracy rates	0.68
34. Civil and precedural remedies	0.75
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.25**
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
Category 9: Membership and Ratification of International Treaties	**2.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 46.00%

Spotlight on the National IP Environment

Past Editions versus Current Score

The UAE's overall score remains unchanged at 46.00% (23.00 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 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 only basic exclusive rights, including reproduction and performance, but with little specific reference to the online environment. For example, no statutory notice-and-takedown mechanism or defined copyright-specific route for injunctive-style relief is in place. Industry reports suggest that there has historically been inconsistent cooperation from the main ISPs. Some additional enforcement activity has taken place through the Telecommunication Regulatory Authority (TRA), which has disabled access to infringing content online on an ad hoc basis. The TRA's internet guidelines also include the violation of IP rights in the list of prohibited content categories. 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. For example, the OECD and EUIPO in the 2021 publication 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 were 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 only outlined 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 2022. The UAE government has rightly identified the creative industries and the protection of copyrighted content as a strategic asset, and it should be commended for seeking to update the legal framework. On a positive note, Article 40 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 the collective management of copyrights. However, as noted at the time of enactment in the Index, the new law does not fundamentally change the legal dynamic in the UAE. For example, the law does not include a notice-and-takedown mechanism or a defined and copyright-specific mechanism of injunctive-style relief.

It also does not include the option of ISPs disabling access to illegal content whether through a judicial or an administrative order.

The past half 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, Canada, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies have also introduced "dynamic" injunctions. Such injunctions address the issue of mirror sites and disable infringing content that reenters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders have become more commonplace, with similar mechanisms available in, for example, Canada, 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.

Of note is how neighboring Saudi Arabia has transformed itself into a regional leader in offering rightsholders a pathway of administrative injunctive relief. Since its inception in 2017-2018, the Saudi Authority for Intellectual Property (SAIP) has worked on improving the national IP environment and rightsholders' ability to enforce their copyrights more effectively. The Authority works directly with rightsholders both as an intermediary, referring cases of infringement to relevant Saudi enforcement authorities, and as an administrative enforcement authority. Indeed, SAIP has made the disabling of access to copyright infringing content a major part of its enforcement remit. In 2022, the authority ordered the disabling of access to close to 1,500 websites and online access points offering copyright infringing content. This was almost double the number of orders issued in 2021 and five times the number in 2020. Much of this copyright infringing content consisted of illicit streaming of TPM- and DRM-protected live sports and audiovisual content. The Index will continue to monitor these developments in 2024.

Membership and Ratification of International Treaties

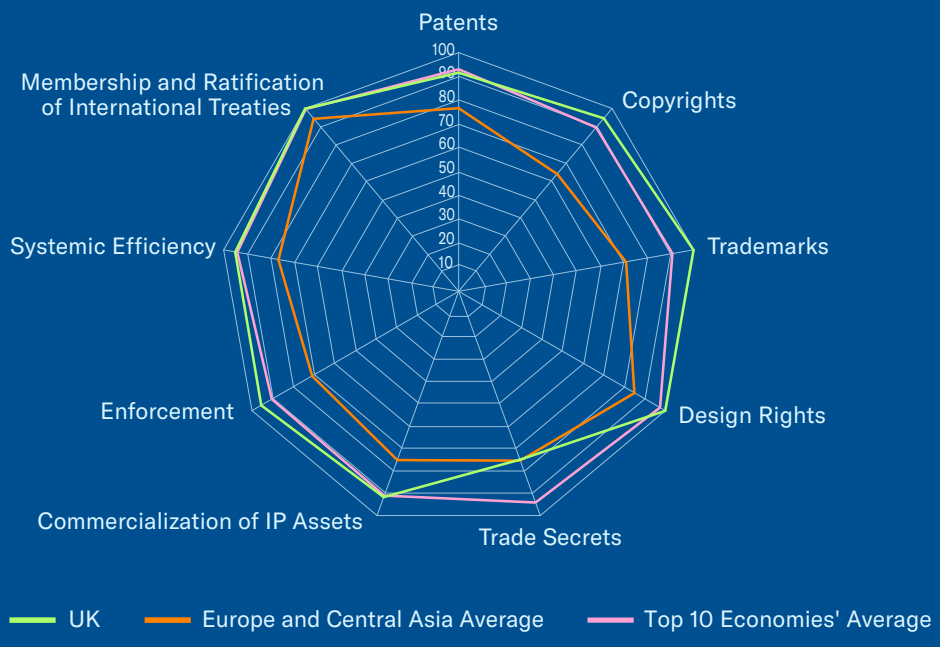
Being a contracting party to key international IP treaties reflects an economy's broader participation in the international IP community and its embrace of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy chooses to both participate in the international IP system and adhere to established standards and best practices. The UAE's score in this category of the Index has increased from 1.00, or 25%, in the second edition of the Index (the first year the UAE was included) to 2.00, or 28.57% of the total available score. This score is higher compared with other Index economies in the Middle East, such as Saudi Arabia and Kuwait, but it is notably lower than most other high-income and/or OECD economies. Virtually all EU member states, Japan, the United States, and Canada achieved a score of 90% or more in this category.

Overall, the UAE is a contracting party and has acceded to the WIPO Internet treaties, the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, and the Patent Cooperation Treaty. The UAE is not a contracting party to the Patent Law Treaty; the Singapore Treaty on the Law of Trademarks; the International Convention for the Protection of New Varieties of Plants, Act of 1991; the Convention on Cybercrime, 2001; or the Hague Agreement Concerning the International Registration of Industrial Designs.

