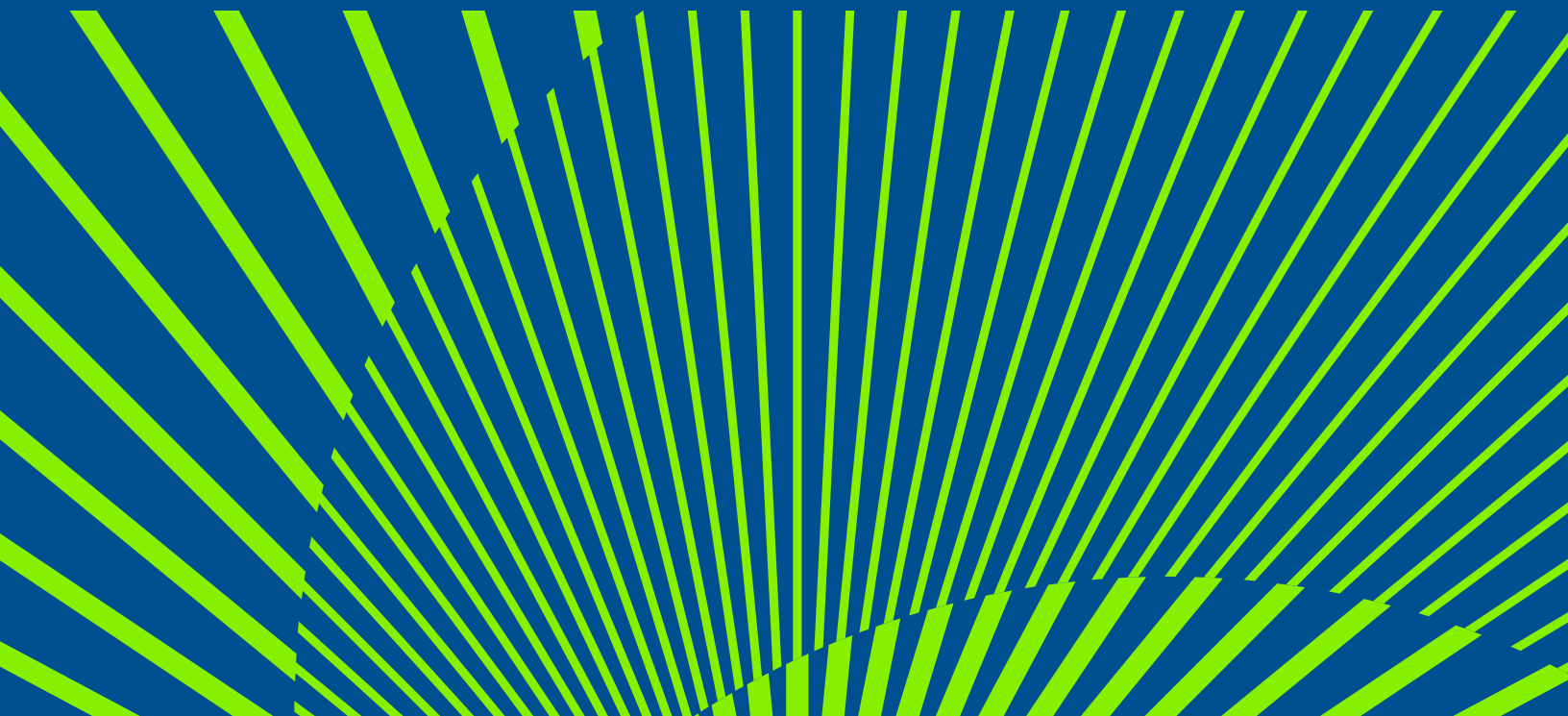




U.S. Chamber of Commerce
Global Innovation
Policy Center

International IP Index

2025 Thirteenth 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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Contents

Foreword 7

Executive Summary..... 8

Overview of the Thirteenth Edition 21

The Global IP Environment in 2024—
Major Developments, Overall Index Scores, and
Category-by-Category Results 25

Economy Overviews..... 70

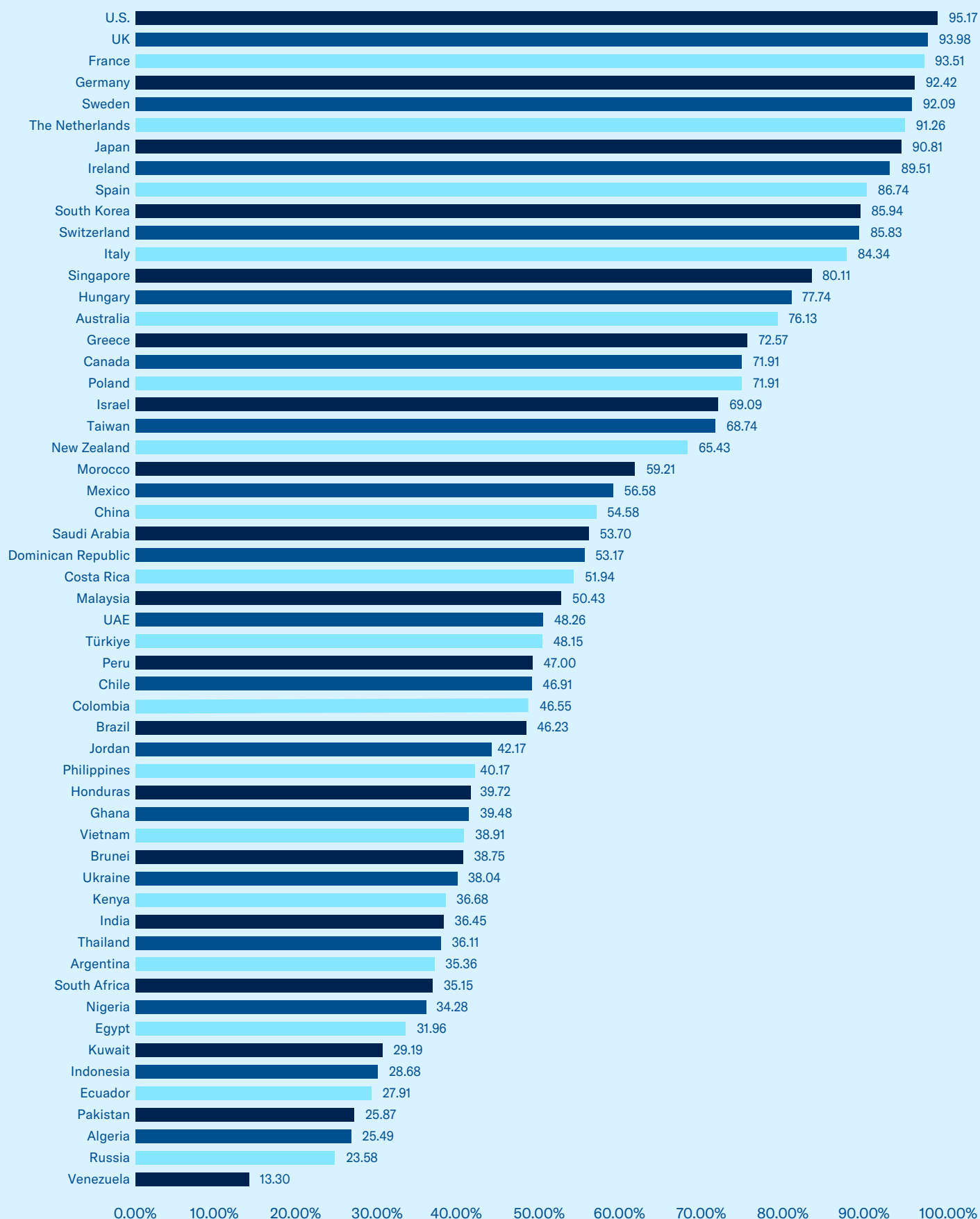
Appendix: Methodology, Sources,
and Indicators Explained 405

Tables and Figures

Table 1: Thirteenth Edition Index Economies by World Bank Region.....	22
Table 2: Thirteenth Edition Index Economies by World Bank Income Group	23
Table 3: New Index Category and Indicators Added in 2025	24
Table 4: Change in Overall Score, Thirteenth Edition versus Twelfth Edition	37
Figure 1: World Total Patent Applications (Direct and Patent Cooperation Treaty National Phase Entries), Design Applications (Direct and via the Hague System), and Trademark Applications (Direct and via the Madrid System), 1995–2023.....	27
Figure 2: Total Patent Applications (Direct and Patent Cooperation Treaty National Phase Entries), Regional Comparison, 1997 versus 2023.....	28
Figure 3: Total Design Applications (Direct and via the Hague System), Regional Comparison, 1994 versus 2023.....	28
Figure 4: Total Trademark Applications (Direct and via the Madrid System), Regional Comparison, 1994 versus 2023.....	29
Figure 5: Charges for the Use of Intellectual Property, Receipts (Balance of Payments, Current U.S. Dollar), World Total	30
Figure 6: Charges for the Use of Intellectual Property, Payments (BoP, Current U.S. Dollar), and Low and Middle Income versus High Income, 1990 versus 2023	31
Figure 7: Category 1: Patent Rights and Limitations, % Available Score	41
Figure 8: Category 2: Copyrights and Limitations, % Available Score.....	45
Figure 9: Category 3: Trademark Rights and Limitations, % Available Score	48

Figure 10:	
Category 4: Design Rights and Limitations, % Available Score.....	50
Figure 11:	
Category 5: Trade Secrets and the Protection of Confidential Information, % Available Score	52
Figure 12:	
Category 6: Commercialization of IP Assets, % Available Score	54
Figure 13:	
Category 7: Enforcement, % Available Score	58
Figure 14:	
Category 8: Systemic Efficiency, % Available Score	60
Figure 15:	
Category 9: Incentives for Cutting-Edge Innovation.....	62
Figure 16:	
Category 10: Membership and Ratification of International Treaties, % Available Score	67

U.S. Chamber International IP Index 2025, Overall Scores, % Available Score



Foreword

Intellectual property (“IP”) protections allow inventors and innovators to develop the next big idea that creates well-paying jobs, raises the standard of living for all, and improves people's lives through better medicines, new products, and more entertainment options. Strong IP policies also allow for increased trade and certainty in international commerce. Conversely, substandard policies negatively impact job creation and economic growth.

The economies that embrace ingenuity and creativity are defined by energy and progress—they lead the world in ground-breaking life sciences innovation, critical technology development, and creative content production. For these economies to continue to thrive, effective intellectual property (IP) must be in place. This is especially true of the United States but also for nations that are economic leaders and emerging economies.

The 2025 IP Index recognizes the policies that make this progress possible and provides a blueprint for every economy to experience the invaluable benefits of IP. Stable, predictable IP protections heighten investment in innovation and creativity and ensure those economies have access to the latest technological breakthroughs. Likewise, creating incentives to pursue IP-driven innovation and creativity—like tax breaks and grant funding—encourages problem-solving around the world's most pressing challenges, like creating well-paying jobs, strengthening public health, addressing food security, and more.

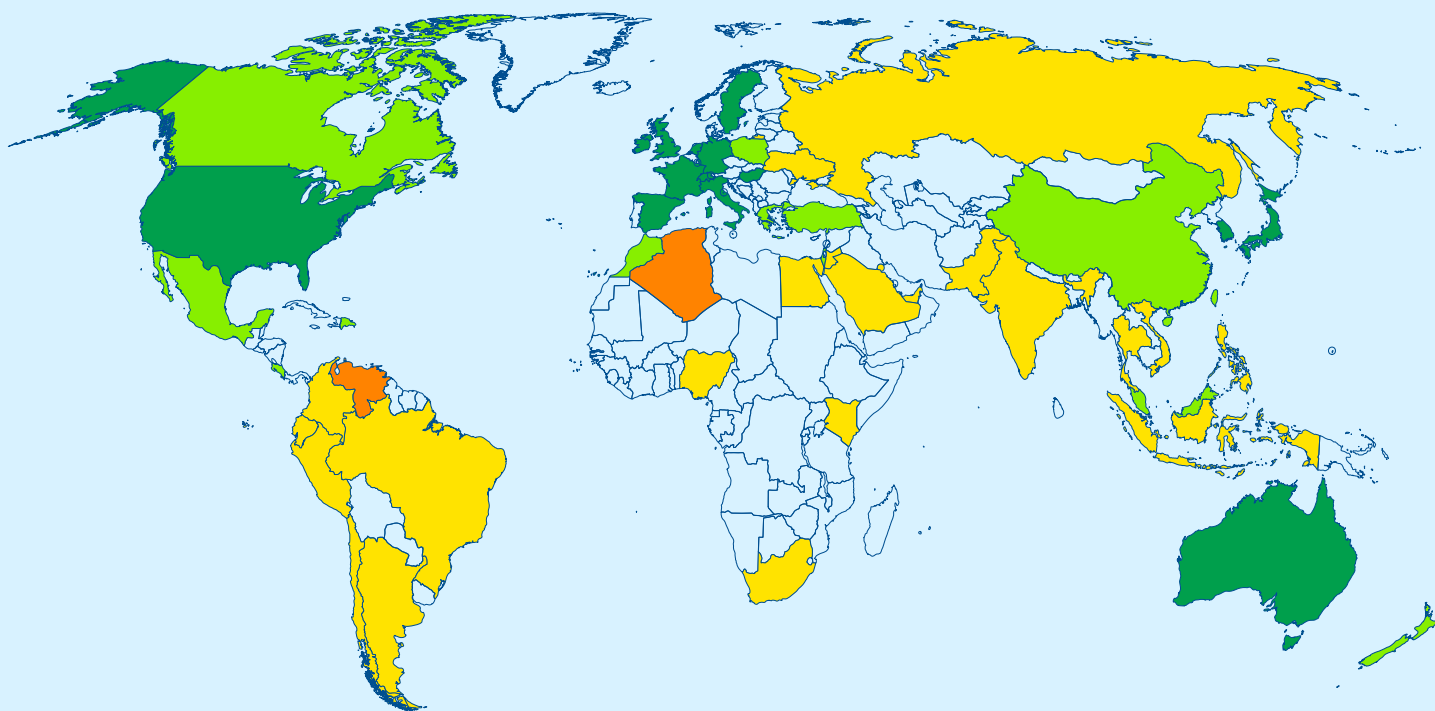
It is critical that leaders consider these approaches on a global scale. We know that advancing IP standards in isolation won't help us reach our shared goals. With fair, enforceable trade rules in place, IP can create productive partnerships between countries and boost collective competitiveness. Conversely, IP theft and forced transfers create mistrust and trade tensions that harm domestic economies and decrease the opportunities for fair trade. We must work together on IP, so we can all go farther.

The Index provides the roadmap for our journey: It outlines the strengths of our global IP system and identifies where more work is needed to unleash the innovation ecosystem's full potential. Policymakers can use the Index to inform conscious IP policy decisions that ensure that everyone with a great, new idea is along for the ride. Only then can we create true prosperity and sustain it for the greater good.

Executive Summary

The 13th edition of the International IP Index benchmarks the IP framework in 55 global economies across 53 unique indicators.

The Index offers a roadmap for economies aiming to boost IP-driven innovation and creativity while also highlighting recent trends in global IP protection.



Overall Economy Scores



1-25%



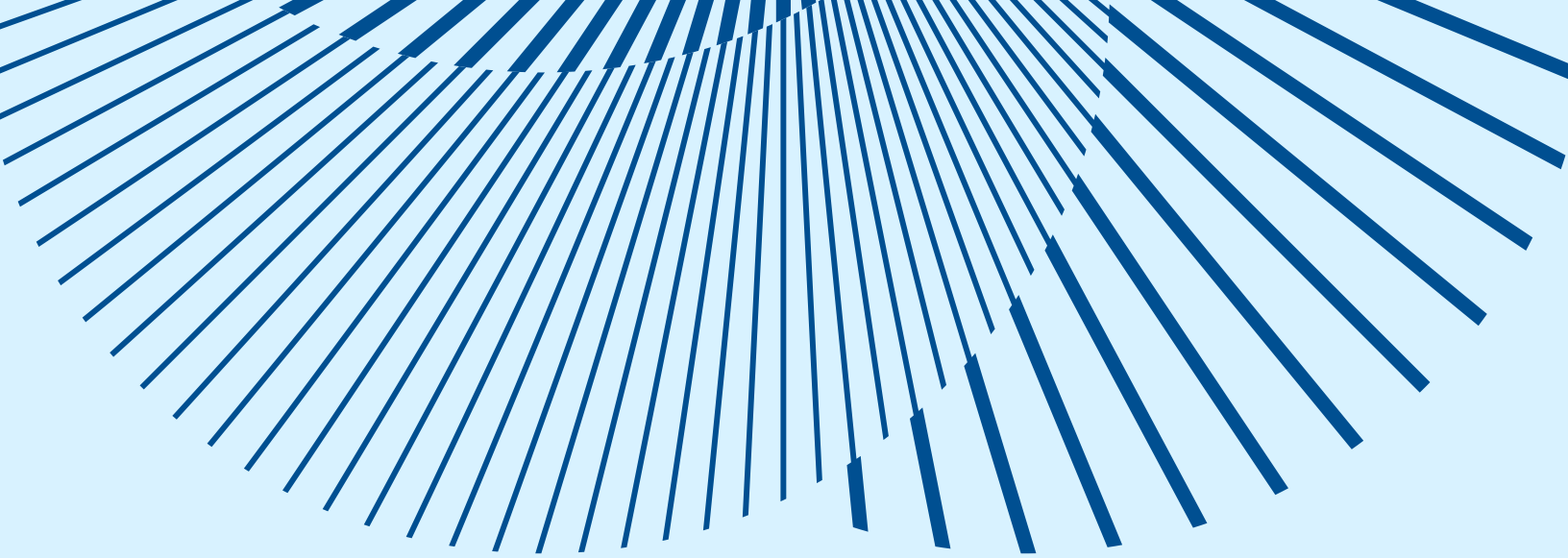
26-50%



51-75%



76-100%



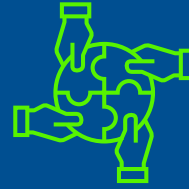
Geographic Coverage

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

Key Findings



The overall score improved in 33 economies, illustrating an increasing recognition of the value of IP protection worldwide.



IP supports economies' competitive advantage in innovation and creativity. The markets that seek to lead the world in ground-breaking medical innovation, critical technologies, and creative content must continue to invest in strengthening their IP ecosystem.

- Saudi Arabia, the United Arab Emirates (UAE), and Kuwait earned the largest improvements in overall score at 17.55%, 11.22%, and 8.87%, respectively, building upon momentum in recent years to strengthen IP protection across the Middle East.
- Twenty economies' scores remained unchanged, while the overall Index score dropped marginally in only two economies.
- There was little movement among the top 10 economies, with the U.S., UK, some EU Member States, Japan, and Korea leading the rankings again in 2025.
- In the United States, ongoing drug price negotiations, continued uncertainty around patentability, and march-in rights proposals weaken the framework for American life sciences innovation.
- In the EU, the General Pharmaceutical Legislation would reduce regulatory data protection and weaken existing IP incentives, in turn undermining investment in innovation and exacerbating the existing trend of investment leaving Europe.
- Continued innovation in areas such as artificial intelligence has the potential to empower creative and innovative processes. Developing these tools responsibly and ethically while also ensuring full respect for IP protection is essential. Evolving artificial intelligence policies must be evaluated in light of these principles.

Key Findings



Across Latin America, the Middle East, and Asia, economies took steps to better combat IP-infringing content online.



In the 30 years since the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement entered into force, the increase in IP registration, IP-related trade, and technology transfer illustrates how IP can enhance trade relations between global economies.

- In Argentina, Brazil, and Colombia, the courts, law enforcement, and the Government disabled access to websites hosting copyright infringing content.
- In Kuwait, the government gave rightsholders the ability to request the disabling of access to sites hosting IP infringing content. In the UAE, the government introduced a new system of administrative injunctive-style relief that aims to disable access to all IP infringing content.
- In the Philippines, the government introduced a voluntary program for participating ISPs to disable access to copyright-infringing content.
- Following the TRIPS Agreement, the rates of IP registration improved the most dramatically in regions that have historically had more underdeveloped IP systems, with a 450% increase in trademark filings in Africa between 1993 and 2023.
- The global volume of trade in IP assets increased over 17 times to \$446 billion between 1990 and 2022.
- The proportion of overall trade in IP assets and technology transfer from high-income to low- and middle-income economies increased threefold from 1990 to 2023.

Key Findings



The enforcement of outstanding trade-related IP commitments is essential for economies aiming to strengthen trade and global competitiveness through more effective IP.

- Mexico has yet to implement the biopharmaceutical-related commitments of the U.S.-Mexico-Canada Agreement (USMCA), including provisions related to patent enforcement, timely marketing authorization, patent term restoration, and regulatory data protection.
- Canada has yet to establish a comprehensive patent term adjustment mechanism as required by USMCA.
- Full implementation of the IP provisions of China's Phase One Agreement with the United States will be key to mitigating trade irritants and enhancing the ecosystem for both foreign and domestic innovation and creativity in China.

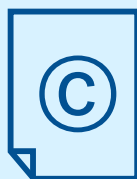
Category-by-Category Results



Patents, Related Rights, and Limitations

Twenty-three economies achieve a score of 70% or more of the available score, and 31 economies achieve a score of 50% or more. The average score on the category is 59.82%, which is the fifth highest scoring category on the Index.

- In the United States, proposed changes to the practice of terminal disclaimers introduce a new requirement to limit the number of claims that can be referred to future infringement action.
- In Australia, the Therapeutic Goods Administration announced that it would not pursue reforms to create a timelier patent notification framework for biopharmaceutical products.
- China released the Patent Law Implementing Regulations and updated Patent Examination Guidelines that make patent term restoration for biopharmaceuticals contingent on first global launch taking place in China.
- In Colombia, the Government granted a compulsory license for an HIV/AIDS treatment.



Copyrights and Limitations

While most Index economies continue to struggle in this category, the average score on this category continued to improve in 2024 from 50.61% last year to 51.45% this year.

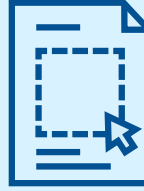
- In Brazil, a new law gave the National Cinema Agency the power to suspend the use of unauthorized protected works, resulting in the creation of two pilot programs to disable access to copyright-infringing audiovisual content and live sporting events.
- In Mexico, the Supreme Court upheld the validity of USMCA copyright-related provisions.
- In Vietnam, the People's Court of Hanoi issued the first criminal court conviction for copyright infringement.
- In Egypt, the Alliance for Creativity and Entertainment facilitated a partnership with law enforcement to disable access to a website that was a central distribution point of infringing-content in Arabic across the Middle East and North Africa.



Trademarks, Related Rights, and Limitations

Most economies sampled in the Index offer basic forms of trademark protection. Only nine of the 55 sampled economies fail to score 50% or more on this category. The average score increased from 62.84% in the twelfth edition to 63.41% in the thirteenth edition.

- In the Philippines, new legislation defines primary and secondary liability for the failure to act upon notification of IP infringement.
- In France, French Customs launched the *National Anti-Counterfeiting Plan 2024–2026* that emphasizes fighting counterfeits sold and marketed online.



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 64.18%, up marginally from 64% last year.

- Saudi Arabia increased the term of protection for design rights from ten years to 15 years.
- Indonesia is considering amendments to the Design Law, which would increase the design rights term of protection to 15 years, if passed into law.
- The EU is considering draft legislation that updates legal definitions, improves registration requirements, and expands the scope of protection for design rights.



Trade Secrets and Protection of Confidential Information

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 one the weakest in the Index at 49.27%, up only marginally from last year.

- The EU is currently considering legislation that reduces the term of regulatory data protection (RDP) and conditions extensions of RDP term on external factors, such as market access.
- In South Korea, new legislation significantly strengthened existing penalties and damages for trade secret violations and misappropriation of confidential information.
- In the United States, the Federal Trade Commission issued a rule banning the use of noncompete agreements, which was overturned by the courts. Noncompete agreements can play a critical role in protecting IP assets from trade secrets theft and misappropriation of confidential information.



Commercialization of IP Assets

Twenty economies of the 55 sampled in the Index fail to achieve a score of 50% or more with twelve scoring 33.33% or less on the category. The average score on this category was 58.88%.

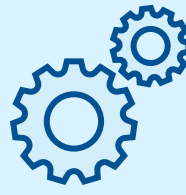
- The Chilean government is considering draft legislation that promotes the use of IP rights to commercialize publicly funded research.
- In the EU, the European Commission withdrew its proposed regulation on standard essential patents.
- The UK introduced changes to British tax law on the incentives for the creation of IP assets that include a new tax regime for R&D-intensive small and medium-sized enterprises (SMEs).



Enforcement

As in years past, a majority of the sampled economies in the Index struggle on this category with only 26 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 on the Index at 50.68%, up only marginally from last year's 50.24%.

- The UAE introduced a new dedicated anti-counterfeiting law that outlaws the importation, exportation, and re-exportation of counterfeit and fraudulent goods; empowers judicial enforcement officers to take *ex officio* action against suspected counterfeit goods; and strengthens criminal sanctions and penalties for IP theft.
- In Saudi Arabia, the number of cases considered for IP infringement with damages awarded continues to increase. Also, the government strengthened criminal enforcement of IP rights through the establishment of a dedicated prosecution office for IP offences.



Systemic Efficiency

The majority of sampled economies in the Index perform well in this category with only 13 economies failing to achieve a score of 50% or above. Overall, the average score on this category continues to be one of the strongest in the Index, at 63.91%, up from 63.55% last year.

- In the Dominican Republic, the government increased the number of IP infringement investigations and seized and destroyed 10 million units of counterfeit and/or illicit tobacco, medicines, alcohol, and other goods.
- In the UAE, the Ministry of Economy launched two new programs to increase the development and registration of IP assets by SMEs through access to financing, technical assistance, and registration support.
- The Israeli Patent Office expanded its technical assistance program to assist SMEs and start-ups in the FemTech industry with the creation and commercialization of IP assets.



Incentives for Cutting-Edge Innovation

The 2025 Index includes a new category that benchmarks the availability of incentives for cutting edge innovation. The average score on this category is the weakest of all included in the Index at 27.39%. Overall, 38 economies fail to achieve any score on the three indicators included in this category.

- The U.S. was the first economy to introduce dedicated incentives for the development and commercialization of medicinal orphan products through the 1983 Orphan Drug Act.
- While EU economies lead the Index rankings in this category, the EU is currently considering proposals that would restrict or reduce the current term and scope of protection for orphan products that, if implemented, would result in a reduction in their score.
- Several economies in the Asia-Pacific—including Taiwan, South Korea, and Japan—provide legal definitions and policies related to rare diseases and orphan drugs and R&D incentives for the development of new treatments and technologies.



Membership and Ratification of International Treaties

This category remains one of the stronger overall categories in the Index. Twenty-two economies have a score of 75% or more with 14 economies achieving a score of over 96%. Overall, the average score on this category is 63.91%.

- While Argentina is a contracting party to the International Union for the Protection of New Varieties of Plants (UPOV) 1978, the government is considering joining the UPOV 1991, which would strengthen protection for new plant varieties.
- The Pakistan Intellectual Property Office is considering joining the Patent Cooperation Treaty (PCT) and hosted a PCT training program for local patent examiners in anticipation of Pakistan's potential accession.
- While the UAE concluded six Comprehensive Economic Partnership Agreements over the past three years, the IP chapters do not conform to the standards of a post-TRIPS free trade agreement.

Regional Rankings

Region	Average overall % Index Score
North America	83.54%
Europe and Central Asia	76.11%
Asia	54.67%
Latin America	42.24%
Africa and Middle East	41.82%

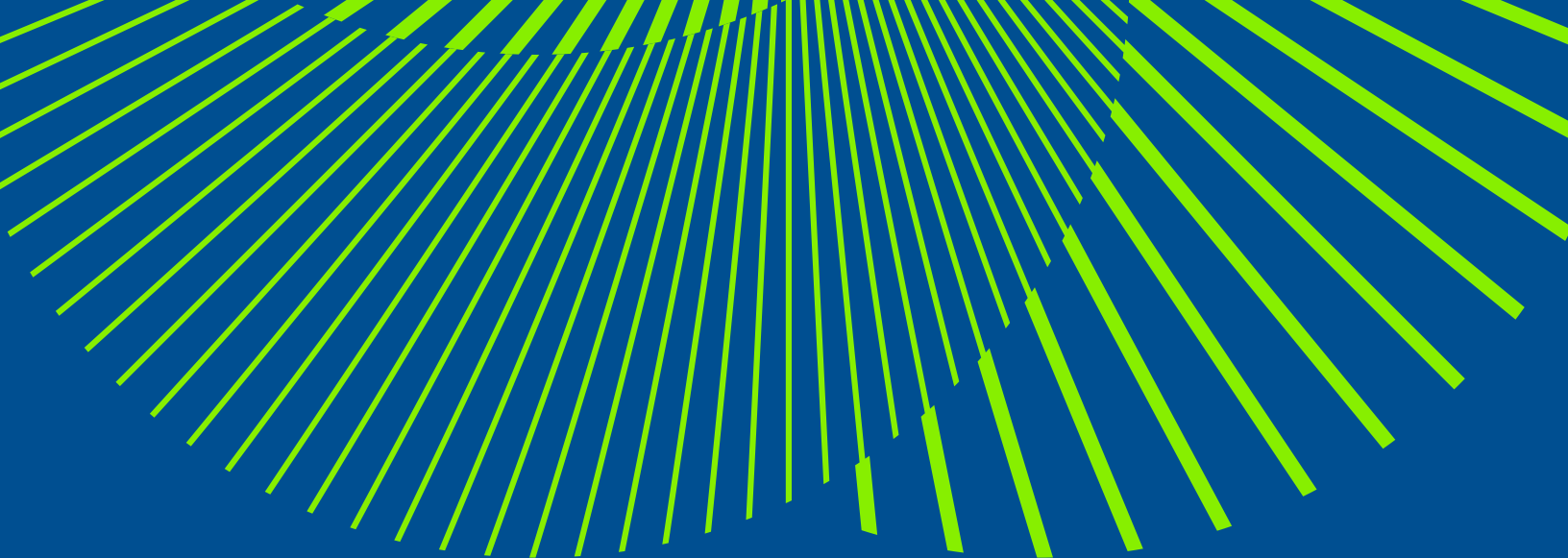
Europe and Central Asia	Overall Score	Regional Ranking
United Kingdom	93.98%	1
France	93.51%	2
Germany	92.42%	3
Sweden	92.09%	4
The Netherlands	91.26%	5
Ireland	89.51%	6
Spain	86.74%	7
Switzerland	85.83%	8
Italy	84.34%	9
Hungary	77.74%	10
Greece	72.57%	11
Poland	71.91%	12
Türkiye	48.15%	13
Ukraine	38.04%	14
Russia	23.58%	15

North America	Overall Score	Regional Ranking
United States	95.17%	1
Canada	71.91%	2

Asia	Overall Score	Regional Ranking
Japan	90.81%	1
South Korea	85.94%	2
Singapore	80.11%	3
Australia	76.13%	4
New Zealand	68.74%	5
Taiwan	65.43%	6
China	54.58%	7
Malaysia	50.43%	8
Phillippines	40.17%	9
Brunei	38.91%	10
Vietnam	38.75%	11
India	36.45%	12
Thailand	36.11%	13
Indonesia	28.68%	14
Pakistan	25.87%	15

Latin America	Overall Score	Regional Ranking
Mexico	56.58%	1
Dominican Republic	53.17%	2
Costa Rica	51.94%	3
Peru	47.00%	4
Chile	46.91%	5
Colombia	46.55%	6
Brazil	46.23%	7
Honduras	39.72%	8
Argentina	35.36%	9
Ecuador	27.91%	10
Venezuela	13.30%	11

Africa and Middle East	Overall Score	Regional Ranking
Israel	69.09%	1
Morocco	59.21%	2
Saudi Arabia	53.70%	3
UAE	48.26%	4
Jordan	42.17%	5
Ghana	39.48%	6
Kenya	36.68%	7
South Africa	35.15%	8
Nigeria	34.28%	9
Egypt	31.96%	10
Kuwait	29.19%	11
Algeria	25.49%	12



Overview of the Thirteenth Edition

Now in its thirteenth 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 clear roadmap 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: Thirteenth 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 (2024)

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: Thirteenth Edition Index Economies by World Bank Income Group

Lower-Middle-Income Economies	Upper-Middle-Income Economies	High-Income Economies	High-Income OECD Members
Egypt	Algeria	Brunei	Australia
Ghana	Argentina	Kuwait	Canada
Honduras	Brazil	Russia	Chile
India	China	Saudi Arabia	France
Jordan	Colombia	Singapore	Germany
Kenya	Costa Rica	Taiwan	Greece
Morocco	Dominican Republic	UAE	Hungary
Nigeria	Ecuador		Ireland
Pakistan	Indonesia		Israel
Philippines	Malaysia		Italy
Vietnam	Mexico		Japan
Ukraine	Peru		The Netherlands
Vietnam	South Africa		New Zealand
	Thailand		Poland
	Türkiye		South Korea
	Ukraine		Spain
	Venezuela (2020)		Sweden
			Switzerland
			UK
			United States

Source: World Bank (2024). The World Bank has since 2020 removed Venezuela pending the release of national accounts statistics. Consequently, the Index uses Venezuela's latest income classification from 2020.

What Is New in the Thirteenth Edition?

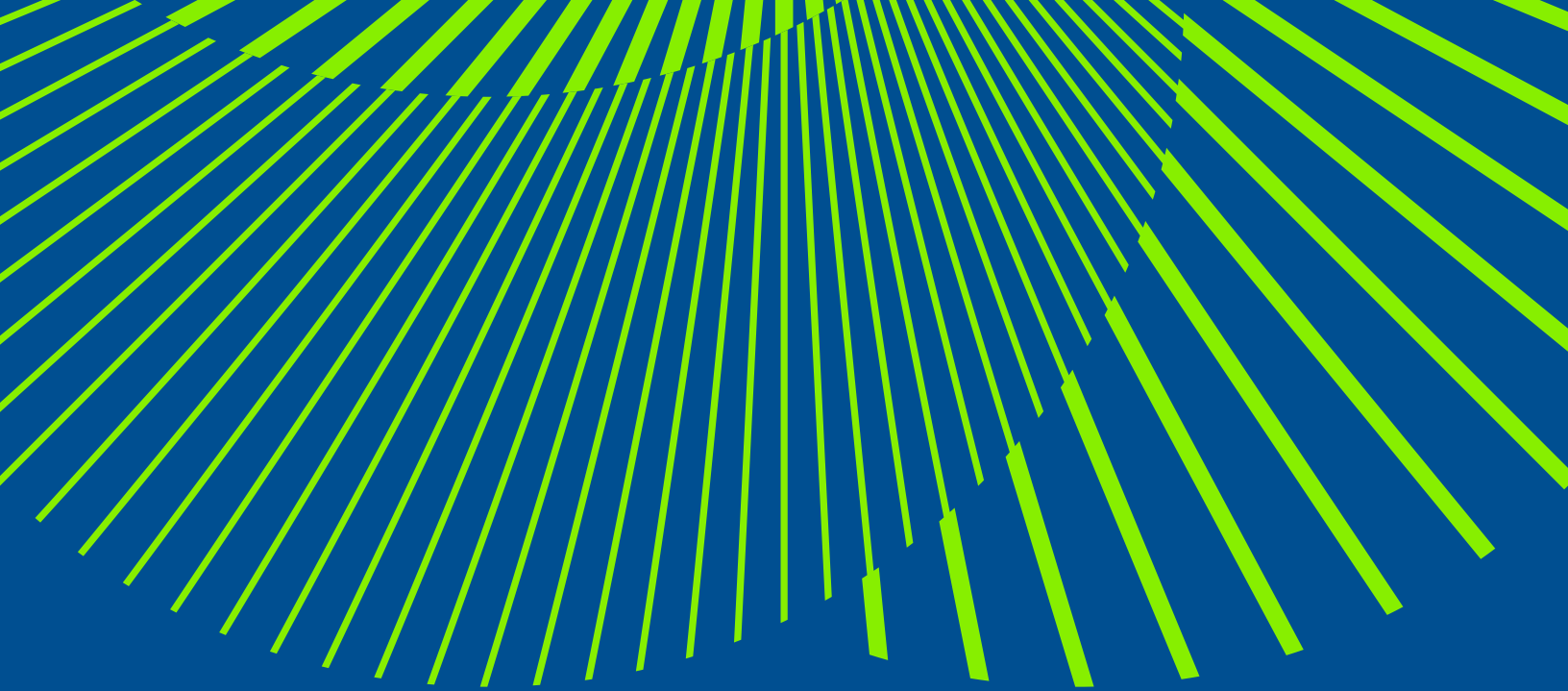
A significant new feature of the 2025 Index is the addition of three indicators in a new, stand-alone category: Category 9: Incentives for Cutting-Edge Innovation. This brings the total number of indicators included in the Index to 53. Since the inaugural edition of the Index in 2012, the number of indicators included in the Index has more than doubled from 25 in the first edition to today’s 53.

Consequently, the maximum possible score in the Index has increased from 25 to 53.

Table 3 provides an overview and summary of the new indicators and what they seek to measure. (The methodology section at the end of this report fully defines and describes the three new indicators.)

Table 3: New Index Category and Indicators Added in 2025

Index Category	New Indicators
Category 9: Incentives for Cutting-Edge Innovation	1. Special market exclusivity incentives for orphan medicinal product development
	2. Special market exclusivity incentives for orphan medicinal product development, term of protection
	3. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development



The Global IP Environment in 2024—Major Developments, Overall Index Scores, and Category-by- Category Results

International Developments

The world of international intellectual property is profoundly transformed from the situation that prevailed at the time the TRIPS Agreement was coming into force. Participation in and benefits from the IP system are increasingly widespread and more equitable.

– Johanna Hill, World Trade Organization (WTO) Deputy Director General, April 25, 2024²

When signed in 1994 as an annex to the Final Act establishing the WTO, the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) was considered by many to be the most comprehensive and ambitious agreement ever reached in the multilateral IP domain. TRIPS aimed to harmonize the global protection of IP rights by establishing a minimum standard for IP frameworks along with provisions on dispute settlements and enforcement to make it effective. Given that TRIPS largely predates globalization and the technological revolution that have allowed complex flows of information, capital, and human capital to move virtually seamlessly around the globe—as the IP standards captured and measured in the Index demonstrates—TRIPS has today been superseded by other more modern IP frameworks at both the national level and through various bilateral and plurilateral free trade agreements. Still, despite this clear dating, the Agreement has provided a critical minimum floor for global IP standards over the past 30 years and, as such, been an economic boon for the world.

As WTO Deputy Director General Hill rightly pointed out in her remarks on the TRIPS Agreement’s 2024 anniversary celebration, this global floor has led to a marked increase in the creation, registration, and economic value added from IP assets across the world.

IP and knowledge-intensive industries today make up a greater proportion of global economic output than at any other time in modern economic history. For example, in the United States, European Union (EU), South Korea, Brazil, and Mexico, IP-intensive industries make up at least 40% of national economic output and over 30% of employment.

Both at the aggregated global total and at the level of individual economies, several economic indicators suggest that these industries and sectors are responsible for a considerable and growing proportion of international trade, national employment, and economic output. TRIPS has made an extraordinary and underappreciated contribution to this development. From developed, high-income economies to low- and middle-income economies, the long-term positive impact of the Agreement can be seen in two distinct areas:

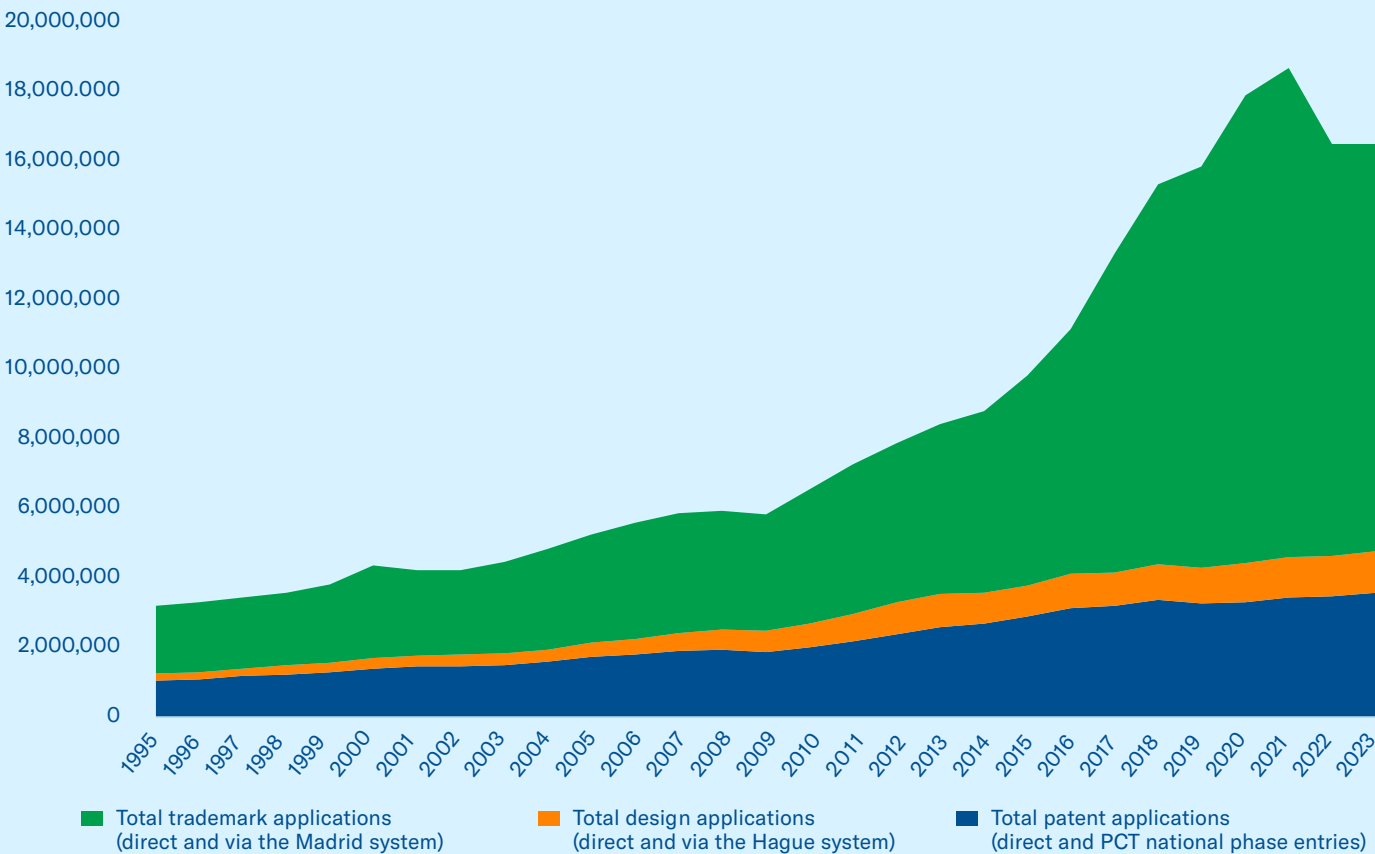
1. The building and usage of the international IP system as we know it today and the accompanying increase in the number of IP assets registered globally.
2. The positive added value, economic activity, and national output contributed through the creation and registration of these IP assets.

Building a Global IP System—How TRIPS Helped Establish Today’s International IP Architecture and Enabled the Creation and Registration of IP Assets Across the World

It is not hyperbole to say that TRIPS helped cement and solidify what has today become “the global IP system.” Although modern international cooperation on IP rights dates to the late 1800s and to the Paris and Berne conventions, the idea that IP rights should be included as an integral part of an international trade agreement like the WTO treaty was in 1994 pathbreaking. By requiring all WTO signatories to put in place a basic IP infrastructure and legal framework, the TRIPS Agreement, in effect, established two new legal and economic reference points.

The first is that IP-based goods and services are in themselves important as international economic assets and, consequently, should be protected as such through an international institution like any other trade-related right. Second, through its specific and detailed legal requirements on different minimum standards of IP protection, legal infrastructure, and enforcement provisions, the Agreement put in place a standardized institutional framework that, once adopted by each Member State, would contribute to the creation and registration of IP assets. Since the conclusion of the TRIPS Agreement, the increased use of this international IP system has been staggering. As Figure 1 shows, across all major registerable industrial IP rights for which standardized international data is available—patents, trademarks, and design rights—there has been a tremendous and sustained increase in the volume of applications worldwide.

Figure 1: World Total Patent Applications (Direct and Patent Cooperation Treaty [PCT] National Phase Entries), Design Applications (Direct and via the Hague System), and Trademark Applications (Direct and via the Madrid System), 1995–2023³



In 1995, there was a global total of 3.2 million total patent, design, and trademark applications—1,048,300, 187,200, and 1,954,500, respectively. In 2023, this had reached a total of 16,370,400—a growth rate of over 500%—with 3,552,100 total patent applications, 1,186,800 design applications, and 11,631,500 trademark applications.

The World Intellectual Property Organization’s (WIPO) statistical database shows how this growth has been driven not just by developed economies in Europe and North America with long-standing, established IP systems.

Instead, some of the strongest growth in the number of applications across these major IP rights has come from lower- and middle-income economies in Asia, Africa, Latin America, and the Caribbean. Figures 2, 3, and 4 compare this growth for total applications for patents, trademarks, and design rights in the world’s major regions as defined by WIPO since the conclusion of the TRIPS Agreement.

Figure 2: Total Patent Applications (Direct and Patent Cooperation Treaty National Phase Entries), Regional Comparison, 1997 versus 2023⁴

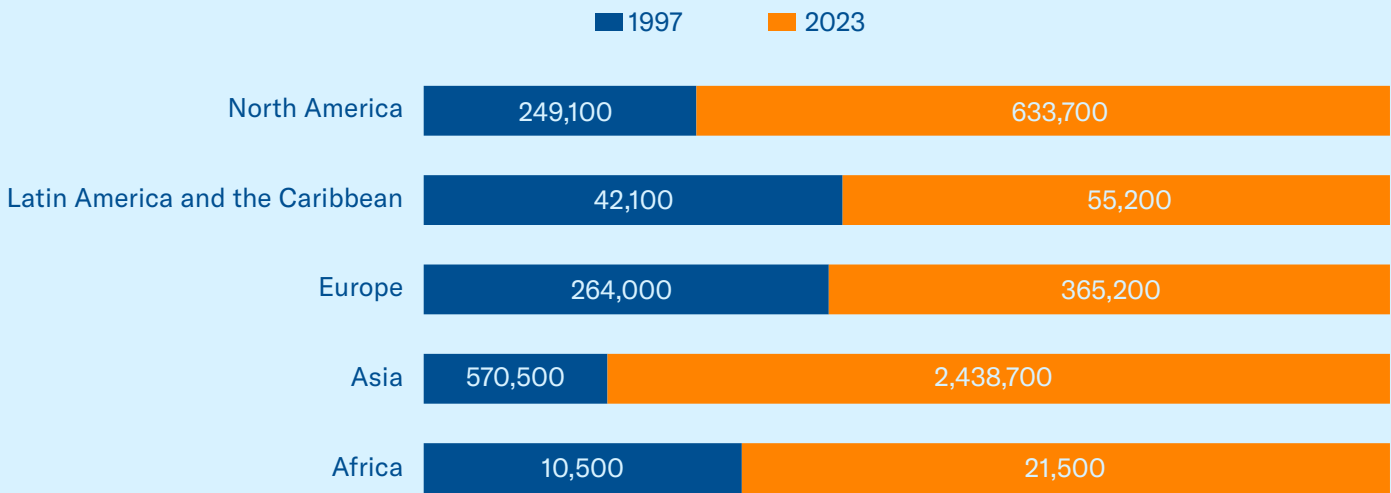


Figure 3: Total Design Applications (Direct and via the Hague System), Regional Comparison, 1994 versus 2023⁵

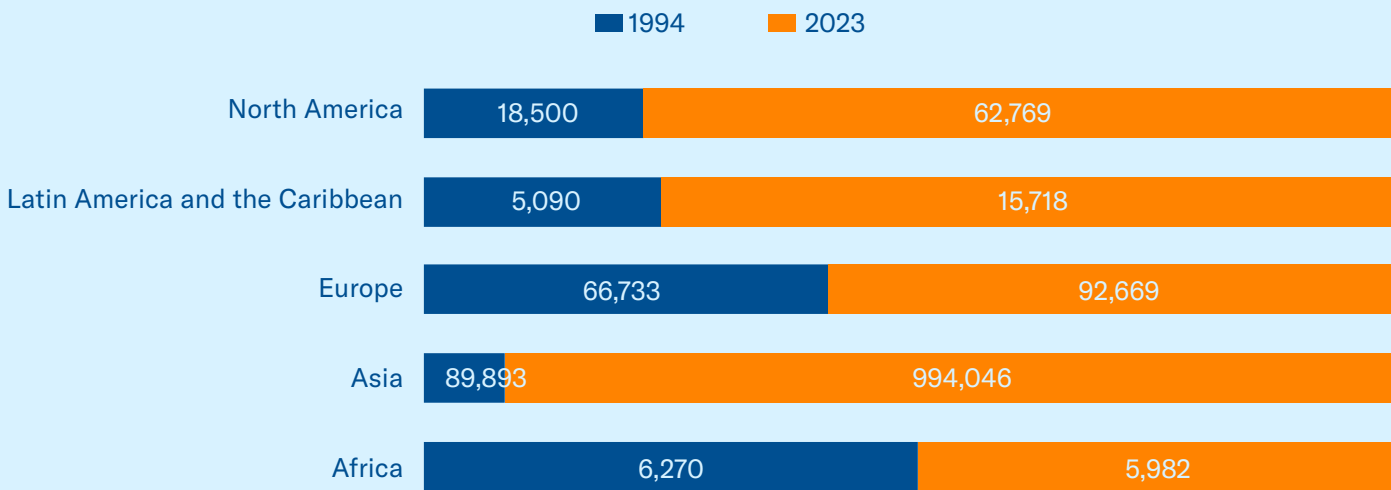
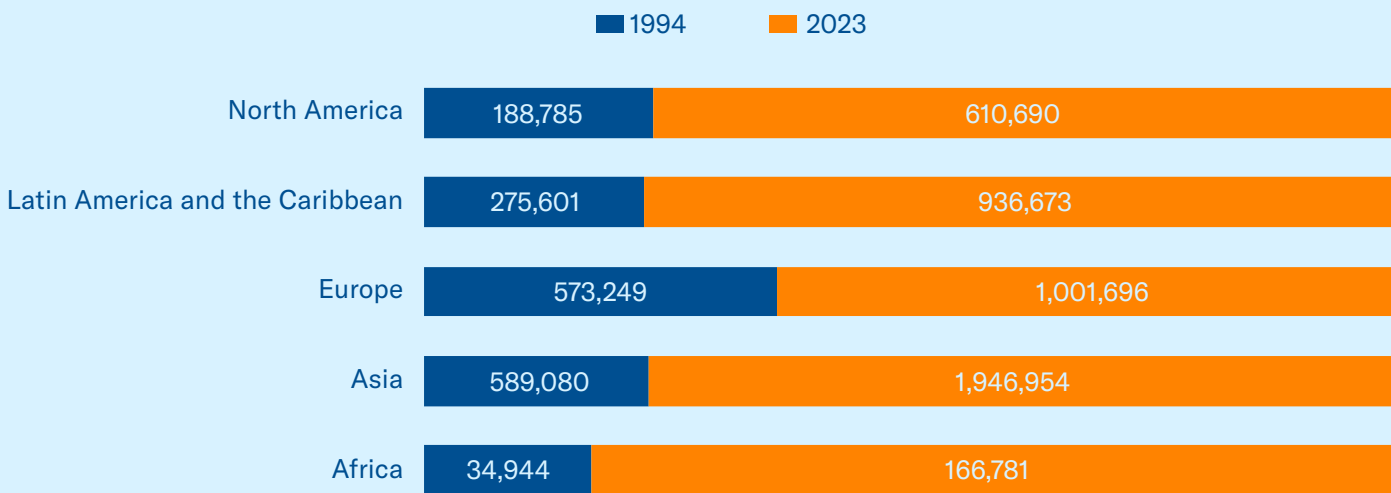


Figure 4: Total Trademark Applications (Direct and via the Madrid System), Regional Comparison, 1994 versus 2023⁶



As these figures suggest, although all major regions saw increased registration activity after TRIPS, Asia, Africa, Latin America, and the Caribbean saw some of the biggest aggregate and percentage jumps. Notably, there was significant growth in the registration of patents, design, and trademarks in Asia. Remarkably, some of the strongest increases in rates of IP registration occurred in those regions that have historically had more underdeveloped IP systems. For example, with respect to trademark registration, Africa saw the greatest percentage increase in the total number of applications of all regions in the period studied, growing from 34,944 applications in 1994 to 166,781 applications in 2023. This is an increase of over 450%. For the economies that make up the Africa region, this data shows how TRIPS made a sustained and meaningful contribution to the building of their national IP systems and accompanying positive socioeconomic impact.

Although the act of registering an IP right does not in itself lead to the successful commercialization of an invention, technology, brand, or design, the filing of a registration application suggests that an applicant perceives a potential economic and commercial value of the IP asset in question and is willing to invest the resources required to legally protect that asset.

As the following subsection demonstrates, the post-TRIPS global boom in increased registration activity of IP assets has in turn created tremendous economic value and output as measured through both international trade data and rates of national economic activity.

Increased Trade in IP Assets, Technology Transfer, and National Economic Output—How TRIPS and IP-Intensive Industries Have Transformed the Global Economy

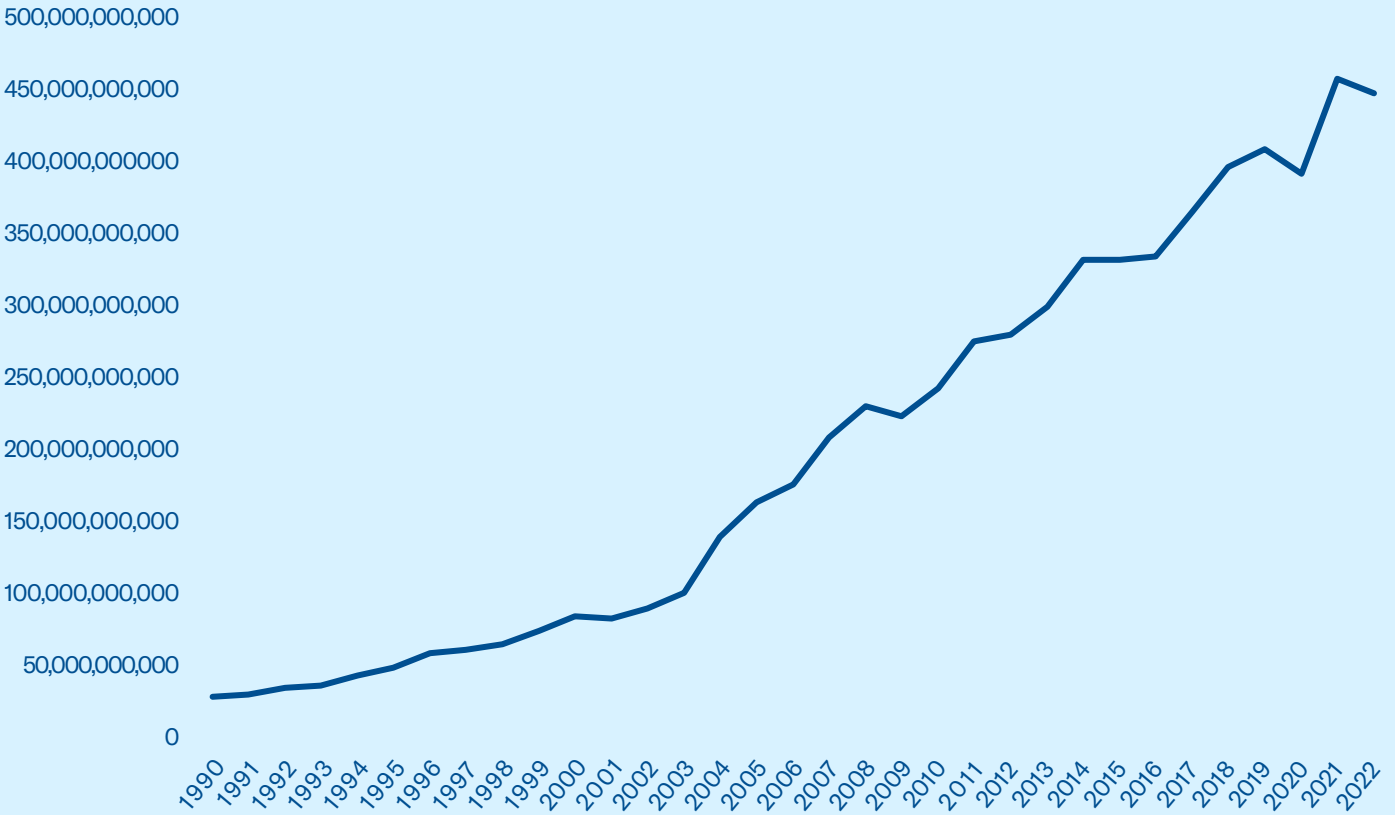
Since the conclusion of the TRIPS Agreement, the economic impact of IP rights at both the macro and micro levels has been a topic of growing interest to economists, social scientists, and governments. Notably, the positive economic impact of TRIPS was discovered and highlighted quickly, within 10 years of the conclusion of the Agreement. For example, in a 2003 Organisation for Economic Cooperation and Development (OECD) study, Park and Lippoldt compared WTO signatories to the TRIPS Agreement and non-WTO members, and found that, overall, IP rights tend to have a positive impact on foreign direct investment (FDI).⁷

With the exception of least developed countries, which may not yet have implemented the TRIPS Agreement because of transition period allowances, WTO members had higher levels of FDI than nonmembers. Similarly, in a 2010 paper, the OECD's Cavazos et al. looked at research & development (R&D) expenditure and technology transfer as well as FDI and found that a 1% change in the strength of a national IP environment (based on a statistical index) was associated with a 2.8% increase in FDI inflows, a 2% increase in service imports, and a 0.7% increase in domestic R&D.⁸ Today a growing body of academic, government, and nongovernmental research shows a positive and sustained relationship among the strengthening of IP rights and economic growth and socioeconomic development, job creation, technology transfer, and increased rates of investment and innovation after the conclusion of TRIPS.

The direct positive economic impact of TRIPS can most clearly be seen in the tremendous growth in the international trade of IP assets and high-value proprietary technologies.

One good proxy that captures inflows of technology and the international trade of different types of IP assets is the World Bank's indicator on payments by residents to nonresidents for the use of IP rights.⁹ The World Bank defines these charges for the use of IP as "payments and receipts between residents and nonresidents for the authorized use of proprietary rights (such as patents, trademarks, copyrights, industrial processes and designs including trade secrets, and franchises) and for the use, through licensing agreements, of produced originals or prototypes (such as copyrights on books and manuscripts, computer software, cinematographic works, and sound recordings) and related rights (such as for live performances and television, cable, or satellite broadcast)." The statistics are based on the International Monetary Fund's *Balance of Payments Statistics Yearbook* and data files. Figure 5 shows the growth in the trade of these IP assets globally from 1990 to 2022.

Figure 5: Charges for the Use of Intellectual Property, Receipts (BoP, Current U.S. Dollar), World Total

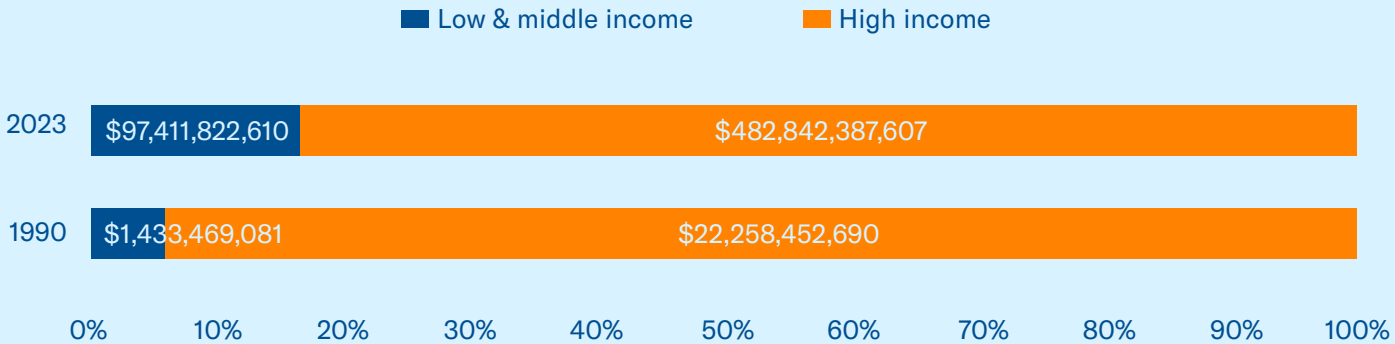


As Figure 5 shows, in 1990, the total global volume of trade for charges for the use of IP assets totaled just over \$26 billion. Fast forward to three decades later, and the latest available data from 2022 shows this trade had increased more than 17 times to \$446 billion, illustrating how significantly IP-related trade has grown since the TRIPS Agreement was signed in 1994. Today's global economy is interlinked, interdependent, and open for business in a way that was impossible logistically, politically, or financially in 1994. Indeed, the sum of the profound technological, cultural, political, and socioeconomic changes of the past three decades amounts to what is truly a paradigm shift in how the global economy works.

In 1990, the internet was not a commercially or publicly available entity. The Soviet Union, although crumbling, was still the world's second most important geopolitical bloc and one of its largest economies. The value of world trade in goods in 1990 was an estimated \$3.5 trillion. Today, the value of global trade is almost 10 times that amount at an estimated \$25 trillion in 2022.

Just-in-time manufacturing and the use of international supply chains were not industry standards and the basis for much of modern commerce. Naturally, the positive economic impact of TRIPS would not be possible without these structural, technological, and political changes to the global economy. Nevertheless, within this larger context and deep structural changes, TRIPS acted as an enabler of the creation, registration, and global trade in IP assets, particularly for low- and middle-income economies. Just like WIPO's registration data referenced earlier, the World Bank's data on the global trade in IP assets also shows how the global distribution and flows of IP assets have changed markedly over the past 30 years. In fact, a growing proportion of the international trade in IP assets is today flowing to low- and middle-income economies. Figure 6 shows payments for the use of IP assets, comparing the proportion of overall trade in IP assets and technology transfer taking place to low- and middle-income economies versus high-income economies in 1990 and today.

Figure 6: Charges for the Use of Intellectual Property, Payments (BoP, Current U.S. Dollar), and Low and Middle Income versus High Income, 1990 versus 2023



As Figure 6 shows, the proportion of overall trade in IP assets and technology transfer taking place to low- and middle-income economies versus high-income economies has increased almost threefold, from 6% of the total in 1990 to 17% of the total in 2023. Notably, this increase has taken place as the aggregated total of trade in IP assets and has grown from \$26 billion to \$446 billion. In other words, a greater percentage of a much larger overall volume of trade in IP assets is today flowing to low- and middle-income economies 30 years after the TRIPS Agreement entered into force. This means that although most payments for IP assets and technology transfer are made by high-income economies, low- and middle-income economies today directly derive an increasing economic benefit from the international IP system.

The growing importance of IP and knowledge-intensive industries to economic activity can also be seen at the national level. In fact, more economies are measuring the contribution that IP and knowledge-intensive industries make to their national economies. Although different economies use slightly different methods of assessing and counting the contribution that IP-intensive industries make to their national economies, the data is unambiguously clear: IP and knowledge-intensive industries today make a substantial and growing contribution to national output and employment.

For example, since 2012, the United States Patent and Trademark Office (USPTO) has measured the economic contribution of IP-intensive industries to the U.S. economy. The latest report from 2022, *Intellectual Property and the U.S. Economy: Third Edition*, found that IP-intensive industries made up an estimated 41% of national economic output.¹⁰ With respect to national employment, IP-intensive industries supported an estimated 63 million jobs, directly and indirectly, or 44% of all national employment.

Similarly, many European institutions study the economic impact of IP-intensive industries in the EU and Europe.

Major institutions that publish studies and research on various aspects of the economic contributions of IP-intensive industries include the European Patent Office (EPO), European Union Intellectual Property Office (EUIPO), EUROSTAT, and the European Commission. In 2019, EUIPO and EPO published their latest study, *IPR-Intensive Industries and Economic Performance in the European Union*.¹¹ This study found that IP-intensive industries contributed an estimated 44.8% of the EU's GDP and 29.2% of direct employment (this aggregated estimate includes estimates for the United Kingdom (UK), which was still an EU Member State at the time the study was conducted). As in the United States, this report also found that there had been a notable increase in the contribution of IP-intensive industries to EU GDP and employment compared to previous studies.

Just as with registration data and international trade in IP assets, IP-intensive industries also make up an increasing proportion of economic activity in emerging, low-income, and middle-income economies.

For example, in 2018, the Korea Intellectual Property Office released a comprehensive assessment of the contribution of Korean IP-intensive industries to national GDP, employment, and R&D investment: the *Economic Contribution Analysis of IP-Intensive Industry*.¹² Based on 2015 statistics collected by the national statistics agency, the report found that IP-intensive industries are a major contributor to national Korean output, employment, and R&D spending. This was estimated at constituting 43.1% of GDP, employing over 6 million people (29.1% of the entire workforce). IP-intensive industries were responsible for close to 80% of R&D investment in Korea.

Similarly, in 2021, the national IP office (INPI) in Brazil published a study of the contribution of Brazilian IP-intensive industries to national GDP, employment, and exports, *Intensive Sectors in Intellectual Property Rights in the Brazilian Economy (Setores Intensivos em Direitos de Propriedade Intelectual na Economia Brasileira)*.

Based on statistics from 2008 to 2016, the report finds that IP-intensive industries are a major contributor to Brazilian national output, employment, and trade. In the latest three-year period studied (2014–2016), this was estimated at averaging 44.2% of total gross value added, and IP-intensive industries directly employed over 19 million people on average (36% of the workforce).

Finally, in 2021, the Mexican national IP office's (IMPI) study also found that IP-intensive industries are a major contributor to national output, employment, and trade. For 2019, this was estimated at 47.8% of national GDP, and IP-intensive industries directly and indirectly employed over 17 million people (33.6% of the workforce).

Unfortunately, the long-term positive impact of TRIPS and the centrality of IP rights to the modern knowledge-based economy are facts that some of the world's most important international institutions and many of their members seem to have lost sight of. During the COVID-19 pandemic, the global IP rights architecture developed over several decades contributed to the rapid availability of lifesaving vaccines and therapies and to other technological solutions that have kept humans safe, connected, and productive to a degree unimaginable in previous health crises. However, over the past four years, those same rights and architecture have been under serious challenge from governmental and nongovernmental activists who misrepresent the role of IP rights in innovation and the global economy. There is no clearer example of this misrepresentation and disconnection than the WTO discussion on the TRIPS waiver.

In a State of Denial? International Institutions and IP Rights

The WTO TRIPS Waiver and Proposed TRIPS Review

At the 12th Ministerial Conference in 2022, the WTO members adopted a waiver of certain patent rights under the 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.”¹³ The waiver gives eligible 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.”

The discussions continued for over two years, but no evidence shows that the WTO TRIPS waiver in any way helped improve access to medicines. In fact, WTO members never made use of the waiver despite the immense harm that has been done to the international IP system by introducing a waiver of IP rights rather than addressing the actual barriers of access to medicines.

In a related development, in 2024, several members put forth proposals to conduct a review of the implementation of the TRIPS Agreement, pursuant to Article 71.1 of the Agreement. In March, Bangladesh, Colombia, Egypt, and India made a formal request with a more fleshed out communication issued by Colombia a few months later.

It remains unclear what these members hope to achieve with any prospective review. Article 71.1 of TRIPS is primarily aimed at reviewing the Agreement’s implementation. Specifically, it states that:

The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments, which might warrant modification or amendment of this Agreement.

Many WTO members have still not fully and adequately implemented commitments made under TRIPS three decades ago. In many Member States, significant gaps remain with respect to both the availability of TRIPS-defined IP rights and, when in place, their practical accessibility and active enforcement. Although Article 71.1 of TRIPS covers an implementation review, some countries are calling for a review beyond this scope. The communication from Colombia, for instance, states that the purpose of the proposed review should be “to identify (or produce) relevant analytical metrics and data, which are currently nonexistent, incomplete, or not appropriately used, to better assess the implementation of the TRIPS Agreement over the years, and better guide the discussions and domestic policymaking process of Members.”¹⁴

As desirable as it would be to compile data and metrics on the impact of the TRIPS Agreement and IP rights on society and economic activity—much of which is already available in the wealth of economic and social scientific research produced over the past 30 years, not to mention the 13 editions of this Index and its accompanying *Statistical Annex*—it is not clear that such an exercise requires a formal WTO review of the Agreement or that the TRIPS Council is the appropriate venue for such research. At the time of publication, it remained unclear what the next steps of the review process would be. The Index will continue to monitor these developments in 2025.

Learning the Wrong Lessons? The Draft WHO Pandemic Agreement

In early 2021, at the height of the COVID-19 pandemic, a group of world leaders published a joint article calling for the establishment of a new World Health Organization (WHO) convention, agreement, or other international instrument on pandemic prevention, preparedness, and response. Since then, WHO Members have been negotiating a “Pandemic Agreement.” In 2024, some amendments to the 2005 International Health Regulations were agreed to at the 77th World Health Assembly, but, at the time of research, no final Pandemic Agreement had been agreed on. Worryingly, all publicly released drafts echo the WTO’s ignorance of some of the most fundamental lessons of the pandemic, especially with respect to IP rights.

Although the draft Agreement’s preamble states that “intellectual property protection is important for the development of new medicines,” the meat of the agreement on the development and distribution of biopharmaceuticals effectively undercut this statement by requiring the sharing and transfer of developed technologies on an involuntary basis and/or actively setting the terms for the licensing and commercialization of a developed technology.

For example, Article 11 would require contracting parties to “promote” and actively “encourage” private rightsholders to share and transfer their technologies, know-how, and IP to other contracting parties to the Pandemic Agreement either on a completely cost-free basis or at a reduced price. It is far from clear what such encouragement and promotion would entail and whether rightsholders who refused to participate would be subject to some sort of sanctions or penalties.

Similarly, Article 9 Research and Development, Subsection 5, states:

Each Party shall develop and implement national and/ or regional policies, adapted to its domestic circumstances, regarding the inclusion of provisions in publicly funded research and development grants, contracts, and other similar funding arrangements, particularly with private entities and public-private partnerships, for the development of pandemic-related health products, that promote timely and equitable access to such products, particularly for developing countries, during public health emergencies of international concern including pandemic emergencies, and regarding the publication of such provisions. Such provisions may include: (i) licensing and/or sublicensing, particularly to manufacturers of developing countries and for the benefit of developing countries, preferably on a non-exclusive basis; (ii) affordable pricing policies; (iii) technology transfer; (iv) publication of relevant information on clinical trial protocols and relevant research results; and (v) adherence to product allocation frameworks adopted by WHO.¹⁵

From a policy perspective, restricting the manner in which publicly funded research and the IP developed from it can be commercialized through setting the terms for future pricing and licensing is unlikely to lead to the innovation and new medical products the WHO presumably desires.

The drafters of the Agreement seem to have overlooked the fact that within the life sciences R&D ecosystem, most publicly funded research does not result in or even seek to result in a finalized, commercially available product. Instead, the translation of basic scientific research into new biopharmaceutical products is done through the partnership of the private sector, which invests the resources and shoulders the accompanying financial risk of the commercialization process. Although critical, basic research—no matter how pathbreaking—is almost never enough to lead to a finished medicine or treatment.

Like the continued discussions at the WTO on the TRIPS waiver, the draft WHO Pandemic Agreement, and the thinking that much of it represents, actively ignores one of the real lessons of the COVID-19 pandemic, which is the centrality of IP rights to the life sciences innovation ecosystem.

The research-based biopharmaceutical industry, together with its partners in academia and the public sector, achieved an incredible feat in developing responses to the virus, including a range of safe and effective vaccines, in 12 months. The scientific and technological capacity that allowed industry, public research organizations, and academic researchers to achieve this technological miracle was not built overnight. Instead, it is based on decades of scientific study, R&D investment, and innovation predicated to a large degree on a system of strong, clear, and reliable IP rights.

Fundamentally, both the WTO and WHO have lost sight of the fact that the availability of medicines—and the ability of patients to effectively access those treatments in health system—is a complex subject. True patient access involves many factors such as health system infrastructure, health financing, logistics, transportation networks, proper storage and distribution, as well as a technical drug regulatory capacity.

During the pandemic, many of these barriers inhibited access to innovative medicines and technologies, ranging from regulatory delays to trade barriers and export restrictions to last-mile delivery issues. For example, in Africa, several economies were unable to effectively distribute and use donated vaccines before expiration.¹⁶ Unfortunately, many economies around the world still lack many of these basic health system features. These challenges have nothing to do with the protection of IP or availability of IP rights.

As international policymakers and domestic legislators around the world should 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 13 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, many WTO members have never fully or faithfully implemented the TRIPS Agreement. Yet, for economies that want to be on the front lines in devising solutions to the next global health crisis, that very same IP architecture provides all the tools necessary for full and effective participation in the innovation ecosystem: enabling allocation of scarce financial resources to risky innovative R&D, facilitating IP licensing for access to critical know-how, and fostering multidirectional technology transfer through contractual partnerships. To effectively prepare for the next pandemic, the WTO and WHO would be well served to focus on the enabling role IP rights play in the response to global health crises, rather than dismantle the system that has successfully supported the response to past pandemics.

National Developments

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 thirteenth edition of the Index and how they compare to last year's edition.

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

Economy	Thirteenth Edition Overall Numeric Score	Twelfth Edition Overall Numeric Score	Change in Overall Score, % Movement, +/-
United States	50.44	47.74	5.66%
UK	49.81	47.06	5.84%
France	49.56	46.56	6.44%
Germany	48.98	46.23	5.95%
Sweden	48.81	46.06	5.97%
The Netherlands	48.37	45.62	6.03%
Japan	48.13	45.63	5.48%
Ireland	47.44	44.69	6.15%
Spain	45.97	43.22	6.36%
South Korea	45.55	42.47	7.25%
Switzerland	45.49	42.99	5.82%
Italy	44.70	41.95	6.56%
Singapore	42.46	42.46	0.00%
Hungary	41.20	38.45	7.15%
Australia	40.35	40.35	0.00%

Economy	Thirteenth Edition Overall Numeric Score	Twelfth Edition Overall Numeric Score	Change in Overall Score, % Movement, +/-
Greece	38.46	35.71	7.70%
Canada	38.11	38.11	0.00%
Poland	38.11	35.37	7.75%
Israel	36.62	36.37	0.69%
Taiwan	35.40	32.66	8.39%
New Zealand	34.68	34.68	0.00%
Morocco	31.38	31.38	0.00%
Mexico	29.99	29.99	0.00%
China	28.93	28.93	0.00%
Dominican Republic	28.18	27.65	1.92%
Costa Rica	27.53	27.52	0.04%
Saudi Arabia	28.46	24.21	17.55%
Malaysia	26.73	26.72	0.04%
UAE	25.58	23.00	11.22%
Türkiye	25.52	25.52	0.00%
Peru	24.91	24.91	0.00%
Chile	24.86	24.86	0.00%
Colombia	24.67	24.42	1.02%
Brazil	24.50	23.26	5.33%
Jordan	22.35	22.35	0.00%
Philippines	21.29	20.79	2.41%
Honduras	21.05	21.08	-0.14%
Vietnam	20.62	20.38	1.18%

Economy	Thirteenth Edition Overall Numeric Score	Twelfth Edition Overall Numeric Score	Change in Overall Score, % Movement, +/-
Brunei	20.54	20.54	0.00%
Ghana	20.53	20.03	2.50%
Ukraine	20.16	20.15	0.05%
Kenya	19.44	18.94	2.64%
India	19.32	19.32	0.00%
Thailand	19.14	19.14	0.00%
Argentina	18.74	18.50	1.30%
South Africa	18.63	18.64	-0.05%
Nigeria	18.17	18.17	0.00%
Egypt	16.94	16.93	0.06%
Kuwait	15.47	14.21	8.87%
Indonesia	15.20	15.20	0.00%
Ecuador	14.79	14.79	0.00%
Pakistan	13.71	13.71	0.00%
Algeria	13.51	13.18	2.50%
Russia	12.50	12.50	0.00%
Venezuela	7.05	7.05	0.00%

This year's Index saw substantial movement in economies' scores with almost two-thirds of the economies sampled seeing a score change. Of the 55 economies included, this year, 20 economies had no score change. However, 33 economies saw an improvement, and in two economies, the overall Index score dropped. Significantly, most of these changes were movements greater than 1%.

The addition of three new indicators and a new, stand-alone category to the Index, Category 9: Incentives for Cutting-Edge Innovation, drove many of the score changes. Specifically, of the 33 economies that had a score increase, this was due to a strong performance on these new indicators in 22. However, as in all preceding editions of the Index, this does not mean that no meaningful score developments occurred in 2024.

On the contrary, three economies—Saudi Arabia, United Arab Emirates (UAE), and Kuwait—saw score improvements of 17.55%, 11.22%, and 8.87%, respectively. These substantial and noteworthy improvements mark what appears to be a new regional trend in the Middle East.

Since its inception in 2017–2018, the Saudi Authority for Intellectual Property (SAIP) has worked to improve the national IP environment. As detailed here in its Economy Overview, SAIP’s reform efforts have 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 in Saudi Arabia. These improvements are reflected in the Kingdom’s improved Index performance over the past six 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 53.70%, a cumulative score increase of over 40%. Although this does not mean that rightsholders face no challenges in Saudi Arabia—the overall score still remains just over 50% of the maximum available score—these are nevertheless real and meaningful improvements to the Saudi national IP environment, and the Saudi Government and SAIP should be congratulated for their efforts.

Like Saudi Arabia in past editions, this year, both the UAE and Kuwait saw score increases primarily because of changes to the IP enforcement environment. In the UAE, this was driven by changes to the copyright enforcement environment as well as institutional improvements to the national IP environment captured in Category 8: Systemic Efficiency.

Although Kuwait’s overall score is still in the lower quartile of the Index—with significant gaps in Category 8: Systemic Efficiency, Category 9: Incentives for Cutting-Edge Innovation, and Category 10: Membership and Ratification of International Treaties—and substantially lower than other high-income Index economies, there have been improvements in the enforcement environment and, specifically, rightsholders’ ability to enforce their copyrights and trademarks in the past two years. All three of these Middle Eastern economies have now introduced systems of administrative injunctive relief whereby rightsholders can directly contact a government authority and request the disabling of access to infringing online content. This marks a significant positive change from previous years.

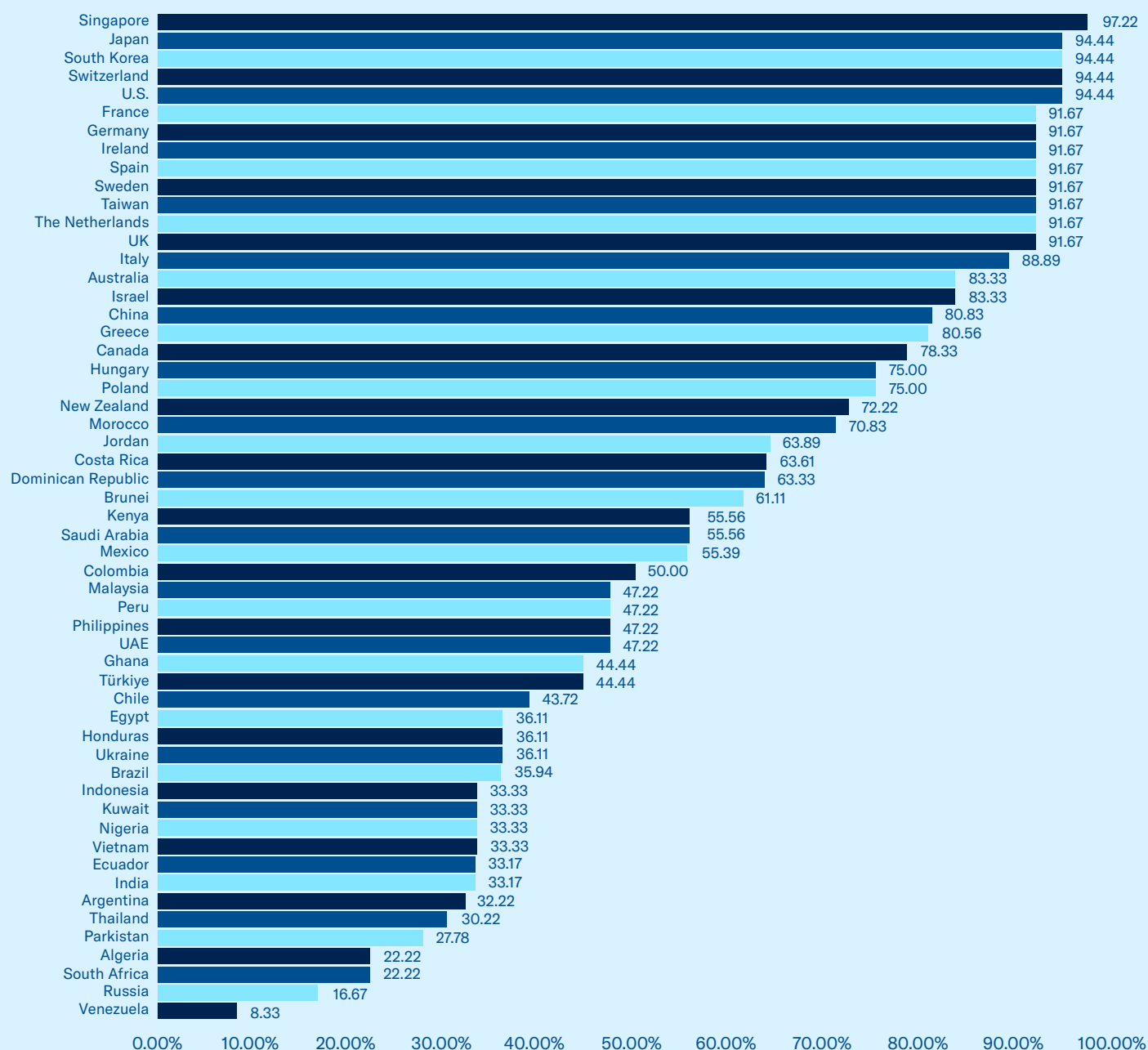
The lack of large score movements in an individual Index economy does not mean that the national IP environment in 2024 stood still. As the following subsections and the individual Economy Overviews in Section 5 detail, a striking number of Index economies put forth policy proposals—both positive and negative—that, if implemented, would amount to substantial overall score changes in future editions of the Index.

Category 1: Patent Rights and Limitations

Figure 7 summarizes the total scores for Category 1. This category measures the strength of an economy's environment for Patent Rights and Limitations.

The category consists of nine indicators with a maximum possible score of 9.00.

Figure 7: Category 1: Patent 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 59.82%, 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 below 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 (PTAB) within the USPTO. Since the Supreme Court decisions in the *Bilski*, *Myriad*, *Mayo*, and *Alice* cases, there has been a high and sustained level of uncertainty about which inventions are patentable in the United States. Efforts to address this long-standing problem continued in 2024. Most promisingly, the Patent Eligibility Restoration Act and Promoting and Respecting Economically Vital American Innovation Leadership Act were introduced into the Senate by Sens. Tillis and Coons in 2023. 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 PTAB. In 2024, Sens. Coons and Cotton introduced the Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive Patent Rights Act. It seeks to address the difficulty rightsholders have had since 2006—and the Supreme Court decision in *eBay v. MercExchange*—in getting permanent injunctions in infringement proceedings. It, too, would address what has become a long-standing challenge. On the other end of the spectrum, several developments occurred in 2024 that would negatively affect the patenting environment in the United States and curtail existing patent rights.

First, in May, the USPTO proposed to change the practice of terminal disclaimers. These disclaimers are required by the agency in relation to nonstatutory double patenting. In its proposals, the USPTO wishes to include a new requirement whereby applicants also agree to limit the number of claims that could be referred to in future infringement action. The agency argues that the proposed rule change would lower “the cost of challenging groups of patents tied by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers.” In other words, the USPTO seeks to limit and reduce existing IP rights because it—not Congress or existing patent statute—believes that doing so would achieve a perceived policy good. In Congress, several bills—S150, HR6986, and S3583—were introduced that all seek to limit the number of patents a rightsholder may assert in an infringement action. Not only do these bills discriminate and selectively target the life sciences sector with these restrictions, but they also embrace a fundamentally anti-IP and anti-innovation logic whereby the restriction of IP rights will lead to lower prices and greater access to a given product, in this case, biopharmaceutical treatments. At the time of research, the proposed laws had not been passed by Congress or signed into law.

In other Index economies, rightsholders also continued to face uncertainty and a challenging environment in 2024.

In the EU, discussions continued on a new cross-European compulsory licensing regime. The European Commission’s proposals are based on the idea that the COVID-19 pandemic and other crises showed the need for a clearer and more “effective” pan-EU compulsory licensing mechanism. However, 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. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission’s proposed regulation.

Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or has not fundamentally challenged the flawed premise on which it is based. More worryingly, the Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable. After European elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, so-called Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. New developments also occurred with respect to Supplementary Protection Certificates (SPCs) for biopharmaceuticals. As noted over the course of the Index, the European Commission has since 2015 sought to recalibrate certain elements of the EU's SPC regime. Since 2019, Regulation 2019/933, which creates an SPC manufacturing and export exemption, has been in force. This law allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. It still remains unclear what material benefits to the EU the introduction of this exemption has had.

Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the EU's IP environment. As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission first outlined several options for reforming the SPC system, including introducing a new centralized system of SPC protection and application. In 2024, the Commission introduced a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications and a subsequent response from the European Parliament.

On the one hand, the Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and as such is a net positive. Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, it is not clear why both the Commission's proposal and Parliament's response includes a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for what is already an existing, duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to challenge the validity of the underlying in-force patent administratively or judicially either regionally through the EPO or nationally in a manner defined in each Member State. As such, it is unclear why the Commission and Parliament have felt the need to add a novel layer of potential opposition. The most likely outcome of this addition is delays in the application process and additional costs imposed on applicants. As with the proposal for a new compulsory licensing regime, it remains to be seen what will happen to the current proposals under a new Commission and European Parliament.

