



U.S. Chamber of Commerce  
Global Innovation  
Policy Center

2022 International IP Index

# Compete for Tomorrow

Tenth Edition





U.S. Chamber of Commerce

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

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



Innovation | Technology Transfer | Intellectual Property | Market Access

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

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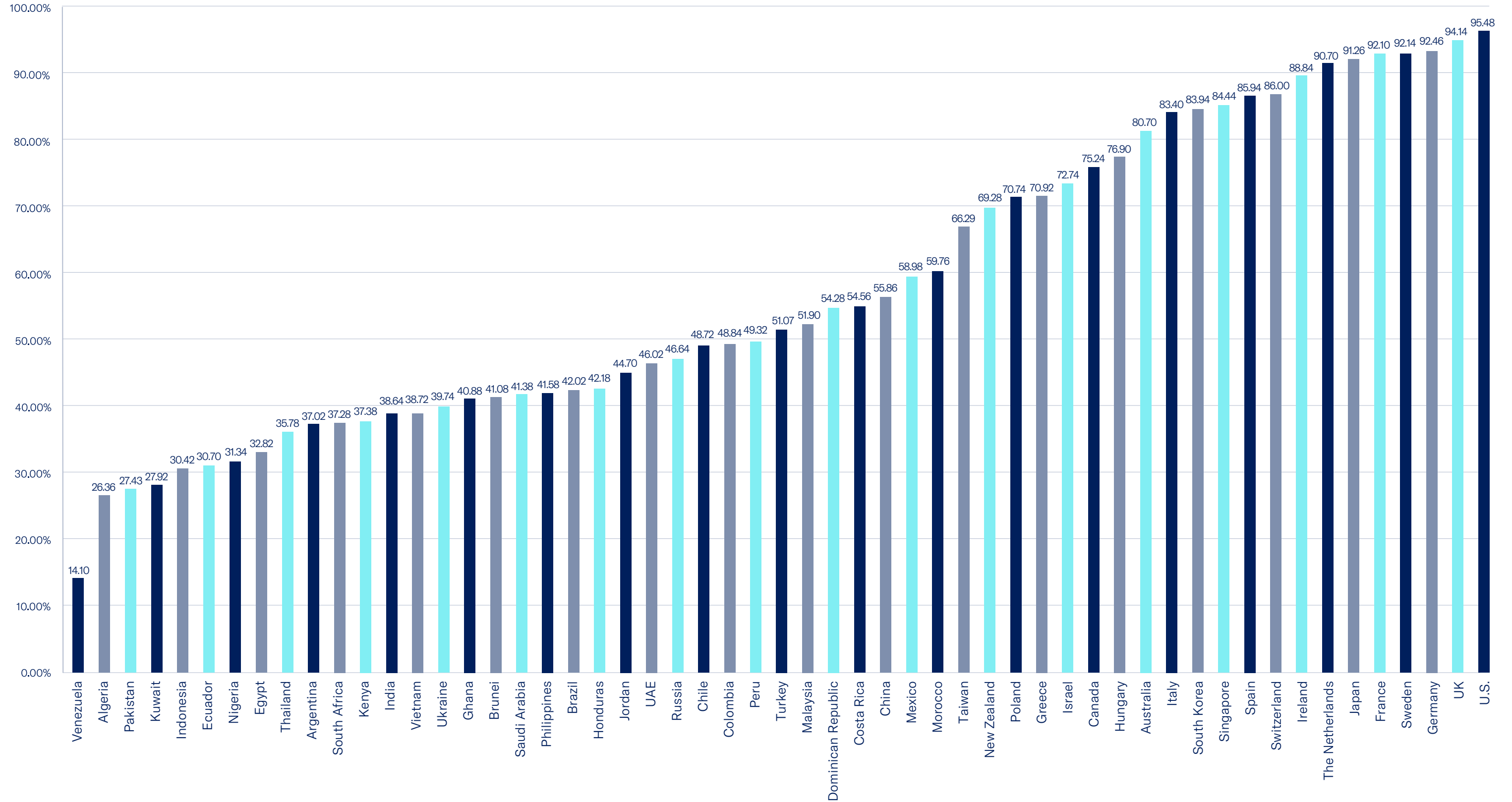
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# U.S. Chamber International IP Index 2022, Overall Scores, % Available Score



# Foreword

If ingenuity is the door to the future, competition is the key. Innovators are constantly competing to deliver the best, brightest tomorrow. They're racing to create the solutions we need to address critical global challenges, like public health, cultural development, environmental sustainability, and economic disparities.

Public policy can spur innovators along - or it can stop them altogether. As the 2022 U.S. Chamber International IP Index (Index) makes clear, effective intellectual property (IP) systems encourage innovators and creators to embrace new ideas, take risks, and drive change.

On the other hand, weak IP systems undermine innovation and creativity and, perhaps more importantly, access to the latest technologies, medicines, and creative content around the world. Dangerous proposals to waive IP commitments threaten to make this a reality.

For ten years, the Index has helped economies better understand their unique IP systems, so they can make improvements and drive progress. Our decade's worth of data shows that the global IP system has grown stronger as a result.

But, it's not finished growing.

To build upon the last decade of momentum, governments must make a choice: they can embrace dangerous proposals to roll back international and domestic baseline commitments, shun innovation and creativity, and deprive their economies of the many benefits strong IP ecosystems provide.

Or they can make a conscious policy decision to invest in their IP framework, until every individual with an idea has a fair shot at the competition for leadership, success and, ultimately, tomorrow.

The Index illustrates the choice is clear. IP protection is the key to a stronger, brighter tomorrow.



— **David Hirschmann**  
President & CEO,  
Global Innovation Policy Center

# Executive Summary

In 2021, COVID-19 continued to dominate our lives, jeopardize our health, and threaten to undermine our fragile economic recovery. While uncertainty around the pandemic persisted, intellectual property (IP) drove the development of innovative vaccines, therapeutics, and technologies that kept us safe, connected, and productive throughout the pandemic.

IP-driven innovation and creativity allowed the global community not only to survive—but to thrive—as we charted a course to the new normal. An effective IP system will be critical to ensuring

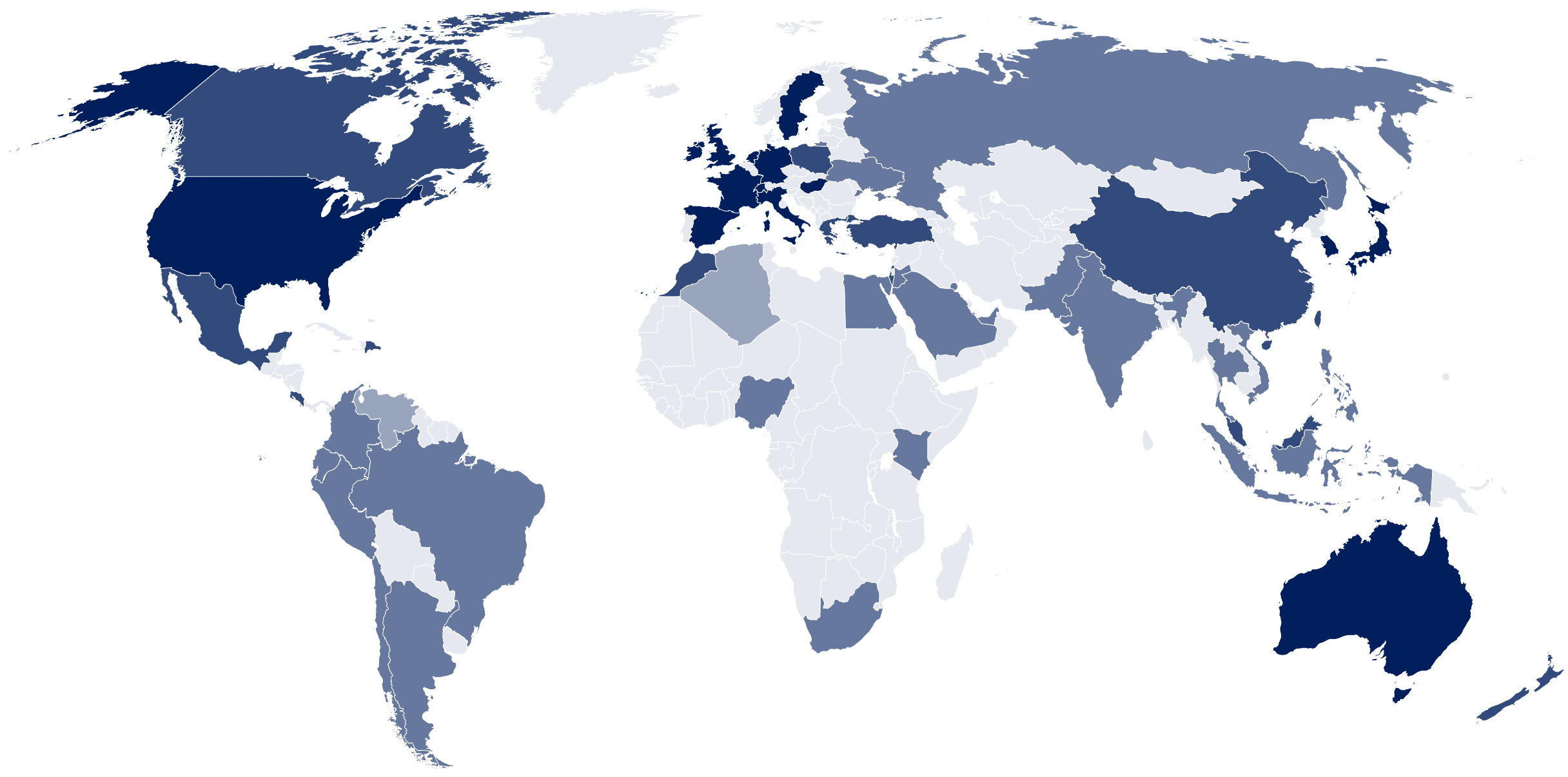
the global community can continue to deliver the next generation of innovative and creative goods and services to compete for a better tomorrow.

Now in its tenth edition, the International IP Index benchmarks the IP framework in 55 global economies across 50 unique indicators. In 2021, Ghana and Honduras were added to the Index. The global pandemic clearly illustrated that innovation and creativity occur in an ecosystem, and the Index sheds light on the health of that ecosystem in global markets.

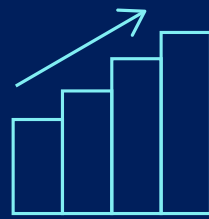


# Geographic Coverage

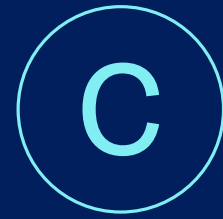
- |                    |                      |
|--------------------|----------------------|
| Algeria            | Malaysia             |
| Argentina          | Mexico               |
| Australia          | Morocco              |
| Brazil             | The Netherlands      |
| Brunei             |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



# Key Findings



Both in 2021 and over the last decade, the global IP environment improved, though challenges remain in many global markets.



Historically, many Index economies have struggled to provide adequate copyright protection as the growth and scale of online piracy increased over the last decade. However, new tools to combat IP infringement online helped strengthen protection for IP owners.



Conversely, enforcement against physical IP-infringing goods has failed to keep pace with the increase in the volume of international trade in counterfeits over the last 10 years.



IP-intensive goods and services were critical to the global response to COVID-19.



Despite the critical role IP has played in response to the pandemic, some members of the World Trade Organization (WTO) have continued to push a proposal to “waive” international IP commitments.