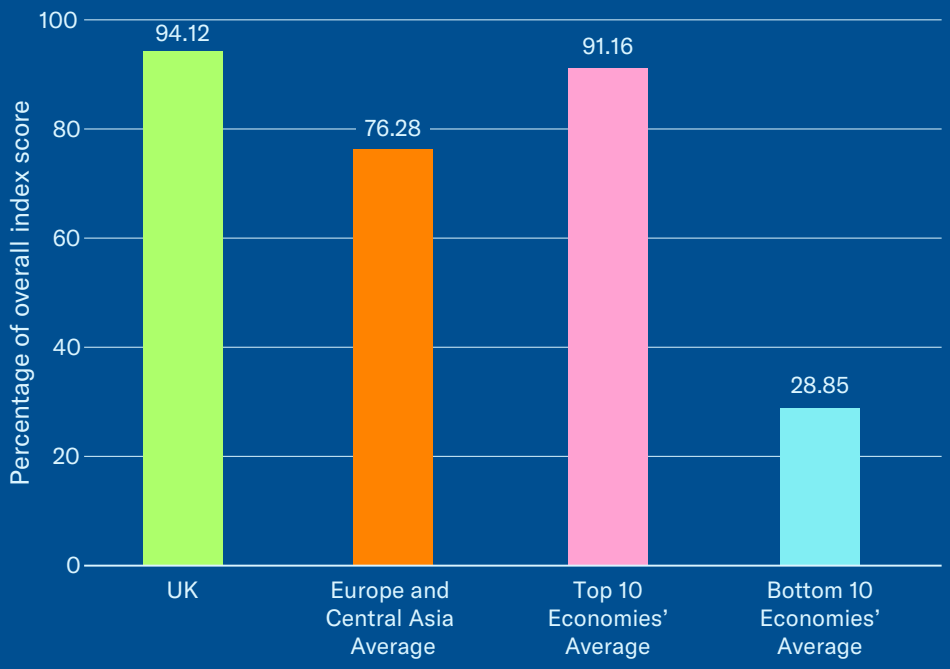
United Kingdom

Rank
2/55

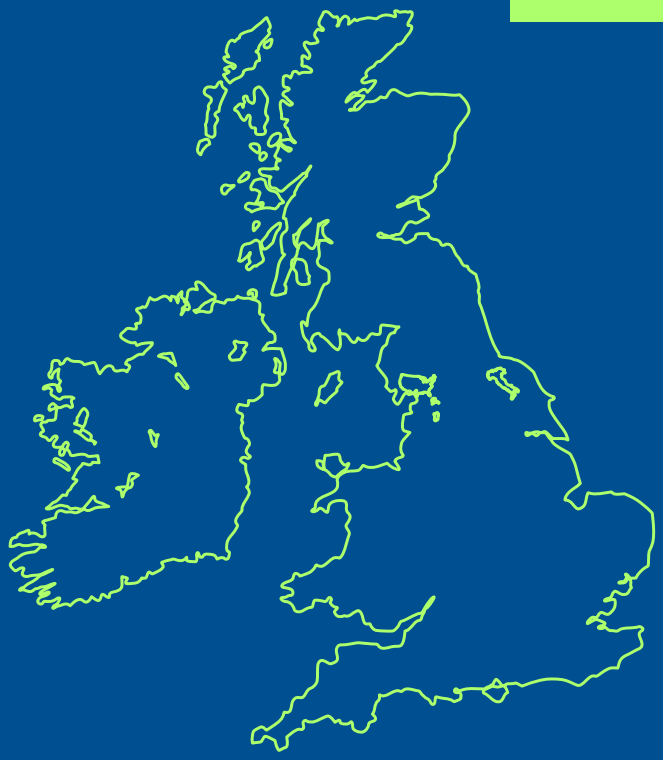
Category Scores



Overall Score in Comparison



United Kingdom



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 is highlighted by the work of a specialist crime unit and cross-industry and government cooperation

Key Areas of Weakness

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

Indicator	Score
Category 6: Commercialization of IP Assets	**5.50**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	1.00
Category 7: Enforcement	**6.68**
32. Physical counterfeiting rates	0.89
33. Software piracy rates	0.79
34. Civil and precedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 94.12%

Spotlight on the National IP Environment

Past Editions versus Current Score

The UK's overall score has decreased from 94.14% (47.07 out of 50) in the eleventh edition to 94.12% (47.06 out of 50). This reflects a score decrease for indicator 32.

Copyrights, Related Rights, and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:
Over the past three years both the British Parliament and government have been working on policy reforms related to AI and machine learning. Like many other Index economies, the UK has identified the application of AI and machine learning as an important area of technological development and future economic activity. In 2021, the government released a National AI Strategy, a 10-year, cross-government plan of action, and over the past two years, it has published many policy proposals, consultations, hearings, and draft legislation. This includes specific proposals and workstreams on the interaction between copyright protection and the use and application of AI and machine learning through both existing general copyright exceptions and specific text and data mining exceptions.

Text and data mining 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. However, this is a new area of copyright law with little in the way of applicable jurisprudence either in the UK or internationally.

Like similar exceptions introduced in other jurisdictions—including the European Union's Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive)—under Section 29A of the Copyright, Designs and Patents Act, copying or communicating for computational analysis can be conducted only for works that have been lawfully obtained or accessed. Given the existing dynamics of the internet and the volume of infringing content available online—much of it made available without rightsholders' permission or even their knowledge—it is essential that this safeguard be strictly adhered to and that rightsholders be able to practically enforce their rights. At the time of research, the UKIPO was working with the creative sector, researchers, and technologists to develop a voluntary code of practice on copyright and AI. The Index will continue to monitor these developments in 2024.

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 has been in place since 2013. R&D incentives have been provided through a super deduction for qualifying expenditure specifically for small companies, with larger business entities entitled to an R&D expenditure credit. The patent box scheme provides an effective rate of 10% corporation tax on income generated by the underlying patent asset.

As discussed last year, the government has over the past three years been reviewing the mechanics of these incentives. In 2022, legislation was introduced to widen the scope of these incentives but also to introduce a new "territoriality" requirement.

The purpose of these amendments was to ensure that the available incentives stimulate UK-based innovation and that the accompanying R&D-based activities take place within the UK. 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, exemptions to this territoriality principle are allowed for qualifying expenditure that takes place outside of the UK.

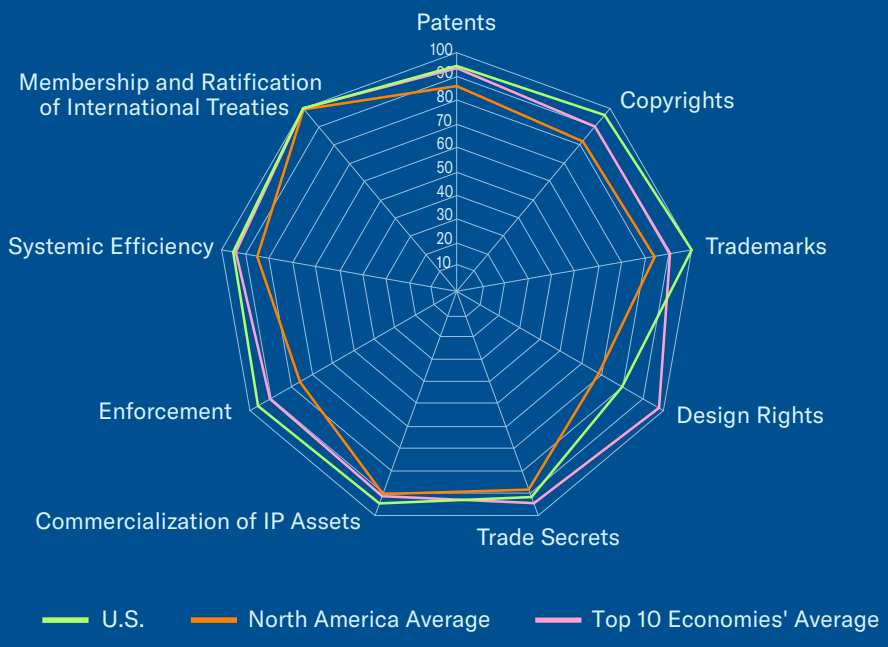
Additional changes to the R&D tax incentives scheme were announced in late 2022 in the Chancellor's "2022 Autumn Statement." These changes include an increase in the headline rate of the R&D expenditure credit for larger entities but a reduction in qualifying incentives for smaller entities. In 2023, HM Revenue & Customs proposed further changes.

Under these proposals, additional tax relief would be made available to the most R&D-intensive small- and medium-sized companies, and the idea was also put forth of merging the R&D scheme for small and large 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 2024.

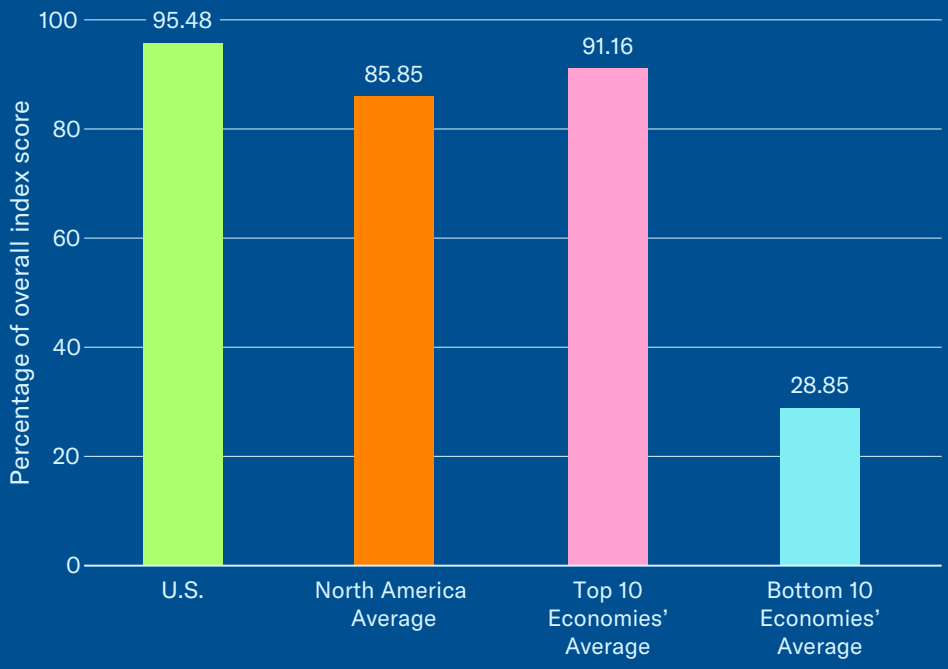
United States

Rank
1/55

Category Scores



Overall Score in Comparison



United States

Key Areas of Strength

- The U.S. national IP system continues to provide international leadership
- Sector-specific rights and protections are in place across all categories of the Index
- 2023 congressional efforts address long-standing challenges and uncertainty about patentable subject matter and PTAB proceedings
- Reform efforts to patent nullity and opposition proceedings by USPTO continued in 2023; the agency should be commended for efforts to provide a greater balance and address concerns about unpredictability and uncertainty within the PTAB process