In Australia, rightsholders saw a notable setback with the Therapeutic Goods Administration (TGA) announcing that it would not move ahead with a set of reforms and creation of a timelier patent notification framework for biopharmaceutical products in 2024. As noted repeatedly in the Index, Australia's pharmaceutical linkage mechanism has several notable deficiencies: 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.

It is unfortunate that after years of review and discussion—and public recognition of the deficits of the current regime—the TGA will not move forward with the necessary reforms.

In late 2023 and early 2024, China released long-awaited Patent Law Implementing Regulations and updated Patent Examination Guidelines. Unfortunately, these regulations and guidelines make patent term restoration for biopharmaceuticals contingent on first a global launch taking place in China. This stands in stark contrast to international best practices, where “new” biopharmaceutical products are defined as those newly approved for that individual market. Given that most innovative medicines are first launched outside of China, this requirement all but negates the practical availability of term restoration to most innovators. Should no action be taken by Chinese authorities and the regulations remain unchanged, the score for indicator 7 will be reduced to 0.

Finally, the Colombian Government granted a compulsory license for the HIV/AIDS treatment dolutegravir in 2024. As noted last year, the issuing of the license is based on a Ministry of Health Resolution and public interest request from 2023. As detailed over the course of the Index, Colombia has moved in a decidedly negative direction on the issue of compulsory licenses. Up until the mid-2010s, the imposition and discussion of compulsory licensing for biopharmaceuticals had not been a recurring issue in Colombia. But over the past 10 years, this has now become viewed as a legitimate health policy and a way to contain pharmaceutical expenditure.

Some positive developments also occurred in 2024.

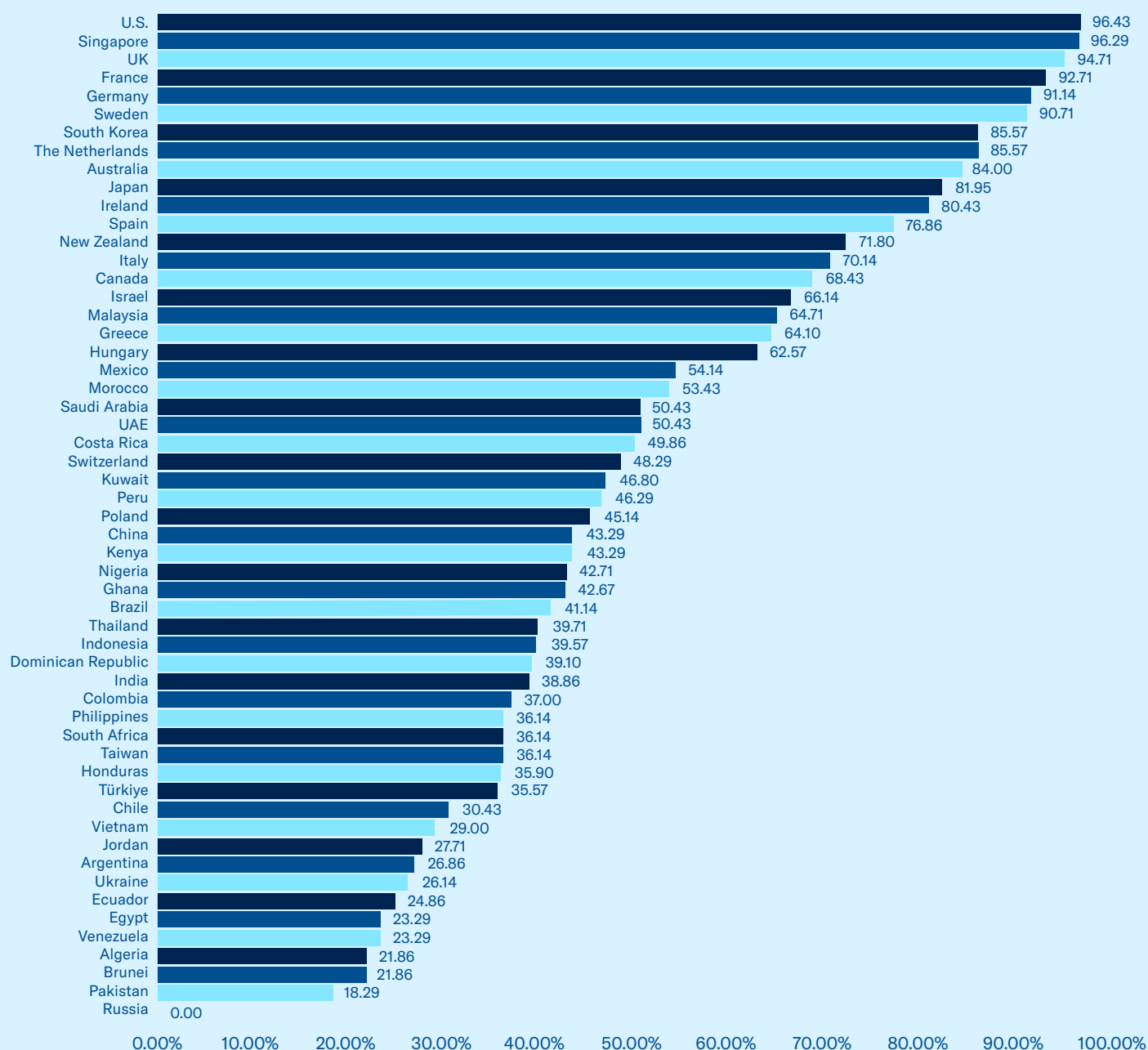
In a historic first, the African Regional Intellectual Property Organization (ARIPO) and the China National Intellectual Property Administration agreed on a Patent Prosecution Highway (PPH) pilot program in 2024. Neither ARIPO nor its two member economies included in the Index, Ghana and Kenya, participate in the IP5 PPH or the Global PPH or have had in place a PPH on a bilateral basis. At the time of research, the Agreement had come into effect and would remain operational for five years. PPH initiatives and increased cooperation among 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.

Category 2: Copyrights and Limitations

Figure 8 summarizes the total scores for Category 2. This category measures the strength of an economy's environment for Copyrights and Limitations.

The category consists of seven indicators with a maximum possible score of 7.00.

Figure 8: Category 2: Copyrights 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 continued to improve in 2024 from 50.61% last year to 51.45% this year. 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 struggled 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 consumers access creative goods. 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. This 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. Expedient legal remedies disabling access to infringing content online 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 slightly differently depending on the legal jurisdiction, but it results in 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, most EU Member States, the UK, India, Singapore, Canada, and other Index economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online.

Often, these injunctions are 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 re-enters 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 2024.

In 2024, the UAE took significant steps to improve the copyright enforcement environment. As part of a broader package of IP reforms (detailed in its Economy Overview), the Ministry of Economy introduced a new system of administrative injunctive-style relief through the InstaBlock program. Introduced in early 2024, the program aims to disable access to all copyright-infringing content online through the active monitoring of the internet by Ministry personnel as well as through direct rightsholder reporting of illicit activity. As part of the initiative, the Ministry also introduced a rapid response tool termed LiveBan. This tool targets live events and broadcasts such as sports and concerts. Finally, the Ministry announced over the summer a new antipiracy partnership with the Spanish soccer league *La Liga*. As has been noted over the course of the Index, rightsholders have historically faced real challenges in protecting their content in the UAE.

Gaps exist in the legal framework, and enforcement has always remained partial. At the time of research, the InstaBlock program was fully operational with access so far disabled to over 1,000 websites and online access points. This is a major positive development and has significantly strengthened rightsholders' ability to protect and enforce their copyrights in the UAE.

As noted in the previous edition of the Index, over the past few years, some welcome developments have occurred on enforcement of copyright in Argentina. In 2023, a federal court ordered the disabling of access to several copyright-infringing websites and included a “dynamic” element. 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. These positive actions continued in 2024. During the summer, Argentine law enforcement disabled access to over 50 websites offering access to pirated sports content. This was followed up by a raid and the arrest of a suspect. The regional rightsholders association *Alianza* played a pivotal role in supporting the local operation.

In Brazil, the government continued to implement several concrete efforts to improve the copyright environment. On the enforcement side, operations continued under Operation 404 Against Piracy (*Operação 404 contra pirataria*), which launched in 2019. 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 four years of operation, over 2,000 websites and applications offering copyright-infringing content were shut down, more than 100 search and seizure warrants were issued and executed across 20 Brazilian states, and several arrests have been made. Similarly, the legislative side had important developments. To begin with, Brazil enacted Law 14,852 in May 2024.

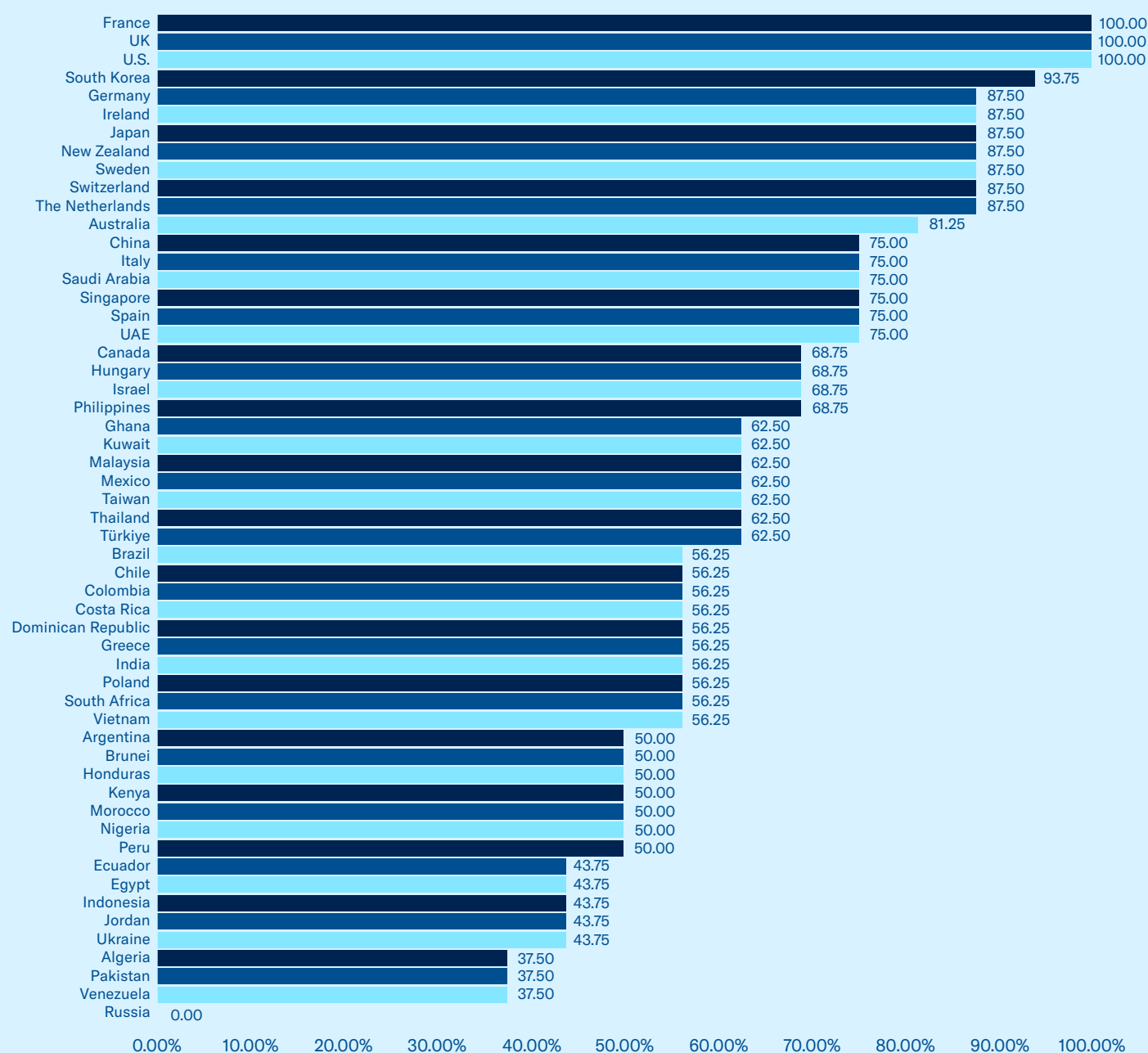
Dedicated to defining and incentivizing the video and electronic gaming industry, the new legislation provides a powerful statement that the gaming industry is a central part of Brazil's burgeoning creative sector and the national economy. From an IP perspective, the new law does not introduce any new forms of IP rights and protections or greater enforcement through existing statutory rights. Both online piracy of video games and the trade in pirated and modified video games and devices remain key piracy challenges in Brazil, with several markets in São Paulo having been included in the Office of the U.S. Trade Representative's (USTR) *Review of Notorious Markets for Counterfeiting and Piracy*, including in the latest edition. Given the growing use of video and computer game technology around the world, it is vital that this industry be better protected in Brazil. At the time of research, no further details had been published on how the law would be implemented and applied. In a separate development, President Lula enacted bill 3,696/2023 earlier in the year. Although primarily concerned with the continued requirement of local content quotas on domestic film distributors, in a potential breakthrough for the creative sector, Article 3 of the law gives the National Cinema Agency the power to “determine the suspension and cessation of unauthorized use of protected Brazilian or foreign works.” In September, the agency announced that it would apply its new powers in two pilot applications, disabling access to the dissemination of audiovisual content and live sporting events. These efforts build on those taken by the Brazilian National Telecommunications Agency in 2023. As noted last year, the agency launched a dedicated campaign against illicit IPTV set-top boxes and their streaming applications online.

Category 3: Trademark Rights and Limitations

Figure 9 summarizes the total scores for Category 3. This category measures the strength of an economy's environment for Trademark Rights and Limitations.

The category consists of four indicators with a maximum possible score of 4.00.

Figure 9: Category 3: Trademark Rights and Limitations, % Available Score



Most economies sampled in the Index offer basic forms of trademark protection. Only 9 of the 55 sampled economies fail to score 50% or more in this category. This Index category saw an increase in the average score from 62.84% in the twelfth edition to 63.41%.

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

As noted over the past few editions of the Index, the Philippines has strengthened the ability to fight the spread of counterfeits and trademark-infringing goods online over the past few years. This continued last year. In late 2023, Republic Act 11967, the Internet Transactions Act, was passed and signed into law. The Act outlines the legal rights and responsibilities of all parties engaging in e-commerce from individual sellers to e-marketplaces and platforms. Notably, Sections 25 and 26 of the Act define primary and secondary liability for the violation of Filipino law and failure to act upon notification of IP infringement. Specifically, e-marketplaces and digital platforms can be found to have secondary liability under Section 26 (b) if they “failed, after notice, to act expeditiously in removing or disabling access to goods or services that either infringe on another’s intellectual property rights or is subject to a takedown order by any appropriate government agency.”

The past year also saw similar improvements in both the UAE and Kuwait.

Historically, the UAE has not had in place a legally defined notification system allowing rightsholders to request the removal of counterfeit goods online. Although it addresses the online environment, it is unclear the extent to which existing statute—including, for instance, Federal Law, Decrees 5 and 34 (both relating to cybercrimes)—could be used for enforcing trademarks online. This lack of legal clarity may now be changing. In late 2023, the UAE enacted a new e-commerce law, Federal Decree, Law No. 14. Notably, Article 3 explicitly states that one objective of the law is to “protect intellectual property rights regarding goods or services purchased through Modern Technology.”

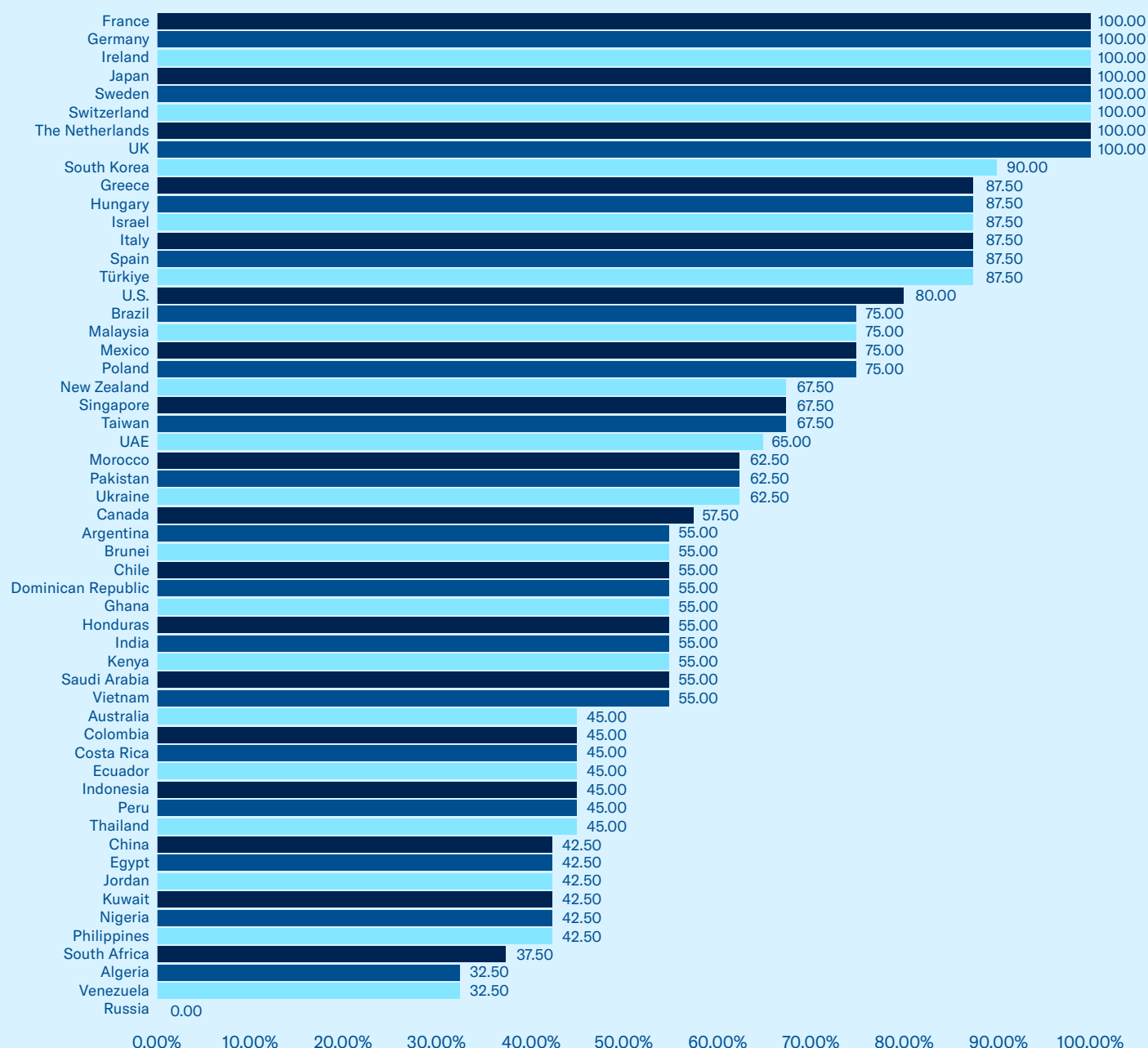
Similarly, the IP trademark enforcement environment in Kuwait has long been difficult. Although civil remedies, including injunctive relief, the suspension of alleged infringing activities, and the seizure of infringing materials and goods, are available, active enforcement has been lacking, and no dedicated measures have tackled IP infringement online. Since 2014–2015, laws related to telecommunications and cybercrime have also included some reference to the protection of IP rights, including allowing online requests for the disabling of websites for copyright infringement. In late 2022, these powers of administrative enforcement were extended to other IP rights, including trademarks. Today, the Ministry of Commerce and Industry offers rightsholders the ability to submit infringement complaints directly through their website. As of 2024, rightsholders can directly lodge complaints and request the disabling of access to any online access point offering access to IP infringing content and/or goods electronically directly via several Government of Kuwait websites. Public reporting suggests that the number of online access points to which access has been disabled over the past few years numbers in the thousands. Significantly, many of these access points were disabled because of IP infringement.

Category 4: Design Rights and Limitations

Figure 10 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 2.00.

These indicators measure the maximum term of protection 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 10: Category 4: Design 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 64.18%, up marginally from 64% last year. Over the past few years, many economies have reformed relevant laws and regulations pertaining to design rights and, in many cases, have extended the term of protection for registered designs. This has often 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 2024.

Significant changes were made to the protection of design rights in Saudi Arabia. In late 2023, Royal Decree M/45 was issued to increase the term of protection for design rights from 10 years to 15 years. Although this is still less than the 25-year term benchmark used by the Index, it is still a positive development.

As noted in the Index, public reports suggest that the Directorate General of Intellectual Property 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 current Industrial Design Law provides a 10-year term of protection for registered designs. At the time of research, the Indonesian parliament (the People's Consultative Assembly of the Republic of Indonesia) was still examining the bill.

Finally, as noted last year, in late 2022, the European Commission proposed changes to the existing legal framework for community designs in the EU. The European Parliament and Council reached an agreement on the final text, and in early 2024, Parliament published its formal response to the Commission's original draft. Although not having a direct impact on EU Member States' Index scores, under a revised directive and regulation on the legal protection of designs, several important changes would be made. For example, the draft legislation updates existing legal definitions and registration requirements to better align the legal framework with current and future technological developments.

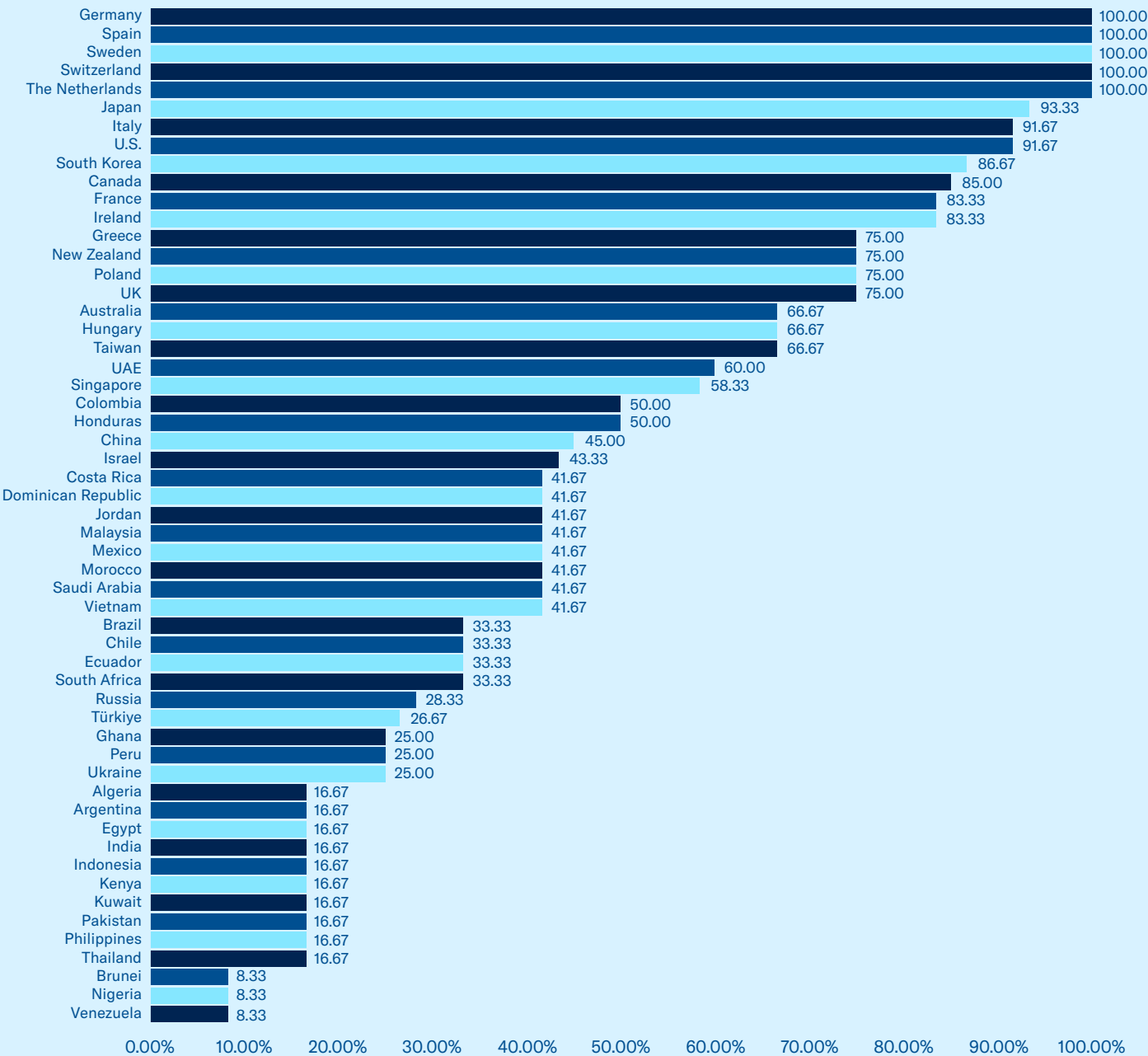
Category 5:

Trade Secrets and the Protection of Confidential Information

Figure 11 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 a regulatory data protection (RDP) term of protection for biopharmaceuticals. In total, the category consists of three indicators with a maximum possible score of 3.00.

Figure 11: Category 5: Trade Secrets and the Protection of Confidential



As noted in past editions of the Index, many Index 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, many economies have sizeable gaps in protection. Trade secrets are not adequately defined in relevant laws and regulations, and courts have limited experience ruling in 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 Index economies—including developed OECD members—do not have statutory criminal sanctions in place for the theft and misappropriation of trade secrets. Likewise, many economies included in the Index do not provide RDP for biopharmaceutical test data submitted during market authorization. Of those that do, many limit or actively attempt to restrict the practical availability of this protection through various terms, conditions, and/or carve-outs. Overall, only 23 of the 55 economies included in the Index achieved a score of 50% or more in this category. Twenty-two economies achieved a score of 33.33% or less. The average score in this category remained one of the weakest in the Index at 49.27%, up only marginally from last year.

As noted in previous editions, in 2023, the European Commission published a package of proposed legislative changes not only to the EU's RDP regime but also 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 fairly 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 authorisation is valid.” At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. After European elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, it was unclear what would happen to the current proposals. 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.

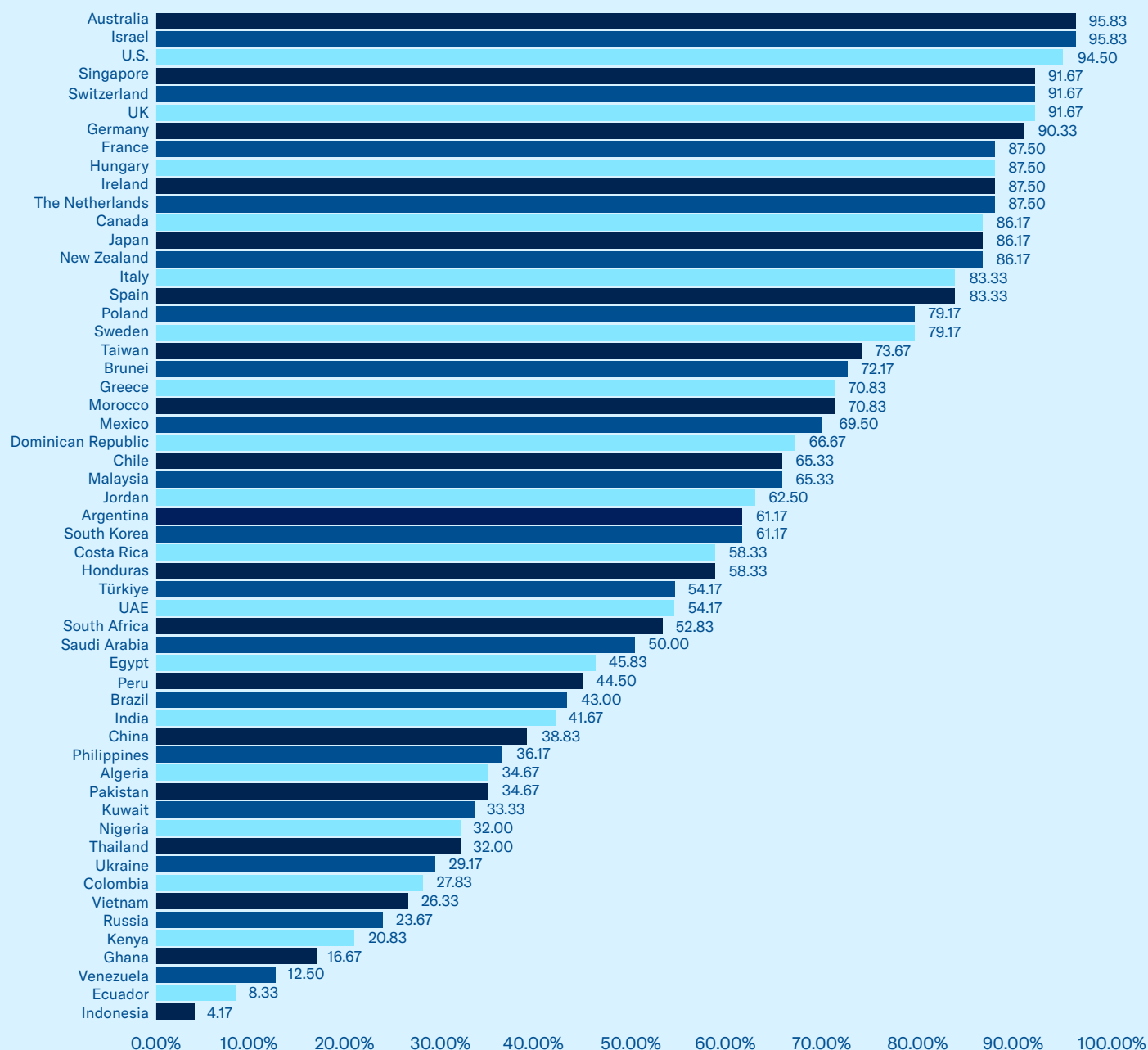
In 2024, important changes were made to South Korea's laws related to the protection of trade secrets and confidential information. Together with similar changes to the Patent Act, in the beginning of the year, amendments to the Unfair Competition Prevention and Trade Secret Protection Act significantly strengthened existing penalties and damages for trade secret violations and misappropriation of confidential information. Specifically, the changes include an almost doubling of existing punitive damages, increased potential criminal penalties for corporate entities engaged in infringement activities, and the introduction of new “corrective orders” or administrative powers granted to the Korea Intellectual Property Office. These changes follow 2019 amendments to Article 18 of the Act, which also strengthened penalties for the theft and misappropriation of trade secrets.

Category 6: Commercialization of IP Assets

Figure 12 summarizes the total scores for Category 6. This category consists of six indicators with a maximum possible score of 6.00. These indicators measure the presence of barriers and incentives in place for the commercialization and licensing of IP assets.

These include 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 12: 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 introduce policies that make it more difficult to access their respective markets or commercialize IP assets. Twenty economies of the 55 sampled in the Index fail to achieve a score of 50% or more, with 12 scoring 33.33% or less in the category. The average score in this category was 58.88%.

In the early and mid-1980s, the U.S. Congress passed several groundbreaking pieces of legislation establishing the basis for our modern-day technology transfer and commercialization framework. Chief among these was the University and Small Business Patent Procedures Act, (the Bayh-Dole Act) of 1980. For the past 40 years, this legislative framework has supplied federal laboratories, small businesses, universities, and other entities using federal funds with the incentives needed to work with the private sector for the purpose of translating early-stage research into usable products in the marketplace for the benefit of the wider public. The legislation resulted in a 400% increase in patenting activity by U.S. universities and between \$333 billion and \$1 trillion added to GDP (measured in 2012 U.S. dollars). At the micro level, the Bayh-Dole framework has led to the invention and commercialization of thousands of products and technologies across all industries, including in the information and communication technology (ICT) and semiconductor industry, manufacturing, and venture capital (including investments in biotechnology).

Over the past two years, the U.S. government has put forth proposals that would undermine the Bayh-Dole framework and all the innovation and socioeconomic gains of the past 40 years. In late 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 when the Department of Commerce and NIST requested comments for potential changes to the way federally funded or supported technologies 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. These march-in rights are not—and have never been—meant to be used as a way for the federal government to insert itself in the innovation and commercialization process of a technology or product. Nor were these rights intended to allow the government the pursuit of a specific federal policy agenda or desired outcome through the imposition of price, access, or production or manufacturing controls on a technology or the abrogation of an existing licensing agreement based on reducing public expenditure or any other stated federal policy goal. This was never the intention of the underlying legislation and would be counter to the legislation's stated policies and objectives. Up until now, this has also been acknowledged by federal agencies through their actions and public statements. For example, then Director of the National Institutes of Health (NIH) Francis Collins in 2017 stated, in public testimony before Congress, that march-in rights do not apply within the context of a medicine price. In a separate development, in May 2024, the NIH issued a Request for Comment on a new policy within its Intramural Research Program. Under the proposed policy, the NIH would require licensees who successfully develop and commercialize a medicinal product (defined by the NIH as “drugs, biologics, vaccines, or devices”) to submit a “plan outlining steps they intend to take to promote patient access to those products.” In January, the NIH announced a finalized policy largely mirroring this proposal. The finalized policy applies only to patents wholly owned by the NIH and not to any IP developed and owned by a third party through an NIH grant. Unfortunately, the policy is unlikely to achieve the NIH's objectives. Instead of achieving greater patient access, the new policy will act as a disincentive to partner with NIH.

This will, in turn, lead to fewer partnerships and fewer new products and technologies developed. The NIH seems to have misunderstood its own role and that of the private sector in the technology transfer process. The overwhelming majority of publicly funded research—whether through the NIH, academic institutions, or other parts of the federal government—does not result in or even seek to result in a finalized, commercially available product. The translation of basic research into new products, services, and technologies is done through the partnership of the private sector, which invests the resources and shoulders all the accompanying financial risk of the commercialization process. In this respect, although critical, basic research—no matter how pathbreaking—is almost never enough to lead to a final product or service. The commercialization process for each licensed technology and invention is unique, and the exact amount of expenditure and commercialization spending ratio between licensee and licensor varies from technology to technology and from transaction to transaction. However, practical experience and research suggest that most investment needed in the development and commercialization of a product is done by the private sector entity to which the invention has been licensed. For example, in a 2012 study, the Congressional Research Service stated, “Although research is often important to innovation, it appears that, on average, it constitutes approximately 25% of the cost of commercializing a new technology or technique, thus requiring the expenditure of a substantial amount of additional resources to bring most products or processes to the marketplace” The new administration could move in a different direction. Instead of adopting a more expansionist and interventionist view of march-in rights and the public-private licensing process, it could revert to a more traditional understanding of both the Bayh-Dole Act and the role of the federal government in the licensing process. Such a change of direction could help ensure that the Bayh-Dole framework continues to stimulate innovation, economic growth, and prosperity for another half a century.

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. In 2023 and 2024, further important judicial developments occurred related to Standard and Essential Patents (SEPs) and the setting of royalty rates in China. In late 2023, in an unprecedented judgment, the First Intermediate People’s Court of Chongqing Municipality set global rates for the licensing of SEPs in the case of *Oppo v. Nokia*. Separately, in early 2024 in *ACT v. Oppo*, the Supreme People’s Court did not seek to set a global licensing rate but instead confined its judgment to the Chinese market. On the legislative side, there have also been several major developments in relation to technology transfer over the past few years. Most importantly in 2022, China enacted a new Anti-Monopoly Law (AML) that greatly expanded the government’s basis for action against anti-competitive behavior and substantially increases fines and penalties. The new law was accompanied by several new draft rules that considerably expanded the powers of investigation, punishment, and meaning of what constitutes anti-competitive behavior within the context of the exercise of IP rights. The rule “Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition” took effect in 2023. Unfortunately, although maintaining some moderate safeguards against potential overreach, the finalized version of the rule did not materially improve on the preceding draft. It, too, contains the same broad and vague language on what constitutes anti-competitive behavior within an IP rights context and vests considerable discretion with the anti-competition authorities in identifying and defining such behavior. Separately, in 2023, the Chinese anti-competition authority (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, interventionist footsteps of both the AML and the “Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition.” In late 2024, a finalized document was published by China’s State Administration for Market Regulation.

Although different in important respects from the preceding draft guidance, overall, this document also preserves the growing interventionism of Chinese antitrust policy.

As a follow-up to the AML in June 2024, the State Council issued National Decree 793, the Fair Competition Review Regulations. These regulations outlined the way all levels of government in China should promote and actively encourage fair competition across the entire economy. On the one hand, and in a positive signal, Articles 8 and 9 limit localization efforts and explicitly eliminate the discrimination of foreign or imported goods. On the other hand, Article 12 all but nullifies the preceding provisions by allowing competition to be restricted or eliminated “to promote scientific and technological progress and enhance the country’s independent innovation capabilities.” In the same month, the Supreme People’s Court released its view of the AML through the “Interpretation of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Civil Disputes over Monopoly.” The interpretation provides some specific references to the handling of IP rights and related disputes, including in relation to the analysis of a dominant position, unfair competition practices, and potential abuse of IP rights. Should rightsholders continue to face challenges in asserting their rights on fair, nondiscriminatory, and equal terms—whether through the Chinese judiciary or administratively through the expanded powers given the anti-competition authorities in the AML and accompanying rules—this will result in a sharp score decrease on relevant Index indicators and negate the positive impact of the Phase I Agreement with the United States.

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

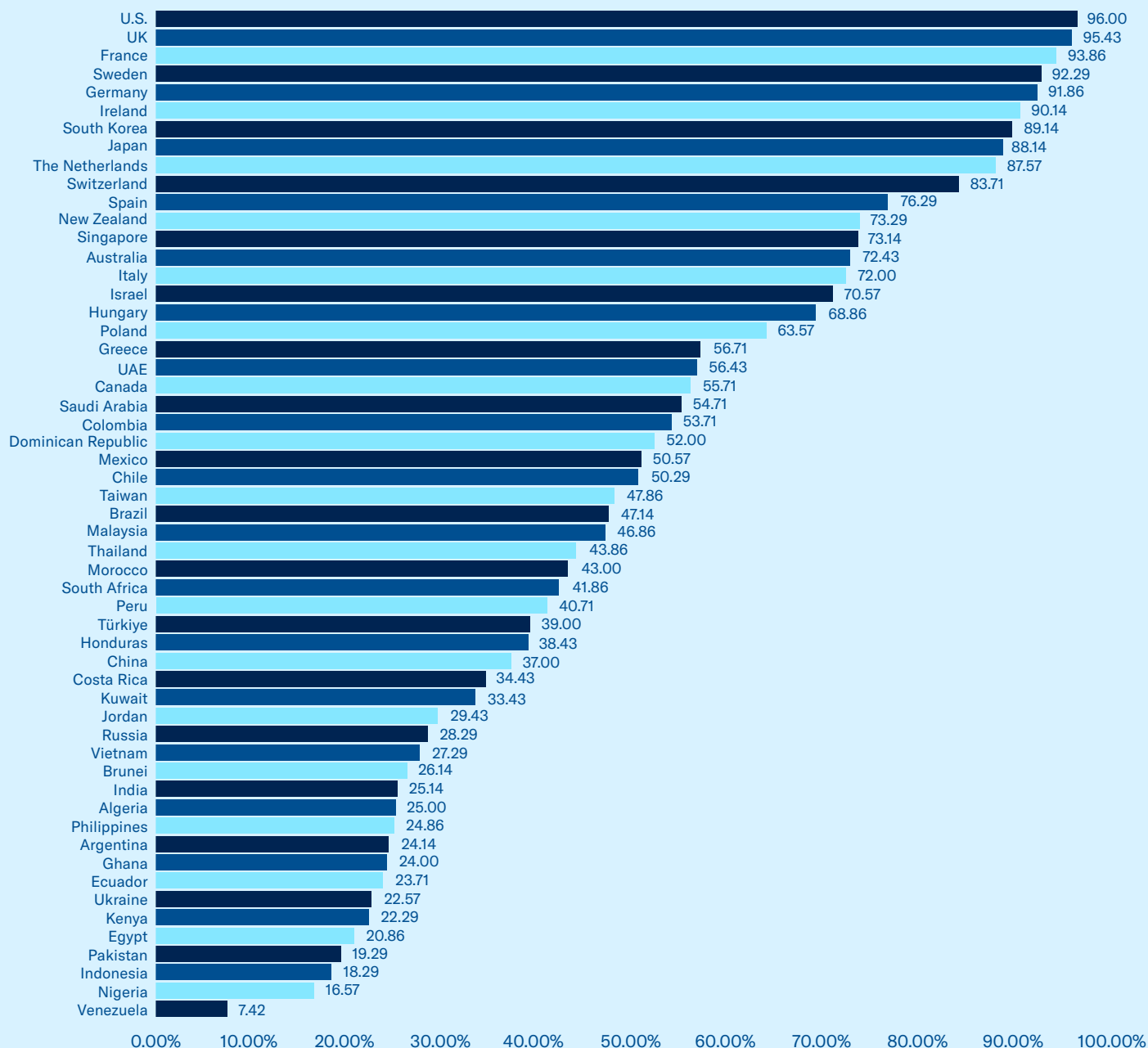
Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and the potential for direct government intervention and management of the SEP negotiating process through the EUIPO, which would become 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 Commission’s proposals 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. In early 2024, the European Parliament responded to the Commission’s ideas with a set of proposed amendments. Unfortunately, just as with the proposals for introducing a new compulsory license mechanism for medicines discussed previously, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, it was unclear what would happen to the current proposals.

Category 7: Enforcement

Figure 13 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 7.00.

Figure 13: Category 7: Enforcement, % Available Score



As in years past, most of the sampled economies in the Index struggle in this category, with only 26 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 50.68%, up only marginally from last year's 50.24%.

In many economies, effective IP enforcement options are not available. Judicial and/or administrative routes of enforcement are overloaded and/or under-resourced. 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 rightsholder. In positive news, over the past few years, several Index economies have come to understand the dangers of counterfeit and pirated goods and as a result have increased enforcement resources and invested in anti-counterfeiting and IP rights-infringing activities with respect to criminal enforcement.

The UAE has long been identified as a central hub for the transshipment and global trade of counterfeit goods. For example, the OECD and EUIPO's 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 physical marketplaces have consistently been included in the USTR's *Review of Notorious Markets for Counterfeiting and Piracy*. The reason for this lack of IP enforcement is a lack of deterrent fines and criminal sanctions and legal ambiguity of existing *ex officio* border enforcement powers in relation to transshipped suspected counterfeit goods and goods in transit. At the end of 2023, the government enacted Federal Law Decree 24, Concerning Anti-Commercial Fraud. A new dedicated anti-counterfeiting law, this legislation significantly strengthens the UAE's IP enforcement environment.

Article 4 explicitly outlaws the importation, exportation, and re-exportation of counterfeit and fraudulent goods. Furthermore, Article 10 empowers Judicial Enforcement Officers to take *ex officio* action against suspected counterfeit goods in any nonresidential facility throughout the UAE. Articles 16 to 18 also include strengthened criminal sanctions and penalties. These positive changes resulted in the UAE's score improving in four Index indicators.

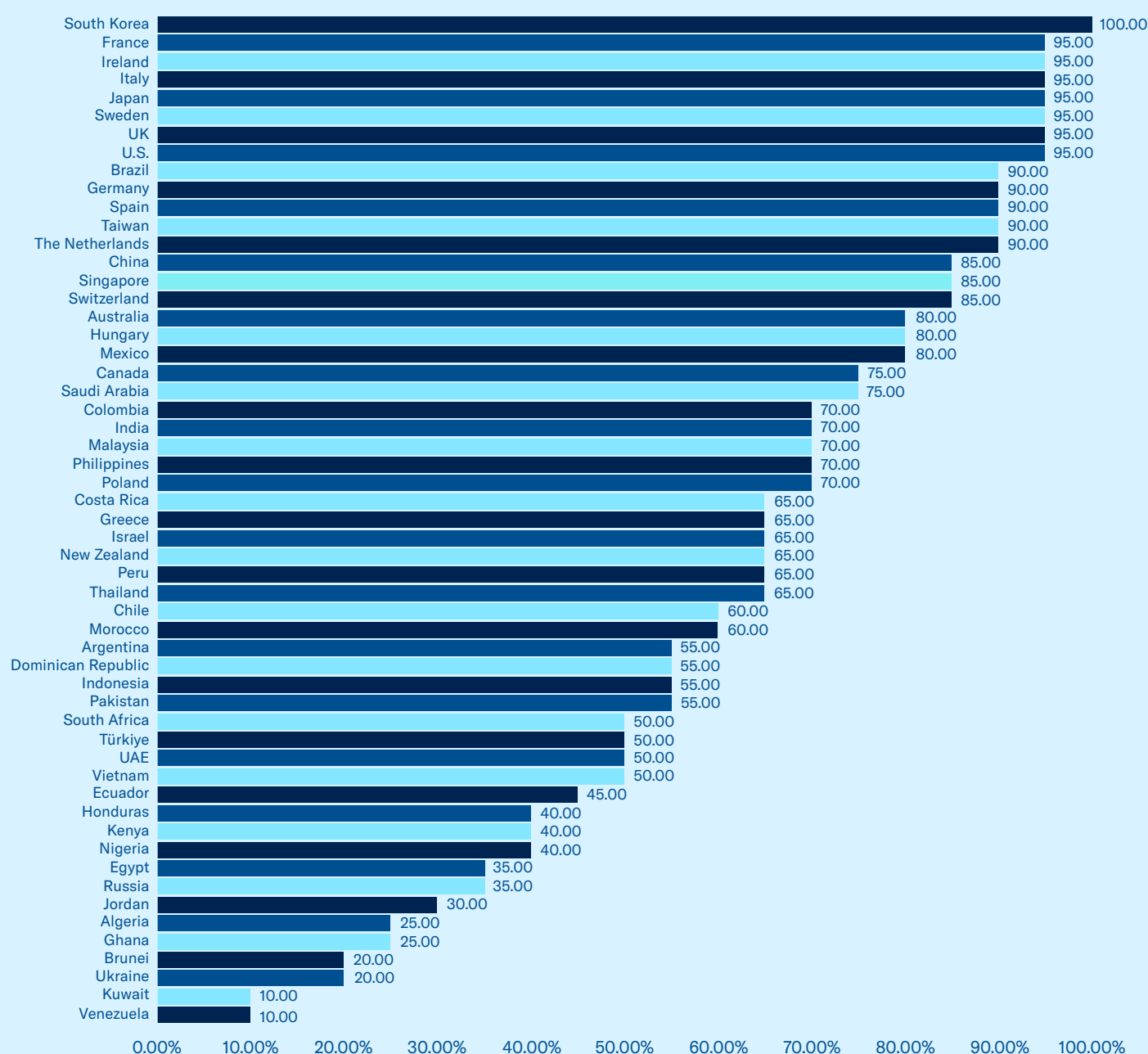
In Saudi Arabia, the government moved forward with important changes to the IP enforcement environment. As noted in previous editions of the Index, over the past three years, the national IP office SAIP has aimed to strengthen the enforcement of IP rights in Saudi Arabia through both institutional improvements and increased levels of transparency and engagement with rightsholders. In 2024, standing committees continued to publish the judgments related to copyright and patent infringement (the "Committee for Review of Violations of the Copyright Protection System" and "Committee for Consideration of Patent Claims"). As stated last year, the publication of these decisions shows that, first, there continues to be an increase in the number of cases considered for IP violations and, second, damages are more consistently awarded. Positive developments also occurred related to criminal enforcement in Saudi Arabia. Historically, criminal enforcement against IP violations has been relatively rare with limited dedicated resources and focus among Saudi law enforcement. Like the efforts taken by SAIP in the sphere of administrative enforcement since 2020, this may now also change with relevant Saudi authorities introducing institutional reforms to the way in which criminal enforcement of IP rights takes place. Specifically, in February 2024, the Public Prosecution Council announced that it had established a dedicated prosecution office for IP offenses. This office will work on investigating and filing criminal charges in cases concerning the violation of IP rights.

Category 8: Systemic Efficiency

Figure 14 summarizes the total scores for Category 8. Indicators included in this category seek to measure national efforts to coordinate 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 5.00.

Figure 14: Category 8: Systemic Efficiency, % Available Score



As in previous editions, most sampled economies in the Index perform well in this category, with only 13 economies failing to achieve a score of 50% or above. Indeed, many Index economies outperform their overall Index scores in this category. This includes several economies that have otherwise challenging national IP environments such as Brazil, Colombia, India, and the Philippines, none of which achieved an overall Index score of 50% or more. Yet, in this category, they all score 70% or more. Overall, the average score in this category continues to be one of the strongest in the Index, at 63.91%, up from 63.55% last year.

In 2024, these positive efforts continued.

In the past few years, several positive developments have occurred with respect to the coordination of IP enforcement in the Dominican Republic culminating in its removal from the USTR Special 301 Watch List in 2024.

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. This recently changed. In 2022, President Abinader issued Decree 776-22 establishing a new coordinating body on IP policy, the National InterMinisterial Council of Intellectual Property. The Council marked its third year of operations in 2024. Significantly, data published by the Council and Ministry of Industry, Trade, and Micro, Small and Medium-sized Enterprises (MSMEs) show increased on-the-ground enforcement activities in 2023 and 2024. For example, the Council's annual report for 2023 activities states that 250 cases were investigated by the Attorney General's Office Intellectual Property Unit.

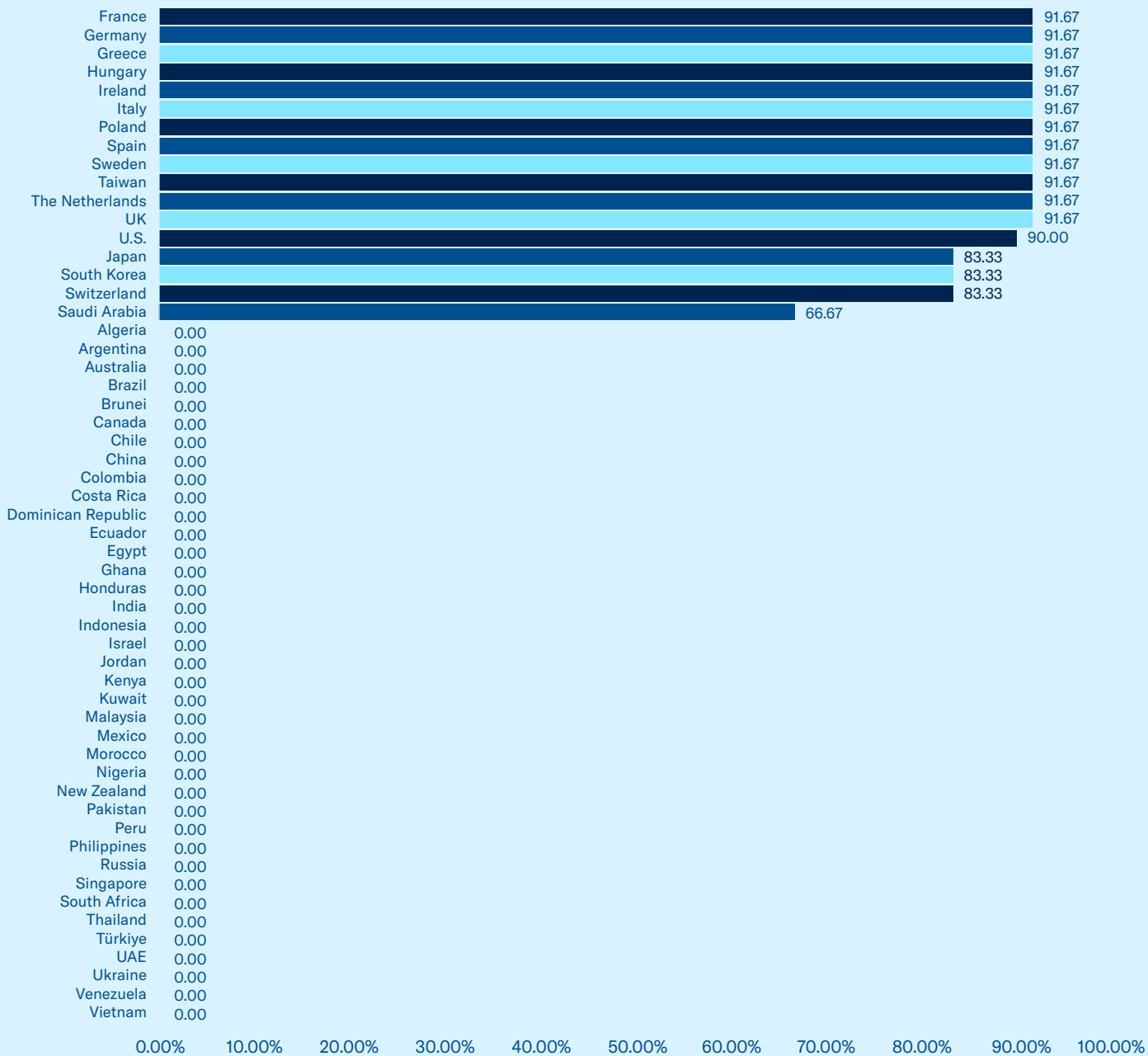
The report also lists the total number of counterfeit seizures and enforcement activity taken against signal piracy by INDOTEL (the Dominican Institute of Telecommunications). As has been noted repeatedly in the Index, the infringement of copyright through signal piracy and online and web-based streaming is highly pervasive and constitutes a major source of illegal content in the Dominican Republic. INDOTEL is reported to have seized and closed illegal operators of sound and broadcasting services as well as issued administrative sanctions against others. Similarly, in 2024, the Council led several high-profile enforcement actions organized by the Council together with other enforcement bodies, including the Ministry of Defense. This includes the seizure and destruction of 10 million units of counterfeit and/or illicit tobacco, medicines, alcohol, and other goods. These are positive and sustained efforts by the Dominican authorities to tackle the long-standing problems of copyright piracy and counterfeit goods.

Historically, the UAE has offered only limited incentives for the creation and use of IP assets by SMEs. Registration fees for SMEs have not been discounted, and there has been no expedited review process. The technical assistance programs in place have not been emirates-wide but available only in Dubai. This may now be changing. In 2024, the Ministry of Economy launched two new SME-specific emirates-wide IP support programs targeting patent registration and financial support: the "Intangible Finance Committee" and the "Patent Incubator." Both programs aim to increase and improve the development and registration of IP assets by SMEs by providing access to financing, technical assistance, and registration support.

Category 9: Incentives for Cutting-Edge Innovation

Figure 15 summarizes the total scores for Category 9. The indicators in this category relate to special, sector-specific, IP-based incentives for innovation. The category consists of three indicators with a maximum possible score of 3.00.

Figure 15: Category 9: Incentives for Cutting-Edge Innovation, % Available Score



As noted in the Index, the biopharmaceutical industry is one of the most research-intensive industries in the world. It invests significantly more in R&D in absolute terms and on a per-employee basis than any other industry. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. It takes 10 to 15 years from the filing of a new patent to the day when a new medicine finally becomes available for patients to use. As difficult a R&D challenge this is for the development of all new medicines, for rare diseases, the challenge is even greater.

Orphan drugs are niche treatments for rare diseases with small patient populations and commercial markets. These rare diseases make up a wide range of complex conditions that are associated with chronic, progressive, degenerative, and/or life-threatening symptoms that affect a relatively small portion of an economy or legal jurisdiction's population. The exact legal definition of what constitutes "rare" varies from economy to economy. For example, in the EU, a disease has historically been defined as rare if it affects up to 5 of 10,000 people. In the United States, the statutory definition has been if the disease in question affects fewer than 200,000 persons. Other Index economies, such as Japan, Australia, Taiwan, and South Korea, use slightly different legal definitions. The number of rare diseases is currently estimated at around 5,500 to 6,000 diseases, with around 250 new conditions described in the medical literature every year and a growing quantity of disease genes identified. Most of these conditions continue to lack a proper treatment. Approved medicines currently cover only a small percentage of known rare diseases, although R&D efforts are ongoing for many more. Commercial, clinical, and regulatory challenges are associated with the development of treatments for rare diseases. The fundamental challenge is that these treatments are less likely to be developed because their market is small and too limited to cover the substantial R&D costs.

In addition, the clinical development process is faced with difficulties linked to the unique characteristics of rare diseases, including the limited number of patients available for trials and few specialized investigators, but also scarce scientific literature and generally limited information on the natural history and mechanisms of the condition being investigated. These elements can translate into difficulties recruiting and retaining patients for trials, identifying comparators and endpoints, and defining adequate preclinical models. In 2021, for the first time, the United Nations adopted a formal resolution on persons with rare diseases. Resolution 76/132 "Addressing the challenges of persons living with a rare disease and their families" specifically included reference to the need for greater access to health care treatment and increased support for research efforts into rare diseases.

Acknowledging these challenges, many Index economies have enacted laws and developed special programs to encourage orphan drug development. Since the 1980s, a series of financial and regulatory incentives have managed to reverse the lack of commercial attractiveness and to convince innovators to invest in the development of new treatments and therapies. On the back of these schemes, as well as key pharmacogenomics discoveries that have fueled interest in the development of niche products, the number of orphan drugs developed and authorized for rare diseases globally has increased exponentially. The most successful of these policies include a significant market exclusivity or IP rights component.

As the results of Category 9 show, most Index economies do not have in place any special market exclusivity incentives for orphan medicinal product development. Overall, 38 economies fail to achieve any score for the three indicators included in this category. The average score in this category is the weakest of all included in the Index at 27.39%.

Of those economies that offer a special market exclusivity incentive for orphan medicinal product development, the level of protection and strength of exclusivity of orphan drug marketing exclusivity can vary.

The United States was the first economy to introduce dedicated incentives for the development and commercialization of medicinal orphan products. The 1983 Orphan Drug Act and subsequent regulations and rules issued by the U.S. Food and Drug Administration (FDA) provide the legislative basis for the designation of orphan drugs in the United States. Under this framework, the United States provides several dedicated incentive programs related to both the financing of drug development and support in the acceleration and facilitation of regulatory and administrative procedures. Specific programs include a seven-year orphan market exclusivity period, grants, tax credits and fee waivers, and fast-track approval.

In 1999, the EU introduced Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”). Entering into force in January 2000, the EU Orphan Regulation was intended to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal product developers will have a sufficient time frame for recouping the high costs of development. The EU offers a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances.

Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, inter alia, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals, including the European Parliament’s response to the Commission’s proposals in early 2024, the current term and scope of protection for orphan products would be restricted or reduced in some shape or fashion. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.

Since the 1970s, Japan has had a dedicated policy program in place for rare diseases. Today, the 2014 Act on Medical Care for Patients with Rare/Intractable Diseases (Act No. 50 of 2014) and relevant sections of the drug regulatory framework provide the legal definitions and policies related to rare diseases and orphan drugs. Specifically, these laws and related programs provide an expedited market approval pathway for new drugs, reduced and/or waived sanitary registration fees, and dedicated funding mechanisms for patients with rare diseases.

With respect to incentives for R&D and the development of new treatments and technologies, designated orphan drugs benefit from an extended data exclusivity period (referred to as “re-examination” period) of 10 years (against eight years for new chemical entities and four years for new indications of drugs already approved).

In Saudi Arabia, since 2013, the Saudi FDA has had in place a dedicated rules document on orphan drug registration and relevant requirements and incentives, the “Guidance for Orphan Drug Designation.” Section 4 of this document includes the provision of a marketing exclusivity incentive for drugs qualifying for orphan designation. However, no further details have been made available as to the length of this exclusivity period.

Since the late 1990s, South Korea has had in place legal definitions and standards related to the designation of orphan drugs. In 2015, a dedicated law on rare diseases was enacted, the Rare Disease Management Law. This law, together with updates to related orphan drug regulations and the drug regulatory framework, provide the legal definitions and policies related to rare diseases and orphan drugs in Korea. Specifically, these laws and related programs provide an expedited market approval pathway for new drugs and reduced and/or waived sanitary registration fees. With respect to incentives for R&D and the development of new treatments and technologies, under Article 18 of the Rare Disease Management Law, designated orphan drugs benefit from an extended data exclusivity period (referred to as a “re-examination” period) of 10 years.

Since the mid-2010s, Switzerland has introduced several initiatives and incentive programs targeting rare diseases and orphan medicines, including the overarching 2014 National Rare Disease Policy. With respect to special market exclusivity incentives for orphan medicinal product development, 2016 legislative changes to the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act) that took effect in 2019 introduced a statutory term of regulatory data protection (termed “document protection”) for orphan drugs.

Under Article 11b(4), the national drug regulatory authority Swiss Medic will “in the case of an important orphan medicinal product...on request, grant document protection for a period of fifteen years.” Orphan status—and eligibility for this extended RDP term—can be withdrawn by Swiss Medic if the product no longer meets relevant eligibility criteria as a treatment for rare diseases.

Since 2000, Taiwan has had in place a dedicated legal framework for rare diseases and orphan drugs. The Rare Diseases Control and Orphan Drugs Act of 2000 provides the legal definitions and policies related to rare diseases and orphan drugs in Taiwan. This law and related programs provide an expedited market approval pathway for new drugs as well as protocol assistance and dedicated funding mechanisms for patients with rare diseases. With respect to incentives for R&D and the development of new treatments and technologies, designated orphan drugs benefit from a 10-year market exclusivity period. During these 10 years, requests to register drugs “of the same kind” will not be accepted by the national drug regulatory authorities (Article 17) unless—as in the United States and the EU—the second drug complies with three conditions: (1) it is clinically superior, (2) it is insufficiently supplied, or (3) the first drug manufacturer agrees to allow market entry to a competing product. However, unlike the United States and EU, Article 18 of the Act also adds a fourth condition that allows for the approval of a similar product during the 10-year exclusivity period if the price of the drug is deemed “unreasonable.”

Before Brexit, as an EU member state, the UK’s legal regime related to rare diseases and incentives for the development of orphan drugs was governed by Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”). Upon leaving the EU, the Human Medicines Regulation was amended with new articles on orphan drugs incorporated through S.I. 2019/1385 “The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019.”

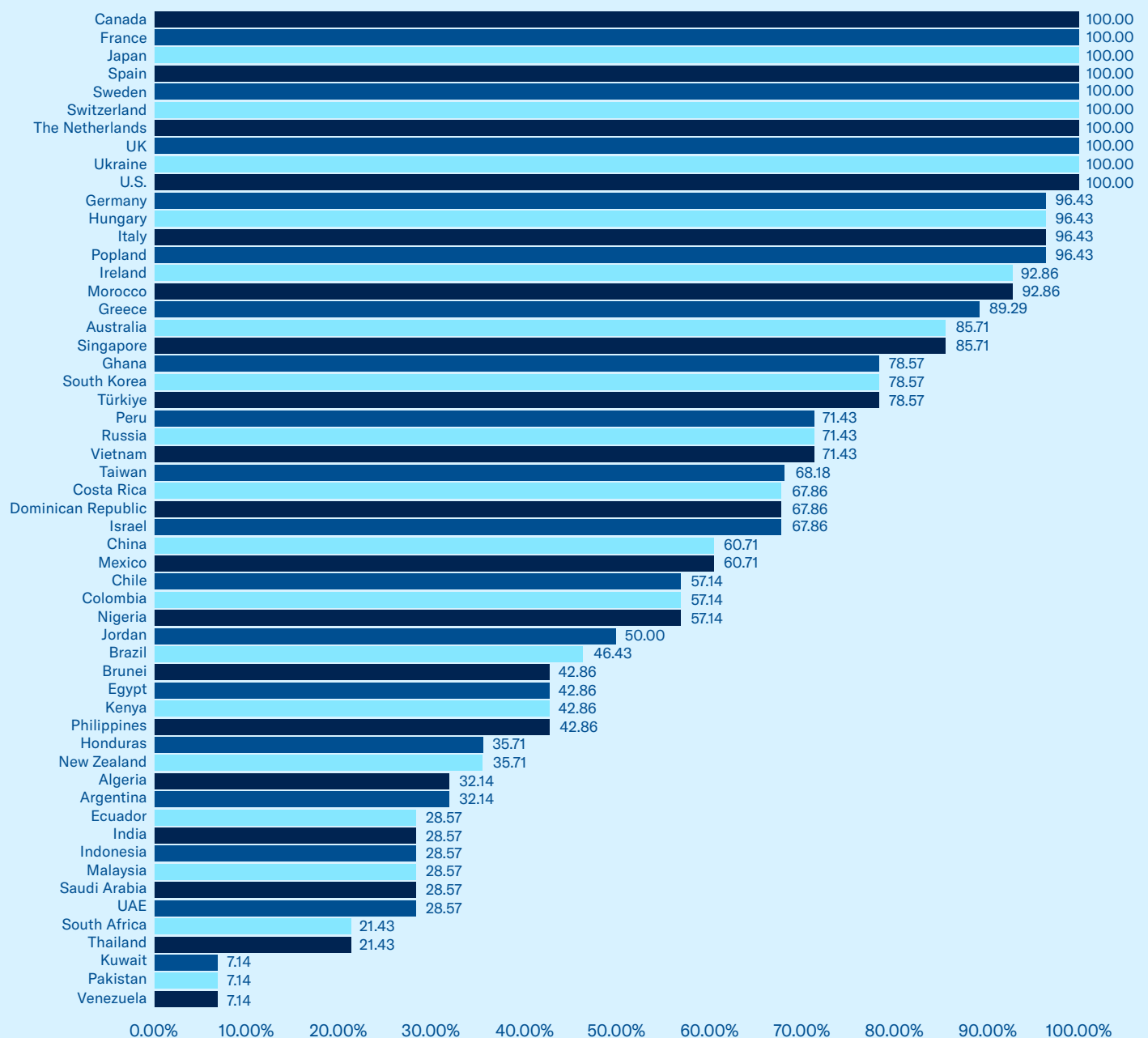
This regime mirrors the underlying orphan regulation with similar incentives offered, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products' developers will have a sufficient time frame for recouping the high costs of development. Specifically, Section 58D provides a baseline 10-year term of market exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. Schedule 9A includes a similar requirement as in the orphan regulation that to remain eligible for the full exclusivity period, licensed products must retain their orphan designation, including with respect to potential return on investment criteria.

Category 10: Membership and Ratification of International Treaties

Figure 16 summarizes the total scores for Category 10. This category measures whether an economy (1) is a signatory of and (2) has ratified or acceded to international treaties on the protection of IP.

The category consists of seven indicators with a maximum possible score of 7.00.

Figure 16: Category 10: 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 63.91%. Many economies achieved a high score in this category: 22 economies have a score of 75% or more, and 14 economies have achieved 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, Argentina, India, Indonesia, 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 trade agreement that included specific obligations to protect IP rights. NAFTA 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 United States have traditionally been leading advocates for stronger IP standards, with strength being 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 jurisdictions, IP rights and their enforcement were central. The benefits have been felt across the world, with inventors and creators from the Andes to North Africa, the Middle East to Asia seeing the positive impact a stronger IP environment has on economic activity, trade, development, and job creation. Unfortunately, the EU's and United States' commitment to strong IP protection in their negotiated FTAs has wavered.

For example, in 2019, the European Commission and the South American trade bloc Mercosur announced that 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 with respect to 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. Although this treaty contains some potentially positive features, it does not conform with the standards of a modern post-TRIPS FTA. For example, 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.

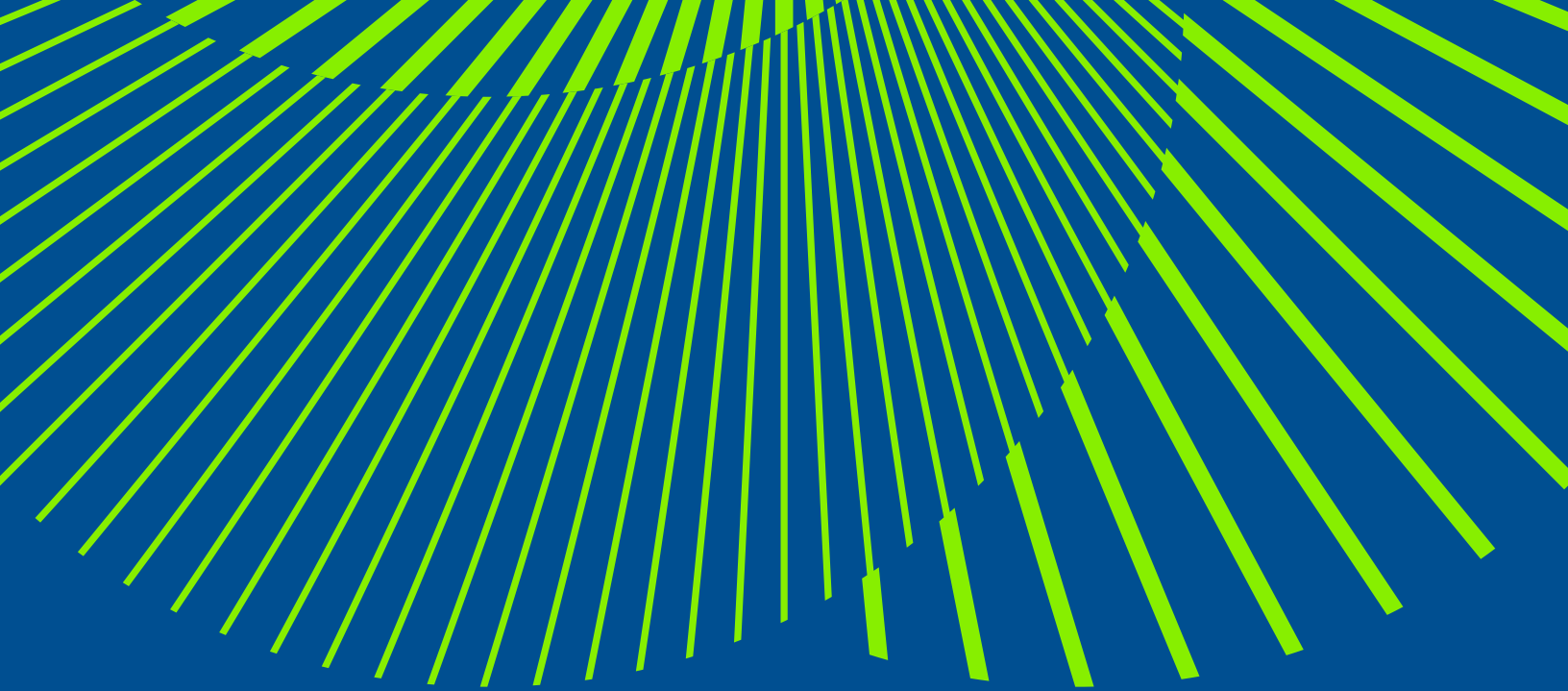
Similarly, as noted in the Index at the time, the United States–Mexico–Canada Agreement (USMCA) was a significant missed opportunity to elevate IP standards through an FTA with the two largest U.S. trading partners. Although the USMCA as originally signed by the parties included many critical 21st-century 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 level.

At the regional level, for example, neither the Regional Comprehensive Economic Partnership nor the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) 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 three years, the UAE has concluded several stand-alone Comprehensive Economic Partnership Agreements (CEPAs) on a bilateral basis. At the time of research, six such agreements had been concluded and come into effect: UAE-India CEPA (2022), UAE-Israel CEPA (2023), UAE-Indonesia CEPA (2023), UAE-Turkey CEPA (2023), UAE-Cambodia CEPA (2024), and UAE-Georgia CEPA (2024). All these CEPAs include a dedicated IP chapter. This is a positive feature of the agreements, and all parties should be congratulated 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 as identified in the Index. Indeed, although some variation exists between 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; no or limited reference is made 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.



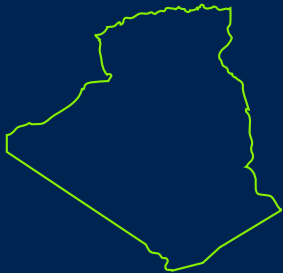
Economy Overviews

Introduction

This section provides an overview and analysis of each individual economy's score for all 53 indicators.

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

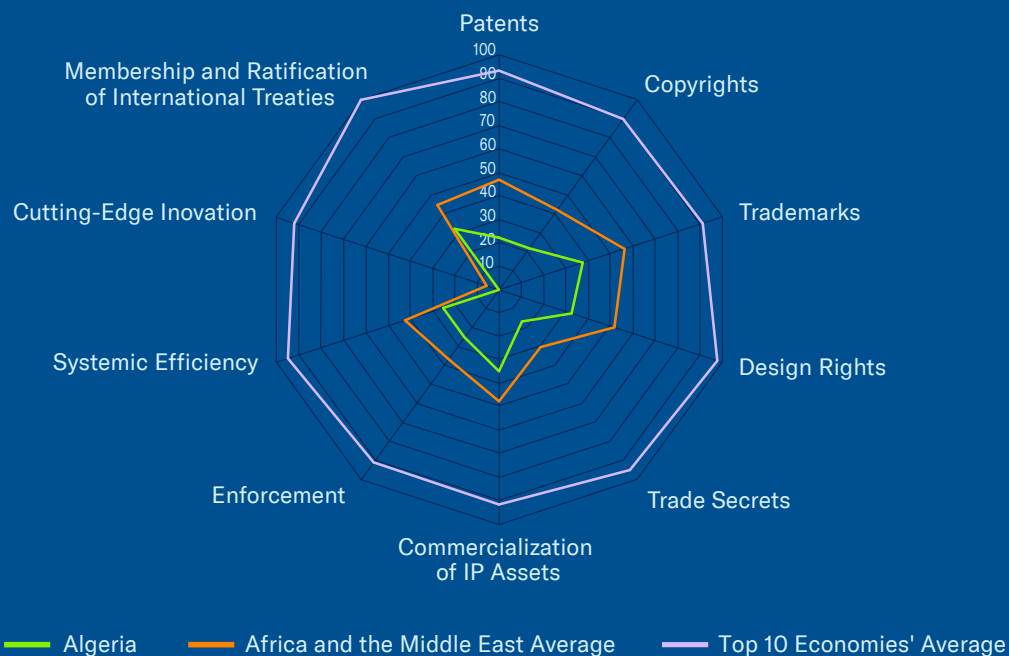
The second figure displays each economy's overall score compared to the regional average for that particular economy and the top- and bottom-performing economies. Specific challenges, debates, and issues related to the most important recent developments under each category are discussed in more detail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



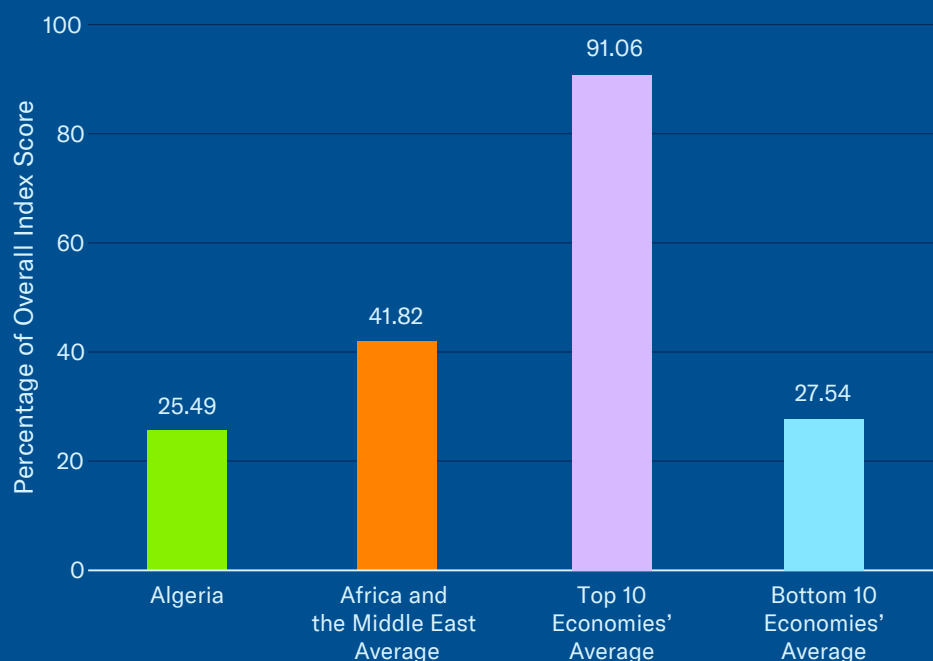
Algeria

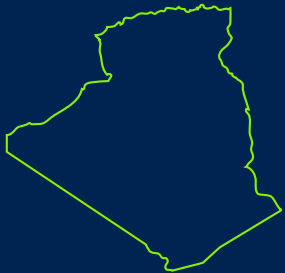
Rank
53/55

Category Scores



Overall Score in Comparison





Algeria

Rank
53/55

Key Areas of Strength

- Finance Law 2023 introduced new R&D-specific tax incentives
- 2022–2023 judicial reforms and the introduction of new “specialized commercial courts”
- Reforms in 2019 and 2020 removed the 51% to 49% local ownership rule and could amount to a sea change in Algeria’s openness to
- Basic framework for IP protection in place
- Contracting party to WIPO Internet Treaties, Patent Cooperation Treaty, Patent Law Treaty, and Madrid Protocol

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Historically a difficult localization policy environment with import substitution, bans, and local ownership requirements; 2021 Finance Law appears to reinstate some of these requirements
- Continued lack of clarity on local ownership
- Weak patenting environment with basic rights missing
- Major holes in copyright framework; limited coverage and applicability of the existing framework to the online environment
- High piracy rates
- Not a WTO member or TRIPS signatory

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	2.00	29. Direct government intervention in setting licensing terms	0.50
1. Term of protection	1.00	30. IP as an economic asset	0.25
2. Patentability requirements	0.00	31. Tax incentives for the creation of IP assets	0.33
3. Patentability of CILs	0.00	Category 7: Enforcement	1.75
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.32
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.18
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precedural remedies	0.25
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.25
8. Membership of a Patent Prosecution Highway	0.00	36. Criminal standards	0.25
9. Patent opposition	0.00	37. Effective border measures	0.25
Category 2: Copyrights and Limitations	1.53	38. Transparency and public reporting by customs	0.25
10. Term of protection	0.53	Category 8: Systemic Efficiency	1.25
11. Exclusive rights	0.25	39. Coordination of IP rights enforcement	0.50
12. Expeditious legal remedies disabling access to infringing content online	0.00	40. Consultation with stakeholders during IP policy formation	0.00
13. Cooperative action against online piracy	0.00	41. Educational campaigns and awareness raising	0.50
14. Limitations and exceptions	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
15. TPM and DRM	0.00	43. IP-intensive industries, national economic impact analysis	0.00
16. Government use of licensed software	0.25	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	1.50	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.25	Category 10: Membership and Ratification of International Treaties	2.25
20. Frameworks against online sale of counterfeit goods	0.00	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	0.65	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.40	49. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights, industrial design rights	0.25	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	51. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
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		

Percentage of Overall Score: 25.49%

• Total Score: 13.51

Spotlight on the National IP Environment

Past Editions versus Current Score

Algeria's overall Index score has increased from 13.18 out of 50 indicators in the twelfth edition to 13.51 out of 53 indicators. This reflects a score increase for indicator 31.

Area of Note

As noted over the course of the Index, the bulk of Algeria's IP laws are almost a quarter of a century old and predate modern globalization and the advent of the knowledge-based economy. Consequently, Algeria's national IP environment lacks many fundamental IP rights and incentives: Patentability standards continue to be outside of international norms, especially for biopharmaceuticals and CILs; the protection of copyright remains underdeveloped and ill-suited to the challenges of the internet era; levels of physical and online counterfeit goods remain high; and 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. In a positive development, recent reports suggest that the Algerian Government is considering reforming its legal framework. At the time of research, no new laws had been enacted or been made available for public comment.

Since 2015, the Index has included a *Statistical Annex*, which investigates a series of correlations that examine the relationship between the strength of national IP environments, as measured by the Index scores, and different types of economic activity, including rates of R&D spending, innovation, technology creation, and creativity.

As the economic data and analysis of the *Statistical Annex* and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for innovation and advanced economic development to take place. For all economies—emerging and developed alike—what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP. Covering 53 indicators across 10 separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products. As the Algerian Government pursues a program of national IP rights reforms, we would encourage it to use the findings of the Index and accompanying *Statistical Annex* as a guide in 2025 and beyond.

Commercialization of IP Assets and Market Access

31. Tax incentives for the creation of IP assets: Historically, Algerian tax law has not offered any R&D-based or IP-specific incentives. Standard tax deductions have been available for qualifying expenditure up to a cap of DZD100 million (about \$750,000). Special incentives, including exemptions from income and corporation tax, have traditionally been in place for industrial production, but these have been general and not aimed at high-tech or IP-intensive industries. This changed with the 2023 Finance Law, which introduced a new R&D specific incentives regime and enhanced the existing standard deduction by doubling it to DZD200 million or 30% of qualifying profits. Specifically, the new law allows qualifying entities to deduct any expenditure to companies registered and operating under the “open innovation” program.

As with all commercial activity in Algeria, tax incentives are subject to long-standing localization requirements and limits on foreign investment (a minority stake of 49% or below in any industrial sector). Unlike a growing number of economies around the world, these legislative changes did not include any IP asset-specific innovation or patent box incentive. Still, this is a positive development and will strengthen Algeria's innovation ecosystem. At the time of research, the new tax regime was operational and had not been amended by subsequent finance laws. As a result, the score for this indicator has increased by 0.33.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

The Algerian Government has over the past decade expressed a growing interest in addressing rare diseases. In 2013, the Ministry of Health issued an order establishing a national list of rare diseases and corresponding approved list of biopharmaceutical treatments. This order listed 28 diseases officially classified as rare. This list was updated in 2022–2023 and now includes over 100 recognized diseases. Algeria does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development, however.



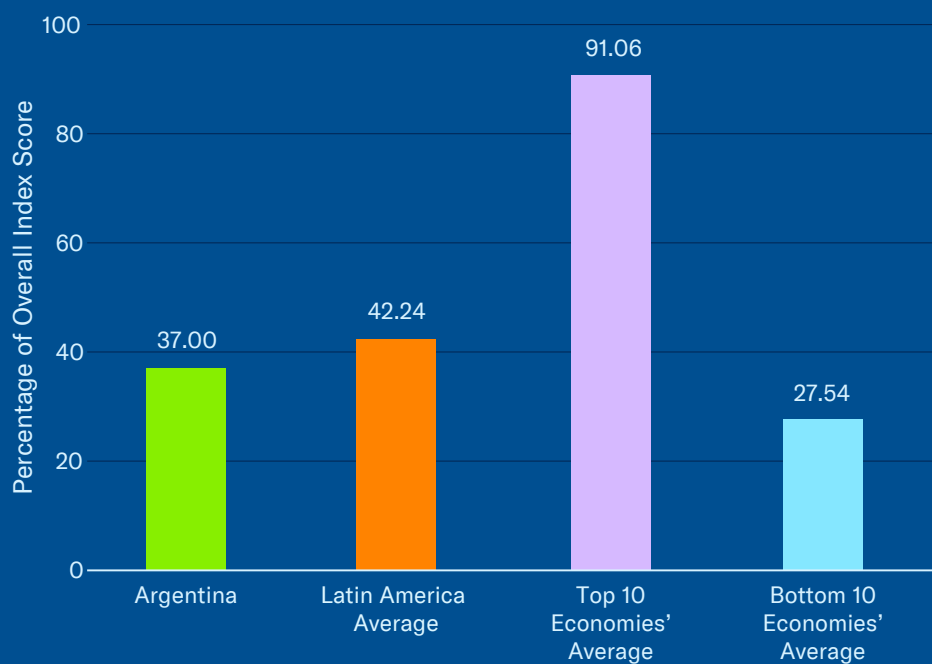
Argentina

Rank
45/55

Category Scores



Overall Score in Comparison





Argentina

Rank
45/55

Key Areas of Strength

- Continued enforcement against copyright infringement in 2024
- 2023 copyright infringement injunction against online piracy includes a “dynamic” element
- Basic framework for IP protection is in place
- Pronounced efforts over the past few years to strengthen international cooperation on IP rights, including through PPHs and increased technical cooperation with the EPO
- Ongoing streamlining of administrative and enforcement bodies
- New 2021 tax incentives for R&D-based activities

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 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, although some important instances of judicial action exist
- Persistently high rates of piracy, including physical counterfeiting
- Limited participant in international treaties; has not acceded to the Patent Cooperation Treaty

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	2.90	29. Direct government intervention in setting licensing terms	1.00
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	0.25	31. Tax incentives for the creation of IP assets	0.67
3. Patentability of CII	0.25	Category 7: Enforcement	1.69
4. Plant variety protection	0.90	32. Physical counterfeiting rates	0.36
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.33
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precedural remedies	0.25
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.00
8. Membership of a Patent Prosecution Highway	0.50	36. Criminal standards	0.25
9. Patent opposition	0.00	37. Effective border measures	0.50
Category 2: Copyrights and Limitations	1.88	38. Transparency and public reporting by customs	0.00
10. Term of protection	0.63	Category 8: Systemic Efficiency	2.75
11. Exclusive rights	0.25	39. Coordination of IP rights enforcement	0.50
12. Expeditious legal remedies disabling access to infringing content online	0.75	40. Consultation with stakeholders during IP policy formation	0.50
13. Cooperative action against online piracy	0.00	41. Educational campaigns and awareness raising	0.50
14. Limitations and exceptions	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
15. TPM and DRM	0.00	43. IP-intensive industries, national economic impact analysis	0.75
16. Government use of licensed software	0.00	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.00	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.25	Category 10: Membership and Ratification of International Treaties	2.25
20. Frameworks against online sale of counterfeit goods	0.25	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	1.10	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.60	49. Patent Law Treaty and Patent Cooperation Treaty	0.25
22. Exclusive rights, industrial design rights	0.50	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	51. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
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		

Percentage of Overall Score: 35.36%

Total Score: 18.74

Spotlight on the National IP Environment

Past Editions versus Current Score

Argentina's overall Index score has increased from 18.50 out of 50 indicators in the twelfth edition to 18.74 out of 53 indicators. This reflects a score increase for indicator 12 and a score decrease for indicator 32.

Area of Note

Following the election of Javier Milei as President in late 2023, the Government of Argentina has embarked on a series of policy initiatives seeking to deregulate and reform the economy. This includes changes to labor laws, tax administration, and the regulation of private trade and practices. Although many of these changes will have a tangible effect on Argentina's national IP system by potentially improving overall business conditions, at the time of research, no major legislative changes had been announced or passed with respect to the national IP environment. As noted over the course of the Index, Argentina's national IP environment lacks many fundamental rights and incentives. Of note is how patentability restrictions continue to remain a serious and long-standing issue, in particular concerning biopharmaceutical products and processes and CIIIs. In violation of TRIPS Article 27, patentability restrictions introduced in 2012 effectively curtail the issuing of patents for a range of biopharmaceutical inventions. This includes Markush-type patent claims as well as claims related to compositions, dosages, salts, esters, ethers, polymorphs, and analogous processes. Subsequent guidelines and rules issued by the national IP office INPI have also curtailed the protection of biotechnology-based inventions. Similarly, Section 6 of the Patent Law excludes computer programs from patentability; copyright is referred to as the primary form of protection for CIIIs.