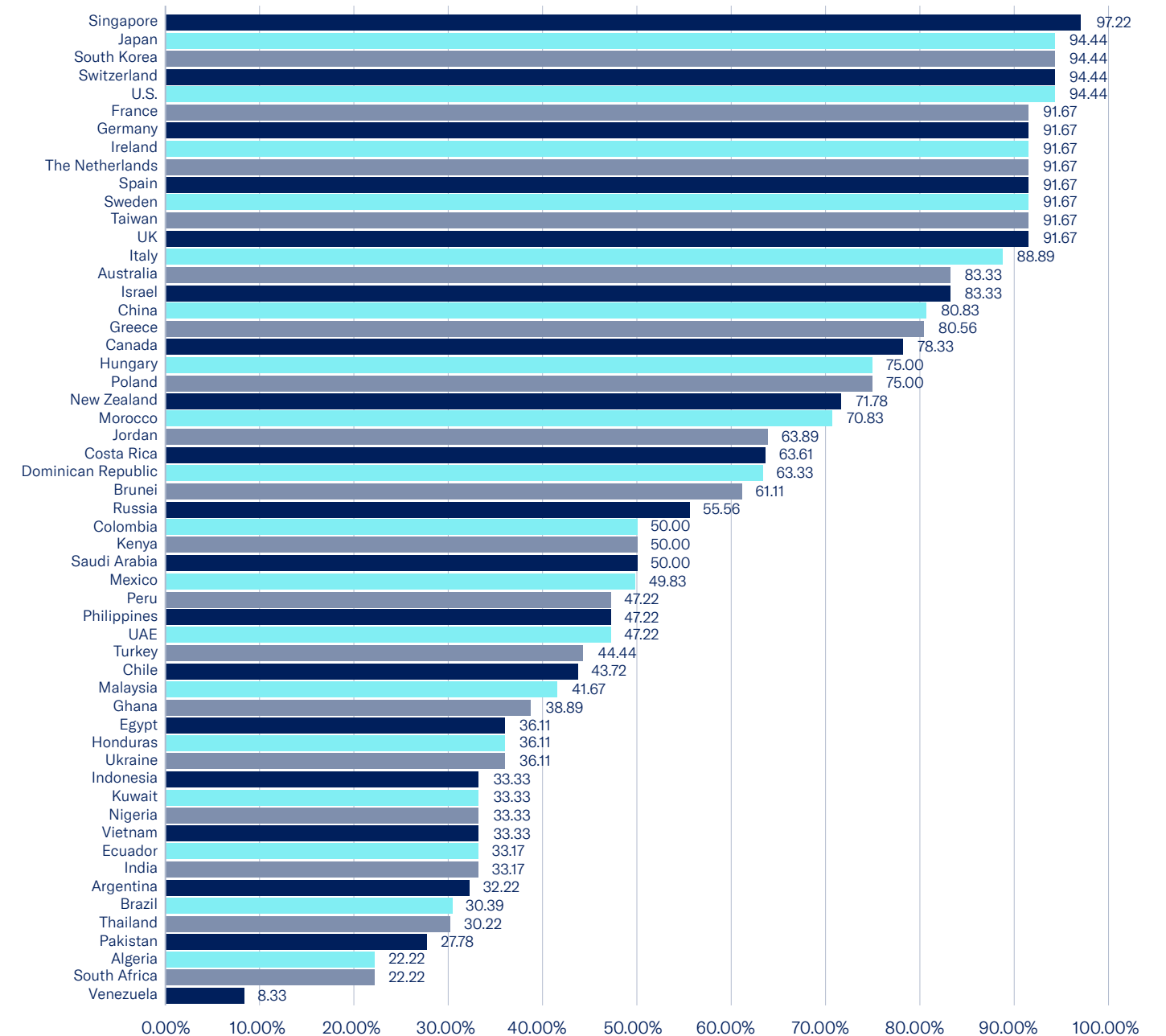
- Out of the 53 economies included in both the ninth and tenth editions, 45 economies saw a net improvement in their scores. **United Arab Emirates (UAE), Nigeria, and Peru** had the largest improvements in score at 4.04%, 3.91%, and 2.76%, respectively.
- Since the inaugural edition of the IP Index, the average score of economies has increased by 1.50%—from 55.72% in 2012 to 57.22% in 2022. The improvement was most pronounced in the patents and international treaties categories, signaling a growing understanding of ways patents drive innovation and the value of global harmonization on IP standards.
- However, the indicators included in the Index represent a gold standard for the protection and enforcement of IP rights. The global average remains less than 60%, illustrating there is still significant room to improve the framework for innovation and creativity in global markets.
- Economies of all levels of development—including the **EU, UK, India, Singapore, Russia, and India**—have utilized injunctive-style relief to disable access to infringing content.
- The use of injunctive-style relief has resulted in a real decrease in piracy. For example, in **Sweden**, survey results show that the number of respondents accessing copyright-infringing content fell from 21% to 14% following the use of these new enforcement tools.
- Over the last five years, the average score on this category has improved from 46.44% to 49.57%, an increase of 3.13%.
- In 2021, studies suggested that aggregated trade in physical counterfeit goods was valued at just under \$500 billion (USD) or 2.5% of global trade.
- Only 27% of 55 sampled economies provide customs officials with *ex officio* authority to seize suspected goods.
- Additionally, 29% of the 55 economies do not publish any statistics on actions taken by their customs authorities with respect to suspected IP-infringing goods.
- The vaccines, therapeutics, and technologies that have led the global community through the pandemic are the fruit of a pre-existing innovation ecosystem that relies on IP rights to enable allocation of resources, formation of partnerships, and transfer of technology on commercial terms.
- Effective IP rights facilitated hundreds of voluntary licensing agreements that allowed the rapid scale-up of global manufacturing. Data indicates that by June 2022, global vaccine manufacturing capacity will reach 24 billion doses.
- This proposal (if agreed and implemented) would waive many of the international IP commitments in the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, which has never been fully or faithfully implemented by most WTO member countries.
- Any waiver of IP rights will impede ongoing and successful efforts to license and scale global production of safe and effective COVID-19 therapies and vaccines. As of January 2022, there were nearly 330 voluntary partnerships and collaborations among manufacturers facilitating the production of billions of doses of vaccines, and over 110 voluntary partnerships facilitating production of therapeutics, all supported by the contractual licensing of IP rights.
- Any move to roll back IP rules or their enforcement would inject uncertainty at an already challenging time, as well as impede ongoing and highly successful efforts to license and scale global production and distribution of safe and effective vaccines.



Category-by-Category  
**Patents**

- 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 on the category is 59.92%, which is the third highest scoring category on the Index.
- While high-income economies scored well on the patent-related indicators, there continues to be a degree of uncertainty about the availability of certain patent rights.
  - » In the **United States**, uncertainty persists regarding patentable subject matter and patent nullity proceeding through the Patent Trial and Appeals Board (PTAB).
  - » In the **EU** and **UK**, there continues to be a high degree of uncertainty regarding the availability of patent term restoration as the supplementary protection certificate (SPC) export waiver exemption remains in force in all EU Member States (and the UK).
  - » In 2021, **Israel** similarly proposed new restrictions on biopharmaceutical patent term restoration through draft amendments to the Patent Law.
- In emerging markets, there was mixed progress in the patent indicators.
  - » While **Brazil** eliminated the prior consent requirement in the patent review process, the Brazilian Supreme Court revoked Article 40 of the Industrial Property Law that provides a 10-year term of patent protection.
  - » In **Russia**, new amendments to the Civil Code Part IV introduced new patentability restrictions and provided further powers to override granted rights related to patents, utility models, and industrial designs.

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





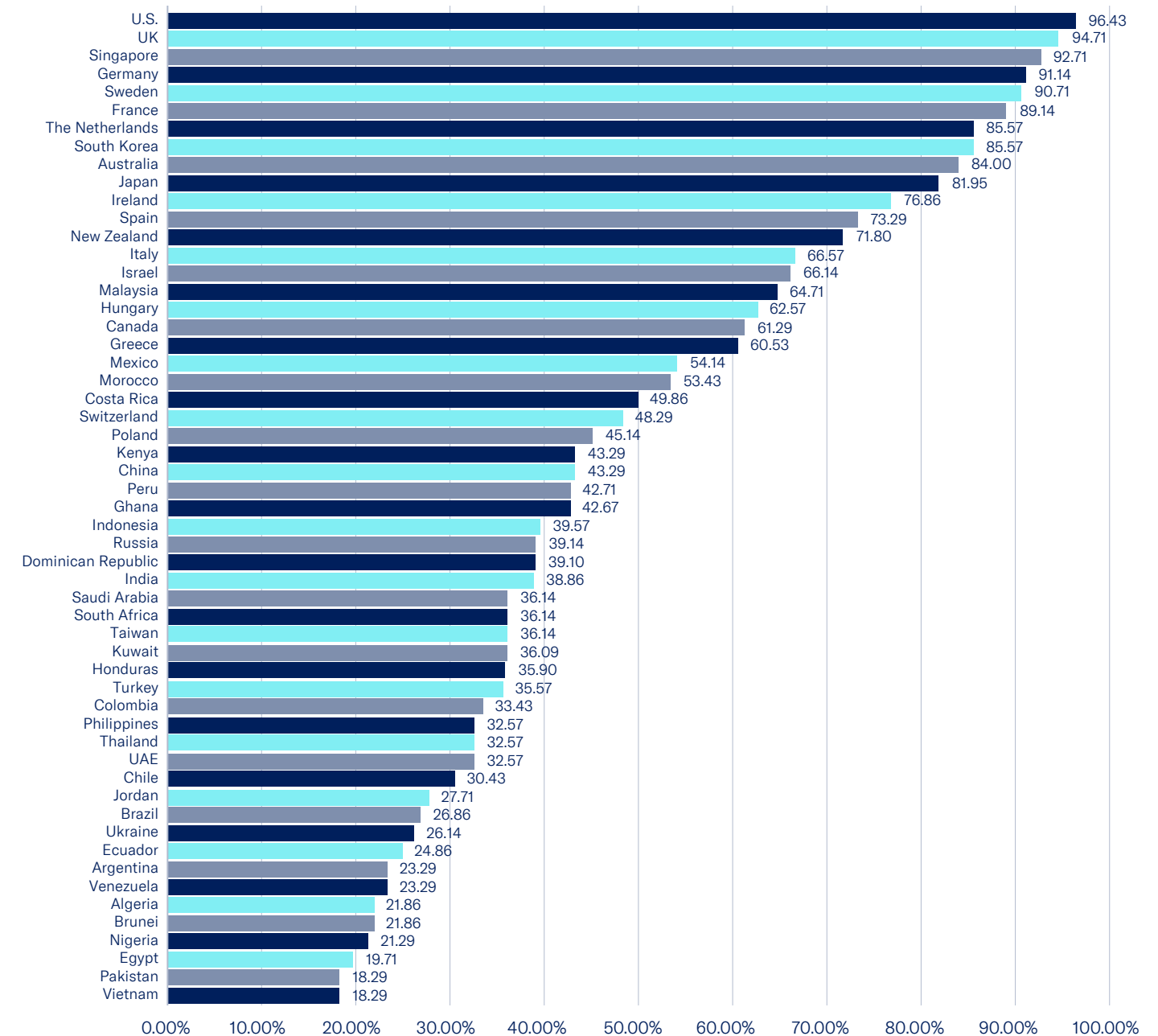


Category-by-Category

# Copyright

- Regardless of income level, most economies in the Index have struggled to safeguard copyrighted and branded content online. While the majority of economies scored less than 50% on this category, there were continued positive developments to combat online infringement in 2021.
- Although rates of online piracy, signal piracy, and copyright infringement remain high in Latin America and Southeast Asia, a number of economies strengthened enforcement against copyright-infringing material online.
  - » The **Colombian** and **Peruvian** governments ordered Internet Service Providers (ISPs) to disable access to copyright-infringing material online in 2021. In **Brazil**, “Operation 404 Against Piracy” took coordinated action to shut down torrent sites and seize suspected copyright-infringing equipment and goods.
  - » In the **Philippines**, the national IP authority launched an enhanced online enforcement program to address the growing presence of counterfeit and pirated goods online. Likewise, in **Malaysia**, the Intellectual Property High Court held that the sale, promotion, or dissemination of set-top boxes constituted copyright infringement.