Key Areas of Weakness

- Long-standing uncertainty about patentability standards for high-tech sectors
- Long-standing uncertainty about PTAB proceedings
- Administrative efforts by USPTO undermine patent examination practices for the life science industry
- “Collaboration” efforts between USPTO and FDA
- Lack of a targeted legal basis for addressing online piracy through other global leaders

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

Indicator	Score
Category 6: Commercialization of IP Assets	**5.67**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	1.00
31. Tax incenstives for the creation of IP assets	0.67
Category 7: Enforcement	**6.72**
32. Physical counterfeiting rates	0.87
33. Software piracy rates	0.85
34. Civil and precedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Membership and Ratification of International Treaties	**7.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 95.48%

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 about what constitutes patent-eligible subject matter in the United States. Since 2014, the USPTO has issued and updated patent examination guidelines on an almost 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 USPTO 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." With respect to Section 101 (patent 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/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 after the guidance's introduction. 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 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 long-standing problem continued within both the executive and legislative branches of government in 2023. Most promisingly, the Patent Eligibility Restoration Act of 2023 was introduced by Senators Tillis and Coons. As discussed with respect to previous iterations of the draft bill, the proposed legislation marks a significant breakthrough on the legislative front. The draft legislation addresses many of the long-standing areas of concern and uncertainty about what constitutes patentable subject matter in the United States. At the time of research, the proposed act had not been passed by Congress or signed into law by President Biden.

In a separate development, in June 2023, the USPTO published its 2022-2026 Strategic Plan. The Plan outlines the agency's goals for the next five years, including with respect to patent examination procedures. As discussed in last year's Index, in 2021, President Biden issued an Executive Order on Promoting Competition in the American Economy. Alleging anticompetitive behavior in several sectors of the economy, the order asked 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 its Strategic Plan, the USPTO appears to have embraced this sentiment by wholeheartedly announcing that biopharmaceutical patent applications will be subject to increased levels of scrutiny on the basis of increasing access to medicines:

"As part of the Biden Administration's ongoing efforts to ensure the accessibility of medications for more Americans, we are collaborating with the FDA to ensure that the USPTO issues robust and reliable patents that promote and protect innovation and are of proper scope to not improperly delay generic and biosimilar competition.

To support this priority, the USPTO will collaborate with the FDA to provide patent examiners with training on publicly available FDA resources that can be used in prior art searches and on the state of the art in the pharmaceutical and biologics fields. The USPTO will also provide new tools for patent examiners to use to search enormous and growing global databases of technical information—including publicly available sources maintained by the FDA—to determine whether similar innovations already exist. The USPTO will also explore ways to improve its procedures to bolster the robustness and reliability of patent rights."

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 have improved health treatment for patients globally and have provided a steady stream of new drugs and health technologies. Since 2000, American companies have developed more than 550 new medicines, roughly half of all drugs launched globally. American research-based biopharmaceutical firms spent an estimated $72.4 billion in 2020 on R&D domestically. 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 shows how critical IP rights are to incentivizing and supporting the development of new medical technologies and products.

In 1979, the total cost of developing and approving a new drug stood at $138 million. Almost 25 years later, in 2003, this figure was estimated at $802 million. A 2012 estimate points to the total cost of drug development being approximately $1.5 billion. More recent research from Tufts University suggests that it costs $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 go on to become a marketable drug. Patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection (RDP) and special exclusivity incentives for the protection and production of orphan drugs, enable research-based companies to invest 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 want their elected representatives to take appropriate action. However, the cost of medicines 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 has provided Americans, and patients around the world, with new and better health technologies and medicines. The Index will continue to monitor these developments in 2024.

9. Patent opposition:
To provide a more cost-effective, efficient alternative to judicial proceedings, the 2011 America Invents Act (AIA) introduced new postgrant opposition and patent nullity proceedings. As has been detailed in previous editions of the Index, despite the intentions of these new AIA mechanisms, the result has been a sustained level of uncertainty and unpredictability for many patent owners. This has been especially the case with the inter partes review (IPR), which occurs before the specialized Patent Trial and Appeals Board (PTAB) within the USPTO.

As noted over the past seven editions 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, including changes to claim construction standards, trial practices, and standard operating procedures. These efforts continued in 2023 with several new reform proposals put forth and public consultations held. This includes an "Advance Notice of Proposed Rulemaking (ANPRM)" published in April 2023. The ANPRM proposes to make substantive changes to PTAB proceedings, including with respect to the USPTO's right to deny the institution of an IPR, the practice of serial petition filing, and increased scrutiny of potential conflicts of interest between petitioning parties.

In a separate development, a new draft law reforming the PTAB—the Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL Act)—was introduced in Congress. Like the Patent Eligibility Restoration Act described previously, this bill would address much of the uncertainty and unpredictability caused by the PTAB. 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 2024.

Copyrights, Related Rights, and Limitations

12. Expeditious injunctive-style relief and disabling of infringing content online:
In May 2023, the USPTO issued a request for comments on an upcoming roundtable hosted by the agency on anticounterfeiting and antipiracy strategies. The agency sought detailed information on existing strategies and what more could be done in the United States and internationally.

As noted over the course of the Index, unlike other jurisdictions, including the European Union, Singapore, and emerging markets like India, copyright holders in the United States have historically faced great difficulty in obtaining an injunction disabling access to infringing content. Instead, rightsholders have been forced to pursue infringement claims through traditional litigation and court proceedings. These can often be lengthy and expensive.

Although the past few years have seen several important cases judged or settled in favor of rightsholders—see, for example, the cases involving BMG and Cox Communications or UMG Recordings et al and Grande Communications—this underscores the wider point that effective redress is difficult through existing practices. As noted last year, in a positive 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 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 "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 in the United States 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 2024.

14. Scope of limitations and exceptions to copyrights and related rights:
Like many other Index economies, the United States has identified the application of AI and machine learning as important areas of technological development and future economic activity.Both the federal government and Congress have over the past year been working on policy reforms related to AI and machine learning.

In October 2023, the White House issued an Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence. The order cuts across all of government and provides guidance on the use of AI-based technologies and tools from a security, privacy, and innovation standpoint. With respect to the protection of copyright, the order directs the USPTO in consultation with the Copyright Office to issue recommendations to the White House on any necessary executive actions. This includes any actions related to "the scope of protection for works produced using AI and the treatment of copyrighted works in AI training."

In a separate development, in August, the Copyright Office issued a "Notice of inquiry request for comments" on the interaction between AI and copyright. And throughout the year, hearings were held in both the House of Representatives and Senate on the interaction between generative AI and the protection of copyright. The use and application of AI and machine learning (including through text and data mining) are important areas 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. However, this is a new area of copyright law with little in the way of applicable jurisprudence either in the United States or internationally. At the time of research, several pending lawsuits were related to the potential use of copyright-protected material in the development of generative AI, both in the United States and abroad. Given the existing dynamics of the internet and the volume of infringing content available online—much of it made available without rightsholders' permission or even their knowledge—it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders be able to practically enforce their rights. The Index will continue to monitor these developments in 2024.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer:
In the mid-1980s, the U.S. Congress passed two groundbreaking pieces of legislation: the Patent and Trademark Law Amendments Act of 1984 and 1986 (the Bayh-Dole Act) and the Stevenson-Wydler Technology Innovation Act, which was later amended by the Federal Technology Transfer Act of 1986 and the Technology Transfer Commercialization Act in 2003. This legislation attempted to supply federal laboratories (including the National Institute of Health) and universities using federal funds with the framework needed to work with industry for the purpose of translating early-stage research into usable products in the marketplace for the benefit of the wider public.