Although Regulation No. 318/2012 allows CIIIs to be patentable under certain conditions, data on patent applications shows only a small number of CII applications filed in Argentina. There is also the issue of patent enforcement and the difficulties rightsholders have historically faced in gaining preliminary injunctions and effectively defending their rights in cases of suspected infringement. The cost of these legal barriers to the Argentinean economy is substantial both in lost opportunities for domestic innovators and in potential foreign direct investment. More broadly, inventors face excessive patent prosecution times and long delays. A substantial backlog of patent applications has existed at INPI for several years: The average time to grant for many high-tech arts (including biopharmaceutical, chemical, and biotechnology patents) was close to a decade. Argentina also remains one of only 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 treaty today has over 150 contracting parties and constitutes one of the most direct and impactful international efforts aimed at helping inventors protect their innovations across the globe.

Since 2015, the Index has included a *Statistical Annex*, which investigates a series of correlations examining the relationship between the strength of national IP environments, as measured by the Index scores, and different types of economic activity, including rates of R&D spending, innovation, technology creation, and creativity. As the economic data and analysis of the *Statistical Annex* and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for innovation and advanced economic development to take place. For all economies—emerging and developed alike—what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP.

Covering 53 indicators across 10 separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rights-holders need to be able to fully develop and commercialize their ideas and products. As the government continues to pursue a program of national economic reforms, we would encourage it to also focus on the national IP environment and use the findings of the Index and accompanying *Statistical Annex* as a guide in 2025 and beyond.

Copyrights and Limitations

12. Expeditious legal remedies disabling access to infringing content online:

As noted in the previous edition of the Index, the past few years have seen some welcomed developments with respect to the enforcement of copyright in Argentina. In 2023, a federal court ordered the disabling of access to several copyright-infringing websites. The order also included a “dynamic” element. 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. 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 online access point. 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 UK. These positive actions continued in 2024.

During the summer, Argentine law enforcement disabled access to over 50 websites offering access to pirated sports content. This was followed up by a raid and the arrest of a suspect. The regional rightsholders association Alianza played a pivotal role in supporting the local operation.

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. This is now two years in a row that there has been a stronger level of copyright enforcement in Argentina and, as a result of this sustained positive activity in 2023 and 2024, the score for this indicator has increased by 0.25. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

The 2011 Law 26.689 introduced a national legal framework and definition of rare diseases, including the right to comprehensive health care. Subsequent implementing regulations have established and defined a national list of approved rare diseases; a special advisory board to the Ministry of Health and National Program for Rare Diseases; technical advisory committees on rare diseases and relevant treatments; and dedicated support functions for specific diseases, including cystic fibrosis and muscular dystrophy. With respect to incentives to R&D and the development of new treatments and technologies, Article 3(s) of Law 26.689 states that the law should “promote the development and production of medicines and medical products intended for the early detection, diagnosis, treatment and recovery of people” with rare diseases. The law does not include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.

Membership and Ratification of International Treaties

50. Membership in the International Convention for the Protection of New Varieties of Plants, Act of 1991:

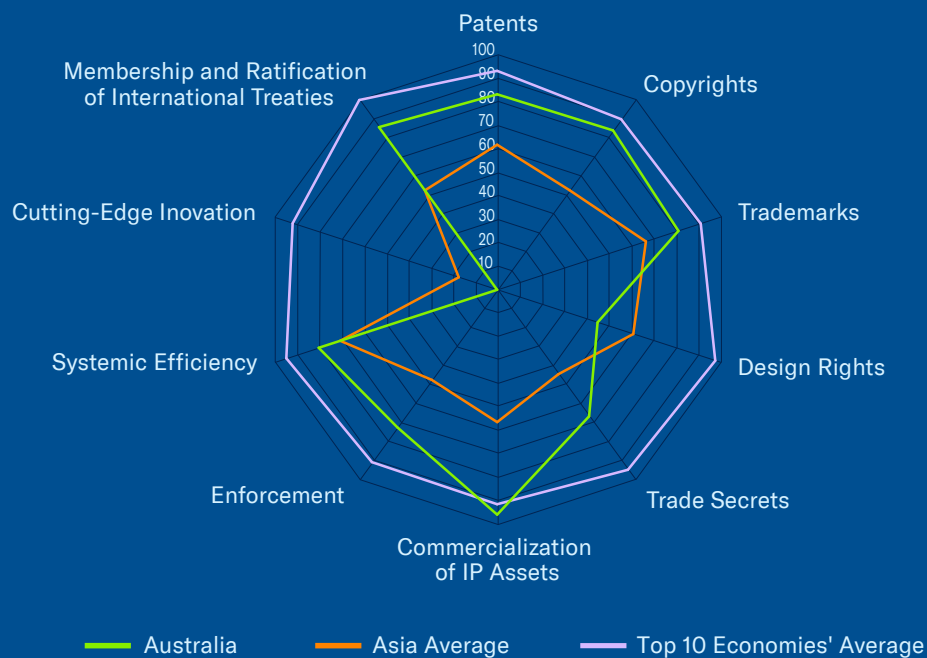
As part of the government's reform efforts and the issuing of the omnibus law Decree 70.2023, there was broad-based discussion in the National Congress for reforming the existing seed law and potentially joining the International Union for the Protection of New Varieties of Plants (UPOV) 1991. As noted in past editions, Argentina is a contracting party to UPOV 1978. The legislative basis for the registration, protection, and commercialization of IP rights pertaining to plant varieties and biotechnological innovation is, consequently, antiquated and, by international standards, restrictive. Adopting the standards of UPOV 1991 and becoming a signatory to this treaty would be a positive development and would lead to a score increase for this indicator. The Index will continue to monitor these developments in 2025.



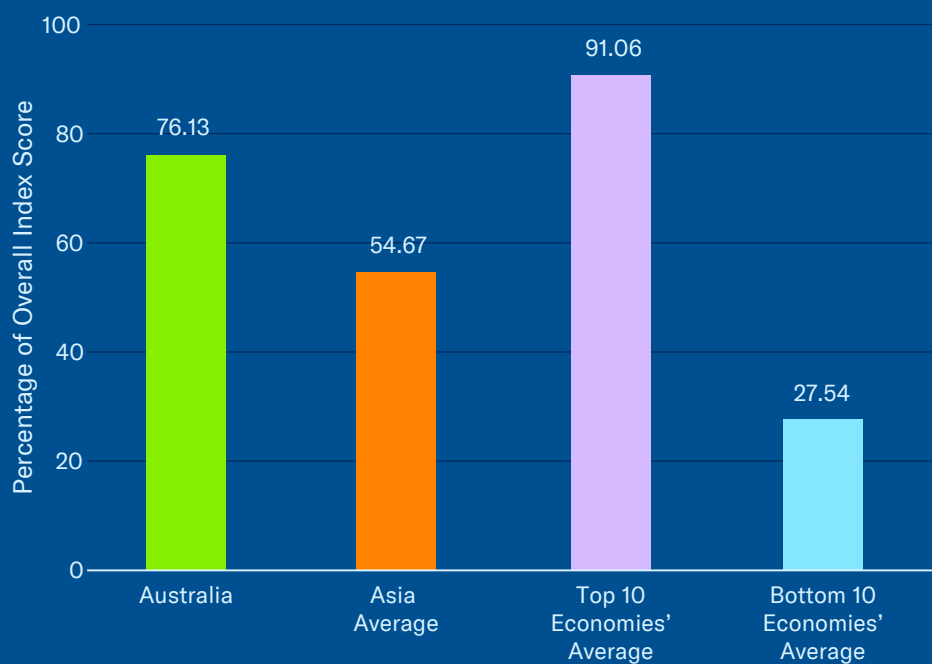
Australia

Rank
15/55

Category Scores



Overall Score in Comparison





Australia

Rank
15/55

Key Areas of Strength

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

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Pre-grant patent opposition system causes significant delays to patent grants
- Not a contracting party to the Hague Agreement
- Gaps exist in the pharmaceutical-related patent enforcement mechanism

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	1.00	30. IP as an economic asset	0.75
3. Patentability of CILs	1.00	31. Tax incentives for the creation of IP assets	1.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.75
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.82
7. Pharmaceutical patent term restoration	1.00	34. Civil and precedural remedies	1.00
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.75
9. Patent opposition	0.00	36. Criminal standards	0.75
Category 2: Copyrights and Limitations		37. Effective border measures	0.50
10. Term of protection	0.63	38. Transparency and public reporting by customs	0.50
11. Exclusive rights	1.00	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	1.00	39. Coordination of IP rights enforcement	0.75
13. Cooperative action against online piracy	0.50	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	1.00	41. Educational campaigns and awareness raising	0.75
15. TPM and DRM	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	0.75	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.50	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.75
21. Industrial design term of protection	0.40	24. Protection of trade secrets (criminal sanctions)	0.75
22. Exclusive rights, industrial design rights	0.50	25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	1.00	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 76.13%

Total Score: 40.35

Spotlight on the National IP Environment

Past Editions versus Current Score

Australia's overall score remains unchanged at 40.35 out of 53 indicators.

Patents and 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: 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 prescription medicines transparency measures. As a result of the consultation, the government announced a plan to introduce legislation to create a timelier patent notification framework. The plan would require that applicants for the first generic and biosimilar form of an originator product notify the patent holder at an earlier stage of the market approval process, namely, when their application is accepted for evaluation by the TGA. This change would 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, the national drug formulary. 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 this new patent notification framework, and no proposed legislation has been published by the TGA or presented to the Australian Parliament since.

In early 2023, the TGA published an update on the timetable and the outlines of an implementation plan on a new patent notification framework. As stated, under this proposed framework, first follow-on applicants would be required to notify the relevant rightsholder when an application has been submitted to the TGA but before the agency begins its review process. As the Index has noted repeatedly regarding this issue, the introduction of such an early notification requirement in this process would constitute a considerable improvement to Australia's existing patent linkage mechanism and would resolve some of the long-standing issues. However, it now seems that these proposals have been shelved. In an update on its website in December 2023, the TGA stated that the agency would not be moving forward with any of its proposals: "Views were mixed regarding earlier notification of generic and biosimilar medicine applications to the innovator. None of the options canvassed during consultation received consensus support and therefore the proposed measure was not progressed." 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 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, but it also limits potential damages for generic manufacturers because no potentially infringing product is ever launched or approved for market.

Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a post-marketing lawsuit. It is highly unfortunate that after years of review and discussion—and public recognition of the deficits of the current regime—the TGA will not be moving forward with the necessary reforms. The Index will continue to monitor these developments in 2025 and beyond.

Copyrights, Related Rights, and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expeditious legal remedies disabling access to infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights:

As noted in previous editions, the attorney general has over the past few years initiated several reviews of various aspects of Australia's copyright environment. In 2022, a "copyright enforcement review" was announced with an "Issues Paper" published together with a 12-week public consultation. The purpose of the review was 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 government had announced that it would develop options "reducing barriers for Australians to use of the legal system to enforce copyright" and, more generally, to improve public understanding and awareness of copyright.

Separately, in 2023, the attorney general hosted a series of four "Ministerial Roundtables on Copyright." The purpose of these meetings was to meet with a range of stakeholders and to discuss pressing copyright issues and priorities.

One roundtable topic covered artificial intelligence (AI) technologies and copyright. Subsequently, in late 2023, the attorney general announced the establishment of a "Copyright and AI Reference Group (CAIRG)." The purpose of this standing discussion group is to "facilitate engagement, information sharing and open discussion between government and non-government sectors on current and emerging copyright-AI issues to better prepare Australia for copyright challenges emerging from AI." As the roundtable and published supporting documentation rightly point out, AI and machine learning are important areas of future economic activity. Advances in computational power and new technological advancements allow for scientific advances and innovation to take place using AI and machine learning and the analysis of large volumes of data and information. However, 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—as well as the ability of scraping technologies to access rightsholders' content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and rightsholders can practically enforce their rights, both in Australia and around the world. Finally, in 2024, the attorney general stated its intention of amending the Copyright Act to ensure that existing educational exceptions and limitations to copyright are applicable not just for in-person tuition but also when a lesson takes place virtually. The Index will continue to monitor all these developments in 2025.

Incentives for Cutting-Edge Innovation

44. *Special market exclusivity incentives for orphan medicinal product development*; 45. *Special market exclusivity incentives for orphan medicinal product development, term of protection*; and 46. *Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development*:

Since the mid-1990s, an orphan drug scheme has been in place. Reformed over the years, this scheme and related programs provide an expedited market approval pathway for new drugs, reduced and/or waived sanitary registration fees, and dedicated funding mechanisms for patients with rare and ultra-rare diseases. In 2020, the Department of Health launched the *National Strategic Action Plan for Rare Diseases*. With respect to incentives to R&D and the development of new treatments and technologies, Pillar 3 of the plan lists the need for increased research into rare diseases, clinical trials, and the translation of basic R&D into new medicines and treatments for patients with rare diseases. From 2024 to 2025, a 10-year “Clinical Trials Activity initiative” will provide AUS 750 million in funding for clinical R&D, including dedicated research streams to rare cancers and rare diseases. However, neither the *National Strategic Action Plan for Rare Diseases* nor any other policy program includes any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.



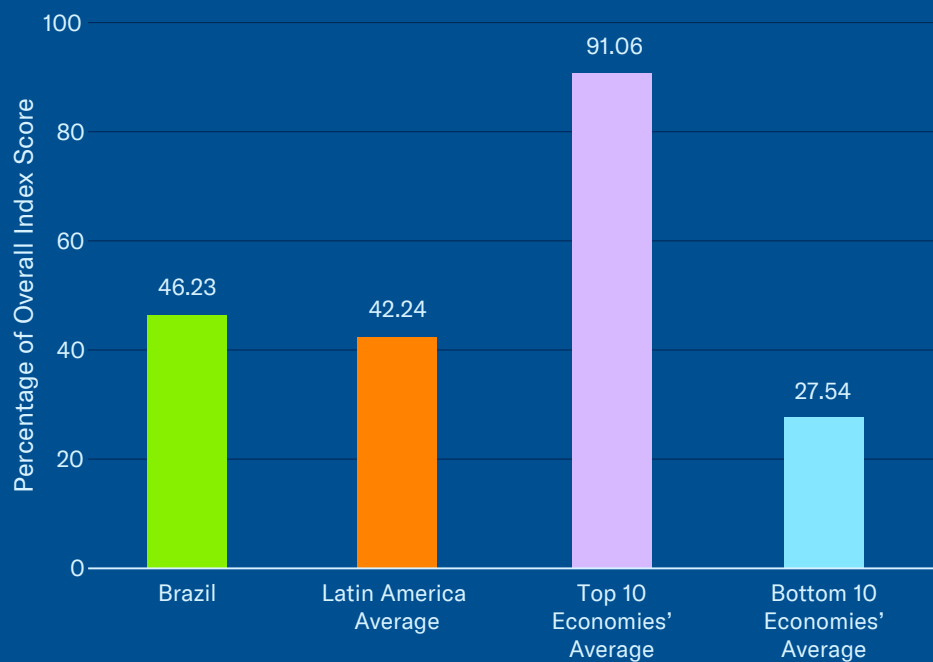
Brazil

Rank
34/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- New Law 3,696/2023 gives the National Cinema Agency, ANCINE, copyright enforcement powers; pilot action programs were announced in 2024
- “Operation Copyright” and “Operation 404 against piracy” continued in full force in 2024; 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
- In 2021, INPI released its first study of IP-intensive industries’ national economic impact in Brazil
- Law No. 14.195/2021 changed Brazil’s IP Law so that ANVISA’s prior consent on patent applications is no longer required

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Article 40 invalidation by the Supreme Court in 2021 weakens Brazil’s patenting standards, retroactively targets the biopharmaceutical industry, and affects thousands of patent applications; this remained unaddressed in 2024
- Compulsory licensing amendments for health emergencies broaden existing emergency powers and authority, potentially generating legal uncertainty
- Key life sciences IP rights are missing, including patent term restoration and RDP, causing an overall challenging patentability environment
- Limited participant in international IP efforts—only a full contracting party to two of nine treaties is included in the Index

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.50
2. Patentability requirements	0.00	30. IP as an economic asset	0.50
3. Patentability of CILs	0.00	31. Tax incentives for the creation of IP assets	0.33
4. Plant variety protection	0.74	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.52
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.53
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.25
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.25
9. Patent opposition	0.50	36. Criminal standards	0.50
Category 2: Copyrights and Limitations		37. Effective border measures	0.50
10. Term of protection	0.63	38. Transparency and public reporting by customs	0.75
11. Exclusive rights	0.50	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.75	39. Coordination of IP rights enforcement	0.75
13. Cooperative action against online piracy	0.00	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.75
15. TPM and DRM	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
16. Government use of licensed software	0.25	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.50
21. Industrial design term of protection	1.00	24. Protection of trade secrets (criminal sanctions)	0.50
22. Exclusive rights, industrial design rights	0.50	25. Regulatory data protection term	0.00
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	0.75	47. WIPO Internet Treaties	0.00
27. Barriers to technology transfer	0.50	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
28. Registration and disclosure requirements of licensing deals	0.00	49. Patent Law Treaty and Patent Cooperation Treaty	0.75
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	0.00

Percentage of Overall Score: 46.23%

Total Score: 24.50

Spotlight on the National IP Environment

Past Editions versus Current Score

Brazil's overall score has increased from 23.26 out of 50 indicators in the twelfth edition to 24.50 out of 53 indicators. This reflects score increases for indicators 12 (expeditious legal remedies disabling access to infringing content online) and 51 (membership of the Convention on Cybercrime, 2001) and a score decrease for indicator 32 (physical counterfeiting rates).

Patent Rights and Limitations

2. Patentability requirements and 3. Patentability of computer-implemented inventions (CIIs):

In 2024, rightsholders continued to face challenges in registering and protecting patent-eligible subject matter in Brazil. In the Brazilian Senate, deliberations continued regarding Bill 2210/2022. Originally introduced in the Chamber of Deputies in 2018, this bill has undergone significant changes over the years. In 2024, a series of amendments introduced in the Senate would change the way patent examination takes place and, specifically, examination timelines used by the Brazilian Patent and Trademark Office, INPI. At the time of research, the bill was still pending and under review in the Science, Technology, Innovation, Communication and Information Technology Committee. However, neither this bill nor any other proposals actively being considered would effectively address the current lack of a TRIPS-compliant minimum term of patent protection in Brazil. Given INPI has historically had a backlog of patent applications ranging from 10 to 13 years—depending on the field of technology—until 2021, the Industrial Property Law had 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 patent delays. In a series of decisions in the spring of 2021, the Brazilian Supreme Court removed this floor. The court declared that Article 40 was unconstitutional and would no longer be available or applicable, and it stated that the ruling should be retroactively applied to granted patents in the biopharmaceutical and health-related fields. As noted over the past few years, the ruling is a step backward in improving Brazil's national IP environment with thousands of biopharmaceutical rightsholders being put at a disadvantage and exclusivity periods cut short. Through this decision, the Brazilian Supreme Court has weakened Brazil's standards of patent protection, and the selective retroactive application of the ruling to one field of technology and innovation violates Article 27(1) of the TRIPS treaty 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. 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 long application processing times are not unique to Brazil or INPI, and a variety of mechanisms can more effectively address this. 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 noted in past editions of the Index, Brazil also lacks many essential biopharmaceutical IP rights, including patent term restoration and a defined term of RDP. As a result of the weakening of the patenting environment and rightsholders' inability to continue to secure a 10-year minimum period of patent protection—noting that the TRIPS defined term is 20 years—Brazil's score for indicators 2 and 3 was 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 2025.

8. Membership of 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 United States Patent and Trademark Office, the Japan Patent Office, the European Patent Office, and the China National Intellectual Property Administration. These positive efforts continued in 2024 with INPI joining the Global Patent Prosecution Highway (GPPH). The GPPH provides the opportunity to request an accelerated examination and to secure early patent grants in its 28 participating offices. PPH initiatives and increased cooperation among IP offices are among 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 and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); and 12. Expeditious legal remedies disabling access to infringing content online:

In 2024, several concrete efforts were made to improve the copyright environment in Brazil. On the enforcement side, operations continued under “Operation 404 against piracy” (*Operação 404 contra pirataria*), which launched in 2019. Spearheaded by a special police enforcement unit (SEOPI), the Ministry of Justice, and with international support from the United States Embassy and UK police, this special enforcement effort has had direct and tangible results. In its first four years of operation, over 2,000 websites and applications offering copyright-infringing content were shut down, more than 100 search and seizure warrants were issued and executed across 20 Brazilian states, and several arrests have been made. In late 2023, rightsholders announced that an additional 600 websites had been disabled in both Latin America and Europe. In 2024, Operation 404 entered its seventh phase, which resulted in the suspension of an additional 675 websites and 14 illegal streaming applications.

Similarly, two important developments occurred on the legislative side. To begin with, in May 2024, Law 14,852 was enacted. Dedicated to defining and incentivizing the video and electronic gaming industry, the new legislation provides a powerful statement that the gaming industry is a central part of Brazil's burgeoning creative sector and the national economy. From an IP perspective, the new law does not introduce any new forms of IP rights and protections or greater enforcement through existing statutory rights.

The video game industry has long noted that both online piracy of video games and the trade in pirated and modified video games and devices remain key piracy challenges in Brazil. Several markets in São Paulo have been included in the USTR's *Review of Notorious Markets for Counterfeiting and Piracy*, including in the latest edition.

The video game industry is one of the fastest-growing areas of the creative sector and is responsible for a growing proportion of economic output. Commissioned by the Entertainment Software Association, the 2020 study, *Video Games in the 21st Century: The 2020 Economic Impact Report*, found that, as a whole, the industry contributed an estimated \$90 billion in total economic output supporting close to half a million jobs in the United States. Given the growing importance of video and computer game technology to people all around the world, it is vital that this industry be better protected in Brazil. At the time of research, no further details had been published on how the law would be implemented and applied.

In a separate development, President Lula enacted bill 3,696/2023 earlier in the year. Although the law is primarily concerned with the continued requirement of local content quotas on domestic film distributors, it provides a potential breakthrough for the creative sector. Article 3 of the law gives the National Cinema Agency (ANCINE) the power to “determine the suspension and cessation of unauthorized use of protected Brazilian or foreign works.” Under Subparagraph 2, these powers are broadly defined: “Measures to suspend and cease unauthorized use of protected works are those that prevent their issuance, dissemination, transmission, retransmission, reproduction, access, distribution, storage, hosting, display and availability and any other means that imply violation of copyright.” In September, ANCINE announced that it would apply its new powers in two pilot applications, disabling access to the dissemination of audiovisual content and live sporting events.

These efforts build on those taken by the Brazilian National Telecommunications Agency, ANATEL. As noted last year, ANATEL launched a dedicated campaign against illicit IPTV set-top boxes and their streaming applications online. These are all positive developments and, as a result, the score for indicator 12 has increased by 0.25.

14. Scope of limitations and exceptions to copyrights and related rights:

The Brazilian Senate recently approved legislation, Bill 2338/2023, regulating AI and machine learning technologies. The AI Bill, which is now pending approval in the Lower House, is the first legislative initiative in Brazil that seeks to establish a framework for the national development and application of AI and machine learning technologies. These technologies are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific breakthroughs and innovation to take place through the analysis of large volumes of data and information. Although Article 42 of the draft law states clearly that text and data mining of copyrighted works by qualifying organizations must not “unjustifiably harm the economic interests of the holders” or “compete with the normal exploitation of the works,” the explanatory note states that “in line with international law, it [the bill] establishes guidelines for conforming copyright and intellectual property rights to the notion that data should be a common good.” However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights. The Index will continue to monitor developments in 2025 as the bill passes through approval procedures in the Lower House.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

In 2014, the Ministry of Health promulgated Ordinance 199, the National Policy for Comprehensive Care for People with Rare Diseases. The ordinance introduced a national framework and definition of rare diseases, including the right to comprehensive health care. With respect to incentives to R&D and the development of new treatments and technologies, Article 8 (VII) of the ordinance states that the law should “promote the exchange of experiences and stimulate the development of studies and research that seek improvement, technological innovation and the dissemination of knowledge aimed at health promotion, prevention, care and rehabilitation/habilitation of people with rare diseases.” The ordinance does not include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.

Membership and Ratification of International Treaties

51. Membership of the Convention on Cybercrime, 2001:

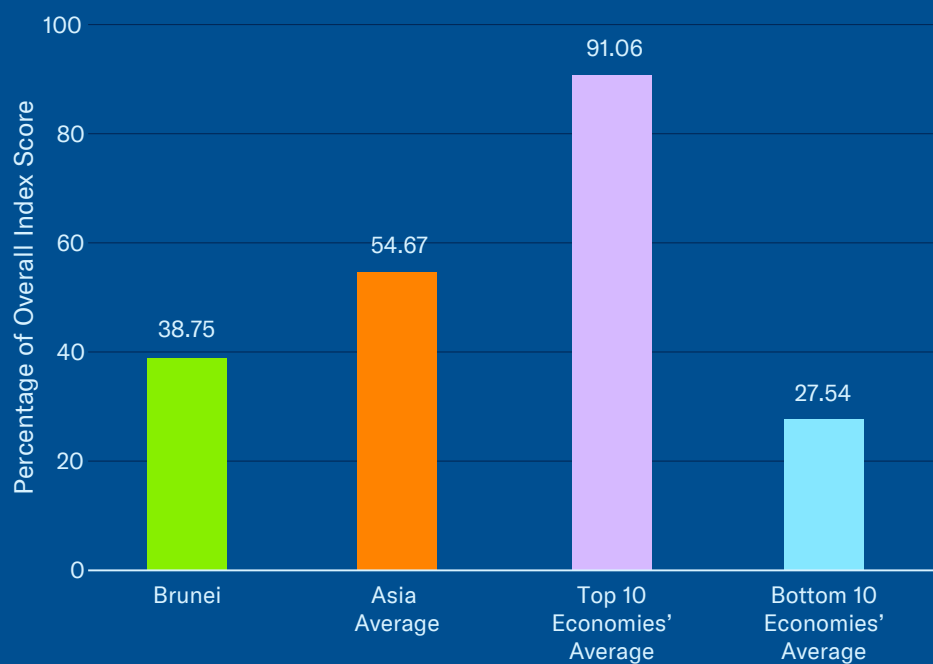
In late 2022, Brazil became a full contracting party to the Convention on Cybercrime by depositing its instrument of accession. The convention entered into force in 2023. As a result, the score for this indicator has increased by 1.00.



Category Scores



Overall Score in Comparison





Key Areas of Strength

- Acceded to the CPTPP in 2023, which has the potential to improve trade secrets protection and enforcement environment if properly implemented
- Acceded to WIPO Internet Treaties in 2017
- Major IP reforms occurred over the past decade, including establishing a national IP office (BruIPO)
- PPH agreement is in place with Japan
- No fundamental administrative or regulatory barriers are in place for execution of licensing agreements

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Limited legal framework for the protection of trade secrets and confidential information
- Life sciences IP rights are lacking
- Regulatory data protection is not available
- Limited framework for addressing online piracy and circumvention devices
- High software piracy rates—64% in latest estimates
- Limited incentives in place for the creation and use of IP assets for SMEs

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.75	30. IP as an economic asset	0.75
3. Patentability of CILs	0.75	31. Tax incentives for the creation of IP assets	0.33
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.47
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.36
7. Pharmaceutical patent term restoration	1.00	34. Civil and preceudural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.25
9. Patent opposition	0.50	36. Criminal standards	0.50
Category 2: Copyrights and Limitations		37. Effective border measures	0.00
10. Term of protection	0.53	38. Transparency and public reporting by customs	0.00
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	0.25
13. Cooperative action against online piracy	0.00	40. Consultation with stakeholders during IP policy formation	0.00
14. Limitations and exceptions	0.25	41. Educational campaigns and awareness raising	0.25
15. TPM and DRM	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
16. Government use of licensed software	0.25	43. IP-intensive industries, national economic impact analysis	0.25
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.00	Category 10: Membership and Ratification of International Treaties	
Category 4: Design Rights and Limitations		47. WIPO Internet Treaties	1.00
21. Industrial design term of protection	0.60	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
22. Exclusive rights, industrial design rights	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
Category 5: Trade Secrets and the Protection of Confidential Information		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
23. Protection of trade secrets (civil remedies)	0.25	51. Membership of the Convention on Cybercrime, 2001	0.00
24. Protection of trade secrets (criminal sanctions)	0.00	52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
25. Regulatory data protection term	0.00	53. Post-TRIPS FTA	0.00
Category 6: Commercialization of IP Assets			
26. Barriers to market access	1.00		
27. Barriers to technology transfer	0.50		
28. Registration and disclosure requirements of licensing deals	0.75		

Percentage of Overall Score: 38.75%

Total Score: 20.54

Spotlight on the National IP Environment

Past Editions versus Current Score

Brunei's overall score remains unchanged at 20.54 out of 53 indicators.

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:*

As noted in last year's edition, in 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 any of the other contracting parties included in the Index under Indicator 53. 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, current Bruneian trademark and copyright laws do not provide 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 to 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, 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 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 the 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 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

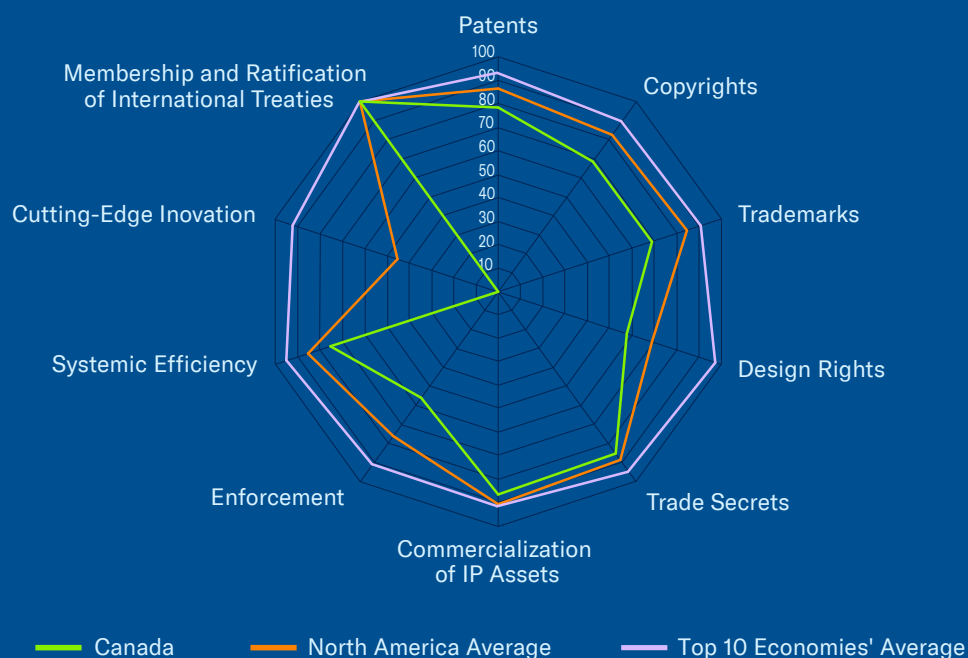
Interest in rare diseases has grown in the Asia-Pacific region. In 2017, the Asia-Pacific Economic Cooperation (APEC) forum (of which Brunei is a member) announced a new initiative geared specifically toward rare diseases, the “APEC Action Plan on Rare Diseases.” The plan’s primary aim is to “address barriers to the diagnosis and treatment of rare diseases in the region.” The plan consists of 30 individual targets across 10 pillars, including the promotion of innovative research and development through financial incentives, expedited market review procedures, and support for domestic R&D. Brunei does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



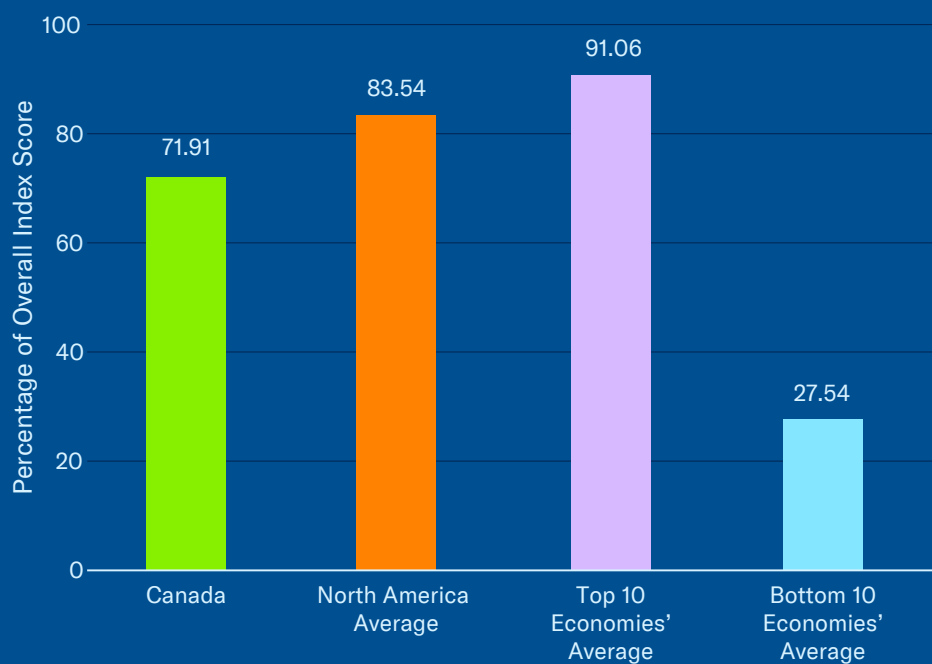
Canada

Rank
17/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Continued issuing of dynamic injunction orders in 2023 further strengthened copyright enforcement in Canada
- USMCA took effect in 2020, resulting in longer copyright terms, 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
- CETA-implementing legislation is in place, which strengthened some rights
- Significant damages were awarded in precedent-setting 2017 federal court case with regard to Canada's DRM provisions

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Continued uncertainty over existing interpretation of educational exceptions to copyright; 2021 Supreme Court decision in Access Copyright case added more layers of uncertainty and legal complexity
- CETA amendments to Patent Act introducing patent term restoration includes restrictive eligibility requirements and an export claw-out, which effectively undermines biopharmaceutical exclusivity
- Deficiencies exist with respect to pharmaceutical patent enforcement and remain unaddressed in PMNOC regulations

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.75	30. IP as an economic asset	0.75
3. Patentability of CILs	1.00	31. Tax incentives for the creation of IP assets	0.67
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.25	32. Physical counterfeiting rates	0.62
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.78
7. Pharmaceutical patent term restoration	0.30	34. Civil and precedural remedies	0.50
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.50
9. Patent opposition	0.75	36. Criminal standards	0.50
Category 2: Copyrights and Limitations		37. Effective border measures	0.75
10. Term of protection	0.79	38. Transparency and public reporting by customs	0.25
11. Exclusive rights	0.50	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	1.00	39. Coordination of IP rights enforcement	0.50
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	0.25	41. Educational campaigns and awareness raising	0.75
15. TPM and DRM	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	1.00	43. IP-intensive industries, national economic impact analysis	0.75
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.75	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	1.00
21. Industrial design term of protection	0.40	24. Protection of trade secrets (criminal sanctions)	0.75
22. Exclusive rights, industrial design rights	0.75	25. Regulatory data protection term	0.80
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	0.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 71.91%

• Total Score: 38.11

Spotlight on the National IP Environment

Past Editions versus Current Score

Canada's overall score remains unchanged at 38.11 out of 53 indicators.

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 reformed 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 include 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 with a new "Discussion Guide," and a series of consultations were held in 2024. Although both the guide and consultations touched on a range of important regulatory issues, a pivotal issue to rightsholders remains the way price comparisons are made and what is judged as "excessive." The PMPRB has developed options ranging from a "median international price" assessment to a "highest international price" assessment. Given that the in-force changes to the basket of economies used for international price comparisons has been changed to reduce average price comparisons, it would be illogical to apply the median international price rather than the highest international price to judge whether a given price in Canada was excessive. At the time of research, no final regulations had been published, and the "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. Data shows 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 between 2012 and 2021 and published by PhRMA 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%).

The changes introduced by the PMPRB's package of regulatory reforms are likely to exacerbate this, 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, the government in 2021 launched the *Biomanufacturing and Life Sciences Strategy*. Significantly, the strategy seeks explicitly to make Canada a more “attractive destination for leading life sciences firms to establish and grow.” Similarly, in 2022, Canada's largest provinces—Ontario and Quebec—released new life sciences strategy documents and plans to encourage local biopharmaceutical R&D and innovation. But developing new medicines is a long-term, high-risk, resource-intensive process. 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 be strengthened and aligned with best practices in the United States, the EU, and leading Asian economies in many respects. Similarly, recognizing 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 reward for their innovation and creativity. The Index will continue to monitor these developments in 2025.

Patent Rights and Limitations

7. Patent term restoration for pharmaceutical products:

As part of commitments made under the Canada-United States-Mexico Agreement (CUSMA), Canada agreed to introduce a patent term adjustment (PTA) mechanism. The purpose of this mechanism is to compensate patent applicants for any undue delay in prosecuting the patent application. In May 2024, the Canadian Intellectual Property Office (CIPO) published draft changes to existing patent regulations introducing this new PTA. Unfortunately, under the office's proposed system, PTA will be difficult, if not impossible, to obtain for most applicants. More broadly, any PTA granted is set to run concurrently with a separate and distinct form of term restoration, namely, supplementary protection for biopharmaceutical patents. Yet these are two completely different types of patent term restoration seeking to compensate rightsholders for different forms of regulatory delay. PTA is due to what is under the CUSMA termed “unreasonable” delays in patent prosecution. Certificates of supplementary protection (CSP) for biopharmaceutical patents are meant to restore time lost during sanitary registration and the marketing authorization process for new medicines and biopharmaceutical technologies. As such, one form of restoration has nothing to do with the other.

The Canadian government's interpretation and implementation of its commitments under the CUSMA is reminiscent of how the government chose to handle the introduction of the CSP mechanism under the Comprehensive Economic and Trade Agreement (CETA) with the EU. The relevant amendments made to the Patent Act (Sections 106–134) and implementing regulations published in the *Canada Gazette* provide an—on paper—maximum restoration period of two years. However, the effective availability of this term of restoration was severely restricted through several technical carve-outs.

To begin with, under Section 116(4), the Canadian government retained the right to reduce the term of protection at its discretion. Second, the implementing regulations contained a “Timely Submission Requirement” that set a timeline for the submission of CSP applications based on the regulatory status of a product in a set of “prescribed economies.” Thus, the availability of a CSP was made contingent on early market entry. Finally, the law also contained an export claw-out, with Section 115(2) effectively exempting the infringement of CSP protection if the activity is for the purpose of export. As noted at the time in the Index, these limitations and restrictions all but nullify the underlying rationale of the mechanism in the first place. And now the same is happening in the case of PTA. Instead of strengthening Canada’s national IP environment and stimulating more R&D and related economic activity, such actions hollow out the national IP environment and incentives for future innovation. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

In 2024, the Canadian legislature continued to examine Bill C-27 (“An Act to enact the Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act and the Artificial Intelligence and Data Act and to make consequential and related amendments to other Acts”), with fresh proposed amendments published by the government late in 2023. This is the first legislative initiative in Canada that seeks to establish a framework for the national development and application of AI and machine learning technologies. These technologies are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific breakthroughs and innovation to take place through the analysis of large volumes of data and information.

With respect to IP, neither the originally proposed draft Artificial Intelligence and Data Act nor the Ministry of Innovation, Science, and Industry’s proposed amendments address copyright protections in the context of AI. However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in Canada and across the world. Additionally, the results of the government’s public consultation “Copyright in the Age of Generative Artificial Intelligence” indicate many rightsholders view this as a critical area in need of reform.

Separately, there was no progress on the long-standing issue of educational exceptions in 2024. 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. The past 12 years have seen several rounds of litigation culminating in a Supreme Court ruling in 2021, yet the issue remains unresolved. As the Index pointed out in 2012, at best, the changes to Canada’s copyright regime would lead to a higher level of uncertainty for publishers and, at worst, a shrinking of their industry and business model. Today, it is clear that both have occurred. Industry figures suggest that the Canadian publishing industry has suffered greatly over the past decade with estimated uncompensated copying outside of fair dealing amounting for 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 decreased publishing income. The bottom line is that after over a decade of litigation and uncertainty, Canadian rightsholders have failed to achieve effective redress for the clear violation of their copyright or to gain any further understanding of what constitutes fair dealing and what does not within the context of education. In 2022, the federal government appears to have finally recognized the dire impact of the 2012 amendments and subsequent Supreme Court rulings. In the 2022 budget, *A Plan to Grow Our Economy and Make Life More Affordable*, the government stated plainly that it would “work to ensure a sustainable educational publishing industry, including fair remuneration for creators and copyright holders, as well as a modern and innovative marketplace that can efficiently serve copyright users.” Unfortunately, the past two years have seen no further action. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development;
45. Special market exclusivity incentives for orphan medicinal product development, term of protection;
and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

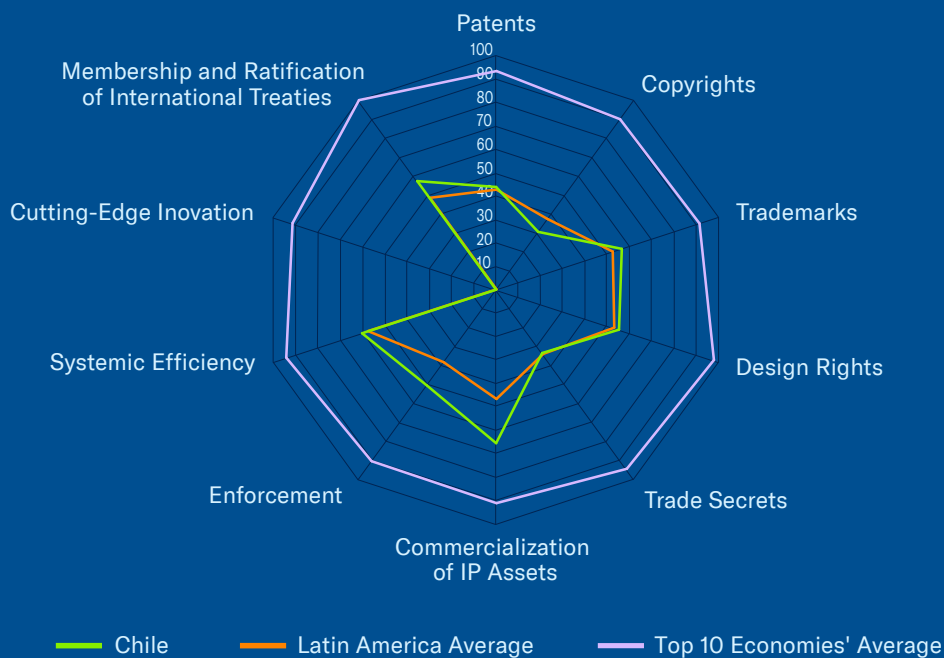
In 2021, the Ministry of Health launched a *National Strategy for Drugs for Rare Diseases*. The strategy consists of four individual components, including the final one, “Investing in Innovation.” However, the strategy does not include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.



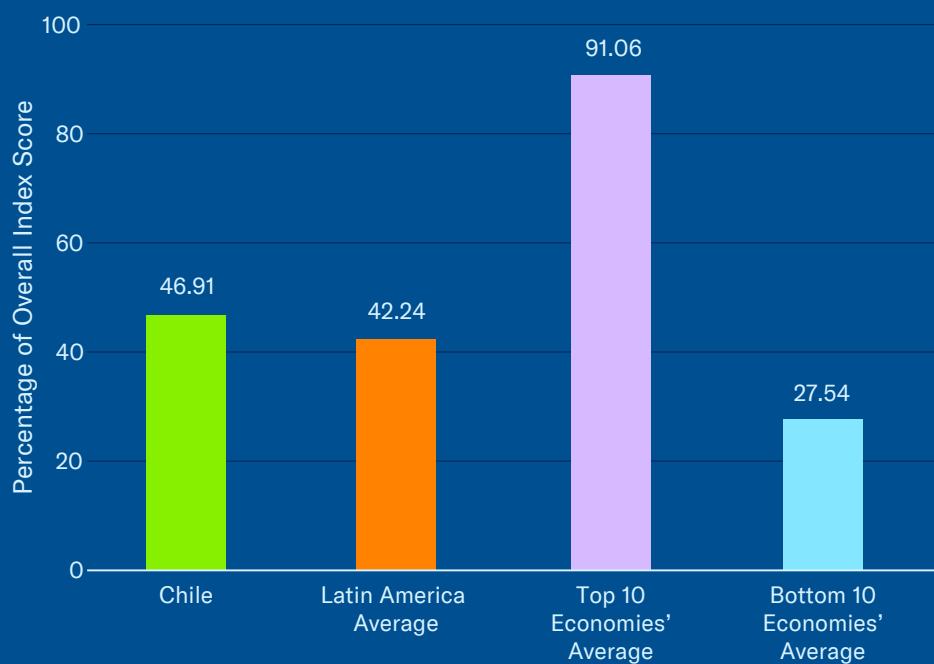
Chile

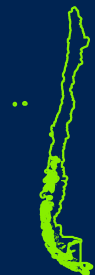
Rank
32/55

Category Scores



Overall Score in Comparison





Chile

Rank
32/55

Key Areas of Strength

- Joined the Madrid Protocol in 2022
- IP law amendments (Law 19,309) extend term of protection for design rights and improve the enforcement environment
- Member of GPPH
- 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

- No special IP incentives for orphan medicinal product development
- Uncertainty on accessibility of term restoration with 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 a sufficient framework to tackle online piracy, although some success in disabling access to infringing websites

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

Percentage of Overall Score: 46.91%

Total Score: 24.86

Spotlight on the National IP Environment

Past Editions versus Current Score

Chile's overall score remains unchanged at 24.86 out of 53 indicators.

Patent 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 considering compulsory licenses for the prostate cancer drug Xtandi and hepatitis C drug Sovaldi. In 2018, these efforts for the issuing of an involuntary license based on cost were endorsed by the outgoing government. In 2018, the Chamber of Deputies approved a resolution that requested the use of compulsory licenses for drugs formulated with sofosbuvir. Subsequently, in response to a request presented by some patient groups and parliamentarians, the Minister of Health issued Resolution 399, which discusses the public health justification for a compulsory license. A third resolution by the Chamber of Deputies with the same request was approved later that same year and, in response to that request, the Minister of Health issued Resolution 1165 rejecting the patentee's challenge to Resolution 399/2018.

In a separate development, in 2019, President Sebastian Pinera urged Congress to approve the Drugs Act II (*Ley de Farmacos II*) as one of the measures of the National Drug Policy that seeks to improve the availability of drugs and to reduce out-of-pocket costs through, among other policies, the expansion of compulsory licenses. During the bill's long iteration through Congress, new provisions have been added that greatly extend the reach of nonvoluntary licenses, incorporating discretionary elements such as "shortage" or "economic inaccessibility" of products as a legitimate ground for issuing a license. The draft bill also includes provisions that effectively reduce a rightsholder's use of its trademarks in the course of trade. At the time of research, the legislation was still pending.

In 2020, in response to the COVID-19 global pandemic, the Chamber of Deputies passed a unanimous resolution endorsing the use of compulsory licenses for any and all products, diagnostics, medical devices, and other medical paraphernalia related to the COVID-19 global pandemic. This was followed up with a legislative proposal and set of amendments published by a group of senators. This proposal, Bulletin 13,572-11, would introduce an expedited and abbreviated process for the hearing and granting of compulsory licensing applications; the pre-fixing of applicable royalties to a maximum of 5% of the sales price of the licensed product; and a broad elimination of liability for manufacturers, individuals, and legal entities that violate existing IP rights (including patent rights and trade secrets) for the production or distribution of any "medicines, vaccines, and other technologies subject to patent rights, utility models, undisclosed information, intended to meet public health needs or other public interest within the national territory, in a context of health alert, epidemic or pandemic decreed by the health authority, and that without knowledge of the existence of affected industrial property rights or acting in good faith, violate the provisions of Law No. 19.039."

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 2025 and beyond, 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. But almost two years after WHO declared the COVID-19 global health emergency to be over, the critical takeaway is clear: the global community today is in a far better position to manage the socioeconomic impact of any future pandemic than it was in 2019. This is in large measure due to the extraordinary efforts of IP-intensive industries and, in particular, the research-based biopharmaceutical industry. The innovative, scientific, and technological progress that has allowed the global community to function during the COVID-19 pandemic did not emerge overnight. Instead, these technologies and products are the fruit of a pre-existing innovation ecosystem that relies on IP rights to enable the allocation of resources, formation of partnerships, and transfer of technology on commercial terms.

Without strong and clear IP rights, it is unlikely that any of the vaccines, treatments, or other medical and nonmedical products and technologies—or the underlying science—that have been essential to help societies function and successfully fight the COVID-19 pandemic would exist. Undermining these 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 and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expeditious legal remedies disabling access to infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation: As noted over the course of the Index, rightsholders face significant challenges in protecting their copyrighted content in Chile. As a contracting party to both the WIPO Internet Treaties and the 2003 United States-Chile Free Trade Agreement (FTA), Chile is obliged to provide a minimum standard of copyright protection for rightsholders that is currently not available. Both the U.S.-FTA and WIPO Internet Treaties contain several important standards and measures related to copyright enforcement in the internet and digital realm, including a defined notice-and-takedown mechanism for communication service providers; extensive TPM and DRM protection provisions; definitions of obligations pertaining to related rights; protection against satellite piracy; and general civil and criminal enforcement procedures for all IP rights, including copyrights. But over 20 years after ratification of the FTA and 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, internet service providers (ISPs) are required to remove infringing content only on having "effective knowledge" (meaning that notice must be by a court, not by a rightsholder). Consequently, rightsholders' ability to practically benefit from and use the takedown system is extremely limited. In addition, although Law No. 20,435 introduced a voluntary system under which ISPs are to forward notices from rightsholders to suspected infringers, this has over the course of the Index shown to be ineffective. 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 affecting 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, and sale of circumvention devices. Proposals have been put forward in the National Congress to amend existing statutes and introduce more robust measures—including in 2021—but, overall, no meaningful action has taken place regarding the existing DRM and TPM legal framework over the course of the Index. This remains a key weakness in Chile's copyright environment. As noted in the Index, this does not mean that no positive developments have occurred over the past 20 years. On the contrary, the past few years have also seen the enactment of several new laws seeking to improve Chile's criminal enforcement environment, including with respect to IP rights.

Although positive, a new signal piracy law enacted in 2018 did not address the issue of circumvention devices. Similarly, the *Ley Corta de INAPI* reform package—in force since 2022—as well as the enactment of Laws 21,426, 21,577, and 21,595 (aimed at combating organized crime and illicit trade, including counterfeit goods) have helped strengthen Chile's IP enforcement environment. Although these efforts are welcomed and may over time help improve the copyright enforcement environment specifically, piracy data suggests that Chile continues to suffer from high rates of copyright infringement. The regional industry association ALIANZA (*Contra La Piratería Audiovisual*) periodically releases statistics on copyright piracy rates for the Latin American region. As of Q4 2023, an estimated 41.4% of Chilean households were consumers of online piracy. Unfortunately, this is not a one-off. Rates of piracy consumption have remained elevated in Chile over the past five years. For example, a 2020 study by the British research consultancy and web monitoring firm Muso found 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 was 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 was almost double: 95 visits per person in Chile versus 58 visits per person in Brazil. The Index will continue to monitor Chile's efforts at reforming its copyright environment in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer:

In April 2024, the government presented the National Congress with a legislative proposal for a new national technology transfer framework. The draft bill (16686-19) would introduce several important changes to Chile's R&D ecosystem and the technology transfer and commercialization process, IP rights included. Technology transfer is a critical mechanism for commercializing and transferring research from public and governmental bodies to private entities for the purpose of developing usable and commercially available technologies. Technology transfer activities based on academic-industry and public-private sector collaborations provide a significant and distinct contribution to the economic strength and well-being of economies in which such activities take place. The process enables public research institutions to obtain access to commercial research funds, state-of-the-art equipment, and leading-edge technologies, while allowing industry to benefit from the extensive knowledge and ingenuity of academic researchers. In the United States, the Patent and Trademark Law Amendments Act of 1980—commonly referred to as the Bayh-Dole Act—and the Stevenson-Wydler Technology Innovation Act have been instrumental in incentivizing technology transfer. These laws give institutions that receive federal support (such as American universities, small businesses, and nonprofits) control and the rights to any resulting intellectual property of their inventions or research. Studies have found a significant correlation in increased patenting activities at American universities after the legislation. The importance of the Bayh-Dole framework to building the modern U.S. innovation and R&D ecosystem cannot be overstated: its positive impact extends to the broader U.S. economy, exports and the development of U.S. international technological leadership.

Many Index economies have over the past two decades introduced similar technology transfer frameworks and have reaped the accompanying socioeconomic rewards. In Chile, the draft legislation seeks to promote the commercialization of publicly funded research through the greater use of IP rights to create and commercialize new IP assets. On a positive note, the draft law would make it easier for academic and public sector researchers to participate in the commercialization process, including in the development and management of spin-off companies. Less clear are other provisions of the bill. For instance, under draft Article 6, the bill would establish a new “National Repository of Scientific and Technological Knowledge and Information.” This repository would require researchers with government funding to deposit their final research and any “data associated” with the repository within 60 days of completion. Under Article 7, the law would support what is termed “open science” through promoting “open access to scientific publications, data and codes linked to said activity.” It remains unclear how the repository and the goals of furthering open access to scientific research and data will, first, operate in practice and, second, be compatible with the overarching goals of commercialization through the greater use of IP rights and the licensing of IP assets. The Index will monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

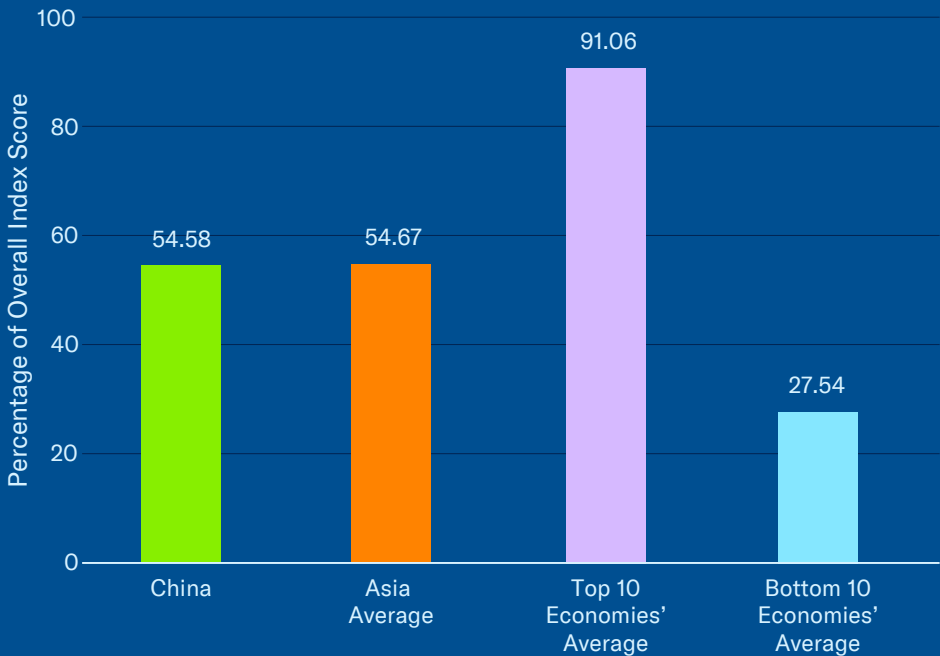
The 2015 Law 20,850 (*Ley Ricarto Soto*) introduced a national definition and framework for covering high-cost medicines, including for many rare diseases. The law does not include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.



Category Scores



Overall Score in Comparison





Key Areas of Strength

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

Key Areas of Weakness

- New Implementing Regulations and Patent Examination Guidelines make pharmaceutical patent term restoration contingent on the first global launch taking place in China; all but negates the practical availability of term restoration to most innovators
- No special IP incentives for orphan medicinal product development
- Despite 2019–2020 positive changes on tech transfer and licensing, continued challenges exist with respect to technology transfer and licensing environment for SEPs; growing trend of rightsholders facing global anti-suit injunctions and restrictions on their ability to assert infringement claims in legal jurisdictions outside China
- 2022 Anti-Monopoly Law greatly expands the government's basis for action against anti-competitive behavior and substantially increases fines and penalties. Finalized 2023 rules contain not only broad and vague language on what constitutes anti-competitive behavior within an IP rights context but also vest considerable discretion with the anti-competition authorities in identifying and defining such behavior
- Uncertainty over 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	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.25
2. Patentability requirements	0.75	30. IP as an economic asset	0.75
3. Patentability of CII	1.00	31. Tax incentives for the creation of IP assets	0.33
4. Plant variety protection	0.78	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.00
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.34
7. Pharmaceutical patent term restoration	1.00	34. Civil and precedural remedies	0.50
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.50
9. Patent opposition	0.25	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	0.00
10. Term of protection	0.53	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	0.75	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	0.50	40. Consultation with stakeholders during IP policy formation	0.50
14. Limitations and exceptions	0.25	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.75	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.50
21. Industrial design term of protection	0.60	24. Protection of trade secrets (criminal sanctions)	0.25
22. Exclusive rights, industrial design rights	0.25	25. Regulatory data protection term	0.60
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	0.25	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	0.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
28. Registration and disclosure requirements of licensing deals	0.00	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
		51. Membership of the Convention on Cybercrime, 2001	0.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 54.58%

Total Score: 28.93

Spotlight on the National IP Environment

Past Editions versus Current Score

China's overall score remains unchanged at 28.93 out of 53 indicators.

Area of Note

In May 2024, an intragovernmental committee released a “Plan for Promoting the Construction of a Powerful Intellectual Property Country.” The plan consists of 100+ action items including legislative reforms, the incorporation of new technologies (such as AI) in IP registration and operations, and increased public awareness and usage of the IP system. At the time of research, no further details had been published. The Index will monitor these developments in 2025.

Patent Rights and Limitations; and Trade Secrets and the Protection of Confidential Information

7. Patent term restoration for pharmaceutical products; and 25. Regulatory data protection (RDP) term:

As noted over the past two editions of the Index, in 2020, new 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.

In December 2023, Implementing Regulations were released together with updated Patent Examination Guidelines. Unfortunately, these regulations and guidelines make term restoration contingent on the first global launch taking place in China. This stands in stark contrast to international best practices, where “new” biopharmaceutical products are defined as those newly approved for that individual market.

Given that most innovative medicines are first launched outside of China, this requirement all but negates the practical availability of term restoration to most innovators. At the time of research, no revisions or updates to the published regulations had been proposed. Should the Chinese authorities take no action and the regulations remain unchanged, the score for indicator 7 will be reduced to 0. Similarly, should this definition of “new” become the norm and apply to other biopharmaceutical IP rights, including RDP, this will also result in a score reduction for indicator 25. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct Government intervention in setting licensing terms:

In 2024, several judicial and legal developments took place in China's technology transfer and licensing environment. As detailed across several editions of the Index, rightsholders have historically faced a growing number of regulatory and procedural barriers that impede technology flows, R&D cooperation, and digital trade. This changed in 2019–2020 as a direct result of the negotiations and conclusion of the “Economic and Trade Agreement Between the Government of the United States and the Government of the People's Republic of China” with several significant and positive changes to China's technology transfer and licensing environment. 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.

In 2021, a new Civil Code came into effect, which also included specific provisions related to technology transfer and contract law in a dedicated chapter, Chapter 20. As noted at the time in the Index, these changes held 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. To begin with, the past few years have seen a growing trend of rightsholders facing global anti-suit injunctions and restrictions on their ability to assert infringement claims in legal jurisdictions outside China. Chinese courts have increasingly claimed global jurisdiction to set global licensing rates for technologies protected by Standard and Essential Patents (SEPs), threatening exorbitant fines and withholding access to the Chinese market to prevent foreign patentholders 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. In January 2025, the EU filed an additional request for consultations again highlighting Chinese courts' practice of setting globally binding licensing terms, including royalty rates. The request rightly emphasizes how such practices are inconsistent with China's obligations under the TRIPS Agreement. At the time of research, a WTO dispute panel had been established and was reviewing the case.

In 2023 and 2024, there were further important judicial developments relating to SEPs and the setting of royalty rates. In late 2023, the First Intermediate People's Court of Chongqing Municipality, in an unprecedented judgment, set global rates for the licensing of SEPs in the case of *Oppo v. Nokia*. Separately, in early 2024, the Supreme People's Court in *ACT v. Oppo* did not seek to set a global licensing rate but instead confined its judgment to the Chinese market. On the legislative side, in the past few years, several major developments have also occurred related to technology transfer. Most importantly in 2022, China enacted a new Anti-Monopoly Law (AML). The AML greatly expands the government's basis for action against anti-competitive behavior and substantially increases fines and penalties. 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 over the past two years in the Index, just like the underlying legislation, this rule considerably expanded the powers of investigation, punishment, and meaning of what constitutes anti-competitive behavior within the context of the exercise of IP rights. This rule came into effect in 2023. Unfortunately, although maintaining some moderate safeguards against potential overreach, the finalized version of the rule did not materially improve the preceding draft. It, too, contains the same broad and vague language on what constitutes anti-competitive behavior within an IP rights context and vests considerable discretion with the anti-competition authorities in identifying and defining such behavior.

Separately, in 2023, the Chinese anti-competition authority (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, interventionist footsteps of both the AML and the “Provisions on Prohibiting Abuse of Intellectual Property Rights to Exclude and Restrict Competition.” In late 2024, SAMR published a finalized document. Although different in important respects from the preceding draft guidance, overall, this document preserves the growing interventionism of Chinese antitrust policy. 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, AI, 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 as well as a concomitant increase in the number of potential legal disputes that could hold up the development and use of these new technologies and industries. However, disputes between licensors and licensees on what constitutes fair, reasonable, and non-discriminatory licensing terms are not new or unique to China. This is an evolving field of IP policy and jurisprudence for a subject matter that is deeply complex. Each licensing negotiation is unique and should not be subject to prescriptive government action or intervention, whether through direct or indirect pressure. Unfortunately, neither the AML, 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. Subsequent government actions have not fundamentally changed this approach. For example, as a follow-up to the AML, in June 2024, the State Council issued National Decree 793, the Fair Competition Review Regulations. These regulations set out the way all levels of government in China should promote and actively encourage fair competition across the entire economy.

On a positive note, Articles 8 and 9 limit localization efforts and explicitly eliminate the discrimination of foreign or imported goods. However, Article 12 all but nullifies the preceding provisions by allowing competition to be restricted or eliminated “to promote scientific and technological progress and enhance the country’s independent innovation capabilities.”

In the same month, the Supreme People’s Court released its view of the AML through the “Interpretation of the Supreme People’s Court on Several Issues Concerning the Application of Law in the Trial of Civil Disputes over Monopoly.” The interpretation provides some specific references to the handling of IP rights and related disputes, including in relation to the analysis of a dominant position, unfair competition practices, and potential abuse of IP rights. Should rightsholders continue to face challenges in asserting their rights on fair, nondiscriminatory, and equal terms—whether through the Chinese judiciary or administratively through the expanded powers given the anti-competition authorities in the AML and accompanying rules—this will result in a sharp score decrease in 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 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Since 2012, a range of laws, policies, and initiatives have been launched by the central government to improve patient access to care and treatment.

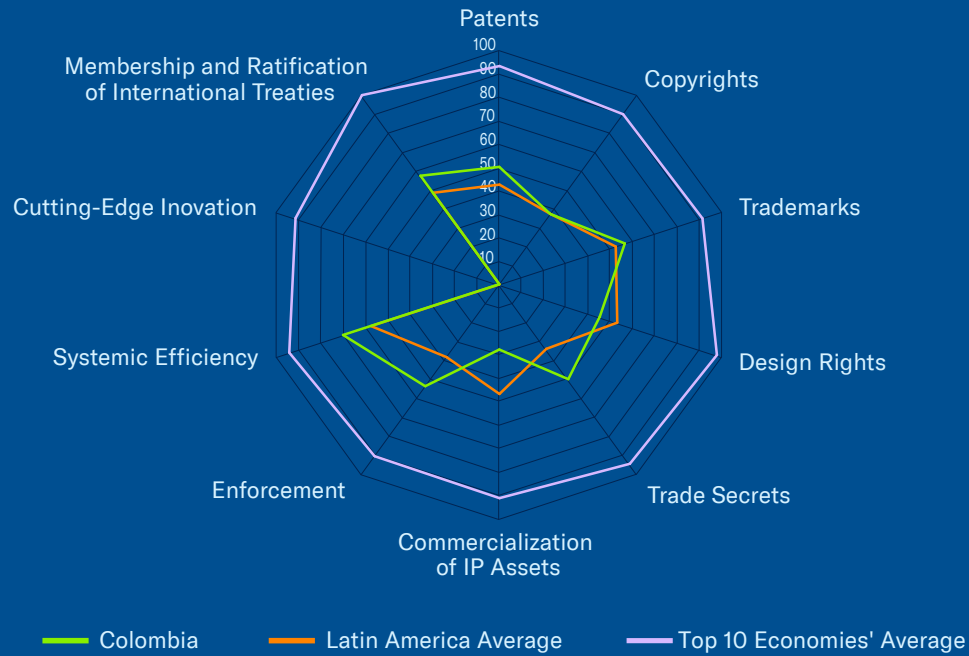
This includes policies accelerating the sanitary registration for qualifying products, protocol assistance, and clinical trial exemptions. With respect to incentives to R&D and the development of new treatments and technologies, the 2022 draft Implementing Regulations of the Drug Administration Law (published by Chinese drug regulatory authority National Medical Products Administration) included a designated market exclusivity period for orphan drugs. Specifically, Article 29 of the draft regulations provided a seven-year period of orphan drug market exclusivity. At the time of research, the regulations were still in draft form and had not taken effect.



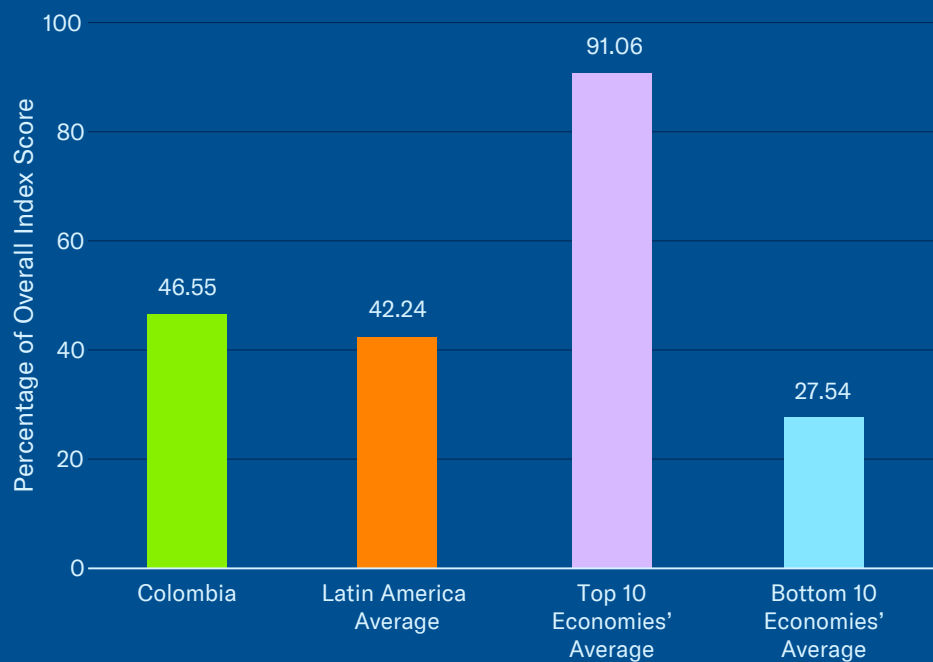
Colombia

Rank
33/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- 2024 judgment ordered the disabling of access to several copyright-infringing websites, including SkyLatinaTV, and included a dynamic element
- Stronger copyright enforcement efforts through DNDA injunctive-style relief action against online piracy
- Acceded to the Convention on Cybercrime in 2020
- 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 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 raise public and stakeholder engagement in IP policymaking and education

Key Areas of Weakness

- 2024 compulsory license issued for the HIV/AIDS treatment dolutegravir
- No special IP incentives for orphan medicinal product development
- 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 about the availability of RDP for biopharmaceuticals
- Inadequate and delayed prosecution of and penalties for IP infringement

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	4.50	29. Direct government intervention in setting licensing terms	0.00
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	0.50	31. Tax incentives for the creation of IP assets	0.67
3. Patentability of CILs	0.50	Category 7: Enforcement	3.76
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.49
5. Pharmaceutical-related enforcement	0.25	33. Software piracy rates	0.52
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precedural remedies	0.50
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.50
8. Membership of a Patent Prosecution Highway	1.00	36. Criminal standards	0.50
9. Patent opposition	0.25	37. Effective border measures	0.75
Category 2: Copyrights and Limitations	2.59	38. Transparency and public reporting by customs	0.50
10. Term of protection	0.84	Category 8: Systemic Efficiency	3.50
11. Exclusive rights	0.25	39. Coordination of IP rights enforcement	0.50
12. Expeditious legal remedies disabling access to infringing content online	0.50	40. Consultation with stakeholders during IP policy formation	0.75
13. Cooperative action against online piracy	0.00	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
15. TPM and DRM	0.25	43. IP-intensive industries, national economic impact analysis	0.50
16. Government use of licensed software	0.50	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.25	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.50	Category 10: Membership and Ratification of International Treaties	4.00
20. Frameworks against online sale of counterfeit goods	0.25	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	0.90	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.40	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	0.50	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.50	51. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.50	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.50	53. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.50		
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		

Percentage of Overall Score: 46.55%

Total Score: 24.67

Spotlight on the National IP Environment

Past Editions versus Current Score

Colombia's overall Index score has increased from 24.42 out of 50 indicators in the twelfth edition to 24.67 out of 53 indicators. This reflects a score increase for indicator 12.

Patent Rights and Limitations

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

In April 2024, the Colombian Government through the Department of Industry and Commerce, SIC (*Superintendencia de Industria y Comercio*), granted to the Ministry of Health a compulsory license for the HIV/AIDS treatment dolutegravir. As noted last year, the issuing of the license is based on a Ministry of Health Resolution and public interest request from June 2023. As detailed over the course of the Index, Colombia has moved in a decidedly negative direction on the issue of compulsory licenses. Up until the mid-2010s, the imposition and discussion of compulsory licensing for biopharmaceuticals had not been a recurring issue in Colombia. But over the past 10 years, the government has used compulsory licenses as a health policy tool to contain pharmaceutical expenditure. 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 the subsequent General Council decision concerning Paragraph 6. The provision allows Colombian authorities to define public health emergencies broadly and to actively seek compulsory licenses, allowing for grounds outside extreme circumstances, including industrial or commercial objectives, to play a role in the issuing of compulsory licenses.

In 2016, the Ministry of Health and the Colombian government actively considered issuing a compulsory license 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 of 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 was 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 in light of 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, instead simply identifying the whole class of products.

In 2020, the government issued Decree 476 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 granted 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, the decree had the same practical impact of eliminating rightsholders’ ability to freely use a granted exclusivity right.

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 intended to address the complex issue of securing biopharmaceuticals and medical supplies during an international health emergency, it also included an exceptionally broad basis for the overriding of IP rights through both automatic compulsory licenses for health technology goods deemed “essential” and the suspension of any and all IP rights through executive fiat. These negative developments were followed by the issuing of the compulsory license for the HIV/AIDS treatment dolutegravir in 2024. Much of the logic in the SIC’s resolution and the underlying request from the Ministry of Health is based on the perceived high cost of dolutegravir. But 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.

Colombia is not a least developed country (as defined by the UN) or a low-income economy as defined by the World Bank’s lending categories. In fact, the World Bank classifies Colombia as an upper-middle-income economy. The latest available figures on national output from the World Bank show that Colombia had a GDP per capita at purchasing power parity of \$21,548 in 2023. This was higher than that of Brazil (\$20,584) and just under the average for the region (\$21,823) and other upper-middle-income economies (\$23,158). In contrast, least developed countries had an average per capita GDP of \$4,215, and low-income economies had an even lower average of \$2,398.

Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratory, research facilities, and researchers are high. Tufts University research from 2016 suggests that it costs \$2.6 billion, on average, to develop a new drug. International experience and the basic economics of the biopharmaceutical industry show how critical IP rights are to incentivize and support this R&D of new medical technologies and products. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market entrants who bore none of the costs of early-stage investment, R&D, and product commercialization.

Many drugs and therapies, including for HIV/AIDS, may not have been discovered without the legal rights provided to innovators through IP laws. Undermining these incentives through compulsory licensing as a cost containment tool hollows out Colombia's national IP environment and any incentives for future biopharmaceutical innovation. More broadly, the overriding of biopharmaceutical IP rights based on cost and price negotiations sets a wholly negative precedent that may be applied to other industries and sectors.

Copyrights and Limitations

12. Expeditious legal remedies disabling access to infringing content online:

In 2024, potential breakthrough developments occurred in Colombia with respect to the enforcement of copyright. In May 2024, a precedent-setting judgment ordered the disabling of access to several copyright infringing websites—including SkyLatinaTV—and included a dynamic element. The granting of this order is potentially of real significance in Colombia because the judgment not only affirmed the right to injunctive relief online but also included the dynamic element and ability to quickly update the order without having to restart legal proceedings. This judgment was followed up by a September 2024 order disabling access to the IPTV websites Latinos IPTV and Redcol IPTV. These 2024 orders come on the heels of a 2021 case whereby the National Directorate of Copyright (DNDA) ordered the disabling of online access to copyright-infringing material in two separate cases: the first case concerned the unauthorized publication of a scientific journal article, and the second case concerned the unauthorized broadcasting and dissemination of copyrighted audiovisual content through a local company IPTV Colombia Premium. Despite these positive developments, as has been detailed in past editions of the Index, overall, the copyright framework in Colombia remains rudimentary.

Colombian copyright law has historically not included reference to or recognized the unique challenges that digital and online piracy pose. The U.S.-Colombia FTA provides for a notice-and-takedown regime similar to the framework under the U.S. Digital Millennium Copyright Act. Despite this long-standing treaty obligation, no law introducing such a framework has to date been passed. As a result, the piracy of audiovisual content represents a major challenge to rightsholders in Colombia. 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 in 2019. The study found that the total pirated or unreported market in Colombia was between 26% and 45% of the total number of potential end users. It is hoped that injunctive-style relief and the disabling of access to websites offering access to copyright-infringing material, in particular the dynamic element, will now be available to rightsholders more broadly and will provide a clear and expeditious path for creators to effectively enforce their rights in Colombia. As a result of these positive developments in 2024, the score for this indicator has increased by 0.25.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

The 2010 Law 1392 introduced a national legal framework and definition of rare diseases, including the right to comprehensive health care.

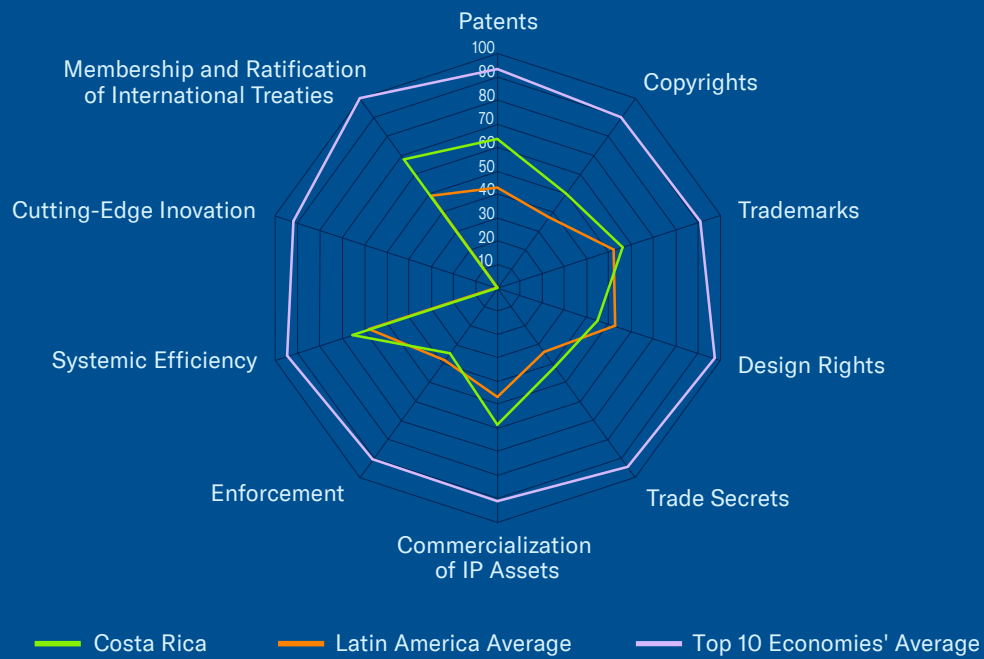
Subsequent implementing regulations have established and defined a national list of approved rare diseases (Resolutions 3681, 2048, and 123). Article 11 of Law 1392 includes reference for the need to encourage and incentivize research into “early diagnoses and possible medications, preventive treatments, psychological and psychiatric aspects associated with these diseases, not only from the point of view of the patients but also from that of their families.” Similarly, Decree 481 of 2004 (which defines “vital” medicines to the Colombian health system) seeks to incentivize research and development. In 2024, the Ministry of Health published a national plan for rare diseases and orphan drugs (*Plan Nacional de Gestión para las Enfermedades Huérfanas/Raras*). Detailing the health needs of the rare disease community, this document also refers to and seeks to promote research on rare disease and orphan drugs in Colombia. However, none of these legislative or regulatory initiatives include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.



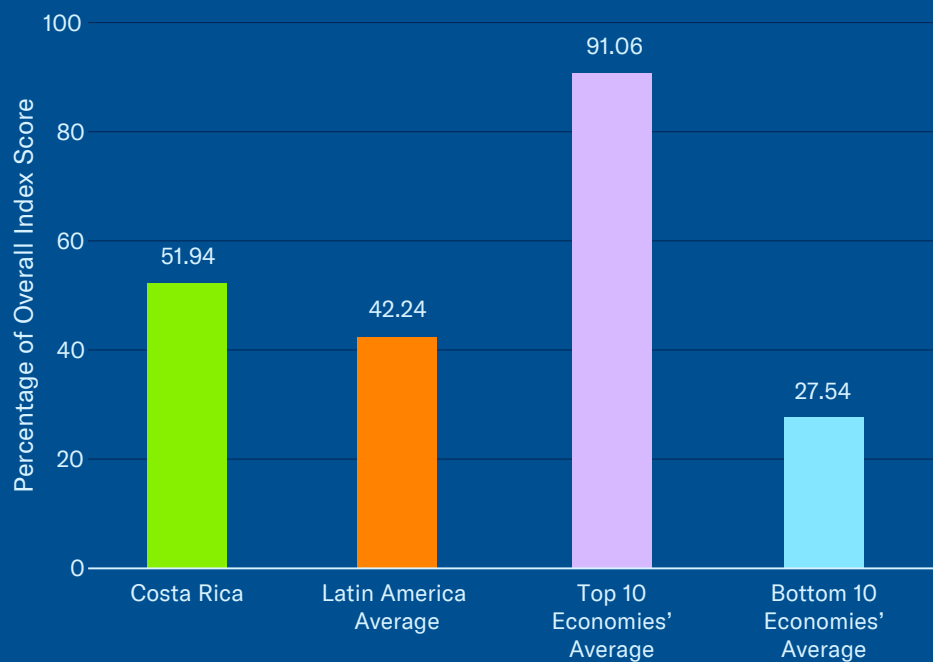
Costa Rica

Rank
27/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Launch of IP technical assistance programs for SMEs in 2023
- Implementation of software management tools for public sector; addresses long-standing issue of the use of unlicensed software
- Expanded support for awareness raising and IP rights educational activities
- Member of the regional PROSUR PPH initiative
- Patent framework in line with international standards, with some exceptions
- Some elements of an advanced online copyright regime in law
- Customs authorities empowered to address various types of infringing goods *ex officio*

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- No significant R&D or IP-based tax incentives are in place
- Delays and significant lack of implementation of online copyright regime
- Gaps exist in effectiveness of life sciences IP rights
- System of enforcement of IP rights is slow and lacks effectiveness
- Inadequate penalties for IP infringement

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.50	30. IP as an economic asset	0.50
3. Patentability of CILs	0.75	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.25	32. Physical counterfeiting rates	0.49
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.42
7. Pharmaceutical patent term restoration	0.48	34. Civil and precluded remedies	0.25
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.50
9. Patent opposition	0.25	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	0.50
10. Term of protection	0.74	38. Transparency and public reporting by customs	0.00
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expedient legal remedies disabling access to infringing content online	0.25	39. Coordination of IP rights enforcement	0.50
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	0.50
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	1.00	43. IP-intensive industries, national economic impact analysis	0.50
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 10: Membership and Ratification of International Treaties	
Category 4: Design Rights and Limitations		47. WIPO Internet Treaties	1.00
21. Industrial design term of protection	0.40	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
22. Exclusive rights, industrial design rights	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
Category 5: Trade Secrets and the Protection of Confidential Information		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
23. Protection of trade secrets (civil remedies)	0.50	51. Membership of the Convention on Cybercrime, 2001	1.00
24. Protection of trade secrets (criminal sanctions)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
25. Regulatory data protection term	0.50	53. Post-TRIPS FTA	1.00
Category 6: Commercialization of IP Assets			
26. Barriers to market access	0.75		
27. Barriers to technology transfer	0.50		
28. Registration and disclosure requirements of licensing deals	0.75		

Percentage of Overall Score: 51.94%

• Total Score: 27.53

Spotlight on the National IP Environment

Past Editions versus Current Score

Costa Rica's overall Index score has increased from 27.52 out of 50 indicators in the twelfth edition to 27.53 out of 53 indicators. This reflects a score increase for indicator 32.

Copyrights and Limitations

16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software:

As noted in previous editions, there has historically been a degree of uncertainty with respect to how the Costa Rican Government monitors and ensures that individual ministries and agencies maintain and use only licensed software. The 2012 Executive Decree No. 37549-JP states clearly that all central government ministries and agencies have an obligation to ensure that all software—whether proprietary or open source—used on public ICT systems should be fully licensed. Article 2 establishes that each relevant ministry should “establish systems and controls to guarantee the use in their computers, solely and exclusively, of those computer programs that comply with the corresponding copyright,” audit this system regularly, and record the “results of the inventory of equipment and licenses acquired.” Up until 2020, only partial evidence showed that relevant government institutions were effectively monitoring the application of these requirements. Some government agencies had published the results of internal software audits, but there was no corresponding government-wide systemic effort.

In its 2019–2020 annual report, *Informe de Labores 2019-2020*, the National Registry Office outlined the basis for a new automated registration, compliance, and software asset management platform, *El sistema de legalización de software*.

This web portal 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. As noted in the ninth edition of the Index, the launch of this platform in 2021 was a positive step and, as a result, Costa Rica's score for this indicator increased by 0.5. However, the U.S. government has over the past year reported that the results of these software audits have not been published or otherwise made publicly available. Consequently, it remains unclear, not only the extent to which ministries and government agencies are using licensed software but also what, if anything, is being done to address any potential government use of unlicensed software. At the time of research, no report on the results of these audits had been made available to the public. The Index will continue to monitor this in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

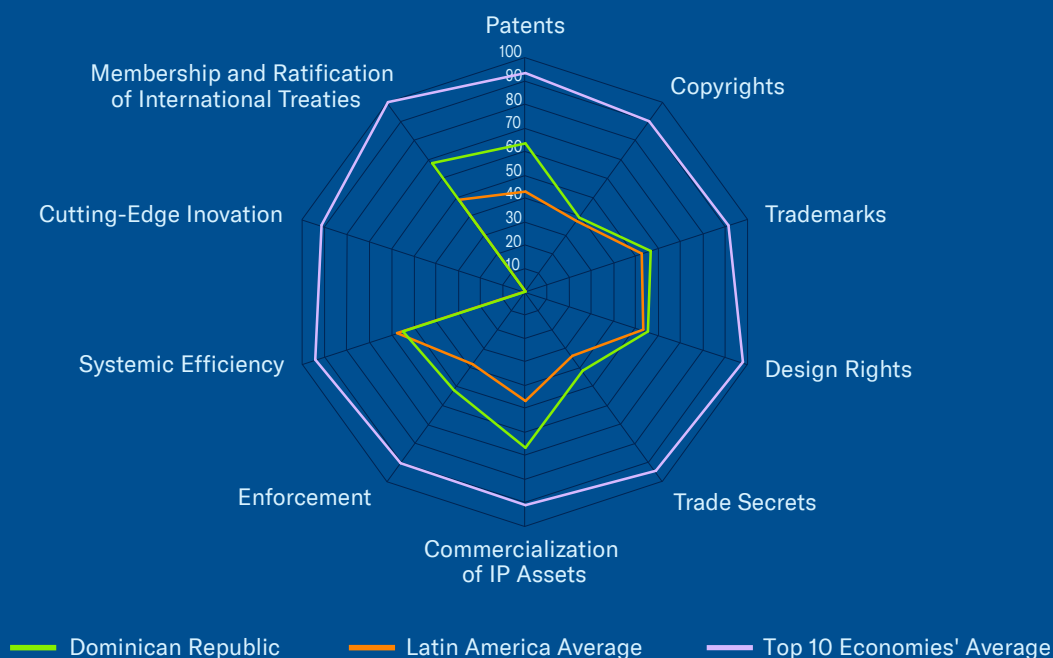
Interest in rare diseases has grown in Costa Rica. In 2022, a draft rare disease law was introduced in the Legislative Assembly (No. 23,257). This draft bill would create a national registry of rare diseases and a national treatment center, provide special funding for therapies and care, and seek to stimulate new R&D and innovation in Costa Rica. At the time of research, the bill had been reintroduced in the 2024 session. The bill does not propose putting in place any special IP-based market exclusivity incentives for orphan medicinal product development.