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

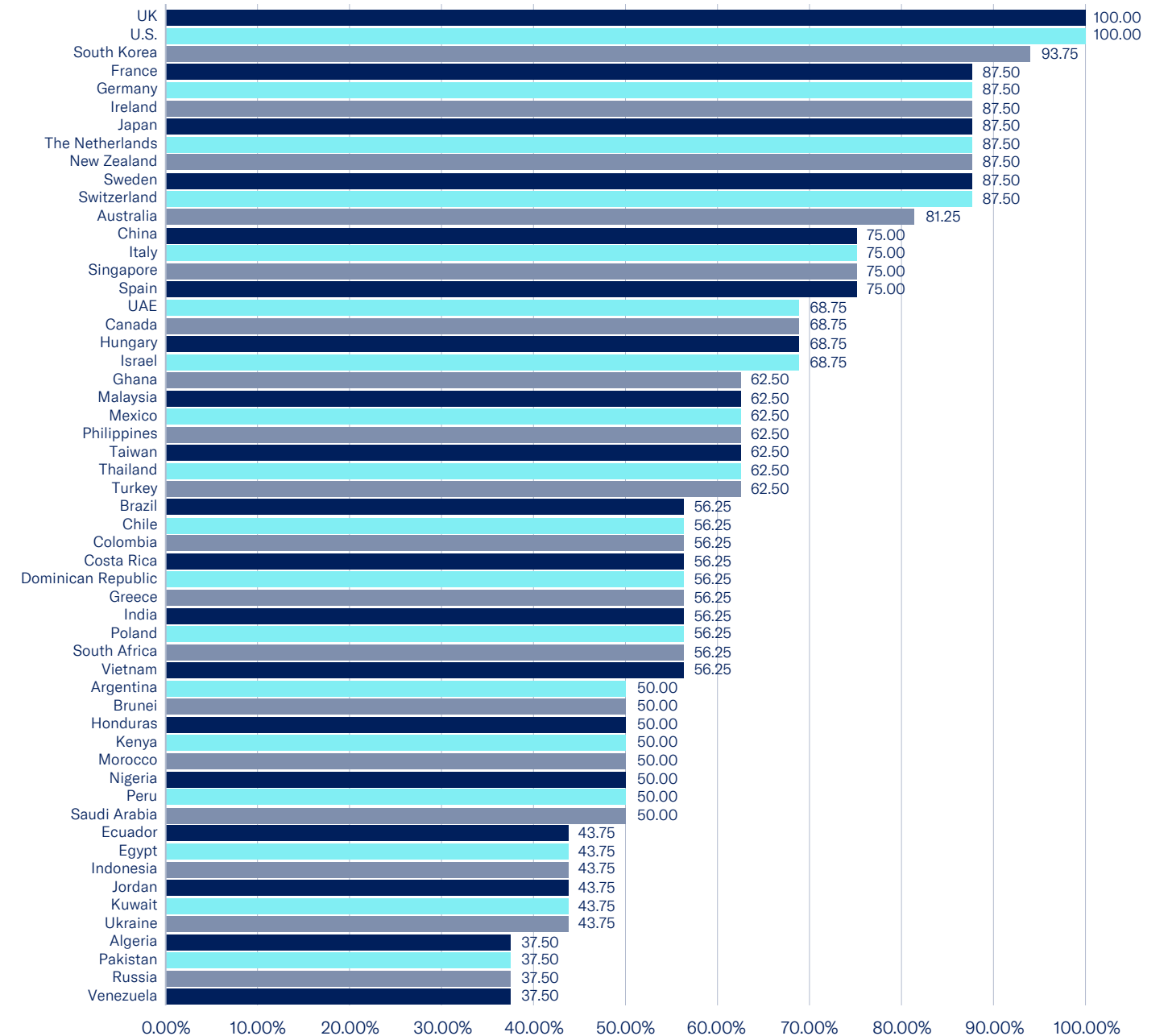




# Trademarks

- Most economies sampled in the Index offer basic forms of trademark protection. Only ten of the 55 sampled economies failed to score 50% or more on this category. Overall, the average score on this category was 62.84%.
- While many economies lack the appropriate resources, technology, or mechanisms to combat the increased sale of counterfeit goods online, there were a number of positive developments in Southeast Asia and the Middle East.
  - » In **Thailand**, both the government and courts ordered ISPs to disable access to websites with trademark-infringing content.
  - » In the **Philippines**, the national IP office (IPOP HL) launched new partnerships to combat trademark infringement online, while the National Bureau of Investigation led a physical raid to seize USD 1.8 million of counterfeit goods.
  - » In **the United Arab Emirates (UAE)**, a new trademark law eliminates registration requirements for trademark licensing agreements, increases potential damages for trademark infringement, clarifies customs officials' authority to take *ex officio* action against suspected goods, and improves protection of well-known marks.

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



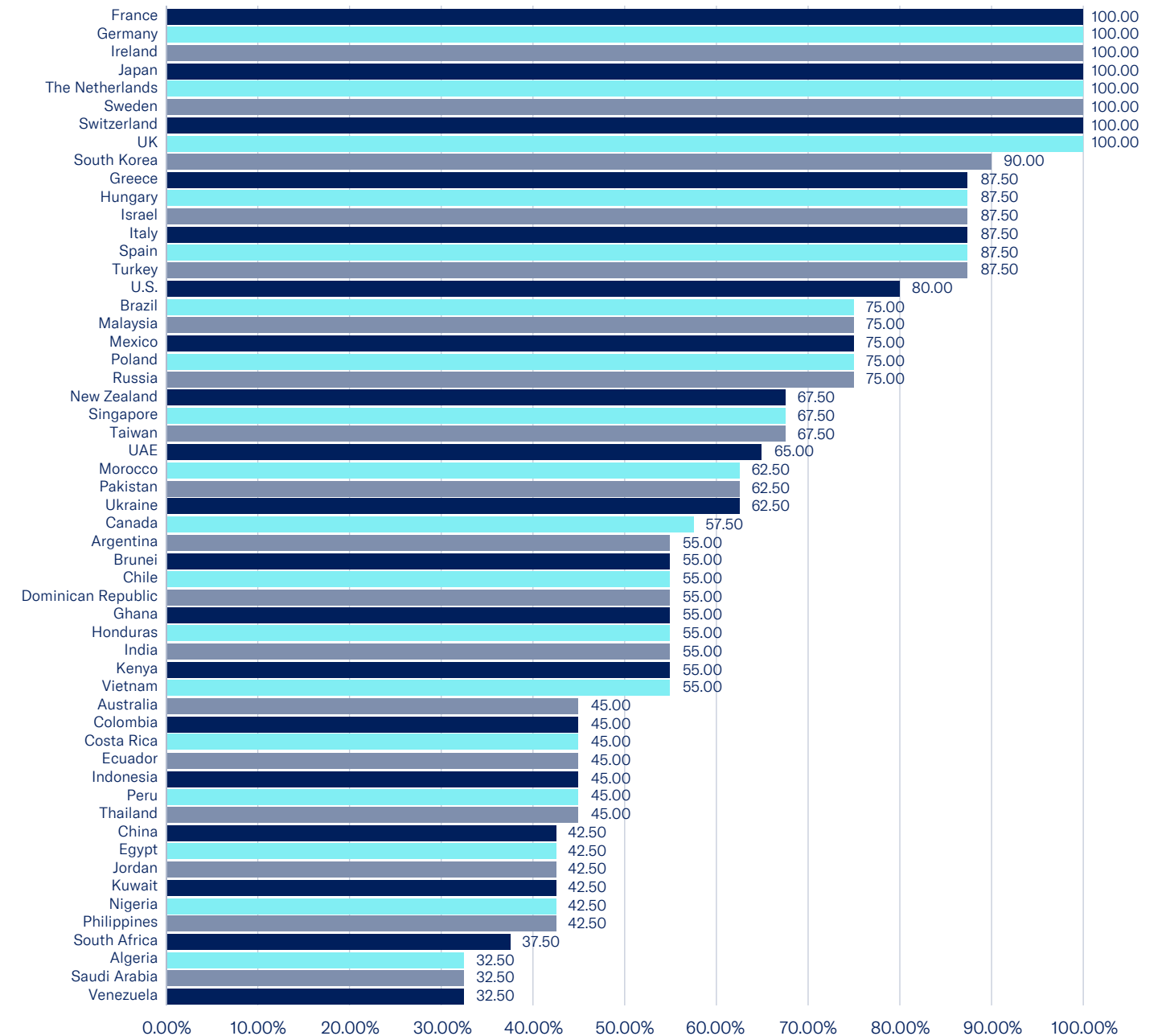


Category-by-Category

# Design Rights

- Most economies included in the Index have some form of statutory law defining design rights and a term of protection for registered design rights. The average score on this category was 65.14%.
- Many economies are increasingly recognizing the importance of design rights to their national economy and reforming relevant laws and regulations accordingly.
  - » In **Chile**, the National Congress extended the term of protection for design rights to 15 years.
  - » In **UAE**, the new industrial property law extended the term of protection for design rights to 20 years.

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

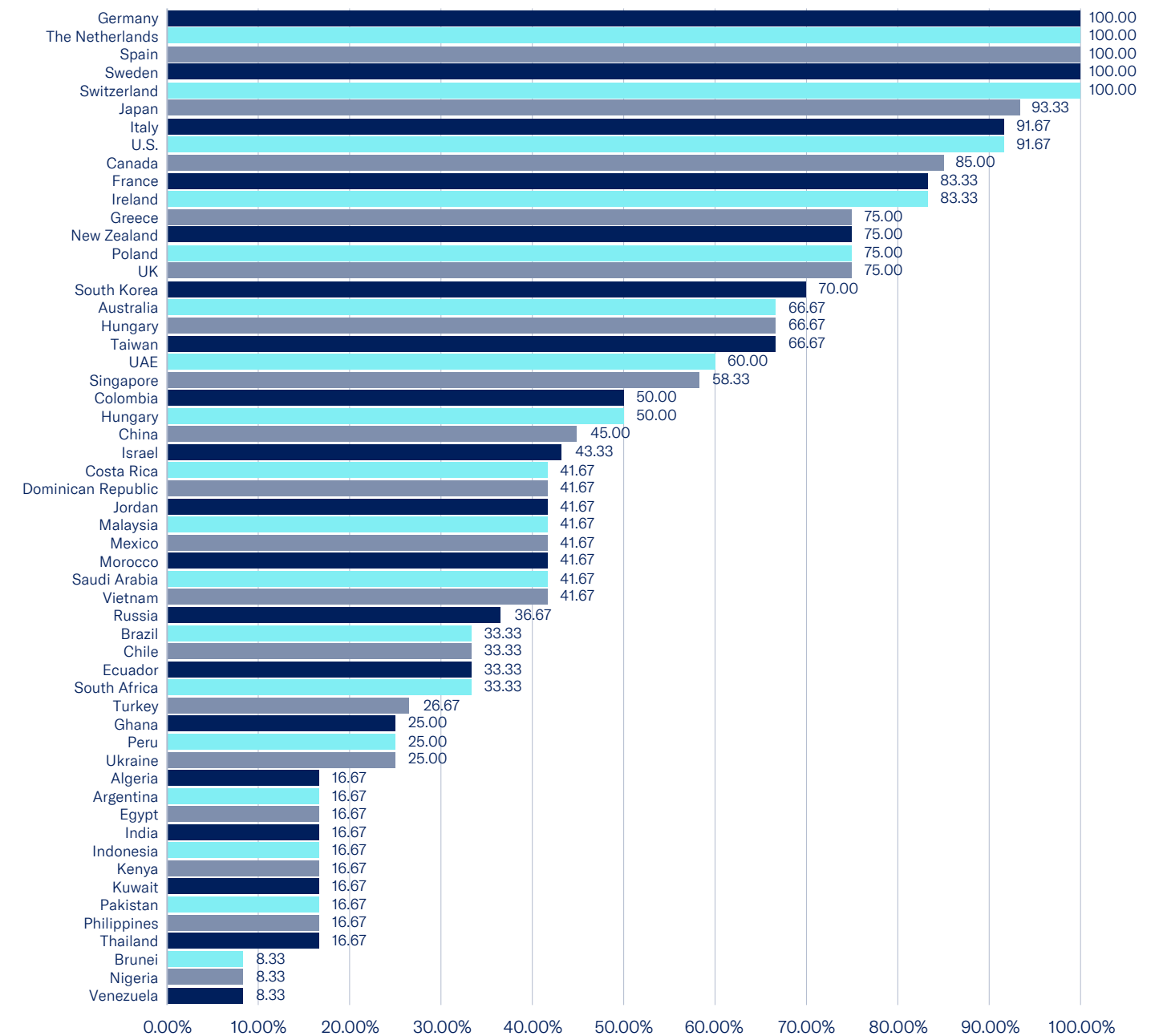




# Trade Secrets

- Only 23 of the 55 economies included in the Index achieved a score of 50% or more on this category. The average score on this category is the weakest on the Index at 49.12%.
- While some economies in Latin America provide a term of regulatory data protection (RDP), the governments also limit the availability of the protection through conditions or carve-outs.
  - » In **Honduras**—a new Index economy in 2022—the five-year term of RDP is contingent upon marketing the biopharmaceutical product in Honduras.
  - » Likewise, in **Ecuador**, implementing regulations to 2016 *Código Ingenios* legislation include similar carve-outs.
- Despite the absence of trade secrets protection in many economies, some emerging markets, including **South Africa**, passed legislation to enhance protection. The Cyber Crime Act 2020 provides a clear avenue for the criminal prosecution of misappropriation and illicit accessing of trade secrets and confidential information.