The legislation sought to secure the above goals through three major changes to the IP system. First, they allowed universities and federally funded bodies to retain ownership of the proprietary knowledge stemming from the research and daily activities of these institutions, including the ability to own patents on their inventions. Second, they encouraged these institutions to become much more proactive and professional in the management and exploitation of their IP rights by creating professional technology transfer offices. Finally, the legislation sought to stimulate the commercial and financial aspects of public-private collaboration, with the intention of creating new businesses (such as spin-off companies) and generating income for the institutions, as well as for the researchers.

The importance of the Bayh Dole framework to U.S. innovation—and especially for the life sciences sector—cannot be overstated. In 2002, the Economist magazine called the law the "most inspired piece of legislation to be enacted in America in the last half-century." This statement aptly sums up the positive impact the legislation has on innovation in the U.S.

Looking at general rates of innovation and commercialization activities, this can be seen in terms of both patenting activity and actual economic impact and output. To begin with, academic research into the effects of the Bayh-Dole framework have found a significant correlation between increased patenting activities at U.S. universities and the Act. For example, a 2004 study found that university share of total patenting in the U.S. increased from 0.69% of total patents at the time of legislation to just under 5% in 1996.

The positive impact of Bayh Dole can also be seen in terms of direct and significant contributions to economic output and employment. For instance, using twenty-five years of data from the annual AUTM survey, a 2022 study estimating the economic contribution of licensing activity by academic institutions found that in the U.S., the contribution of academic licensing to gross industry output ranged from $631 billion to $1.9 trillion (measured in 2012 U.S. dollars). Contributions to GDP were equally significant estimated at between $333 billion to $1 trillion (measured in 2012 U.S. dollars).

Perhaps the most telling statistic is the strong growth in industry-university collaboration and the institutionalization of this partnership as the foundation of modern drug development. New technologies and research insights generated at universities and within public research are very seldom finished medical products ready to be commercialized. Instead, it often takes years of translational research and development by industry and biopharmaceutical manufacturers to take these technologies and generate a safe and effective medical product. For example, a decade after Bayh-Dole was passed, the combined campuses of the University of California became the top recipient in the U.S. of biotechnology patents; a position formally held by Merck.

Similarly, looking at licensing income for U.S. universities, not only has this grown exponentially since the mid-1980s, but the life sciences sector is the predominant source of this income. For example, in 2023, Nature Biotechnology examined licensing income and sector-specific sources of this income for top U.S. universities and research institutes and found that, of the $1 billion in total gross licensing income in 2013, over $977 million (97%) came from the life sciences sector. The number was similar with regards to the number of start-ups and licenses executed with the vast majority being in the life sciences sector.

More recent data paints a similar picture. Findings from the AUTM survey cited above shows that the vast majority—about 80%—of licensing income to universities and non-profit institutions, including research hospitals, is derived from the life sciences. Perhaps the most noteworthy example is the $750 million in licensing income the University of Pennsylvania has received through the research of Katalin Karikó and Drew Weissman on the use of mRNA technology in vaccines.

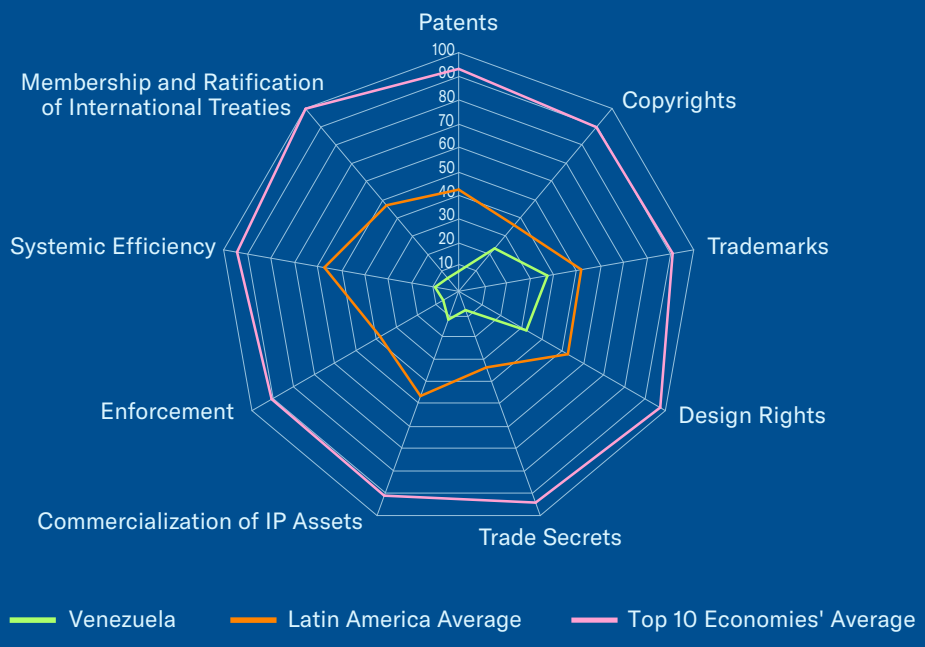
In December 2023, the National Institute of Standards and Technology (NIST) published a "Request for Information" on a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights. A primary focus of the Draft is the extent to which the price of a relevant invention can be considered as justifying the federal government's ability to override any existing IP exclusivity. This follows a similar discussion in 2021. In January 2021, the Department of Commerce and the NIST requested comments for potential changes to the way federally funded or supported technologies developed are transferred and licensed. Part of the discussion around the proposed rule changes in 2021 related to the issue of so-called "march-in-rights." Such rights grant the federal government a mechanism to access a given technology under very specific circumstances.

Then, as now, these march-in-rights are not meant to be used as a lever to reduce the cost of commercialization of a given technology or abrogate an existing licensing agreement on the basis of cost—an idea that seems to be the focus of this latest request for information. It is vital to all high-tech sectors, industries and their publicly funded partners that have close partnerships and R&D that the concept of march-in-rights are not misconstrued or presented as a basis for introducing price controls with regards to, for example, biopharmaceutical products and technologies. This was never the intention of the underlying legislation. Indeed, should such a flawed interpretation of Bayh-Dole be adopted by the federal government it would in all likelihood lead to the destruction of the current life sciences R&D ecosystem which is built around mutually beneficial public-private partnerships.

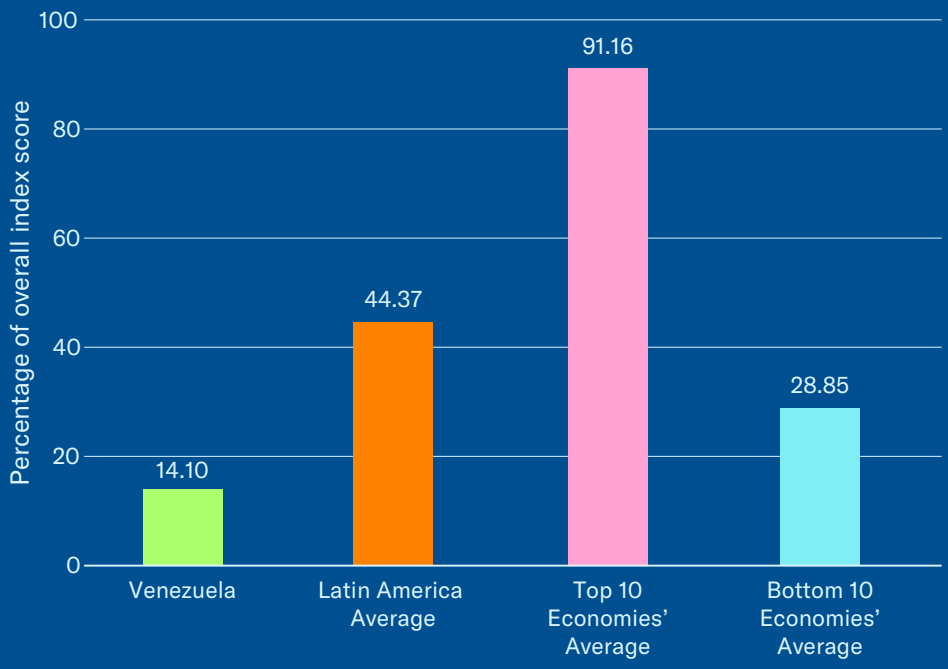
Venezuela

Rank
55/55

Category Scores



Overall Score in Comparison



Venezuela

Key Areas of Strength

- Basic copyright, trademark, and industrial design frameworks are in place
- Awareness-raising and capacity building efforts highlight the importance and use of IP rights
- Venezuela's IP service may have granted hundreds of patents in 2022, which is a significant increase, but that information has not been corroborated

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

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

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

Total: 14.10%

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. Venezuela lacks most basic IP 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 most modern IP frameworks and international best practices. Venezuela remains on the USTR's Priority Watch List, most recently in the 2023 Special 301 Report.