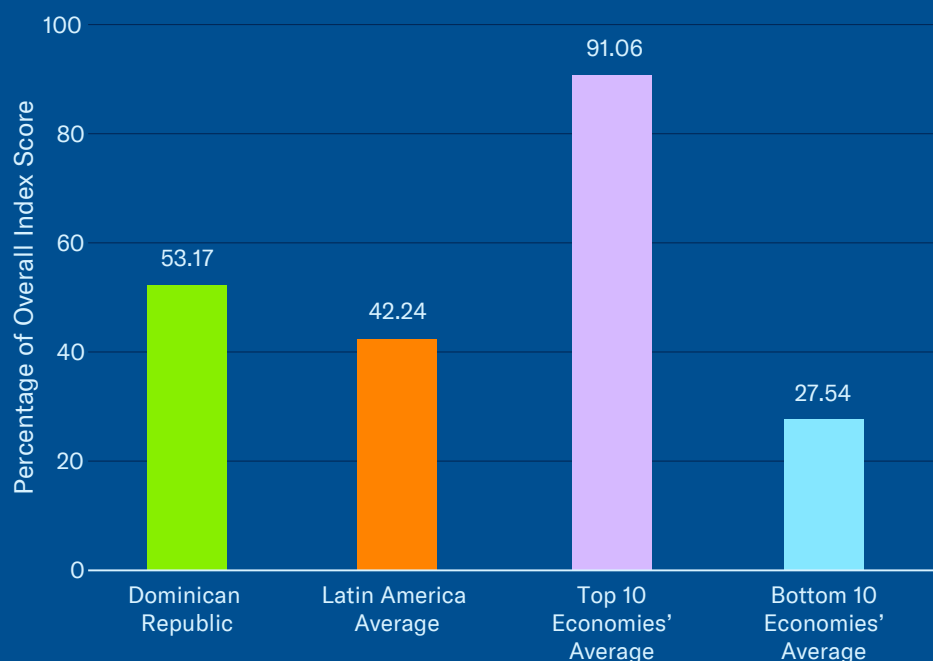
Dominican Republic

Rank
26/55

Category Scores



Overall Score in Comparison





Dominican Republic

Rank
26/55

Key Areas of Strength

- 2024 saw the National Inter_Ministerial Council of Intellectual Property take enforcement action against IP piracy
- 2023 saw the launch of a new IP enforcement coordinating body of the National Inter_Ministerial Council of Intellectual Property
- 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
- Fairly strong legal requirements and administrative practices on public consultations

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Patentability standards outside international norms—no second use claims for biopharmaceuticals and virtually no patent protection for CIIIs
- RDP term not being granted although required by law
- Enforcement of copyright is highly challenging and is one of the main reasons the Dominican Republic has remained on the USTR's 301 Watch List for years
- Infringement of copyright through signal piracy, online, and web-based streaming is highly pervasive and constitutes a major source of illegal content—not effectively addressed by 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	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.25	30. IP as an economic asset	0.75
3. Patentability of CILs	0.25	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00		
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.39
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.25
7. Pharmaceutical patent term restoration	0.70	34. Civil and precluded remedies	0.50
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.50
9. Patent opposition	0.50	36. Criminal standards	0.75
		37. Effective border measures	0.50
Category 2: Copyrights and Limitations		38. Transparency and public reporting by customs	0.75
10. Term of protection	0.74		
11. Exclusive rights	0.25	Category 8: Systemic Efficiency	
12. Expedient legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	0.75
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.50
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	0.25
Category 3: Trademarks Rights and Limitations			
17. Term of protection	1.00	Category 9: Cutting-Edge Innovation	
18. Protection of well-known marks	0.50	44. IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.50	45. IP incentives for orphan medicinal product development, term of protection	0.00
20. Frameworks against online sale of counterfeit goods	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
Category 4: Design Rights and Limitations			
21. Industrial design term of protection	0.60	Category 10: Membership and Ratification of International Treaties	
22. Exclusive rights, industrial design rights	0.50	47. WIPO Internet Treaties	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
23. Protection of trade secrets (civil remedies)	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
24. Protection of trade secrets (criminal sanctions)	0.25	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
25. Regulatory data protection term	0.50	51. Membership of the Convention on Cybercrime, 2001	1.00
Category 6: Commercialization of IP Assets		52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
26. Barriers to market access	1.00	53. Post-TRIPS FTA	1.00
27. Barriers to technology transfer	0.75		
28. Registration and disclosure requirements of licensing deals	0.50		

Percentage of Overall Score: 53.17%

Total Score: 28.18

Spotlight on the National IP Environment

Past Editions versus Current Score

The Dominican Republic's overall Index score has increased from 27.65 out of 50 indicators in the twelfth edition to 28.18 out of 53 indicators. This reflects score increases for indicators 32, 36, and 39.

Patent Rights and Limitations

8. Membership of a Patent Prosecution Highway (PPH):

The Dominican Republic is not a participant in the IP5 PPH nor a member of the Global PPH. The Dominican Republic is, however, a member of an operational PPH program through the Latin American Regional Cooperation System on Industrial Property, PROSUR. In a positive development, in 2024, the National Office of Industrial Property concluded an “Accelerated Patent Grant” agreement with the USPTO. The grant program allows applicants who have been issued a U.S. patent to apply for a grant of a corresponding application in the Dominican Republic without the need for substantive examination. At the time of research, the agreement had come into effect and would remain operational for five years. PPH initiatives and increased cooperation among IP offices is one of the most tangible ways in which the administration and functioning of the international IP system can be improved and harmonized to help inventors and rightsholders.

Enforcement and Systemic Efficiency

36. Criminal standards, including minimum imprisonment and minimum fines; and 39.

Coordination of IP rights enforcement:

As noted in previous editions, the past few years have seen several positive developments in IP enforcement culminating in the USTR removing the Dominican Republic from its Special 301 Watch List in 2024. In 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*). 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. This has now changed with the Council entering its third year of operations.

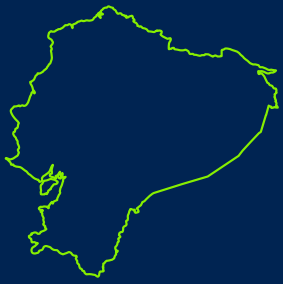
Data published by the Council and Ministry of Industry, Trade, and MSMEs shows increased on-the-ground enforcement activities in both 2023 and 2024. For example, in the Council's annual report for 2023 activities, a total of 250 cases were investigated by the Attorney General's Office of Intellectual Property Unit. The report also lists the total number of counterfeit seizures and enforcement activity taken against signal piracy by the Dominican Institute of Telecommunications (INDOTEL). As has been noted repeatedly in the Index, the infringement of copyright through signal piracy, online and web-based streaming is highly pervasive and constitutes a major source of illegal content in the Dominican Republic. INDOTEL is reported to have seized and closed illegal operators of sound and broadcasting services and to have issued administrative sanctions against others.

Similarly, 2024 saw several high-profile enforcement actions organized by the Council together with other enforcement bodies, including the Ministry of Defense. This includes the seizure and destruction of 10 million units of counterfeit and/or illicit tobacco, medicines, alcohol, and other goods. These are positive and sustained efforts by the Dominican authorities to tackle the long-standing problems of copyright piracy and counterfeit goods. As a result, the score for indicators 36 and 39 have increased by 0.25, respectively.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

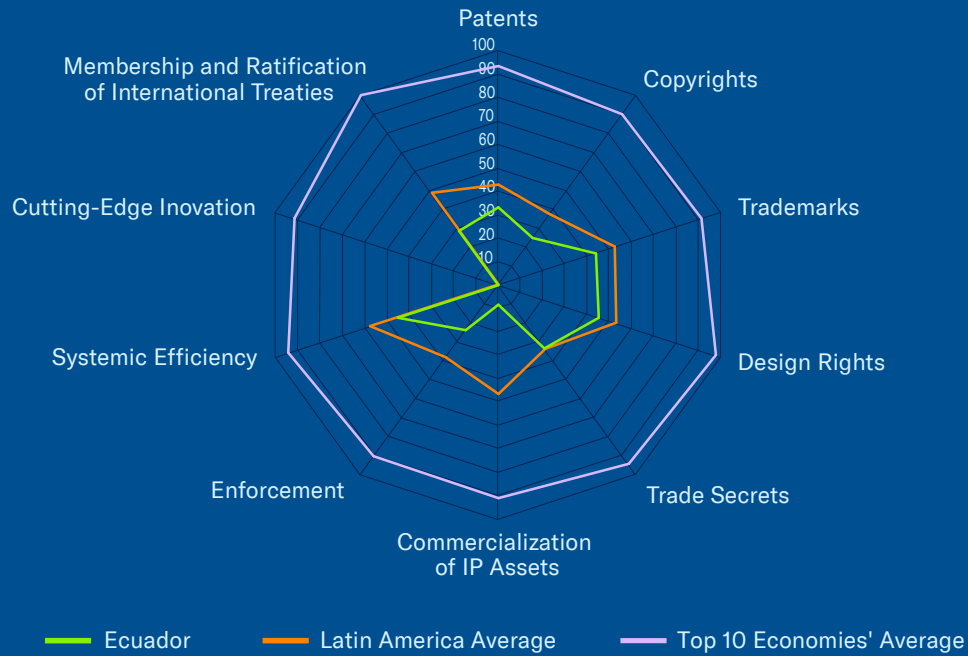
Interest in rare diseases has grown in the Dominican Republic. Several patient groups and clinicians are highlighting the needs of patients with rare diseases, including the Dominican Alliance of Patient Associations (Adapa), which has developed a draft legislative package. There is currently no specific legislative framework in place in the Dominican Republic for rare diseases, a national registry, or special IP-based market exclusivity incentives for orphan medicinal product development.



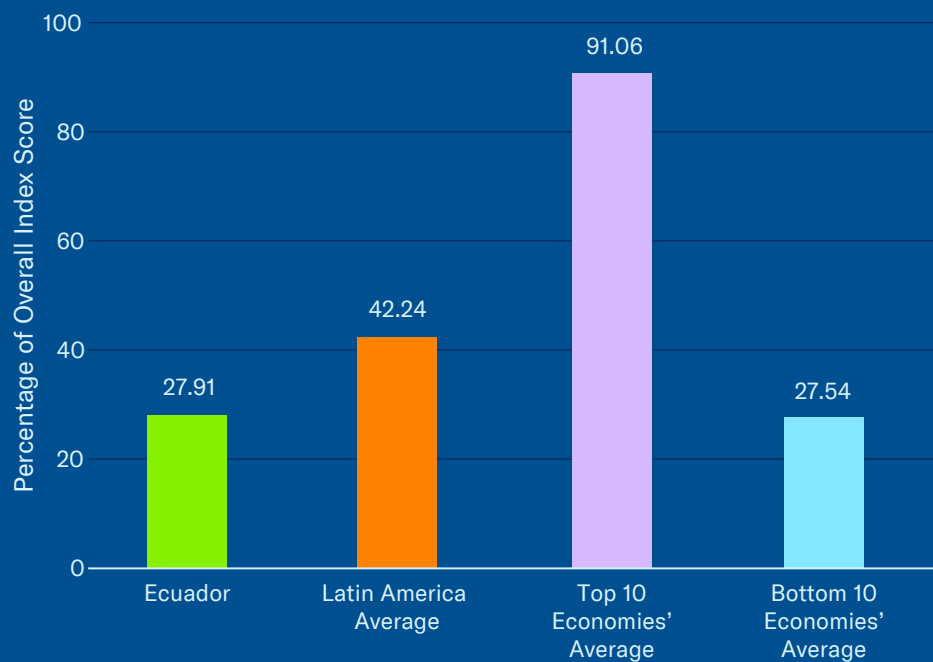
Ecuador

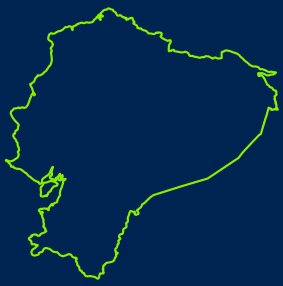
Rank
51/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Strengthened support for SMEs through 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 law *Código Ingenios*
- Limited re-criminalization of IP rights through 2016 criminal law amendments
- Member of PPH

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Implementing regulations potentially undermine *Código Ingenios* RDP term of protection
- Plant variety protection term is shorter than internationally accepted term
- 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
- *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 in and ratification of international treaties

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	2.99	29. Direct government intervention in setting licensing terms	0.00
1. Term of protection	1.00	30. IP as an economic asset	0.25
2. Patentability requirements	0.50	31. Tax incentives for the creation of IP assets	0.00
3. Patentability of CILs	0.00	Category 7: Enforcement	1.66
4. Plant variety protection	0.74	32. Physical counterfeiting rates	0.34
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.32
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precluded remedies	0.25
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.25
8. Membership of a Patent Prosecution Highway	0.50	36. Criminal standards	0.25
9. Patent opposition	0.25	37. Effective border measures	0.00
Category 2: Copyrights and Limitations	1.74	38. Transparency and public reporting by customs	0.25
10. Term of protection	0.74	Category 8: Systemic Efficiency	2.25
11. Exclusive rights	0.25	39. Coordination of IP rights enforcement	0.25
12. Expedient legal remedies disabling access to infringing content online	0.25	40. Consultation with stakeholders during IP policy formation	0.25
13. Cooperative action against online piracy	0.00	41. Educational campaigns and awareness raising	0.75
14. Limitations and exceptions	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
15. TPM and DRM	0.25	43. IP-intensive industries, national economic impact analysis	0.25
16. Government use of licensed software	0.00	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	1.75	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.25	Category 10: Membership and Ratification of International Treaties	2.00
20. Frameworks against online sale of counterfeit goods	0.25	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	0.90	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.40	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	0.50	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.00	51. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.50
25. Regulatory data protection term	0.50		
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		

Percentage of Overall Score: 27.91%

• Total Score: 14.79

Spotlight on the National IP Environment

Past Editions versus Current Score

Ecuador's overall score remains unchanged at 14.79 out of 53 indicators.

Enforcement; and Membership and Ratification of International Treaties

37. Effective border measures; and 50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices:

As noted in last year's edition, 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 that "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*, as well as Articles 458 to 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. National customs officers are the first line of defense against the menace of counterfeit goods. It is essential that they can 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 was reduced in last year's edition to 0.

In 2023, Ecuador concluded a new Trade Association Agreement (*Acuerdo de Asociación Comercial*) with Costa Rica. This agreement was ratified by both economies and came into effect in 2024. Chapter 16 of this agreement is dedicated to IP rights. This is a positive feature of the agreement, and both parties should be congratulated for recognizing the importance of IP-intensive industries and the centrality of IP rights to future trade and economic development in all economies. As has been noted in the Index, this is not always the case. Many 21st-century post-TRIPS FTAs do not include a dedicated IP chapter or skirt meaningful provisions on IP rights altogether. Unfortunately, the agreement does 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, 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 Marrakesh, 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 the agreement, there is no reference to patent protection or related rights; copyright provisions are relatively limited with no reference to the challenges that the online environment or infringement represents to rightsholders; and there is no or limited reference to sector-specific provisions, including biopharmaceutical IP rights such as RDP and patent term restoration.

On a positive note, the agreement includes 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. Specifically, Article 16.12(6) states, “Each Party shall provide that the competent authorities are empowered to initiate border measures *ex officio*, without the need for a formal request from the right holder or a third party, when there are reasons to believe or suspect that the goods being imported, exported or in transit are counterfeit or pirated.” Should Ecuador fully transpose and implement this requirement, its score for this indicator would increase. The Index will monitor this in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

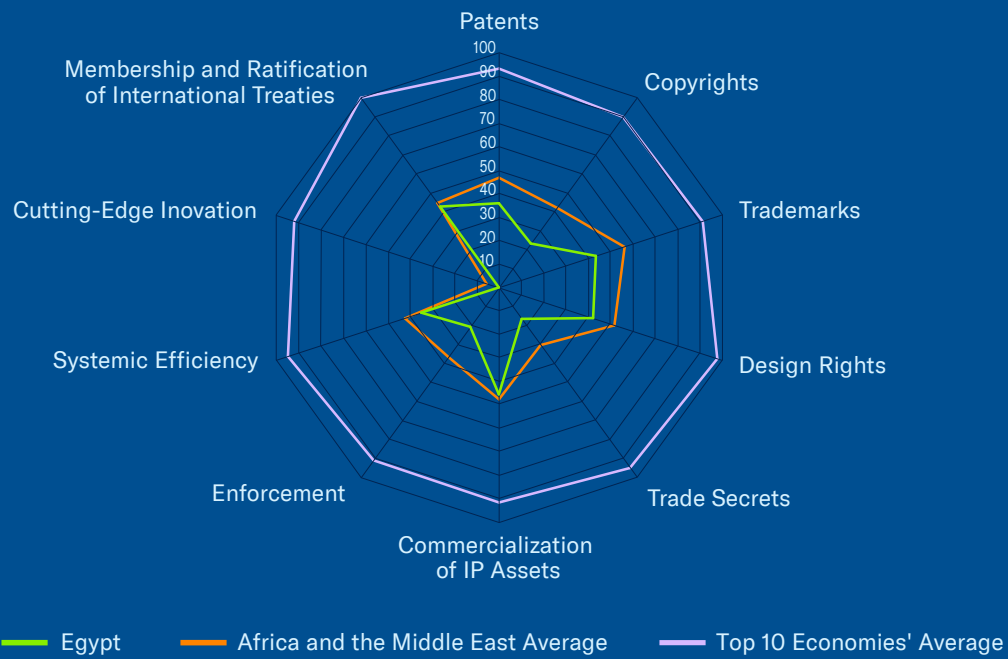
The national health law (Ley 67 *Organica de Salud*) includes five separate articles dedicated to defining the rights of patients with rare diseases and accompanying obligations on behalf of the government and relevant national authorities. Specifically, the law outlines an obligation on the part of the Ministry of Health and related health service authorities to provide for medical treatment, access to medicines, the creation of a national registry, the timely supply and distribution of relevant treatments, and incentives for R&D. The law does not include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.



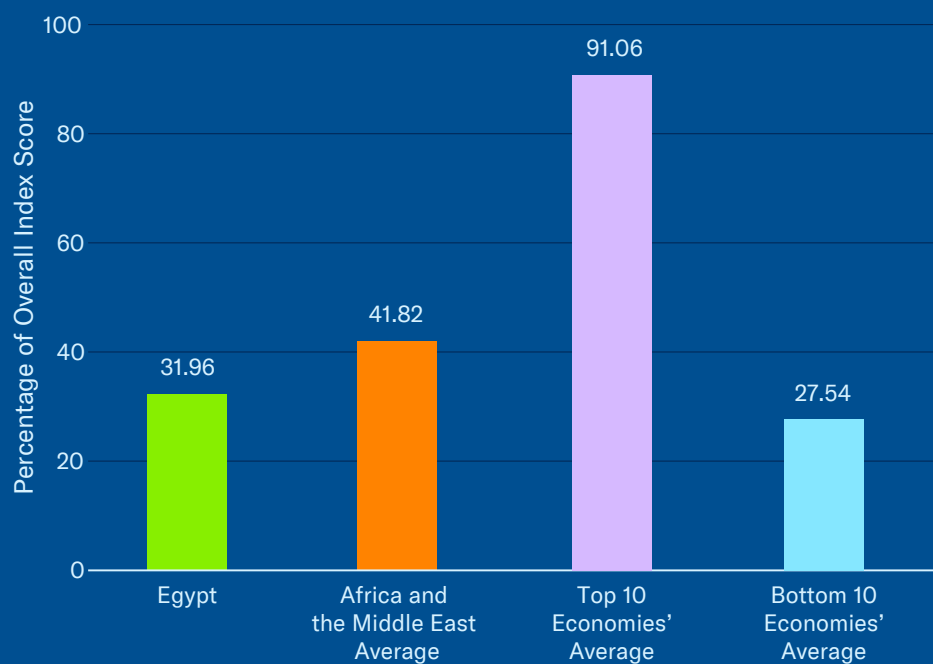
Egypt

Rank
48/55

Category Scores



Overall Score in Comparison





Egypt

Rank
48/55

Key Areas of Strength

- 2023 saw increased copyright enforcement
- Member of the 1991 UPOV agreement
- Since 2015, a PPH has been in place with the JPO
- Relative freedom to patent CILs and support from government agencies
- Relatively strong push from the government to raise awareness of counterfeit products, particularly medicines

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 2020 data protection law will potentially impose new localization requirements
- 2020 compulsory license decree and establishment of new Ministerial Committee with expansive powers to override IP rights
- Limited framework for the protection of life sciences IP rights
- Gaps exist in copyright law and framework, particularly with regard to the protection of online content
- High levels of piracy; BSA estimated a 59% software piracy rate
- Challenging enforcement environment and lack of border measures

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.50
2. Patentability requirements	0.25	30. IP as an economic asset	0.50
3. Patentability of CILs	0.50	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.30
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.41
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.00
9. Patent opposition	0.00	36. Criminal standards	0.50
Category 2: Copyrights and Limitations		37. Effective border measures	0.00
10. Term of protection	0.38	38. Transparency and public reporting by customs	0.00
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.25	39. Coordination of IP rights enforcement	0.50
13. Cooperative action against online piracy	0.00	40. Consultation with stakeholders during IP policy formation	0.25
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.25
15. TPM and DRM	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	0.00	43. IP-intensive industries, national economic impact analysis	0.25
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.25
21. Industrial design term of protection	0.60	24. Protection of trade secrets (criminal sanctions)	0.25
22. Exclusive rights, industrial design rights	0.25	25. Regulatory data protection term	0.00
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	0.75	47. WIPO Internet Treaties	0.00
27. Barriers to technology transfer	0.50	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
28. Registration and disclosure requirements of licensing deals	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	0.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	0.00

Percentage of Overall Score: 31.96%

Total Score: 16.94

Spotlight on the National IP Environment

Past Editions versus Current Score

Egypt's overall Index score has increased from 16.93 out of 50 indicators in the twelfth edition to 16.94 out of 53 indicators. This reflects a score increase for indicator 32.

Area of Note

As noted last year, in a positive development, the government established the Egyptian Intellectual Property Authority (EIPA). The launch of the EIPA constitutes an important part of Egypt's realization of its *National Intellectual Property Strategy*, which was introduced in 2022. As a long-term vision for reforming Egypt's national IP environment, the strategy intends to overhaul the existing legal framework. As noted over the course of the Index, the bulk of Egypt's IP laws are over 20 years old and largely mirror commitments made under the WTO TRIPS Agreement. Consequently, this legal system largely predates globalization and the advent of the knowledge-based economy.

Egypt's national IP environment lacks many fundamental IP rights and incentives. Patentability standards continue to be outside of international norms, especially for biopharmaceuticals and CII; the protection of copyright remains underdeveloped and ill-suited to the challenges of the internet era; 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.

Since 2015, the Index has included a *Statistical Annex* that investigates a series of correlations of the relationship between the strength of national IP environments, as measured by the Index scores, and different types of economic activity, including rates of R&D spending, innovation, technology creation, and creativity. As the economic data and analysis of the *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 53 indicators across 10 separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products. As the EIPA and Egyptian Government pursue a program of national IP rights reforms, they are encouraged to use the Index findings and accompanying *Statistical Annex* as a guide in 2025 and beyond.

Patent 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 registered 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 has been 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 progressing slowly; it can take years to reach a verdict. Egypt is ranked low on international indices pertaining to the ability to seek legal judicial redress. For example, 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 took, 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 limited ability to protect and defend their IP from infringement. This issue remained unresolved in 2024.

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In 2020, Decree 251/2020 was issued establishing a new Ministerial Committee with the authority to override any existing IP rights and issue compulsory licenses. It remains unclear why this committee was established and what purpose it continues to serve. 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. The Index will continue to monitor these developments.

Copyrights and Limitations; and Enforcement

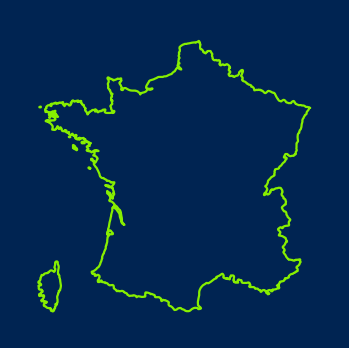
12. Expeditious legal remedies disabling access to infringing content online; and 36. Criminal standards, including minimum imprisonment and minimum fines:

As noted over the past two editions, Egyptian authorities have together with an international rightsholders' coalition—the Alliance for Creativity and Entertainment—successfully and in a sustained fashion begun to tackle the entrenched levels of copyright infringement. Access to several notable websites streaming pirated content throughout the region have been disabled, domain names have been seized, and arrests have been made. Rightsholders have historically faced significant challenges in protecting their content in Egypt. The existing legal copyright framework has major gaps, and enforcement remains inadequate. As a result of this greater enforcement activity, Egypt's score for indicators 12 and 36 increased in last year's Index. These positive efforts have continued over the past year. In late 2023, access to the website CIMACLUB was disabled. CIMACLUB was a central distribution point across the Middle East and North Africa) region of copyright-infringing content in Arabic. Similarly, the "Cima4U" portal was shut down a few months later in early 2024. These successful efforts were, again, the result of the strong cooperation between local Egyptian law enforcement and rightsholders acting through the Alliance for Creativity and Entertainment. Although the scale of copyright infringement means that challenges remain, Egypt is becoming an example of what can be achieved when the public and private sectors join forces and work together. The Index will continue to monitor these developments in 2025.

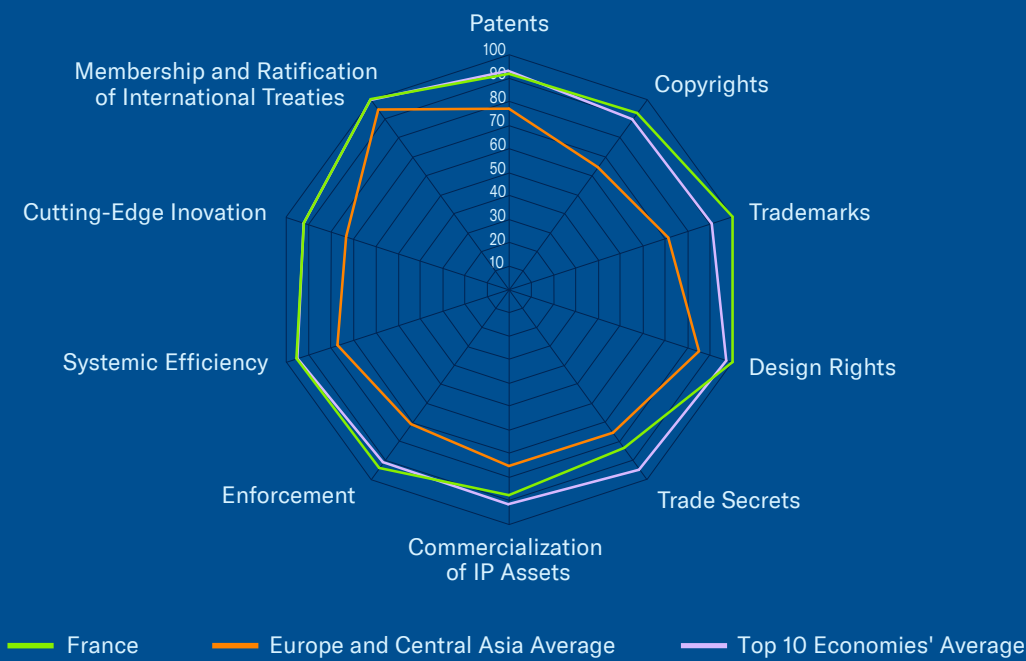
Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

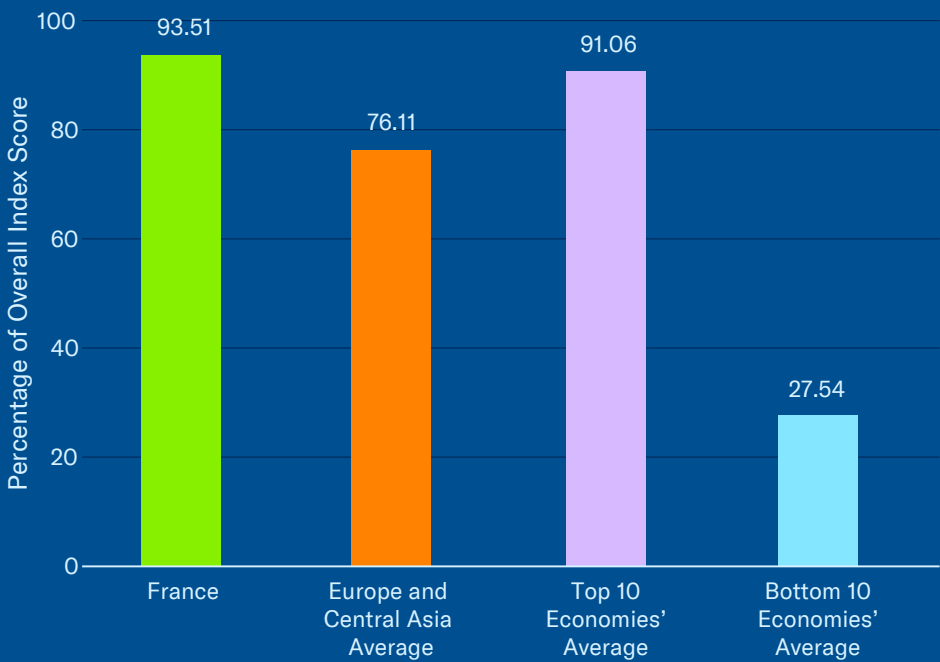
Interest in rare diseases has grown in Egypt. Although no specific legislative framework is in place (including with respect to R&D and IP-based market exclusivity incentives for orphan medicinal product development), the Egyptian Government announced in 2024 that patients with rare diseases would have access to a special emergency medical fund to cover medical treatment. Furthermore, the past few years have seen a growing research interest from Egyptian academic institutions in investigating the prevalence of rare diseases in Egypt, with hundreds of research papers published over the past few years.



Category Scores



Overall Score in Comparison





Key Areas of Strength

- Since 2000, orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and development of new treatments and medicines for rare diseases
- Under Law 2021-1382, copyright enforcement powers were expanded to allow HADOPI to take quicker action against mirror sites; establish a blacklist 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 (with a 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

- EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- A new EU-wide compulsory licensing regime would undermine patent rights in Europe
- A new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- Licensing agreements include registration requirements
- Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to France's and the EU's research and IP-based biopharma industry

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

Percentage of Overall Score: 93.51%

• Total Score: 49.56

Spotlight on the National IP Environment

Past Editions versus Current Score

France's overall Index score has increased from 46.56 out of 50 indicators in the twelfth edition to 49.56 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

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

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. However, the data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU.

As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, the Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope.

The position of EU Member States in the legislative process appears to be more reasonable. After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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.

Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU. As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each Member State. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024.

The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application, and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they comply with existing copyright law. Some of the positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity. Advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

Trademark Rights and Limitations

20. Availability of frameworks that promote action against online sale of counterfeit goods:

The past few years have seen French authorities step up enforcement efforts against the online dissemination and sale of counterfeit goods. In 2022, the Directorate-General of Customs and Indirect Taxes announced the results of a 22-month special operation conducted against the online sale of counterfeit toys and children’s articles. In a cross-European operation led by French authorities involving law enforcement in seven EU Member States and Europol, over 16 million counterfeit goods were either seized or taken down online. Similarly, in 2022, France’s IP office INPI launched the *France Anti-Contrefaçon* campaign, a national coordination, awareness-raising, and enforcement effort that partners with both public and private sector entities in the fight against counterfeiting. This campaign released its first annual report in late 2023 and presented its work within the auspices of the national *Comité National Anti-Contrefaçon*. A major part of the campaign is tackling the online sale of counterfeit goods through a combination of stronger trading standards and enforcement efforts. In 2024, the French Customs launched the *National Anti-Counterfeiting Plan 2024–2026*.

Building on the strong enforcement efforts of the past three years, this second three-year initiative places a special emphasis on fighting counterfeits sold and marketed online. Of special note is the program’s plan to expand the number of dedicated customs officers working online and the expanded use of new powers granted of “digital injunctions.” As a result of France’s continued strong efforts in this space of IP enforcement, the score for this indicator has increased by 0.25.

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.

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, detailed under Category 9. 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.

The Commission's proposal 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 Commission's 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. Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing "competitiveness gap" for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. While constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in EU Member States, including France, seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become 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 Commission’s proposals 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.

In early 2024, the European Parliament responded to the Commission’s ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

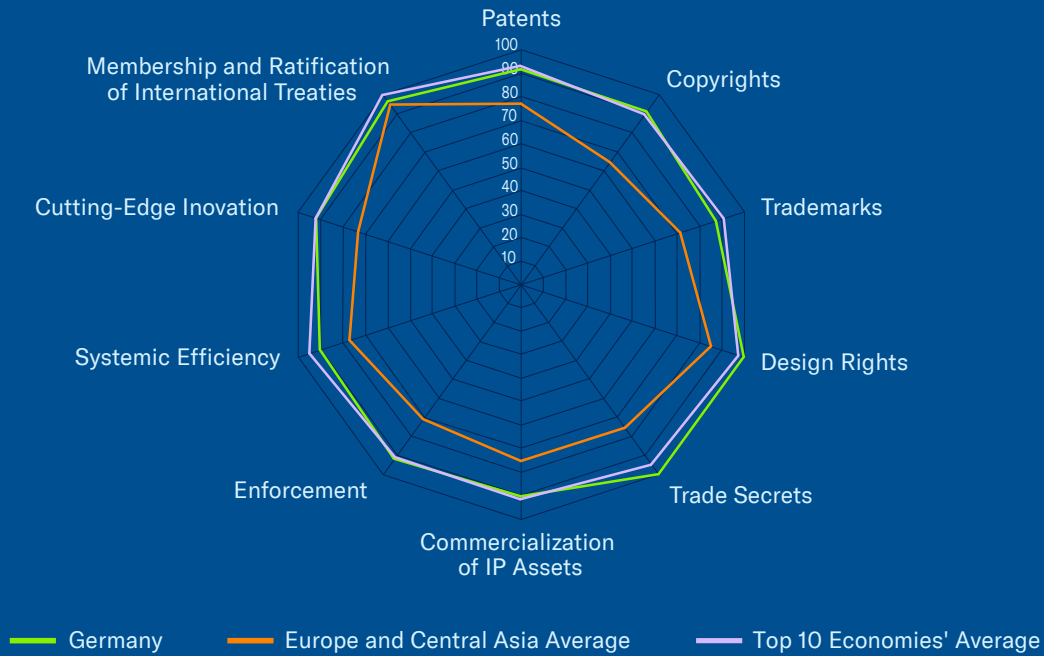
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals, including the European Parliament’s response to the Commission’s proposals in early 2024, the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index, including France, seeing a score reduction for indicators 45 and 46.



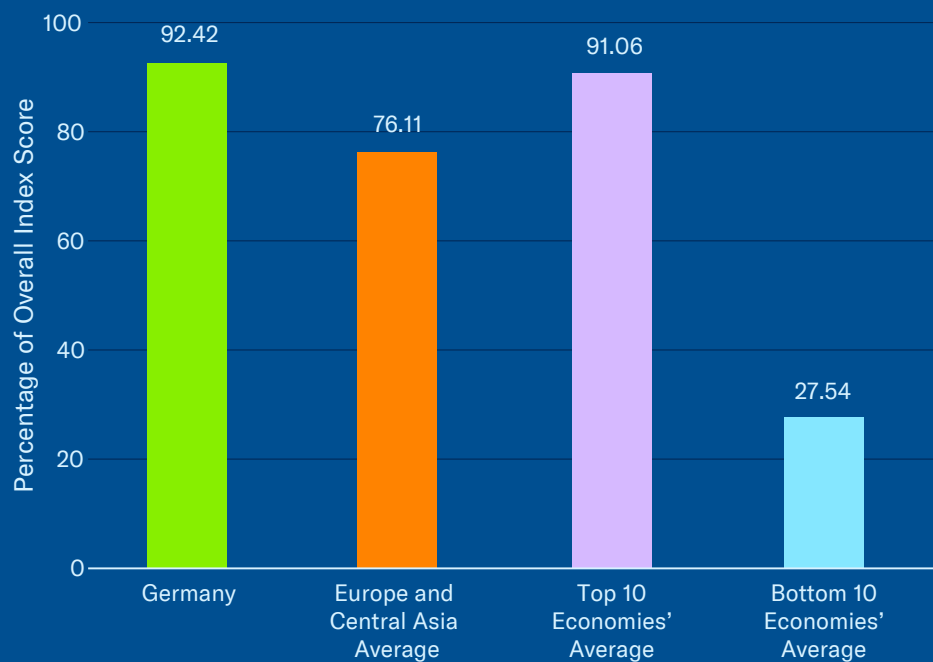
Germany

Rank
4/55

Category Scores



Overall Score in Comparison





Germany

Rank
4/55

Key Areas of Strength

- Since 2000, orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and development of new treatments and medicines for rare diseases
- Additional R&D tax credits were introduced in 2020
- Advanced and sophisticated national IP environment
- Sector-specific IP rights are in place
- Member of all major international PPH tracks through the national patent office and EPO

Key Areas of Weakness

- EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- A new EU-wide compulsory licensing regime would undermine patent rights in Europe
- A new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- 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
- The Patent Law Treaty was signed but not ratified

Spotlight on the National IP Environment

Past Editions versus Current Score

Germany's overall Index score has increased from 46.23 out of 50 indicators in the twelfth edition to 48.98 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

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

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, the Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and the European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each Member State. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024.

The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application, and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they comply with existing copyright law. Some positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act. AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

In a separate development, 2024 saw the first instance judgment in the case *Kneschke v. LAION*, a legal dispute concerning the extent to which AI training models can use copyrighted content for training purposes. To this the effect, the Hamburg Regional Court found that the use by LAION—a nonprofit research entity—of images that it had accessed on the internet, without the explicit permission or consent from the author, fell under existing text and data mining exceptions for scientific research. The judgment argued that given how LAION did not have a direct commercial interest in the research—the relevant datasets were published and distributed free of charge—the research, per definition, qualified as scientific and noncommercial. Yet, as the judgment itself concedes, it is not at all clear that the end research product distributed by LAION would not be used by commercial entities. Somewhat confusingly, the judgment acknowledges both this reality and the potential illegality of such use but claims it is not pertinent to this dispute: “Whether the data set—as the plaintiff claims with regard to the services... is also used by commercial companies to train or further develop their AI systems is irrelevant because research by commercial companies is still research—even if not privileged as such under Sections 60c et seq. of the Copyright Act.”

This is an important judgment because it constitutes one of the first European court cases on the interaction between copyright protection and the use and application of AI. It remains to be seen whether its interpretation of the relevant statute will be upheld in any future appeals procedure or shared by other European courts. The Index will continue to monitor these developments in 2025

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. 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, detailed under Category 9. 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.

The Commission's proposal 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 Commission's 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. Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing "competitiveness gap" for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU Member States seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become 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 Commission’s proposals 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.

In early 2024, the European Parliament responded to the Commission’s ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

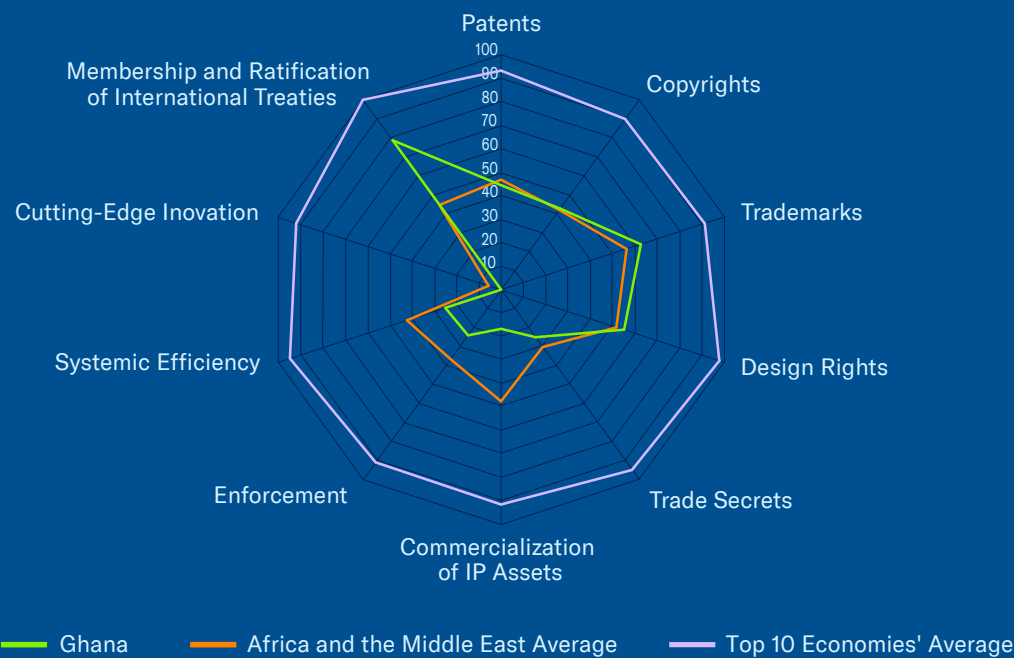
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals—including the European Parliament’s response to the Commission’s proposals in early 2024—the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.



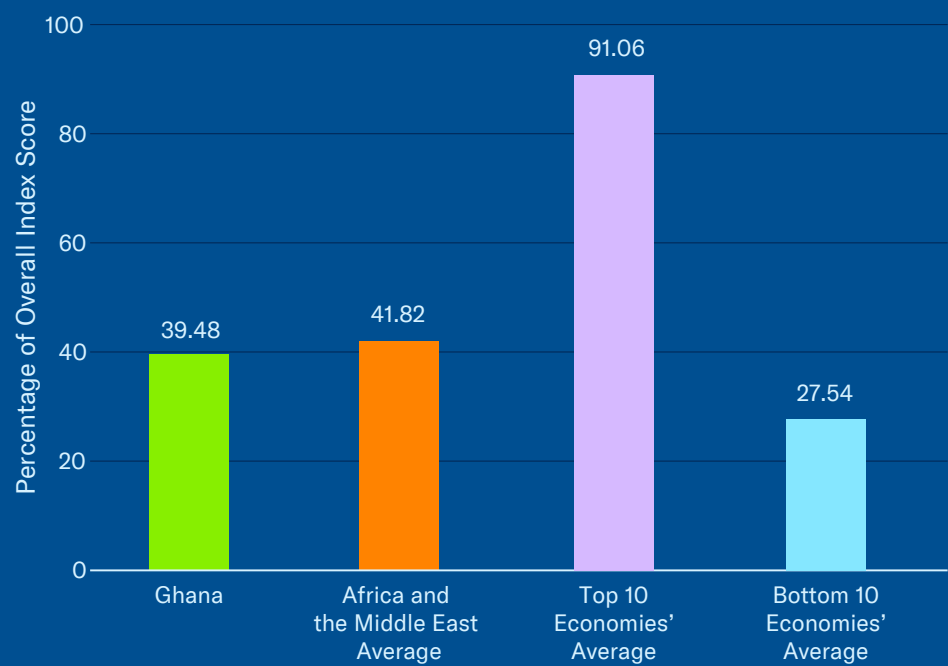
Ghana

Rank
38/55

Category Scores



Overall Score in Comparison





Ghana

Rank
38/55

Key Areas of Strength

- 2024 ARIPO-China National Intellectual Property Administration (CNIPA) PPH—first PPH for Ghana and other ARIPO parties
- 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 CIIIs)
- New Plant Variety Protection Act 2020
- Electronic Transactions Act 2008 includes definition and description of liability for service providers and intermediaries, including potential court-ordered injunctive-style relief
- WTO TRIPS member

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Legal framework remains rudimentary for most IP rights, with many key IP rights and incentives unavailable
- Enforcement environment remains highly fraught with counterfeit and IP-infringing goods widely available—physical and online
- High levels of counterfeit and substandard medicines
- Judicial enforcement is characterized by long delays

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

Percentage of Overall Score: 39.48%

Total Score: 20.53

Spotlight on the National IP Environment

Past Editions versus Current Score

Ghana's overall Index score has increased from 20.03 out of 49 indicators in the twelfth edition to 20.53 out of 52 indicators. This reflects a score increase for indicator 8.

Patent Rights and Limitations

4. Plant variety protection, term of protection; and 47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991:

As noted in previous editions of the Index, the past few years have seen significant positive developments for plant variety protection in Ghana. Up until 2020, Ghana did not have any relevant laws or regulations in place that provided plant variety protection. This changed in 2020 with the passing of Act 1050, the Plant Variety Protection Act 2020. Section 27 of the Act provides a 20-year baseline term of protection extended to a 25-year term of protection for trees and vines. This is in line with the benchmark measured in the Index and international standards. In 2021, in a further positive development, Ghana acceded to the International Convention for the Protection of New Varieties of Plants, Act of 1991. These positive efforts continued in 2024. In late 2023, Ghana formally ratified the Arusha Protocol for the Protection of New Varieties of Plants. Ghana is now the fourth member of the African Regional Intellectual Property Organization (ARIPO) to have ratified the protocol and, in so doing, brought it into force.

8. Membership of a Patent Prosecution Highway (PPH):

Historically, neither Ghana nor the ARIPO have participated in the IP5 PPH or the Global PPH or have had in place a PPH on a bilateral basis. This changed in 2024 with the announcement that ARIPO and the China National Intellectual Property Administration had agreed on a PPH pilot program. At the time of research, the agreement had come into effect and would remain operational for five years. PPH initiatives and increased cooperation among 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. As a result of this positive development, the score for this indicator has increased by 0.5.

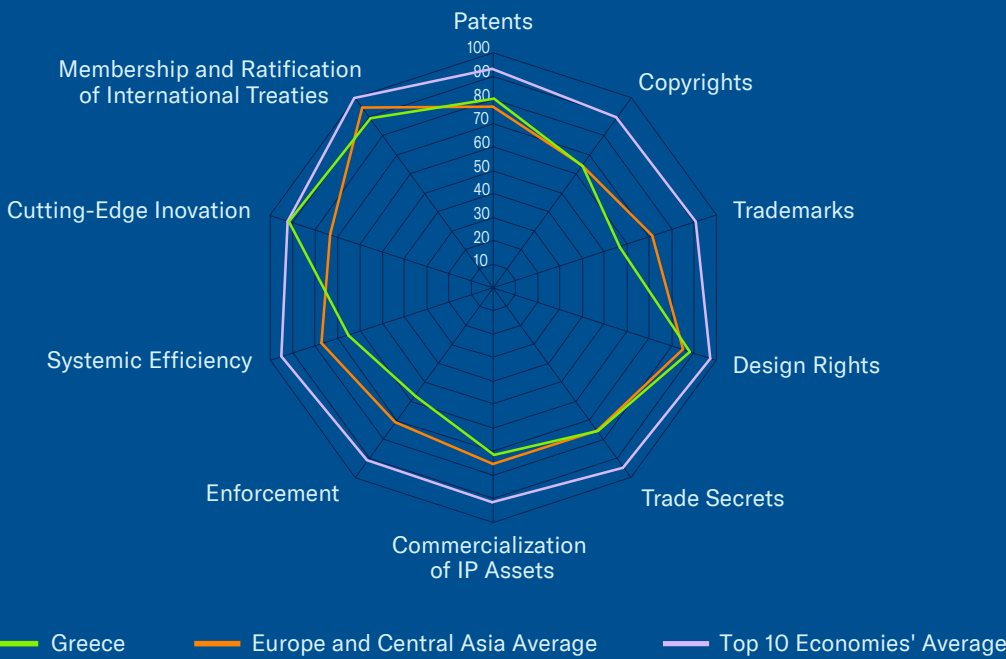
Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

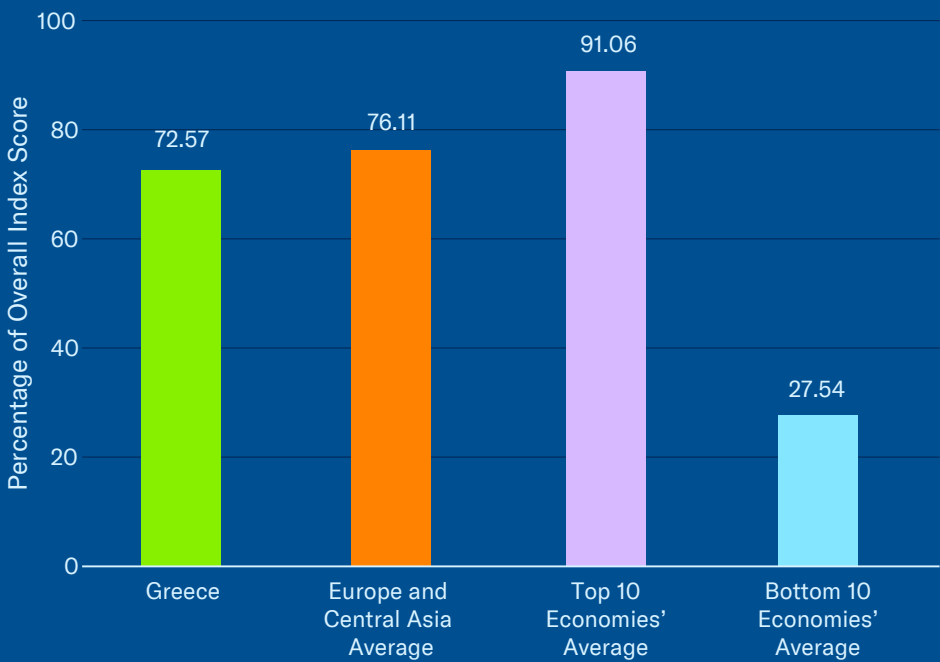
Interest in rare diseases has grown Ghana. Although the 2020 *National Health Policy* did not refer specifically to rare diseases or the need for building rare disease-specific health infrastructure, such as registries or treatment and diagnostics centers, several patient groups and clinicians highlight the needs of patients with rare diseases, including the national advocacy group Rare Disease Ghana. No specific legislative framework in place, including R&D and IP-based market exclusivity incentives for orphan medicinal product development.



Category Scores



Overall Score in Comparison





Key Areas of Strength

- Since 2000, the orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and development of new treatments and medicines for rare diseases
- CDSM Directive transposed 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
- Membership of all major international PPH tracks through the EPO

Key Areas of Weakness

- The EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- A new EU-wide compulsory licensing regime would undermine patent rights in Europe
- A new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations; 2019 changes to compulsory licensing regime 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
- BSA estimated rates of the use of unlicensed software suggests that Greece has since 2011 had a remarkably high rate of software piracy for an EU and OECD Member State
- The software piracy rate has consistently stayed between 61% and 63% (in 2018, it was an estimated 61%) compared to an average estimated rate of 26% for the rest of Western Europe
- Regulation 2019/933 and the existing SPC exemption for exports of biopharmaceuticals pose significant risk to Greece's and the EU's research and IP-based biopharma industry
- Registration requirement for licensing deals in Greece

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

Percentage of Overall Score: 72.57%

• Total Score: 38.46

Spotlight on the National IP Environment

Past Editions versus Current Score

Greece's overall Index score has increased from 35.71 out of 50 indicators in the twelfth edition to 38.46 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

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

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based on. More worryingly, the Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After European elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and the European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each Member State.

As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024.

The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application, and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they comply with existing copyright law. Some positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and across the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

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.

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, detailed under Category 9.

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.

The Commission’s proposal 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 Commission’s 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. Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU Member States seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become 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 Commission's proposals 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.

In early 2024, the European Parliament responded to the Commission's ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries that are loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

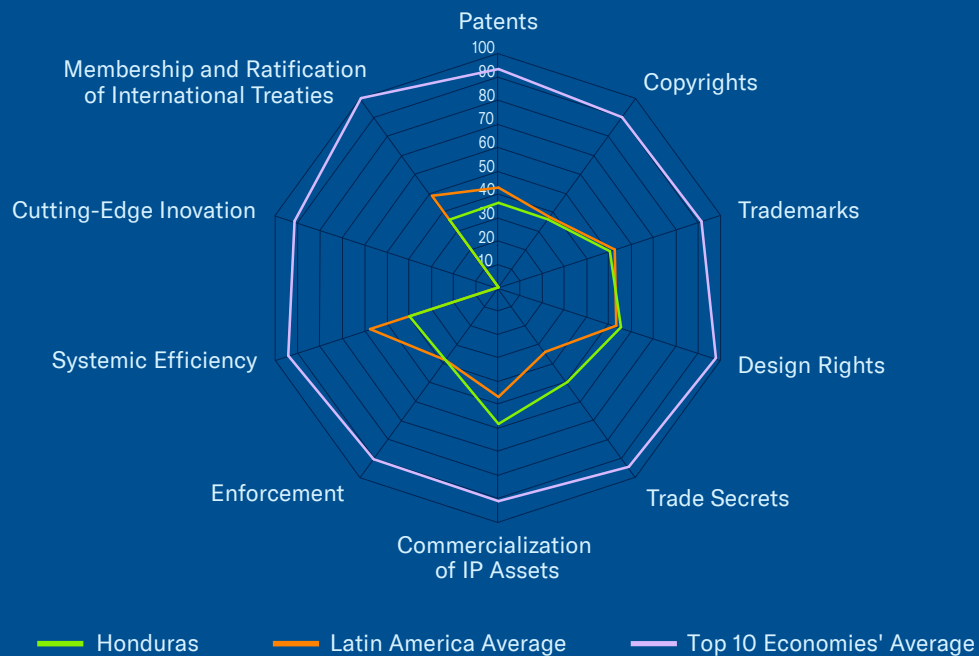
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals—including the European Parliament’s response to the Commission’s proposals in early 2024—the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.



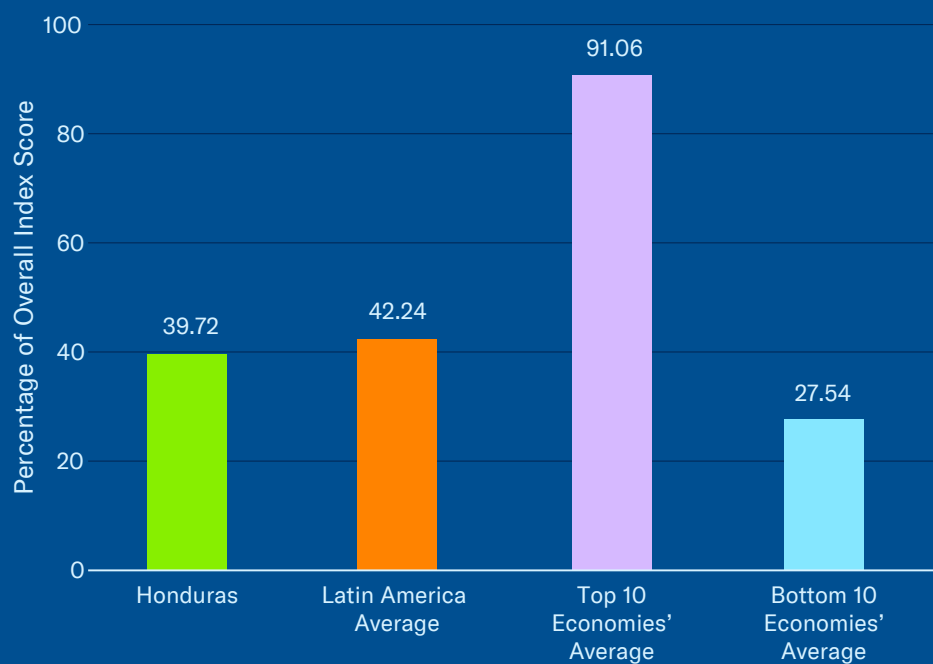
Honduras

Rank
37/55

Category Scores



Overall Score in Comparison





Honduras

Rank
37/55

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

- No special IP incentives for orphan medicinal product development
- Patentability standards are outside international norms—key problem areas include second use claims for biopharmaceuticals and patent protection for CIIIs
- Uncertainty over access to a statutory period of RDP: 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, online, and web-based streaming is highly pervasive and constitutes a major source of illegal content not effectively addressed by the 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: total pirated or unreported market in Honduras is estimated at 50% of the total number of potential end users

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.25	30. IP as an economic asset	0.50
3. Patentability of CIIIs	0.25	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.44
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.25
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.50
8. Membership of a Patent Prosecution Highway	0.00	35. Pre-established damages	0.50
9. Patent opposition	0.25	36. Criminal standards	0.50
Category 2: Copyrights and Limitations		37. Effective border measures	0.50
10. Term of protection	0.76	38. Transparency and public reporting by customs	0.00
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	0.75
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	0.25
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.50
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	0.25	43. IP-intensive industries, national economic impact analysis	0.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.50
21. Industrial design term of protection	0.60	24. Protection of trade secrets (criminal sanctions)	0.50
22. Exclusive rights, industrial design rights	0.50	25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	0.50	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
28. Registration and disclosure requirements of licensing deals	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
		51. Membership of the Convention on Cybercrime, 2001	0.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 39.72%

Total Score: 21.05

Spotlight on the National IP Environment

Past Editions versus Current Score

Honduras' overall Index score has decreased from 21.08 out of 50 indicators in the twelfth edition to 21.05 out of 53 indicators. This reflects a score decrease for indicator 32.

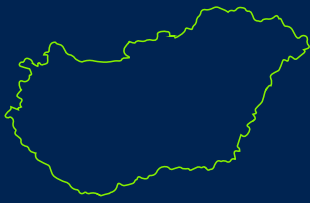
Copyrights and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); and 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*) 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. Although Honduras was not included in this year's watch list, the USTR noted in the *2024 Special 301 Report* that "Honduras continues to have 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 ongoing concerns that a major cable provider in the country is offering unlicensed programming, is using that pirated content to expand its market share, and is now moving to illegal streaming as well." Elevated rates of signal and copyright piracy have remained the case in Honduras despite the fact that 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 2025.

Incentives for Cutting-Edge Innovation

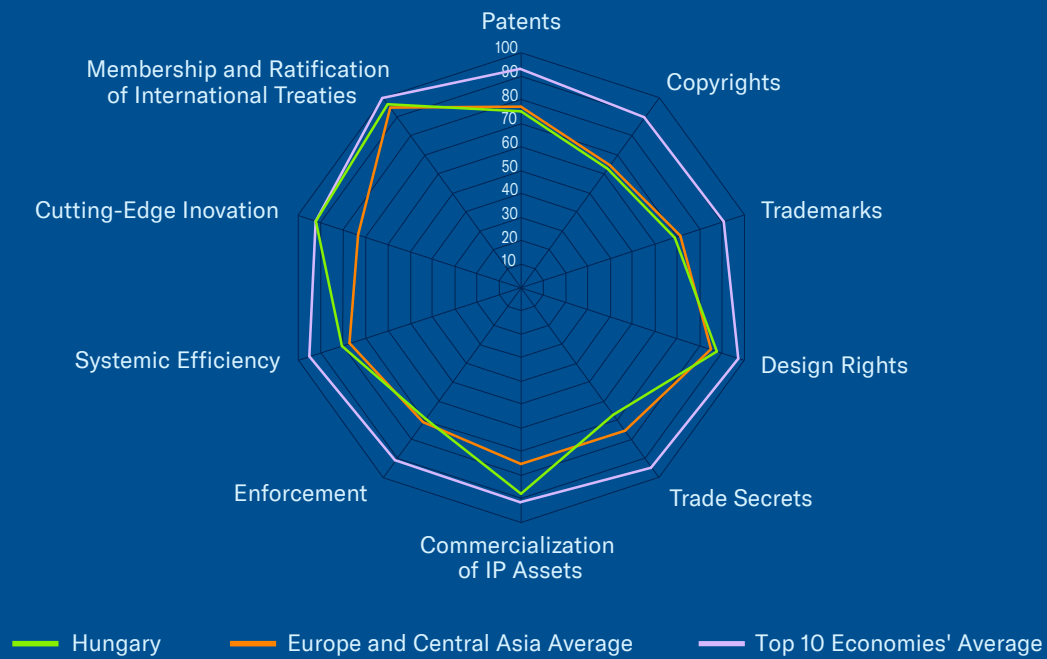
44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development: No specific legislative framework is in place in Honduras for rare diseases, a national registry, or any special IP-based market exclusivity incentives for orphan medicinal product development.



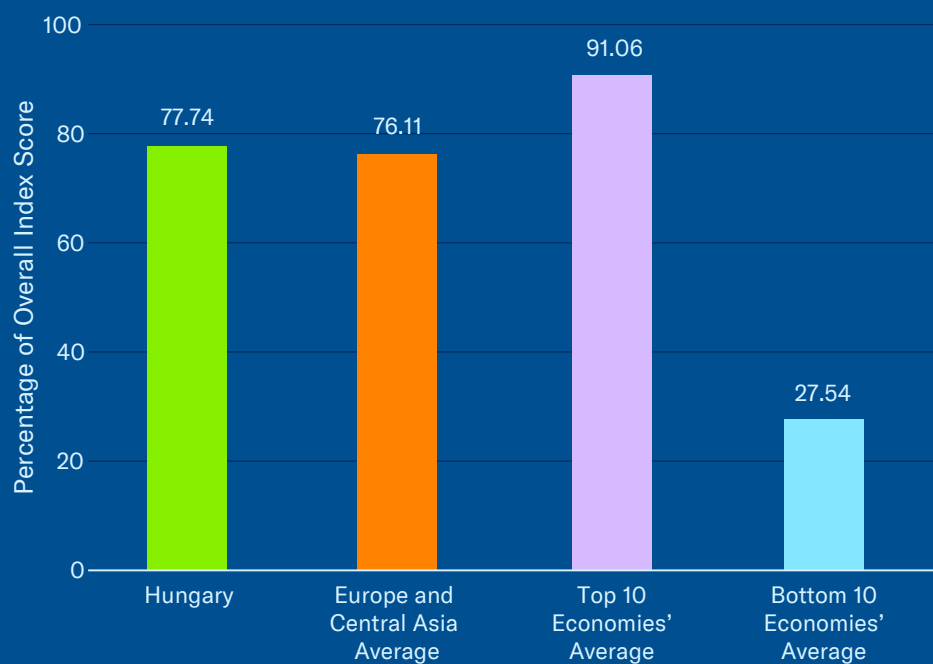
Hungary

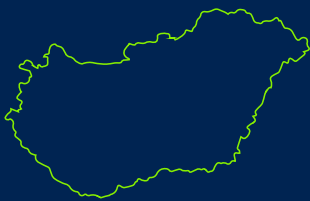
Rank
14/55

Category Scores



Overall Score in Comparison





Hungary

Rank
14/55

Key Areas of Strength

- Since 2000, the orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- Transposed the EU Trade Secrets Directive into Hungarian Law through Act LIV of 2018 on the Protection of Trade Secrets
- Generous R&D and IP-specific tax incentives are in place
- Fairly strong and sophisticated IP system conferred through EU membership
- Sector-specific IP rights are in place

Key Areas of Weakness

- The EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- The new EU-wide compulsory licensing regime would undermine patent rights in Europe
- The new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- 2020 compulsory license issued for drug remdesivir
- Regulation 2019/933 and the 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	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.75	30. IP as an economic asset	0.50
3. Patentability of CII	0.75	31. Tax incentives for the creation of IP assets	1.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.68
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.64
7. Pharmaceutical patent term restoration	0.75	34. Civil and precedural remedies	0.50
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.50
9. Patent opposition	1.00	36. Criminal standards	0.50
Category 2: Copyrights and Limitations		37. Effective border measures	1.00
10. Term of protection	0.63	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	0.50	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.75	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	0.75	40. Consultation with stakeholders during IP policy formation	0.75
14. Limitations and exceptions	0.75	41. Educational campaigns and awareness raising	0.75
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	1.00
19. Exclusive rights, trademarks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
20. Frameworks against online sale of counterfeit goods	0.50	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.75
21. Industrial design term of protection	1.00	24. Protection of trade secrets (criminal sanctions)	0.25
22. Exclusive rights, industrial design rights	0.75	25. Regulatory data protection term	1.00
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	0.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
28. Registration and disclosure requirements of licensing deals	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 77.74%

• Total Score: 41.20

Spotlight on the National IP Environment

Past Editions versus Current Score

Hungary's overall Index score has increased from 38.45 out of 50 indicators in the twelfth edition to 41.20 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

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

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and the European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each Member State. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years beorking on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024.

The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application, and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they comply with existing copyright law. Some of the positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

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.

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, detailed under Category 9.

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. The Commission’s proposal 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 Commission’s 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.”

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Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU member states seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become 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 Commission's proposals 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.

In early 2024, the European Parliament responded to the Commission's ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

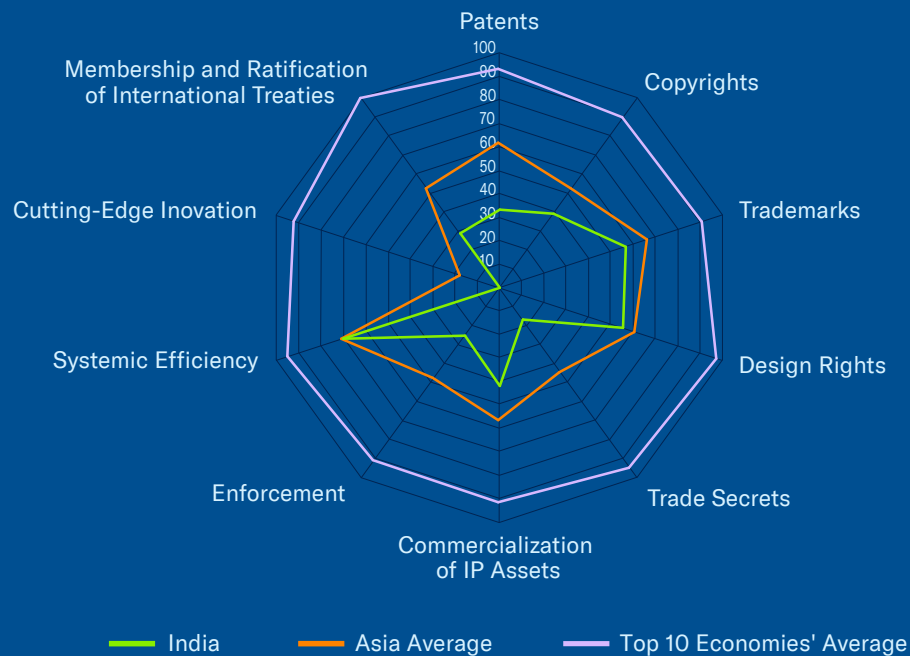
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals—including the European Parliament’s response to the Commission’s proposals in early 2024—the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.



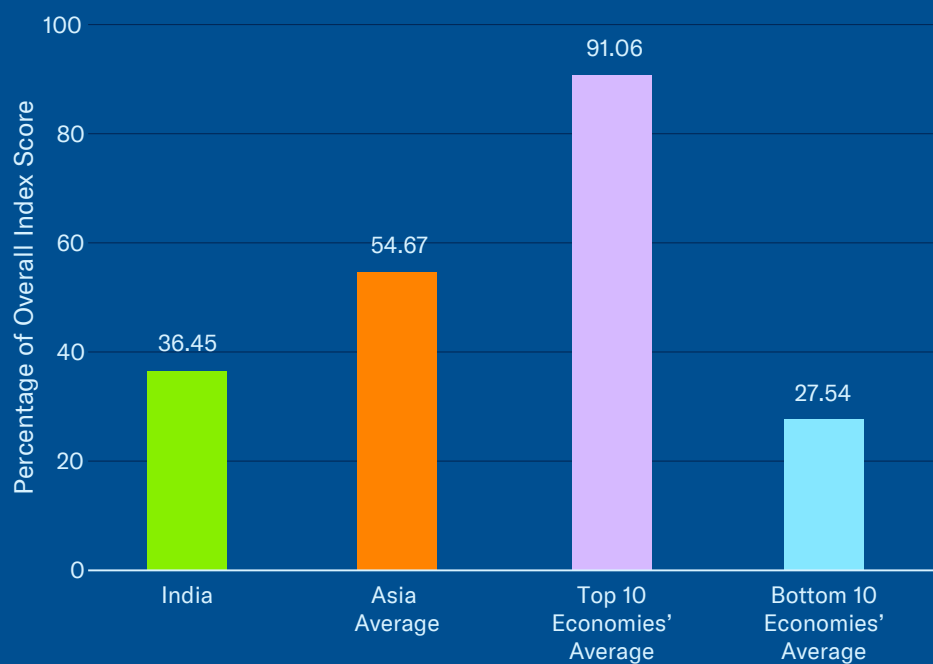
India

Rank
43/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Updated 2024 Patent Rules improve the existing pre-grant opposition procedure and compliance requirements under Form 27
- Continued strong efforts on copyright piracy through issuing of dynamic injunction orders
- 2019 precedential case law on online trademark infringement and damages
- PPH program with the JPO is a positive step
- Generous R&D and IP-based tax incentives
- Global leader on targeted administrative incentives for the creation and use of IP assets for SMEs
- Strong awareness-raising efforts on the negative impact of piracy and counterfeiting
- Capacity building and the number of examiners increased

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 2021 dissolution of the Intellectual Property Appellate Board, combined with the long-standing issue of an underresourced and overstretched judiciary, raises serious concerns about rightsholders' ability to enforce their IP rights in India and to resolve IP-related disputes
- 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
- No RDP or patent term restoration for biopharmaceuticals is available
- Lengthy pre-grant opposition proceedings
- Previously used compulsory licensing for commercial and nonemergency situations
- Limited participation in international treaties
- No patent linkage or effective patent enforcement mechanism is in place

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	2.99	29. Direct government intervention in setting licensing terms	0.25
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	0.00	31. Tax incentives for the creation of IP assets	1.00
3. Patentability of CILs	0.75	Category 7: Enforcement	1.76
4. Plant variety protection	0.74	32. Physical counterfeiting rates	0.34
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.42
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precedural remedies	0.25
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.25
8. Membership of a Patent Prosecution Highway	0.50	36. Criminal standards	0.25
9. Patent opposition	0.00	37. Effective border measures	0.25
Category 2: Copyrights and Limitations	2.72	38. Transparency and public reporting by customs	0.00
10. Term of protection	0.47	Category 8: Systemic Efficiency	3.50
11. Exclusive rights	0.50	39. Coordination of IP rights enforcement	0.25
12. Expeditious legal remedies disabling access to infringing content online	1.00	40. Consultation with stakeholders during IP policy formation	1.00
13. Cooperative action against online piracy	0.25	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.00	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
15. TPM and DRM	0.25	43. IP-intensive industries, national economic impact analysis	0.25
16. Government use of licensed software	0.25	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.25	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.25	Category 10: Membership and Ratification of International Treaties	2.00
20. Frameworks against online sale of counterfeit goods	0.50	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	1.10	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	0.50	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	51. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
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		

Percentage of Overall Score: 36.45%

Total Score: 19.32

Spotlight on the National IP Environment

Past Editions versus Current Score

India's overall Index score remains unchanged at 19.32 out of 53 indicators.

Patent Rights and Limitations

9. Patent opposition:

In 2024, some notable positive developments occurred with respect to patent opposition proceedings. As noted last year, in 2023, the Controller General published the “Draft Patents (Amendment), Rules, 2023” for public consultation. The proposed changes included some improvements to the existing pre-grant opposition mechanisms, including introducing more defined timelines as well as vesting more discretion with the Controller General as to whether a filed opposition should be considered. In March 2024, most of these changes came into effect with an updated Patent Rules published. Notably, the new rules now grant the Controller General the power to decide whether an opposition filing provides a “*prima facie*” case against the relevant patent application and should be accepted and considered. The changes also introduce filing fees for opponents; until now, opposition filings were at no charge. The new rules also make changes to Form 27. Historically, patent holders were required to file this form annually and to provide information on the extent to which a granted patent has been worked by patentees and/or licensees. The updated Form 27 has now removed the annual filing requirement and has replaced it with a three-year requirement. Rightsholders are also no longer required to report on the approximate value of the patented technology. The pre-grant opposition mechanism in India has long been criticized for adding significantly to the already lengthy patent prosecution timelines.

Although more wholesale reform of the pre-grant opposition mechanism and complete elimination of the Form 27 filing requirement would have been better, nevertheless, the changes introduced in the 2024 Patent Rules are positive developments. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

AI and machine learning technologies are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific breakthroughs and innovation to take place through the analysis of large volumes of data and information. In fact, a foundational lawsuit in India could affect how the country handles IP rights related to large language models. OpenAI is currently facing a copyright lawsuit in India, initiated by ANI Media and supported by other major publishers. The case involves allegations that OpenAI used copyrighted content without permission to train its AI models, including ChatGPT. At the time of research, the Delhi High Court was set to begin detailed hearings in the first quarter of 2025. 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—as well as the ability of scraping technologies to access rightsholders' content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in India and around the world.

The Minister of State for Commerce and Industry, Som Parkash, acknowledged the challenges that the development and application of these technologies pose to copyright industries and creators, stating, “The exclusive economic rights of a copyright owner... granted by the Copyright Act, 1957 obligates the user of Generative AI to obtain permission to use their works for commercial purposes if such use is not covered under the fair dealing exceptions.” At the time of research, no draft addressing AI-specific legislation had been published. The Index will continue to monitor these developments in 2025.

Trade Secrets and the Protection of Confidential Information

23. Protection of trade secrets (civil remedies); and 24. Protection of trade secrets (criminal sanctions):

As has been noted in previous editions, Indian statutory law does not provide specific protection for trade secrets or confidential information for civil or criminal infringement. The current applicable statute for civil cases is the 1872 Contract Act and existing case law. With respect to criminal infringement, the Information Technology Act 2000 provides limited potential recourse and only in relation to computer-related offenses such as unauthorized access to computer systems, accessing of data, and hacking. Although common law provides a measure of protection—and there is some judicial precedent—overall rightsholder’s ability to effectively enforce and protect their trade secrets in India is limited. This lack of adequate protection has been recognized by the Indian Government. For example, the 2016 *National Intellectual Property Rights Policy* emphasized the need to introduce a legislative framework for the protection of trade secrets and confidential information.

In a positive development, 2024 saw the introduction of a new draft law on trade secrets. In March, the Law Commission of India (an advisory body to the Government of India) published “The Protection of Trade Secrets Bill, 2024” as part of Report No. 289. The draft contains a workable definition of what constitutes a trade secret, misappropriation of trade secrets, and potential civil recourse such as injunctions and damages. These are much needed and positive first steps in providing a statutory basis to help rightsholders protect their trade secrets, know-how, and confidential information. Unfortunately, the bill as currently drafted contains several negative features. To begin with, Section 6 defines a compulsory licensing regime granting the government broad powers to override and, essentially, confiscate trade secrets in “circumstances of national emergency or extreme urgency involving substantial public interest, including situations of public health emergency, national security etc.” Moreover, the draft law does not include any provisions related to criminal sanctions, including statutory fines and imprisonment, or a definition of such acts either by individuals or legal entities. Also, no reference is made to a defined period of RDP for undisclosed biopharmaceutical test data submitted during sanitary registration. These substantial deficiencies aside, it is nevertheless a net positive development that the Government of India is proposing a new trade secret law. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

A national policy framework was first developed by the Ministry of Health in 2017 with a finalized *National Policy for Treatment of Rare Diseases* launched in 2021. The policy introduced a national framework and definition of three main groups of rare diseases and a focus on screening and expanding access to low-cost treatments. Although the policy refers to the need for more research and the development of new medicines and treatments for rare diseases, it does not include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.

Membership and Ratification of International Treaties

India's score in this category of the Index has increased from 0.00 in the first edition of the Index to now achieving 2.00, or 28.57%, of the total available score. This is notably less than other BRICS 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.

53. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices:

In March 2024, India and the European Free Trade Association signed a Trade and Economic Partnership Agreement (TEPA). The agreement is the culmination of over 15 years of discussions with 21 separate rounds of negotiations. A positive feature of the agreement is a dedicated IP chapter in Annex 8.A. This is an encouraging development because many 21st-century post-TRIPS FTAs do not include a dedicated IP chapter with meaningful provisions on IP rights. Unfortunately, the TEPA 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. Indeed, much of the IP chapter is linked to rights defined and specified in TRIPS. In terms of specific gaps in the TEPA, the agreement includes limited copyright provisions with no reference to the challenges that the online environment or infringement represents to rightsholders and limited reference to sector-specific protections, including biopharmaceutical IP rights such as RDP and patent term restoration. Although Article 19(5) of Annex 8.A requires that each party grant its customs authorities the ability to suspend the release of suspected IP-infringing goods on their own initiative, Subclause 7 explicitly exempts goods in transit. As such, no score has been allocated to India under indicator 53.



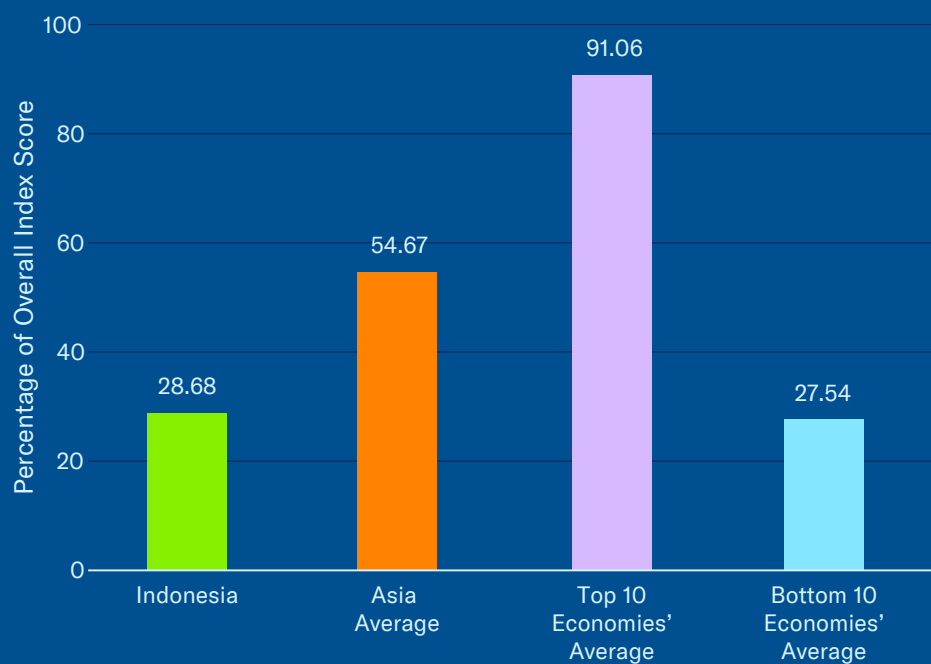
Indonesia

Rank
50/55

Category Scores



Overall Score in Comparison





Indonesia

Rank
50/55

Key Areas of Strength

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

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Expansive criteria for compulsory licensing and government use provisions, with a long history of issuing such licenses, the latest from 2021
- Significant barriers are in place for licensing and commercialization of IP assets, including technology transfer
- Biopharmaceutical patentability standards are outside international norms
- Challenging copyright environment with high levels of piracy, as administrative measures do not address mirror and linking sites
- Limited participation in international IP treaties

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.00
2. Patentability requirements	0.00	30. IP as an economic asset	0.25
3. Patentability of CILs	0.25	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.37
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.17
7. Pharmaceutical patent term restoration	0.00	34. Civil and precluded remedies	0.25
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.00
9. Patent opposition	0.25	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	0.25
10. Term of protection	0.52	38. Transparency and public reporting by customs	0.00
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expedient legal remedies disabling access to infringing content online	0.75	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	0.50	40. Consultation with stakeholders during IP policy formation	0.75
14. Limitations and exceptions	0.25	41. Educational campaigns and awareness raising	0.25
15. TPM and DRM	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	0.25	43. IP-intensive industries, national economic impact analysis	0.25
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 10: Membership and Ratification of International Treaties	
Category 4: Design Rights and Limitations		47. WIPO Internet Treaties	1.00
21. Industrial design term of protection	0.40	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
22. Exclusive rights, industrial design rights	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
Category 5: Trade Secrets and the Protection of Confidential Information		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
23. Protection of trade secrets (civil remedies)	0.25	51. Membership of the Convention on Cybercrime, 2001	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
25. Regulatory data protection term	0.00	53. Post-TRIPS FTA	0.00
Category 6: Commercialization of IP Assets			
26. Barriers to market access	0.00		
27. Barriers to technology transfer	0.00		
28. Registration and disclosure requirements of licensing deals	0.00		

Percentage of Overall Score: 28.68%

Total Score: 15.20

Spotlight on the National IP Environment

Past Editions versus Current Score

Indonesia's overall Index score has decreased from 15.21 out of 50 indicators in the twelfth edition to 15.20 out of 53 indicators. This reflects a score decrease for indicator 32.

Patent Rights and Limitations

2. Patentability requirements:

Important new developments occurred in the patenting environment in Indonesia in 2024. At the time of research, a draft set of amendments to the Patent Law had passed through a second reading and debate in the People's Representative Council. These amendments include potentially important changes to patentability requirements. Specifically, draft changes released to the public included the elimination of a heightened efficacy requirement targeting biopharmaceutical products and outlawed second use claims, which were first introduced in the 2016 Patent Law, Law 13 2016. The elimination of this requirement would be a welcome and positive development. Unfortunately, the draft amendments retain many negative aspects of the 2016 Law. For example, draft Article 167 continues to allow the parallel importation of follow-on products under patent protection in Indonesia but approved for consumption in other markets. Similarly, as detailed in indicator 6, suggested changes to the compulsory licensing and government use regime do not improve what is already a highly challenging and negative environment. On a positive note, the Omnibus Job Creation Bill has now come into effect, including changes to Article 20 of the 2016 Patent Law. As detailed in past editions of the Index, Article 20 of the 2016 Law seemed to make the granting of a patent conditional on localizing manufacturing and/or R&D in Indonesia.

Although the final passed version of the Omnibus law did not eliminate the working requirement, Article 107(2) defined the use and “implementation” of patents in Indonesia as including domestic creation, importation, or the licensing of the relevant invention. This version of the law remains in effect today. The Index will continue to monitor these developments in 2025.

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

The Indonesian Government's focus on compulsory licensing as public health policy continued in 2024. The draft amendments to the Patent Law discussed earlier also include changes to relevant articles related to compulsory licensing and government use. Notably, Article 84A vests considerable authority to override duly granted patent rights to the national competition authorities (the Business Competition Supervisory Commission). Specifically, the article states that the standard process for considering and issuing a compulsory license can be exempted if the commission finds “the implementation of a patent is proven to have resulted in monopolistic practices and/or unfair business competition.” It remains unclear how any duly granted patent could not, as a matter of course, result in a time-limited and legally sanctioned monopoly: that is the whole rationale underlying all forms of registered IP rights, including patents. Should this article stand as written, it would potentially undermine and all but nullify all granted patent rights in Indonesia.

Indonesia has a long history of actively using and viewing compulsory licensing as a health policy tool. The government has since the mid-2000s issued several “government use” compulsory licenses overriding existing biopharmaceutical patents primarily for hepatitis, HIV drugs and, most recently, COVID-19 treatments.

Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratories, research facilities, and researchers are high. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market entrants who bore none of the costs of early-stage investment, R&D, and product commercialization. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws. Undermining these incentives through the active use of compulsory licensing and the overriding of IP rights is counterproductive. Over time, such action will hollow out the national IP environment and incentives for future biopharmaceutical innovation. The negative effect will be the same for Indonesian and foreign innovators.