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



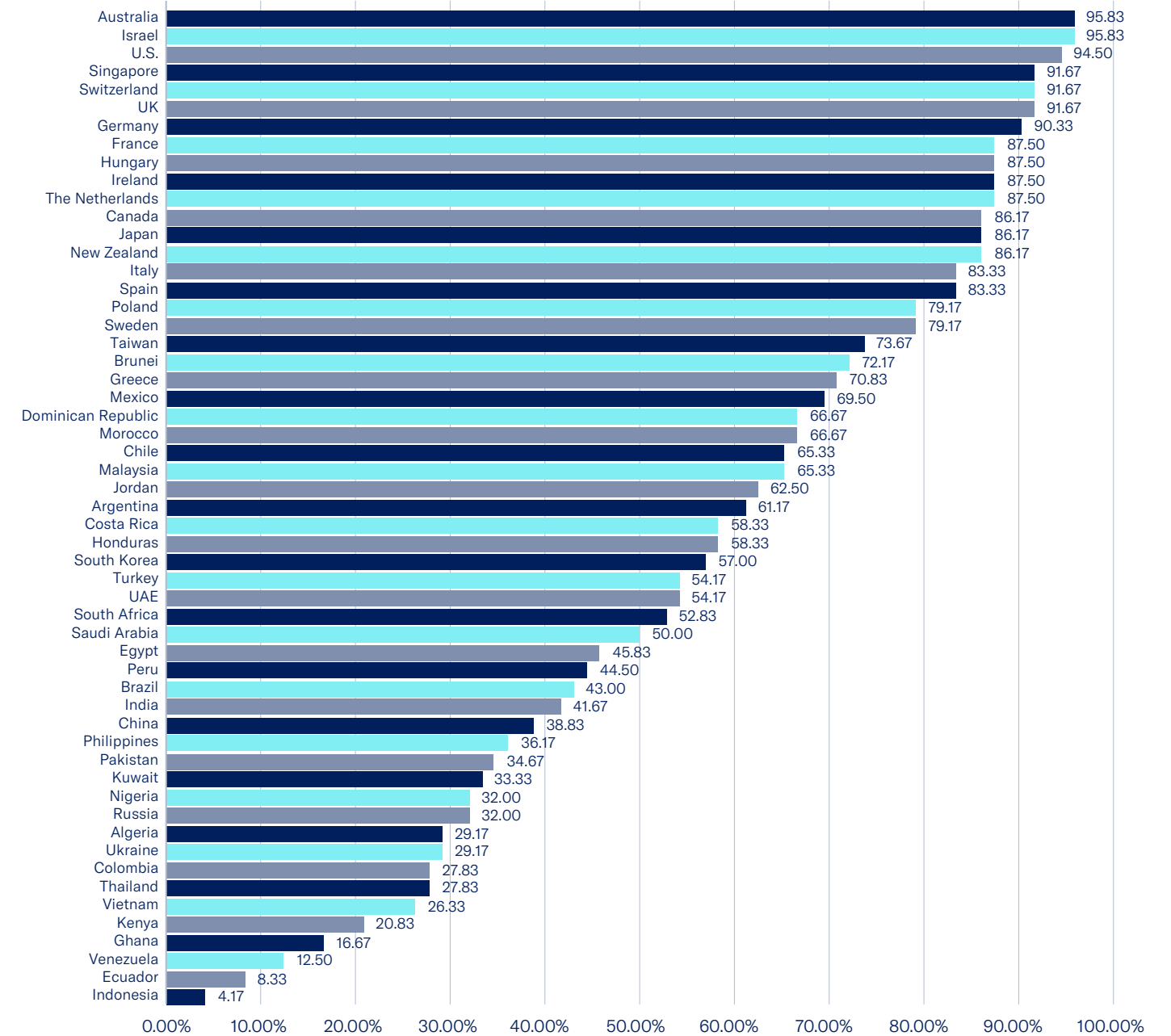


Category-by-Category

# Commercialization of IP Assets

- Many of the economies benchmarked in the Index are introducing policies that make it more difficult to access their respective markets or commercialize IP assets. Of the 55 sampled economies, 20 failed to achieve a score of 50% or more, with a full 13 scoring 33.33% or less on the category. The average score on this category was 58.62%.
- IP rightsholders continue to face a myriad of barriers to market access in economies around the world.
  - » In **Kenya**, draft regulations outline a range of localization requirements where data processing must be a carrier in Kenya.
  - » Similarly, in **Turkey**, the Parliament passed amendments requiring social media providers to store data locally in Turkey.
- However, countries of varying levels of development took steps to strengthen the framework for commercialization of IP assets.
  - » In **Japan**, the government released a new guide to improve the framework for licensing standard essential patents.
  - » In **Jordan**, the government launched a series of programs to improve the technology transfer and commercialization environment through the creation of technology incubators and partnerships with local non-governmental organizations and the private sector.

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



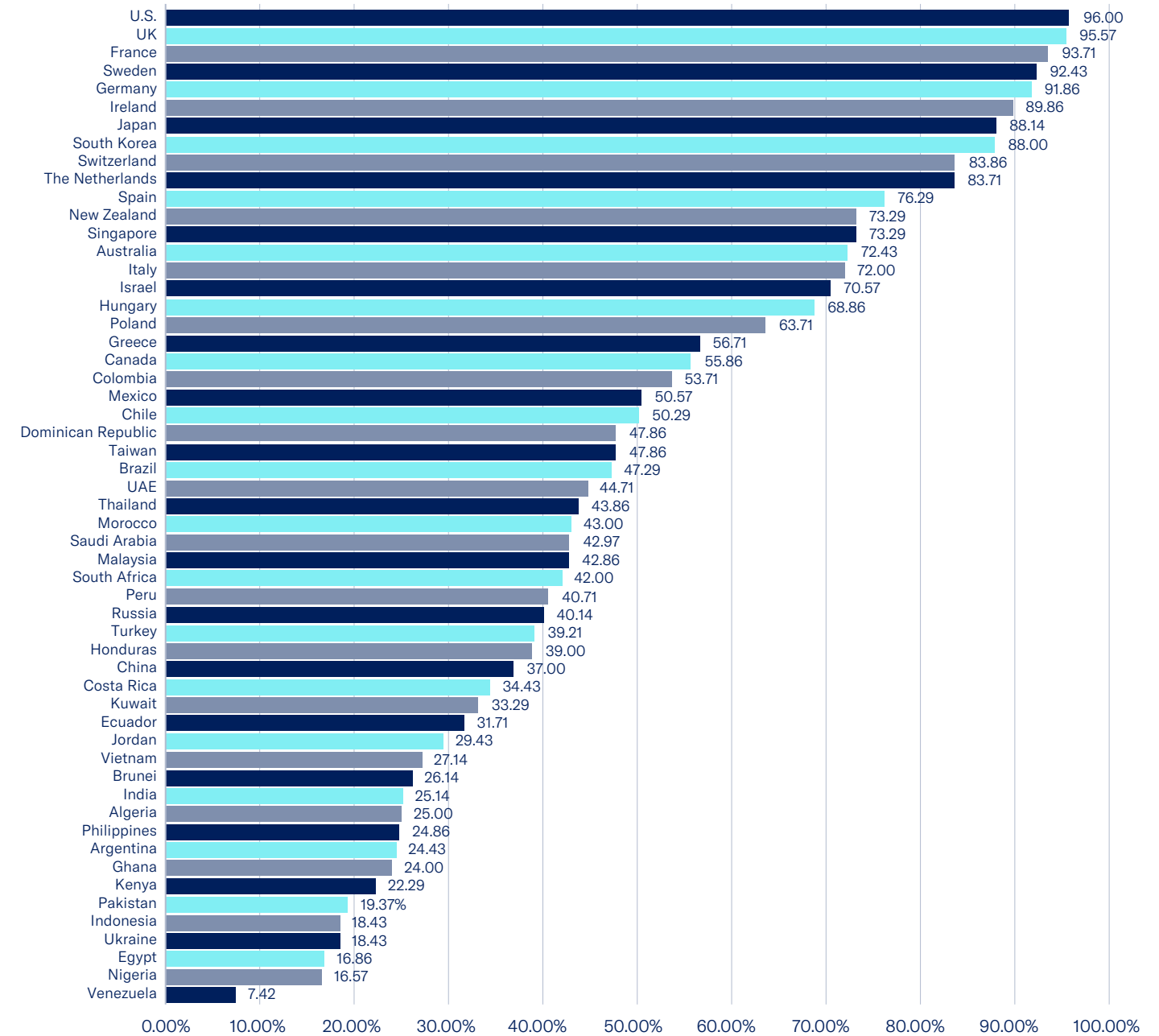


Category-by-Category

# Enforcement

- As in years past, a clear majority of the sampled economies in the Index struggled in this category. Only 23 economies (41.89% of the sample) achieved a score of 50% or more on this category, and only 11 economies achieved a score of 75% or more.
- The average score in this category is one of the weakest on the Index, at 50.11%. However, there were some positive development in 2021.
  - » In **Chile**, the National Congress amended the Industrial Property Law to provide statutory damages and a minimum prison sentence for trademark infringement.
  - » In **Indonesia**, the Directorate General of Intellectual Property introduced new anti-counterfeiting and anti-piracy initiatives and provided greater transparency on cross-agency IP enforcement activity.

## Category 7: Enforcement, % Available Score



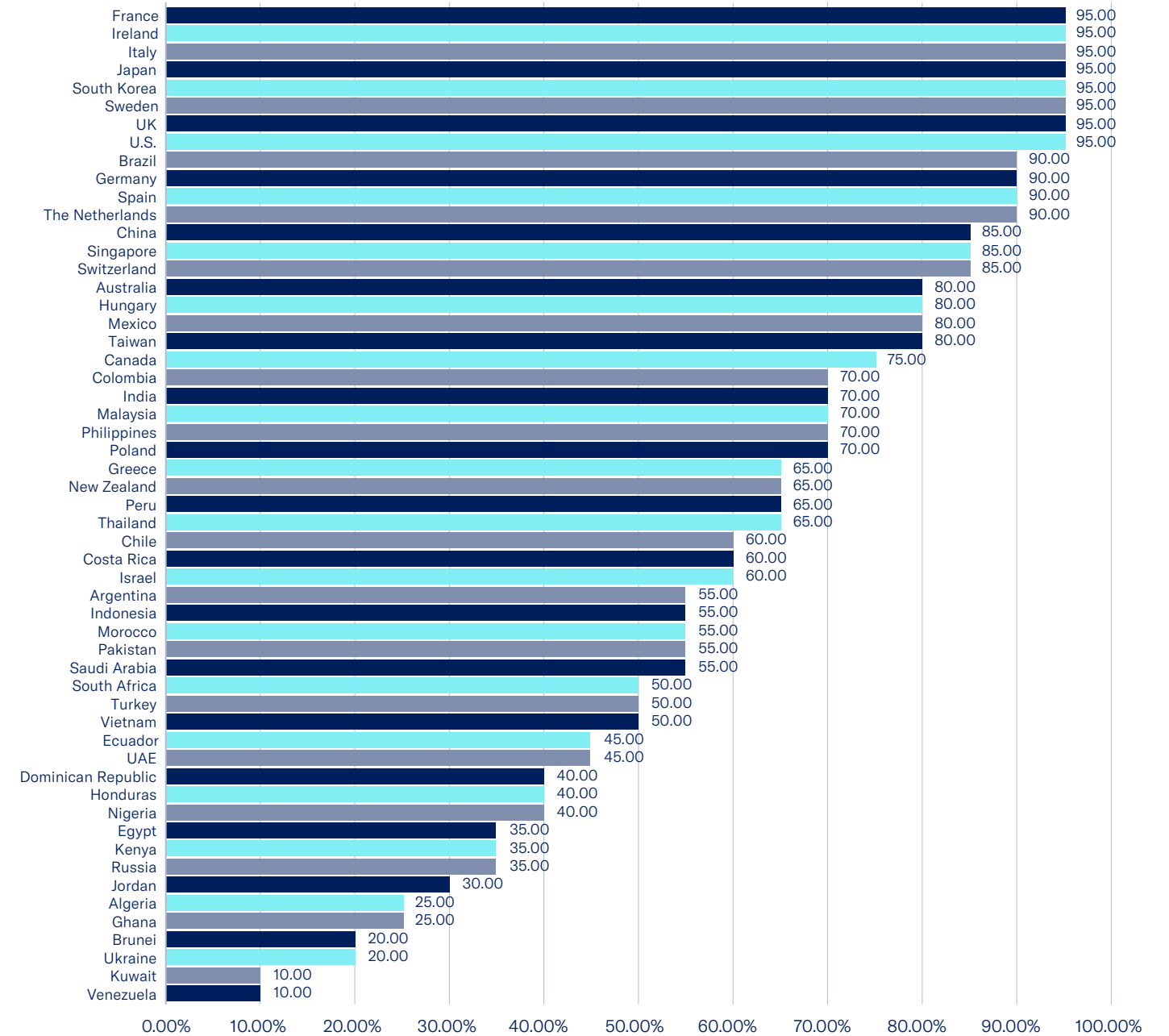


Category-by-Category

# Systemic Efficiency

- The majority of sampled economies in the Index performed well on this category, with only 15 economies failing to achieve a score of 50% or above. Indeed, several economies with otherwise challenging IP frameworks, such as **Colombia, India,** and the **Philippines,** outperformed their overall Index scores on this category, achieving a score of over 70%.
- Overall, the average score on this category is one of the strongest on the Index, at 62.55%, with a series of positive developments occurring throughout 2021 in Latin America and the Middle East.
  - » The governments in **Brazil** and **Mexico** released studies on the contributions of IP-intensive industries to their national economies. In **Peru** and **Venezuela,** the government launched new programs to provide small and medium-sized enterprises (SMEs) with assistance managing IP assets.
  - » In **Saudi Arabia,** in a very positive move, the Saudi IP Authority took a centralized role in the enforcement of trademark infringement and created a new committee to coordinate the enforcement of IP rights more broadly across government agencies within the Kingdom.