With respect to Category 1: Patents, Related Rights, and Limitations, legal standards of patentable subject matter are firmly outside existing international standards. In violation of TRIPS Article 27, chemical preparations, 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 means have also not been patentable. The standard term of protection for patents has also been half of the TRIPS minimum of 20 years 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.

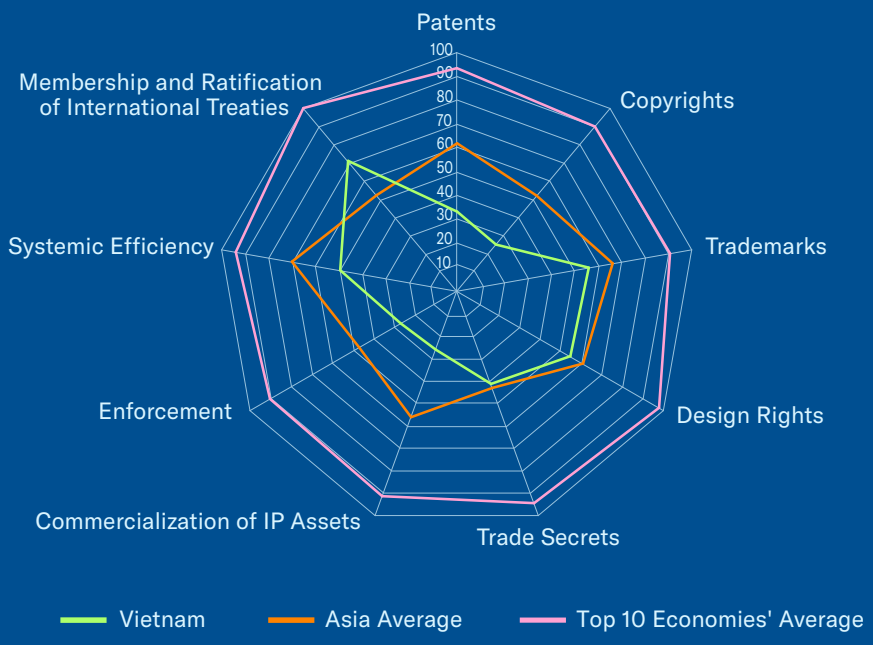
As noted in last year's Index, in an encouraging development, local reports suggested that SAPI has begun to process and grant patents again. Although information is not provided for 2023, SAPI states on its website that it granted 326 patents in 2022. However, this figure cannot be corroborated. International patent statistics housed by WIPO have patent data only up to and including 2021. Similarly, the latest available industrial property bulletin from SAPI (Boletin de la Propiedad Industrial) is dated May 2022. WIPO's database shows 291 patent applications for 2021 with no data for the total number of patents granted that year (direct and PCT national phase entries). The latest available year for which information on patents granted is available is 2020, during which 58 patents were granted.

Should rightsholders be able to consistently obtain patent protection under TRIPS standards for a minimum term of 20 years in accordance with Venezuela's WTO obligations in a timely fashion, this would mark a significant and positive improvement in Venezuela's national IP environment and would result in score increases for indicators 1 and 2. The Index will continue to monitor these developments in 2024.

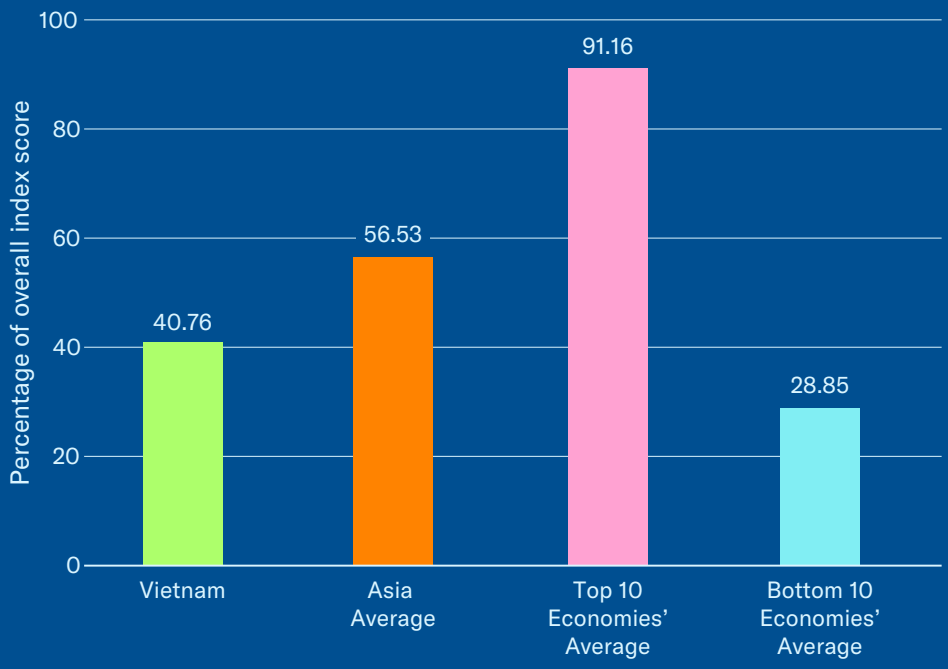
Vietnam

Rank
40/55

Category Scores



Overall Score in Comparison



Vietnam

Key Areas of Strength

- The 2022 amendments to the Law on Intellectual Property (IP Law) improve copyright protection
- Acceded to the WIPO Performances and Phonograms Treaty in 2022
- Acceded to the WIPO Copyright Treaty in 2021
- Ratified the EU-Vietnam FTA in 2020
- Basic IP protections and enforcement framework are in place
- Growing integration into international IP platforms, for example, through the EU-Vietnam FTA
- Long-standing effort to coordinate IP enforcement

Key Areas of Weakness

- Inadequate protection of life science patents, with a challenging enforcement environment
- 2022 amendments notwithstanding, gaps in copyright protection remain, 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 are in place on digital trade and cross-border data transfers through the Law on Cybersecurity
- Enforcement is generally poor; penalties are insufficient in practice, with administrative inaction

Indicator	Score
Category 1: Patents, Related Rights, and Limitations	**3.00**
1. Term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of CIIs	0.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and active use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.25
Category 2: Copyrights, Related Rights, and Limitations	**1.78**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.00
15. Digital rights management	0.50
16. Government use of licensed software	0.00
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**1.58**
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.75
31. Tax incenstives for the creation of IP assets	0.33
Category 7: Enforcement	**1.92**
32. Physical counterfeiting rates	0.41
33. Software piracy rates	0.26
34. Civil and precedural remedies	0.25
35. Pre-established damages	0.25
36. Criminal standards	0.50
37. Effective border measures	0.25
38. Transparency and public reporting by customs	0.00
Category 8: Systemic Efficiency	**2.50**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**5.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. Post-TRIPS FTA	1.00

Total: 40.76%

Spotlight on the National IP Environment

Past Editions versus Current Score

Vietnam's overall score has increased from 40.74% (20.37 out of 50) in the eleventh edition to 40.76% (20.38 out of 50). This reflects a score increase for indicator 32.

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 terms of the Vietnam-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. Regulations implementing the IP Law were published in August 2023. Under article 42 of Decree 65/2023 there is no mention of patent term restoration. Instead, compensation is again specified as a reduction in relevant usage and renewal fees during the period of delay. This does not constitute term restoration. Consequently, Vietnam's score for this indicator remains unchanged at 0.