Design Rights 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 and the government have proposed new amendments to the Design Law, and these include an increase in the term of protection available up to 15 years. Such 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 People's Consultative Assembly of the Republic of Indonesia was still examining the bill. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

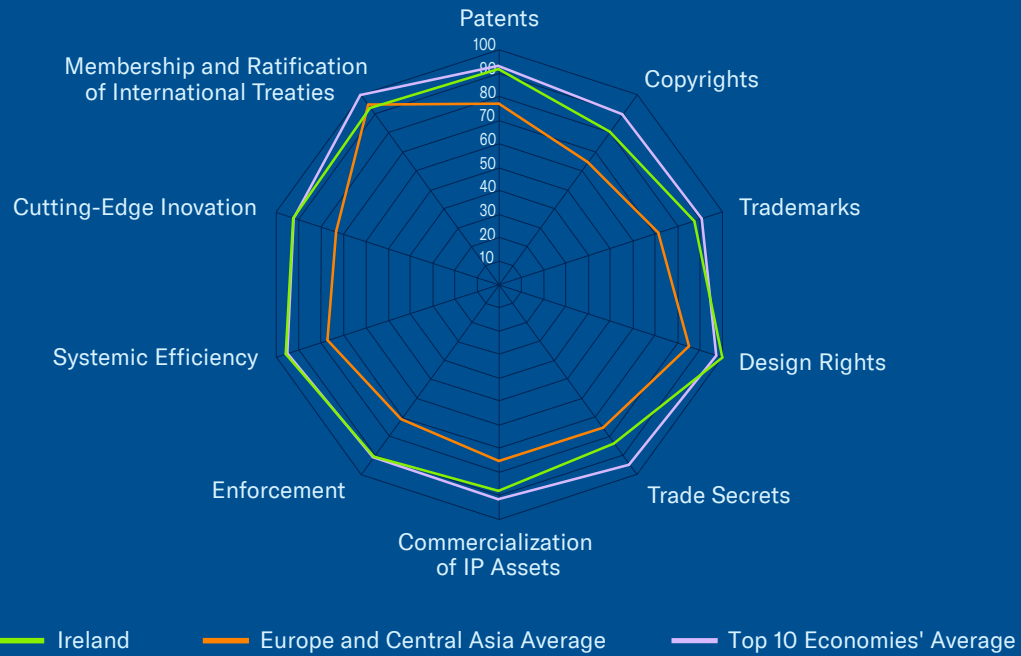
Interest in rare diseases has grown in the Asia-Pacific region. In 2017, the Asia-Pacific Economic Cooperation (APEC) forum (of which Indonesia is a member) announced a new initiative geared specifically toward rare diseases, the “APEC Action Plan on Rare Diseases.” The plan aims to “address barriers to the diagnosis and treatment of rare diseases in the region.” It consists of 30 individual targets across 10 pillars, including the promotion of innovative R&D through financial incentives, expedited market review procedures, and support for domestic R&D. Indonesia does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



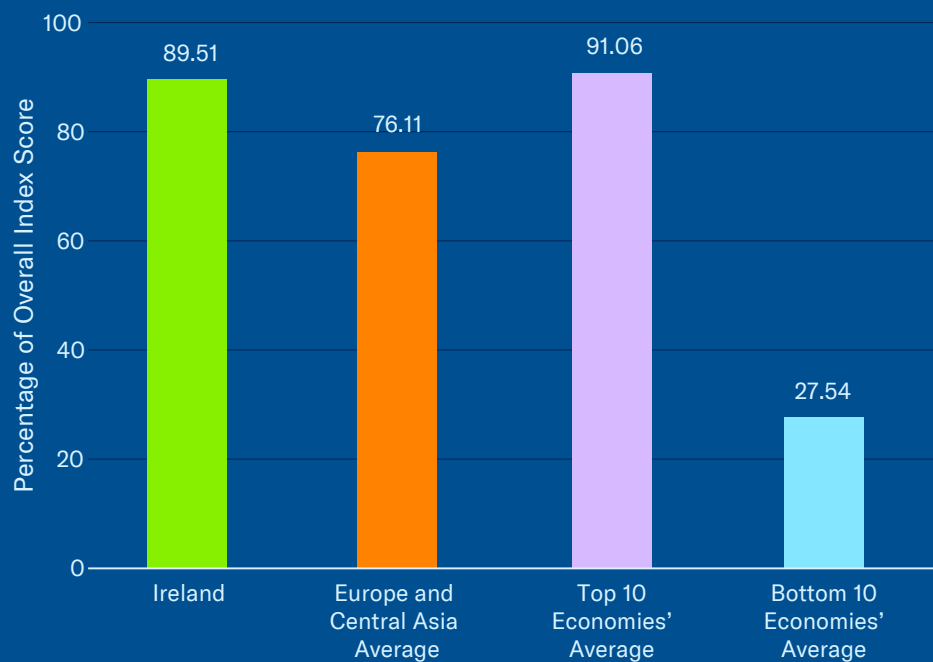
Ireland

Rank
8/55

Category Scores



Overall Score in Comparison





Ireland

Rank
8/55

Key Areas of Strength

- Since 2000, the orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- Transposed EU Directive 2019/790 on Copyright and Related Rights in the DCDSM Directive into law
- Transposed EU Trade Secrets Directive through EU (Protection of Trade Secrets) Regulations 2018 (No. 188 of 2018) into law
- 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 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- The new EU-wide compulsory licensing regime would undermine patent rights in Europe
- The new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- Licensing registration requirements
- Regulation 2019/933 and the existing SPC exemption for exports of biopharmaceuticals pose significant risk to Ireland's and the EU's research and IP-based biopharma industry

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	1.00	30. IP as an economic asset	0.75
3. Patentability of CII	1.00	31. Tax incentives for the creation of IP assets	1.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.85
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.71
7. Pharmaceutical patent term restoration	0.75	34. Civil and precedural remedies	1.00
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	1.00
9. Patent opposition	1.00	36. Criminal standards	0.75
Category 2: Copyrights and Limitations		37. Effective border measures	1.00
10. Term of protection	0.63	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	0.75	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	1.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	1.00	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	0.75	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	0.75	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	0.75	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	1.00	45. IP incentives for orphan medicinal product development, term of protection	1.00
19. Exclusive rights, trademarks	1.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
20. Frameworks against online sale of counterfeit goods	0.50	Category 6: Commercialization of IP Assets	
Category 4: Design Rights and Limitations		26. Barriers to market access	1.00
21. Industrial design term of protection	1.00	27. Barriers to technology transfer	1.00
22. Exclusive rights, industrial design rights	1.00	28. Registration and disclosure requirements of licensing deals	0.50
Category 5: Trade Secrets and the Protection of Confidential Information		Category 1: Patents Rights and Limitations	
23. Protection of trade secrets (civil remedies)	1.00	1. Term of protection	1.00
24. Protection of trade secrets (criminal sanctions)	0.50	2. Patentability requirements	1.00
25. Regulatory data protection term	1.00	3. Patentability of CII	1.00

Percentage of Overall Score: 89.51%

• Total Score: 47.44

Spotlight on the National IP Environment

Past Editions versus Current Score

Ireland's overall Index score has increased from 44.69 out of 50 indicators in the twelfth edition to 47.44 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

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

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each member state. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024.

The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application, and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they comply with existing copyright law. Some of the positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and across the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

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.

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, detailed under Category 9.

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. The Commission’s proposal 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 Commission’s 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.

Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU member states seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become 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 Commission's proposals 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.

In early 2024, the European Parliament responded to the Commission's ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

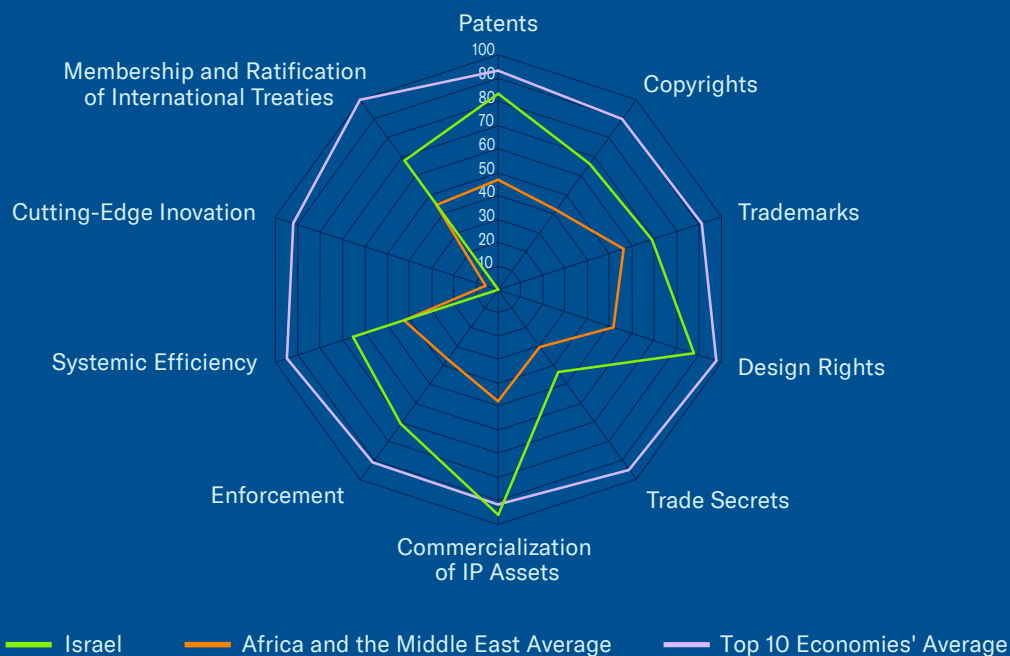
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals—including the European Parliament’s response to the Commission’s proposals in early 2024—the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.



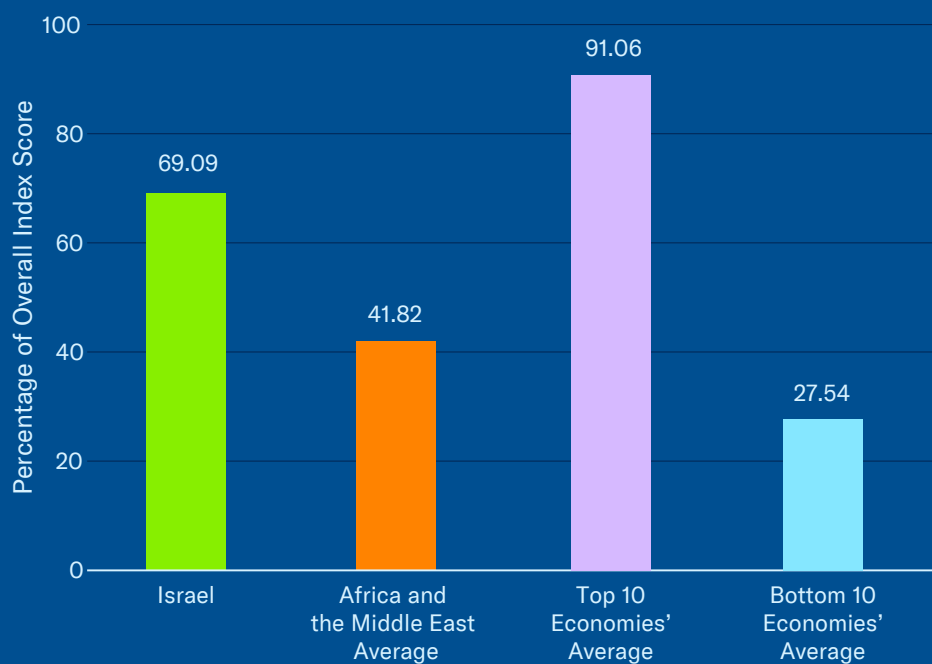
Israel

Rank
19/55

Category Scores



Overall Score in Comparison





Israel

Rank
19/55

Key Areas of Strength

- 2019 copyright amendments strengthened enforcement against online infringement and introduced the possibility of injunctive-style relief
- Global leader on technology transfer and international licensing activity; no administrative or regulatory barriers are in place
- Generous R&D and IP-specific tax incentives in place
- The Israeli Patent Office is an active participant in all major PPH tracks
- Life sciences IP rights reform efforts have considerably strengthened Israel's IP environment
- Industrial design law passed in 2017
- Joined the Hague Agreement in 2019

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 2021 proposed amendments to the 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 pre-grant patent opposition proceedings are characterized by long delays to patent prosecution
- Unclear the extent to which current RDP applies to large molecule products
- Has more limited participation in international treaties than other high-income OECD economies

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	7.50	29. Direct government intervention in setting licensing terms	1.00
1. Term of protection	1.00	30. IP as an economic asset	0.75
2. Patentability requirements	1.00	31. Tax incentives for the creation of IP assets	1.00
3. Patentability of CILs	1.00	Category 7: Enforcement	4.94
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.71
5. Pharmaceutical-related enforcement	0.50	33. Software piracy rates	0.73
6. Legislative criteria and use of compulsory licensing	1.00	34. Civil and precedural remedies	0.75
7. Pharmaceutical patent term restoration	1.00	35. Pre-established damages	0.75
8. Membership of a Patent Prosecution Highway	1.00	36. Criminal standards	0.75
9. Patent opposition	0.00	37. Effective border measures	0.75
Category 2: Copyrights and Limitations	4.63	38. Transparency and public reporting by customs	0.50
10. Term of protection	0.63	Category 8: Systemic Efficiency	3.25
11. Exclusive rights	0.75	39. Coordination of IP rights enforcement	0.50
12. Expeditious legal remedies disabling access to infringing content online	0.75	40. Consultation with stakeholders during IP policy formation	1.00
13. Cooperative action against online piracy	0.50	41. Educational campaigns and awareness raising	0.25
14. Limitations and exceptions	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
15. TPM and DRM	0.00	43. IP-intensive industries, national economic impact analysis	0.75
16. Government use of licensed software	1.00	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.75	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.75	Category 10: Membership and Ratification of International Treaties	4.75
20. Frameworks against online sale of counterfeit goods	0.25	47. WIPO Internet Treaties	0.50
Category 4: Design Rights and Limitations	1.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights, industrial design rights	0.75	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.30	51. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.00	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.30		
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		

Percentage of Overall Score: 69.09%

Total Score: 36.62

Spotlight on the National IP Environment

Past Editions versus Current Score

Israel's overall Index score has increased from 36.37 out of 50 indicators in the twelfth edition to 36.62 out of 53 indicators. This reflects a score increase for indicator 42.

Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs:

Several Israeli government departments and agencies are deeply engaged in facilitating the creation, registration, and commercialization of IP assets by all corporate entities, including SMEs. For example, the Israeli Innovation Authority (formerly the Office of the Chief Scientist) and other public entities actively engage in and support the creation and commercialization of IP assets through technology transfer, direct R&D grants, and technical assistance. Although not exclusive to SMEs, the bulk of this support is for start-ups, micro entities, and SMEs. The Israeli Patent Office offers reduced filing fees for SMEs applying to register a patent, but there is no expedited fast-track examination specific to SMEs. Accelerated examination is available for environmentally friendly “green” technologies, including applications from SMEs. In 2024, the Patent Office—in partnership with WIPO and the Canadian Intellectual Property Office—announced that it was expanding its technical assistance program with a dedicated effort to assist SMEs and start-ups in the FemTech industry. This is a growing research field and industry specializing in women's health and related products and services. The program will offer a range of services, including technical assistance and the evaluation of IP strategy and assets. As a result of this positive development, the score for this indicator has increased by 0.25.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

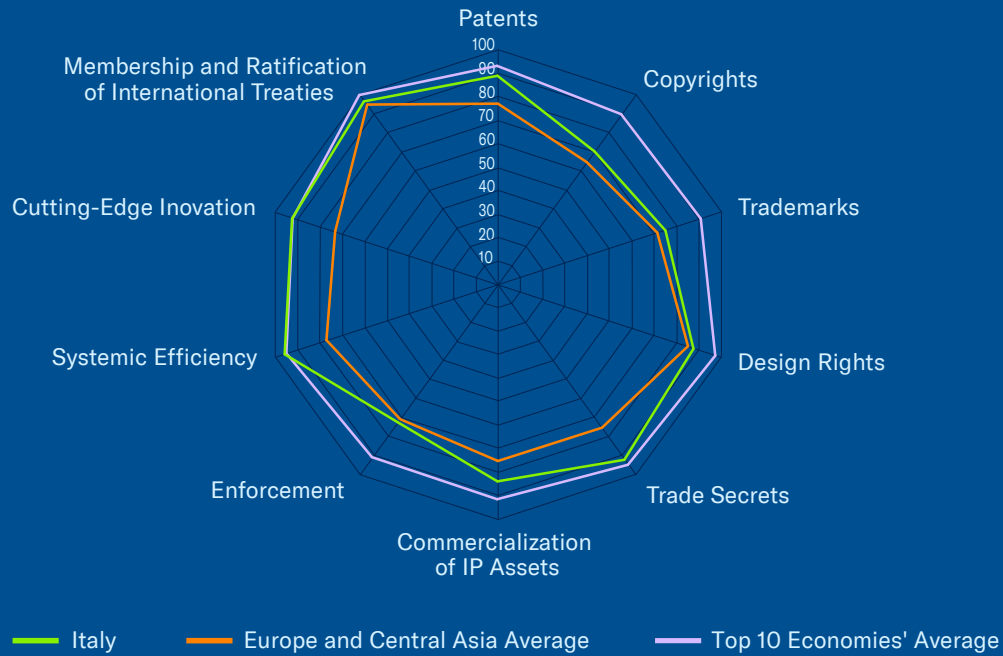
Interest in rare diseases has grown among public and private sector entities in Israel. Israel is a center for clinical research and the testing and development of new treatments for rare disease. Since 2020, the Ministry of Health has designated and funded specific medical treatment centers for patients with rare diseases. New orphan drugs and treatment options are also added to the national basket of publicly reimbursed medicines on an annual basis. However, no specific legislative framework is in place in Israel for rare diseases or any special IP-based market exclusivity incentives for orphan medicinal product development.



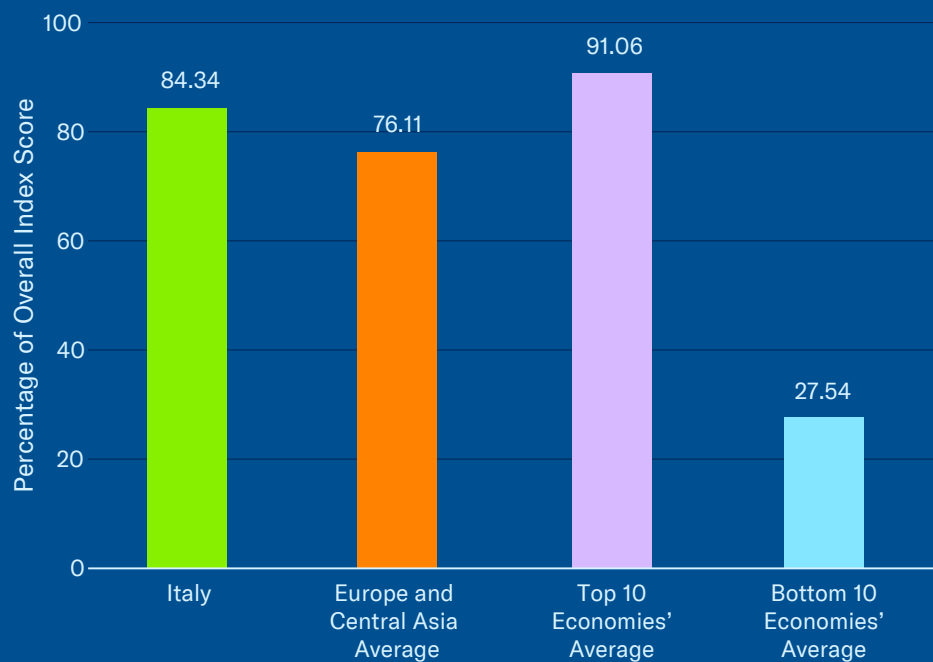
Italy

Rank
12/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Since 2000, the orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- Transposed the EU Directive 2019/790 on Copyright and Related Rights CDSM Directive into law
- 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 for addressing online copyright infringement
- Public consultation during policy formation and efforts to raise awareness of IP importance are present

Key Areas of Weakness

- The EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- The new EU-wide compulsory licensing regime would undermine patent rights in Europe
- The new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- Registration requirements for licensing agreements
- Regulation 2019/933 and the existing SPC exemption for exports of biopharmaceuticals pose significant risk to Italy's and the EU's research and IP-based biopharma industry

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	8.00	29. Direct government intervention in setting licensing terms	1.00
1. Term of protection	1.00	30. IP as an economic asset	0.75
2. Patentability requirements	0.75	31. Tax incentives for the creation of IP assets	1.00
3. Patentability of CILs	1.00	Category 7: Enforcement	5.04
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.72
5. Pharmaceutical-related enforcement	0.50	33. Software piracy rates	0.57
6. Legislative criteria and use of compulsory licensing	1.00	34. Civil and preceudural remedies	0.75
7. Pharmaceutical patent term restoration	0.75	35. Pre-established damages	0.50
8. Membership of a Patent Prosecution Highway	1.00	36. Criminal standards	0.50
9. Patent opposition	1.00	37. Effective border measures	1.00
Category 2: Copyrights and Limitations	4.91	38. Transparency and public reporting by customs	1.00
10. Term of protection	0.66	Category 8: Systemic Efficiency	4.75
11. Exclusive rights	0.50	39. Coordination of IP rights enforcement	1.00
12. Expeditious legal remedies disabling access to infringing content online	1.00	40. Consultation with stakeholders during IP policy formation	1.00
13. Cooperative action against online piracy	1.00	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
15. TPM and DRM	0.50	43. IP-intensive industries, national economic impact analysis	1.00
16. Government use of licensed software	0.75	Category 9: Cutting-Edge Innovation	2.75
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18. Protection of well-known marks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
19. Exclusive rights, trademarks	0.75	Category 10: Membership and Ratification of International Treaties	6.75
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25. Regulatory data protection term	1.00		
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		

Percentage of Overall Score: 84.34%

Total Score: 44.70

Spotlight on the National IP Environment

Past Editions versus Current Score

Italy's overall Index score has increased from 41.95 out of 50 indicators in the twelfth edition to 44.70 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

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

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and the European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each Member State. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

11. *Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); and*
12. *Expeditious legal remedies disabling access to infringing content online:*

As noted over the course of the Index, Italy has historically been one of the more challenging EU Member States for effective copyright enforcement. Estimates on copyright piracy have traditionally been high. An analysis from the mid-2010s by the Sturza Institute placed music piracy at around 50% and film piracy at just under 40%. Although rightsholders in Italy still face significant challenges, as noted in the Index, the past five years have seen a significant increase in enforcement activity through the introduction and active use of injunctive-style relief mechanisms. Through both legislative changes and a strong body of case law at the EU level and in Italy, the Italian Communications Regulatory Authority (AGCOM) is today empowered to receive complaints from rightsholders and to order ISPs to remove or prevent access to illegally published content. In fact, the agency's legal remit has been strengthened over the course of the Index and now includes the power to ask ISPs to implement notice-and-takedown measures, issuing of preliminary injunctions that disable access to infringing websites within three days upon receiving notification from the rightsholder (including dynamic injunctions that address alias sites), enforcement on social platforms and telephone or instant messaging platforms, and the issuing of administrative fines from EUR10,000 up to 2% of an accused entity's prior year turnover. Furthermore, in 2023, AGCOM's remit was further expanded with the enactment of a new anti-piracy law (Law 93/2023). The primary purpose of this new legislation was to enhance AGCOM's ability to fight online piracy of live broadcasts, including sporting events.

Overall, AGCOM's and Italy's antipiracy efforts have proven to be highly effective. Italy's overall score in this category of the Index has increased from 56.83% of the total available score in 2016 (the fourth edition of the Index) to 70.14% in this edition. That is a notable and significant achievement.

At the same time, rates of online piracy have also decreased. For example, in 2023, EUIPO found in the study *Online Copyright Infringement in the European Union: Films, Music, Publications, Software and TV (2017–2022)* that measured on a standardized basis (the total number of pirated accesses per internet user for film, music, and TV), online piracy had dropped in Italy from almost 10 accesses per internet user in March 2017 to four accesses in late 2022. Although this bounced back slightly to over five accesses at the end of 2022, this is still a substantive long-term reduction in overall piracy levels.

In 2024, AGCOM launched a new antipiracy tool, the "Piracy Shield," specifically targeting IPTV content. Figures from AGCOM suggest that thousands of online access points had successfully been disabled. However, reports also suggest that access had been disabled to several content delivery networks. Subsequent public testimony by the head of AGCOM, Giacomo Lasorella, explained that this had occurred because both illicit and legal content was hosted through the same online access point. The Index will continue to monitor these developments in 2025.

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024. The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally.

The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are required to (1) make public summaries of the main sources used for such educational purposes and (2) ensure they comply with existing copyright law. Some positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

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.

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, detailed under Category 9.

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. The Commission’s proposal 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 Commission’s 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.

Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU Member States seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become 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 Commission's proposals 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.

In early 2024, the European Parliament responded to the Commission's ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

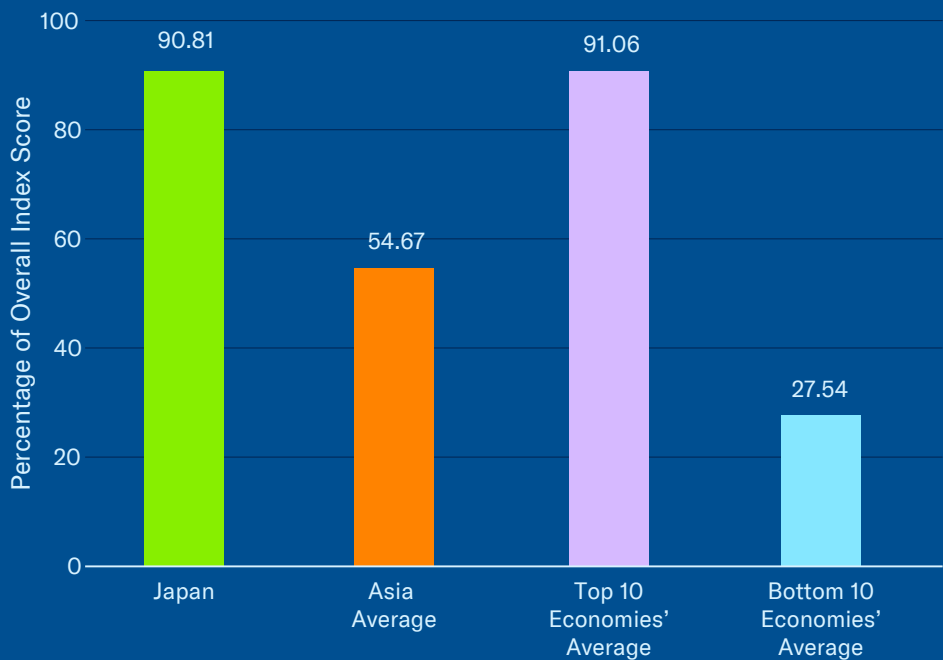
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals, including the European Parliament’s response to the Commission’s proposals in early 2024, the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU member states included in the Index seeing a score reduction for indicators 45 and 46.

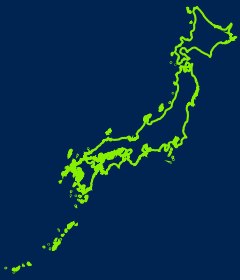


Category Scores



Overall Score in Comparison





Japan

Rank
7/55

Key Areas of Strength

- Since the mid-2010s, Japan has provided an extended data exclusivity period (referred to as a “re-examination” period) of 10 years for designated orphan drugs
- Continued strong copyright enforcement efforts
- 2020 amendments to the Copyright Act continued to strengthen the copyright environment
- Design Act amendments came into effect in 2020, which included an increase in the term of protection
- 2019 copyright amendments strengthen TPM laws and increase the term of protection
- Global leader with respect to targeted administrative incentives for the creation and use of IP assets for SMEs
- Economic Partnership Agreement with EU 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

Key Areas of Weakness

- Concerns over the protection of biopharmaceutical patent rights after approval of several follow-on drugs in 2020 by the Japanese drug regulatory authority
- No IP-specific tax incentives is in place such as a patent box regime
- Remedies against online copyright infringement remain underdeveloped compared to other OECD economies

Percentage of Overall Score: 90.81% • Total Score: 48.13

Spotlight on the National IP Environment

Past Editions versus Current Score

Japan's overall Index score has increased from 45.63 out of 50 indicators in the twelfth edition to 48.13 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism:

As noted in previous editions of the Index, after the conclusion of a patent invalidation action lodged in 2019 with the Japan Patent Office (JPO), in 2020, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved several generic follow-on products for a reference product. This occurred even though the JPO had upheld several of the innovator's claims and rights in the patent invalidation action. After the approval, the rightsholder initiated patent infringement proceedings against the approved generic products. Industry reports suggest that this was not an isolated example but that the MHLW has subsequently approved several more follow-on products despite the reference products in question being under a term of IP exclusivity. Once a follow-on product has been approved for market, it is automatically eligible for inclusion in Japan's national formulary and, by extension, Japanese patients. There is a potential high cost to any national IP system that is unable to effectively resolve any biopharmaceutical patent infringement dispute before the marketing of a product and to provide effective interim relief. In this respect, biopharmaceutical products are unique because they involve not only the potential infringing party and the rightsholder but also patients whose health and well-being depend on the products in question.

Consequently, the introduction of a potentially infringing product onto the marketplace puts both patients and the follow-on manufacturers at risk. In short, this situation creates significant uncertainty for innovators and generic manufacturers alike and could result in products being prescribed to Japanese patients that ultimately have to be withdrawn from the market based on the outcome of the pending litigation. Reports suggest that in 2024, the MHLW was considering introducing a more formalized patent and IP exclusivity review process.

As this Index has consistently argued, 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 and stimulating early market entry of follow-on generic products. Such linkage ensures that any disputes are resolved before the marketing of a follow-on product. This grants innovators a fair opportunity to secure a return on their long-term, high-risk R&D investment—by ensuring they can effectively use their legally granted exclusivity—but it also limits potential damages for generic manufacturers because no potentially infringing product is ever launched or approved for market. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a postmarketing lawsuit. The introduction of a clearly defined and formalized linkage mechanism in Japan would constitute an improvement to Japan's biopharmaceutical IP environment and would result in a potential score increase for this indicator. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the Japanese Agency for Cultural Affairs Copyright Division (part of the Ministry of Education, Culture, Sports, Science and Technology) has been actively discussing the interaction between copyright protection and the use and application of AI and machine learning for the past few years. In 2023, the agency held a seminar and released a presentation setting out its views. This work continued in 2024 with the agency making several important policy contributions—most notably the publication of a concept paper “Thoughts on AI and Copyright” in March 2024—and hosting an additional stakeholder seminar. The paper provides an in-depth technical analysis of AI and related technologies and Japan’s copyright law and exceptions regime. By and large, the analysis follows the same reasoning as the 2023 agency presentation by drawing a distinction between what is termed an “AI development/learning stage” and a “Generation/Usage stage.” A detailed analysis of existing Japanese copyright exceptions and the meaning and application of Section 30(4) is provided. The concept paper rightly notes that this is a novel and challenging area of copyright law requiring much nuance and a case-by-case analysis of the type of technologies used, the purpose of the AI application, the extent to which any copyrighted works have been studied, how these works have been used (and what proportion of the works have been used), and how these works were acquired. Based on a close reading of Article 30(4), the paper draws a distinction between the “enjoyment” of a copyrighted work in question and its “non-enjoyment.”

Essentially, the agency argues that the use of copyrighted material is allowed in cases whereby the training of the AI application (the “developmental/learning stage”) falls under the category of “non-enjoyment” of the work “when a work is used for information analysis, including for the purposes of AI training, it is considered to fall under the provision of Article 30-4 of the Act, which states that ‘the work does not aim to enjoy for oneself or to allow others to enjoy the ideas or emotions expressed in the work.’” Yet this reasoning fails to account for the fact that any application using a copyrighted work for learning and developmental purposes is, by definition, an “enjoyment” of the work. Regardless of the extent to which an eventual AI output resembles the copyrighted work used or the quantity of copyrighted works used during the AI developmental process, the copyrighted work in question constitutes part of the technology’s learning and, hence, “enjoyment.” Without access to materials to learn from, the AI-based application would not be able to learn and, consequently, not be able to produce any desired output. More broadly, this logic holds true for any type of learning or developmental activity whether for machines or human beings. For example, human beings who want to learn and develop from copyrighted works must acquire them lawfully to be able to make use of and, potentially, “enjoy” them. There is no reason why this logic should not be applied to computer software and the development of AI applications. More broadly, and as noted last year, the narrow exceptions to copyright protection defined under Article 30(4) are all 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 of or access to copyrighted works.

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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, 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, both in Japan and around the world. The concept paper acknowledges that the existence, dissemination and, potential use of pirated content in AI development is a problem: “The damage caused by pirated copies to Japan’s content industry is enormous, and it goes without saying that we must take measures against pirated copies, including regulating reach sites.” But overall, the paper seems to suggest that the responsibility for enforcement lies with rightsholders and that, in contrast, AI developers have only a relatively limited duty of care:

Whether data on the Internet is a pirated or other infringing copy is ultimately difficult for anyone other than the copyright holder of the work to which the copy pertains, and it is likely to be difficult in practice to ask those who are trying to collect learning data for AI training to make this judgment. In addition, infringing copies include a wide range of things, from those posted on pirate sites that upload a large number of original manga and other works without permission, to those posted by individual users on SNS and other sites that do not meet the requirements of the rights restriction provisions for citations, etc. For this reason, when collecting training data on the internet for AI training, the data to be collected may contain pirated copies or other copies that have been uploaded in violation of copyright...

AI development businesses and AI service providers are required to take sufficient care when collecting training data from websites that host pirated copies to ensure that such actions do not encourage infringement of rights, such as an increase in new pirated copies, by making it easier to access such websites or generating advertising revenues or other financial benefits for those who operate such websites. In this regard, it is desirable for rights holders to provide relevant parties such as these businesses with information about known websites that host pirated copies in advance to an appropriate extent, so that businesses can recognize websites that host pirated copies and take measures such as excluding them from the collection of training data, thereby realizing a situation that does not encourage infringement of rights through pirated copies.

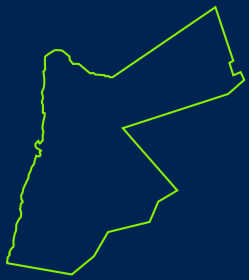
After the agency’s seminar and publications, the Japan Newspaper Publishers and Editors Association released a statement demanding, as described by *The Japan Times*, “consent and accuracy from generative AI.” This follows a similar 2023 statement issued by a collection of Japanese publishers and rightsholders calling for more clarity on the interpretation of existing copyright statute and the need for the government to engage rightsholders in this issue. The Index will monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. Since the 1970s, Japan has had a dedicated policy program in place for rare diseases. Today, the 2014 Act on Medical Care for Patients with Rare/Intractable Diseases (Act No. 50 of 2014) and relevant sections of the drug regulatory framework provide the legal definitions and policies related to rare diseases and orphan drugs. Specifically, these laws and related programs provide an expedited market approval pathway for new drugs, reduced and/or waived sanitary registration fees, and dedicated funding mechanisms for patients with rare diseases.

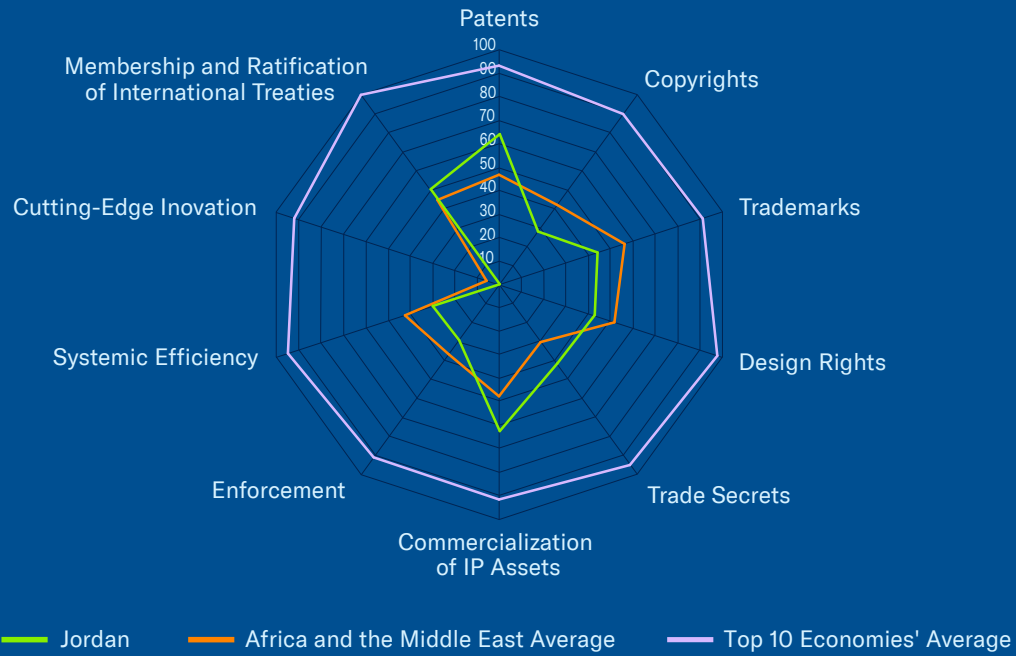
With respect to incentives to R&D and the development of new treatments and technologies, designated orphan drugs benefit from an extended data exclusivity period (referred to as “re-examination” period) of 10 years (against eight years for new chemical entities and four years for new indications of drugs already approved).



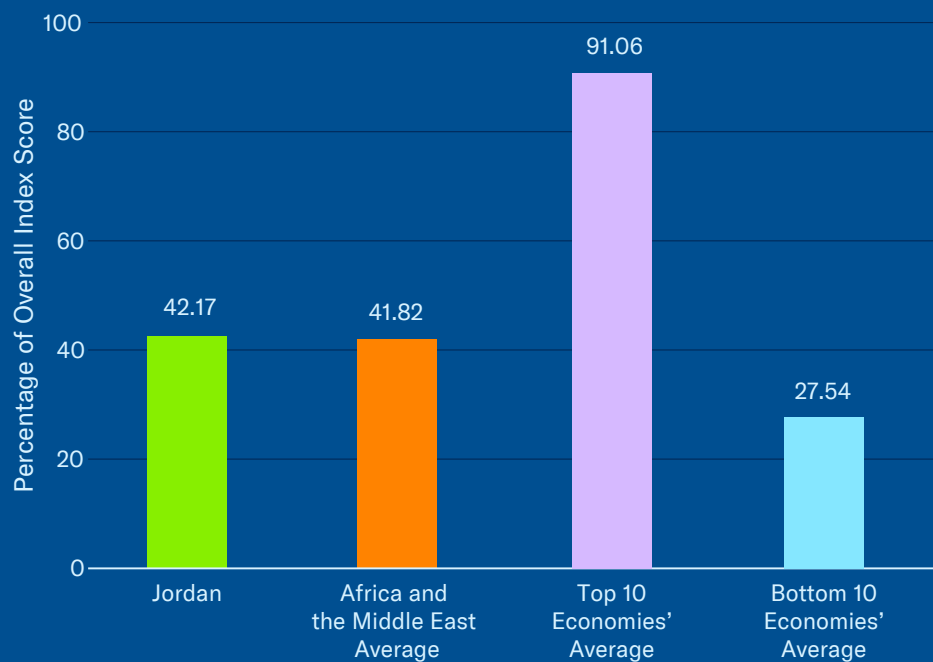
Jordan

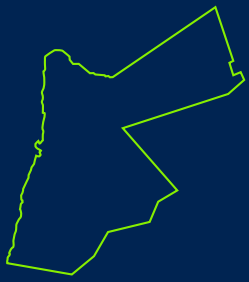
Rank
35/55

Category Scores



Overall Score in Comparison





Jordan

Rank
35/55

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 special IP incentives for orphan medicinal product development
- 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 availability of patents for CII

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.50	30. IP as an economic asset	0.25
3. Patentability of CILs	0.25	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	1.00	32. Physical counterfeiting rates	0.36
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.45
7. Pharmaceutical patent term restoration	1.00	34. Civil and preceudural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.00	35. Pre-established damages	0.25
9. Patent opposition	0.00	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	0.50
10. Term of protection	0.44	38. Transparency and public reporting by customs	0.00
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	0.25
13. Cooperative action against online piracy	0.00	40. Consultation with stakeholders during IP policy formation	0.25
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.50
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
16. Government use of licensed software	0.25	43. IP-intensive industries, national economic impact analysis	0.50
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 6: Commercialization of IP Assets	
Category 4: Design Rights and Limitations		26. Barriers to market access	1.00
21. Industrial design term of protection	0.60	27. Barriers to technology transfer	0.50
22. Exclusive rights, industrial design rights	0.25	28. Registration and disclosure requirements of licensing deals	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		Percentage of Overall Score: 42.17%	
23. Protection of trade secrets (civil remedies)	0.50	Total Score: 22.35	
24. Protection of trade secrets (criminal sanctions)	0.25		
25. Regulatory data protection term	0.50		

Spotlight on the National IP Environment

Past Editions versus Current Score

Jordan's overall Index score remains unchanged at 22.35 out of 53 indicators.

Copyrights and Limitations; Enforcement

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expeditious legal remedies disabling access to infringing content online; and 36. Criminal standards, including minimum imprisonment and minimum fines:

Like many Index economies in the Middle East and North Africa region, the infringement of copyrighted content through set-top boxes and illicit streaming devices is becoming widespread in Jordan. The USTR in both the *Review of Notorious Markets for Counterfeiting and Piracy* and *Special 301 Report* have included reference to a Jordanian entity, Spider, which 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 there is no established mechanism 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.

As noted last year, some positive developments occurred in 2022 and 2023 with greater enforcement efforts through domestic law enforcement and the disabling of access to pirate websites through the Jordanian Media Commission. Unfortunately, these positive efforts did not carry over into 2024. The Index will continue to monitor this activity in 2025.

Systemic Efficiency

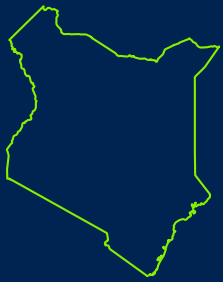
43. IP-intensive industries, national economic impact analysis:

As noted in past editions, the Jordanian Industrial Property Protection Directorate (IPPD) does not have a dedicated research program examining the relationship between IP rights and economic activity. Although IP rights figure only tangentially in national development programs, including the flagship *Jordan 2025, A National Vision and Strategy*, other examples of government commissioned or supported research examine this relationship, such as the 2012 *The Economic Contribution of Copyright-Based Industries in the Hashemite Kingdom of Jordan*, a review of the creative economy in Jordan sponsored by WIPO and supported by several parts of the Jordanian Government, including the Ministry of Culture. In 2024, the National Scientific Research and Innovation Support Fund (lodged within the Ministry of Higher Education and Scientific Research) announced that measuring the economic impact of creative and cultural industries in Jordan would be one of its research and funding priorities over the course of the year. The publication of such a study with new, up-to-date data would be an important contribution to better understanding the important role that IP-intensive industries play in Jordan's national economy. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

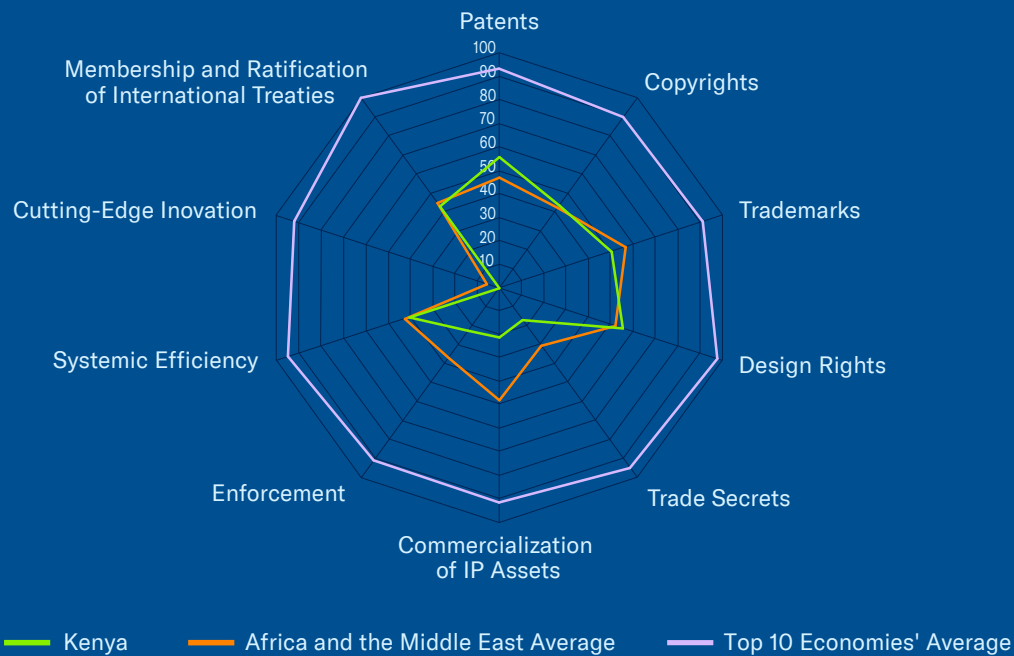
Interest in rare diseases has grown in the Middle East and North Africa region. In 2003, the Centre for Arab Genomic Studies was established to map and improve the state of care for patients with genetic diseases in the Arab world. Today, the Center has become the leading research point on rare diseases in the region. Several Index economies in the region, including Saudi Arabia and the UAE, have introduced a defined regulatory sanitary registration pathway and special incentives for orphan products. Jordan does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



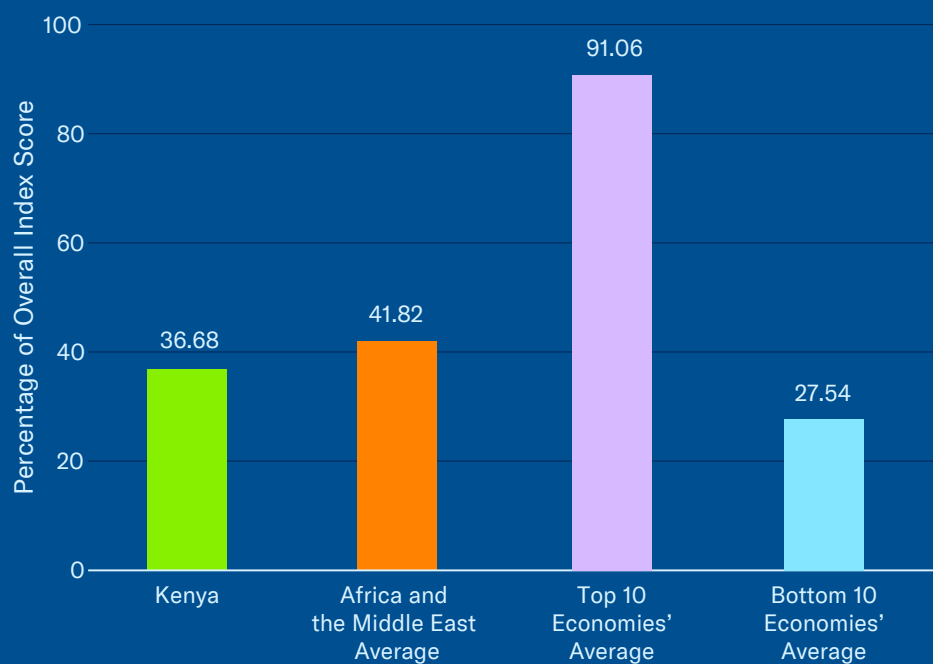
Kenya

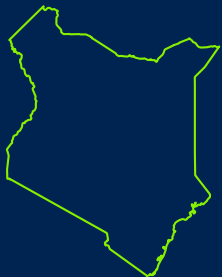
Rank
42/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- 2024 ARIPO-China National Intellectual Property Administration (CNIPA) PPH—first PPH for Kenya and other ARIPO parties
- 2021 Anti-Counterfeit Amendment Regulations allow rightsholders to register their rights with the Anti-Counterfeit Authority
- 2020 Anti-Counterfeit Act amendments strengthen enforcement powers
- 2019 copyright amendments strengthened protection of copyright in Kenya
- Basic IP framework is in place, including several sector-specific rights
- Dedicated IP bodies and enforcement agencies
- Recent efforts to improve knowledge and frameworks for proper use and commercialization of IP assets

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Data Protection (General) Regulations 2021 do not provide clarity on potential data localization requirements under the 2019 Data Protection Act
- Draft IP Bill would combine IP authorities under one office; it is unclear whether each section would have enough resources and staff
- Barriers are in place for licensing and technology transfer
- No R&D or IP-specific tax incentives are in place
- No targeted incentives for the creation and use of IP assets for SMEs
- Weak and backlogged judicial system with notable deficiencies in criminal enforcement
- Important gaps exist in copyright protection and enforcement, particularly in the digital space
- Legislative and resource barriers to border enforcement

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.00
2. Patentability requirements	0.50	30. IP as an economic asset	0.50
3. Patentability of CII	0.25	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00		
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.30
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.26
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.00
9. Patent opposition	0.75	36. Criminal standards	0.25
		37. Effective border measures	0.25
Category 2: Copyrights and Limitations		38. Transparency and public reporting by customs	0.25
10. Term of protection	0.53		
11. Exclusive rights	0.50	Category 8: Systemic Efficiency	
12. Expeditious legal remedies disabling access to infringing content online	0.25	39. Coordination of IP rights enforcement	0.50
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	0.25
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.50
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	0.50
Category 3: Trademarks Rights and Limitations			
17. Term of protection	1.00	Category 9: Cutting-Edge Innovation	
18. Protection of well-known marks	0.50	44. IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
20. Frameworks against online sale of counterfeit goods	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
Category 4: Design Rights and Limitations			
21. Industrial design term of protection	0.60	Category 10: Membership and Ratification of International Treaties	
22. Exclusive rights, industrial design rights	0.50	47. WIPO Internet Treaties	0.50
Category 5: Trade Secrets and the Protection of Confidential Information		48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
23. Protection of trade secrets (civil remedies)	0.25	49. Patent Law Treaty and Patent Cooperation Treaty	0.75
24. Protection of trade secrets (criminal sanctions)	0.25	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
25. Regulatory data protection term	0.00	51. Membership of the Convention on Cybercrime, 2001	0.00
Category 6: Commercialization of IP Assets		52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
26. Barriers to market access	0.50	53. Post-TRIPS FTA	0.00
27. Barriers to technology transfer	0.25		
28. Registration and disclosure requirements of licensing deals	0.00		

Percentage of Overall Score: 36.68%

Total Score: 19.44

Spotlight on the National IP Environment

Past Editions versus Current Score

Kenya's overall Index score has increased from 18.94 out of 50 indicators in the twelfth edition to 19.44 out of 53 indicators. This reflects a score increase for indicator 8.

Patent Rights and Limitations

8. Membership of a Patent Prosecution Highway (PPH):

Historically, neither Kenya nor ARIPO have participated in the IP5 PPH or the Global PPH or have had in place a PPH on a bilateral basis. This changed in 2024 with the announcement that ARIPO and the China National Intellectual Property Administration had agreed on a PPH pilot program. At the time of research, the agreement had come into effect and would remain operational for five years. PPH initiatives and increased cooperation among 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. As a result of this positive development, the score for this indicator has increased by 0.5.

Copyrights and Limitations

11. Legal measures that provide necessary exclusive rights preventing infringement of copyrights and related rights (including web hosting, streaming, and linking; 12. Expeditious legal remedies disabling access to infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy:

As noted over the course of the Index, rightsholders in Kenya have long struggled with high and persistent levels of copyright piracy with the availability of physical and digital pirated music, film, and other copyrighted content high.

Up until 2019, the Copyright Act only provided for basic exclusive rights to redress copyright infringement with limited reference to the digital or online sphere. The passing and signing into law of the Copyright (Amendment) Act of that year introduced new copyright enforcement mechanisms, including clear definitions of ISP and service providers' liability as well as an injunctive-style relief mechanism. In addition to these changes, the Amendment Act also extended copyright protection to computer programs and criminalized the circumvention of technological protection measures or the manufacture of devices to circumvent technical protections. As a result of this positive action, the scores for indicators 11, 12, and 13 increased in the eighth edition of the Index.

Yet, despite these positive legal developments, copyright enforcement in Kenya has remained fraught. As internet penetration continues to rise with an increasing number of the population having access either through a fixed broadband connection or, more frequently, mobile telephone services, online piracy has also increased. For example, figures produced by "Partners Against Piracy," a local Kenyan antipiracy group, estimates that online piracy cost the Kenyan economy just under KSH100 billion (about \$750 million) in 2022. To help address this issue, in late 2023, the Kenya Copyright Board announced the launch of a new "Blank Tape Levy" scheme. Emulating similar levy systems in place in other economies in Africa and Europe, the purpose of this program is to raise funds by imposing an additional surcharge on blank media that, in the words of the board's public notice, "may be used to carry copyright protected content for private copying." At the time of research, the scheme was not operational and was facing legal action. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Kenya is in the midst of developing its health system and national health policies. The expansion of health services and provision of universal health coverage is a fundamental component of Kenya's *Vision 2030*. In 2020, the Ministry of Health released the policy blueprint *Kenya Universal Health Coverage Policy 2020–2030*. This document did not refer specifically to rare diseases or the need for building rare disease-specific health infrastructure such as registries or treatment and diagnostics centers. However, several patient groups and clinicians highlight the needs of patients with rare diseases, including the national advocacy group Rare Disorders Kenya. No specific legislative framework is in place for rare diseases, including with respect to R&D and IP-based market exclusivity incentives for orphan medicinal product development.

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 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. Kenya's score in this category of the Index has increased from a score of 1.50, or 37.50%, in the fifth edition of the Index (the first year Kenya was included) to now achieving a score of 3.00, or 43%, of the total available score.

Overall, Kenya 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; and the International Convention for the Protection of New Varieties of Plants, Act of 1991. Kenya is a signatory but has not acceded to the WIPO Internet treaties, the Patent Law Treaty, and the Singapore Treaty on the Law of Trademarks. Kenya is not a contracting party to 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:

Kenya has, in the past few years, either concluded or has been in the process of negotiating several FTAs and economic partnerships. For example, Kenya is a contracting party to the African Continental Free Trade Area, signed by 44 African economies in 2018. The agreement holds the potential to fundamentally revolutionize economic activity in Africa by reducing barriers to trade and economic interaction across the entire continent. Parts of the Free Trade Area (Phase I) came into force in 2019 and 2021. At the time of research, outstanding issues to be negotiated as Phase II of the agreement include a Protocol on Intellectual Property. Similarly, Kenya has been in negotiations with the United States on both a traditional FTA and, under the Biden administration, a Strategic Trade and Investment Partnership. In 2024, Kenya concluded a Comprehensive Economic Partnership Agreement (CEPA) with the UAE. Over the past three years, the UAE has on a bilateral basis concluded several CEPAs, including 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 congratulated for recognizing the importance of IP-intensive industries and the centrality of IP rights to future trade and economic development in all economies.

As has been noted in the Index, this is not always the case. Many 21st-century post-TRIPS FTAs do not include a dedicated IP chapter or skirt meaningful provisions on IP rights altogether. 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 between the individual agreements, many of the IP chapters are 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.

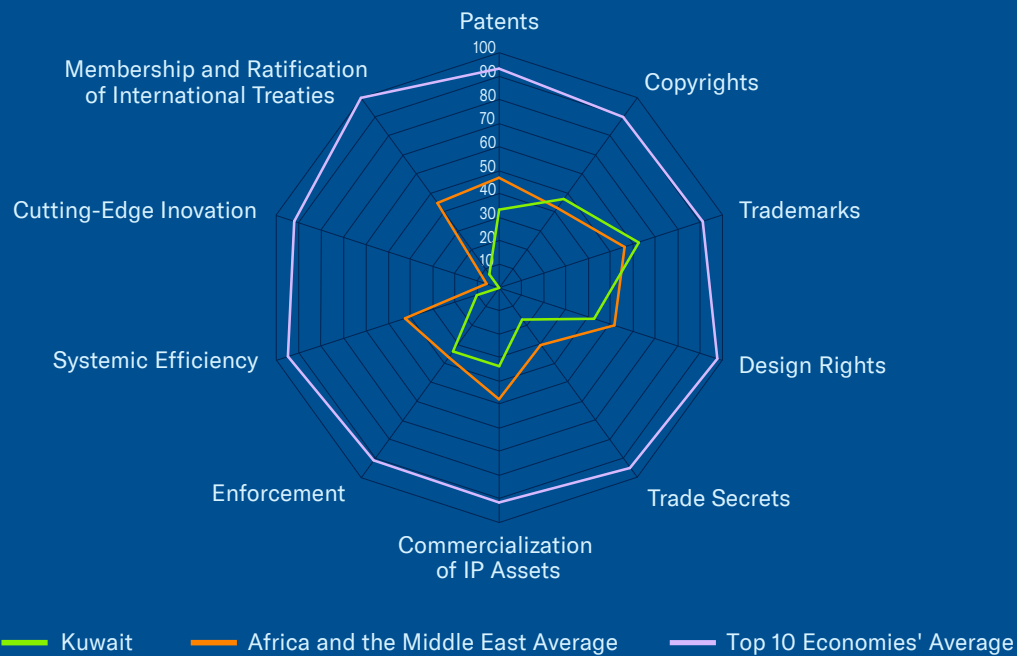
But 30 years after Marrakesh, TRIPS is outdated and no longer represents or includes all the standards and protections that a modern, innovation-based economy needs. In terms of specific feature and IP rights missing from these agreements, copyright provisions are relatively limited with no reference to the challenges that the online environment or infringement represents to rightsholders; no or limited reference is made 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. At the time of research, the finalized Kenya-UAE CEPA had not been made available to the public and, for the purposes of this indicator, could not be assessed. The Index will continue to monitor these developments in 2025.



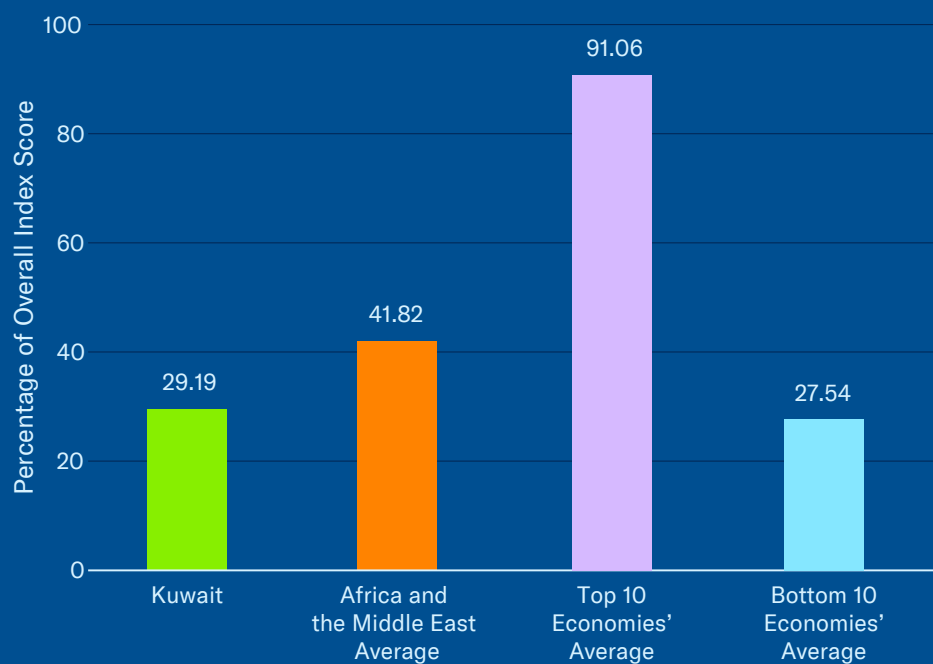
Kuwait

Rank
49/55

Category Scores



Overall Score in Comparison





Kuwait

Rank
49/55

Key Areas of Strength

- The administrative IP enforcement option is available and in use through the National Library and Ministry of Commerce and Industry; led to the disabling of access to thousands of websites offering counterfeit and IP-infringing goods
- Basic IP framework is in place
- Participant in regional patent and trademark harmonization efforts through GCC

Key Areas of Weakness

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

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.50
2. Patentability requirements	0.50	30. IP as an economic asset	0.50
3. Patentability of CII	0.25	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	0.00	Category 7: Enforcement	
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.41
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.43
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.00	35. Pre-established damages	0.25
9. Patent opposition	0.25	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	0.50
10. Term of protection	0.53	38. Transparency and public reporting by customs	0.25
11. Exclusive rights	0.50	Category 8: Systemic Efficiency	
12. Expeditious legal remedies disabling access to infringing content online	0.75	39. Coordination of IP rights enforcement	0.00
13. Cooperative action against online piracy	0.00	40. Consultation with stakeholders during IP policy formation	0.25
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.25
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	0.00
Category 3: Trademarks Rights and Limitations		Category 9: Cutting-Edge Innovation	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.50	Category 10: Membership and Ratification of International Treaties	
Category 4: Design Rights and Limitations		47. WIPO Internet Treaties	0.00
21. Industrial design term of protection	0.60	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
22. Exclusive rights, industrial design rights	0.25	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
Category 5: Trade Secrets and the Protection of Confidential Information		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
23. Protection of trade secrets (civil remedies)	0.25	51. Membership of the Convention on Cybercrime, 2001	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
25. Regulatory data protection term	0.00	53. Post-TRIPS FTA	0.00
Category 6: Commercialization of IP Assets			
26. Barriers to market access	0.00		
27. Barriers to technology transfer	0.50		
28. Registration and disclosure requirements of licensing deals	0.50		

Percentage of Overall Score: 29.19%

• Total Score: 15.47

Spotlight on the National IP Environment

Past Editions versus Current Score

Kuwait's overall Index score has increased from 14.21 out of 50 indicators in the twelfth edition to 15.47 out of 53 indicators. This reflects a score increase for indicators 11, 12, 18, 19, and 20.

Copyrights and Limitations; and Trademark Rights and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expeditious disabling of infringing content online; 18. Protection of well-known marks; 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:

The IP enforcement environment in Kuwait has long been difficult. Although civil remedies, including injunctive relief, the suspension of alleged infringing activities, and the seizure of infringing materials and goods are available for most major IP rights, active enforcement has been lacking.

In a positive development, over the past few years, some notable improvements have been made to Kuwait's national IP environment and, in particular, the enforcement of IP rights online. As noted in the Index at the time, in 2019, Law 75 on Copyright and Related Rights, was enacted. This made some important changes to Kuwait's copyright regime with potential new avenues for 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 the coming into force of these amendments, offered rightsholders the option of filing copyright infringement complaints directly through an online portal. This administrative enforcement option comes on top of a pre-existing mechanism run by the Communications and Information Technology Authority (CITRA).

Since 2014–2015, 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 IP rights. 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 for 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 its website. As of 2024 rightsholders can directly lodge complaints and request the disabling of access to any online access point offering access to IP infringing content and/or goods electronically directly via several Government of Kuwait websites. As a result, public reporting suggests that the government disabled thousands of online access points over the past few years. Significantly, many of these access points were disabled based on IP infringement. As a result of these continued positive efforts, the scores for indicators 11, 12, 18, 19, and 20 have increased.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Interest in rare diseases has grown in the Middle East and North Africa region. In 2003, the Centre for Arab Genomic Studies was established to map and improve the state of care for patients with genetic diseases in the Arab world. Today, the Center has become the leading research point for rare diseases in the region. Several Index economies in the region, including Saudi Arabia and the UAE, have introduced a defined regulatory sanitary registration pathway and special incentives for orphan products.

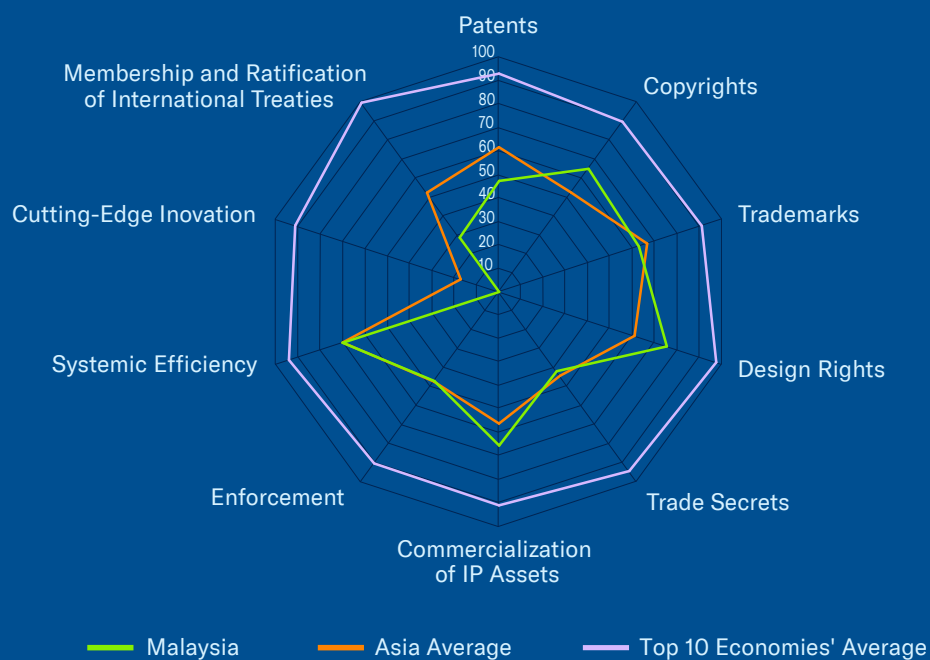
Since 1979, the Kuwait Medical Genetic Centre has provided genetic screening services and patient care. In 2018, the Ministry of Health introduced fast-track sanitary registration of orphan products. The Ministry of Health also runs a national newborn screening program. Kuwait does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



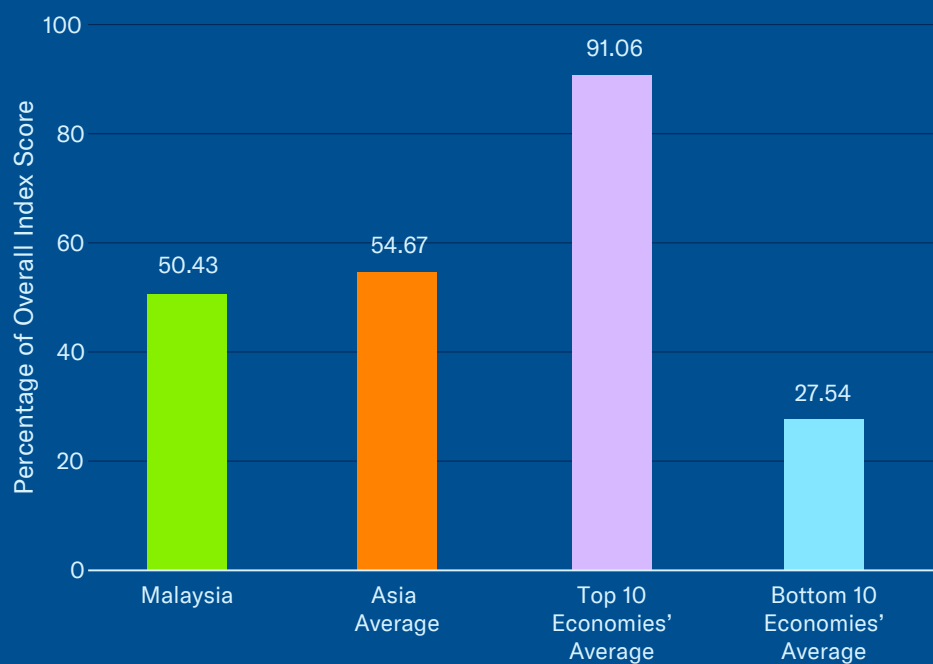
Malaysia

Rank
28/55

Category Scores



Overall Score in Comparison





Malaysia

Rank
28/55

Key Areas of Strength

- Strong enforcement efforts against infringing set-top boxes continued through Malaysian Communications and the Multimedia Commission and Ministry of Domestic Trade and Consumer Affairs
- 2022 amendments to the Patent Act provide for a defined pathway of postgrant opposition proceedings
- 2020 Trademark Act amendments strengthen the enforcement environment
- Generous R&D and IP-specific tax incentives are in place
- The Intellectual Property Corporation of Malaysia has PPH agreements in place with both EPO and JPO
- Strong focus by the Malaysian government on IP as a commercial asset and technology transfer

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 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

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	4.25	29. Direct government intervention in setting licensing terms	0.00
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	1.00	31. Tax incentives for the creation of IP assets	0.67
3. Patentability of CILs	0.25	Category 7: Enforcement	3.28
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.54
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.49
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precluded remedies	0.50
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.50
8. Membership of a Patent Prosecution Highway	0.50	36. Criminal standards	0.75
9. Patent opposition	0.50	37. Effective border measures	0.50
Category 2: Copyrights and Limitations	4.53	38. Transparency and public reporting by customs	0.00
10. Term of protection	0.53	Category 8: Systemic Efficiency	3.50
11. Exclusive rights	0.75	39. Coordination of IP rights enforcement	0.75
12. Expedient legal remedies disabling access to infringing content online	0.75	40. Consultation with stakeholders during IP policy formation	1.00
13. Cooperative action against online piracy	0.75	41. Educational campaigns and awareness raising	0.75
14. Limitations and exceptions	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
15. TPM and DRM	0.75	43. IP-intensive industries, national economic impact analysis	0.75
16. Government use of licensed software	0.50	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.50	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.75	Category 10: Membership and Ratification of International Treaties	2.00
20. Frameworks against online sale of counterfeit goods	0.25	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	1.50	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	0.50	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.25	51. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.50		
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		

Percentage of Overall Score: 50.43%

Total Score: 26.73

Spotlight on the National IP Environment

Past Editions versus Current Score

Malaysia's overall Index score has increased from 26.72 out of 50 indicators in the twelfth edition to 26.73 out of 53 indicators. This reflects a score increase for indicator 32.

Copyrights and Limitations; and Enforcement

14. Scope of limitations and exceptions to copyrights and related rights:

Like many other Index economies, the use of machine learning and AI-based technologies and applications is increasing in Malaysia. Over the past few years, the Malaysian Government has responded with several new initiatives aimed at establishing an appropriate legal and policy environment for the use and application of these technologies. This includes, for example, the Ministry of Science, Technology and Innovation's *Malaysia National Artificial Intelligence Roadmap 2021–2025*. This roadmap sets out the overarching policy objectives of developing and harnessing the power of AI and machine learning technologies to help boost Malaysia's economic development, innovation capacity, and international competitiveness. These efforts continued in 2024 with the government announcing that a designated "National AI Office" would be established together with a code of ethics and governance. At the time of research, no draft policy had been published or made available to the public. As noted in the Index, AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, concerns exist about how the development, application, and use of these technologies will affect creators and rightsholders across the world.

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—as well as the ability of scraping technologies to access rightsholders' content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in Malaysia and around the world. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Interest in rare diseases has grown in the Asia-Pacific region. In 2017, the Asia-Pacific Economic Cooperation (APEC) forum (of which Malaysia is a member) announced a new initiative geared specifically toward rare diseases, the "APEC Action Plan on Rare Diseases." The plan's primary aim is to "address barriers to the diagnosis and treatment of rare diseases in the region." The plan consists of 30 individual targets across 10 pillars, including the promotion of innovative R&D through financial incentives, expedited market review procedures, and support for domestic R&D.

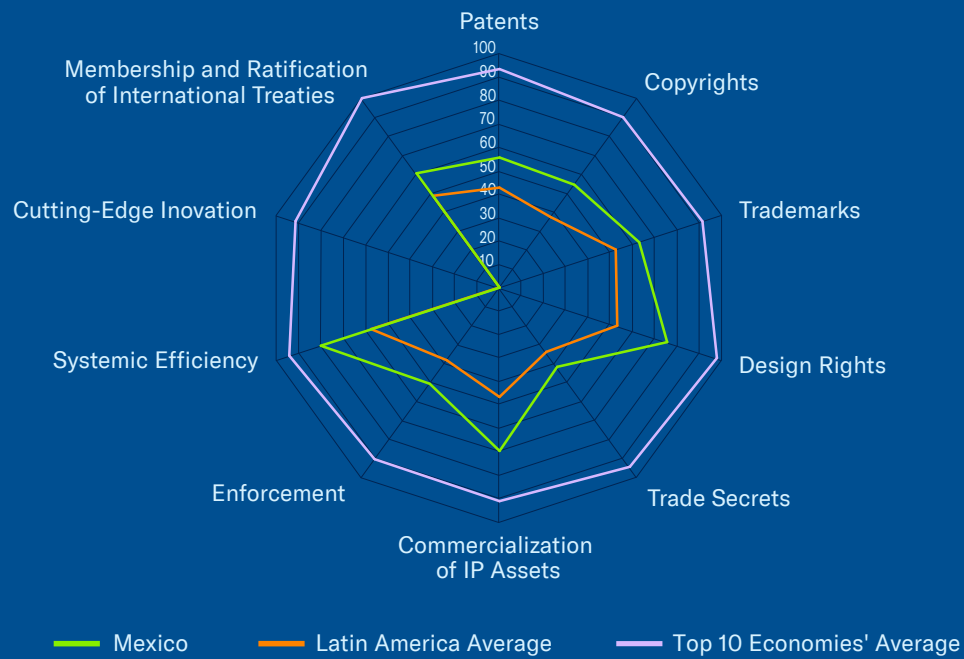
In Malaysia, too, policymakers and the government are increasingly focused on addressing rare diseases and improving patient access to care and treatments. Since 2012, the Malaysia *National Medicines Policy* has included reference to orphan drugs stating, “There shall be appropriate procedures to enhance accessibility of life-saving products and orphan medicines without compromising safety, quality and efficacy.” More recently, in 2021, the Ministry of Health issued an *Orphan Medicines Guideline* that reaffirms the Ministry’s commitment to rare diseases within its national health policy and includes policies on the registration and designation of orphan medicines. The guideline also included a national list of rare diseases recognized by the Ministry with an updated list published in 2023. However, Malaysia does not offer any special IP-based market exclusivity incentives for orphan medicinal product development.



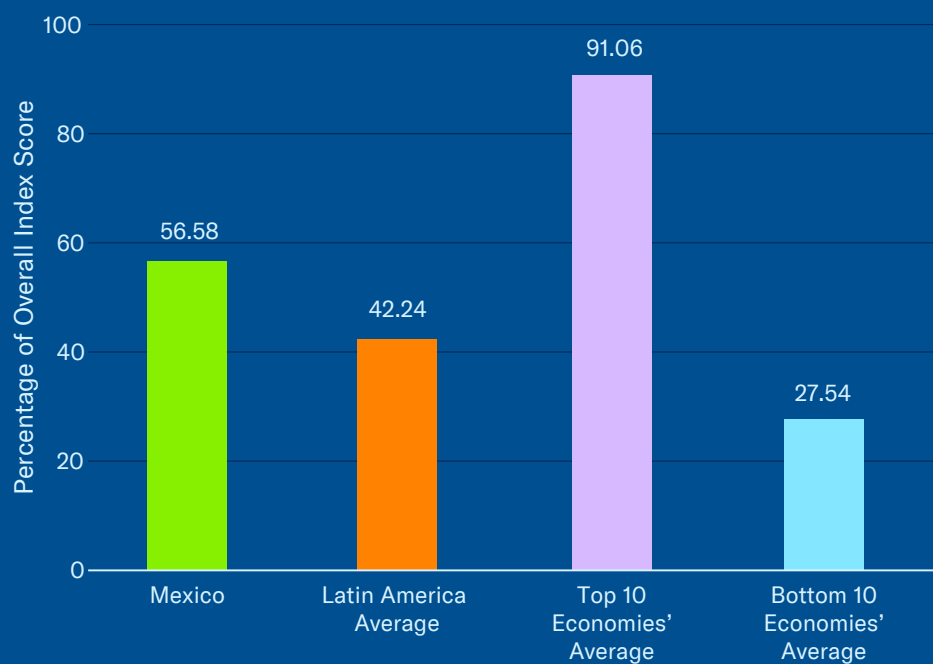
Mexico

Rank
23/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- 2021 publication of IMPI study on economic impact of IP-intensive industries in Mexico: analysis carried out with EUIPO and modeled on EPO and USPTO studies
- 2020 amendments to Industrial Property Law implements some provisions of USMCA
- 2020 amendments to the Federal Law on Copyright implements many provisions of USMCA
- Term of protection for industrial design rights extended to 25 years
- Efforts to ease ability to commercialize IP assets and develop public-private partnerships, particularly for public research organizations and universities
- Dedicated endeavor to streamline IP review process and criminal justice system and to harmonize to international standards
- Efforts to increase awareness of importance of IP rights

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Partial and ambiguous protection for life sciences IP
- Gaps exist in enforcement against online piracy
- Significant gaps exist 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

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	4.99	29. Direct government intervention in setting licensing terms	1.00
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	0.50	31. Tax incentives for the creation of IP assets	0.67
3. Patentability of CILs	0.00	Category 7: Enforcement	3.54
4. Plant variety protection	0.74	32. Physical counterfeiting rates	0.53
5. Pharmaceutical-related enforcement	0.25	33. Software piracy rates	0.51
6. Legislative criteria and use of compulsory licensing	1.00	34. Civil and precedural remedies	0.50
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	1.00
8. Membership of a Patent Prosecution Highway	1.00	36. Criminal standards	0.75
9. Patent opposition	0.50	37. Effective border measures	0.00
Category 2: Copyrights and Limitations	3.79	38. Transparency and public reporting by customs	0.25
10. Term of protection	0.79	Category 8: Systemic Efficiency	4.00
11. Exclusive rights	0.50	39. Coordination of IP rights enforcement	0.50
12. Expeditious legal remedies disabling access to infringing content online	0.25	40. Consultation with stakeholders during IP policy formation	0.75
13. Cooperative action against online piracy	0.50	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
15. TPM and DRM	0.50	43. IP-intensive industries, national economic impact analysis	1.00
16. Government use of licensed software	0.75	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.50	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.50	Category 10: Membership and Ratification of International Treaties	4.25
20. Frameworks against online sale of counterfeit goods	0.50	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	1.50	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
21. Industrial design term of protection	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	0.50	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.25	51. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.50	53. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.25		
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		

Percentage of Overall Score: 56.58%

Total Score: 29.99

Spotlight on the National IP Environment

Past Editions versus Current Score

Mexico's overall score remains unchanged at 29.99 out of 53 indicators.

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 potential infringement and is not formally involved in the adjudication process. Furthermore, the regulatory enforcement pathway has 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. Some reform proposals have been introduced over the course of the Index, but they have failed to sufficiently address the shortcomings of the existing system with some instead compounding the existing deficiencies.

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, through the USMCA, is bound to introduce a more comprehensive and practical system of biopharmaceutical patent enforcement.

Article 20.50 of the USMCA provides a clear requirement that the contracting parties provide “a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use...[and] adequate time and sufficient opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies.”

As noted in previous editions of the Index, Mexico's revised Industrial Property Law (which implements the USMCA) does not contain any legal provisions related to the existing linkage regime. Transitional paragraph (5) of the law states that the IMPI shall “participate” with the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) “in the establishment of the corresponding technical collaboration mechanism for inventions in the field of allopathic drugs.” At the time of research, no new implementing regulations had been issued by either agency.

In 2023, IMPI began publishing a dedicated list of patents related to biopharmaceutical inventions. In this document, the agency stated that the publication of this list fulfills its legal requirements under the Industrial Property Law, established case law, and the requirements set out in the Health Regulations. This list is to be updated and republished every six months. In a separate development, COFEPRIS began publishing lists of follow-on applications allowing relevant patent holders the opportunity to oppose any applications. As mentioned last year, although these are positive developments, this does not constitute 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.

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 the market. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit. In summary, 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 Mexico. The USMCA's language on the requirements for an effective pharmaceutical-related patent enforcement and resolution mechanism is clear. Full implementation and application of these requirements in Mexican law and practice will result in a score increase for this indicator. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation:

In 2024, a potentially impactful development occurred with respect to copyright enforcement in Mexico. In May, the Supreme Court upheld the validity of a series of critical amendments introducing a notice-and-takedown system in the 2020 amendments to the Federal Law on Copyright, part of Mexico's commitments under the USMCA. As has been noted over the course of the Index, Mexico has historically had one of the more challenging copyright environments in the OECD, lacking in both substantive IP rights and enforcement against online and hard goods piracy. The Federal Law on Copyright sets out standard exclusive rights of reproduction, public transmission, use, distribution, and sale but has not included provisions or mechanisms that are more specific to addressing internet or online infringement. Proposed copyright reforms have up until now not been successful. The USMCA contains several provisions that would strengthen standards of copyright protection in Mexico, including with regards to digital rights management and technological protection measures, cable and satellite piracy, and the introduction of a notice-and-takedown regime.

In 2020, amendments to the Federal Law on Copyright were published and incorporated many of the most important copyright provisions of the USMCA. Overall, the amendments strengthen the level of protection for copyrighted works in Mexico, extending this protection to the internet and the digital environment.

Specific changes include (1) a new notification system whereby ISPs are obliged to act expeditiously and remove suspected content upon receiving a notification (Articles 114 and 232); (2) robust DRM and TPM provisions outlawing the use, manufacture, sale, importation distribution, or otherwise offering to the public circumvention devices and technologies (Article 232); and (3) making illegal the use, manufacture, import, or other form of distribution of satellite signal decoders (Article 145). These are positive developments and resulted in score increases for indicators 11, 13, and 15 in the ninth edition of the Index.

However, as noted at the time, some parts of the amendments are unclear. For example, with respect to potential ISP liability for infringing content, Article 114(8) is clear that ISPs will not be responsible for any damage caused by potential copyright infringement as long as they act expeditiously and in good faith to remove infringing content and take measures to prevent the same infringing content from reappearing. However, in the same article, Subsection V, the law states that the “inability of an Internet Service Provider to meet the requirements set forth in this article by itself does not generate liability for damages for violations of copyright and related rights protected by this Law.” For any notification system to be effective in addressing online infringement, it must be clear what the responsibilities and legal expectations are for each affected party. As has been noted in the Index, the Mexican authorities have not implemented regulations or further guidance. Given the positive 2024 ruling by the Mexican Supreme Court, this should now clear the way for any remaining regulatory processes to be executed and for the notice-and-takedown mechanism to finally become operational. It has now been over five years since the conclusion of the USMCA, and Mexico has still not put in place the relevant legal framework as agreed. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

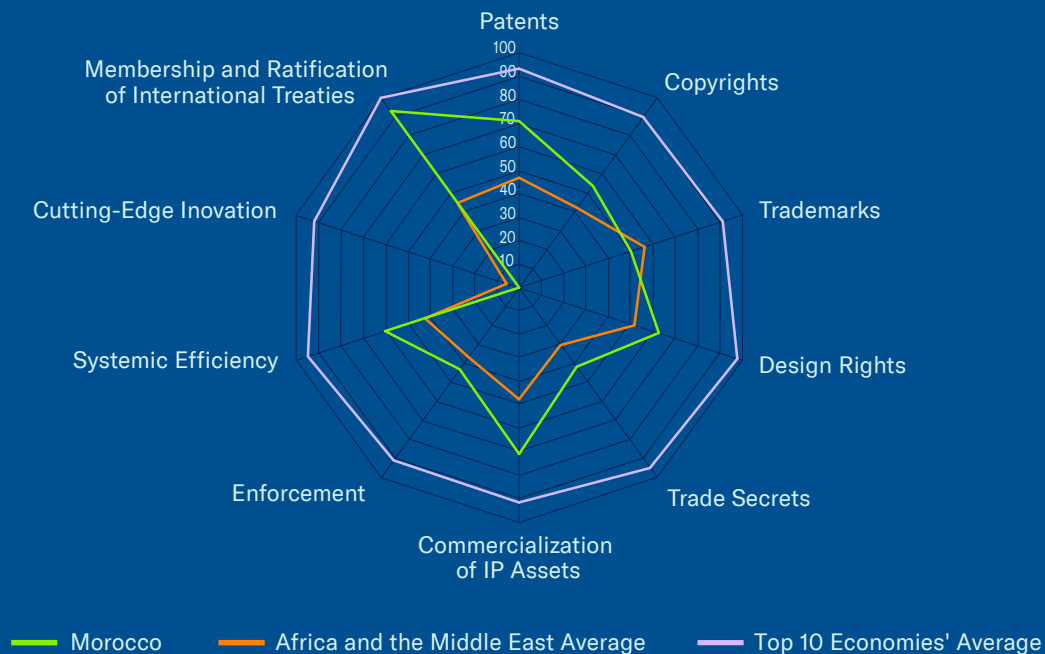
Interest in rare diseases has grown in Mexico in addressing rare diseases. In 2017, a federal commission was instituted to monitor and analyze rare diseases in Mexico. In 2023, the National Health Council announced that it was formally recognizing the World Health Organization’s classification of rare diseases, some 5,500 conditions. The Council further instructed all relevant federal and local agencies to prioritize the diagnosis and access to care for patients with rare diseases, including the listing and availability of orphan drugs. With respect to incentives for R&D and the development of new treatments and technologies, Mexico does not currently have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



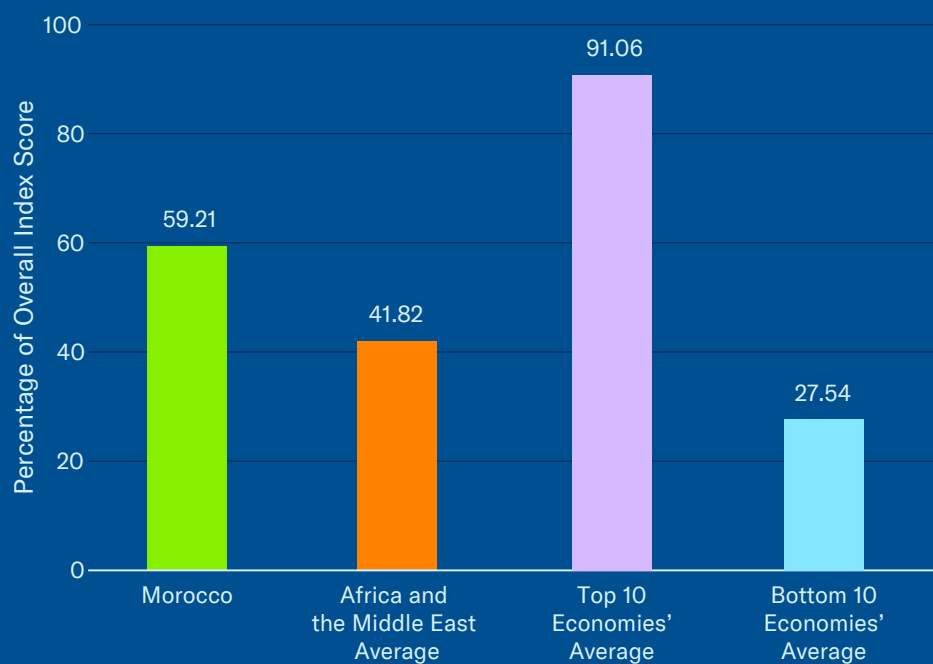
Morocco

Rank
22/55

Category Scores



Overall Score in Comparison





Morocco

Rank
22/55

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
- 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

- No special IP incentives for orphan medicinal product development
- Challenging enforcement environment: high rates of physical counterfeiting and online piracy
- BSA estimates a software piracy rate of 64%
- Some uncertainty over practical availability of patents for CIIIs

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.75	30. IP as an economic asset	0.75
3. Patentability of CILs	0.50	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	1.00	32. Physical counterfeiting rates	0.40
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.36
7. Pharmaceutical patent term restoration	0.63	34. Civil and precedural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.50
9. Patent opposition	0.00	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	0.50
10. Term of protection	0.74	38. Transparency and public reporting by customs	0.75
11. Exclusive rights	0.50	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.50	39. Coordination of IP rights enforcement	0.50
13. Cooperative action against online piracy	0.50	40. Consultation with stakeholders during IP policy formation	0.50
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.50
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	0.75
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.50
21. Industrial design term of protection	1.00	24. Protection of trade secrets (criminal sanctions)	0.25
22. Exclusive rights, industrial design rights	0.25	25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	0.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	0.75	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 59.21%

• Total Score: 31.38

Spotlight on the National IP Environment

Past Editions versus Current Score

Morocco's overall score remains unchanged at 31.38 out of 53 indicators.

Patent Rights and Limitations

8. Membership of the Patent Prosecution Highway (PPH):

Although Morocco is not a member of either 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, OMPIC has also offered a validation service for EPO-issued patents. Under this agreement, 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 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. As noted in last year's Index, in 2023, OMPIC announced that an additional PPH had been agreed on with USPTO. These positive efforts continued in 2024 with the announcement of a new PPH with the Saudi Authority for Intellectual Property. PPH initiatives and increased cooperation among IP offices is one of the most tangible ways in which the administration and functioning of the international IP system can be improved and harmonized to help inventors and rightsholders.

Copyrights and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expeditious 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 discussed in previous editions of the Index, a key challenge for rightsholders in Morocco has long been the lack of effective enforcement against copyright piracy, particularly with respect to satellite decoding and broadcasting signal piracy. Decoders have been readily available and used across North Africa and Morocco 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 on the internet through streaming. This remains unchanged in 2024, with rightsholders reporting that levels of copyright infringement remain high. For example, the USTR, in its *2024 Special 301 Report*, continued to include reference to Morocco as an economy with “notable levels of piracy through ISDs and illicit IPTV apps” as reported by stakeholders. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

: Interest in rare diseases has grown in the Middle East and North Africa region. In 2003, the Centre for Arab Genomic Studies was established to map and improve the state of care for patients with genetic diseases in the Arab world. Today, the Center has become the leading research point for rare diseases in the region.