## Category 8: Systemic Efficiency, % Available Score



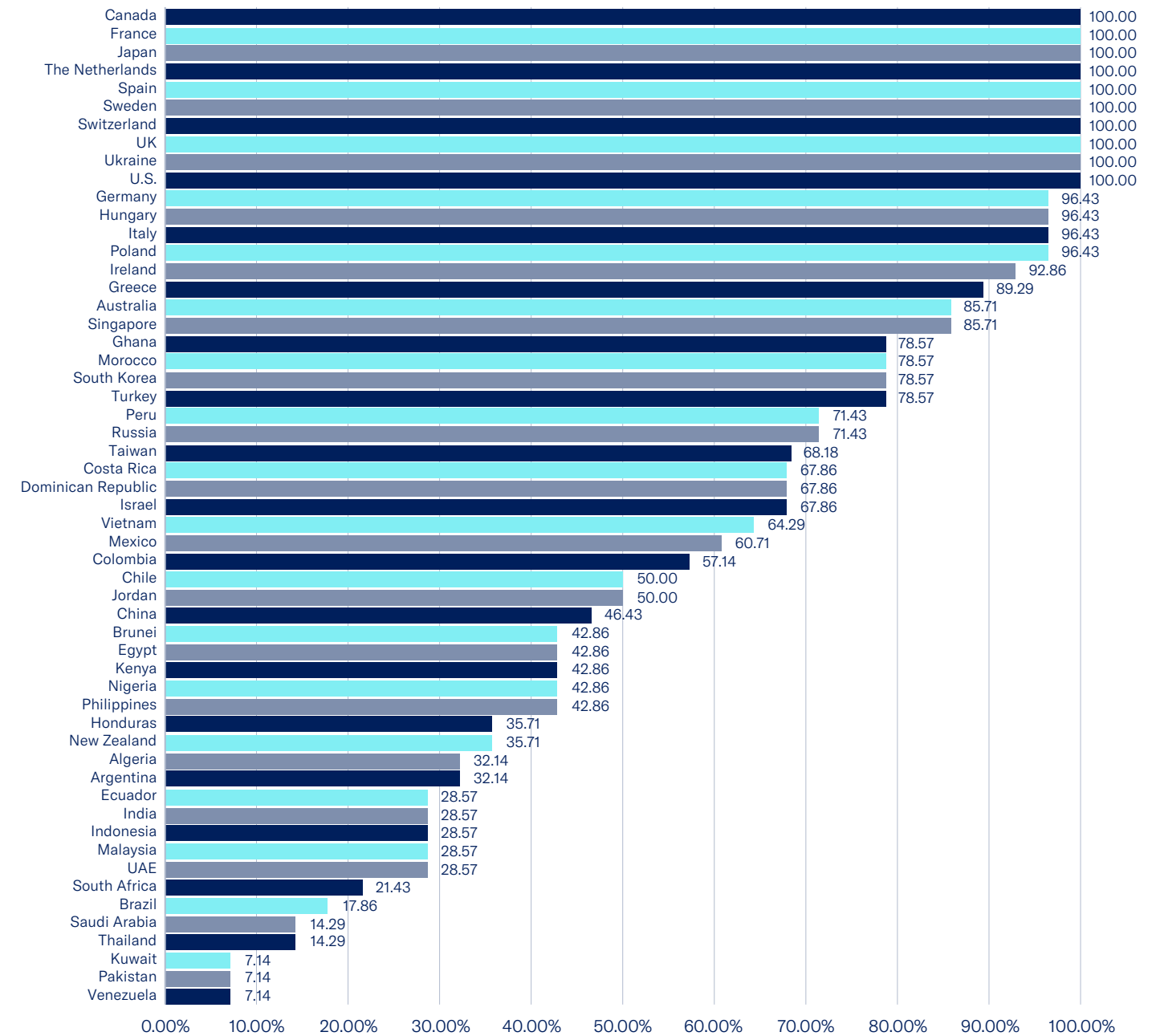


Category-by-Category

# Membership & Ratification of International Treaties

- A large number of economies received a high score on this category: 22 economies achieved a score of 75% or more, with 14 economies achieving a score of over 96%. Overall, the average score is 61.43%.
- However, a surprisingly large number of high-income economies are not contracting parties to many international IP treaties included in the Index. **Kuwait, Saudi Arabia, UAE, and New Zealand** all achieved a score of 36% or less. However, each of these countries have acceded to international treaties not benchmarked in the Index.
  - » **Nigeria and Ghana** acceded to the International Convention for the Protection of New Varieties of Plants (UPOV), Act of 1991.
  - » **Pakistan and UAE** acceded to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks.
  - » While **Sweden** became a contracting party to the Convention on Cybercrime in 2001, Parliament ratified the treaty in 2021.
- In 2021, economies in Africa, the Middle East, and the EU had score improvement in this category.

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







# Overview of the Tenth Edition

Now in its tenth edition, the U.S. Chamber of Commerce's International IP Index continues to provide an important industry perspective on the IP standards that influence both long- and short-term business and investment decisions. The Index is a unique and continuously evolving instrument. Not only does it assess the state of the international IP environment, but it also provides a clear roadmap for any economy that wishes to be competitive in the 21<sup>st</sup> century's knowledge-based global economy. Large or small, developing or developed, economies from around the world can utilize the insights about their own national IP environments as well as 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, with Ghana and Honduras added as two new economies in the tenth edition. Together, these 55 economies represent both a geographical cross-section of the world and most of the global economic output, together contributing over 90% of global GDP.

As Table 1 shows, the Index includes economies from all major regions of the world and is truly a global measure.<sup>1</sup>

Table 1: Tenth Edition Index Economies by World Bank Region

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

Source: World Bank (2021)

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



Table 2: Tenth Edition Index Economies by World Bank Income Group

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

Source: World Bank (2021). The World Bank has temporarily unclassified Venezuela pending the release of national accounts statistics. Consequently, the Index classifies Venezuela per its 2020 classification.

## Regional Rankings

Region	Average overall % Index Score
North America	85.36%
Europe and Central Asia	77.43%
Asia	55.82%
Latin America	43.70%
Africa and Middle East	41.55%

Africa and Middle East	Overall Score	Regional Ranking
Israel	72.74%	1
Morocco	59.76%	2
UAE	46.02%	3
Jordan	44.70%	4
Saudi Arabia	41.38%	5
Ghana	40.88%	6
Kenya	37.38%	7
South Africa	37.28%	8
Egypt	32.82%	9
Nigeria	31.34%	10
Kuwait	27.92%	11

Asia	Overall Score	Regional Ranking
Japan	91.26%	1
Singapore	84.44%	2
South Korea	83.94%	3
Australia	80.70%	4
New Zealand	69.28%	5
Taiwan	66.29%	6
China	55.86%	7
Malaysia	51.90%	8
Philippines	41.58%	9
Brunei	41.08%	10
Vietnam	38.72%	11
India	38.64%	12
Thailand	35.78%	13
Indonesia	30.42%	14
Pakistan	27.43%	15

Europe and Central Asia	Overall Score	Regional Ranking
UK	94.14%	1
Germany	92.46%	2
Sweden	92.14%	3
France	92.10%	4
The Netherlands	90.70%	5
Ireland	88.84%	6
Switzerland	86.00%	7
Spain	85.94%	8
Italy	83.40%	9
Hungary	76.90%	10
Poland	70.74%	11
Greece	70.67%	12
Turkey	51.07%	13
Russia	46.64%	14
Ukraine	39.74%	15

Latin America	Overall Score	Regional Ranking
Mexico	58.98%	1
Costa Rica	54.56%	2
Dominican Republic	54.28%	3
Peru	49.32%	4
Colombia	48.84%	5
Chile	48.72%	6
Honduras	42.18%	7
Brazil	42.02%	8
Argentina	37.02%	9
Ecuador	30.70%	10
Venezuela	14.10%	11

North America	Overall Score	Regional Ranking
U.S.	95.48%	1
Canada	75.24%	2



# Evolution of the Global IP Environment: What a Decade of the IP Index Has Taught Us about International IP Policy

In 2012, the U.S. Chamber released the inaugural edition of the International IP Index. The Index provides a rigorous, academic tool by which countries can assess the strength of their IP system and compare it to that of their neighbors and economic competitors. To achieve this, the breadth and depth of the Index has grown significantly over time. Since 2012, the number of economies included in the Index has increased substantially from 11 economies benchmarked in the first edition to 55 in the tenth edition, an increase of sampled economies of almost 500%. The economies included in the Index represent both a geographical cross-section of the world and over 90% of global economic output. Similarly, since the inaugural edition, the indicators benchmarked have doubled from 25 to 50. These 50 discrete indicators across nine separate categories measure the strength of

a national IP environment with respect to both the legal situation and levels of IP rights enforcement on the ground. The indicators included cover all major cross-sectoral IP rights as well as sector-specific rights. As the Index has changed over time, so too has the global IP environment.

With ten years of data on the IP frameworks in a sample of global economies, we can take stock of some of the major changes in the international IP environment over the last decade. By examining some of the major developments over the last ten years, we can assess whether the global IP environment has improved, deteriorated, or broadly stood still. The insights offered by the Index can help inform businesses and policymakers about what the international IP environment will look like ten years from now.

## What Do the Numbers Say? The Global IP Environment as Reflected in Ten Editions of Index Scores

While the primary purpose of the IP Index has always been to measure and benchmark the strength of the national IP environment in the economies sampled, a secondary function of the Index is to serve as a proxy for the state of the global environment. What does the global IP environment look like today as measured by the Index, and how does this compare with when the Index was first launched? Have things improved or weakened?

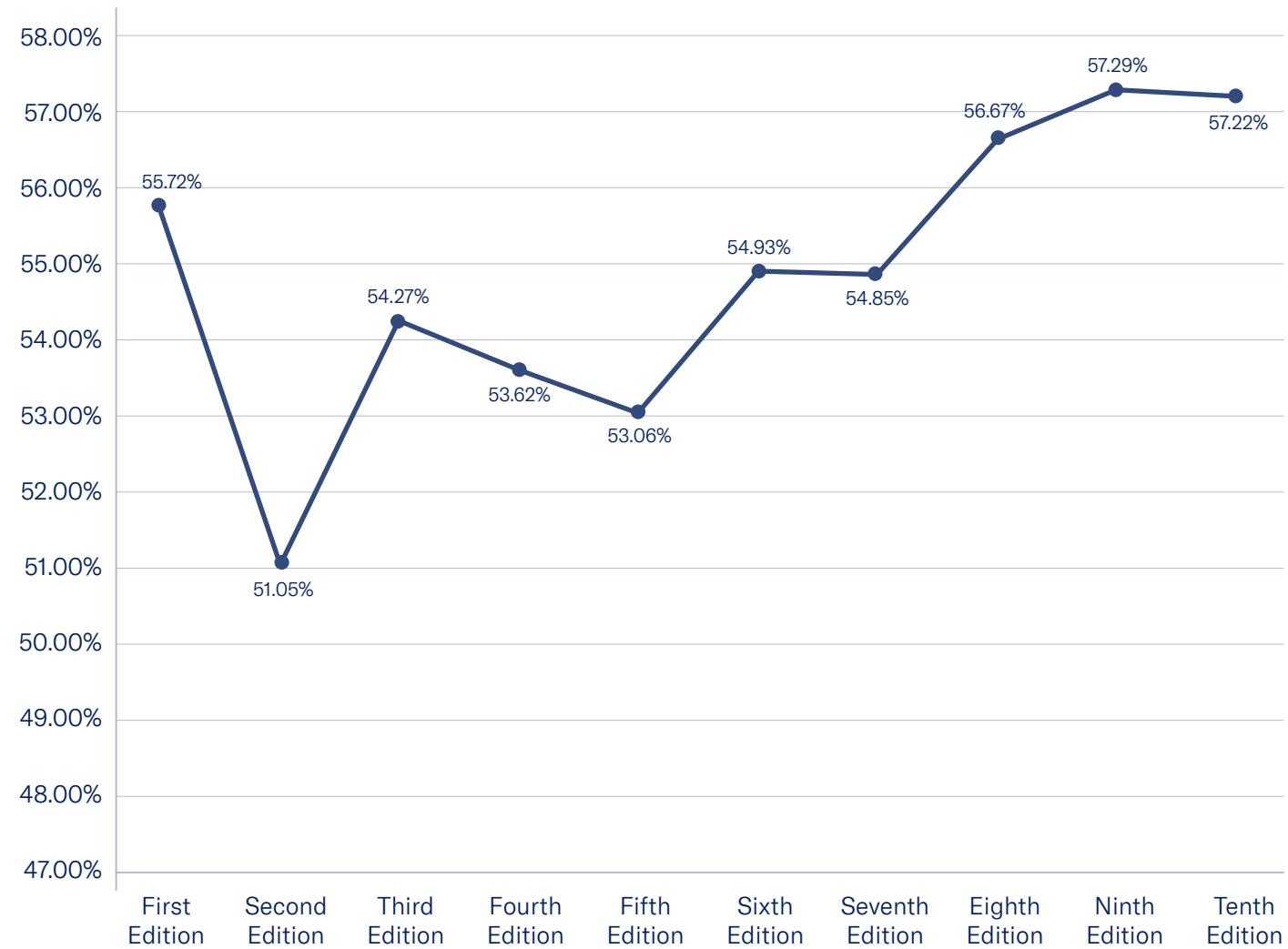
With Index scores now going back to 2012, there is a sufficient amount of data to analyze and spot trends. Indeed, looking at the movement of Index scores over time allows us to get a sense of how

the global IP policy environment has evolved and what some of the underlying factors are shaping this movement, both positive and negative.