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 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, with limited reference to the protection of copyright online. For example, the USTR noted in the 2023 Special 301 Report that "in particular, online piracy, including the use of illicit streaming devices and associated piracy applications to access unauthorized audiovisual content, remains a significant concern" in Vietnam. Positive enforcement and legislative efforts moved forward in 2023.

In a positive development, the rightsholders' group Alliance for Creativity and Entertainment reported in February that it had successfully disabled access to a Vietnam-based illegal live-streaming website USTVGO. This website had been providing access to copyright infringing content since 2018. On the legislative front, as discussed last year, the 2022 IP Law amendments address some of the long-standing copyright challenges in Vietnam. Article 198(b) introduced a legal framework that promotes cooperative action against online piracy. The framework provides internet intermediaries with defined responsibilities related 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."

In 2023, implementing regulations in Decree 17/2023 were released. Under Articles 110-114, the decree outlines the step-by-step nature of the mechanism and the responsibilities of identified intermediaries and service providers. This includes the clear responsibility to, upon notification, disable access to the alleged infringing content. The Index will monitor the extent to which this decree, the relevant new provisions of the IP Law, and relevant authorities' enforcement efforts improve the ability of rightsholders to enforce their copyrights in Vietnam in 2024.

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
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 from 0 to 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 exists in a given economy).

Numerical indicators are those indicators that, for example, measure terms of exclusivity or are based on a quantitative source. Terms of exclusivity are calculated by dividing the actual term of exclusivity of each relevant indicator by a standard baseline. For example, the standard baseline used for the copyright term is 95 years provided in the United States to orphan works.[38] 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 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 these:

1. Primary and/or secondary legislation (regulation) in place

2. The actual application and enforcement of that primary and/or secondary legislation

Mixed indicators are most 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 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 result is that economies can receive partial scores for an indicator, which, in some cases, are a better approximation of their reality.

Finally, there are also a few instances in which rather than the de jure and *de facto* existence of a single element, a mixed indicator is split between two separate elements. For example, in Category 9: Membership and Ratification of International Treaties, the indicators are measured by the signature and ratification or accession to an 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: (1) the existence of a term of patent restoration for pharmaceutical products due to the prolonged research, development, and regulatory approval periods for such products and (2) the existence of any exemptions, waivers, or similar carve-outs for the full and effective use of such a term of restoration, including for industrial policy purposes. For this indicator, 0.75 of the available score 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 based on an economy providing any exemptions, waivers, or similar carve-outs for 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

Baselines	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 piracy and counterfeiting 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 the case for online piracy.

Second, studies of rates of piracy and counterfeiting are often either specific to one or a handful of economies or global and do not provide data at an individual economy level.

The result is a relative paucity in the number of studies that measure and compare levels of piracy and counterfeiting with a sample of economies sufficient to make large-scale comparisons empirically robust.

Finally, because measures of piracy and counterfeiting are inexact, estimates of their economic impact can vary widely depending on the methodology and data samples used.[39]

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

1. The OECD's General Trade-Related Index of Counterfeiting of Economies (GTRIC-e), which measures the relative rates of physical counterfeiting[40]

2. Software piracy rates compiled by the Business Software Alliance (BSA) (2018 being the latest published survey)

These sources are both robust and internationally recognized measures. Furthermore, they cover a large sample of economies and provide 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, the use of these measures has caveats, in particular, the GTRIC-e.

First, the GTRIC-e Index measures the relative rates of physical counterfeiting and is based on international trade statistics and customs interception data. The GTRIC-e does not consider 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 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 U.S. Chamber of Commerce and Pugatch Consilium developed it to provide a new global measure of physical, trade-related counterfeiting. This measure of physical counterfeiting is also used for this edition of the Index, and it provides the basis for the score for indicator 32.

The measure provides a total and per economy estimate of rates of physical trade-related counterfeiting for each of the economies included in the Index. 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 in Category 7: Enforcement of the Index. These include the following:

- 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
- Transparency and public reporting by customs authorities of trade-related IP infringement

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

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

The third factor used is the rate of perceived corruption within an economy, as measured by Transparency International's Corruption Perceptions Index. This assumes that a strong relationship exists between corruption and counterfeiting. That is, 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 in 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 range of sources. All sources used are publicly available and are free and accessible to all. The following is an outline of the types of sources used.

Government

Sources from government branches and agencies include the following:

- 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
- Internal departmental guidelines, policies, assessments, and audits

Legal

Sources from judicial authorities and legal practitioners include the following:

- Court cases and decisions
- Legal opinions written by judges
- Legal analysis and opinions written by legal practitioners

International Institutions & Third Parties

These sources include the following:

- 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
- Reports from nongovernmental organizations and consumer organizations

Academic

Academic sources include the following:

- Academic journals, books, published manuscripts
- Legal journals

News

News sources include the following:

- Newspapers
- News websites
- Trade press

In addition to these 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 updates on legislative and regulatory initiatives, details of various government policies such as antipiracy initiatives, and statistics on anticounterfeiting and activities to fight online piracy.

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

Indicators Explained

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

Category 1: Patents, Related Rights, and Limitations

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

1. Patent term of protection
This indicator is measured by the basic patent term offered in the TRIPS Agreement. This is a numerical indicator.

2. Patentability requirements
This indicator is measured by the extent to which patentability requirements are in line with international standards of novelty, inventive step, and industrial applicability.[41] It is measured by (1) existing de jure patentability guidelines and regulations and (2) *de facto* standards established through the application of these guidelines and regulations through the examination process and judicial review. This is a mixed indicator.

3. Patentability of computer-implemented inventions
This indicator is 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
This indicator is measured by the maximum term of protection offered with the baseline term of protection being not less than 20 years (25 years for trees and vines) in accordance with the International Convention for the Protection of New Varieties of Plants.[42] This is a numerical indicator.

5. Pharmaceutical-related patent enforcement and resolution mechanism
This indicator is 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 or enforcement. If no mechanism is in place, the maximum score that can be achieved is 0.5. Such a score is based on the extent to which *de facto* practices (such as expeditious preliminary injunctive relief) are in place that achieve a similar result. This is a mixed indicator.

6. Legislative criteria and use of compulsory licensing of patented products and technologies
This indicator is 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: (1) the issuing should exclude any requirement for domestic manufacturing; (2) it should not apply to patented innovations that have not yet reached the market; (3) in the case of biopharmaceutical products, the use of compulsory licensing under the framework of TRIPS provisions for public health should not be for commercial purposes, such as for price negotiations or in support of domestic industries; and (4) adequate and well-defined recourse mechanisms should be in place for parties affected by the issuing of the license. This is a binary indicator.

7. Patent term restoration for pharmaceutical products

This indicator consists of two distinct variables: (1) the existence of a term of patent restoration for pharmaceutical products due to the prolonged research, development, and regulatory approval periods for such products and (2) the existence of any exemptions, waivers, or similar carve-outs for the full and effective use of such a term of restoration, including for industrial policy purposes. For this indicator, 0.75 of the available score 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 based on a given economy providing any exemptions, waivers, or similar carve-outs for the full and effective use of such a term of restoration, including for industrial policy purposes. This indicator does not include other forms of patent term restoration that are granted based on prolonged examination periods, including for the granting of patents. This is a mixed indicator.

8. Membership in a Patent Prosecution Highway (PPH)

This indicator measures whether an economy's relevant IP or patent office has joined international efforts toward streamlining and improving patent prosecution by membership in 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 in the different tracks. Economies that are members of either (or both) the Global Patent Prosecution Highway or the IP5 Patent Prosecution Highway will receive a full score of 1.[43] 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

This indicator is 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
This indicator is 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 different minimum terms of protection exist for different forms of copyright, all major terms are added together and divided by 95. This is a numerical indicator.

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

12. Expeditious injunctive-style relief and disabling of infringing content online
This 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
This indicator is 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
This indicator is 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).[44] 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
This indicator is measured by the extent to which economies have (1) passed primary and/or secondary legislation related to TPM and DRM and (2) have applied this legislation. 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
This indicator is measured by the extent to which (1) policies and guidelines are in place stipulating the use of only licensed proprietary software and (2) these policies and guidelines are applied. This is a mixed indicator.