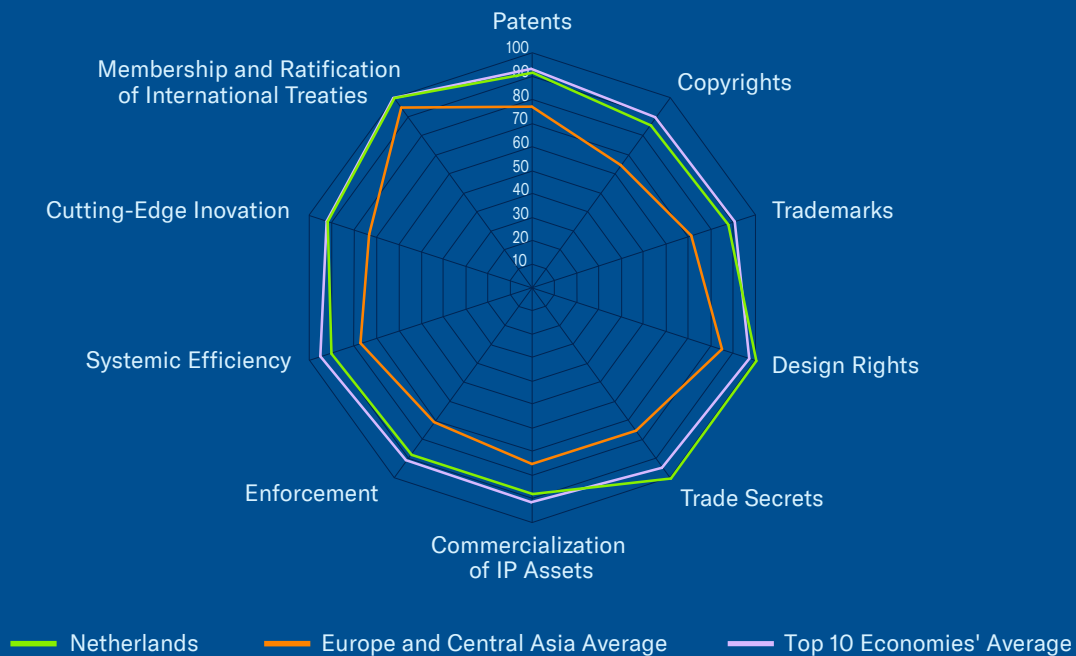
Moreover, several Index economies in the region, including Saudi Arabia and the UAE, have introduced a defined regulatory sanitary registration pathway and special incentives for orphan products. In Morocco, a National Rare Disease Program was launched in 2019 in a public-private partnership with Sanofi SA. The purpose of the program is to develop a national disease registry and new specialized treatment centers of excellence and to expand existing medical training of general health practitioners in the diagnosis and treatment of rare diseases. Morocco does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



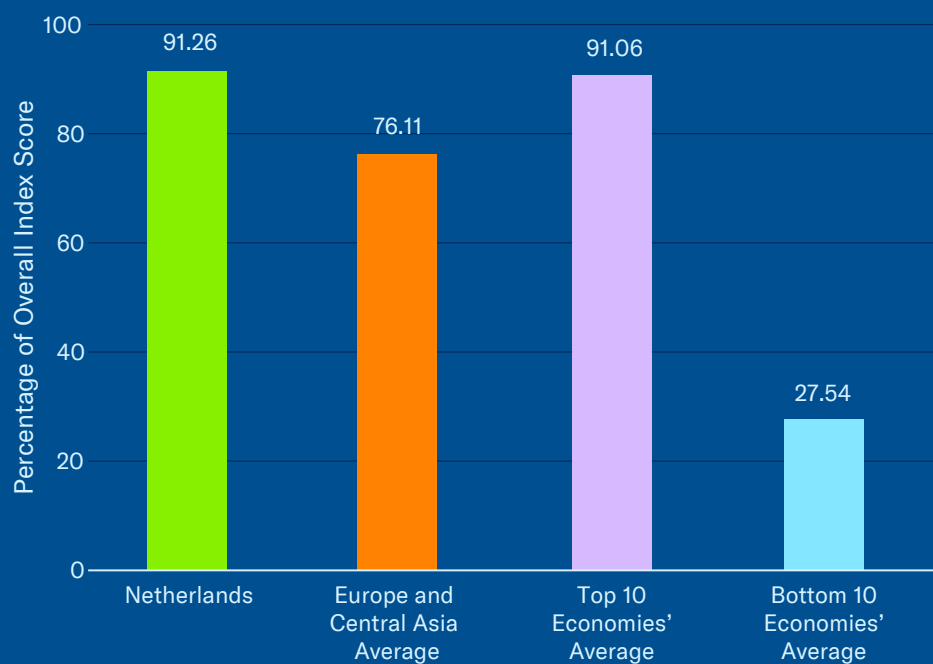
Netherlands

Rank
6/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Since 2000, the orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- Continued leader in copyright enforcement; private-public initiatives led by the national copyright foundation BREIN and the Dutch Government
- Transposed the EU Trade Secrets Directive into law in 2018, which improved 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 EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- The new EU-wide compulsory licensing regime would undermine patent rights in Europe
- The new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- Registration requirements are in place for licensing agreements
- Regulation 2019/933 and the existing SPC exemption for exports of biopharmaceuticals pose significant risk to the Netherlands' and the EU's research and IP-based biopharma industry
- Proposals to explore the use of compulsory licensing for medicines whose price is deemed excessive is outside international norms

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	1.00	30. IP as an economic asset	0.75
3. Patentability of CII	1.00	31. Tax incentives for the creation of IP assets	1.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.85
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.78
7. Pharmaceutical patent term restoration	0.75	34. Civil and precedural remedies	1.00
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.75
9. Patent opposition	1.00	36. Criminal standards	0.75
Category 2: Copyrights and Limitations		37. Effective border measures	1.00
10. Term of protection	0.74	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	1.00	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	1.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	1.00	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	0.75	41. Educational campaigns and awareness raising	0.75
15. TPM and DRM	0.75	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	0.75	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	1.00	45. IP incentives for orphan medicinal product development, term of protection	1.00
19. Exclusive rights, trademarks	1.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
20. Frameworks against online sale of counterfeit goods	0.50	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	1.00
21. Industrial design term of protection	1.00	24. Protection of trade secrets (criminal sanctions)	1.00
22. Exclusive rights, industrial design rights	1.00	25. Regulatory data protection term	1.00
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	1.00	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 91.26%

Total Score: 48.37

Spotlight on the National IP Environment

Past Editions versus Current Score

The Netherlands' overall Index score has increased from 45.62 out of 50 indicators in the twelfth edition to 48.37 out of 53 indicators. This reflects a strong performance on the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

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

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC as well as a new centralized procedure for other applications, and the European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each member state. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024.

The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they are in compliance with existing copyright law. Some positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

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.

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, detailed under Category 9.

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. The Commission’s proposal 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 Commission’s 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.

Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU Member States seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become 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 Commission's proposals 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.

In early 2024, the European Parliament responded to the Commission's ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

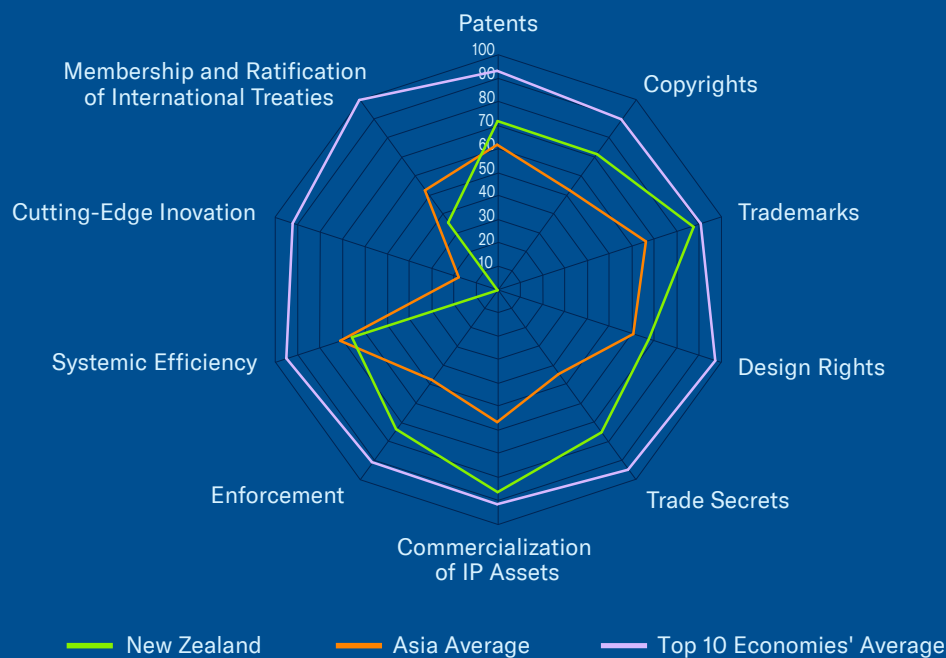
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals—including the European Parliament’s response to the Commission’s proposals in early 2024—the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.



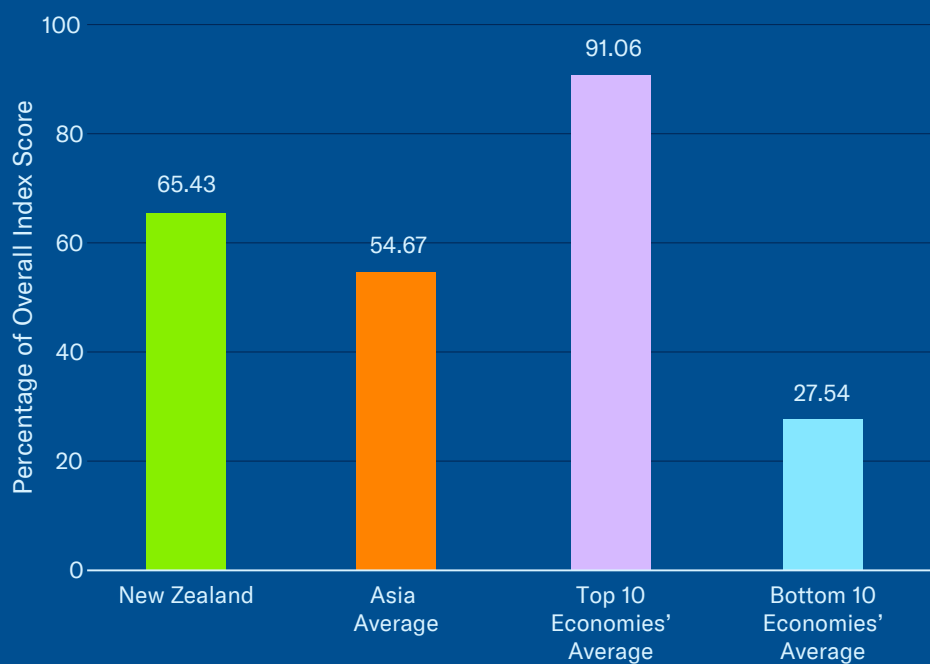
New Zealand

Rank
21/55

Category Scores



Overall Score in Comparison





New Zealand

Rank
21/55

Key Areas of Strength

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

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Practical application and net effect of the Copyright (Infringing File Sharing) Amendment Act have been mixed at best, with few cases heard by the Copyright Tribunal and most dismissed on technicalities
- No patent term restoration is in place for biopharmaceuticals
- Limited membership of international IP treaties

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

Percentage of Overall Score: 65.43%

Total Score: 34.68

Spotlight on the National IP Environment

Past Editions versus Current Score

New Zealand's overall score remains unchanged at 34.68 out of 53 indicators.

Patent Rights and Limitations; and Trade Secrets and the Protection of Confidential Information

7. Patent term restoration for pharmaceutical products; 25. Regulatory data protection (RDP) term:

As noted in past editions of the Index, New Zealand lacks many biopharmaceutical-specific IP rights and incentives. To begin with, no patent term restoration exists for pharmaceutical products. Although discussed during the patent reform debates more than a decade ago, the 2013 Patent Act did not address this issue. The Government of New Zealand publicly committed to introducing a period of term restoration in 2015–2016 as part of its accession to the original Trans-Pacific-Partnership (TPP). However, the reworked agreement—the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)—fundamentally revised many parts of the original treaty and suspended many biopharmaceutical-specific IP rights, including patent term restoration. As a result, New Zealand continues to be one of a small number of OECD economies that does not offer a defined term of restoration for innovators in the life sciences.

With respect to RDP, Section 23B of the Medicines Act provides protection for submitted clinical test data for five years, which 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. In mid-2023, the New Zealand Parliament passed the Therapeutic Products Act 2023 (TPA), and the law is now in force. The TPA did not change the existing RDP regime or introduce a system of patent term restoration.

After general elections in late 2023 and the formation of a new government, the government announced that the TPA would be repealed and replaced with a new law. At the time of research, no new law had been enacted. As the New Zealand Parliament and Ministry of Health pursue a program of pharmaceutical reforms, we would encourage them to also consider introducing a term of pharmaceutical patent term restoration and strengthening the existing RDP framework by aligning the term of protection offered in New Zealand with that of other high-income OECD economies. The Index will monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

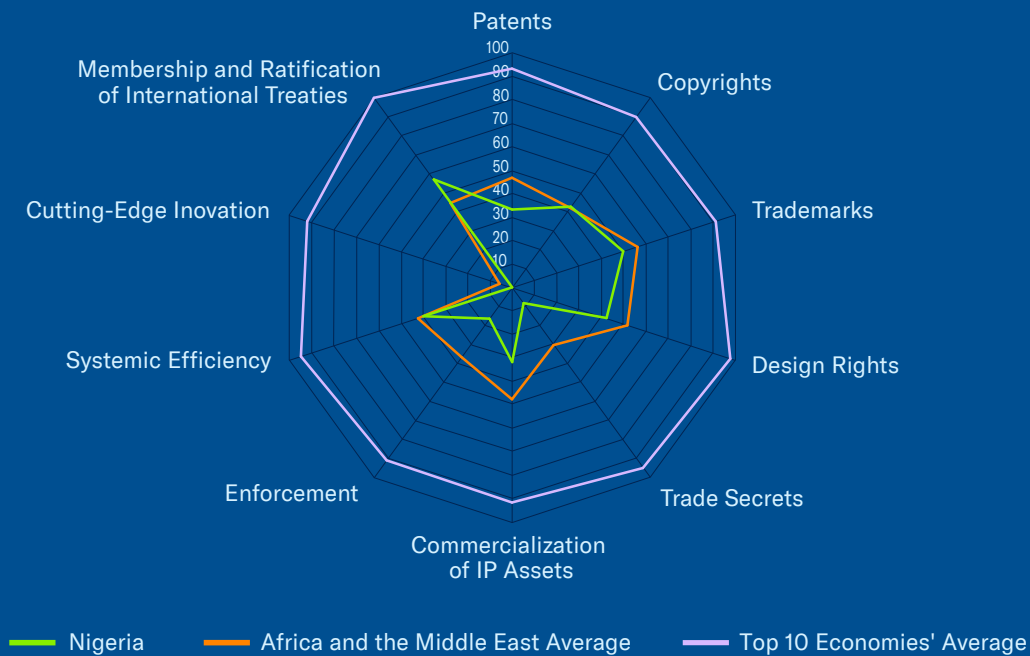
Interest in rare diseases has grown in New Zealand. In 2024, the Ministry of Health released the policy document *Aotearoa New Zealand Rare Disorders Strategy*. This is the first comprehensive policy document for rare diseases introduced in New Zealand. The strategy provides a “framework and long-term priorities that will guide health entities in improving health and wellbeing outcomes” for patients with rare diseases. These priorities include improving the delivery of health care to patients with rare diseases, training and educating health care professionals on the specific needs of patients with rare diseases, and better incorporating the rare disease community into health policy. Although the strategy mentions the need for better access to new and innovative therapies as well as the need for developing new medicines and treatments for rare diseases, there are no concrete policy suggestions. For example, no proposals introduce any special IP-based market exclusivity incentives for orphan medicinal product development.



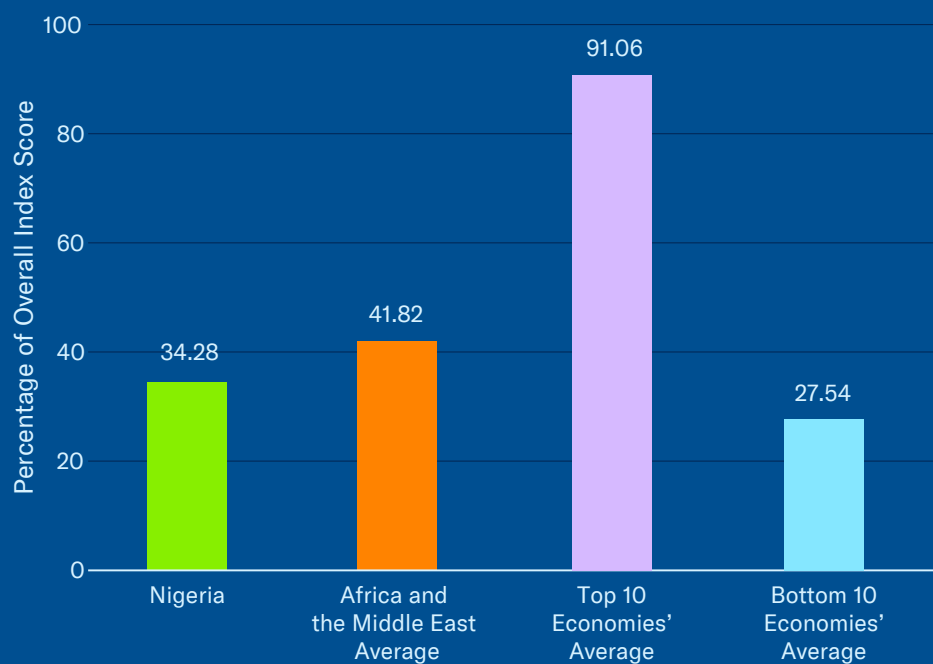
Nigeria

Rank
47/55

Category Scores



Overall Score in Comparison





Nigeria

Rank
47/55

Key Areas of Strength

- 2023 Copyright Act improves Nigeria's national IP environment
- Joined the Convention on Cybercrime in 2022
- Plant Variety Protection Act 2021
- Joined 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

- No special IP incentives for orphan medicinal product development.
- Overall weak and limited legal and regulatory framework with major forms of IP rights not in place
- Enforcement challenges persist with only ad hoc efforts rather than national coordination
- Persistently high rates of physical and growing online piracy
- Software piracy estimated at 80% by BSA
- Localization barriers and restrictions are in place on technology transfer and licensing activities, which intensified in 2020
- 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	Indicator	Score
Category 1: Patents Rights and Limitations	3.00	29. Direct government intervention in setting licensing terms	0.00
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	0.00	31. Tax incentives for the creation of IP assets	0.67
3. Patentability of CILs	0.00	Category 7: Enforcement	1.16
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.21
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.20
6. Legislative criteria and use of compulsory licensing	1.00	34. Civil and precedural remedies	0.25
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.00
8. Membership of a Patent Prosecution Highway	0.00	36. Criminal standards	0.25
9. Patent opposition	0.00	37. Effective border measures	0.00
Category 2: Copyrights and Limitations	2.99	38. Transparency and public reporting by customs	0.25
10. Term of protection	0.74	Category 8: Systemic Efficiency	2.00
11. Exclusive rights	0.50	39. Coordination of IP rights enforcement	0.25
12. Expeditious legal remedies disabling access to infringing content online	0.50	40. Consultation with stakeholders during IP policy formation	0.75
13. Cooperative action against online piracy	0.50	41. Educational campaigns and awareness raising	0.50
14. Limitations and exceptions	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
15. TPM and DRM	0.50	43. IP-intensive industries, national economic impact analysis	0.25
16. Government use of licensed software	0.00	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.00	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.50	Category 10: Membership and Ratification of International Treaties	4.00
20. Frameworks against online sale of counterfeit goods	0.25	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	0.85	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
21. Industrial design term of protection	0.60	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights, industrial design rights	0.25	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.25	51. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.00	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
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		

Percentage of Overall Score: 34.28%

Total Score: 18.17

Spotlight on the National IP Environment

Past Editions versus Current Score

Nigeria's overall score remains unchanged at 18.17 out of 53 indicators.

Area of Note

Over the past two years, the Nigerian Government has worked with the local WIPO office and other stakeholders in developing a *National IP Policy and Strategy*. This work continued in 2024 with an Inter-Ministerial Steering Committee established to review and finalize the document. Public reporting suggests that several participants at the meeting reiterated the need for significant and structural reforms to Nigeria's national IP environment and the close link between Nigeria's future economic development and its IP system.

At the time of research, no final document had been published. Since 2015, the Index has included a *Statistical Annex*, which investigates a series of correlations examining the relationship between the strength of national IP environments, as measured by the Index scores, and different types of economic activity, including rates of R&D spending, innovation, technology creation, and creativity. As the economic data and analysis of the *Statistical Annex* and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for innovation and advanced economic development to take place. For all economies—emerging and developed alike—what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP. Covering 53 indicators across 10 separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators and rightsholders need to be able to fully develop and commercialize their ideas and products.

As the Nigerian Government and National Assembly pursue a program of national IP rights reforms, we would encourage them to use the Index findings and accompanying *Statistical Annex* as a guide in 2025 and beyond.

Copyrights and Limitations

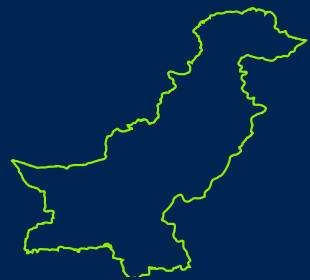
11. *Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking);* 12. *Expeditious legal remedies disabling access to infringing content online;* 13. *Availability of frameworks that promote cooperative action against online piracy;* and 15. *Technological Protection Measures (TPM) and digital rights management (DRM) legislation:* As noted last year, in 2023, a new Copyright Act was enacted in Nigeria. Although not perfect, overall, this new Act provides a much-needed update to Nigeria's copyright laws. The old 2004 Copyright Act only provided rightsholders with general and basic exclusive rights and contained only limited references to the online space. 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 to 60 outline a notice-and-takedown regime requiring 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 increased in last year's Index.

Unfortunately, as mentioned last year, 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 remains unclear how this power vested in the Nigeria Copyright Commission will be exercised or for what purpose. Furthermore, the Act not only retains pre-existing broad personal and educational use exceptions to copyright, but it 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 2025 and beyond.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

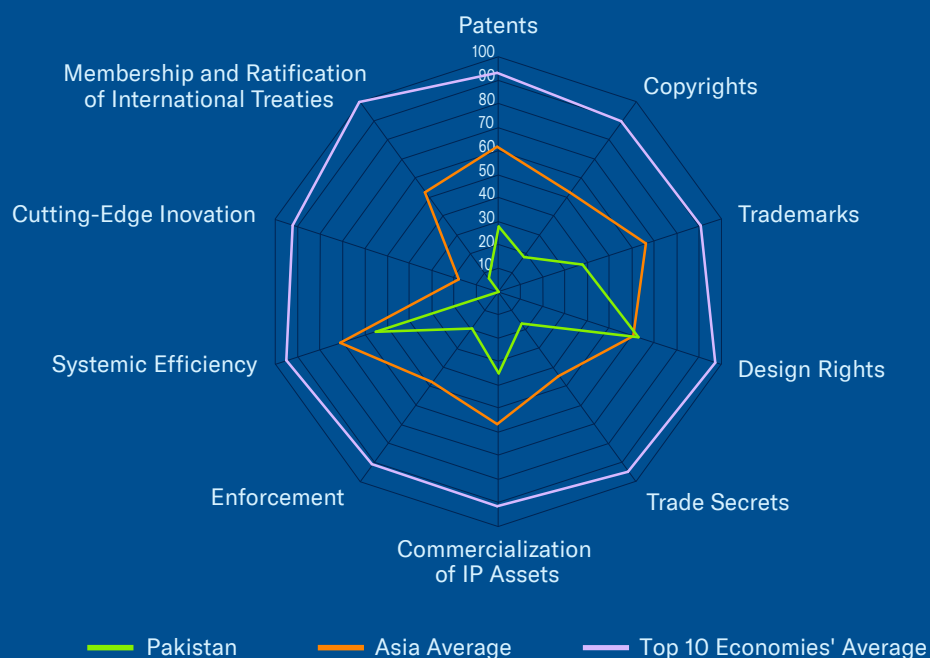
Interest in rare diseases has grown in in sub-Saharan Africa. Through both public and private initiatives, several Index economies in the region have introduced specific health programs and awareness-raising efforts. Nigeria does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



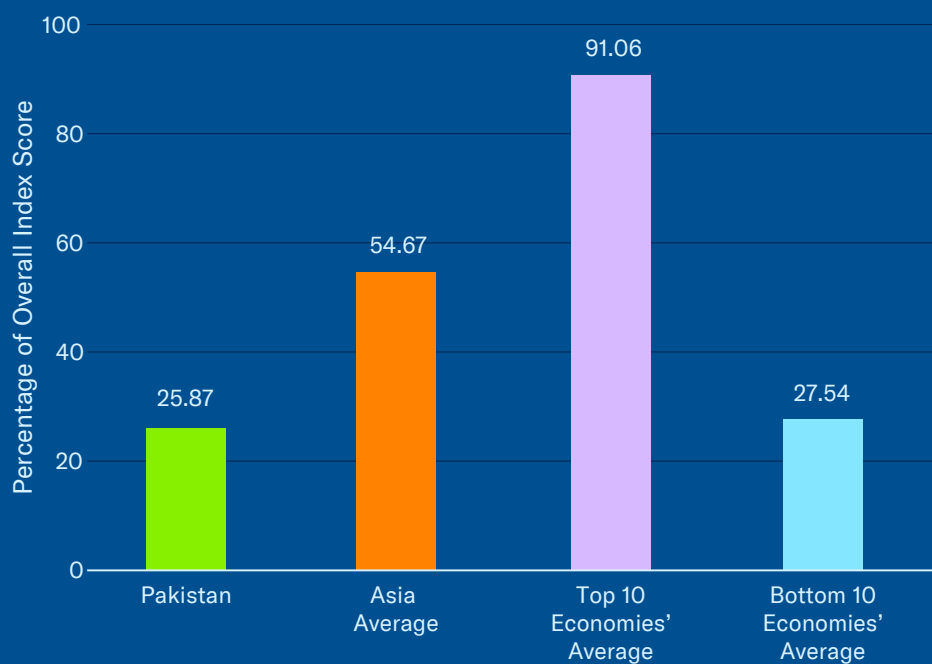
Pakistan

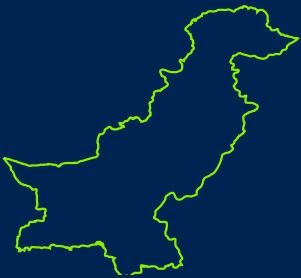
Rank
52/55

Category Scores



Overall Score in Comparison





Pakistan

Rank
52/55

Key Areas of Strength

- Acceded to the Madrid Protocol in 2021
- Basic IP laws and legal framework are in place
- Specialized IP courts and capacity building were introduced in 2015
- Greater efforts made regarding public education, modernization of IP laws, and enhancing coordination among enforcement agencies

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Limited sector-specific IP protections are available
- A significant discrepancy exists between IP rights in law and the 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 CII and new-form biopharmaceuticals

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	2.50	29. Direct government intervention in setting licensing terms	0.25
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	0.25	31. Tax incentives for the creation of IP assets	0.33
3. Patentability of CILs	0.25	Category 7: Enforcement	1.35
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.18
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.17
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precedural remedies	0.25
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.00
8. Membership of a Patent Prosecution Highway	0.00	36. Criminal standards	0.25
9. Patent opposition	0.00	37. Effective border measures	0.50
Category 2: Copyrights and Limitations	1.28	38. Transparency and public reporting by customs	0.00
10. Term of protection	0.53	Category 8: Systemic Efficiency	2.75
11. Exclusive rights	0.25	39. Coordination of IP rights enforcement	0.75
12. Expeditious legal remedies disabling access to infringing content online	0.00	40. Consultation with stakeholders during IP policy formation	0.50
13. Cooperative action against online piracy	0.00	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
15. TPM and DRM	0.00	43. IP-intensive industries, national economic impact analysis	0.25
16. Government use of licensed software	0.25	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	1.50	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.25	Category 10: Membership and Ratification of International Treaties	0.50
20. Frameworks against online sale of counterfeit goods	0.00	47. WIPO Internet Treaties	0.00
Category 4: Design Rights and Limitations	1.25	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	0.00
22. Exclusive rights, industrial design rights	0.25	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	51. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
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		
Percentage of Overall Score: 25.87% Total Score: 13.71			

Spotlight on the National IP Environment

Past Editions versus Current Score

Pakistan's overall score remains unchanged at 13.71 out of 53 indicators.

Patent Rights and Limitations

2. Patentability requirements; and 3. Patentability of computer-implemented inventions (CII):

The Intellectual Property Organization of Pakistan (IPO-Pakistan) is in the process of proposing new amendments to the Patent Ordinance with several draft changes published in 2022 and late 2023. 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 historically stood outside of international norms, especially with respect to high-tech arts such as computer software and biopharmaceuticals. Unfortunately, the revised Section 7 of the draft amendments to the Patent Ordinance further limits or eliminates the potential patentability of CII and biopharmaceutical innovation. Under the existing statute, CII were not explicitly excluded, and the possibility remained to seek and gain patent protection. However, the new amendments explicitly exclude "computer programs" as inventions. Given that computer software and CII are at the heart of virtually all socioeconomic activity (such as desktop PCs, smartphones, AI, 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 ICT-based technologies in Pakistan.

Similarly, a new Subsection (7(4)(f)) on 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 subsection would appear to restrict the eligibility of incremental biopharmaceutical innovation, including changes to form and the application of a known substance. This is a curious change to Pakistan's patent law because incremental innovation is an essential and, in many respects, elemental 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 the 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. Thus, it is critical for countries to have in place the IP protection needed to encourage continued investment in innovation. Should these amendments be enacted into law, the score for indicators 2 and 3 will be reduced.

9. Patent opposition:

As noted last year, in a positive move, the 2022 proposed amendments to the Patent Ordinance published by IPO-Pakistan would eliminate Section 23 and the system of pre-grant oppositions. Under existing patent statute, an *inter-partes* opposition system is in place, which can be triggered within four months after an application is published. Unfortunately, the updated draft amendments published in 2023 have retained this system of pre-grant opposition. If adopted in their current form, amendments to the Patent Ordinance would result in no score change with the score for this indicator remaining at 0.

Copyrights and Limitations; Enforcement

15. Technological protection measures (TPM) and digital rights management (DRM) legislation; and 36. Criminal standards, including minimum imprisonment and minimum fines:

IPO-Pakistan is also in the process of drafting proposed amendments to the Copyright Ordinance with proposed changes published in both 2022 and late 2023. 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 because relevant enforcement mechanisms are weak and nondeterrent. The proposed amendments do not include a notice-and-takedown notification system for online piracy or an injunctive-style relief option whereby rightsholders can directly request the disabling of access to infringing content through a court of law or administrative mechanism. However, the amendments include new provisions related to TPM and DRM. Until now, no legal definitions or provisions in copyright law related to the use of circumvention devices and overriding or disabling 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 not defined or structured in a way to apply to circumvention devices or copyright infringement. New Sections 56A and 56B of the Copyright Ordinance would remedy this and would provide legal definitions and remedies for the violation of TPMs and DRMs. 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.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Interest in rare diseases has grown in South Asia. Through both public and private initiatives, several Index economies in the region have introduced specific health programs and awareness-raising efforts. Pakistan does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.

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 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. Pakistan's score in this category of the Index has increased from a score of 0.00 in the fifth edition of the Index (the first year Pakistan was included) to a score of 0.50, or 7.14% of the total available score.

This score is notably lower than most other economies included in the Index, regardless of income level or stage of development. Overall, Pakistan is a contracting party and has acceded to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. Pakistan is not a contracting party to WIPO Internet Treaties; the Patent Cooperation Treaty; 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. Pakistan has concluded several post-TRIPS FTAs, however, none of these treaties include “substantive IP provisions and chapters in line with international best practices” as defined under this indicator.

49. Patent Law Treaty and Patent Cooperation Treaty:

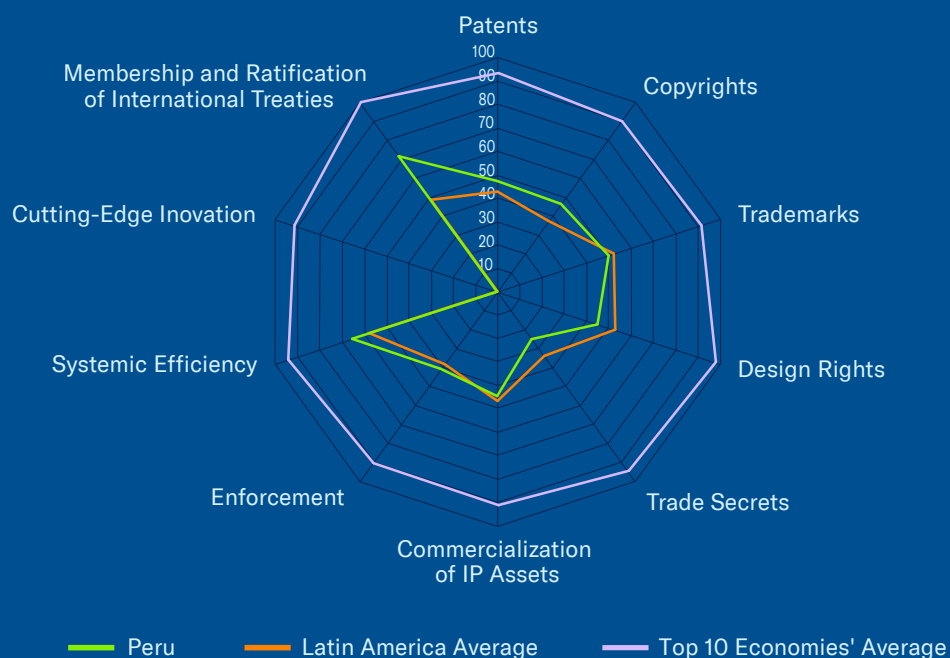
In a potential positive development, as part of its proposed amendments to the Patent Ordinance, in November 2023, the Pakistan IPO announced that it was considering joining the PCT. In 2024, the IPO hosted a WIPO PCT training program for local patent examiners in anticipation of Pakistan’s potential accession. Pakistan remains one of only a handful of Index economies that is not a contracting party to the PCT. The 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. Pakistan joining the PCT would be a meaningful and positive development and would result in a score increase for this indicator. The Index will continue to monitor these developments in 2025.



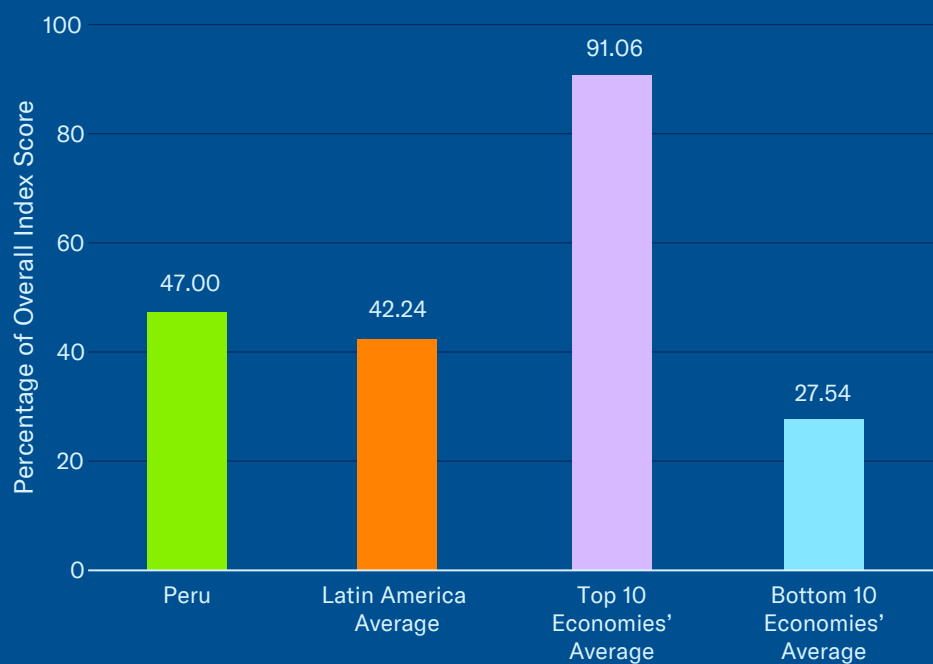
Peru

Rank
31/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Continued injunctive-style relief and copyright enforcement by the national IP office INDECOPI in 2024
- 2021 Decree 063-2021 strengthens public consultation and stakeholder participation in the lawmaking and regulatory process
- INDECOPI support for SMEs strengthened in 2021, creating new technical assistance and IP asset identification programs
- Joined the Global Patent Prosecution Highway in 2019
- INDECOPI continued suspending access to copyright-infringing websites
- Basic IP protections available
- Border measures provided for in legislation
- Efforts made to coordinate IP rights enforcement across government agencies and to raise awareness of the importance of IP protection

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Compulsory license is actively being considered for biopharmaceuticals based on cost
- Administrative and regulatory barriers are in place for licensing and technology transfer
- Limited patentability and lack of effective IP protection for life sciences
- Rudimentary digital copyright regime (with some exceptions)
- High rates of counterfeiting and piracy
- Gaps exist in IP enforcement on the ground

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

Percentage of Overall Score: 47.00%

Total Score: 24.91

Spotlight on the National IP Environment

Past Editions versus Current Score

Peru's overall score remains unchanged at 24.91 out of 53 indicators.

Copyrights and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expedient legal remedies disabling access to infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy:

In 2024, positive legislative developments occurred, and Peru's national IP authority INDECOPI continued to strongly clamp down on online copyright piracy. First, legislative Decree 1649—issued in September 2024—amends Article 217 of the Penal Code. The decree strengthens existing criminal remedies for illegal recording and/or the distribution and dissemination of copyrighted content. On the enforcement side, INDECOPI continued its administrative enforcement activity. In late 2023, the office ordered the shutdown of 328 websites offering illegal access to a range of creative works, including film, television, music, and other copyrighted content. A portion of this enforcement activity relates to a broader international effort to disable copyright piracy across Latin America, *Operation 404*. First initiated in Brazil in 2020 and 2021, *Operação 404 contra pirataria* has also received international support from the U.S. Embassy in Brasília, UK law enforcement, and other Latin American economies, including Peru.

INDECOPI took additional enforcement actions against online piracy over the summer with access disabled to 29 copyright-infringing websites. Finally, the agency released a new public registry listing individuals and companies sanctioned for copyright infringement. The Index continues to recognize and commend the Government of Peru and INDECOPI for their continued efforts and regional leadership regarding this issue. Over the course of the Index, Peru's score on Category 2: Copyrights and Limitations; and Enforcement 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.

Unfortunately, this sustained positive activity against online piracy has not been matched by substantive copyright reform. Most notably, despite the 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. Reform proposals have been put forth over the years—for example, in the various iterations of the General Internet Law, *Proyecto de Ley n° 00878/2021-CR. Ley General de Internet*—but 15 years since the agreement came into force, Peru still is no closer to a functioning notice-and-takedown mechanism. The introduction of such a system would result in a potential score increase for indicator 13. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

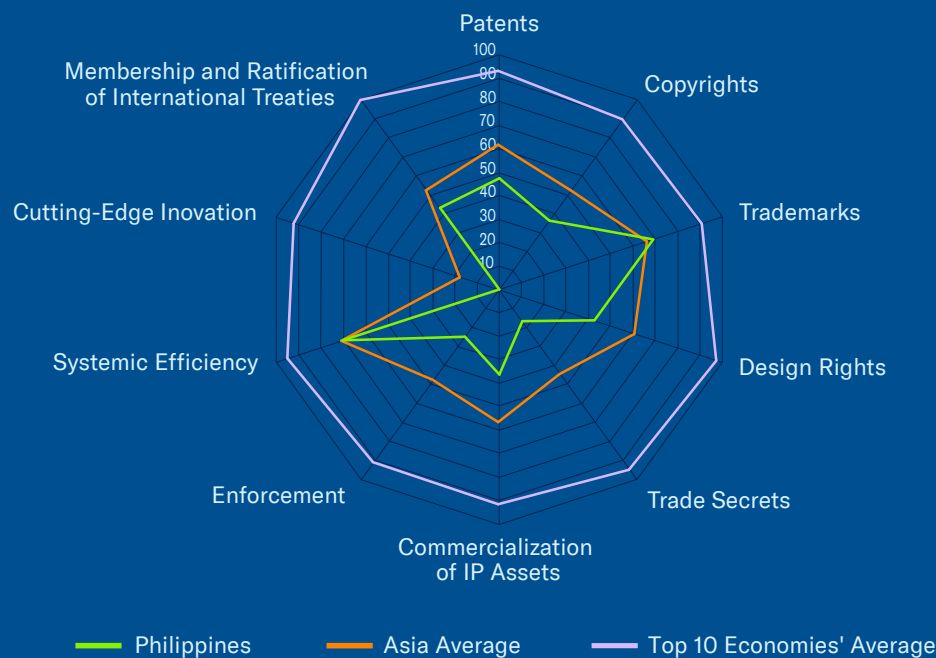
The 2011 Law 29,698 introduced a national legal framework and definition of rare diseases, including the right to comprehensive health care and identification and procurement of relevant medicines and treatments. Subsequent regulations and additional ministerial resolutions have established and defined a national list of approved rare diseases, health technology assessment practices, and additional technical guidelines (Ministerial Resolutions 579-2011, 691-2012, 497-2019, 526-2019, 565-2019, 109-2022, and 112-2022). Based on this work, a national plan was approved in 2020. However, none of these initiatives include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.



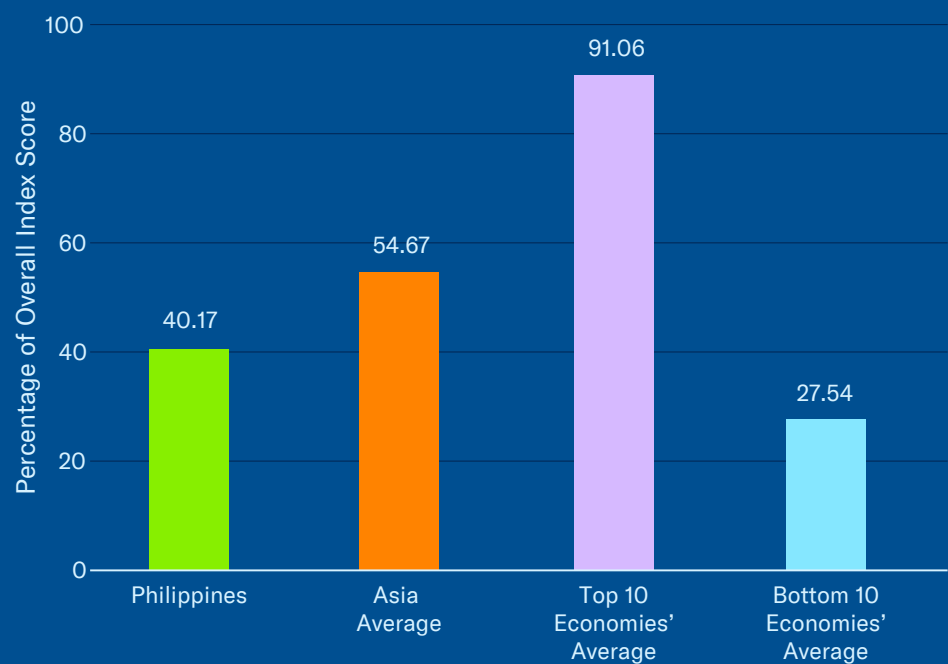
Philippines

Rank
36/55

Category Scores



Overall Score in Comparison





Philippines

Rank
36/55

Key Areas of Strength

- New IPOPHL Circular and 2024 Internet Transactions Act strengthen the ability to enforce IP rights online
- IPOPHL's strong IP enforcement efforts online continued 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

- No special IP incentives for orphan medicinal product development
- Barriers are in place for licensing and technology transfer
- Significant gaps exist in life sciences and content-related IP rights
- Online piracy is high, with digital protection largely unaddressed
- BSA estimates software piracy to be at 64%

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	4.25	29. Direct government intervention in setting licensing terms	0.25
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	0.50	31. Tax incentives for the creation of IP assets	0.67
3. Patentability of CILs	0.50	Category 7: Enforcement	1.74
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.38
5. Pharmaceutical-related enforcement	0.25	33. Software piracy rates	0.36
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precedural remedies	0.25
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.25
8. Membership of a Patent Prosecution Highway	0.50	36. Criminal standards	0.25
9. Patent opposition	0.50	37. Effective border measures	0.00
Category 2: Copyrights and Limitations	2.53	38. Transparency and public reporting by customs	0.25
10. Term of protection	0.53	Category 8: Systemic Efficiency	3.50
11. Exclusive rights	0.25	39. Coordination of IP rights enforcement	0.75
12. Expeditious legal remedies disabling access to infringing content online	0.50	40. Consultation with stakeholders during IP policy formation	0.75
13. Cooperative action against online piracy	0.25	41. Educational campaigns and awareness raising	0.75
14. Limitations and exceptions	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
15. TPM and DRM	0.25	43. IP-intensive industries, national economic impact analysis	0.50
16. Government use of licensed software	0.50	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.75	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.50	Category 10: Membership and Ratification of International Treaties	3.00
20. Frameworks against online sale of counterfeit goods	0.75	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	0.85	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	0.25	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.50	51. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.00		
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		

Percentage of Overall Score: 40.17%

• Total Score: 21.29

Spotlight on the National IP Environment

Past Editions versus Current Score

The Philippines' overall Index score has increased from 20.79 out of 50 indicators in the twelfth edition to 21.29 out of 53 indicators. This reflects score increases for indicators 12 and 20.

Copyrights and Limitations

12. Expeditious disabling of infringing content online:

In 2024, the Philippines adopted more effective mechanisms to fight online copyright infringement. In late 2023, the national IP office, IPOPHL, issued Memorandum Circular No. 2023-025. Under this circular, access to websites that provide and distribute copyright-infringing content can be disabled by participating ISPs. The scheme is voluntary and builds on IPOPHL's work over the past few years to expand its enforcement remit. At the time of research, one order had been issued after a written request. As a result of these positive developments, the score for indicator 12 has increased by 0.25.

In a separate development, the Senate examined two draft bills that would further expand IPOPHL's enforcement powers and vest such powers with the office. The draft legislation—Bills 2150 and 2385—are the Senate versions of Bill HB 7600, passed by the House of Representatives last year. The centerpiece of the proposed legislation is an amended Section 216 of the IP Code. This amendment would grant IPOPHL the administrative power to order the disabling of access to infringing content online.

Under the proposed system, rightsholders would contact IPOPHL directly and file a complaint asking for the disabling of access to the alleged infringing online activity. IPOPHL 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 IPOPHL 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 re-enters the public domain by simply being moved to a different access point online. Should these proposed amendments to the IP Code be enacted, this would result in further score increases for indicators 12 and 13. The Index will continue to monitor these developments in 2025.

Trademark Rights and Limitations

20. Availability of frameworks that promote cooperative private action against online sale of counterfeit goods:

In late 2023, Republic Act 11967, the Internet Transactions Act, was passed and signed into law. The Act sets out the legal rights and responsibilities of all parties engaging in e-commerce, from individual sellers to e-marketplaces and platforms. Of note is that the Act includes provisions related to IP protection. Sections 25 and 26 of the Act define primary and secondary liability for the violation of Filipino law and failure to act upon notification of IP infringement.

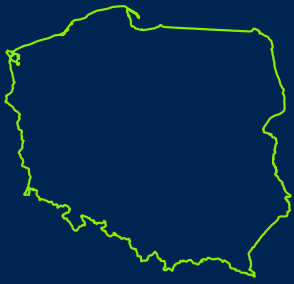
Specifically, e-marketplaces and digital platforms can be found to have secondary liability under Section 26 (b) if they “failed, after notice, to act expeditiously in removing or disabling access to goods or services that either infringe on another’s intellectual property rights or is subject to a takedown order by any appropriate government agency.” As a result of these legislative developments, the score for indicator 20 has increased by 0.25.

Similarly, the *2022 Integrated Rare Diseases Management Program (IRDMP) Strategic Plan for 2022–2026*, published by the Department of Health, includes support of clinical research into rare diseases as a strategic objective (“Strategic objective 4: Provide evidence for policy and program planning through research and development”). However, none of these initiatives include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

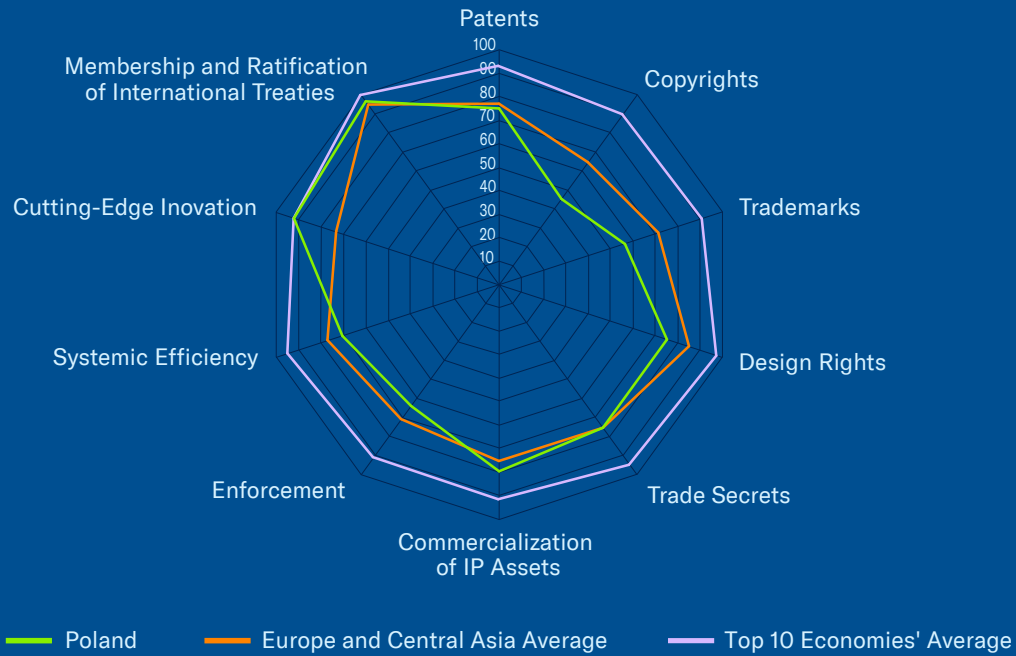
The 2015/16 Republic Act No. 10747 (the Rare Disease Act) introduced a national legal framework and definition of rare diseases, including the right to comprehensive health care and identification and procurement of relevant medicines and treatments. With respect to research and development, Article 1, Section 3, states that one of the Act’s objectives is to “provide regulatory and fiscal incentives to support research and development studies on rare diseases and to facilitate the manufacture and importation of affordable orphan drugs and orphan products.”



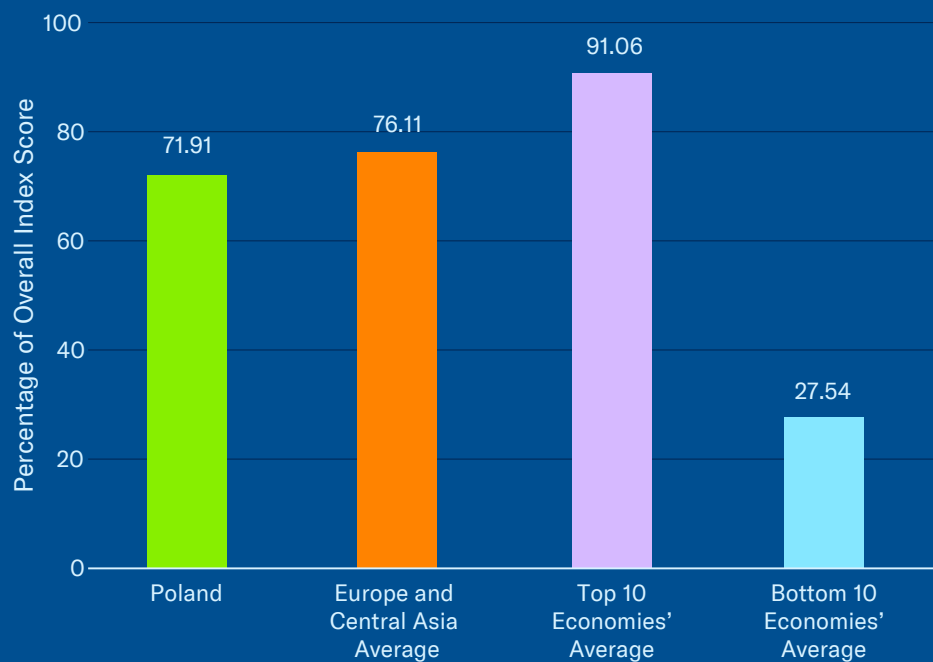
Poland

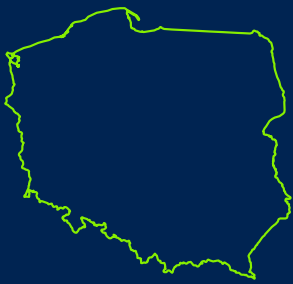
Rank
18/55

Category Scores



Overall Score in Comparison





Poland

Rank
18/55

Key Areas of Strength

- Since 2000, the orphan regulation provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- R&D tax incentives are in place
- Transposed EU Trade Secrets Directive into law in 2018 to harmonize Polish trade secret law with EU standards
- The legal framework for IP protection is largely aligned with EU standards

Key Areas of Weakness

- The EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- The new EU-wide compulsory licensing regime would undermine patent rights in Europe
- The new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- Regulation 2019/933 and the existing SPC exemption for exports of biopharmaceuticals pose significant risk to Poland's and the EU's research and IP-based biopharma industry
- Gaps exist in online copyright protection, including an effective notice-and-takedown system
- Relatively high levels of online piracy compared with other high-income economies

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.50	30. IP as an economic asset	0.75
3. Patentability of CILs	0.25	31. Tax incentives for the creation of IP assets	1.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.25	32. Physical counterfeiting rates	0.66
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.54
7. Pharmaceutical patent term restoration	0.75	34. Civil and precedural remedies	0.50
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.50
9. Patent opposition	1.00	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	1.00
10. Term of protection	0.66	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.75	39. Coordination of IP rights enforcement	0.50
13. Cooperative action against online piracy	0.50	40. Consultation with stakeholders during IP policy formation	0.50
14. Limitations and exceptions	0.25	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	1.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
20. Frameworks against online sale of counterfeit goods	0.25	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.75
21. Industrial design term of protection	1.00	24. Protection of trade secrets (criminal sanctions)	0.50
22. Exclusive rights, industrial design rights	0.50	25. Regulatory data protection term	1.00
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	0.75	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	0.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	0.75
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 71.91%

• Total Score: 38.11

Spotlight on the National IP Environment

Past Editions versus Current Score

Poland's overall Index score has increased from 35.37 out of 50 indicators in the twelfth edition to 38.11 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation and a score decrease for indicator 32.

Patent Rights and Limitations

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

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged its flawed premise. More worryingly, Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and the European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each member state. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

12. Expeditious legal remedies disabling access to 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 have historically been more limited than in other EU Member States. Specifically, the legal framework on both notice-and-take-down and injunctive-style relief is underdeveloped. The Polish Act on Providing Services by Electronic Means, 2002 (which implements the E-Commerce Directive), provides limited liability for persons (including ISPs) that 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. Consequently, rightsholders continue to report of high levels of copyright piracy. A 2023 report authored by Deloitte—commissioned by the Polish Sygnal Association—found that copyright infringement cost the Polish audiovisual market close to EUR700 million per year.

With respect to the transposition and implementation of EU Directive 2019/790 on copyright and related rights in the CDSM Directive, in July 2024, the Polish Parliament finally passed a set of amendments transposing the directive into Polish law. As noted in the Index, Poland had been the sole EU Member State yet to incorporate the law into its domestic statute, having originally challenged the legality of the directive before the Court of Justice of the European Union (CJEU) and, specifically, the responsibilities defined under Article 17.

In 2022, the court 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, the Polish president had not signed the bill into law. The Index will continue to monitor these developments in 2025.

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an “Artificial Intelligence Act.” In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024. The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed.

Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they are in compliance with existing copyright law. Some positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

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. 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, detailed under Category 9. 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. The Commission's proposal 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 Commission's 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. Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences.

Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU member states seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process.

Under the proposal, EUIPO would become 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 Commission's proposals 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.

In early 2024, the European Parliament responded to the Commission's ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the "Fourth Industrial Revolution"—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential. Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances.

Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

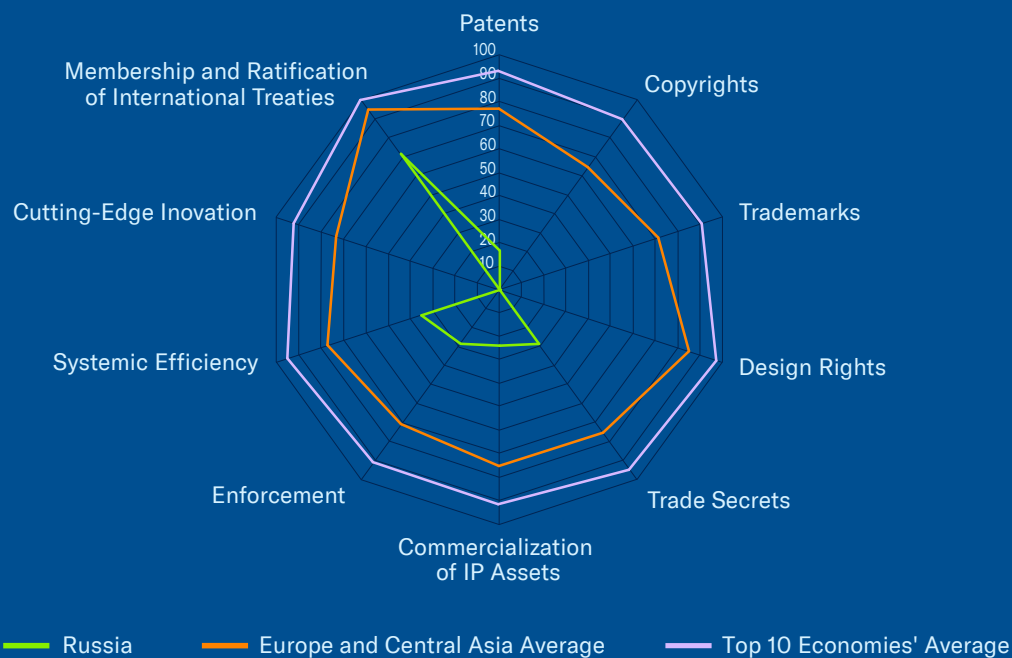
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals—including the European Parliament’s response to the Commission’s proposals in early 2024—the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.



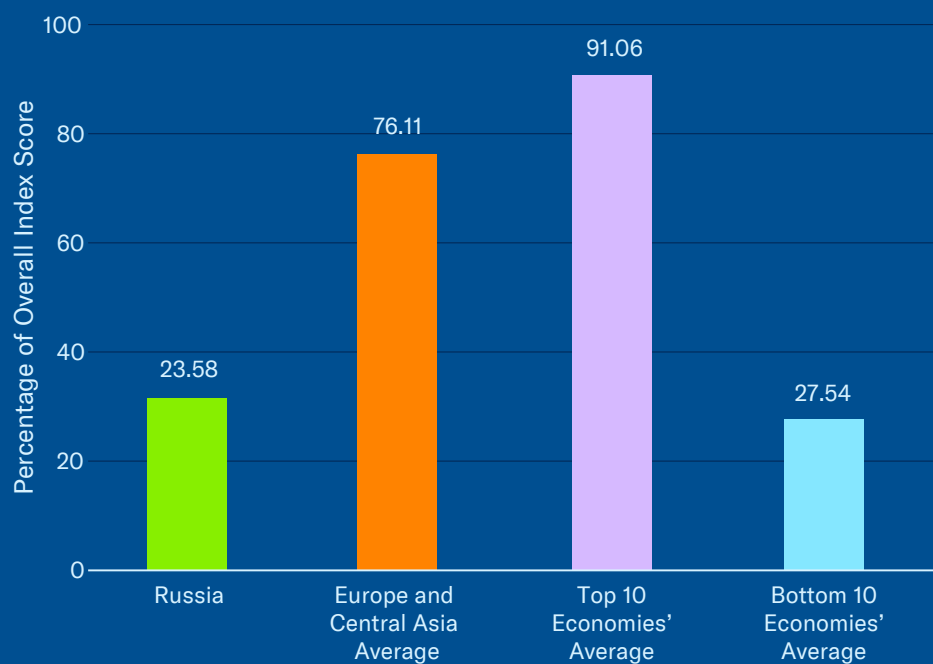
Russia

Rank
54/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- ROSPATENT has in place numerous PPHs and is a full participant in the GPPH
- Participant in international IP treaties benchmarked in the Index

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 2022 Federal Laws 46-FZ and 213-FZ nullify existing duly granted IP protection under Civil Code Part IV for all major IP rights covered in the IP Index
- Deep and abiding uncertainty over the extent to which rightsholders will, in practice, at any point in the future be able to register and enforce their IP rights in Russia
- Continued weakening of the life sciences environment through administrative barriers for patentability and term restoration
- Use and threat of compulsory licenses and the overriding of IP rights as public health policy: compulsory license issued in 2020 and new 2021 amendments to Civil Code Part IV broaden existing basis for action
- Administrative and regulatory barriers are in place for licensing activities, including direct government intervention
- Increasingly punitive localization requirements target ICT and the biopharmaceutical sector
- Data localization requirements for technology companies have been in place for a long time and have intensified over the past few years
- For biopharmaceuticals, industrial localization policies have fused together with IP policy and broader health policy on the pricing and procurement of medicines

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	0.00	29. Direct government intervention in setting licensing terms	0.00
2. Patentability requirements	0.00	30. IP as an economic asset	0.25
3. Patentability of CILs	0.00	31. Tax incentives for the creation of IP assets	0.67
4. Plant variety protection	0.00		
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.35
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.38
7. Pharmaceutical patent term restoration	0.00	34. Civil and precluded remedies	0.00
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.00
9. Patent opposition	0.50	36. Criminal standards	0.25
		37. Effective border measures	0.50
Category 2: Copyrights and Limitations		38. Transparency and public reporting by customs	0.50
10. Term of protection	0.00		
11. Exclusive rights	0.00	Category 8: Systemic Efficiency	
12. Expedient legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	0.25
13. Cooperative action against online piracy	0.00	40. Consultation with stakeholders during IP policy formation	0.50
14. Limitations and exceptions	0.00	41. Educational campaigns and awareness raising	0.25
15. TPM and DRM	0.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
16. Government use of licensed software	0.00	43. IP-intensive industries, national economic impact analysis	0.50
Category 3: Trademarks Rights and Limitations			
17. Term of protection	0.00	Category 9: Cutting-Edge Innovation	
18. Protection of well-known marks	0.00	44. IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
20. Frameworks against online sale of counterfeit goods	0.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
Category 4: Design Rights and Limitations			
21. Industrial design term of protection	0.00	Category 10: Membership and Ratification of International Treaties	
22. Exclusive rights, industrial design rights	0.00	47. WIPO Internet Treaties	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
23. Protection of trade secrets (civil remedies)	0.00	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
24. Protection of trade secrets (criminal sanctions)	0.25	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
25. Regulatory data protection term	0.60	51. Membership of the Convention on Cybercrime, 2001	0.00
Category 6: Commercialization of IP Assets		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
26. Barriers to market access	0.00	53. Post-TRIPS FTA	0.00
27. Barriers to technology transfer	0.00		
28. Registration and disclosure requirements of licensing deals	0.50		

Percentage of Overall Score: 23.58%

Total Score: 12.50

Spotlight on the National IP Environment

Past Editions versus Current Score

Russia's overall score remains unchanged at 12.50 out of 53 indicators.

Area of Note

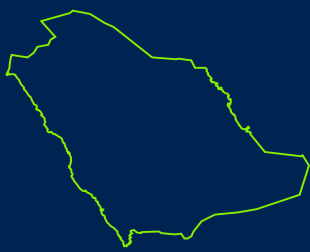
As noted in the Index, the Russian Government has over the past three years made significant negative changes to its national IP environment affecting most major IP rights benchmarked in the Index. Under Federal Laws 46 and 213, Decrees 79, 81, 95, 299, 322, and Decree Order 430, the Russian Government has targeted the IP rights of rightsholders, 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 related to the use of patented technologies, utility models, or industrial designs. 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 in the eleventh edition of the Index. No positive changes to Russia's national IP environment occurred in 2024, and these reductions remain in place.

Instead, additional negative developments have further hollowed out Russia's national IP environment. Of note is the government's issuing of Resolution 380 in March 2024. This resolution establishes a mechanism whereby the involuntary use of registered industrial property rights, including patents, utility models, and design rights, is now explicitly institutionalized and sanctioned by the Russian state. This expansion of the involuntary licensing and appropriation of IP rights builds on previous efforts detailed in the Index.

For example, in 2022, Decree 299 was issued targeting 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. Similarly, in 2021, the Russian Duma passed, and President Putin signed into law amendments to the Civil Code Part IV. These changes amended Article 1360, inserting further justification for the overriding of any granted rights related to patents, utility models, and industrial designs. Press reports suggest that several involuntary licenses had been issued or were under consideration in 2024 in the pharmaceutical sector. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

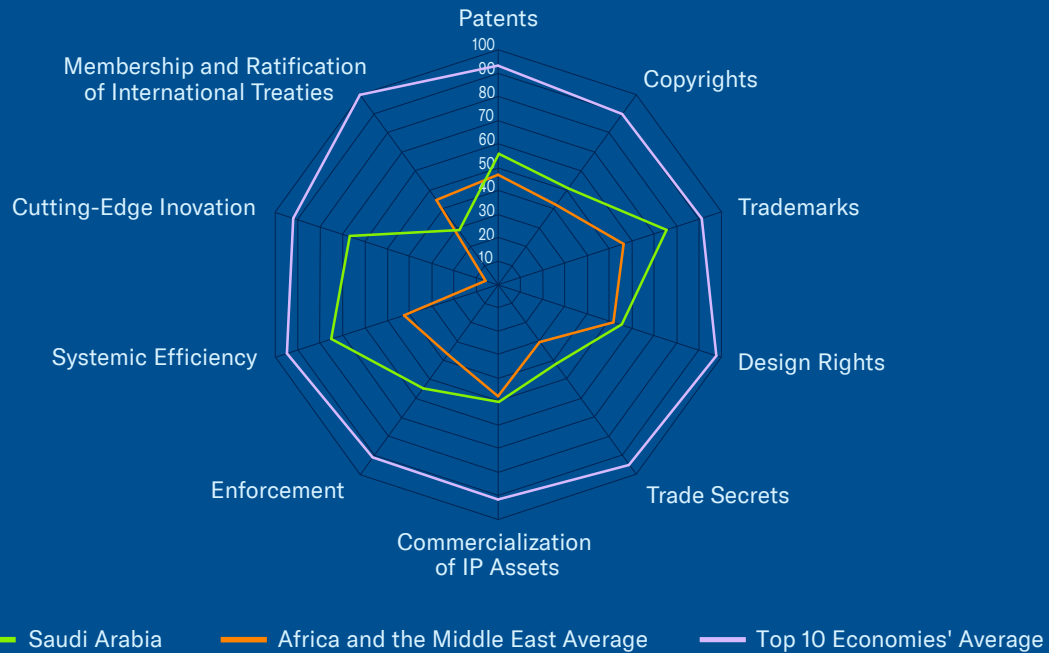
44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:
Russia does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



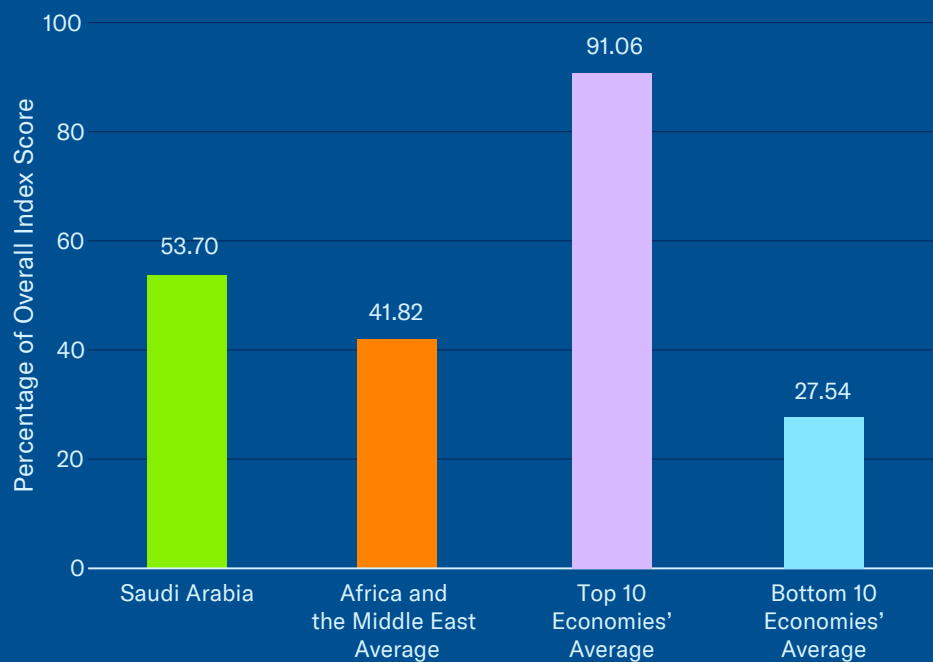
Saudi Arabia

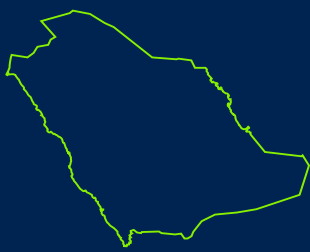
Rank
25/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Royal Decree M/45 extends design rights term of protection from 10 to 15 years
- IP incentives for orphan medicinal development are in place through Saudi FDA
- Saudi Authority for Intellectual Property (SAIP) continues to assume leadership on IP policy and enforcement with a marked increase in online copyright and trademark enforcement since 2022
- SAIP has put in place an ambitious reform agenda and is revamping the administration of the Kingdom's national IP environment; these positive efforts continued in 2023
- SAIP is leading and coordinating IP enforcement in the 2021 National Committee for the Enforcement of Intellectual Property Rights
- SAIP joined multiple PPHs in 2019–2020
- Increased consultation and awareness-raising activities occurred 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

Key Areas of Weakness

- Pharmaceutical patent protection and linkage mechanism were suspended through SFDA actions in 2017
- Significant gaps exist in the copyright legal framework, chiefly related to protection online
- Increasing number of localization requirements
- Industry reports a lack of practical availability of RDP; the government has allowed indirect reliance on innovators' data when reviewing follow-on products

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.50
2. Patentability requirements	0.50	30. IP as an economic asset	0.75
3. Patentability of CIIIs	0.75	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.55
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.53
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.50
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.50
9. Patent opposition	0.75	36. Criminal standards	0.75
Category 2: Copyrights and Limitations		37. Effective border measures	0.50
10. Term of protection	0.53	38. Transparency and public reporting by customs	0.50
11. Exclusive rights	0.50	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	1.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	0.00	40. Consultation with stakeholders during IP policy formation	0.75
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	0.50
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	1.00
20. Frameworks against online sale of counterfeit goods	0.75	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.50
21. Industrial design term of protection	0.60	24. Protection of trade secrets (criminal sanctions)	0.25
22. Exclusive rights, industrial design rights	0.50	25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	0.50	47. WIPO Internet Treaties	0.00
27. Barriers to technology transfer	0.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
28. Registration and disclosure requirements of licensing deals	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
		51. Membership of the Convention on Cybercrime, 2001	0.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	0.00

Percentage of Overall Score: 53.70%

Total Score: 28.46

Spotlight on the National IP Environment

Past Editions versus Current Score

Saudi Arabia's overall Index score has increased from 24.21 out of 50 indicators in the twelfth edition to 28.46 out of 53 indicators. This reflects score increases for indicators 16, 21, 32, 35, 36, 42, and 52 as well as a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism:

As noted in previous editions of the Index, in 2022, the Saudi FDA and 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) affirming that the follow-on application does not infringe any existing IP rights. This declaration is to be accompanied by a "freedom to operate" analysis and certification that no outstanding patent exclusivity is in place by an IP agent licensed by SAIP.

As noted by the Index at the time of publication, the release of this procedure is a positive move by the Saudi FDA. 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.

For example, the procedure does not contain a notification mechanism to the relevant rightsholder or an automatic stay period ensuring that 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 and stimulating early market entry of follow-on 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 follow-on manufacturers because no potentially infringing product is ever launched or approved for market. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit. In summary, a well-balanced linkage system recognizes the crucial role of IP protection in promoting innovation and the role of follow-on products in providing patients access to lower cost biopharmaceuticals. The introduction of a functioning linkage regime that provides rightsholders with the 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 2025.

Copyrights and Limitations

16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software:

As noted in past editions of the Index, rightsholders have historically faced challenges in ensuring the use of licensed software by Saudi government ICT systems. The U.S. government has in the past noted the use of unlicensed or “underlicensed” software by public sector entities. In 2012, a Royal Decree was issued requiring the use of licensed software on all government ICT systems, but to date, internal auditing and compliance efforts have been limited. Since 2020, SAIP has built a dedicated program—the “IP Respect Officer Initiative”—to raise awareness of and compliance with IP rights in public and private sector organizations. The authority provides a training and certification program, and, upon completion, officers are dispatched to their respective organizational entity. The initiative consists of six separate tracks, including compliance and self-assessment. To date, close to 150 officers have been certified, and over 80% are working in public sector entities. As a result of this dedicated effort to raise IP compliance in the public sector, the score for this indicator has increased by 0.25.

Design Rights and Limitations

21. Industrial design term of protection:

In 2024, some significant changes were made to the protection of design rights in Saudi Arabia. In late 2023, Royal Decree M/45, increased the term of protection for design rights from 10 years to 15 years. Although this is still less than the 25-year term benchmark used by the Index, this is still a positive development. As a result, the score for this indicator has increased.

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 about the actual availability of this protection. Industry reports have suggested that follow-on products have been approved through the use of “indirect reliance” on submitted clinical research data. International standards and best practices for RDP are clear on this subject: neither direct nor indirect reliance on submitted clinical test data should be used to approve follow-on products within any specified and granted term of exclusivity.

In 2020, SAIP released new draft implementing regulations on how confidential commercial information would be protected in Saudi Arabia. Although SAIP should be applauded for publishing these draft regulations, holding a public consultation, and inviting stakeholder feedback on the matter, as noted in the Index at the time, the regulations themselves were deeply flawed and stood outside established international standards of RDP. Specifically, Article 4(1) of the regulations stated that any term of protection offered in Saudi Arabia would begin “the date of the first registration of the preparation in another country”.

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 Saudi FDA released a statement reaffirming their support for the availability of regulatory data protection in the Kingdom. The U.S. State Department in its 2022 *Investment Climate Statement* 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 2025.

Enforcement

35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement:

As noted last year, SAIP has aimed to strengthen the enforcement of IP rights in Saudi Arabia through both institutional improvements and increased levels of transparency and engagement with rightsholders over the past three years. In 2024, SAIP continued to publish judgments reached by standing committees related to copyright and patent infringement (the "Committee for Review of Violations of the Copyright Protection System" and "Committee for Consideration of Patent Claims"). As stated last year, the publication of these decisions shows that, first, the number of cases considered for IP violations continues to increase and, second, damages are more consistently awarded. As a result, the score for this indicator has increased by 0.25 for the second consecutive year.

36. Criminal standards, including minimum imprisonment and minimum fines:

Historically, criminal enforcement against IP violations has been relatively rare with limited dedicated resources and focus among Saudi law enforcement. Like the efforts taken by SAIP since 2020 related to administrative enforcement, this may now also change with relevant Saudi authorities introducing institutional reforms to strengthen criminal enforcement of IP rights. Specifically, in February 2024, the Public Prosecution Council announced that it had established a dedicated prosecution office for IP offenses. This office will work on investigating and filing criminal charges in cases concerning the violation of IP rights. As a result of these positive efforts, the score for this indicator has increased by 0.25.

Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs:

Historically, Saudi and GCC IP authorities have not offered any special IP incentives targeting SMEs. No reduced fees or expedited approval process has been on offer for SMEs nor has much technical assistance been offered. The GCC Patent Office has offered wider support programs for IP practitioners and inventors, but these have not been targeted at SMEs. Although the King Abdullah University of Science and Technology and King Abdulaziz City for Science and Technology provides several programs and support for innovators, including SMEs, this support is not within the specific context of IP development but more broadly in terms of economic development and innovation. This includes, for example, the SMEs Support Initiative run by King Abdulaziz City for Science and Technology. However, in the past few years, there has been a substantial expansion of support, training, and educational programs available through SAIP. These programs often target SMEs and start-ups. For example, in 2020, SAIP launched the "Intellectual Property Advisory Clinics Program."

This program seeks to help SMEs develop, register, and commercialize IP assets. In 2020, SAIP also released an “Intellectual Property Policies Manual” to assist SMEs, academic institutions, and individual inventors. Similarly, since 2020, SAIP has opened over 50 technology and innovation support centers as part of a national network of IP centers often in partnership with WIPO. The authority has more recently developed a comprehensive suite of online training and educational programs on all aspects of IP development, protection, and commercialization, many of which have been developed specifically for SMEs and entrepreneurs. As a result of these continued positive efforts, the score for this indicator has increased by 0.25.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Interest in rare diseases has grown in the Middle East and North Africa region. In 2003, the Centre for Arab Genomic Studies was established to map and improve the state of care for patients with genetic diseases in the Arab world.

Today, the Center has become the leading research point on rare diseases in the region.

Moreover, several Index economies in the region, including Saudi Arabia, have introduced a defined regulatory sanitary registration pathway and special incentives for orphan products. Since 2023, the Saudi FDA has had in place a dedicated rules document on orphan drug registration and relevant requirements and incentives, the “Guidance for Orphan Drug Designation.” Section 4 of this document includes the provision of a marketing exclusivity incentive for drugs qualifying for orphan designation. However, no further details have been made available as to the length of this exclusivity period.

Membership and Ratification of International Treaties

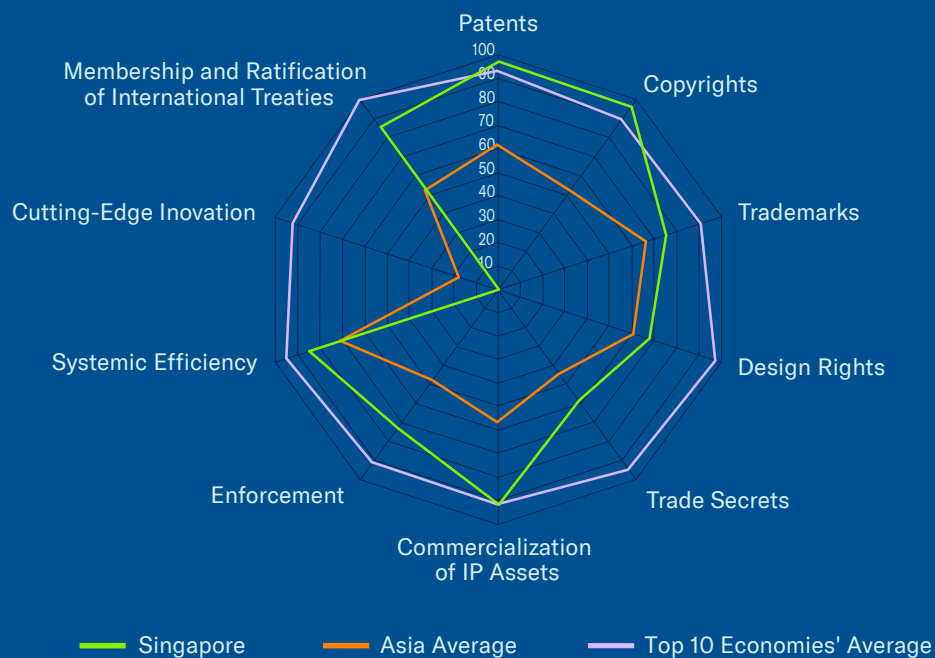
52. The Hague Agreement Concerning the International Registration of Industrial Designs
January 2025, Saudi Arabia acceded to the full Hague Agreement, including the Geneva Act. As a result, the score for this indicator has increased by 1.00.



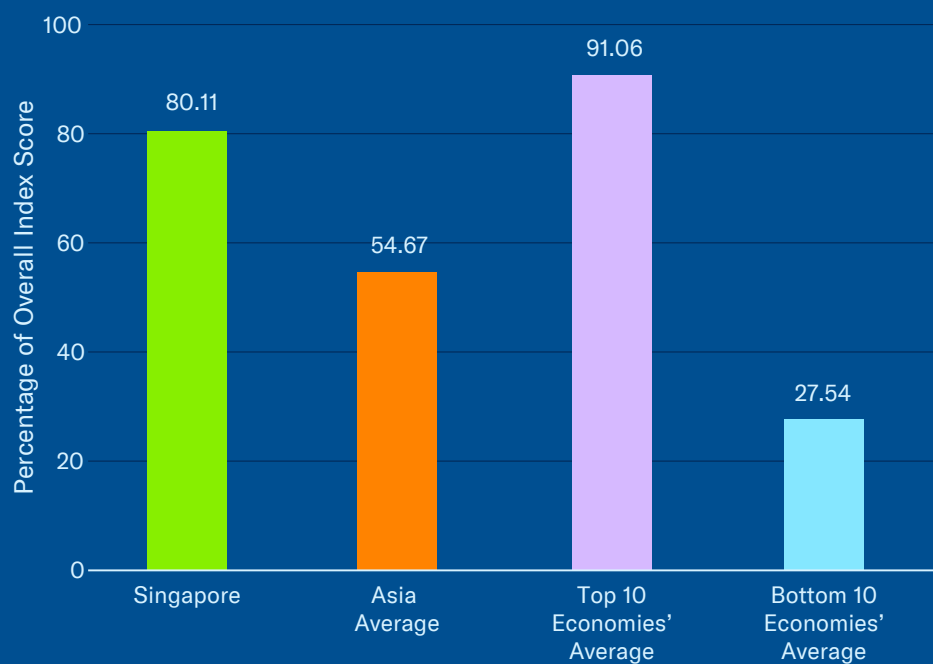
Singapore

Rank
13/55

Category Scores



Overall Score in Comparison





Singapore

Rank
13/55

Key Areas of Strength

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

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- The 2021 Copyright Act expanded the existing copyright exceptions regime
- Estimated software piracy has decreased from 35% in 2009 to 27% today but is still high for a developed high-income economy
- Lack of transparency and data on customs seizures of IP-infringing goods

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	1.00	30. IP as an economic asset	0.75
3. Patentability of CII	1.00	31. Tax incentives for the creation of IP assets	1.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	1.00	32. Physical counterfeiting rates	0.64
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.73
7. Pharmaceutical patent term restoration	1.00	34. Civil and precedural remedies	1.00
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	1.00
9. Patent opposition	0.75	36. Criminal standards	0.75
Category 2: Copyrights and Limitations		37. Effective border measures	0.75
10. Term of protection	0.74	38. Transparency and public reporting by customs	0.25
11. Exclusive rights	1.00	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	1.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	1.00	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	1.00	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	1.00	43. IP-intensive industries, national economic impact analysis	0.75
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.25	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	1.00
21. Industrial design term of protection	0.60	24. Protection of trade secrets (criminal sanctions)	0.25
22. Exclusive rights, industrial design rights	0.75	25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	1.00	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	0.75	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	0.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 80.11%

• Total Score: 42.46

Spotlight on the National IP Environment

Past Editions versus Current Score

Singapore's overall score remains unchanged at 42.46 out of 53 indicators.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

In April 2024, the Ministry of Law and the Intellectual Property Office of Singapore (IPOS) issued a public consultation on certain copyright exceptions and limitations related to TPM and DRM. Specifically, IPOS and the Ministry sought comments on the extent to which (1) these existing exceptions were adequate and should remain in place and (2) whether a new set of TPM and DRM exceptions should be introduced. As noted in the Index, the 2021 changes to the Copyright Act included significant changes to Singapore's general copyright limitations and exceptions regime, including for TPM and DRM. Conceptually, the new Act changed the regime from a "fair dealing" framework to one of "fair use."

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 can 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 included 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), there is also an indirect access control measure in the sense that works accessed on the internet can be circulated only through the network that is operated by or through an educational institution and to 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.

Unfortunately, the consultation document did not seek to address this outstanding weakness. Instead, in addition to preserving a set of access control exceptions defined in Part 7 of the Copyright Act, Annex B of the document also proposes to broaden text and data mining exceptions (called "computational data analysis"). The 2021 amendments included a clarification on the extent to which such text and data mining is allowed for research purposes. Like similar exceptions introduced in other jurisdictions, including the European Union's Directive 2019/790 on Copyright and Related Rights in the CDSM Directive, under Section 244(2)(d) of the Act, copying or communicating for computational analysis can be carried out only on works that have been lawfully obtained or accessed.

But 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—as well as the ability of scraping technologies to access rightsholders' content without their permission, 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, both in Singapore and around the world.

Unfortunately, under the proposed amendments, it is not clear that this safeguard will be retained.