To begin with, we can calculate the overall average score of all sampled economies vis-à-vis the maximum available total score in the Index. Without controlling for changes in the composition of the Index with respect to the number of economies sampled or the addition of new indicators, the total aggregated results do provide a good starting point as a snapshot and point of comparison. Below, Figure 1 shows the average score of the economies sampled as a percentage of the maximum score for each of the ten editions of the Index.



**Figure 1: Overall Average Score, Percentage Available Score, First to Tenth Edition of the Index**



A simple comparison between the inaugural edition in 2012 with the latest edition from 2022 shows an increase in the average score of 1.50%. On this basis it is fair to say that, today, ten years after the launch of the Index, the global IP environment is stronger than what it was in 2012. Equally, when looking at the different categories of the Index, the evidence also suggests that, for

most categories, there has been an improvement in the global IP environment. Below, Table 3 and Figure 2 show the average score for the nine categories of the Index over the ten editions.

**Table 3: Average Score, % Available Score, Index Categories, First to Tenth Edition of the Index<sup>2</sup>**

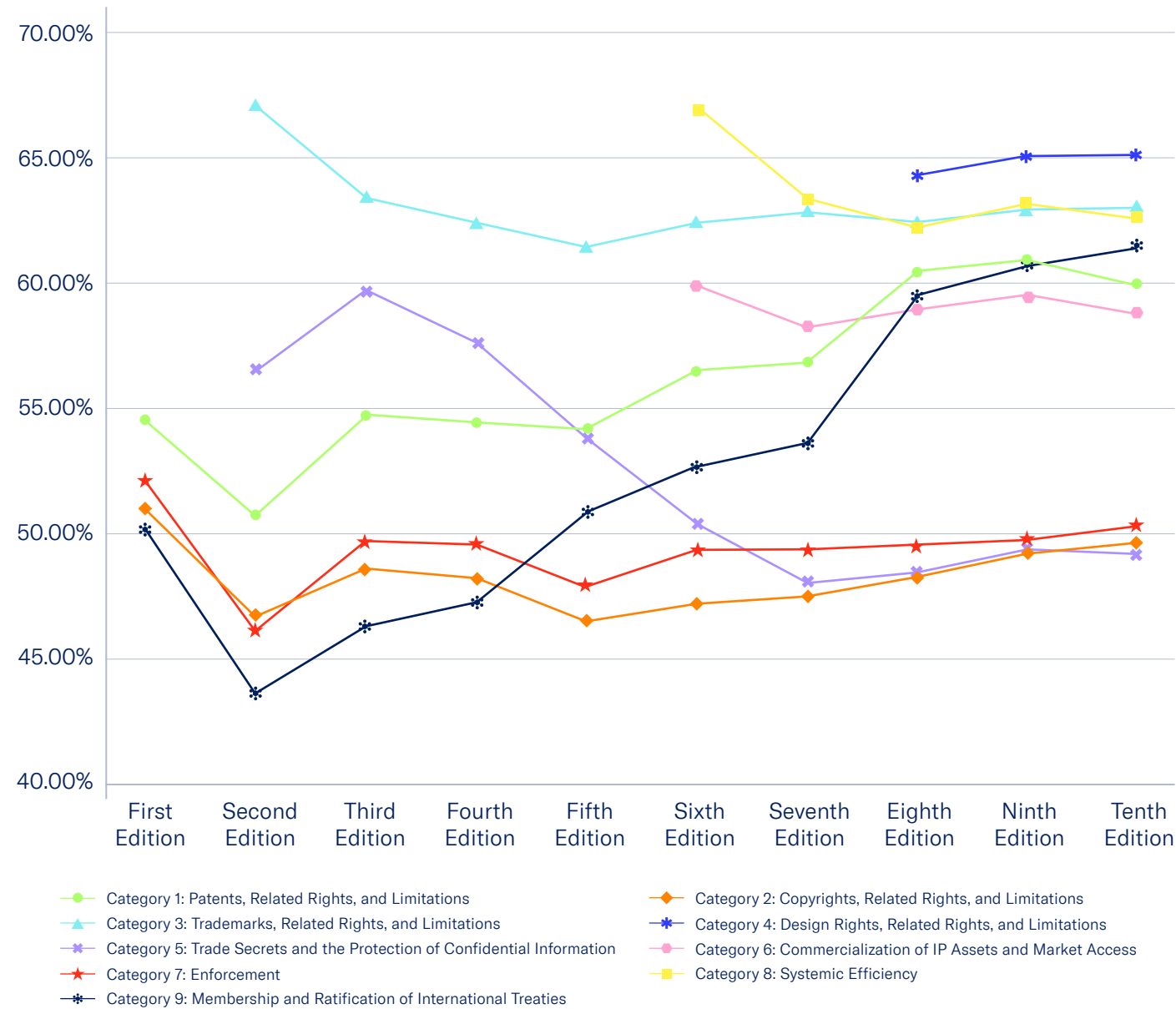
	First Edition	Second Edition	Third Edition	Fourth Edition	Fifth Edition
<b>Category 1: Patents, Related Rights, and Limitations</b>	54.48%	50.57%	54.69%	54.38%	54.01%
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	50.92%	46.63%	48.46%	48.07%	46.44%
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	95.45%	67.00%	63.33%	62.28%	61.34%
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	NA	NA	NA	NA	NA
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	NA	56.50%	59.58%	57.62%	53.66%
<b>Category 6: Commercialization of IP Assets and Market Access</b>	NA	NA	NA	NA	NA
<b>Category 7: Enforcement</b>	52.13%	45.97%	49.66%	49.57%	47.86%
<b>Category 8: Systemic Efficiency</b>	NA	NA	NA	NA	NA
<b>Category 9: Membership and Ratification of International Treaties</b>	50.00%	43.50%	46.25%	47.14%	50.78%

	Sixth Edition	Seventh Edition	Eighth Edition	Ninth Edition	Tenth Edition
<b>Category 1: Patents, Related Rights, and Limitations</b>	56.35%	56.79%	60.50%	60.87%	59.92%
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	47.17%	47.45%	48.23%	49.15%	49.57%
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	62.44%	62.66%	62.38%	62.97%	62.95%
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	NA	NA	64.20%	64.95%	65.14%
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	50.30%	48.03%	48.43%	49.40%	49.12%
<b>Category 6: Commercialization of IP Assets and Market Access</b>	59.83%	58.19%	59.00%	59.42%	58.70%
<b>Category 7: Enforcement</b>	49.28%	49.28%	49.45%	49.67%	50.26%
<b>Category 8: Systemic Efficiency</b>	67.00%	63.25%	62.26%	63.11%	62.55%
<b>Category 9: Membership and Ratification of International Treaties</b>	52.63%	53.63%	59.50%	60.65%	61.43%



Figure 2: Average Score, % Available Score, Index Categories, First to Tenth Edition of the Index



While Figure 1 illustrates the aggregated average score improved between 2012 and 2022, Table 3 and Figure 2 similarly show that there has been an improvement over time for most categories of the Index. Simply put, there is more “green” and higher average scores on most categories today in 2022 than in 2012. Notably, there has been a substantial strengthening of the global IP environment in

Category 1: Patents, Related Rights, and Limitations and Category 9: Membership and Ratification of International Treaties. Compared with the starting point in 2012, the average score on these categories has improved by 5.44% and 11.43%, respectively.

Yet these aggregated comparisons can only take us so far.

The Index in 2012 was very different from the Index in 2022. In addition to changes in the national IP environment, two main methodological factors potentially affect this movement: the number of economies sampled and the addition of new indicators to the Index. As mentioned, the first edition of the Index contained only 11 economies and 25 indicators. Today, the Index benchmarks the performance in 55 economies across 50 different indicators. In this respect, the number of variables measured has doubled and the number of economies increased five-fold. That is a sizable increase, particularly for the number of economies included. Depending on the strength of the national IP environment of those economies added, the overall results of a given edition of the Index can move up or down. If a large number of economies with relatively strong IP environments are added, then the overall average score will increase regardless of what has changed in the underlying global environment. The same logic applies with reverse effect if most economies added in a given year have relatively weaker environments.

With this in mind, we must narrow down our points of comparison to get a more granular picture of how the global IP environment has changed over the course of the Index. By controlling for these changes, the Index can provide more sophisticated comparisons over time.

**But first, it is worth recognizing a fundamental insight that the aggregated score comparison over the last ten editions of the Index shows: If the indicators included in the Index represent a gold standard for the protection and enforcement of IP rights (regardless of whether there are 25 or 50 indicators), then a global score of between 51% to 57% demonstrates clearly the large amount of work to be done to give rightsholders the protections they need to continue to innovate and create new IP-based products, services, and technologies.**

## Comparing Apples to Apples and Oranges to Oranges: Controlling for the Addition of New Economies

The primary challenge in making comparisons over time has been the composition of the Index and specifically the growth in the number of economies sampled. Over the course of the Index, this is the one variable that has seen the greatest amount of change, growing from 11 economies in the first edition of the Index to today’s Index covering 55 different economies. Over the following pages we try and control for this by isolating and examining the results for a sub-group of economies. Specifically, we track

the 25 economies included in the second edition of the Index. Looking at only these economies, it is possible to track movement over time on a like-for-like basis regardless of the addition of new indicators on the Index. How have these economies performed vis-à-vis the Index as well as each other over the course of the past nine years? Below, Table 4 shows the 25 economies sampled from the second edition of the Index according to income group as defined by the World Bank.



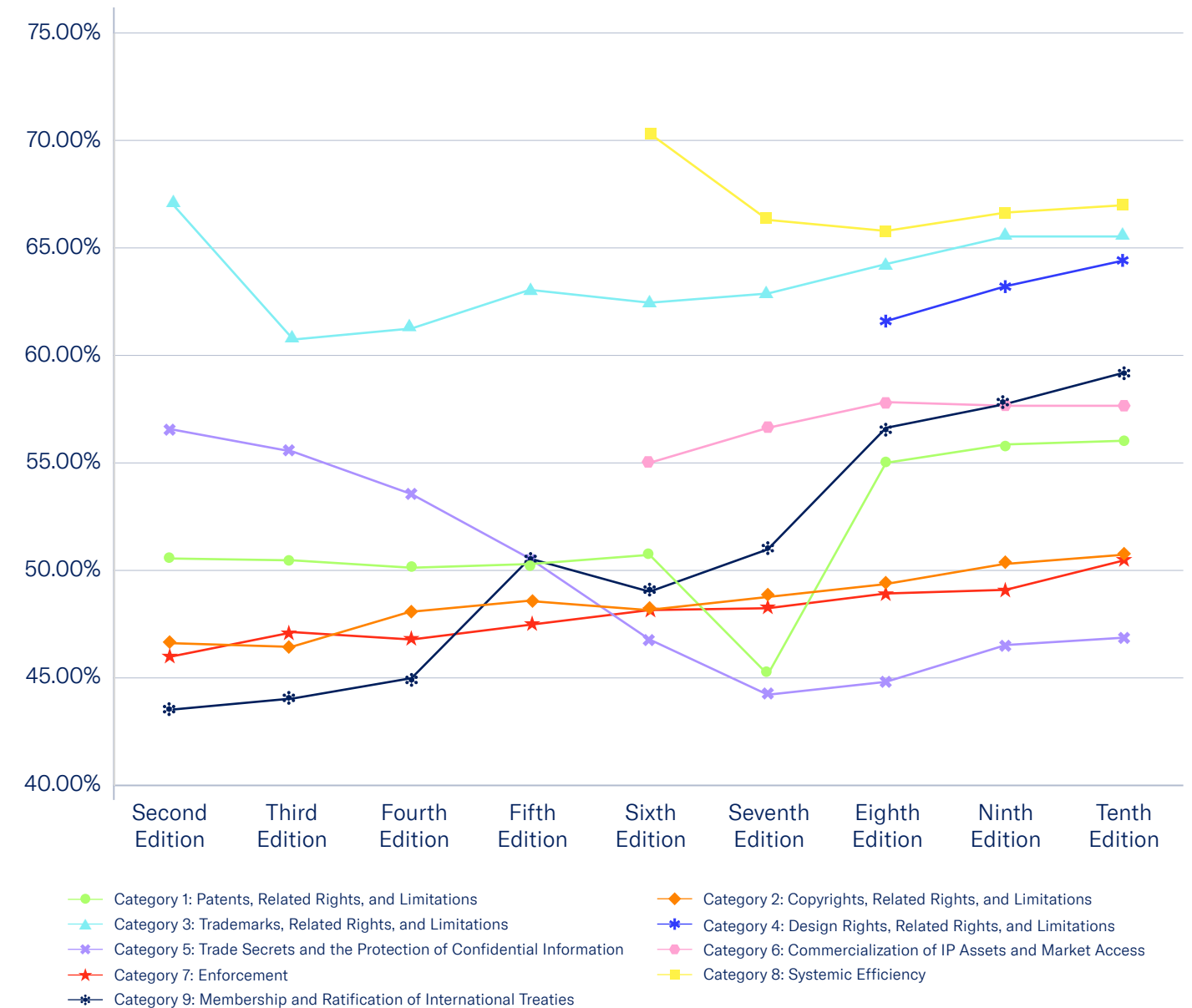
**Table 4: 25 Economies Sampled from the Second Edition of the Index by World Bank Income Group**

Lower-middle-income economies	Upper-middle-income economies	High-income economies	High-income OECD Members
India	Argentina	Singapore	Australia
Indonesia	Brazil	UAE	Canada
Nigeria	China		Chile
Ukraine	Colombia		France
Vietnam	Malaysia		Japan
	Mexico		New Zealand
	Russia		UK
	South Africa		U.S.
	Thailand		
	Turkey		

To begin with, it is worth looking at the category-by-category movement; this shows how the average Index scores for these 25 economies have changed over the course of the nine editions sampled. For which categories has there been positive movement and for which categories has there been

a regression? Below, Figure 3 shows the percentage movement on a category-by-category basis for the nine categories of the Index for these 25 economies between the second and tenth editions of the Index.