Category 3:
Trademarks, Related Rights, and Limitations

The indicators in this category relate to trademark protection, design rights, and related rights and limitations.

17. Trademarks term of protection (renewal periods)
This indicator is measured by the renewal term of protection being offered. The baseline term is 10 years as provided by the Singapore Treaty on the Law of Trademarks. This is a numerical indicator.

18. Protection of well-known marks
This indicator is 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
This indicator is measured by the extent to which economies (1) have in place laws and procedures that provide necessary causes of action to address violations of a trademark owner's rights (such as infringement of registered trademarks, unfair competition, false designation of origin, false advertising, dilution of famous trademarks, cybersquatting, and violation of rights associated with a corresponding trade dress), which create a likelihood of public confusion about source, sponsorship, or affiliation and (2) apply these laws to prevent, deter, and remedy infringement of trademarks and related rights. This is a mixed indicator.

20. Availability of frameworks that promote action against online sale of counterfeit goods
This indicator is 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.[45]

Category 4:
Design Rights, Related Rights, and Limitations

The indicators in this category relate to design rights and related rights and limitations.

21. Industrial designs term of protection
This indicator is measured by the maximum term of protection being offered (including renewable periods). The baseline term is 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
This indicator is measured by the extent to which economies (1) have in place laws and procedures that provide necessary exclusive rights (including making, marketing, trading, and use of an industrial design) and (2) apply these laws to prevent, deter, and remedy infringement of industrial design rights. This is a mixed indicator.

Category 5:

Trade Secrets and the Protection of Confidential Information

The indicators in this category relate to trade secrets, related rights and limitations, and the protection of confidential information.

23. Protection of trade secrets (Civil Remedies)
This indicator is measured by the existence of (1) legislation that offers protection for trade secrets or confidential business information and (2) the application of this legislation in the court or law enforcement system. This is a mixed indicator.

24. Protection of trade secrets (Criminal Sanctions)
This indicator is measured by the existence of (1) legislation that provides criminal sanctions for the misappropriation, improper acquisition, use, or disclosure of trade secrets or confidential business information and (2) the application of this legislation and effective access to these remedies. This is a mixed indicator.

25. Regulatory data protection (RDP) term
This indicator is 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.[46] 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
This indicator measures 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 (1) existing laws and procedures make market access contingent on the sharing and disclosure of intellectual property and know-how and (2) the application of such laws or in the absence of such laws the existence of *de facto* practices and standards that achieve a similar effect. This is a mixed indicator.

27. Barriers to technology transfer
This indicator is measured by the extent to which laws and regulations or *de facto* practices act as barriers to technology transfer and commercialization activities of publicly funded and supported research. This is a mixed indicator.

28. Registration and disclosure requirements of licensing deals
This indicator is measured by the extent to which licensing agreements must be registered and/or disclosed with relevant authorities to carry legal effect. This is a mixed indicator.

29. Direct government intervention in setting licensing terms
This indicator is measured by the extent to which relevant government authorities directly intervene and set licensing terms between licensee and licensor.[47] This can be done through, for example, government preapproval for any licensing agreement between two parties as well as government intervention in the setting of licensing terms, including royalty rates. This is a mixed indicator.

30. IP as an economic asset
This indicator is measured by the extent to which relevant institutions (including, for example, public and private institutions for higher education and national IP offices) in an economy are actively engaged in capacity building and training on using 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
This indicator is measured by the extent to which governments provide tax incentives for the creation and use of IP assets. This indicator consists of three layers corresponding to an equal share of the available score:

Layer 1 consists of economies that offer 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 is the extent to which the described incentives are not hampered by onerous localization and/or administrative requirements linked to the availability and use of the tax incentive or mechanism.

Category 7: Enforcement

The indicators in this category measure the prevalence of IP rights infringement, the criminal and civil legal procedures available to rightsholders, the authority of customs officials to carry out border controls and inspections, and transparency of customs authorities' actions.

32. Counterfeiting piracy rates
This indicator is 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
This indicator is measured by rates of software piracy. This is a numerical indicator.

34. Civil and procedural remedies
This indicator is measured by (1) the existence of civil and procedural remedies, including injunctions, damages for injuries, and destruction of infringing and counterfeit goods and (2) their effective application. This indicator also reflects administrative enforcement measures where applicable. This is a mixed indicator.

35. 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
This indicator is measured by the extent to which (1) actual legislation is in place and (2) legislation is applied (i.e., where reliable source material is available, the actual level of prosecution and penalties is applied). This is a mixed indicator.

37. Effective border measures
This indicator is 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**
This indicator is measured by the extent to which customs authorities in an economy publish statistics and data on trade-related IP infringement. It measures (1) the extent to which data are published on a regular and systematic basis and (2) 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
This indicator refers to the existence of coordinated efforts in IP rights enforcement at the national government level. It measures the extent to which a national government institution or formalized structure is in place to provide 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 an economy's national government. This is a mixed indicator.

41. Educational campaigns and awareness raising
This indicator measures (1) 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 (2) the extent to which these campaigns and awareness-raising efforts (if in place) are systematic and sustained over time. This is a mixed indicator.

42. Targeted incentives for the creation and use of IP assets for SMEs
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 an economy seek to map and measure the economic impact and importance of IP-intensive industries to their national economies. Economies are scored based on (1) how the mapping and measuring of the economic impact and importance of IP-intensive industries to national economic activity are taking place and (2) the extent to which such mapping and measuring are systematic and occur 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 (1) is a signatory of and (2) has ratified or acceded to international treaties on the protection of IP; some international treaties only allow for accession, that is, membership is either conferred or not conferred. 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 in the International Convention for the Protection of New Varieties of Plants, Act of 1991
This is a binary indicator.

48. Membership in 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.[48]

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. The 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 (2023), "Country and Lending Groups."
2. WTO (2022), "Ministerial Decision on the TRIPS Agreement," June 17, 2022, Ministerial Conference, Twelfth Session Geneva, Switzerland.
3. Communication from India and South Africa (2020), "Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19," October 2, 2020.
4. Communication from the Delegations of Argentina, Bangladesh, the Plurinational State of Bolivia, Egypt, India, Indonesia, Pakistan, South Africa and the Bolivarian Republic of Venezuela on Behalf of the Co-Sponsors of the IP/C/W/669/Rev. 1 Proposal, "Decision Text on Extension of the June 17, 2022, Ministerial Decision to COVID-19 Therapeutics and Diagnostics," December 6, 2022, WTO TRIPS Council.
5. ITC (2023), COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Washington, D.C.
6. ITC (2023), COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Washington, D.C., p. 63
7. The "WTO-IMF Vaccine Trade Tracker" was suspended with the website stating, "We have stopped collecting the information and will no longer provide updates to the WTO-IMF COVID-19 Vaccine Trade Tracker." WTO-IMF Vaccine Trade Tracker website main page (accessed December 13, 2022), https://www.wto.org/english/tratop_e/covid19_e/vaccine_trade_tracker_e.html
8. IMF-WHO (2022), "IMF-WHO COVID-19 Vaccine Tracker," last updated September 8, 2022.
9. ITC (2023), COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Washington, D.C., p. 33
10. WTO (2023), "Members Continue Discussion on TRIPS Decision Extension to Therapeutics and Diagnostics," WTO News Items, March 17, 2023, Geneva, Switzerland.
11. ITC (2023), COVID-19 Diagnostics and Therapeutics: Supply, Demand, and TRIPS Agreement Flexibilities, Washington, D.C., p. 26.
12. European Commission (2022), Pharmaceutical Strategy for Europe, p. 6, Brussels, Belgium.
13. EFPIA (2023), The Pharmaceutical Industry in Figures Key Data 2023, p. 3, Brussels, Belgium.
14. U.S. FDA website, "Developing Products for Rare Diseases & Conditions."
15. Paul D. Maher & Marlene Haffner (2006), "Orphan Drug Designation and Pharmacogenomics: Options and Opportunities," BioDrugs 20:71

16. Pugatch Consilium (2019), Benchmarking Success: Evaluating the Orphan Regulation and Its Impact on Patients and Rare Disease R&D in the European Union, pp. 7-9, Bicester, UK.