Specifically, the consultation sought “feedback on whether the prohibition on circumventing access control measures has impaired or adversely affected, or is likely to impair or adversely affect, any dealings with copyright works or protected performances that would be non-infringing based on a permitted use in Annex B.” The most notable exception listed in Annex B relates to Part 5, Division 8 of the Copyright Act, that is, “Permitted use of copyright works and protected performances for computational data analysis.” At the time of research, no formal legislative proposal or amendments had been published by IPOS or the Ministry of Law. However, should Singapore move ahead and further expand the existing exceptions regime related to computational analysis and, essentially, nullify any control rightsholders have over how their creations and copyrighted content is accessed, used, and disseminated, such actions would go against both long-standing legal precedence in Singapore and international standards dating to the Berne Convention and currently codified in the TRIPS Agreement. Article 13 of TRIPS states, “Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the rights holder.” The adoption of such an expansive exceptions regime related to computational analysis would also result in a sharp score decrease for indicators 14 and 15.

In a separate development, the Infocomm Media Development Authority and its AI-specialized subsidiary, the Verify Foundation, released *Model Governance Framework for Generative AI, Fostering a Trusted Ecosystem* in May 2024. The purpose of this framework is to “set forth a systematic and balanced approach to address generative AI concerns while continuing to facilitate innovation.” The framework is not a legal document and, as such, has no legal effect. With respect to the interaction between AI technologies and copyright, the framework does recognize the basic conflict and potential for copyright infringement, particularly at the development and training stages.

The document states that:

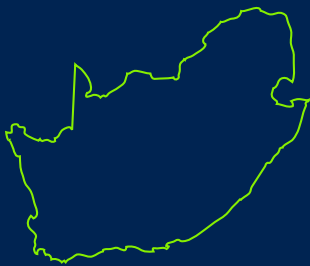
From a model development perspective, the use of copyright material in training datasets and the issue of consent from copyright owners is starting to raise concerns, particularly as to remuneration and licensing to facilitate such uses. Models are also increasingly being used for generating creative output — some of which mimic the styles of existing creators and give rise to considerations of whether this would constitute fair use.

Unfortunately, the framework does not propose any concrete solutions. Instead, it calls for further discussion and states that “policymakers should foster open dialogue amongst all relevant stakeholders to understand the impact of the fast-evolving generative AI technology, and ensure that potential solutions are balanced and in line with market realities.” The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

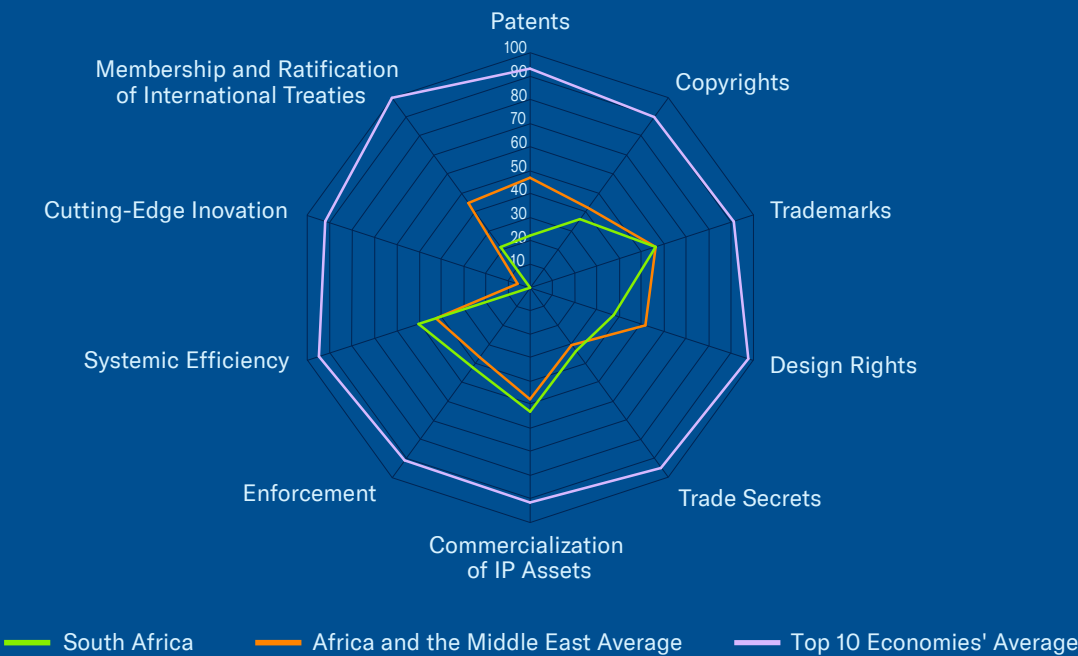
Public interest in rare diseases has grown in Singapore. The Ministry of Health and related health and regulatory agencies provide support for rare disease treatment and access programs through the national health system, MediShield Life, with additional financial support coming from the Rare Disease Fund. However, with respect to research and development, there is no reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.



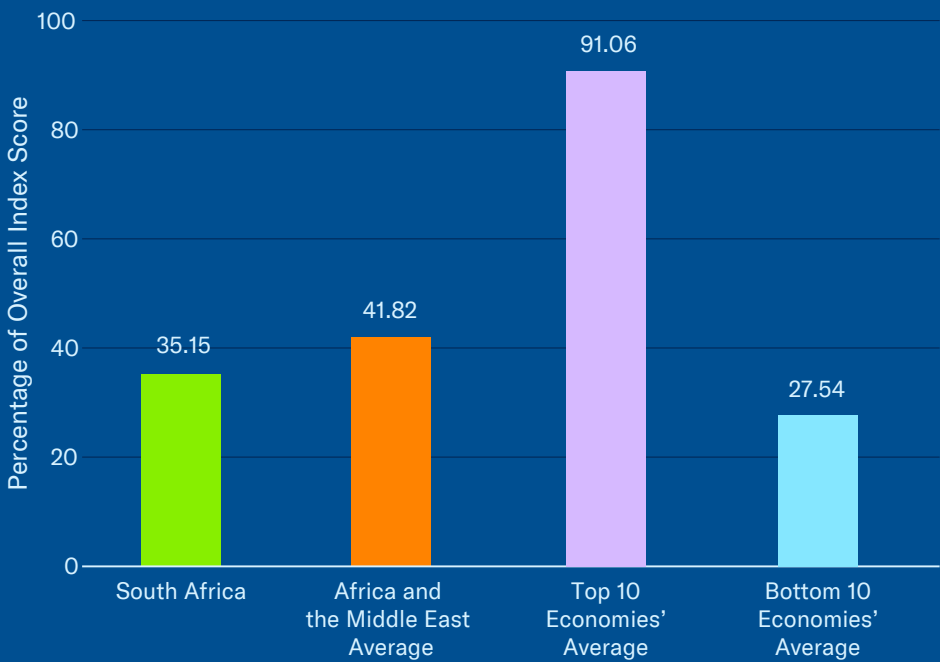
South Africa

Rank
46/55

Category Scores



Overall Score in Comparison





South Africa

Rank
46/55

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 in place
- Relatively low level of software piracy—32%—compared to other African economies

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 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 innovation and development of new IP in South Africa but on the use of existing developed IP through CLs, parallel imports, and restricting patentability of pharmaceuticals
- Proposed copyright amendments create uncertainty for rightsholders through expansive "fair use" definitions
- Major gaps exist in laws and enforcement across all categories of the Index

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

Percentage of Overall Score: 35.15%

Total Score: 18.63

Spotlight on the National IP Environment

Past Editions versus Current Score

South Africa's overall Index score has decreased from 18.64 out of 50 indicators in the twelfth edition to 18.63 out of 53 indicators. This reflects a score decrease for indicator 32.

Area of Note

As noted under Category 2: Copyrights and Limitations, South Africa has been in the process of reforming its copyright laws for over a decade. In 2024, in testimony before Parliament, the Department of Trade, Industry and Competition outlined plans for expanding these reform efforts to other areas of South Africa's national IP environment, including in relation to patents and design rights. Specifically, the department proposes to translate key ideas contained in the 2018 document, *Intellectual Property Policy of The Republic of South Africa Phase I*, into new legislation and/or official policies. As noted in the Index at the time of its publication, this document—and the thinking it represents—is fundamentally flawed. It focuses almost exclusively on ways in which South Africa could better access existing and developed forms of IP rather than on the manner in which IP can be created and commercialized and become an industrial asset in South Africa. For all economies—emerging and developed alike—what drives innovation, technological advances, and, ultimately, economic development and growth is the creation of new forms of intangible assets and IP. Yet the IP policy is silent on this. Instead, it proposed to introduce new more restrictive standards of patentability, change the existing framework for the issuing and use of compulsory licenses, introduce the use of parallel importation for medicines, and introduce a new pre- and postgrant patent opposition mechanism.

Although no draft bill had been published at the time of research, the department's legislative plans presented to Parliament fully embrace these ideas, especially with respect to compulsory licensing and parallel imports, which are listed as the second of three key priority areas.

Since 2015, the Index has included a *Statistical Annex* that investigates a series of correlations of the relationship between the strength of national IP environments, as measured by the Index scores, and different types of economic activity, including rates of R&D spending, innovation, technology creation, and creativity. As the economic data and analysis of the *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. Covering 53 indicators across 10 separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products. As the Department of Trade, Industry and Competition and the South African Government pursue a program of national IP rights reforms, we would encourage them to use the Index findings and accompanying *Statistical Annex* as a guide in 2025 and beyond.

Copyrights and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 14. Scope of limitations and exceptions to copyrights and related rights; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation:

As discussed in previous editions of the Index, South Africa has over the past decade been engaged in reforming its copyright laws with draft amendments considered for both the Copyright Act and Performers' Protection Act. In 2019, a final bill was approved by both the National Assembly and the National Council of Provinces and sent to President Ramaphosa for his assent. However, the president refused to sign the draft law, citing its potential unconstitutionality, and sent it back to the National Assembly for further review. In 2021, this draft bill was formally rescinded by the National Assembly, and the legislative process started anew. A fresh set of stakeholder consultations were held in 2021 and 2022 by the Department of Trade, Industry and Competition, and a new draft law was passed by the National Assembly in 2022. In 2023, continued public consultations and hearings were held at both the provincial level and in the National Assembly. In early 2024, the department presented an update on the status of the bill to Parliament, including legislative input from the National Council of Provinces. At the time of research, the bill had been referred by the President to the Constitutional Court for further evaluation.

As the Index has detailed, since the first draft amendments were published, the proposed legislation has always suffered from several serious deficiencies. On the one hand, South African policymakers correctly identified the need for modernizing 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 and industries and businesses, economic interaction is today shaped by digital and mobile technologies. Platforms and business models that did not exist a generation ago have been enabled by the advent of digital technologies. 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, modern copyright regime that encourages innovation and creativity is critical to making the most of the socioeconomic opportunities that these deep structural changes offer.

In 2010, the South African Government together with WIPO examined the contribution of the copyright-based industries to the South African economy. The report found that these industries contributed 4.11% to the GDP and 4.08% to national employment. Although substantial, these contributions are smaller compared to those in other economies with more modernized copyright frameworks, such as the United States and Korea, where the contribution was estimated by WIPO to be over 10%. Given the size and breadth of the creative sector in South Africa, with the right IP-based incentives in place, the 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 copyright infringement 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 and several remarkably broad statutory exceptions and limitations, particularly for educational use. Exceptions and limitations to copyright should be considered against the three-step test embodied in the Berne Convention and the WTO TRIPS Agreement. Yet, as noted by the Index throughout the review of the draft law, it was always unclear how the new exceptions and proposed system of fair use would work in practice without negating the exclusive rights of copyright owners and imperiling the legitimate markets for creative works. Similarly, although the proposed amendments would introduce protection for DRM and TPMs into the Copyright Act (currently legal provisions only exist in the Electronic Communications and Transactions Act), these provisions are undermined by the broad limitations and exceptions regime. Overall, it remains the case today that the proposed amendments do little in the way of fundamentally strengthening rightsholders’ ability to 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, India, Singapore, Malaysia, Brazil, 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 an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. They have proven to be effective in reducing the availability of copyright-infringing content within these jurisdictions. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Interest in rare diseases has grown in South Africa. Since 2019, the Rare Diseases Access Initiative has worked to highlight the needs of patients with rare diseases, including improving access to medical treatment and medicines. No specific legislative framework is in place in South Africa with special IP-based market exclusivity incentives for orphan medicinal product development.



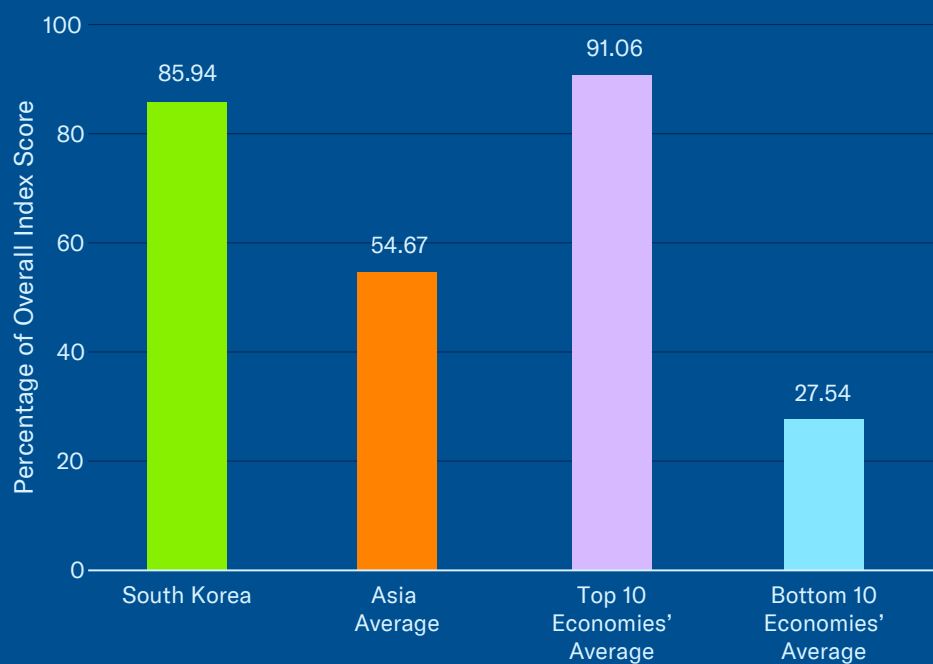
South Korea

Rank
10/55

Category Scores



Overall Score in Comparison





South Korea

Rank
10/55

Key Areas of Strength

- 2024 amendments to the Unfair Competition Prevention and Trade Secret Protection Act significantly strengthened existing penalties and damages for trade secret violations and misappropriation of confidential information
- Extended data exclusivity period (referred to as “re-examination” period) of 10 years for designated orphan drugs available since 2016
- Increasingly active stance taken 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
- Patenting standards are in line with international best practices
- Relatively robust legal framework for trademark and design protection
- Membership in Global PPH and IP5 and a new post-grant patent opposition mechanism help streamline patent office review
- KIPO provides SMEs with a variety of educational and technical assistance programs as well as the right to reduced filing fees

Key Areas of Weakness

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

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	8.50	29. Direct government intervention in setting licensing terms	0.50
1. Term of protection	1.00	30. IP as an economic asset	0.75
2. Patentability requirements	1.00	31. Tax incentives for the creation of IP assets	0.67
3. Patentability of CILs	1.00	Category 7: Enforcement	6.24
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.81
5. Pharmaceutical-related enforcement	0.50	33. Software piracy rates	0.68
6. Legislative criteria and use of compulsory licensing	1.00	34. Civil and precluded remedies	0.75
7. Pharmaceutical patent term restoration	1.00	35. Pre-established damages	1.00
8. Membership of a Patent Prosecution Highway	1.00	36. Criminal standards	1.00
9. Patent opposition	1.00	37. Effective border measures	1.00
Category 2: Copyrights and Limitations	5.99	38. Transparency and public reporting by customs	1.00
10. Term of protection	0.74	Category 8: Systemic Efficiency	5.00
11. Exclusive rights	1.00	39. Coordination of IP rights enforcement	1.00
12. Expedient legal remedies disabling access to infringing content online	1.00	40. Consultation with stakeholders during IP policy formation	1.00
13. Cooperative action against online piracy	1.00	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.75	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
15. TPM and DRM	1.00	43. IP-intensive industries, national economic impact analysis	1.00
16. Government use of licensed software	0.50	Category 9: Cutting-Edge Innovation	2.50
Category 3: Trademarks Rights and Limitations	3.75	44. IP incentives for orphan medicinal product development	1.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.50
18. Protection of well-known marks	1.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	1.00
19. Exclusive rights, trademarks	0.75	Category 10: Membership and Ratification of International Treaties	5.50
20. Frameworks against online sale of counterfeit goods	1.00	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	1.80	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	0.80	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	1.00	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.60	51. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	1.00	52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	1.00	53. Post-TRIPS FTA	1.00
25. Regulatory data protection term	0.60		
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		

Percentage of Overall Score: 85.94%

Total Score: 45.55

Spotlight on the National IP Environment

Past Editions versus Current Score

South Korea's overall Index score has increased from 42.47 out of 50 indicators in the twelfth edition to 45.55 out of 53 indicators. This reflects score increases for indicators 23, 24, and 32 and a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Area of Note

In late 2024, the Korean National Assembly passed a series of legislative amendments to several major IP laws and related acts, including the Patent Act, the Utility Model Act, the Trademark Act, the Industrial Technology Protection Act, and the National Advanced Strategic Industries Act. The primary purpose of these amendments is to increase the protection of Korean industrial technology and oversight of the export of technologies considered to be of high national importance. From the Index's perspective the most noteworthy changes relate to the provision of patent term restoration for biopharmaceutical products discussed under indicator 7.

Patent Rights and Limitations

7. Patent term restoration for pharmaceutical products:

The Patent Act provides a clear five-year term of term restoration for patent term lost during the regulatory review and product registration process for biopharmaceuticals. As noted in past editions of the Index, industry has raised several concerns over the years about the practical availability of this restoration.

This includes, for example, the inclusion of clinical trials conducted outside Korea in the calculation of patent term to be restored, the extent to which additional uses of a patented invention are included under any restoration granted, and the wholesale rejection of all term restoration for unsuccessful applications. In late 2024, the National Assembly passed a set of amendments, including for patent term restoration, that have introduced several potential new barriers. Under amendments to the Patent Act, a new 14-year maximum patent term (including any term restoration) has been put in place together with new limitations on the number of patents eligible for restoration for each product. These changes were set to come into effect in the second half of 2025. The Index will monitor the extent to which these legislative changes affect rightsholders' ability to access term restoration on a nondiscriminatory and fair basis.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation:

In late 2023, the Ministry of Culture, Sports and Tourism released *A Guide on Generative AI and Copyright*. The guide is the culmination of the work of a special working group established by the Ministry and Korea Copyright Commission. Although not a legal document, the purpose of the guide is to provide a summary of the existing legal framework and its applicability to the development and application of generative AI. Improvements 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.

The guide provides an important contribution to policy discussions in Korea and globally. Notably, the guide states clearly and unequivocally that copyright should be respected by AI developers and that “an AI business, even when using a work solely for AI training, should try to prevent possible disputes by securing authorization from the rights holder prior to the use, whether by paying adequate remuneration or through other means.” 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in South Korea and around the world.

In a separate development, the Korean National Assembly has been considering several bills related to AI and machine learning technologies. Bill 2204250 (“Special Act on Promotion of Artificial Intelligence Industry and Securing Trust”) would establish a special national committee focused on AI development and industrial incentives. Bill 2124685 includes a proposed amendment to the Copyright Act and the introduction of new text and data mining exceptions for “information analysis for education, research, and investigation purposes.” The proposed exceptions would be available only to predefined organizations and would be used for noncommercial purposes. The proposed law also states clearly that any copyrighted work used for information analysis must be legally accessed. At the time of research, neither bill had been voted on. The Index will continue to monitor these developments in 2025.

Trade Secrets and the Protection of Confidential Information

23. Protection of trade secrets (civil remedies); and 24. Protection of trade secrets (criminal sanctions):

In 2024, important changes were made to South Korea’s laws related to the protection of trade secrets and confidential information. Together with similar changes to the Patent Act, amendments to the Unfair Competition Prevention and Trade Secret Protection Act significantly strengthened existing penalties and damages for trade secret violations and misappropriation of confidential information. Specifically, the changes include an almost doubling of existing punitive damages, increased potential criminal penalties for corporate entities engaged in infringement activities, and the introduction of new “corrective orders” administrative powers granted to the Korea Intellectual Property Office. These changes follow 2019 amendments to Article 18 of the Act, which also strengthened penalties for the theft and misappropriation of trade secrets. As a result of these positive legislative developments, the scores for indicators 23 and 24 have increased by 0.25, respectively.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. This includes South Korea, which has had in place legal definitions and standards related to the designation of orphan drugs since the late 1990s. In 2015, a dedicated law on rare diseases was enacted, the Rare Disease Management Law. This law, together with updates to related orphan drug regulations and the drug regulatory framework, provide the legal definitions and policies related to rare diseases and orphan drugs in Korea.

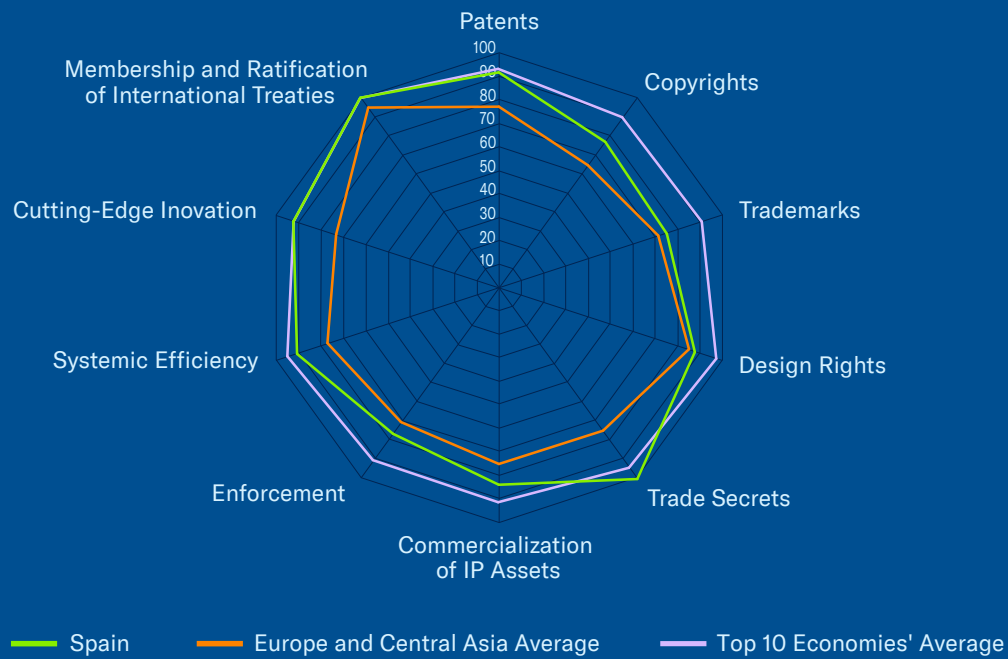
Specifically, these laws and related programs provide an expedited market approval pathway for new drugs and reduced and/or waived sanitary registration fees. With respect to incentives for R&D and the development of new treatments and technologies, under Article 18 of the Rare Disease Management Law, designated orphan drugs benefit from an extended data exclusivity period (referred to as “re-examination” period) of 10 years.



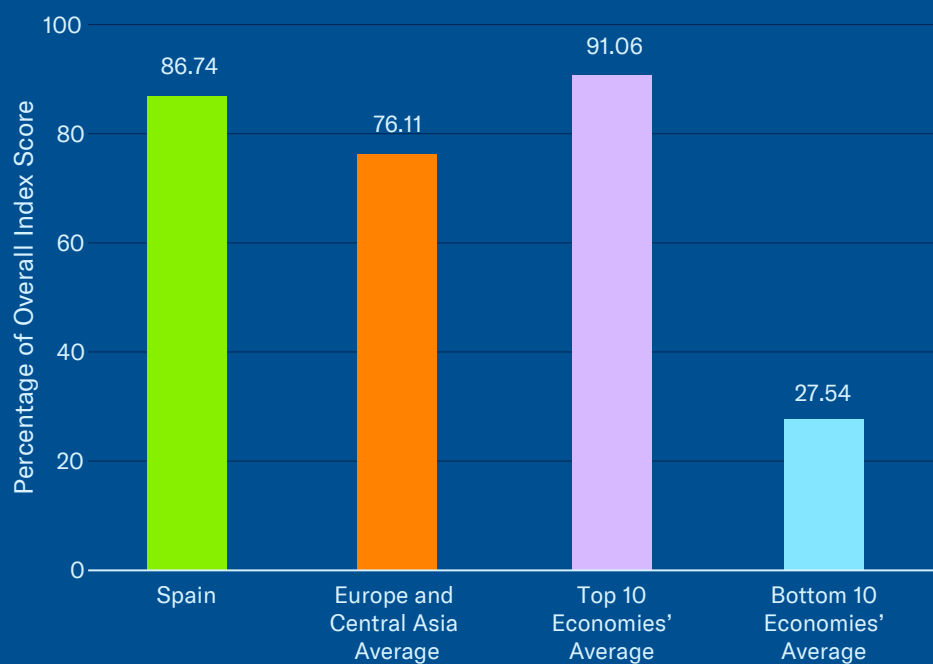
Spain

Rank
9/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Since 2000, the orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- Royal Decree-Law 24/2021 transposed EU Directive 2019/790 on Copyright and Related Rights in the CDSM Directive into law
- 2021 Protocol to Strengthen the Protection of Intellectual Property Rights further strengthens Spanish enforcement efforts
- Stronger copyright enforcement measures in place through Royal Decree Law 2/2018; continued enforcement efforts through the Ministry of Culture
- As an EU Member State, Spain has in place an advanced IP system

Key Areas of Weakness

- EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- The new EU-wide compulsory licensing regime would undermine patent rights in Europe
- The new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- Regulation 2019/933 and the existing SPC exemption for exports of biopharmaceuticals pose significant risk to Spain's and the EU's research and IP-based biopharma industry
- Counterfeiting and piracy levels remain high compared to other EU economies, with software piracy estimated at 42%

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	8.25	29. Direct government intervention in setting licensing terms	1.00
1. Term of protection	1.00	30. IP as an economic asset	0.75
2. Patentability requirements	1.00	31. Tax incentives for the creation of IP assets	1.00
3. Patentability of CILs	1.00	Category 7: Enforcement	5.34
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.76
5. Pharmaceutical-related enforcement	0.50	33. Software piracy rates	0.58
6. Legislative criteria and use of compulsory licensing	1.00	34. Civil and precluded remedies	0.75
7. Pharmaceutical patent term restoration	0.75	35. Pre-established damages	0.50
8. Membership of a Patent Prosecution Highway	1.00	36. Criminal standards	0.75
9. Patent opposition	1.00	37. Effective border measures	1.00
Category 2: Copyrights and Limitations	5.38	38. Transparency and public reporting by customs	1.00
10. Term of protection	0.63	Category 8: Systemic Efficiency	4.50
11. Exclusive rights	0.75	39. Coordination of IP rights enforcement	0.75
12. Expedient legal remedies disabling access to infringing content online	1.00	40. Consultation with stakeholders during IP policy formation	1.00
13. Cooperative action against online piracy	1.00	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.75	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
15. TPM and DRM	0.75	43. IP-intensive industries, national economic impact analysis	1.00
16. Government use of licensed software	0.50	Category 9: Cutting-Edge Innovation	2.75
Category 3: Trademarks Rights and Limitations	3.00	44. IP incentives for orphan medicinal product development	1.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	1.00
18. Protection of well-known marks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
19. Exclusive rights, trademarks	0.75	Category 10: Membership and Ratification of International Treaties	7.00
20. Frameworks against online sale of counterfeit goods	0.50	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	1.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
21. Industrial design term of protection	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
22. Exclusive rights, industrial design rights	0.75	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	3.00	51. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	1.00	52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	1.00	53. Post-TRIPS FTA	1.00
25. Regulatory data protection term	1.00		
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		

Percentage of Overall Score: 86.74%

Total Score: 45.97

Spotlight on the National IP Environment

Past Editions versus Current Score

Spain's overall Index score has increased from 43.22 out of 50 indicators in the twelfth edition to 45.97 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies:
As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:
As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and the European Parliament subsequently responded to the Commission's proposal.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each Member State. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024.

The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application, and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they are in compliance with existing copyright law. Some positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

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. 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, detailed under Category 9.

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. The Commission’s proposal 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 Commission’s 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.

Yet the European Commission's proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU member states seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become 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 Commission's proposals 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.

In early 2024, the European Parliament responded to the Commission's ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

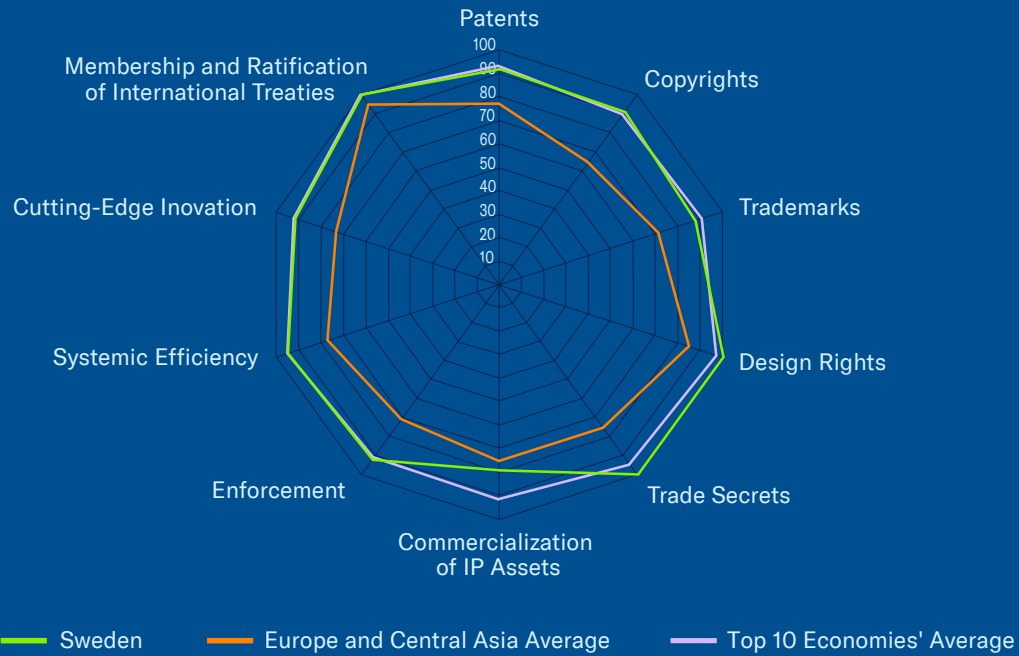
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals—including the European Parliament’s response to the Commission’s proposals in early 2024—the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.



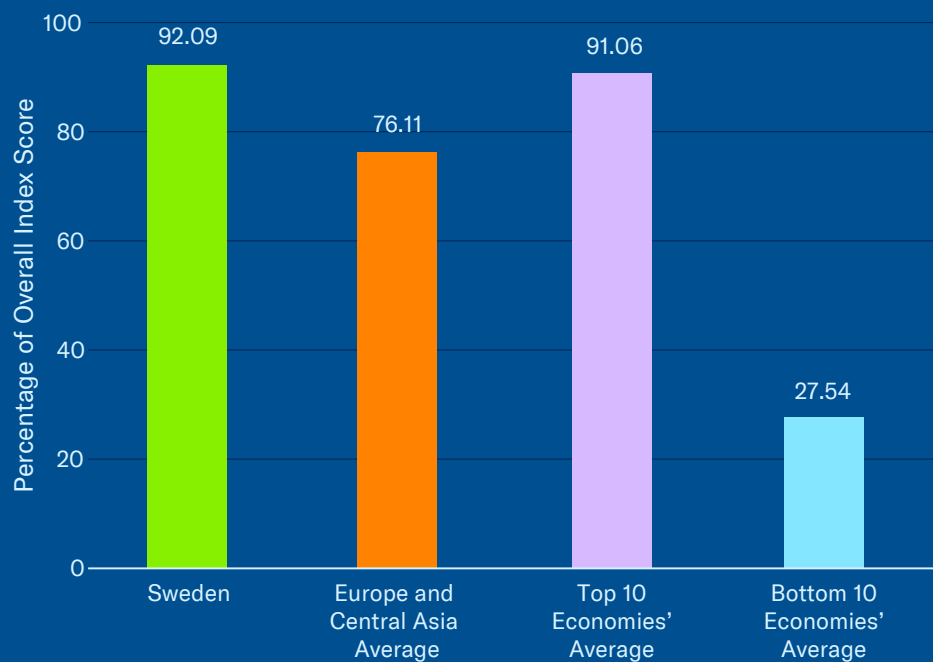
Sweden

Rank
5/55

Category Scores



Overall Score in Comparison





Sweden

Rank
5/55

Key Areas of Strength

- Since 2000, the orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- Acceded to the Convention on Cybercrime in 2021
- Strong and sophisticated national IP environment
- Online copyright enforcement has improved over past few years with stronger police enforcement and precedent-setting court decisions on ISP responsibility
- 2020 case law creates more certainty as to under what circumstances Swedish ISPs and internet mediators will be ordered to disable access to infringing content

Key Areas of Weakness

- The EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- The new EU-wide compulsory licensing regime would undermine patent rights in Europe
- The new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- 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	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	1.00	30. IP as an economic asset	0.75
3. Patentability of CII	1.00	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.90
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.81
7. Pharmaceutical patent term restoration	0.75	34. Civil and precedural remedies	0.75
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	1.00
9. Patent opposition	1.00	36. Criminal standards	1.00
Category 2: Copyrights and Limitations		37. Effective border measures	1.00
10. Term of protection	0.60	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	1.00	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	1.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	0.75	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	1.00	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	1.00	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	1.00	45. IP incentives for orphan medicinal product development, term of protection	1.00
19. Exclusive rights, trademarks	1.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
20. Frameworks against online sale of counterfeit goods	0.50	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	1.00
21. Industrial design term of protection	1.00	24. Protection of trade secrets (criminal sanctions)	1.00
22. Exclusive rights, industrial design rights	1.00	25. Regulatory data protection term	1.00
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	1.00	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 92.09%

Total Score: 48.81

Spotlight on the National IP Environment

Past Editions versus Current Score

Sweden's overall Index score has increased from 46.06 out of 50 indicators in the twelfth edition to 48.81 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

In 2024, the Swedish Government published a proposal for amending the Patent Act. The amendments are primarily aimed at better aligning Swedish patent law with the European Patent Convention, the European Unitary Patent, and the Unified Patent Court. With respect to the unitary patent, Sweden is a full participating Member State and has been part of the EU's enhanced cooperation in this area. Sweden is also a party and has acceded to the Agreement on a Unified Patent Court. At the time of research, the draft bill was under review, and no new legislation had been enacted. The Index will monitor these developments in 2025.

6. Legislative criteria and use of compulsory licensing of patented products and technologies: As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights.

This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable. After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products: As noted over the course of the Index, since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile during the last six months of the validity of the SPC for the domestic market. 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.

Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and the European Parliament subsequently responded to the Commission's proposal. The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel SPC opposition mechanism. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration is for an already existing duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each member state. As such, it seems unnecessary to add a novel layer of potential opposition.

The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024. The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally. The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed.

Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are (1) required to make public summaries of the main sources used for such educational purposes and (2) ensure they are in compliance with existing copyright law. Some positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. However, 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—as well as the ability of scraping technologies to access rightsholders' content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

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. 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, detailed under Category 9. 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. The Commission's proposal 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 Commission's 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. Yet the European Commission’s proposal 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.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences.

Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament’s proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission’s proposed baseline terms, Parliament’s draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index’s perspective, moving forward with the draft changes to the EU’s RDP regime would result in all EU Member States seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process.

Under the proposal, EUIPO would become 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 Commission’s proposals 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. In early 2024, the European Parliament responded to the Commission’s ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or 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. At the time of research, reports suggest that the European Commission had withdrawn its proposal. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. In 1999, the EU introduced Regulation (EC) No 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient timeframe for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential. Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances.

Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

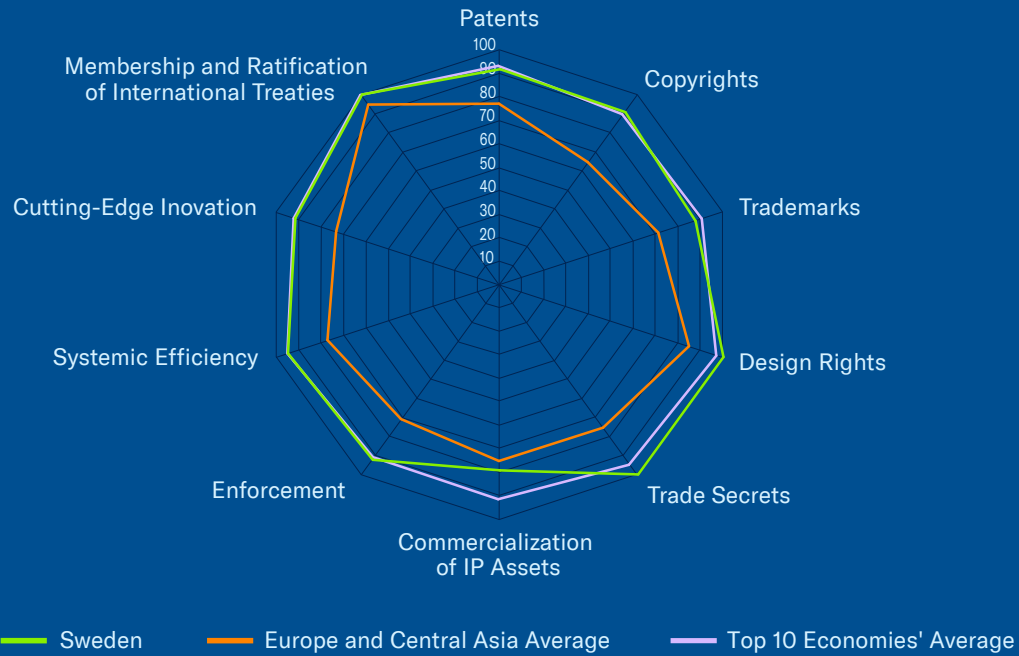
Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals—including the European Parliament’s response to the Commission’s proposals in early 2024—the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU Member States included in the Index seeing a score reduction for indicators 45 and 46.



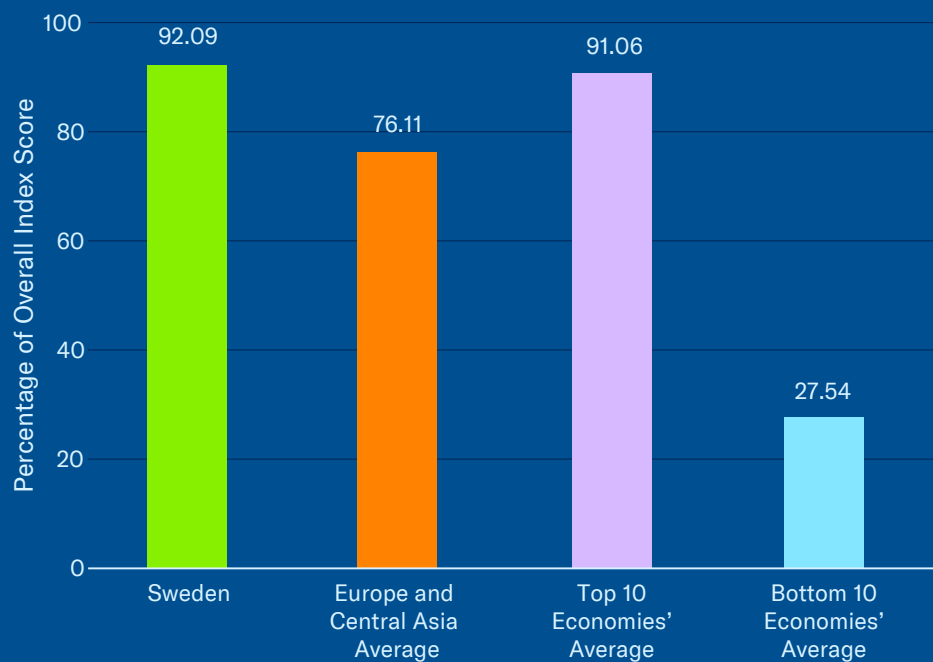
Switzerland

Rank
11/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Provided an extended data exclusivity period of up to 15 years for designated orphan drugs since 2019
- 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

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

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	1.00	30. IP as an economic asset	0.75
3. Patentability of CILs	1.00	31. Tax incentives for the creation of IP assets	1.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.82
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.79
7. Pharmaceutical patent term restoration	1.00	34. Civil and preceudural remedies	0.75
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.75
9. Patent opposition	1.00	36. Criminal standards	0.75
Category 2: Copyrights and Limitations		37. Effective border measures	1.00
10. Term of protection	0.63	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	0.50	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	0.50	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	0.25	41. Educational campaigns and awareness raising	0.75
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	1.00	43. IP-intensive industries, national economic impact analysis	0.75
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.50
19. Exclusive rights, trademarks	1.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	1.00
20. Frameworks against online sale of counterfeit goods	0.50	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	1.00
21. Industrial design term of protection	1.00	24. Protection of trade secrets (criminal sanctions)	1.00
22. Exclusive rights, industrial design rights	1.00	25. Regulatory data protection term	1.00
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	1.00	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	0.75	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 85.83%

Total Score: 45.49

Spotlight on the National IP Environment

Past Editions versus Current Score

Switzerland's overall Index score has increased from 42.99 out of 50 indicators in the twelfth edition to 45.49 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

In May 2024, the Swiss Federal Council proposed a set of amendments to the Patent Act. These suggested changes would introduce a new “clearing house” hosted by the Federal Institute of Intellectual Property (IPI) for patents relating to plant varieties. Under a proposed new notification procedure, prospective plant breeders would notify IPI of their intention to use a specific plant variety and inquire about the existence of any related patent rights. IPI would subsequently forward this notification to the registered rightsholder who would have 90 days to assert any existing right. Under draft Article 35d(3), a rightsholder's failure to make such an assertion would automatically allow the prospective breeder to use the relevant plant variety for its commercial purposes, regardless of any preexisting and duly granted patent rights. The Index will monitor these developments in 2025.

9. Patent opposition:

As noted last year, in late 2022, the Swiss Federal Council published draft amendments to the Patent Act. The proposed amendments are built on proposals first developed by IPI and shared with the public in 2019–2020. In March 2024, the Swiss National Council and Council of States voted for a finalized set of amendments to the Act. These changes introduce the possibility of a full patent examination upon request and introduce important changes to patent nullity and opposition proceedings.

Specifically, the amendments have eliminated the existing administrative opposition route. Instead, challenges to any decision taken by IPI, including the granting of a patent right, will now take place via the judiciary and the Federal Patent Court. Unlike the 2022 proposals, Article 59c(5) of the final bill makes clear that any third-party patent challenge has no suspensive effect on any existing duly granted patents. At the time of research, it was unclear whether these legislative changes would require a referendum to become law.

Copyrights 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 legal remedies disabling access to infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights:

As noted in previous editions of the Index, online piracy in Switzerland is a long-standing issue and a departure from Switzerland's otherwise gold-standard IP regime. The landmark 2010 Federal Supreme Court decision *Federal Data Protection and Information Commissioner v. Logistep AG* established a broad precedent that IP addresses were viewed as constituting “personal data.” This ruling has severely limited the ability to identify and build cases against infringing users and has discouraged Swiss prosecutors from taking on such cases. Although rightsholders have successfully been able to defend their rights in some cases, overall, the enforcement environment has been difficult.

For example, a 2014 judgment in the Zurich Canton High Court (*Obergericht Zürich*, case UE130087) on illegal file sharing recommended the prosecution of the alleged infringing activity, but the case also reaffirmed that the monitoring of the alleged infringer's activity was a violation of the individual's privacy. Without a legal tool for targeting infringing users or the platforms on which they operate, digital and online piracy has remained widespread, and Switzerland has become a hub for sites hosting infringing content.

The USTR's list of notorious marketplaces (*Review of Notorious Markets for Counterfeiting and Piracy*) continues to include references to sites and platforms hosted in or through Swiss entities. The Swiss Government has long recognized this broader problem and has announced an ambitious reform plan following the recommendations by the Swiss Working Group on Copyright (AGUR12) in 2014. In December 2015, as draft copyright law was presented for public discussion, but given the more than 1,200 contributions received, it underwent further review by a new multistakeholder group (AGUR12 II). In late 2017, the Swiss Federal Department of Justice and Police (*Eidgenössische Justiz und Polizeidepartement*) published new draft amendments and announced that copyright reforms would finally go ahead. These amendments were approved by the Swiss Federal Council (*Bundesrat*) in November 2017 and by the Federal Assembly (*Schweizer Parlament*) in 2019, and they finally became law in April 2020. As the Index has noted throughout this drawn-out legislative process, the Swiss Government should be commended for finally taking legislative action and attempting to address a long-standing weakness in its national IP environment. The final amendments introduced new measures to fight piracy. Specifically, the amendments require ISPs to both remove and keep infringing content off their servers.

A new Article 39d of the Copyright Act inserted a legal obligation on the part of internet hosting services to act against infringing content upon notification. The law states clearly that a "provider of an internet hosting service which stores information entered by users is required to prevent a work or other protected subject matter from being unlawfully remade available to third parties through the use of its services". The Swiss Federal Institute of Intellectual Property (*Eidgenössisches Institut für Geistiges Eigentum*) has publicly stated that this requirement amounts to a requirement for a "stay down" mechanism whereby hosting services must ensure that infringing content is not made accessible again after a notification of infringement has been made and acted on. The law also attempted to address the issue of the processing of personal data when filing criminal complaints. Article 77i clarifies that rightsholders filing a criminal complaint may access and use personal data for this purpose. However, as the Index also noted at the time, this does not apply to civil proceedings, which, under the new law, can only be filed once criminal proceedings have commenced. Furthermore, the amendments did not change the existing dynamic with respect to defined personal and private use exceptions to copyright. Historically, Switzerland's private use exception has been interpreted broadly and has been confirmed by the Swiss Government and existing case law to include the downloading and sharing of infringing content. Article 19 of the Copyright Act asserts that the downloading of content (other than software) for private use is not a copyright infringement (although distribution of such content that does not amount to private use, as well as any uploading of the content, represents an infringement). Such an expansive private use exception differs from other broad private copy exceptions—such as in Germany—in that, in Swiss law, no distinction is made in whether or not the downloaded copy is itself a legal version. In other words, even if the material has been made available in an illegal manner, the private use exception still applies in Switzerland.

This remains unchanged to this day. Indeed, the Federal Institute of Intellectual Property clearly stated at the time of enactment of the 2020 amendments that the changes to Swiss copyright law did not affect existing personal use exceptions: “Nothing changes for consumers of illegal content. They are allowed, for example, to continue downloading music which was published online without the permission of the rights holder for private use.” Finally, it remains unclear what the legal consequences, if any, will be for internet hosts that fail to comply with the conditions of Article 39d or under what circumstances a refusal to comply with the law is acceptable.

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

The past five years have 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 re-enters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, the UK, and Canada.

The limitations and questions about the effectiveness of the Swiss amendments and rightsholders’ ability to enforce their rights remained unaddressed in 2024. In fact, the USTR noted in the *2024 Special 301 Report* that Switzerland continued to have “high levels of online piracy and lacked effective enforcement.” The Index will continue to monitor these developments in 2025.

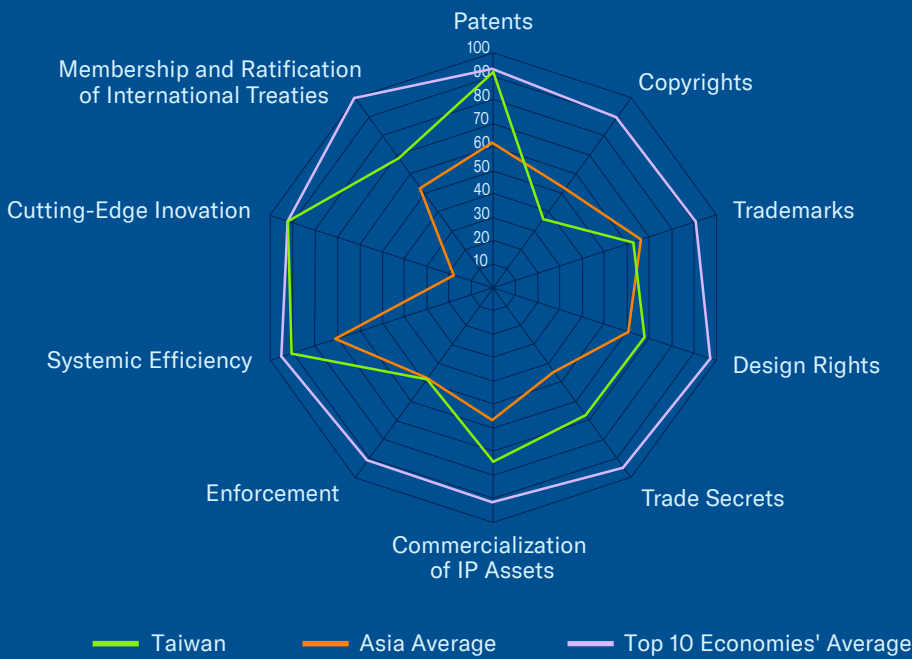
Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

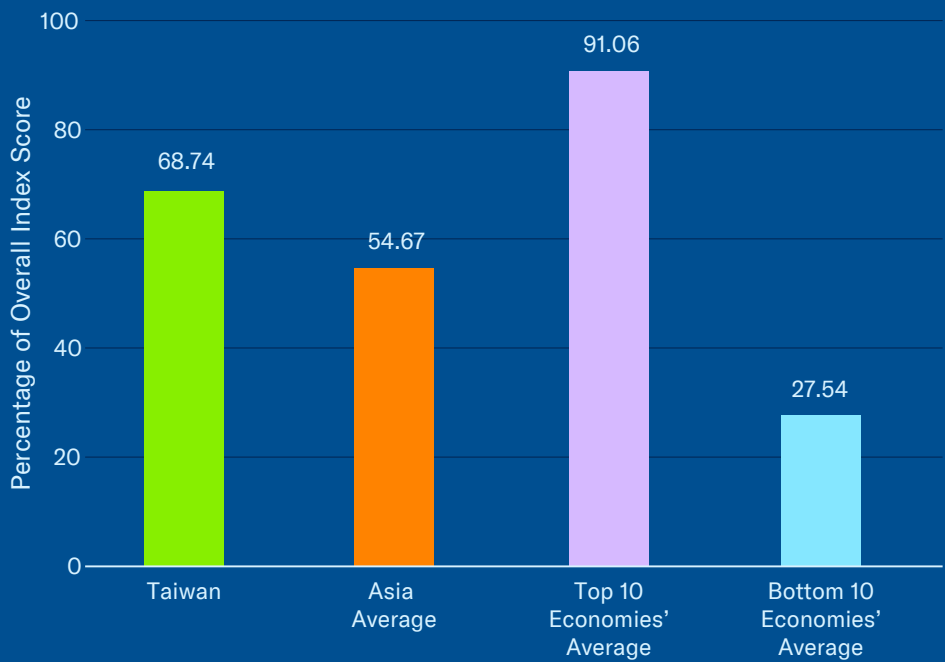
Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. Since the mid-2010s, Switzerland has introduced several initiatives and incentive programs targeting rare diseases and orphan medicines, including the overarching 2014 *National Rare Disease Policy*. With respect to special market exclusivity incentives for orphan medicinal product development, 2016 legislative changes to the Federal Act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA), which took effect in 2019, introduced a statutory term of regulatory data protection (termed “document protection”) for orphan drugs. Under Article 11b(4), the national drug regulatory authority, Swiss Medic, will “in the case of an important orphan medicinal product...on request, grant document protection for a period of fifteen years.” Orphan status and eligibility for this extended RDP term can be withdrawn by Swiss Medic if the product no longer meets relevant eligibility criteria as a treatment for rare diseases.



Category Scores



Overall Score in Comparison





Taiwan

Rank
20/55

Key Areas of Strength

- A 10-year exclusivity period for designated orphan drugs has been in place since 2000
- TIPO offers support for SMEs developing IP assets through a fast-track examination procedure and expanded technical assistance
- 2020 amendments to the trade secrets law improved the IP environment
- The pharmaceutical linkage regime strengthens the 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 has faced political hurdles to becoming a contracting party, Taiwan has in many cases implemented the provisions of several international IP treaties

Key Areas of Weakness

- Important gaps in the digital copyright regime are not addressed by the 2022 Copyright Act amendments
- 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

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	8.25	29. Direct government intervention in setting licensing terms	0.50
1. Term of protection	1.00	30. IP as an economic asset	0.75
2. Patentability requirements	1.00	31. Tax incentives for the creation of IP assets	0.67
3. Patentability of CILs	1.00	Category 7: Enforcement	3.35
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.44
5. Pharmaceutical-related enforcement	1.00	33. Software piracy rates	0.66
6. Legislative criteria and use of compulsory licensing	1.00	34. Civil and precluded remedies	0.50
7. Pharmaceutical patent term restoration	1.00	35. Pre-established damages	0.25
8. Membership of a Patent Prosecution Highway	0.50	36. Criminal standards	0.25
9. Patent opposition	0.75	37. Effective border measures	0.50
Category 2: Copyrights and Limitations	2.53	38. Transparency and public reporting by customs	0.75
10. Term of protection	0.53	Category 8: Systemic Efficiency	4.50
11. Exclusive rights	0.25	39. Coordination of IP rights enforcement	0.75
12. Expedient legal remedies disabling access to infringing content online	0.25	40. Consultation with stakeholders during IP policy formation	1.00
13. Cooperative action against online piracy	0.25	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
15. TPM and DRM	0.50	43. IP-intensive industries, national economic impact analysis	0.75
16. Government use of licensed software	0.25	Category 9: Cutting-Edge Innovation	2.75
Category 3: Trademarks Rights and Limitations	2.50	44. IP incentives for orphan medicinal product development	1.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	1.00
18. Protection of well-known marks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
19. Exclusive rights, trademarks	0.50	Category 10: Membership and Ratification of International Treaties	3.75
20. Frameworks against online sale of counterfeit goods	0.50	47. WIPO Internet Treaties	0.75
Category 4: Design Rights and Limitations	1.35	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.60	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	0.75	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	2.00	51. Membership of the Convention on Cybercrime, 2001	0.50
23. Protection of trade secrets (civil remedies)	0.75	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.50
24. Protection of trade secrets (criminal sanctions)	0.75	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.50		
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		

Percentage of Overall Score: 68.74%

Total Score: 35.40

Spotlight on the National IP Environment

Past Editions versus Current Score

Taiwan's overall Index score has increased from 32.66 out of 48.50 indicators in the twelfth edition to 35.40 out of 51.50 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation but a score decrease for indicator 32.

Patent Rights and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism:

First announced by the Taiwanese authorities in 2017, a patent linkage system came into effect in 2019 covering both chemical and biologic products. This system allows rightsholders to record their patent information on a list housed by the Taiwan Food and Drug Authority (TFDA). In conjunction with sanitary registration, follow-on manufacturers must declare that their product does not infringe on any listed patent and must notify the patent holder. As noted at the time in the Index, the introduction of this linkage system by Taiwan was a positive development and was awarded with a score increase for this indicator. However, since the introduction of the linkage mechanism, there has been uncertainty about what constitutes a “new” medicine. Specifically, TFDA has taken the view that changes to a product's dosage or strength do not qualify as “new” and, consequently, are not eligible for inclusion in the mechanism. This view has been challenged in several lawsuits by rightsholders who have had their products removed from TFDA's linkage registration system. In 2023, final verdicts were issued in several of these cases by both lower and higher courts. Unfortunately, these judgments were not consistent. The Taipei High Administrative Court found that in two cases pertaining to challenges from Novartis and Cima Labs, TFDA had erred in its interpretation.

However, in two other cases, the same court found the opposite, that is, TFDA's interpretation was the correct one. Appeals were subsequently filed in all four cases with the final verdict issued by the superior court—the Taiwan Supreme Administrative Court—being in favor of TFDA in all four cases. This is a regrettable outcome for the rightsholders in question and for Taiwan's national IP environment.

Changes in form and application of a known substance are some of the most important forms of biopharmaceutical innovation. This type of “incremental innovation,” which results in new 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. At the time of research, it was unclear how, or if, the Taiwanese Government would respond with any potential legislative changes and broader definitions of what constitutes a new drug under the Pharmaceutical Affairs Act. The Index will continue to monitor these developments in 2025.

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. However, rightsholders report that, since 2018, uncertainty surrounds how current regulatory practices recognize and assess the period of exclusivity to be restored. Specifically, the current Patent Examination Guidelines no longer align with international best practices. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

In a positive development, 2024 saw the continued criminal prosecution of operators of piracy websites in Taiwan. Early in the year, the responsible parties for the GimmyTV website and online portals received significant prison sentences. This follows the successful prosecution and sentencing of a major online piracy network in 2023—the 8maple network. As documented in the Index, despite being in the process of reforming its copyright laws for the past decade, Taiwan continues to lack many of the fundamental building blocks for effective copyright enforcement. The Copyright Act includes digital piracy as an actionable criminal offense that does not require a formal complaint provided certain thresholds of estimated economic damages are met. However, the Act does not include a defined and copyright-specific mechanism of injunctive-style relief and the option to give ISPs the ability to disable access to illegal content whether through a court order 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, India, Singapore, Brazil, Malaysia, and other Index economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing dynamic injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These have proven to be effective in reducing the availability of copyright-infringing content within these jurisdictions. The Index will continue to monitor Taiwan's efforts to improve its copyright environment in 2025.

14. Scope of limitations and exceptions to copyrights and related rights:

In mid-2024, the National Science and Technology Commission released a draft version of the “Basic Law on Artificial Intelligence.” This is the first legislative initiative in Taiwan that seeks to establish a framework for the national development and application of AI and machine learning technologies. These technologies are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific breakthroughs and innovation to take place through the analysis of large volumes of data and information. As such, the draft bill is instructive in that it recognizes the dilemma posed by AI and machine learning technologies to copyright holders and the risk for widespread infringement and use of illicit content. Specifically, Article 15 of the bill states that the “government should strive to improve the quality and quantity of artificial intelligence use materials in our country to ensure that training results maintain the country’s multicultural values and protect intellectual property rights.” 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, 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, both in Taiwan and around the world. At the time of research, the bill had not been enacted. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. Since 2000, Taiwan has had in place a dedicated legal framework for rare diseases and orphan drugs. The Rare Diseases Control and Orphan Drugs Act of 2000 provides the legal definitions and policies related to rare diseases and orphan drugs in Taiwan. This law and related programs provide an expedited market approval pathway for new drugs as well as protocol assistance and dedicated funding mechanisms for patients with rare diseases.

With respect to incentives for R&D and the development of new treatments and technologies, designated orphan drugs benefit from a 10-year market exclusivity period. During these 10 years, requests to register drugs “of the same kind” will not be accepted by the national drug regulatory authorities (Article 17) unless—as in the United States and the EU—the second drug complies with three conditions: (1) it is clinically superior, (2) it is insufficiently supplied, and (3) the first drug manufacturer agrees to allow market entry to a competing product. However, unlike the United States and EU, Article 18 of the Act also adds a fourth condition that allows for the approval of a similar product during the 10-year exclusivity period if the price of the drug is deemed “unreasonable.”



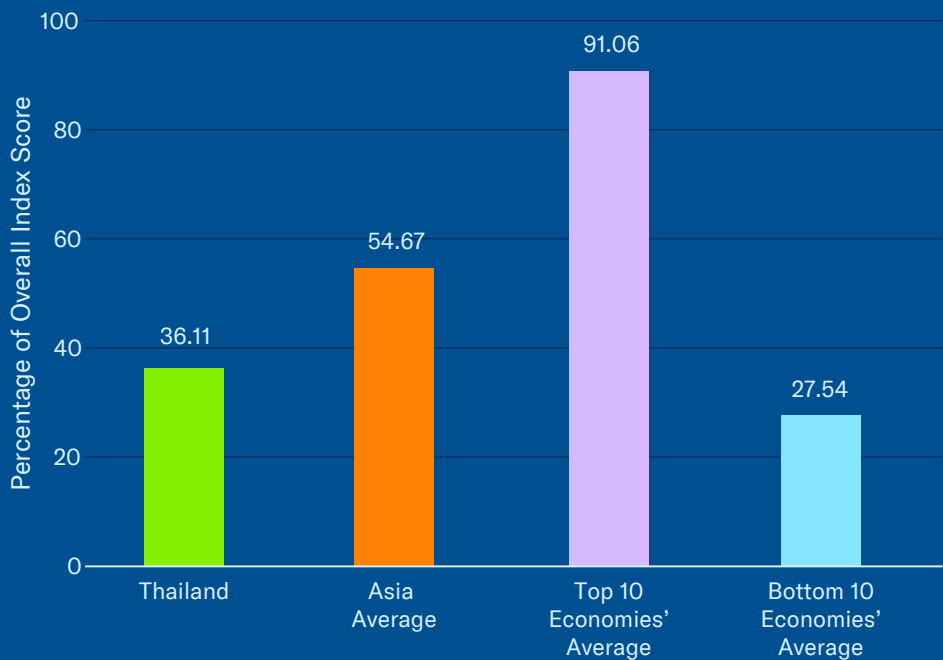
Thailand

Rank
44/55

Category Scores



Overall Score in Comparison





Thailand

Rank
44/55

Key Areas of Strength

- The 2022 Copyright Act amendments introduce 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 the technology transfer environment
- An injunctive-style relief mechanism under the Computer Crime Act is used against trademark infringement
- The Customs Act amendments have resulted in greater anti-counterfeiting efforts against infringing goods in transit
- Thailand moved from the Priority Watch List to the Watch List on USTR's Special 301 Out-of-Cycle Review as a result of stronger enforcement and coordination within the Thai Government
- A basic level of protection and a registration system are in place for copyrights, trademarks, and designs

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Inadequate patent protection, including gaps in patentability for high-tech arts, including life sciences and CIIIs
- History of long patent backlogs
- Many sector-specific IP rights are missing, including patent term restoration for biopharmaceuticals and RDP
- History of the use of compulsory licensing for biopharmaceuticals
- High physical counterfeiting and digital piracy rates, with software piracy estimated at 64%
- Limited participation in international treaties

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.00
2. Patentability requirements	0.25	30. IP as an economic asset	0.75
3. Patentability of CII	0.25	31. Tax incentives for the creation of IP assets	0.67
4. Plant variety protection	0.72	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.48
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.34
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.25
9. Patent opposition	0.00	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	0.75
10. Term of protection	0.53	38. Transparency and public reporting by customs	0.75
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.50	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	0.50
14. Limitations and exceptions	0.25	41. Educational campaigns and awareness raising	0.75
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
16. Government use of licensed software	0.50	43. IP-intensive industries, national economic impact analysis	0.50
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.75	Category 10: Membership and Ratification of International Treaties	
Category 4: Design Rights and Limitations		47. WIPO Internet Treaties	0.50
21. Industrial design term of protection	0.40	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
22. Exclusive rights, industrial design rights	0.50	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
Category 5: Trade Secrets and the Protection of Confidential Information		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
23. Protection of trade secrets (civil remedies)	0.25	51. Membership of the Convention on Cybercrime, 2001	0.00
24. Protection of trade secrets (criminal sanctions)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
25. Regulatory data protection term	0.00	53. Post-TRIPS FTA	0.00
Category 6: Commercialization of IP Assets			
26. Barriers to market access	0.00		
27. Barriers to technology transfer	0.50		
28. Registration and disclosure requirements of licensing deals	0.00		

Percentage of Overall Score: 36.11%

• Total Score: 19.14

Spotlight on the National IP Environment

Past Editions versus Current Score

Thailand's overall Index score remains unchanged at 19.14 out of 53 indicators.

Patent Rights and Limitations

Revisions to the Patent Act in Thailand have been ongoing for years with several iterations of draft proposals put forth since 2018. At the time of research, it was still unclear what final drafts of these bills would look like. On a positive note, there have been indications that amendments will include important changes to industrial design rights with an extension of the term of protection from its current statutory basis of a maximum of 10 years. Similarly, there have been reports that the upcoming changes would seek to improve patent processing times. As noted over the course of the Index, patent prosecution times in Thailand have historically been long and can stretch to over a decade depending on the technology field. Finally, in August 2024, the national IP office, the Department of Intellectual Property held a public consultation soliciting general comments and feedback on the legal regime related to IP rights, including patents. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

As noted in the Index, Thailand has been reforming various parts of its national IP environment for over five years. This includes changing statutory law, implementing regulations, and IP office examination manuals. With respect to copyright law, in anticipation of Thailand's accession to the WIPO Internet Treaties, 2022 saw the enactment of a new and updated Copyright Act. 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. After these positive reforms, Thailand acceded to the WIPO Copyright Treaty in late 2022. At the time of research, discussions were still ongoing on further copyright reforms to enable Thailand to join the WIPO Performances and Phonograms Treaty. In June 2024, the Ministry of Commerce announced that draft amendments to both the Copyright Act and the Protection of Geographic Indications Act had been completed and would be presented to the Cabinet for consideration. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Interest in rare diseases has grown in the Asia-Pacific region. In 2017, the Asia-Pacific Economic Cooperation (APEC) forum (of which Thailand is a member) announced a new initiative geared specifically toward rare diseases, the “APEC Action Plan on Rare Diseases.” The plan’s primary aim is to “address barriers to the diagnosis and treatment of rare diseases in the region.” The plan consists of 30 individual targets across 10 pillars, including the promotion of innovative research and development through financial incentives, expedited market review procedures, and support for domestic R&D.

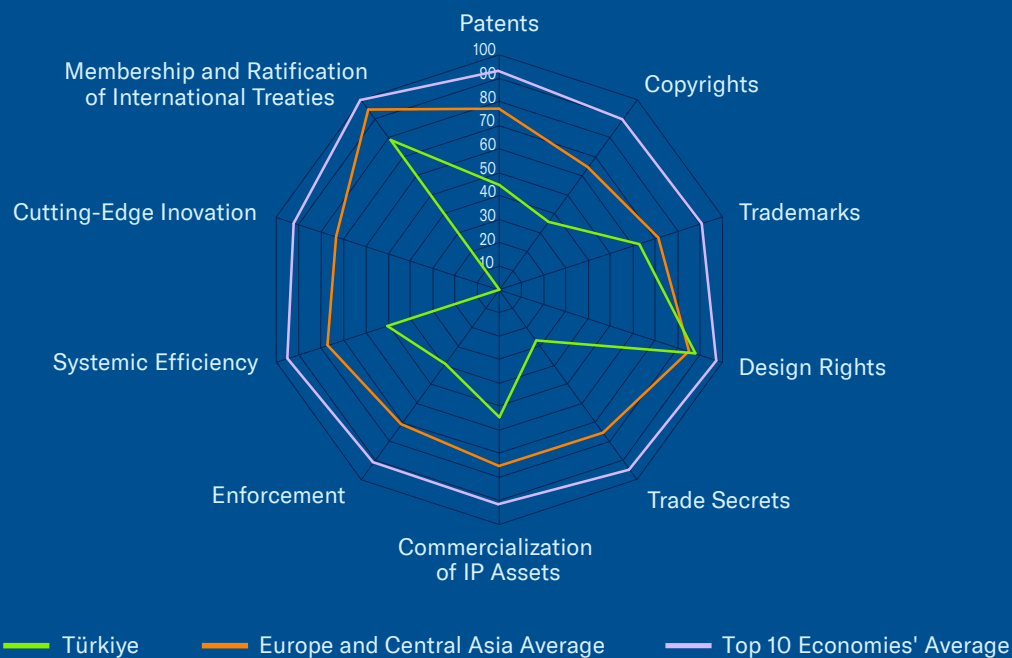
In Thailand, too, policymakers and the government are increasingly focused on addressing rare diseases and improving patient access to care and treatments. A policy aimed at rare disease was established in 2020, and orphan drugs are regularly added to the national essential medicines list. With respect to incentives to R&D and the development of new treatments and technologies, Thailand does not offer any special IP-based market exclusivity incentives for orphan medicinal product development.



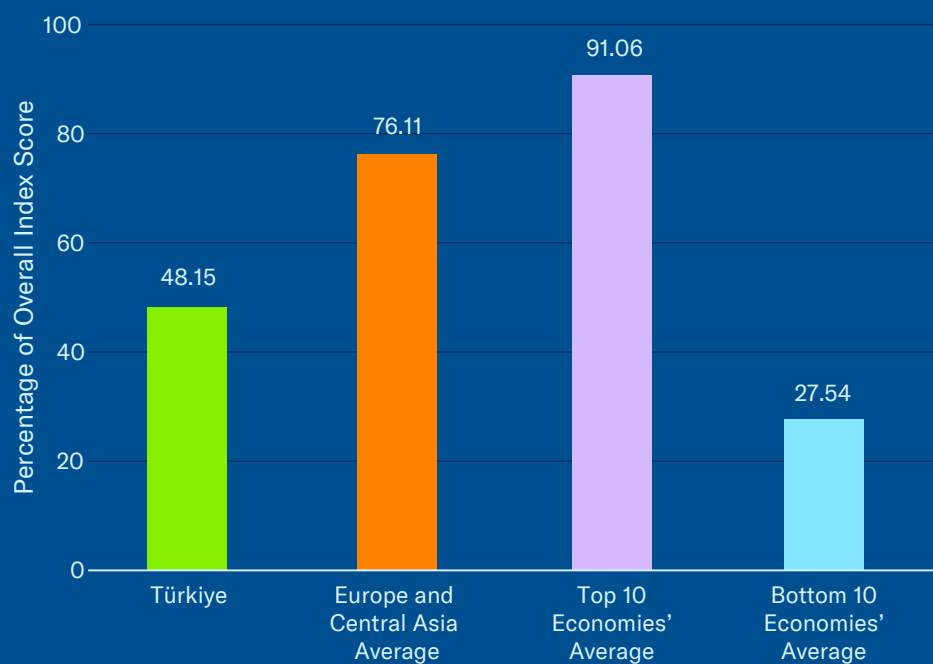
Türkiye

Rank
30/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Biopharmaceutical localization environment was reformed in 2023 after the WTO ruling
- Efforts to align the national IP environment with EU standards
- Active promotion of the importance of IP protection and use as an economic asset among the public and SMEs
- Generous R&D and IP-specific tax incentives are in place

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Localization policies targeting high-tech sectors are becoming a more prominent feature of industrial and economic policy
- RDP is not granted to biologics
- Key gaps persist in the copyright environment and in patent protection and enforcement
- Industrial localization policies for biopharmaceuticals have fused together with IP policy and broader health policy on the pricing and procurement of medicines
- High counterfeiting and piracy rates, with software piracy estimated at 56%

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations	4.00	29. Direct government intervention in setting licensing terms	0.50
1. Term of protection	1.00	30. IP as an economic asset	0.75
2. Patentability requirements	0.50	31. Tax incentives for the creation of IP assets	1.00
3. Patentability of CILs	0.50	Category 7: Enforcement	2.73
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.29
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.44
6. Legislative criteria and use of compulsory licensing	0.00	34. Civil and precluded remedies	0.25
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.25
8. Membership of a Patent Prosecution Highway	0.50	36. Criminal standards	0.25
9. Patent opposition	0.50	37. Effective border measures	0.50
Category 2: Copyrights and Limitations	2.49	38. Transparency and public reporting by customs	0.75
10. Term of protection	0.74	Category 8: Systemic Efficiency	2.50
11. Exclusive rights	0.25	39. Coordination of IP rights enforcement	0.50
12. Expedient legal remedies disabling access to infringing content online	0.25	40. Consultation with stakeholders during IP policy formation	0.50
13. Cooperative action against online piracy	0.25	41. Educational campaigns and awareness raising	0.75
14. Limitations and exceptions	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
15. TPM and DRM	0.25	43. IP-intensive industries, national economic impact analysis	0.50
16. Government use of licensed software	0.50	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	2.50	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.50	Category 10: Membership and Ratification of International Treaties	5.50
20. Frameworks against online sale of counterfeit goods	0.25	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	1.75	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
21. Industrial design term of protection	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	0.75
22. Exclusive rights, industrial design rights	0.75	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	0.80	51. Membership of the Convention on Cybercrime, 2001	1.00
23. Protection of trade secrets (civil remedies)	0.25	52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
24. Protection of trade secrets (criminal sanctions)	0.25	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.30		
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		

Percentage of Overall Score: 48.15%

Total Score: 25.52

Spotlight on the National IP Environment

Past Editions versus Current Score

Türkiye's overall Index score remains unchanged at 25.52 out of 53 indicators.

Patents, Related Rights and Limitations, and Enforcement

5. Pharmaceutical-related patent enforcement and resolution mechanism; and 34. Civil and procedural remedies:

IP laws in Türkiye provide for basic civil remedies, which include injunctions, damage awards, and the confiscation of goods and equipment used to produce infringing material for patents and trademarks. However, practical enforcement in Türkiye has historically been characterized by inefficiency and long delays. The 2020 edition of the World Bank's *Doing Business* found that, on average, it took 623 days to enforce a contract—almost two years—at an estimated cost of 24.9% of the claim value. These long delays were up by almost 200 days from an average of 449 days from 2004 to 2015. For IP rights specifically, there remains a general dearth of expertise and experience on the part of the judiciary and public prosecutors.

As noted over the course of the Index, some positive developments have occurred over the past decade. The most prominent development was the introduction of specialized IP courts in select cities and the establishment of a special prosecutor's agency responsible for IP rights investigations. Today, 25 civil and criminal IP courts are spread across Türkiye's major cities. Despite these institutional changes, industry reports suggest that these courts are overburdened and that rightsholders continue to face difficulties in gaining redress, most notably with respect to preliminary injunctions.

For example, for the research-based biopharmaceutical industry, a long-standing issue has been the early marketing of follow-on products, despite existing granted IP exclusivity periods being in place. Türkiye does not have a pharmaceutical linkage mechanism whereby Turkish drug regulatory authorities condition the approval of a follow-on biopharmaceutical product on there being no relevant period of market exclusivity for the underlying reference product. Instead, biopharmaceutical rightsholders must rely on the court system and, specifically, on gaining preliminary injunctions when an infringing product is launched. Historically, such injunctions have been difficult to obtain. The result has been the early launch of follow-on products and a corresponding price drop once a generic product is listed in the national formulary and publicly reimbursed. Local legal reports suggest that this may now be changing with a potentially precedent-setting injunction issued by the IP Court in Ankara in late 2023. Should this case improve rightsholders' ability to obtain preliminary injunctions in the future, it would mark a significant improvement to Türkiye's national IP environment and a potential score increase for indicators 5 and 34. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

26. Barriers to market access:

As detailed over the course of the Index, over the past two decades, Turkish industrial and economic policy has increasingly been driven by an effort to localize industrial production and R&D. A major part of these efforts has been localization and import substitution policies that actively discriminate against foreign entities and favor domestic Turkish companies.

Many of these localization and discriminatory policies have targeted the ICT and research-based biopharmaceutical industries. With regards to the ICT sector, in 2024, important amendments to the Law on the Protection of Personal Data came into effect together with new implementing regulations on cross-border data transfers.

Turkish laws have historically placed 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 have technically been allowed under the Law on the Protection of Personal Data, such transfers could only take place after explicit consent had been obtained from the data subject or if the legal jurisdiction to which data was transferred provided an equivalent level of protection as in Türkiye. Until the 2024 amendments, this option was not available as the Turkish Personal Data Protection Authority had not designated any jurisdiction as functionally equivalent.

In March 2024, as part of a broader package of reforms (the Amendment to the Code of Criminal Procedure and Certain Laws), changes were introduced to the Law on the Protection of Personal Data and underlying regulations. Although still fundamentally restricted, cross-border data transfers will now be allowed under a broader set of circumstances, including the use of standardized contracts as defined under Article 10 of the July 2024 implementing regulations (“Procedures and Rules for Transferring Personal Data Abroad, Regulation on Principle”).

Cross-border flows of data are ingrained in countless services relied on by consumers with numerous digital, automated, and virtual services relying on the seamless movement and storage of data in various locations. Reducing existing restrictions and barriers on such free flows of data with these legislative changes would be a positive development and would reverse what has been an intensification of localization requirements over the past five years. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

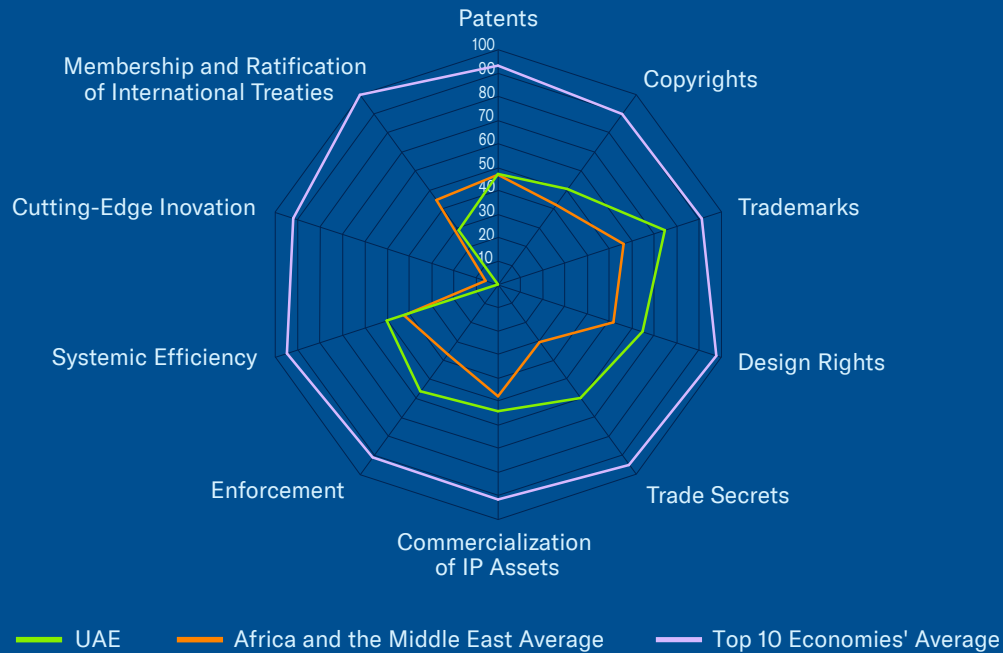
Interest in rare diseases has grown in Türkiye. In 2022, the Ministry of Health published “Rare Diseases Health Strategy Document and Action Plan.” The document provides an overarching national policy for addressing rare diseases, including awareness raising, expanding access to treatment, and supporting new forms of biopharmaceutical R&D in Türkiye. With respect to incentives to R&D and the development of new treatments and technologies, under Section 4 of the report, “Treatment and Care Services,” Subsection 4.2.2.1 sets the goal of introducing a specific national orphan drug law with corresponding intellectual property incentives in place for drug development and greater access to new treatments. At the time of research, no legislative action had been taken.



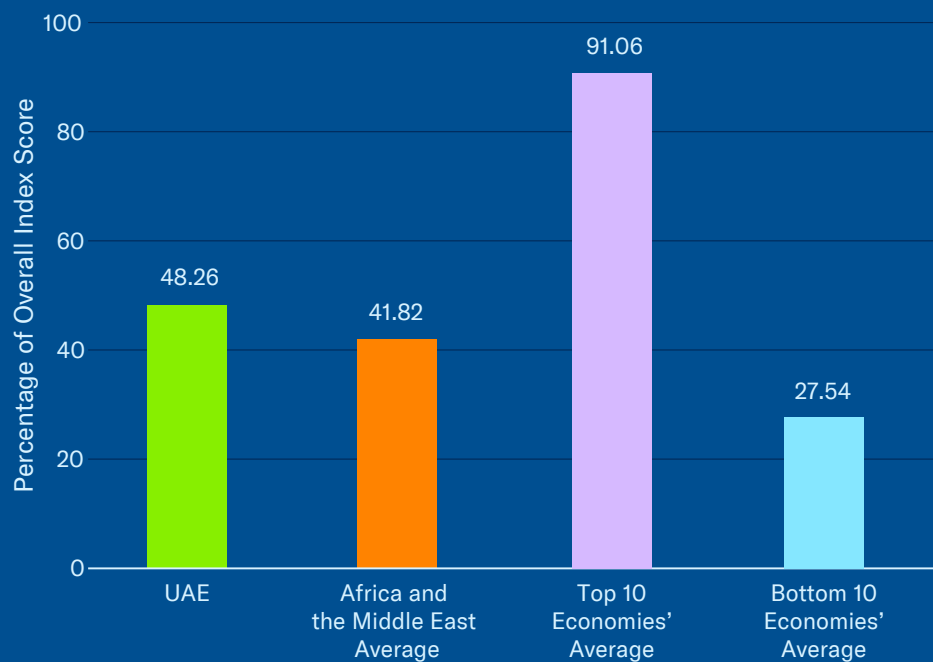
United Arab Emirates

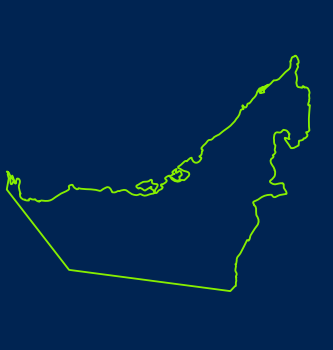
Rank
29/55

Category Scores



Overall Score in Comparison





United Arab Emirates

Rank

29/55

Key Areas of Strength

- The 2024 e-commerce law, Federal Decree-Law No. 14, and a new system of administrative injunctive-style relief significantly strengthened the IP environment
- 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
- A defined RDP term was introduced in 2020
- The Foreign Direct Investment Law offers the possibility of 100% foreign ownership, granting 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 anti-counterfeiting efforts, including criminal penalties/Awareness-raising and capacity building efforts on the importance and value of IP rights

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 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
- Deep uncertainty over protection for biopharmaceutical patents as 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	Indicator	Score
Category 1: Patents Rights and Limitations	4.25	29. Direct government intervention in setting licensing terms	0.50
1. Term of protection	1.00	30. IP as an economic asset	0.50
2. Patentability requirements	0.50	31. Tax incentives for the creation of IP assets	1.00
3. Patentability of CILs	0.50	Category 7: Enforcement	3.95
4. Plant variety protection	1.00	32. Physical counterfeiting rates	0.52
5. Pharmaceutical-related enforcement	0.00	33. Software piracy rates	0.68
6. Legislative criteria and use of compulsory licensing	1.00	34. Civil and preceudural remedies	0.75
7. Pharmaceutical patent term restoration	0.00	35. Pre-established damages	0.50
8. Membership of a Patent Prosecution Highway	0.00	36. Criminal standards	0.75
9. Patent opposition	0.25	37. Effective border measures	0.75
Category 2: Copyrights and Limitations	3.53	38. Transparency and public reporting by customs	0.00
10. Term of protection	0.53	Category 8: Systemic Efficiency	2.50
11. Exclusive rights	0.75	39. Coordination of IP rights enforcement	0.25
12. Expeditious legal remedies disabling access to infringing content online	1.00	40. Consultation with stakeholders during IP policy formation	0.50
13. Cooperative action against online piracy	0.00	41. Educational campaigns and awareness raising	1.00
14. Limitations and exceptions	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
15. TPM and DRM	0.50	43. IP-intensive industries, national economic impact analysis	0.25
16. Government use of licensed software	0.25	Category 9: Cutting-Edge Innovation	0.00
Category 3: Trademarks Rights and Limitations	3.00	44. IP incentives for orphan medicinal product development	0.00
17. Term of protection	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.00
18. Protection of well-known marks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.75	Category 10: Membership and Ratification of International Treaties	2.00
20. Frameworks against online sale of counterfeit goods	0.50	47. WIPO Internet Treaties	1.00
Category 4: Design Rights and Limitations	1.30	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
21. Industrial design term of protection	0.80	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
22. Exclusive rights, industrial design rights	0.50	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 5: Trade Secrets and the Protection of Confidential Information	1.80	51. Membership of the Convention on Cybercrime, 2001	0.00
23. Protection of trade secrets (civil remedies)	0.50	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
24. Protection of trade secrets (criminal sanctions)	0.50	53. Post-TRIPS FTA	0.00
25. Regulatory data protection term	0.80		
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		

Percentage of Overall Score: 48.26%

Total Score: 25.58

Spotlight on the National IP Environment

Past Editions versus Current Score

The UAE's overall Index score has increased from 23.00 out of 50 indicators in the twelfth edition to 25.58 out of 53 indicators. This reflects score increases for indicators 11, 12, 20, 35, 36, 37, and 42.

Area of Note

In 2024, the UAE's Ministry of Economy launched a series of ambitious IP reforms under the umbrella term "A New IP System." This reform program covers 11 separate initiatives and cuts across all major IP rights. Specific support programs have been announced for increasing patent and trademark registrations, improving copyright enforcement (discussed in detail under Category 2: Copyrights and Limitations), increasing technical assistance programs for IP registration, and introducing new IP training programs and data tools. The Government of the UAE should be congratulated for taking such robust action in 2024, especially with respect to the creative sector and the enforcement of copyright. After the program's launch, the Ministry held dedicated stand-alone events and policy initiatives for each of the specified areas throughout the year. Finally, at the end of the year, the Ministry's Economic Integration Committee announced that it was reviewing a list of existing laws related to economic activity and the ease of doing business in the UAE. The Committee and Minister Bin Touq reiterated their support for economic reform and the continued "transition towards a new knowledge and innovation-based economic model." Notably, the Committee emphasized the importance of the generation of new IP assets to the UAE's future economic development.

For all economies—emerging and developed alike—the creation of new forms of intangible assets and IP drives innovation, technological advances, and, ultimately, economic development and growth.

Covering 53 indicators across 10 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 UAE continues to pursue a program of national IP rights reforms, we would encourage it to use the Index findings and accompanying *Statistical Annex* as a guide in 2025 and beyond.

Copyrights and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); and
12. Expeditious legal remedies disabling access to infringing content online:

In 2024, significant improvements were made to the copyright enforcement environment in the UAE. As part of a broader package of IP reforms (detailed earlier), the Ministry of Economy introduced a new system of administrative injunctive-style relief through the InstaBlock program. Introduced in early 2024, the program aims to disable access to all copyright-infringing content online through the active monitoring of the internet by Ministry personnel as well as through direct rightsholder reporting of illicit activity. As part of the initiative, the Ministry also introduced a rapid response tool termed "LiveBan." This tool targets live events and broadcasts such as sports and concerts. Finally, the Ministry announced over the summer a new antipiracy partnership with the Spanish soccer league *La Liga*.