**Figure 3: % Movement, Average Score, 25 Economies, Second to Tenth Edition of the Index, Category-by-Category**



Just as with Table 3 above and the heatmap for the entire aggregated sample of all economies, Figure 3 shows a very similar progression over time: On most categories of the Index there has, on average, been an improvement in the national IP environment for the 25 economies sampled. In this sense the results for this isolation exercise reinforce the overall findings of the aggregated scores.

As with the aggregated comparisons, these improvements were particularly strong for Category 1: Patents, Related Rights, and Limitations and Category 9: Membership and Ratification of International Treaties. Compared with the starting point in the second edition of the Index, the average score on these categories has, on average, improved by 5.45% and 15.64%, respectively, for the



25 economies examined. However, just as with the total sample of economies, becoming a member and contracting party to an international IP treaty is only the first step in improving an economy's national IP environment. Critically, economies can only benefit from improved standards of IP protection if these are fully implemented and enforced. As governments and international institutions move forward with fresh trade negotiations, this should always be at the forefront. Unlike the aggregated sample, these 25 economies also saw improvements on Category 2: Copyrights, Related Rights, and Limitations and Category 7: Enforcement. Compared with the starting point in the second edition of the Index, the average score on these categories has improved by 4.1% and 4.52%, respectively. In contrast, the aggregated sample saw a weakening on both these categories.

Digging a little deeper at the individual economy level, these average results make sense. Several of the 25 sampled economies have made significant improvements to their national IP environments by becoming contracting parties to several international treaties. **Canada** and **Japan** stand out as making dramatic improvements on Category 9: Membership and Ratification of International Treaties. This is in part due to a dedicated commitment from both governments to join several major IP treaties over the past decade as well as the addition of new treaties to the Index. In the first edition of the Index, Canada achieved a score of 1 out of a total available score of 5 (20%). In this year's edition of the Index, Canada achieves a score of 7 out of a possible 7 (100%). In 2019, Canada acceded to three international treaties included in the Index: the Singapore Treaty on the

Law of Trademarks; the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; and the Patent Law Treaty.

Similarly, Japan joined several major IP treaties over the course of the Index, including the Singapore Treaty, the Madrid Protocol, and the EU-Japan Economic Partnership Agreement. Of the 25 second edition economies isolated and tracked over time, other economies too have over the last decade become contracting parties to IP treaties included in the Index. This includes **Colombia, India, Malaysia, Nigeria, the UAE, and Vietnam**. While rightsholders face many challenges with the actual implementation of these treaty standards in individual economies, these are nevertheless important commitments made. Being a contracting party to key international IP treaties reflects a given economy's broader participation in the international IP community and its embrace of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adheres to established standards and best practices.

Finally, comparing the aggregated average score for all economies across all editions of the Index with the aggregated average score for the 25 economies isolated from the second edition, shows that both groups have broadly moved in the same direction over much of the last decade. Below, Figure 4 shows the average aggregated score for both the entire sample of economies and the 25 economies across nine editions of the Index.

**Figure 4: Overall Average Score, Percentage Available Score, Second to Tenth Edition of the Index, % Movement, Aggregated Score for all Economies Versus 25 Economies from Second Edition of the Index**



Remarkably, the two samples share a similar trajectory together across most of the Index. Apart from the first few editions of the Index, the overall direction—positive or negative—of both sampled groups is quite similar. Over the last three editions of the Index, in particular, both groups have a similar trajectory and are separated by less than 0.5% in average overall score.



# From the Macro to the Micro: Examining Major IP Developments over Ten Editions of the Index through Case Studies

In addition to examining the changes in the Index’s overall and category-by-category scores, it is also possible to gain insight into what some of the major developments in IP policy have been,

through a selection of individual case studies. The following sub-sections look at two key areas where the IP policy environment today is fundamentally different than what it was in 2012.

## Case Study 1: Enforcement through injunctive-style-relief—how rightsholders are successfully using a new tool in the fight against online copyright piracy

Ten years ago, rightsholders across the globe were struggling to effectively enforce their copyrights against online piracy. Beginning in the mid-to-late 1990s, advances in computer-based technology and the advent of the internet fundamentally changed how creative goods are consumed and accessed by consumers. In 1998, sales of physical compact discs accounted for 83.3% of total music sales. Twenty years later—in 2018—compact discs accounted for only 7.1% of total sales. Instead, digital downloads and streaming services (advertisement supported and paid) constituted close to 70% of total sales volume. In a growing number of the world’s economies, internet penetration and the use of mobile devices is almost ubiquitous. Even in developing economies that often lack sophisticated technological infrastructure, consumers are able to access a growing range of digital services and content through the use of mobile devices.

In the U.S., more than eight out of ten Americans today own a smartphone and internet penetration is near universal. The growth and scale of online piracy since the late 1990s—whether

through downloading, streaming, or some other technology—has mirrored this growth in broadband and mobile device connectivity. The scale and volume of online infringement has resulted in a growing strain and burden on rightsholders to effectively protect their content and economic rights. The adverse economic impact on the content industry has been staggering. A recent report by NERA Consulting, commissioned by the U.S. Chamber of Commerce’s GIPC, found that global online piracy costs the American economy nearly USD 30 billion in lost sales each year. As this data suggests, online piracy remains a pervasive and existential threat to creators and rightsholders across the world. But beginning in the early 2010s, rightsholders have identified and successfully applied a new tool in this battle: injunctive-style relief.

What is “injunctive-style relief”? Essentially, it is the ability of a given rightsholder to have the option of seeking redress for an infringement of copyright either through a court of law or, administratively, with a government authority. The mechanism can

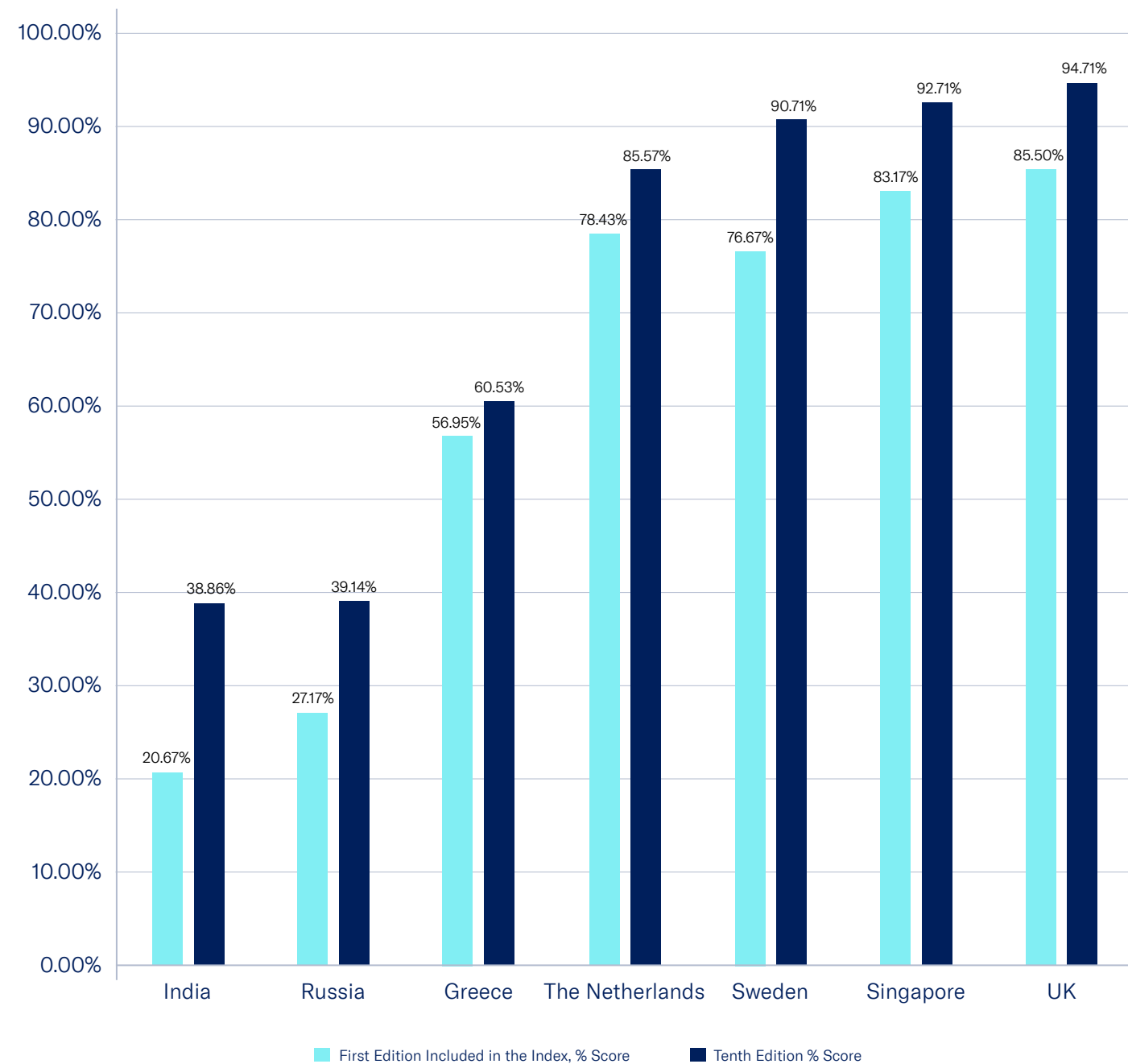
look and work slightly differently depending on the legal jurisdiction, but the end result is an order to disable access to the infringing content. The last decade has seen a sharp increase in the number of economies that are using this type of judicial or administrative mechanism to effectively disable access to infringing content. Today, many **EU Member States, the UK, India, Singapore, Russia,** and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called “dynamic” injunctions. Such an injunction addresses the issue of mirror sites

and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the **Netherlands, Greece, Singapore, India, the UK, and Russia.** The positive impact on these economies’ Index scores can be seen below in Figure 5, which compares a sample of these economies’ first percentage score on Category 2: Copyright, Related Rights, and Limitations with their latest score on the tenth edition of the Index.





Figure 5: Category 2: Copyrights, Related Rights, and Limitations, % Score Change, Sample of Index Economies



As Figure 5 shows, all of these economies have seen a substantial increase in their scores on this category of between 4% and 18%. This has, in large measure, been due to the introduction and enforcement of injunctive-style relief mechanisms.

Indeed, the net effect of the use of these types of mechanisms has been a steady decrease in rates of online piracy and use of legitimate, licensed content in those economies that have adopted these measures. For example, the Netherlands research

commissioned by the Dutch copyright foundation BREIN suggests that since the initial injunction disabling access was issued in 2018, web traffic and usage of the *Pirate Bay* in the Netherlands has fallen by 80-90%. Similarly, in Sweden (long a haven for online piracy and known as a host for websites providing access to illegal content including the *Pirate Bay*, which was founded there in 2003), rightsholders who for years struggled to effectively address the illegal accessing of their content online can now effectively enforce their rights through the judiciary and established court-set precedents that grant them direct access to injunctive-style relief. The positive impact of these new enforcement tools can be seen in a drop in rates of online piracy.

In November 2019, the Swedish Patent Office commissioned an online survey of internet users and levels of copyright infringement. The survey found a notable decrease in the number of users engaging in piracy and accessing illegal content compared to the previous survey conducted in 2017. Overall, the number of respondents saying they accessed copyright-infringing content fell from 21% to 14%. Of note is the even steeper drop in the age category 16-29 where the number of respondents saying they accessed copyright-infringing content fell from almost half (46%) of the respondents to 28%.

In many cases, these positive enforcement efforts have led to increased creative output and related economic activity. For example, over the past decade, **South Korea** has taken an increasingly active stance toward combating online piracy. In 2009, amendments to the Copyright Act introduced a graduated warning system operated by the Ministry of Culture, Sport, and Tourism and the Korean Communication Commission (KCC). Under the law, the KCC sends three sets of notices to infringing users and online service providers and can order the suspension of users' accounts for up to six months if an inadequate response is

secured. Korea also has in place an administrative mechanism for responding to rightsholders' requests for removing access to infringing content online. The legal basis is found in Article 102(2)f of the Korean Copyright Act, which provides limited liability for ISPs that respond to a court (or related administrative body) order to delete or disable access to infringing content. Industry reports suggest that more than 400 infringing websites have been disabled in Korea under this mechanism.