17. Commission of the European Communities, Commission Staff Working Document on the experience acquired as a result of the application of Regulation (EC) No. 141/2000 on orphan medicinal products and account of the public health benefits obtained, p. 9, Brussels, June 20, 2006, https://ec.europa.eu/health/sites/health/files/files/orphanmp/doc/orphan_en_06-2006_en.pdf.

18. Commission of the European Communities, Commission Staff Working Document on the experience acquired as a result of the application of Regulation (EC) No. 141/2000 on orphan medicinal products and account of the public health benefits obtained, p. 13, Brussels, June 20, 2006.

19. Zamora et al. (2017), "Comparing Access to Orphan Medicinal Products (OMPs) in the United Kingdom and other European Countries," Office of Health Economics.

20. This is the average duration for England, Scotland, Wales, France, Germany, Italy, and Spain. Germany is excluded because all products are reimbursed upon approval. When Germany is included, the average duration drops from 23.4 months to 20 months.

21. European Commission (2022), Pharmaceutical Strategy...

22. V. Loise & A.J. Stevens (2010). "The Bayh-Dole Act Turns 30," Les Nouvelles, December 2010, pp. 185-186, http://www.bu.edu/otd/files/2011/02/The_Bayh-Dole_Act_Turns_30.pdf.

23. hane, S. (2004), "Encouraging University Entrepreneurship? The Effect of the Bayh-Dole Act on University Patenting in the United States," Journal of Business Venturing, 19, pp. 127-151. See the introduction to this article for a full discussion of the academic debate over the effects of Bayh-Dole.

24. L. Pressman et al. (2022), The Economic Contribution of University/Nonprofit Inventions in the United States: 1996-2020, BIO 2022, p. 3.

25. Ibid.

26. USPTO (2006), "Technology Profile Report: Patenting Examining Technology Center Groups," 1630-1660, Biotechnology, Washington, 2006

27. B. Huggett (2014), "Top US Universities and Institutes for Life Sciences in 2013," Nature Biotechnology, Vol. 32, No. 11, November 2014.

28. L. Pressman et al. (2022), pp. 11-12.

29. N. Pallas (2022), "Penn Researchers Receive Royalties of $750 Million for Breakthrough Vaccine Development," The Daily Pennsylvanian, June 23, 2022.

30. World Bank Data Bank, Trade, Merchandise Exports (current US$)

31. Ibid.

32. 32. OECD (2009), "Magnitude of Counterfeiting and Piracy of Tangible Products: An Update," November 2009, OECD Publishing.

33. 33. OECD/EUIPO (2021), Global Trade in Fakes: A Worrying Threat, Illicit Trade, OECD Publishing, Paris. See also OECD/EUIPO (2019), Trends in Trade in Counterfeit and Pirated Goods, Illicit Trade, OECD Publishing, Paris/European Union Intellectual Property Office.

34. Ibid. p. 28. Table 4.1 is copied verbatim.

35. Ibid. p. 58.

36. Ibid. p. 48.

37. Ibid. p. 88.

38. 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 only uses 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.

39. These difficulties of measuring piracy are particularly pronounced for online piracy. No comprehensive studies exist that measure and compare rates of online piracy for a large sample of economies. Because of this, the indicators measuring piracy and counterfeiting in the Index are primarily based on physical piracy and counterfeiting, with the data from BSA 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 to $650 billion and $1,220 to $1,770 billion, respectively. Of this total, digitally pirated products were estimated at $30 to $75 billion in 2008 and forecast to be $80 to $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 to $20 billion worth of digitally pirated recorded music was consumed in the United States, with an additional $1.4 to $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).

40. OECD (2016), Trade in Counterfeit and Pirated Goods, pp.110-111.

41. 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.”

42. Act of 1991, International Convention for the Protection of New Varieties of Plants, Article 19, Duration of the Breeder’s Right

43. Non-IP5 Index economies can achieve a full score of 1 if they have equivalent, unrestricted, separate bilateral PPH agreements in place with all IP5 offices.

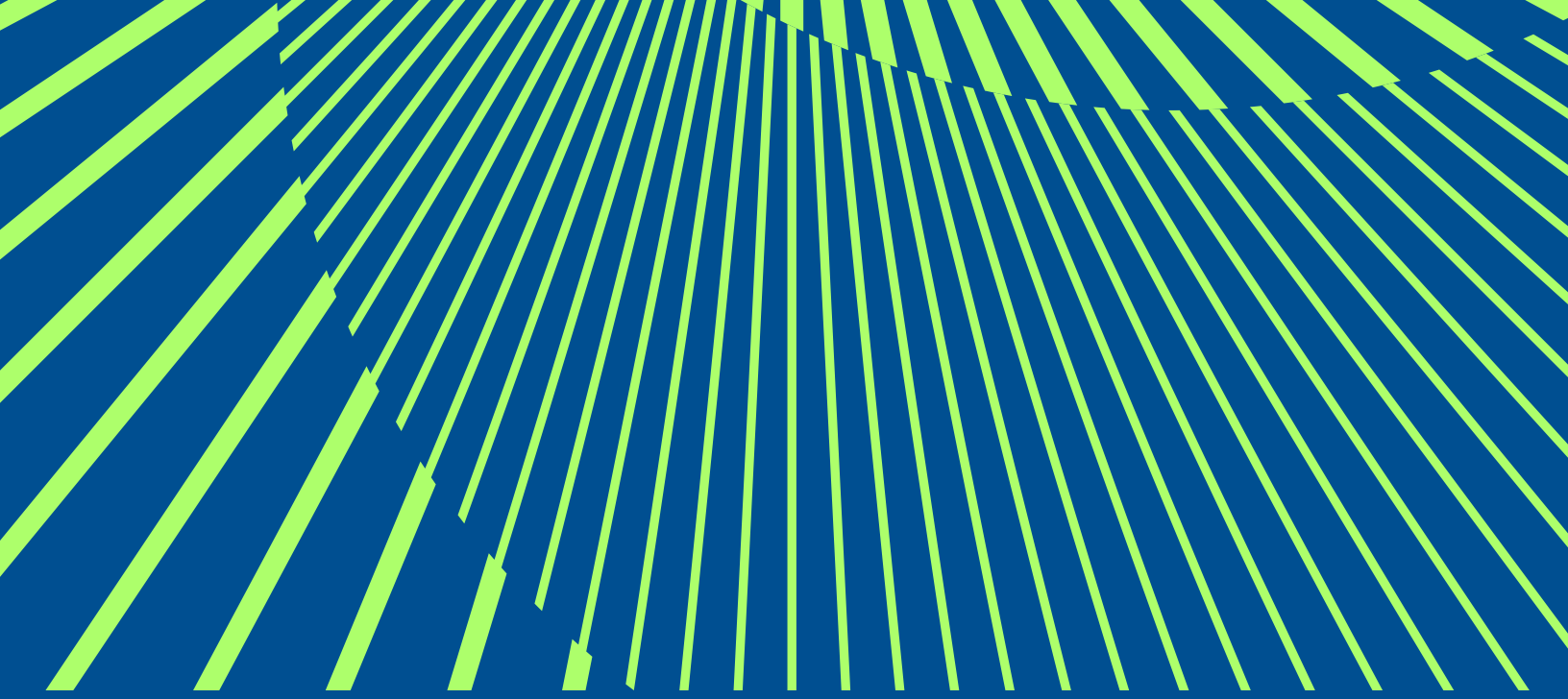
44. The Berne three-step test generally requires that limitations and exceptions to copyrights (1) be confined to special cases, (2) not conflict with a normal exploitation of the work, and (3) not unreasonably prejudice the legitimate interests of the rightsholder. (TRIPS Agreement, Article 13.)

45. 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 take down 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.

46. 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 for this indicator is 0.5. The EU's baseline numerical term used is that of 10 years (8+2) of marketing exclusivity.

47. This indicator is not concerned with commercial litigation brought by private parties and settled by an independent judiciary.

48. The Hague Agreement Concerning the International Registration of Industrial Designs consists of several separate acts, specifically the Hague Agreement of 1960 (Hague Act) and the Geneva Act of 1999. The score for this indicator is evenly assessed between membership and accession to both treaties.



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