As has been noted over the course of the Index, rightsholders have historically faced challenges in protecting their content in the UAE. Gaps exist in the legal framework, and enforcement has always remained partial. At the time of research, the InstaBlock program was fully operational with access disabled to over 1,000 websites and online access points. This major positive development has significantly strengthened rightsholders' ability to protect and enforce their copyrights in the UAE. As a result of this program's introduction and its active deployment, the scores for indicators 11 and 12 have increased by 0.25 and 1.00, respectively.

Trademark Rights and Limitations; and Enforcement

20. Availability of frameworks that promote action against online sale of counterfeit goods; 35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement; 36. Criminal standards, including minimum imprisonment and minimum fines; and 37. Effective border measures:

As noted over the course of the Index, the UAE has long been identified as a central hub for the transshipment and global trade of counterfeit goods. The OECD and EUIPO, for example, 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 physical marketplaces have consistently been included in the USTR's *Review of Notorious Markets for Counterfeiting and Piracy*. One reason for this lack of IP enforcement is a lack of deterrent fines and criminal sanctions and legal ambiguity of existing *ex officio* border enforcement powers in relation to transshipped suspected counterfeit goods and goods in transit.

At the end of 2023 and 2024, several important legal developments took place, which should, collectively, help address both these legal shortcomings and improve the enforcement environment. To begin, the Federal Law Decree 24, Concerning Anti-Commercial Fraud, was enacted at the end of 2023. A new dedicated anti-counterfeiting law, this legislation significantly strengthens the UAE's IP enforcement environment. Article 4 explicitly outlaws the importation, exportation and re-exportation of counterfeit and fraudulent goods. Furthermore, Article 10 empowers Judicial Enforcement Officers to take *ex officio* action against suspected counterfeit goods in any nonresidential facility throughout the UAE. Articles 16–18 also include strengthened criminal sanctions and penalties.

In a related development, important improvements were also made to the legal framework for the online sale and distribution of counterfeit goods in 2024. As noted at the time in the Index, as part of a larger package of IP reform in 2021, a new trademarks law, Federal Decree-Law No. 36/2021 on Trademarks, was introduced and came into effect. The new law introduced several improvements to the protection of trademarks in the UAE, including elimination of registration requirements for trademark licensing agreements, increased potential damages for trademark infringement, and strengthening of the protection of well-known marks. As a result of these positive efforts, the UAE's score for relevant indicators increased in the tenth edition of the Index. However, the new legislation was silent with respect to the infringement of trademarks online, through online shopping and e-commerce. Historically, the UAE has not had in place a legally defined notification system allowing rightsholders to request the removal of counterfeit goods online.

Although addressing the online environment, it is unclear the extent to which existing statute, including, for instance, Federal Law-Decrees 5 and 34 (both related to cybercrimes), could be used for enforcing trademarks online. Although Article 53 of Law-Decree 34 imposes criminal sanctions on offenders that make available “illegal content” online and refuse, upon notification, to remove or take down the content, this is not explicitly defined within the context of trademark or IP infringement. Some private sector efforts have been made to address this issue, including, for example, Souq.com, which has historically offered rightsholders the ability to contact them directly in cases of suspected infringement. This lack of legal clarity may now be changing. In late 2023, the UAE enacted a new e-commerce law, Federal Decree-Law No. 14. Notably, Article 3 explicitly states that one objective of the law is to “protect intellectual property rights regarding goods or services purchased through Modern Technology.” The introduction of this requirement within the context of e-commerce and online infringement of trademarks is a welcome development and, if fully implemented, has the potential to strengthen rightsholders’ ability to protect their trademarks. As a result of the UAE’s legislative reform efforts over the past year, the scores for indicators 20, 35, 36, and 37 have increased by 0.25, respectively.

Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs:

Historically, the UAE has offered only limited incentives for the creation and use of IP assets by SMEs. Registration fees for SMEs have not been discounted, and there has been no expedited review process. The technical assistance programs that have been in place have not been emirates wide but available only in Dubai. This may now be changing.

In 2024, the Ministry of Economy launched two new SME-specific emirates-wide IP support programs targeting patent registration and financial support: the “Intangible Finance Committee” and the “Patent Incubator.” Both programs aim to increase and improve the development and registration of IP assets by SMEs by providing access to financing, technical assistance and registration support. As a result of these positive efforts, the score for this indicator has increased by 0.25.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

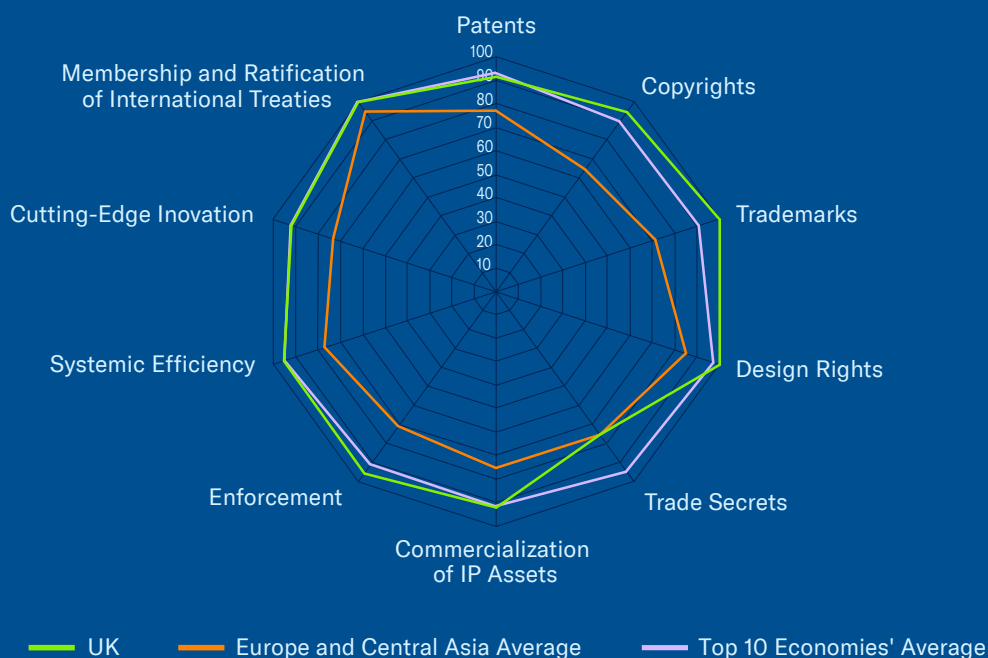
Interest in rare diseases has grown in the Middle East and North Africa region. In 2003, the Centre for Arab Genomic Studies was established to map and improve the state of care for patients with genetic diseases in the Arab world. Today, the Center has become the leading research point for rare diseases in the region. Since the 2018 introduction of Ministerial Resolution No. 28, the UAE has had a dedicated fast-track pathway for innovative and orphan drug approvals. Under the resolution, the UAE has one of the fastest market approval processes in the world for qualifying products, with the registration process taking less than a month. The UAE does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



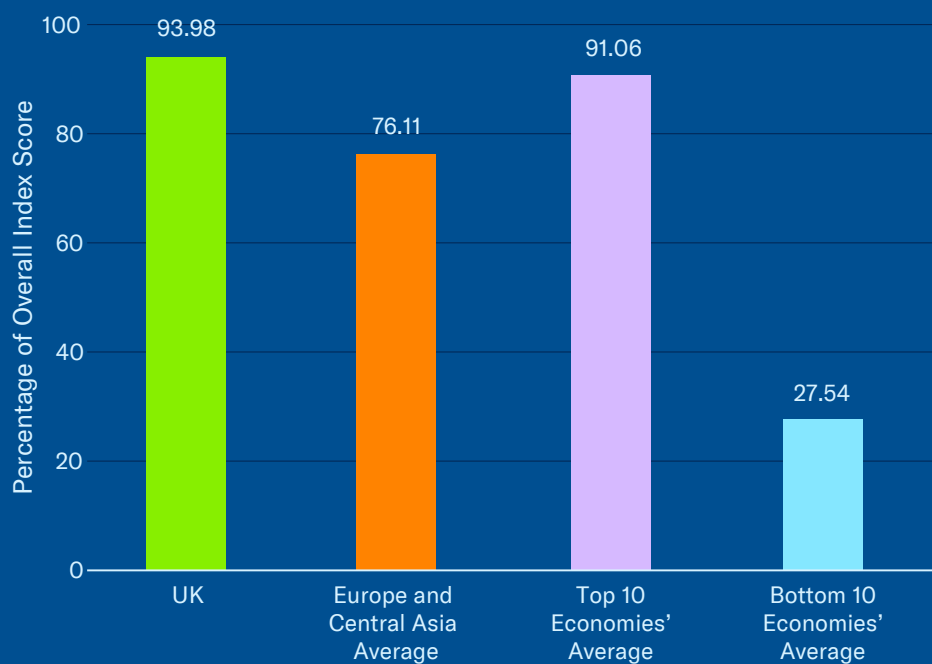
United Kingdom

Rank
2/55

Category Scores



Overall Score in Comparison





United Kingdom

Rank
2/55

Key Areas of Strength

- Since 2000, the orphan regulation (now SI 2019/1385) has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- Strong and sophisticated national IP environment
- UK is a model for injunctive-style relief for rightsholders when battling online infringement
- The 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 the 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

Percentage of Overall Score: 93.98% • Total Score: 49.81

Spotlight on the National IP Environment

Past Editions versus Current Score

The UK's overall Index score has increased from 47.06 out of 50 indicators in the twelfth edition to 49.81 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:

As noted in past editions of the Index, both the British Parliament and Government have been working on policy reforms related to AI and machine learning over the past four years. In 2024, several important developments occurred, including the election of a new British Government. Early in the year, in response to a public consultation held in 2023, the previous government published *A Pro-Innovation Approach to AI Regulation*. The key message from this was that the government would not pursue any new regulations and statutory changes with respect to AI and machine learning. Instead, the UK would take a “pro-innovation” approach and “legislate when we are confident that it is the right thing to do.”

At about the same time, the government also announced that talks hosted by UK Intellectual Property Office with the creative sector, researchers, and technologists to develop a voluntary code of practice on copyright and AI would not move forward. AI and machine learning technologies are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific breakthroughs and innovation to take place through the analysis of large volumes of data and information.

However, 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—as well as the ability of scraping technologies to access rightsholders' content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the UK and around the world.

In mid-2024, the newly elected Labour Government announced that it would introduce a new proposed legal framework for AI technologies. At the time of research, no proposal had been published. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

31. Tax incentives for the creation of IP assets:

In 2024, important changes were made to British tax law and existing incentives for the creation and commercialization of IP assets. Historically, R&D tax incentives have been provided through two different tax schemes: (1) a super deduction for qualifying expenditure for small companies and (2) an R&D expenditure credit for larger business entities. For tax year 2024 and forward, these two separate schemes have been merged into one larger scheme, with a subsidiary additional regime in place for what is termed “R&D-intensive SMEs.” Under the new merged scheme, qualifying entities are entitled to a 20% R&D expenditure credit. It remains somewhat unclear the extent to which R&D work performed overseas and through third parties would qualify for the credit.

A growing proportion of high-tech R&D is multijurisdictional in nature and often involves several different legal entities conducting the relevant research. This includes, for example, clinical trials for new medicines and medical technologies. Importantly, the UK has maintained the existing patent box scheme, which will continue to provide an effective rate of 10% corporation tax on income generated by the underlying patent assets and in line with the Nexus scheme and taxation principles agreed through the OECD. The Index will continue to monitor these developments in 2025.

Specifically, Section 58D provides a baseline 10-year term of market exclusivity that can potentially be expanded by two years upon completion of additional pediatric studies. Schedule 9A includes a similar requirement as in the orphan regulation that to remain eligible for the full exclusivity period, licensed products must retain their orphan designation, including with respect to potential return on investment criteria.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

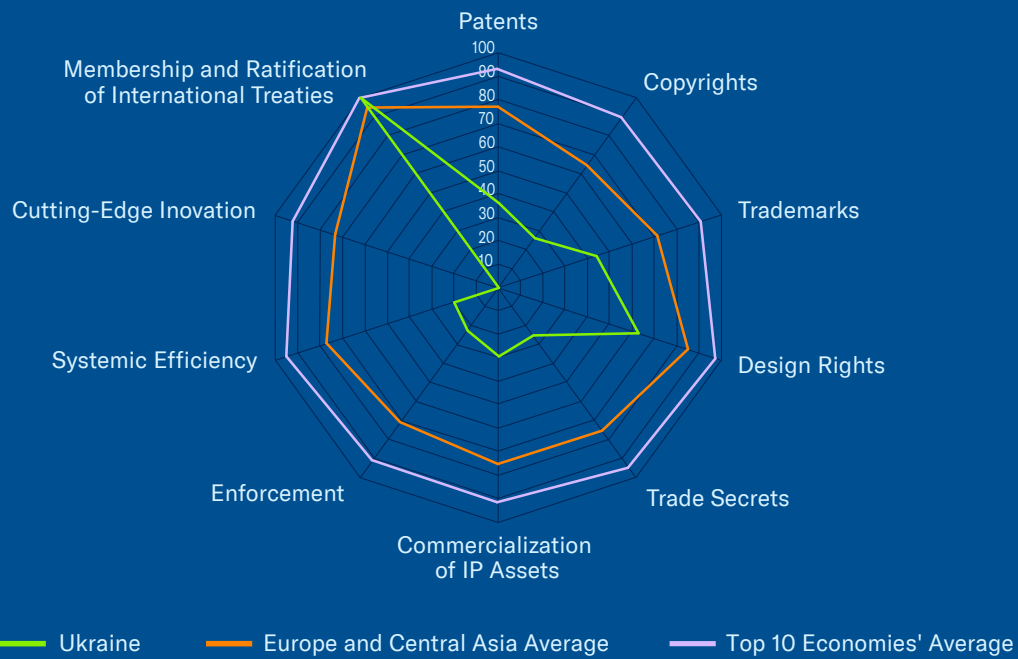
Before Brexit, as an EU Member State, the UK's legal regime related to rare diseases and incentives for the development of orphan drugs was governed by Regulation (EC) No. 141/2000 (the "EU Orphan Regulation"). Upon leaving the EU, the Human Medicines Regulation was amended with new articles on orphan drugs incorporated through S.I. 2019/1385, "The Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019." This regime mirrors the underlying orphan regulation with similar incentives offered, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products' developers will have sufficient time to recoup the high costs of development.



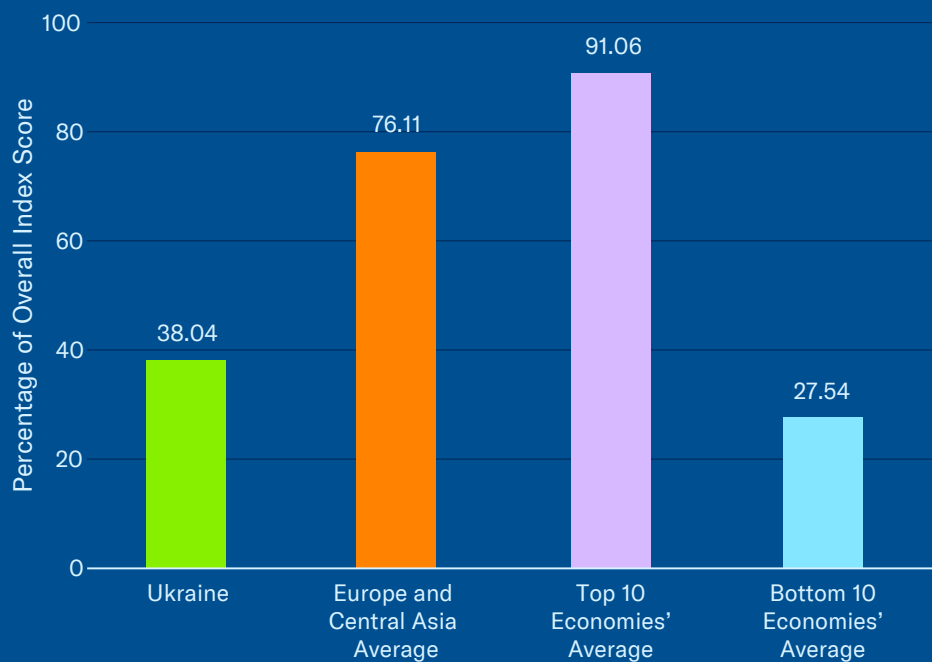
Ukraine

Rank
41/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

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

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- 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
- 2020 amendments restrict patentability of biopharmaceutical inventions and introduce export exemption for products under patent term restoration (modeled on EU's Regulation 2019/933)
- Major gaps exist across all categories of the Index through both a lack of relevant IP laws and weak enforcement
- 80% software piracy rate in latest BSA estimates and a continued lack of effective effort to reduce use of unlicensed software by the public sector
- High rates of physical counterfeiting; Ukraine is a key transit point for counterfeits entering the EU
- Gaps exist in customs activities, notably a lack of effective procedures for the destruction of counterfeits

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.25
2. Patentability requirements	0.00	30. IP as an economic asset	0.50
3. Patentability of CILs	0.00	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.25	32. Physical counterfeiting rates	0.38
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.20
7. Pharmaceutical patent term restoration	0.75	34. Civil and preceudural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.00	35. Pre-established damages	0.25
9. Patent opposition	0.25	36. Criminal standards	0.25
Category 2: Copyrights and Limitations		37. Effective border measures	0.25
10. Term of protection	0.58	38. Transparency and public reporting by customs	0.00
11. Exclusive rights	0.25	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	0.25
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	0.25
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	0.25
15. TPM and DRM	0.25	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
16. Government use of licensed software	0.00	43. IP-intensive industries, national economic impact analysis	0.25
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.50	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.25	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.00	Category 10: Membership and Ratification of International Treaties	
Category 4: Design Rights and Limitations		47. WIPO Internet Treaties	1.00
21. Industrial design term of protection	1.00	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
22. Exclusive rights, industrial design rights	0.25	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
Category 5: Trade Secrets and the Protection of Confidential Information		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
23. Protection of trade secrets (civil remedies)	0.25	51. Membership of the Convention on Cybercrime, 2001	1.00
24. Protection of trade secrets (criminal sanctions)	0.00	52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
25. Regulatory data protection term	0.50	53. Post-TRIPS FTA	1.00
Category 6: Commercialization of IP Assets			
26. Barriers to market access	0.25		
27. Barriers to technology transfer	0.25		
28. Registration and disclosure requirements of licensing deals	0.50		

Percentage of Overall Score: 38.04%

Total Score: 20.16

Spotlight on the National IP Environment

Past Editions versus Current Score

Ukraine's overall Index score has increased from 20.15 out of 50 indicators in the twelfth edition to 20.16 out of 53 indicators. This reflects a score increase for indicator 32.

Area of Note

In 2024, the war between Russia and Ukraine continued. 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 Ukrainian state ministries and agencies continued to function. In 2024, the Ukrainian National Office for Intellectual Property and Innovations (UANIPIO) continued to provide users with a full range of its services and launched a new *Strategic Development Plan*. The plan puts a strong emphasis on fundamentally improving all aspects of Ukraine's national IP environment, including legislative changes, stronger enforcement, and an enhanced institutional capacity. As such, the plan is a comprehensive document outlining how UANIPIO can put IP policy at the center of Ukraine's efforts to rebuild and reconstruct its economy through a range of reform efforts.

For all economies—emerging and developed alike—what drives innovation, technological advances, and, ultimately, economic development and growth is the creation of new forms of intangible assets and IP. Covering 53 indicators across 10 separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products.

As the Government of Ukraine continues to pursue a program of national IP rights reforms, we would encourage it to use the Index findings and accompanying *Statistical Annex* as a guide in 2025 and beyond. In addition to these efforts, the UANIPIO also continued to deepen 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 2022. In late 2023, the European Council announced that it had authorized the Commission to begin formal negotiations on EU accession. In June 2024, these negotiations were launched with the first interministerial meeting held. The Index commends the Government of Ukraine and UANIPIO for its positive work under such trying circumstances.

Enforcement

34. Civil and procedural remedies:

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, a dearth of knowledge of IP rights within the judiciary, and infrequent civil prosecutions. Although there have been instances in which damages have been successfully claimed from infringing companies in the past, 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 last year, in 2023, the Ukrainian Parliament passed Law 6,464 “On making changes to some legislative acts of Ukraine regarding strengthening the protection of intellectual property rights,” and President Zelensky signed the bill into law in April. The amendments strengthened existing civil remedies related to IP infringement and the circulation of infringing goods and the manner in which damages are assessed and awarded. These positive efforts continued in 2024.

In June, UANIPIO announced that the office’s Appeals Chamber was operational. The Appeals Chamber provides rightsholders with a mechanism for administrative hearings on IP disputes, including with respect to invalidation and opposition proceedings for all industrial property rights. More broadly, UANIPIO announced the launch of an IP Rights Infringement Monitoring Center. The Center is to improve the environment for IP rights enforcement and awareness through greater coordination and training of government agencies such as customs and law enforcement as well as international cooperation. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

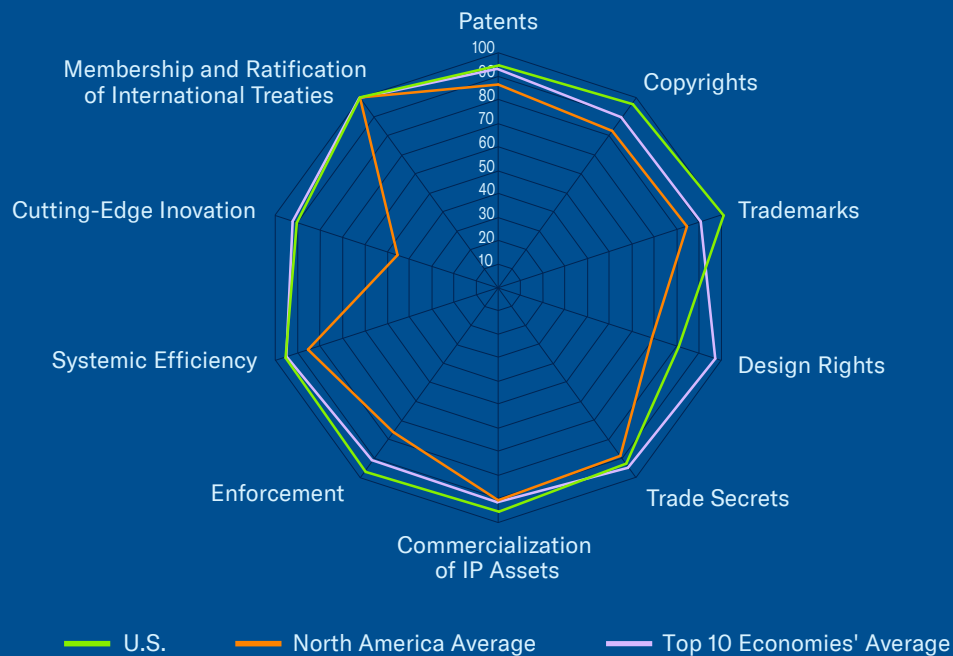
Interest in rare diseases has grown in Ukraine. In 2021, a national policy and framework was introduced (Cabinet Order 377, April 2021). This policy seeks to create a national registry of rare diseases, ensure access to therapies and care, improve awareness and understanding of rare diseases among health care professionals as well as the public at large, and seek to stimulate new R&D. Neither the order nor other relevant statute referring to orphan drugs—including the 2022 revisions to the Law on Medicines—contains any special IP-based market exclusivity incentives for orphan medicinal product development.



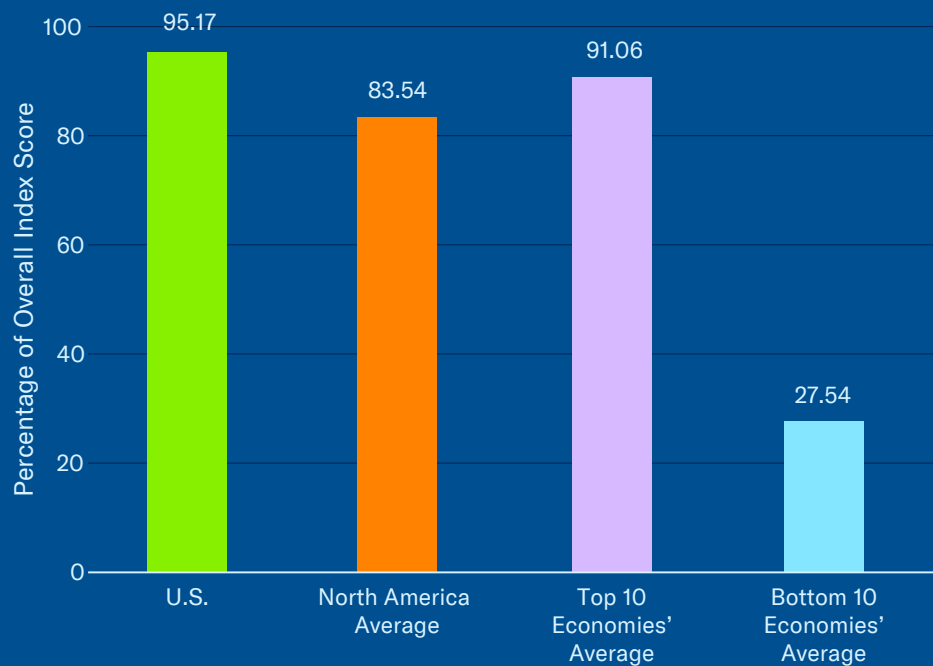
United States

Rank
1/55

Category Scores



Overall Score in Comparison





United States

Rank
1/55

Key Areas of Strength

- Since the mid-1980s, the Orphan Drugs Act has provided a world leading seven-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- The U.S. national IP system continues to provide international leadership
- Sector-specific rights and protections are in place across all Index categories
- Congressional efforts to address long-standing challenges and uncertainty over patentable subject matter and PTAB proceedings
- Continued efforts made to reform patent nullity and opposition proceedings in 2024; USPTO should be commended for efforts to provide a greater balance and to address concerns over unpredictability and uncertainty within the PTAB process

Key Areas of Weakness

- 2024 FTC blanket banning of noncompete agreements puts IP assets at risk
- 2024 bills S150, HR6986, and S3583 all fundamentally seek to limit the number of patents a rightsholder may assert in an infringement action
- 2025 NIH changes to the Intramural Research Program puts U.S. innovation and economic growth at risk
- 2023 NIST proposals for exerting “march-in rights” fundamentally undermine patent rights
- Long-standing uncertainty about patentability standards for high-tech sectors
- Long-standing uncertainty about PTAB proceedings
- USPTO administrative efforts to undermine patent examination practices for the life sciences industry
- Past administration pushed “collaboration” efforts between USPTO and FDA
- No targeted legal basis for addressing online piracy along the lines of other global leaders

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.75	30. IP as an economic asset	1.00
3. Patentability of CII	1.00	31. Tax incentives for the creation of IP assets	0.67
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	1.00	32. Physical counterfeiting rates	0.87
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.85
7. Pharmaceutical patent term restoration	1.00	34. Civil and precedural remedies	1.00
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	1.00
9. Patent opposition	0.75	36. Criminal standards	1.00
Category 2: Copyrights and Limitations		37. Effective border measures	1.00
10. Term of protection	1.00	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	1.00	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.75	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	1.00	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	1.00	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	1.00	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.70
19. Exclusive rights, trademarks	1.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	1.00
20. Frameworks against online sale of counterfeit goods	1.00	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	1.00
21. Industrial design term of protection	0.60	24. Protection of trade secrets (criminal sanctions)	1.00
22. Exclusive rights, industrial design rights	1.00	25. Regulatory data protection term	0.75
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	1.00	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
28. Registration and disclosure requirements of licensing deals	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	1.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 95.17%

• Total Score: 50.44

Spotlight on the National IP Environment

Past Editions versus Current Score

The United States' overall Index score has increased from 47.74 out of 50 indicators in the twelfth edition to 50.44 out of 53 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent 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, uncertainty surrounds what constitutes patentable subject matter in the United States. Since 2014, the USPTO has issued and updated patent examination guidelines almost on an annual basis. Lower and circuit court decisions in patent infringement proceedings have not always been consistent. The net result is that rightsholders are left without a clear sense of how decisions on patent eligibility will be made, or, when granted patents are subsequently challenged or reviewed either through the courts or through the *inter partes* proceedings within the USPTO, which patent claims will be upheld. The USPTO has recognized this dilemma and has sought to reformulate its position and the approach to be taken by its examiners. In 2019, the office released new guidance covering Section 101, Patentability, and Section 112, Claims, related to computer inventions, the “2019 Revised Patent Subject Matter Eligibility Guidance,” and “Examining Computer-Implemented Functional Claim Limitations for Compliance With 35 U.S.C. 112.” With respect to Section 101, Patentability, the guidance provided more of a principle-based analysis of how patentability would be judged, and it described the stepwise approach examiners should follow to understand and apply the Supreme Court’s *Alice/Mayo* test.

As the guidance rightly pointed out, the key challenge for USPTO examiners and courts has been to “consistently distinguish between patent-eligible subject matter and subject matter falling within a judicial exception.” The guidance recognized this and sought, to the extent 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 introduction of the guidance. As the USPTO rightly noted at the time of publication, this is positive news.

Unfortunately, as noted repeatedly by the Index, uncertainty about 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 PTAB or through the judiciary. For instance, 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 in 2024. The Patent Eligibility Restoration Act—introduced into the Senate in 2023 by Senators Tillis and Coons—marks a significant breakthrough on the legislative front. As noted in the Index last year, the draft legislation addresses many of the long-standing areas of concern and uncertainty about what constitutes patentable subject matter in the United States. In another positive development in Congress, Senators Coons and Cottons introduced the Realizing Engineering, Science, and Technology Opportunities by Restoring Exclusive (RESTORE) Patent Rights Act in 2024. The RESTORE Act seeks to address the difficulty rightsholders have had since in getting permanent injunctions in infringement proceedings since the 2006 Supreme Court decision in *eBay v. MercExchange*.

On the other end of the spectrum, in 2024, several developments occurred that would negatively affect the patenting environment and curtail existing patent rights. First, in May, the USPTO proposed to change the practice of terminal disclaimers. The agency requires these disclaimers in relation to nonstatutory double patenting. The USPTO wants to include a new requirement whereby applicants also agree to limit the number of claims that could be referred to in future infringement action. The agency argues that the proposed rule change would lower “the cost of challenging groups of patents tied by terminal disclaimers, resulting in reduced barriers to market entry and lower costs for consumers.” In other words, the USPTO seeks to limit and reduce existing IP rights because the agency—not Congress or existing patent statute—believes that doing so would achieve a perceived policy good.

In Congress, several bills—S150, HR6986, and S3583—were introduced that all seek to limit the number of patents a rightsholder may assert in an infringement action.

Not only do these bills discriminate and selectively target the life sciences sector with these restrictions, but they also embrace a fundamentally anti-IP and anti-innovation logic whereby the restriction of IP rights will lead to lower prices and greater access to a given product, in this case, biopharmaceutical treatments.

As detailed across numerous editions of the Index and most clearly illustrated by the life-saving innovation and product development witnessed during the COVID-19 pandemic, biopharmaceutical breakthroughs by American firms are improving health treatment for patients globally, providing a steady stream of new drugs and health technologies. Since 2000, American companies have developed more than 550 new medicines, roughly half of all drugs launched globally. The latest *Annual Membership Survey* from the Pharmaceutical Research and Manufacturers of America (PhRMA) shows that in 2024, American research-based biopharmaceutical firms spent an estimated \$71.3 billion in 2023 on R&D domestically in the United States and over \$96 billion globally.¹⁷ This leadership in global biopharmaceutical research and manufacturing also translates into large economic dividends for Americans. In 2022, the research-based industry directly employed over 1 million workers and supported an additional 3.8 million jobs, bringing the total number of jobs supported in the U.S. economy to 4.9 million.¹⁸ In terms of added value and contributions to national economic output, these were estimated at 3.4% and 3.6% of the GDP, respectively.¹⁹ The basic economics of the biopharmaceutical industry show how critical IP rights are to incentivize and support the development of new medical technologies and products.

In 1979, the total cost of developing and approving a new drug stood at approximately \$138 million. Today, the most recent research from Tufts University suggests that it costs \$2.6 billion, on average, to develop a new drug.

Only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. Patents and other forms of exclusivity for biopharmaceuticals, such as RDP and special exclusivity incentives for the protection and production of orphan drugs, enable research-based companies to invest these vast sums in R&D and the discovery of new drugs, products, and therapies. Instead of achieving the goal of lowering costs, proposals that undermine these IP rights and 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 2025.

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, which occurs before the specialized PTAB within the USPTO. As noted over the course of the Index, the U.S. government (chiefly through the USPTO) has recognized the unintended effects of the PTAB system and has publicly pledged to work with all stakeholders to address and remedy them. As a result, many important changes have since been introduced, including changes to claim construction standards, trial practices, and standard operating procedures. These efforts continued in 2024 with several USPTO rule changes coming into effect.

These include changes to Standard Operating Procedure 4 and the internal review of PTAB decisions, the Director Review process and replacement of the Precedential Opinion Panel, and legal representation rules before the USPTO. At the time of research, the USPTO had not finalized additional proposed rules related to serial and parallel petitions. In 2024, Congress continued reviewing the Promoting and Respecting Economically Vital American Innovation Leadership Act (PREVAIL Act). As discussed last year, the PREVAIL Act would address much of the uncertainty and unpredictability caused by PTAB. At the time of research, no legislative proposals had been passed by Congress or signed into law. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

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 worked on policy reforms related to AI and machine learning over the past two years. The Copyright Office issued a “notice of inquiry request for comments” on the interaction between AI and copyright. In 2024, the Copyright Office published the first in a series of reports on AI and copyright. This report addresses the issue of digital replicas, that is, the use of computer software technologies, including AI and machine learning applications, to replicate human beings’ voice and appearance. The office has already announced that future reports will examine copyright within the context of the development and application of AI and machine learning tools.

Separately, Congress introduced several bills related to AI and copyright. These include the NO FAKES Act, the Generative AI Copyright Disclosure Act, the Transparency and Responsibility for Artificial Intelligence Networks Act, and several others. Many of these bills would address the issue of digital replicas identified by the Copyright Office and would put in place new transparency requirements on developers of generative AI and machine learning technologies.

In 2024, lawsuits related to the potential use of copyright protected material in the development of generative AI increased. At the time of research, these suits remained pending. The use and application of AI and machine learning is an important area of future economic activity as advances in computational power and new technological breakthroughs allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. However, 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—as well as the ability of scraping technologies to access rightsholders’ content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can enforce their rights, both in the United States and around the world. The Index will continue to monitor these developments in 2025.

Trade Secrets and the Protection of Confidential Information

In April 2024, the Federal Trade Commission (FTC) issued a rule banning the effective use of noncompete agreements. Historically, these agreements have been an important component in an organization’s ability to protect its trade secrets and confidential information.

Noncompete agreements prevent employees from potentially using any trade secrets or confidential information acquired over the course of their employment. Ultimately, the FTC’s rule was vacated in court. Given the rise in trade secret theft and the misappropriation of confidential information, if rightsholders are unable to protect their IP assets with the support of noncompete agreements, this would pose a new and unnecessary risk to the United States’ national IP environment and national security. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer:

In the early and mid-1980s, the U.S. Congress passed several groundbreaking pieces of legislation establishing the basis for our modern-day technology transfer and commercialization framework. Chief among these was the University and Small Business Patent Procedures Act, (the Bayh-Dole Act) of 1980. Over the past 40 years, this legislative framework has supplied federal laboratories, small businesses, universities, and other entities using federal funds with the incentives needed to work with the private sector for the purpose of translating early-stage research into usable products in the marketplace for the benefit of the wider public. This framework—together with subsequent changes and legal amendments—secured these goals through four major changes to the U.S. 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 use of their IP rights by creating professional technology transfer offices. Third, 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 institutions and researchers. Finally, by codifying under what specific and highly unique circumstances the federal government has the power to use march-in-rights, the Bayh-Dole framework provided relevant institutions and rightsholders legal certainty on their ownership rights and title to developed IP assets. The importance of the Bayh-Dole framework to U.S. innovation cannot be overstated.

In 2002, *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 had on U.S. innovation. To begin with, 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. In 1981, the number of Bayh-Dole patents granted in the United States totaled 1,635. Over the next four decades, this has increased by over 400% with over 7,000 patents issued per year. Indeed, a 2004 academic 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. More broadly, this positive impact can also be seen in terms of the direct and significant contributions to U.S. economic output and employment. For instance, using 25 years of data from the annual Association of University Technology Managers 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).

Contributions to GDP were equally significant and estimated at between \$333 billion and \$1 trillion (measured in 2012 U.S. dollars). And at the micro level, the Bayh-Dole framework has led to the invention and commercialization of thousands of products and technologies on which consumers, patients, and businesses today rely. This innovation has not been concentrated in any one industry or economic sector but has been broad-based across all industries and the entire U.S. economy. For example, this positive impact can be seen in the ICT and semiconductor industry, manufacturing, and venture capital (including investments in biotechnology).

Over the past two years, the federal government has put forth proposals that would undermine the Bayh-Dole framework and all the innovation and socioeconomic gains of the past 40 years. In late 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 when the Department of Commerce and 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 specific circumstances. These march-in-rights are not—and have never been—meant to be used as a way for the federal government to insert itself in the innovation and commercialization process of a technology or product.

These rights were also not intended to allow the government to impose price, access, or production/manufacturing controls on a technology or the abrogation of an existing licensing agreement to reduce public expenditure or achieve any other stated federal policy goal. This was never the intention of the underlying legislation, and it would be counter to the legislation's stated policies and objectives. Until now, this has also been acknowledged by federal agencies through their actions and public statements. For example, then NIH Director Francis Collins in 2017 stated, in public testimony before Congress, that march-in rights do not apply within the context of the price of medicine.

In a separate development, in May 2024, NIH issued a Request for Comment on a new policy within its Intramural Research Program. Under the proposed policy, NIH would require licensees who successfully develop and commercialize a medicinal product (defined by NIH as “drugs, biologics, vaccines, or devices”) to submit a “plan outlining steps they intend to take to promote patient access to those products.” In January, NIH announced a finalized policy largely mirroring this proposal. The finalized policy only applies to patents wholly owned by NIH and not to any IP developed and owned by a third party through an NIH grant. Unfortunately, the policy is unlikely to achieve NIH's objectives. Instead of achieving greater patient access, the new policy will simply act as a disincentive to partner with NIH. This will, in turn, lead to fewer partnerships and fewer new products and technologies developed. Fundamentally, NIH seems to have misunderstood its role and that of the private sector in the technology transfer process. The overwhelming majority of publicly funded research—whether through the NIH, academic institutions or other parts of the federal government—does not result in or even seek to result in a finalized, commercially available product.

The translation of basic research into new products, services, and technologies is done through the partnership of the private sector, which invests the resources and shoulders all of the accompanying financial risk of the commercialization process. In this respect, although critical, basic research, no matter how pathbreaking, is almost never in itself enough to lead to a final product or service. The commercialization process for each licensed technology and invention is unique, and the exact amount of expenditure and commercialization spending ratio between licensee and licensor varies from technology to technology and from transaction to transaction. However, practical experience and research suggests that most investment needed in the development and commercialization of a product is done by the private sector entity to which the invention has been licensed. For example, in a 2012 study, the Congressional Research Service stated, “Although research is often important to innovation, it appears that, on average, it constitutes approximately 25% of the cost of commercializing a new technology or technique, thus requiring the expenditure of a substantial amount of additional resources to bring most products or processes to the marketplace [emphasis added].” The new administration has the opportunity to move in a different direction. Instead of adopting a more expansionist and interventionist view of march-in rights and the public-private licensing process, it could revert to a more traditional understanding of both the Bayh-Dole Act and the role of the federal government in the licensing process. Such a change of direction could help ensure that the Bayh-Dole framework continues to stimulate innovation, economic growth, and prosperity for another 50 years.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

The United States was the first economy to introduce dedicated incentives for the development and commercialization of medicinal orphan products. The 1983 Orphan Drug Act and subsequent regulations and rules issued by the U.S. FDA provides the legislative basis for the designation of orphan drugs in the United States.

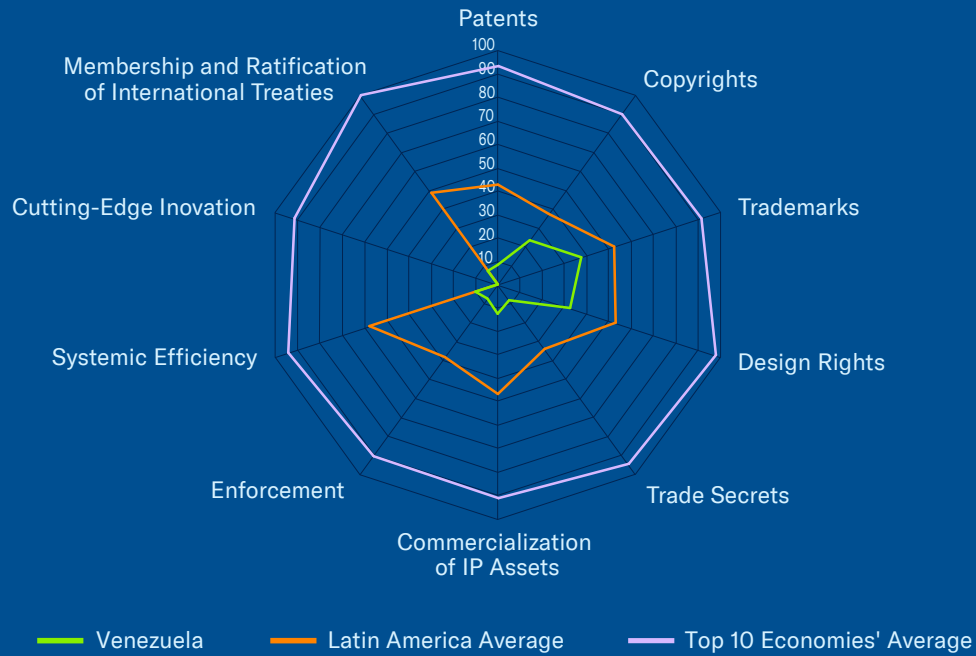
Under this framework, the U.S. provides several dedicated incentive programs related to both the financing of drug development and support in the acceleration and facilitation of regulatory and administrative procedures. Specific programs include a seven-year orphan market exclusivity period, grants, tax credits and fee waivers, and fast-track approval.



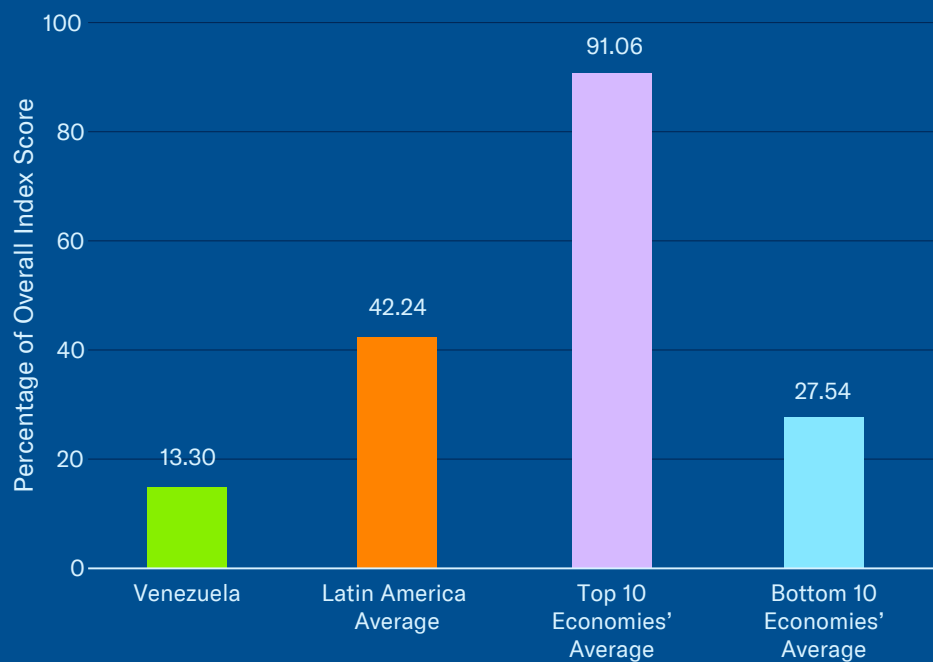
Venezuela

Rank
55/55

Category Scores



Overall Score in Comparison





Venezuela

Rank
55/55

Key Areas of Strength

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

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Weak patent framework, with sector-specific patents and other IP rights not available
- Major holes exist 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
- Government interference and regulatory barriers to commercialization of IP assets

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	0.50	29. Direct government intervention in setting licensing terms	0.00
2. Patentability requirements	0.00	30. IP as an economic asset	0.50
3. Patentability of CILs	0.25	31. Tax incentives for the creation of IP assets	0.00
4. Plant variety protection	0.00		
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.16
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.11
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.00	35. Pre-established damages	0.00
9. Patent opposition	0.00	36. Criminal standards	0.00
		37. Effective border measures	0.00
Category 2: Copyrights and Limitations		38. Transparency and public reporting by customs	0.00
10. Term of protection	0.63		
11. Exclusive rights	0.25	Category 8: Systemic Efficiency	
12. Expeditious legal remedies disabling access to infringing content online	0.00	39. Coordination of IP rights enforcement	0.00
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	0.00
14. Limitations and exceptions	0.25	41. Educational campaigns and awareness raising	0.50
15. TPM and DRM	0.00	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
16. Government use of licensed software	0.25	43. IP-intensive industries, national economic impact analysis	0.00
Category 3: Trademarks Rights and Limitations			
17. Term of protection	1.00	Category 9: Cutting-Edge Innovation	
18. Protection of well-known marks	0.25	44. IP incentives for orphan medicinal product development	0.00
19. Exclusive rights, trademarks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
20. Frameworks against online sale of counterfeit goods	0.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
Category 4: Design Rights and Limitations			
21. Industrial design term of protection	0.40	Category 10: Membership and Ratification of International Treaties	
22. Exclusive rights, industrial design rights	0.25		
Category 5: Trade Secrets and the Protection of Confidential Information		47. WIPO Internet Treaties	0.50
23. Protection of trade secrets (civil remedies)	0.25	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
24. Protection of trade secrets (criminal sanctions)	0.00	49. Patent Law Treaty and Patent Cooperation Treaty	0.00
25. Regulatory data protection term	0.00	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
Category 6: Commercialization of IP Assets		51. Membership of the Convention on Cybercrime, 2001	0.00
26. Barriers to market access	0.00	52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
27. Barriers to technology transfer	0.00	53. Post-TRIPS FTA	0.00
28. Registration and disclosure requirements of licensing deals	0.25		

Percentage of Overall Score: 13.30%

• Total Score: 7.05

Spotlight on the National IP Environment

Past Editions versus Current Score

Venezuela's overall score remains unchanged at 7.05 out of 53 indicators.

Area of Note

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 more modern IP frameworks and international best practices. Venezuela remained on the USTR's Priority Watch List in the *2024 Special 301 Report*. The report noted a lack of "any notable progress toward improving IP protection in 2023." In a positive development, public statements in 2024 suggest that the Venezuelan Government is in the process of developing a *National Strategy on Intellectual Property*. The development of this strategy is part of the Government's broader socioeconomic reform plan "7T" (7 Transformaciones). Several public meetings had been hosted by the Venezuelan Autonomous Intellectual Property Service (SAPI) and other related government agencies and ministries throughout the spring and summer months. At the time of research, no finalized document had been made available to the public.

Since 2015, the Index has included a *Statistical Annex* that investigates a series of correlations examining the relationship between the strength of national IP environments, as measured by the Index scores, and different types of economic activity, including rates of R&D spending, innovation, technology creation, and creativity.

As the economic data and analysis of the *Statistical Annex* and the experiences of other economies strongly suggest, IP rights and incentives are the fundamental building blocks for innovation and advanced economic development to take place. For all economies—emerging and developed alike—what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP. Covering 53 indicators across 10 separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rights-holders need to be able to fully develop and commercialize their ideas and products. As the Government of Venezuela pursues a program of national IP rights reforms, we would encourage it to use the Index findings and accompanying *Statistical Annex* as a guide in 2025 and beyond.

Patent Rights and Limitations

With respect to Category 1: Patent Rights and Limitations, legal standards of patentable subject matter in Venezuela 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, SAPI stopped processing and granting patents for all arts and technologies.

As noted in preceding editions, in an encouraging development, local reports suggest that SAPI has over the past several years begun to process and grant patents again. 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 a score increase for indicators 1 and 2. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

The Bolivarian Constitution provides a general and universal right to health and social security for all citizens of Venezuela. Current and long-standing health laws and policies elaborate on this right and the way the national health system should provide universal access to medical care and treatment for all illnesses and diseases.

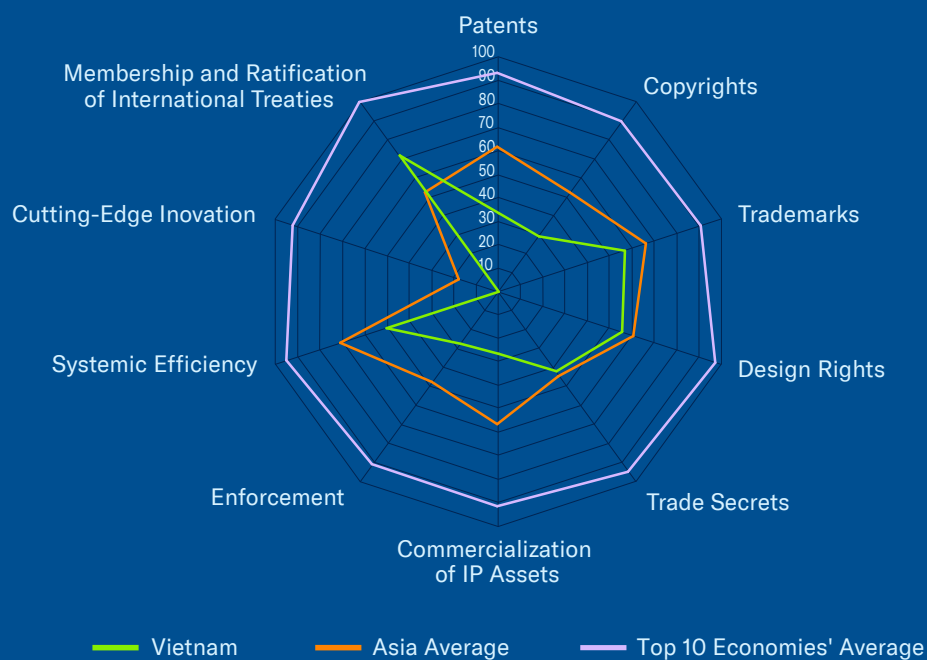
Given Venezuela's long-standing and ongoing political and socioeconomic crisis, the provision of health care and basic medical services has been and remains highly fraught. Publicly available data suggests that access to all forms of health care in Venezuela has deteriorated markedly over the past decade and that, even before the pandemic, rates of preventable diseases, such as malaria, had increased and life expectancy had dropped by almost three years between 2000 and 2021. With respect to rare diseases, Venezuela does not have in place any special IP-based market exclusivity incentives for orphan medicinal product development.



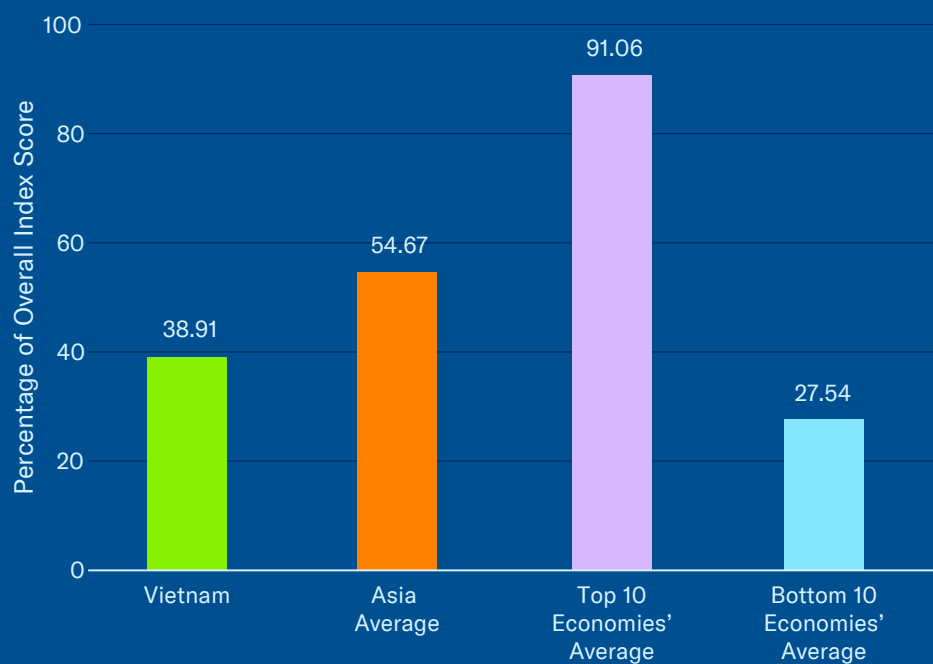
Vietnam

Rank
39/55

Category Scores



Overall Score in Comparison





Vietnam

Rank
39/55

Key Areas of Strength

- First criminal conviction was issued for copyright infringement in 2024
- 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, such as through the EU-Vietnam FTA
- Long-standing effort to coordinate IP enforcement

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Inadequate protection of life sciences patents, with a challenging enforcement environment
- 2022 amendments notwithstanding, gaps remain in copyright protection remain, including a lack of measures to address online infringements
- High physical counterfeiting rates and online infringement with an estimated software piracy rate of 74%
- Restrictions to digital trade and cross-border data transfers through the Law on Cybersecurity
- Enforcement is generally poor; penalties are insufficient in practice; administrative inaction

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	0.00
2. Patentability requirements	0.25	30. IP as an economic asset	0.75
3. Patentability of CII	0.00	31. Tax incentives for the creation of IP assets	0.33
4. Plant variety protection	1.00	Category 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.00	32. Physical counterfeiting rates	0.40
6. Legislative criteria and use of compulsory licensing	0.00	33. Software piracy rates	0.26
7. Pharmaceutical patent term restoration	0.00	34. Civil and precedural remedies	0.25
8. Membership of a Patent Prosecution Highway	0.50	35. Pre-established damages	0.25
9. Patent opposition	0.25	36. Criminal standards	0.50
Category 2: Copyrights and Limitations		37. Effective border measures	0.25
10. Term of protection	0.53	38. Transparency and public reporting by customs	0.00
11. Exclusive rights	0.50	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	0.25	39. Coordination of IP rights enforcement	0.75
13. Cooperative action against online piracy	0.25	40. Consultation with stakeholders during IP policy formation	0.50
14. Limitations and exceptions	0.00	41. Educational campaigns and awareness raising	0.75
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
16. Government use of licensed software	0.00	43. IP-intensive industries, national economic impact analysis	0.50
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	0.00
18. Protection of well-known marks	0.25	45. IP incentives for orphan medicinal product development, term of protection	0.00
19. Exclusive rights, trademarks	0.50	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
20. Frameworks against online sale of counterfeit goods	0.50	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	0.50
21. Industrial design term of protection	0.60	24. Protection of trade secrets (criminal sanctions)	0.25
22. Exclusive rights, industrial design rights	0.50	25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	0.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	0.25	48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
28. Registration and disclosure requirements of licensing deals	0.25	49. Patent Law Treaty and Patent Cooperation Treaty	0.50
		50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
		51. Membership of the Convention on Cybercrime, 2001	0.00
		52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
		53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 38.91%

Total Score: 20.62

Spotlight on the National IP Environment

Past Editions versus Current Score

Vietnam's overall Index score has increased from 20.38 out of 50 indicators in the twelfth edition to 20.38 out of 53 indicators. This reflects a score increase for indicator 11 and a score decrease for indicator 32.

Patent 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 loss of patent term time for biopharmaceutical products due to 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. Subsequent regulations implementing the IP Law published in 2023 have not altered this. Under Article 42 of Decree 65/2023, patent term restoration is not mentioned. Instead, compensation is again specified as a reduction in relevant usage and renewal fees during the period of delay. This does not constitute patent term restoration. New draft amendments published in 2024 do not address this deficiency. Consequently, Vietnam's score for this indicator remains unchanged at 0.

Copyrights and Limitations; and Enforcement

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); and 36. Criminal standards, including minimum imprisonment and minimum fines:

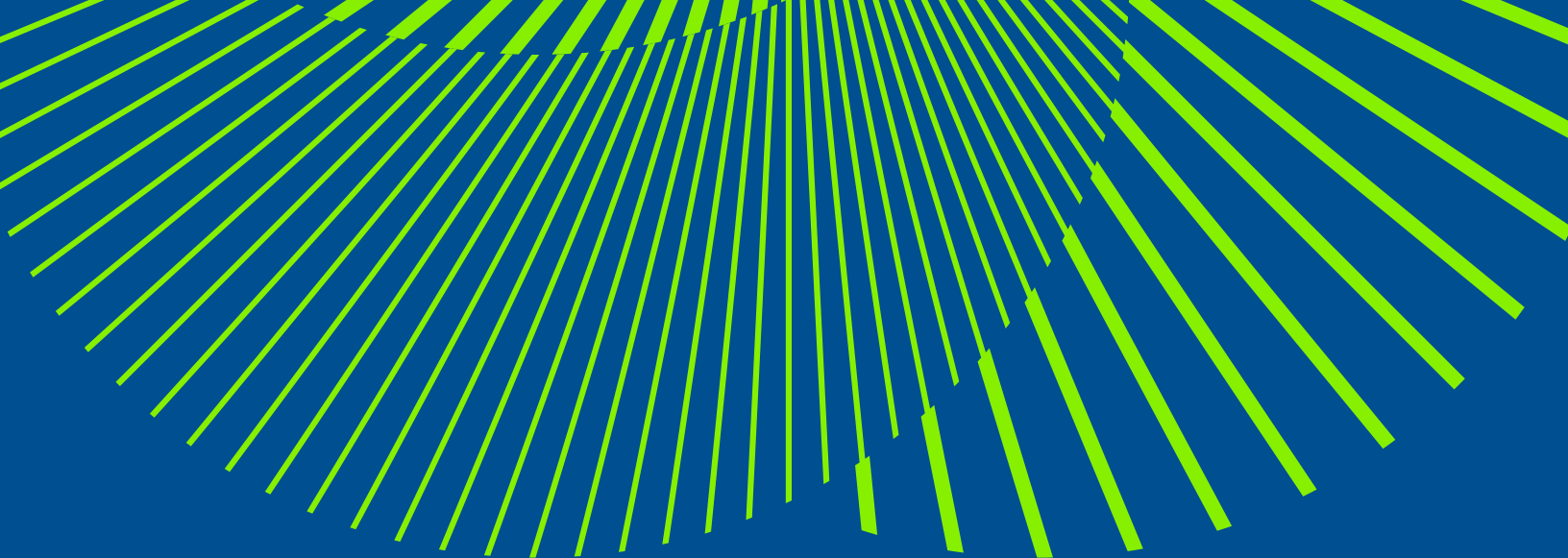
In 2024, there significant developments occurred with respect to criminal copyright enforcement in Vietnam. In April 2024, the People's Court of Hanoi handed down a guilty verdict against the proprietor of BestBuyIPTV, a website providing illegal access to the streaming of live sports. The case marks the first criminal court conviction ever in Vietnam for copyright infringement. The lawsuit was the result of a private-public partnership between local law enforcement and a coalition of rightsholders. As has been noted over the course of the Index, rightsholders have historically faced significant challenges in protecting their content in Vietnam with piracy rates high and both civil and criminal enforcement through the judiciary challenging. Hopefully, this case will lead to an increase in criminal prosecution and further convictions through the Vietnamese court system. As a result of these positive enforcement efforts, the score for indicator 11 has increased by 0.25.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:

Interest in rare diseases has grown in the Asia-Pacific region. In 2017, the Asia-Pacific Economic Cooperation (APEC) forum (of which Vietnam is a member) announced a new initiative geared specifically toward rare diseases, the “APEC Action Plan on Rare Diseases.” The plan’s primary aim is to “address barriers to the diagnosis and treatment of rare diseases in the region.” The plan consists of 30 individual targets across 10 pillars, including the promotion of innovative research and development through financial incentives, expedited market review procedures, and support for domestic R&D. In Vietnam, too, policymakers and the government are increasingly focused on addressing rare diseases and improving patient access to care and treatments.

The Ministry of Health has established several policies and regulations related to rare disease, including a national list of orphan drugs. With respect to incentives to R&D and the development of new treatments and technologies, Article 7 of the Law on Pharmacy states that the government should provide “incentives for investment in the manufacture of drugs and drug materials, essential drugs, drugs for prevention and control of social diseases, vaccines, biological products, drugs from medicinal materials, traditional drugs and rare drugs; to provide incentives for scientific research in.” However, neither this law nor any related regulations provide any special IP-based market exclusivity incentives for orphan medicinal product development.



Appendix: Methodology, Sources, and Indicators Explained

The Index consists of 53 indicators across 10 separate categories:

1. Patent Rights and Limitations
2. Copyrights and Limitations
3. Trademark Rights and Limitations
4. Design 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. Incentives for Cutting-Edge Innovation
10. Membership and Ratification of International Treaties

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

Scoring Methodology

As in previous editions of the Index, each indicator can score values between 0 and 1, and the cumulative score of the Index ranges from a minimum of 0 to a maximum of 53. 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 that of 95 years provided in the United States to orphan works.²⁰ If an economy has a copyright term of 95 years, the value it scores in this indicator is 1. If it has a copyright term of less than 95 years, then the value is less than 1. Details of the individual baselines used for different types of IP rights are provided.

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 two:

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 used most 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 an indicator. Specifically, it is possible to assign a partial score, rather than only a 0 or 1. Five possible scores are available within a mixed indicator: 0, 0.25, 0.5, 0.75, and 1. The range of scores available for mixed indicators means that greater nuance can be used when individual indicators are scored. The practical end result is that economies can receive partial scores for an indicator, which, in some cases, are a better approximation of their reality.

Finally, a few instances also exist 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 10: Membership and Ratification of International Treaties, the indicators are measured by the signature and ratification or accession to a given international treaty. Thus, 0.5 is given for being a signatory of a treaty, and 0.5 is given for ratifying or acceding to that treaty. This is also the case for indicator 7, Pharmaceutical patent term restoration. This indicator consists of two distinct variables: (1) the existence of a term of patent restoration for pharmaceutical products due to the prolonged research, development, and regulatory approval periods for such products and (2) the existence of any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. The available score of 0.75 for this indicator is allocated to the existing term of protection compared to the current baseline rate of five years' term restoration used in the United States, EU, and Japan. The remaining 0.25 is allocated based on an economy providing any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes.

Baselines Used

When possible, the Index uses baseline values, measures, and models. These values are based on best practices regarding terms of protection, enforcement mechanisms (*de jure* and *de facto*), and/or model pieces of primary or secondary legislation that can be found at the national and international levels.

Where no adequate baselines are found in international law or treaties, the baselines and values used are based on what rightsholders view as an appropriate environment and level of protection.

IP Rights Baselines

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
Orphan exclusivity	10	EU

Measuring Counterfeiting and Piracy

Indicators 32 and 33 of the Index measure rates of physical counterfeiting and software piracy, respectively. Attempting to measure counterfeiting and piracy has several challenges.

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

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

Finally, because measures of counterfeiting and piracy are inexact, estimates of their economic impact can vary widely depending on the methodology and data samples used.²¹

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

1. The OECD's General Trade-Related Index of Counterfeiting of Economies (GTRIC-e), which measures the relative rates of physical counterfeiting²²
2. Software piracy rates compiled by the Business Software Alliance (BSA) (2018 is the latest published survey)

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

Still, the use of these measures has caveats, particularly the GTRIC-e.

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

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

The measure provides a total and per economy estimate for each of the economies included in the Index of rates of physical trade-related counterfeiting.

The full details of the building of the model, methodology, sources used, and an assessment of the wider threat of physical counterfeiting are provided in the report *Measuring the Magnitude of Global Physical Counterfeiting* available on the GIPC's and U.S. Chamber of Commerce's website.

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

The first factor is a subset of the scores for the indicators within Category 7: Enforcement:

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

The third factor used is the rate of perceived corruption within an economy, as measured by Transparency International's Corruption Perceptions Index. This is based on the assumption that a strong relationship exists between corruption and counterfeiting, 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 wide range of sources. All sources used are publicly available and are freely available and accessible to all. The following is an outline of the different types of sources used.

Government

Sources from government branches and agencies include 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:

- Court cases and decisions
- Legal opinions written by judges
- Legal analysis and opinions written by legal practitioners

International Institutions and Third Parties

These sources include:

- Data, studies, and analysis from international organizations such as the OECD, WTO, WIPO, and others
- Publicly available reports, studies, and government submissions by industry organizations
- Reports from nongovernmental organizations and consumer organizations

Academic

Academic sources include:

- Academic journals, books, published manuscripts
- Legal journals

News

News sources include:

- Newspapers
- News websites
- Trade press

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

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

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

Indicators Explained

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

Category 1: Patent Rights and Limitations

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

1. **Patent term of protection**

Measured by the basic patent term offered in the TRIPS Agreement. This is a numerical indicator.

2. **Patentability requirements**

The extent to which patentability requirements are in line with international standards of novelty, inventive step, and industrial applicability.²³ 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 (CII)**

Measured by the extent to which primary and/or secondary legislation explicitly allows for the patentability of CII. This is a mixed indicator.

4. **Plant variety protection, term of protection**

Measured by the maximum term of protection being offered with the baseline term of protection being not less than 20 years (25 years for trees and vines) in accordance with the International Convention for the Protection of New Varieties of Plants.²⁴ This is a numerical indicator.

5. **Pharmaceutical-related patent enforcement and resolution mechanism**

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

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

Measured by the extent to which primary and/or secondary legislation on the use of compulsory licensing (on the basis of the essential facilities doctrine) and its application or enforcement is transparent and consistent with the following criteria: (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 on public health should not be for commercial purposes, such as for price negotiations or in support of domestic industries; and (4) adequate and well-defined recourse mechanisms should be in place for parties affected by the issuing of the license. This is a binary indicator.

7. Patent term restoration for pharmaceutical products

This indicator consists of two distinct variables: (1) the existence of a term of patent restoration for pharmaceutical products due to the prolonged research, development, and regulatory approval periods for such products and (2) the existence of any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. The available score of 0.75 for this indicator is allocated to the existing term of protection compared to the current baseline rate of five years' term restoration used in the United States, EU, and Japan. The remaining 0.25 is allocated based on an economy providing any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration including for industrial policy purposes. This indicator does not include other forms of patent term restoration that are granted based on prolonged examination periods, including for the granting of patents. This is a mixed indicator.

8. Membership of a Patent Prosecution Highway (PPH)

This indicator measures if an economy's relevant IP or patent office has joined international efforts toward streamlining and improving patent prosecution by membership of a PPH. Given the three main tracks of international PPH (PPH, Global Patent Prosecution Highway, and IP5 Patent Prosecution Highway), economies will be scored differently depending on their level of participation and membership of the different tracks. Economies that are members of either (or both) the Global Patent Prosecution Highway or IP5 Patent Prosecution Highway will receive a full score of 1.²⁵ Economies that are members of a PPH and have bilateral and multilateral agreements to this effect will receive a score of 0.5.

9. Patent opposition

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

Category 2:

Copyrights and Limitations

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

10. Copyright (and related rights) term of protection

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

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking)

Measured by the extent to which economies (1) have in place laws and procedures that provide necessary exclusive rights and (2) apply these laws to prevent, deter, and remedy online infringement of copyright and related rights. This is a mixed indicator.

12. Expeditious legal remedies disabling access to infringing content online

This indicator measures the existence and extent of an official national government administrative or judicial injunctive relief mechanism available to rightsholders to address online copyright infringement. Economies around the world have employed, and/or are considering employing, a range of different remedies to combat digital piracy with varying levels of success, including court proceedings for intellectual property infringement, injunctive relief, and criminal actions against bad actors, seeking to stem the proliferation of online pirated content. The mechanism should provide for the effective and timely disabling of access to websites that seem to exist solely to offer or make available infringing content online.

Such a mechanism should be based on a clear, transparent, expeditious, and standardized procedure and include due process protections. This is a mixed indicator.

13. Availability of frameworks that promote cooperative action against online piracy

Measured by the existence of clear standards for the limitation of liability for copyright and related rights infringement by ISPs that expeditiously remove infringing material upon obtaining knowledge of it, in the context of an overall system that does not unduly burden ISPs, promotes cooperation between them and rightsholders to address online piracy, and respects and protects users' rights. This is a mixed indicator.

14. Scope of limitations and exceptions to copyrights and related rights

Measured by the extent to which exceptions and limitations are consistent in text and in application with the three-step test originating in the Berne Convention (Berne three-step test).²⁶ The score for this indicator is evenly divided between legislation and application in the court system. This is a mixed indicator.

15. Technological protection measures (TPM) and digital rights management (DRM) legislation

Measured by the extent to which (1) economies have passed primary and/or secondary legislation relating to TPM and DRM and (2) this legislation is applied. This is a mixed indicator.

16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software

Measured by the extent to which (1) policies and guidelines are in place stipulating the use of only licensed proprietary software and (2) these policies and guidelines are applied. This is a mixed indicator.

Category 3:

Trademark Rights and Limitations

The indicators in this category relate to trademark protection, design rights, and related rights and limitations.

17. Trademarks term of protection (renewal periods)

Measured by the renewal term of protection offered, with the baseline term being 10 years as provided by the Singapore Treaty on the Law of Trademarks. This is a numerical indicator.

18. Protection of well-known marks

Measured by the extent to which existing laws and regulations and/or *de facto* practices allow for trademark protection through use of the mark, regardless whether the trademark owner registers the mark. This is a mixed indicator.

19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks

Measured by the extent to which economies (1) have in place laws and procedures that provide necessary causes of action to address violations of a trademark owner's rights (such as infringement of registered trademarks, unfair competition, false designation of origin, false advertising, dilution of famous trademarks, cybersquatting, and violation of rights associated with a corresponding trade dress), which create a likelihood of public confusion as to source, sponsorship, or affiliation and (2) apply these laws to prevent, deter, and remedy infringement of trademarks and related rights. This is a mixed indicator.

20. Availability of frameworks that promote action against online sale of counterfeit goods

Measured by the existence of clear rules and standards for the expeditious removal of trademark-infringing material by online service providers upon obtaining knowledge of the infringement, in the context of an overall system that does not unduly burden such providers, promotes cooperation between them and 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.²⁷

Category 4:

Design Rights and Limitations

The indicators in this category relate to design rights and related rights and limitations.

21. Industrial designs term of protection

Measured by the maximum term of protection offered (including renewable periods), with the baseline term being 25 years, which is the maximum term afforded in the European Union. This is a numerical indicator.

22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights

Measured by the extent to which economies (1) have in place laws and procedures that provide necessary exclusive rights (including making, marketing, trading, and use of an industrial design) and (2) apply these laws to prevent, deter, and remedy infringement of industrial design rights. This is a mixed indicator.

Category 5:

Trade Secrets and the Protection of Confidential Information

The indicators in this category relate to trade secrets, related rights, and limitations and the protection of confidential information.

23. Protection of trade secrets (civil remedies)

Measured by the existence of (1) legislation that offers protection for trade secrets or confidential business information and (2) the application of this legislation in the court or law enforcement system. This is a mixed indicator.

24. Protection of trade secrets (criminal sanctions)

Measured by the existence of (1) legislation that provides criminal sanctions for the misappropriation, improper acquisition, use, or disclosure of trade secrets or confidential business information and (2) the application of this legislation and effective access to these remedies. This is a mixed indicator.

25. Regulatory data protection term

Measured by the optimal desired term, which is the term of exclusivity used by the EU for new biopharmaceutical products containing new active ingredients, regardless of molecular size and/or complexity.²⁸ This is a numerical indicator.

Category 6:

Commercialization of IP Assets and Market Access

The indicators in this category seek to measure the extent to which a given national IP environment recognizes the value of IP as an asset and encourages the commercialization of IP regardless of its national origins.

26. Barriers to market access

The extent to which laws and regulations or *de facto* practices make access to an economy's market contingent on the sharing and/or disclosure of intellectual property and know-how with a local or domestic entity. This is measured by the extent to which (1) existing laws and procedures make market access contingent on the sharing/disclosure of intellectual property and know-how and (2) the application of such laws or, in the absence of such laws, the existence of *de facto* practices and standards achieve a similar effect. This is a mixed indicator.

27. Barriers to technology transfer

The extent to which laws and regulations or *de facto* practices act as barriers to technology transfer and commercialization activities of publicly funded and supported research. This is a mixed indicator.

28. Registration and disclosure requirements of licensing deals

The extent to which licensing agreements must be registered and/or disclosed with relevant authorities to carry legal effect. This is a mixed indicator.

29. Direct government intervention in setting licensing terms

The extent to which relevant government authorities directly intervene and set licensing terms between licensee and licensor.²⁹

This can be done through, for example, governmental preapproval for any licensing agreement between two parties or government intervention in the setting of licensing terms, including royalty rates. This is a mixed indicator.

30. IP as an economic asset

The extent to which relevant institutions (including, for example, public and private institutions for higher education as well as national IP offices) in an economy are actively engaged in capacity building and training on how to use IP as a commercial and economic asset. Examples of capacity building include academic (university or tertiary level) courses on the commercialization and use of IP as an economic and financial asset and the extent to which national IP offices host and/or engage in similar training programs. This is a mixed indicator.

31. Tax incentives for the creation of IP assets

The extent to which governments provide tax incentives for the creation and use of IP assets. This indicator consists of three layers corresponding to an equal share of the available score:

Layer 1:

Consists of economies offering general tax incentives for the creation of IP assets through, for example, general R&D incentives and/or tax credits.

Layer 2:

Incentives are targeted specifically at the creation of IP through, for example, innovation and patent boxes.

Layer 3:

The extent to which these incentives are not hampered by onerous localization and/or administrative requirements linked to the availability and use of the tax 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

Measured by estimated rates of general trade-related physical counterfeiting using the U.S. Chamber's Global Measure of Physical Counterfeiting. This is a numerical indicator.

33. Software piracy rates

Measured by rates of software piracy. This is a numerical indicator.

34. Civil and procedural remedies

Measured by (1) the existence of civil and procedural remedies, including injunctions, damages for injuries, and destruction of infringing and counterfeit goods and (2) their effective application. This indicator also reflects administrative enforcement measures where applicable. This is a mixed indicator.

35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement

This is a mixed indicator.

36. Criminal standards, including minimum imprisonment and minimum fines

Measured by the extent to which (1) actual legislation is in place and (2) it is applied (i.e., where reliable source material is available, the actual level of prosecution and penalties applied). This is a mixed indicator.

37. Effective border measures

Measured by the extent to which border guards have the *ex officio* authority to seize suspected counterfeit and pirated goods, including goods in-transit, without complaint from the rightsholder. This is a mixed indicator.

38. Transparency and public reporting by customs authorities of trade-related IP infringement

—The extent to which customs authorities in an economy publish statistics and data on trade-related IP infringement. This indicator measures (1) the extent to which data is published on a regular and systematic basis and (2) the level of detail of this data. This is a mixed indicator.

Category 8:

Systemic Efficiency

The indicators in this category seek to measure how a national IP system actually works.

39. Coordination of IP rights enforcement efforts

The existence of coordinated efforts of IP rights enforcement at the national government level. This indicator measures the extent to which a national government institution or formalized structure is in place that provides cross-governmental coordination to national IP enforcement efforts. This is a mixed indicator.

40. Consultation with stakeholders during IP policy formation

This indicator measures the extent to which stakeholders (public, private, national, and international) have the right and opportunity to contribute comments and submissions on proposed changes to IP laws and regulations made by a given economy's national government. This is a mixed indicator.

41. Educational campaigns and awareness raising

This indicator measures (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 and national economic impact analysis

The extent to which the relevant authorities in a given economy seek to map and measure the economic impact and importance of IP-intensive industries to their national economies. Economies are scored based on (1) 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 is systematic and occurs on a periodic and recurring basis. This is a mixed indicator.

Category 9:

Incentives for Cutting-Edge Innovation

The indicators in this category relate to special, sector-specific, IP-based incentives for innovation.

44. Special market exclusivity incentives for orphan³⁰ medicinal product development

Measured by the existence of a statutory defined market exclusivity incentive and period of protection for the development of new products and treatments for rare diseases.³¹ This is a binary indicator.

45. Special market exclusivity incentives for orphan medicinal product development, term of protection

Measured by a baseline term of protection of 10 years.³² This is a numerical indicator.

46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development

Measured by the extent to which rightsholders can effectively make use of any existing market exclusivity incentives for orphan medicinal product development without any undue restrictions. Potential restrictions include, but are not limited to, the wholesale withdrawal or shortening of any existing term of protection based on changed circumstances outside of the rightsholder's control; the conditioning of the granting of market exclusivity on future therapeutic outcomes; the health system cost of an orphan medicinal product; or any other potential exemptions, waivers, or similar carve-outs on the full and effective use of the full term of protection. This is a mixed indicator.

Category 10:

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 allow for only accession, that is, membership is either conferred or it is not. The following treaties each make up one indicator with some indicators consisting of two treaties:

47. 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.

48. 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.

49. 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.

50. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991

This is a binary indicator.

51. Membership of the Convention on Cybercrime, 2001

This is a mixed indicator.

52. The Hague Agreement Concerning the International Registration of Industrial Designs

This is a mixed indicator.³³

53. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices

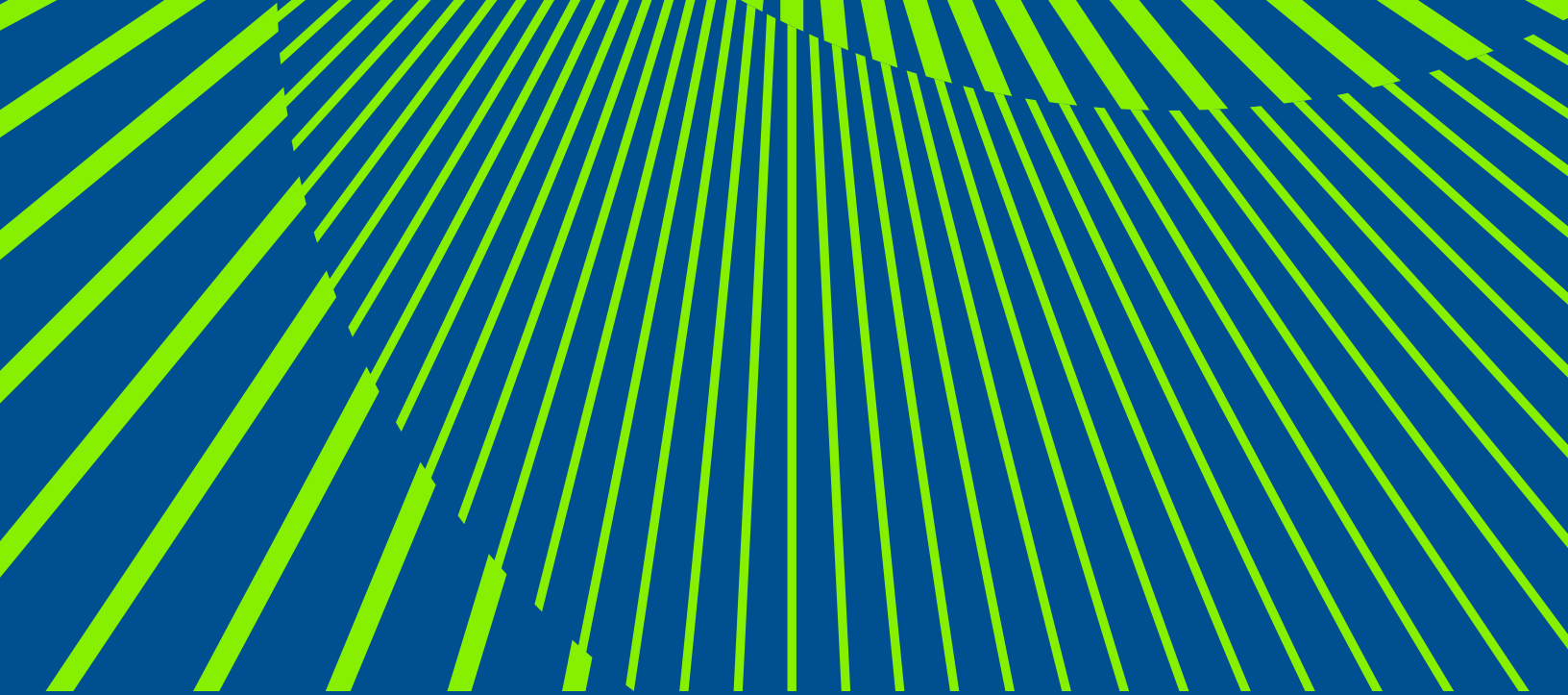
This is a mixed indicator.

Endnotes

1. Note that the World Bank's geographic classifications have been somewhat amalgamated. Middle East and North Africa have been combined with Sub-Saharan Africa, and East Asia and Pacific have been combined with South Asia. See World Bank (2024), "Country and Lending Groups."
2. J. Hill (2024), "30 Years of TRIPS High-Level Dialogue: Charting the Way Ahead, Keynote Speech, Deputy Director-General Johanna Hill," April 25, 2024, WTO, Geneva, Switzerland.
3. WIPO statistics database, accessed December 2024.
4. Ibid.
5. Ibid.
6. Ibid.
7. Park, W.G., and Lippoldt, D. (2003), *The Impact of Trade-Related Intellectual Property Rights on Trade and Foreign Direct Investment in Developing Countries*, OECD publishing.
8. Cavazos, R., et al. (2010), *Policy Complements to the Strengthening of IPRS in Developing Countries*, OECD Trade Policy Working Papers, No. 104, OECD Publishing.
9. World Bank databank. Charges for the use of intellectual property, payments, and receipts (BoP, current US\$)
10. USPTO (2022), *Intellectual Property and the U.S. Economy: Third Edition*, USPTO, Washington, D.C., p. iii.
11. EUPIO & EPO (2019), *IPR-Intensive Industries and Economic Performance in the European Union*, September 2019, pp. 70–2.
12. Korea Institute of Intellectual Property (2018), *Analysis on Economic Contribution of IP-Intensive Industries*, Korea IP Office.
13. WTO (2022), "Ministerial Decision on the TRIPS Agreement," June 17, 2022, Ministerial Conference, Twelfth Session Geneva, Switzerland.
14. Communication from Colombia, "Review of the Implementation of the TRIPS Agreement: Article 71.1," April 15, 2024, Council for Trade-Related Aspects of Intellectual Property Rights, WTO, Geneva, Switzerland.
15. WHO (2024), "Proposal for the WHO Pandemic Agreement, Ninth Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response, November 2024.
16. CNN (2021). "African Countries Have Struggled to Secure Enough COVID-19 Vaccines. So Why Are Thousands of Doses Going to Waste?" May 19, 2021.

17. PhRMA (2024), *2024 PhRMA Annual Membership Survey*, p. 3, Washington, D.C.
18. PhRMA (2024), *The Economic Impact of the U.S. Biopharmaceutical Industry: 2022 National and State Estimates*, p. 1, May 2024, Washington, D.C.
19. Ibid.
20. Many economies have a copyright term that is measured by the life of an author plus an additional number of years. Given the difficulties in measuring and estimating an average life of an author, and thus an average term of protection, this indicator uses only minimum terms that 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.
21. These difficulties of measuring piracy are particularly pronounced for online piracy. No comprehensive studies 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 \$30–75 billion in 2008 and forecast to be \$80–240 billion in 2015. Furthermore, this report found that online piracy in the United States made up a large share of this digital piracy figure. For 2008, the report estimated that \$7 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 have 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).
22. OECD (2016), *Trade in Counterfeit and Pirated Goods*, pp.110-1;
23. 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.”
24. Act of 1991, International Convention for the Protection of New Varieties of Plants, Article 19, Duration of the Breeder’s Right
25. 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.
26. 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).

27. 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 at pages.ebay.com/vero/intro/index.html.
28. Half (0.5) of the available score is based on the term available for biologics or large molecule compounds. If a country's relevant legislation or regulation, either *de jure* or *de facto*, does not cover such compounds, then the maximum score that can be achieved in this indicator is 0.5. The baseline numerical term used is that by the EU of 10 years (8+2) of marketing exclusivity.
29. This indicator is not concerned with commercial litigation brought by private parties and settled by an independent judiciary.
30. Orphan medicines are niche treatments for diseases with small patient populations and commercial markets. These rare diseases make up a wide range of complex conditions associated with chronic, progressive, degenerative, and/or life-threatening symptoms that affect a relatively small portion of an economy or a legal jurisdiction's population.
31. The exact legal definition of what constitutes "rare" can vary from economy to economy. For example, in the EU, a disease has historically been defined as rare if it affects up to 5 of 10,000 people. In the United States, the statutory definition has been if the disease in question affects fewer than 200,000 persons. Other Index economies, such as Japan, Australia, Taiwan and South Korea, use slightly different legal definitions.
32. This indicator uses the EU Regulation on Orphan Medicinal Products (Regulation [EC] No. 141/2000) as a baseline 10-year term of orphan drug marketing exclusivity. (The Orphan Regulation, has been under review for an extended period as part of a larger initiative to reform the EU's pharmaceutical legal framework. At the time of research, no new finalized regulation had been enacted. Under all published proposals, the current term of protection would be restricted or reduced. Should the legal term of protection in the EU be materially altered, this indicator would continue to use and refer to the old term of protection as its baseline.) The level of protection and strength of exclusivity of orphan drug marketing exclusivity can vary. As originally defined in the United States in the 1980s, and subsequently in the EU, orphan drug market exclusivity ensures that regulators will not approve applications for generic products or secondary inventions based on the same active substance and same indications, even if the second application is based on independent data. This is critical when comparing the exclusivity provided by orphan drug designation versus, for example, standard forms of regulatory data protection (data exclusivity). Protection under data exclusivity does not preclude the submission of independent clinical data in support for a market approval. Instead, regulatory data protection provides protection only during the specified term against the reliance by a follow-on applicant on the submitted clinical test data. Index economies in which the orphan drug market exclusivity is akin to an extended form of data exclusivity can score a maximum of 0.5 (half of the available score) for this indicator if offering a full 10-year length of protection matching this indicator's baseline term.
33. 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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