A 2016 study by the Motion Picture Association found a 90% drop, on average, in visits to disabled sites within three months of an order to disable access. In addition, the data suggested a 15% drop in visits to infringing websites and a 50% reduction for peer-2-peer (P2P) sites following three instances of disabling a given site. The result of these reforms has been that copyright piracy in Korea has decreased substantially. This has been achieved at the same time as internet connectivity and speed have increased manifold, with more Koreans than ever accessing content online.

At the same time, the creative sector in Korea has flourished. For example, the 2012 World Intellectual Property Organization (WIPO)-commissioned study, *The Economic Contribution of Copyright-Based Industries in the Republic of Korea*, found that the copyright industries made a substantial contribution to both national economic output and employment in Korea. The economic impact was estimated at 9.89% of total national economic output (GDP) and 6.24% of total employment. More recent research suggests that the economic impact of Korea's cultural industries and the creative economy were substantial and valued at over USD 12 billion in exports in 2019. As such, Korea stands as an example, to economies not only in southeast Asia but around the world, of what strong and consistent protection of copyright can achieve in terms of stimulating innovation, cultural production, and income-generating economic activity.



## Case Study 2: A growing menace—how the spread of counterfeit goods poses a threat to the health and safety of consumers around the world

Today’s global economy is interlinked, interdependent, and open for business in a way that it was impossible logistically, politically, or financially a mere generation ago. Just-in-time manufacturing and the use of international supply chains are today cross-sectoral industry standards and the basis for much of modern commerce. Everyday consumer goods are designed in one part of the world, manufactured in a different location, and then seamlessly sold and shipped to consumers all around the globe. Through the growth and advent of international trade, even small businesses can today reach potential customers and consumers in markets inaccessible a generation ago. The result has been a significant increase in the volume and value of global trade. In 1990 the value of world trade in goods was an estimated USD 3.5 trillion.<sup>3</sup> Today, the value of global trade in goods is almost six times that amount at an estimated pre-COVID-19 pandemic USD 19.65 trillion in 2018—and this figure does not include trade in services, which has grown exponentially over the last two decades.<sup>4</sup> However, as international trade has increased, so too has the circulation of counterfeit and pirated goods.

Definitions of “counterfeit” and “pirated” goods vary depending on the legal jurisdiction. Often there are differences in civil and criminal definitions and remedies depending on the type of IP right being infringed by the counterfeit or pirated good. Under the TRIPS Agreement, counterfeit trademark goods are defined as “any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark and which thereby infringes the rights of the owner of the trademark in question under

the law of the country of importation.”<sup>5</sup> TRIPS defines “pirated” goods as being those goods “which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.”<sup>6</sup>

Regardless of definitions, the intention behind counterfeiting and piracy is the same. For counterfeiting, it is to produce lower cost versions of legitimate products that free-ride on the brand’s established value and credibility in the marketplace. Indeed, a given brand or mark reflects a certain level of quality and content linked to the product(s) bearing the mark that is exploited by counterfeiters. The level of forgery or imitation can vary significantly in terms of the counterfeit product’s quality, from very poor, cheap imitations to products of close likeness to the original product. For example, footwear, jewelry, apparel, and fashion items can mimic distinguished features of the brand, logo, trade dress, and other rights (including design rights), but the materials and assembly may be of lower quality. Likewise, counterfeit wines may imitate the brand’s packaging and design but consist of an inferior-quality wine. Piracy differs from counterfeiting in the nature of the activity, as it consists of creating an unauthorized exact copy of an item. This is usually, but not always, media such as computer software, films, computer games, and video games, which are protected by an IP right such as copyright.

Irrespective of if it is a “counterfeit” or “pirated” good, the act of imitating and/or falsifying a legitimate good is an infringement of one or more IP

rights and is a threat not only to the rightsholders in question, but also to the health and safety of consumers everywhere. Counterfeit and pirated goods jeopardize consumer health and often pose a serious safety risk: fake toys contain hazardous and prohibited chemicals and detachable small parts; counterfeit medicines pose a direct risk to the health and safety of patients around the world; brake pads made of compressed grass compromise automotive safety; and counterfeit microchips for civilian aircrafts endanger air passengers. Counterfeit and pirated products are also a drag on national economies, as they are per definition the result of criminal and black-market trading activity. As a result, they deprive governments of legitimate tax revenue and undermine legitimate markets for innovators and creators everywhere.

One area of growing concern relates to the trade in substandard and counterfeit medicines. Medicines and pharmaceutical treatments are today manufactured, sold, distributed, and dispensed across the globe. Complex and interlinked supply and demand chains mean manufacturers, distributors, wholesalers, pharmacists, healthcare professionals, and patients all make up a global network of producers, sellers, and consumers of pharmaceuticals. The globalization of the health care sector and the free movement of its goods and services have had enormous benefits: for example, patients can now access medicines that were in the past either not produced locally or far too expensive to import and access. However, the globalization of pharmaceutical markets and production has also increased the spread and prevalence of unsafe medicines. Broadly speaking, unsafe medicines can be divided into two categories: counterfeit medicines and substandard medicines. Counterfeit medicines are defined by the World Health Organization (WHO) as being “deliberately and fraudulently mislabeled with respect to identity and/or source.”<sup>7</sup> Substandard pharmaceuticals, on the other hand, are those that have been legally authorized for manufacturing and, more often than

not, approved for market and sale by a national or regional Drug Regulatory Authority (DRA) but that do not meet the required quality or safety requirements for that particular drug or treatment.

The United States Pharmacopeia (USP), the official public standards-setting authority for all medicines, pharmaceutical, and health products in the United States, defines substandard drugs as being “genuine products that do not conform to the pharmacopeial standards set for them.”<sup>8</sup> The most common reasons why drugs become substandard are poor manufacturing practices, the use of impure formulation ingredients, and the inadequate quality of active ingredients (that is the main therapeutic ingredient of a medicine), which can be caused by, among other things, decomposition due to high temperatures and humidity. There are also many instances in which impure and toxic ingredients have been added to the manufacturing process, rendering the medicines produced not only substandard but harmful. Counterfeit and substandard drugs make up a growing share of the total drugs supply. Estimates by the WHO, U.S. Food and Drug Administration (FDA), and others put the number of counterfeit drugs between 10% and 15% of the total drugs market, with some areas in Asia and Africa reaching levels of almost 50%.<sup>9</sup> Estimating the amount of substandard drugs on the market is much more difficult. This is because so many substandard drugs are legitimately manufactured and regulatory approved medicines. However, the few studies that do exist have found that in some cases, and countries, the number of substandard drugs can be as high as 40% of the total sample size.<sup>10</sup>

In 1997 a team of researchers using a survey of 96 samples of chloroquine, an anti-malaria drug, and selected antibacterials from Nigeria and Thailand, found that 36.5% of samples were substandard with respect to pharmacopeial limits, and that 36% of samples from Nigeria and 40% of samples from Thailand contained quantities of active ingredients



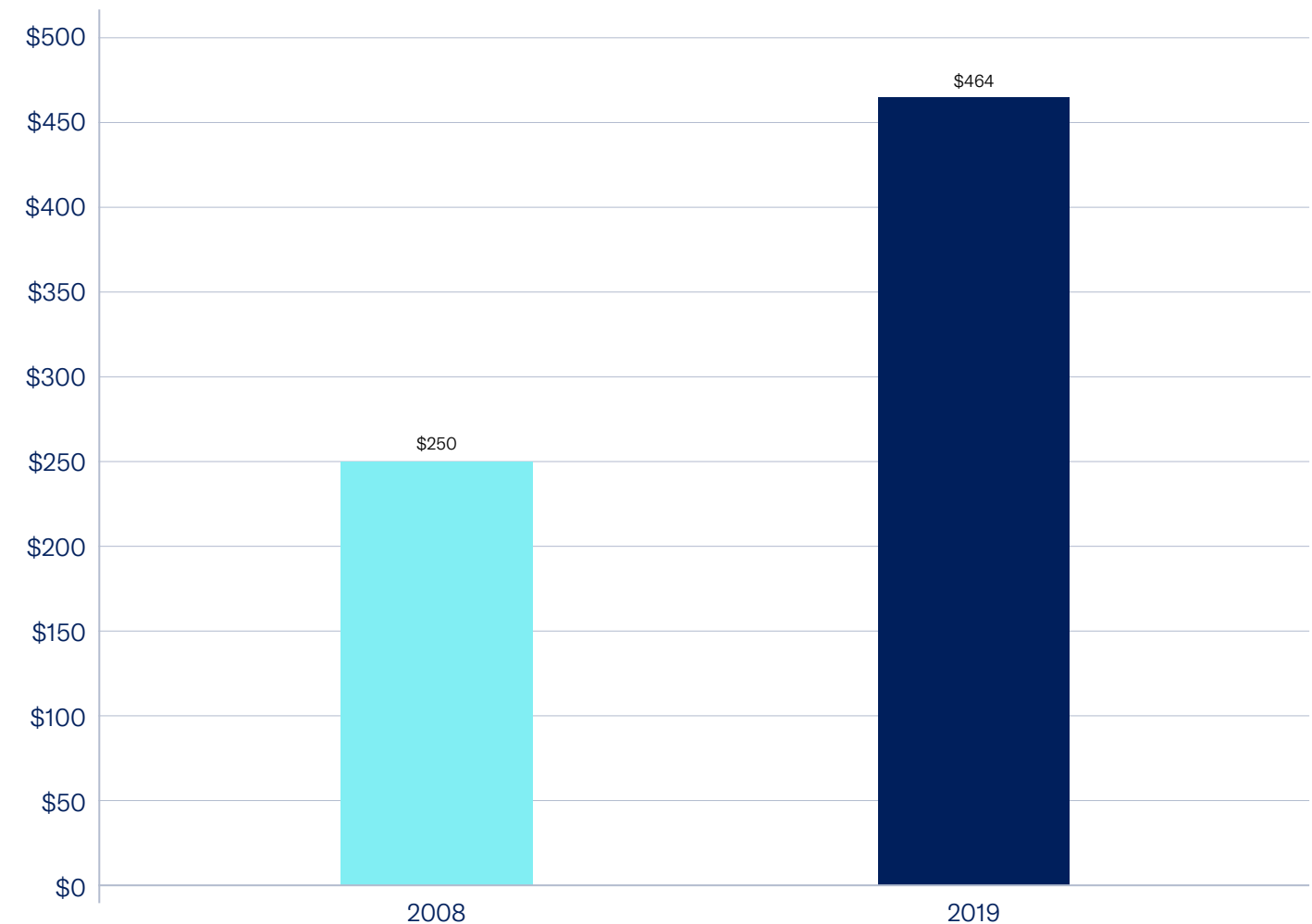
that were outside British pharmacopeial limits.<sup>11</sup> Six drugs had no active ingredient at all.<sup>12</sup>

Critically, the prevalence of counterfeit and substandard treatments is increasing as a response to the COVID-19 pandemic. The last two years have seen a marked circulation of counterfeit and/or substandard COVID-19 treatments, vaccines, and related medical supplies. For example, in March 2021, the WHO’s Director-General Tedros Adhanom Ghebreyesus warned the public of the dangers of counterfeit and substandard vaccines: “We urge all people not to buy vaccines outside government-run vaccination programs. Any vaccine outside these programs may be substandard or falsified, with the potential to cause serious harm.”<sup>13</sup> Similarly, the general secretary of Interpol warned in a November 2021 article in the *British Medical Journal* that counterfeiters were targeting COVID-19 vaccines.<sup>14</sup>

International efforts to track and measure the scale and circulation of counterfeit and pirated goods have increased over the course of the Index. This work has primarily been driven by the OECD and European Union Intellectual Property Office (EUIPO), which have been instrumental in developing new metrics and regular assessments of levels of trade-related counterfeiting. In 2008

the OECD published *The Economic Impact of Counterfeiting and Piracy*, which embedded seizure data, customs and industry survey data, and international trade data into an econometric model known as the GTRIC-e that provided an estimation of the magnitude of trade-related physical counterfeiting both in aggregate internationally and within each economy. The study concluded that global physical counterfeiting accounted for some USD 200 billion in 2005. In 2009 this estimate was updated to account for the growth and changing composition in global trade, increasing the magnitude of global physical counterfeiting to USD 250 billion.<sup>15</sup> These studies have since been updated with new estimates of the volume of the international trade in counterfeit and pirated goods released in 2013, 2016, 2019, and 2021. These estimates show that the volume and scope of counterfeit and pirated goods is steadily increasing. The latest estimates from 2021 suggest that this aggregated trade was valued at just under USD 500 billion (USD 464 billion), or 2.5% of global trade.<sup>16</sup> Below, Figure 6 shows the growth in this trade over the course of the Index.

**Figure 6: Estimated Rates of Global Trade in Counterfeit and Pirated Products, USD Billions, OECD 2008 Versus 2019**



As Figure 6 shows, the growth in the volume and value of the international trade in counterfeit and pirated goods has been astounding over the last decade—almost doubling over the ten editions of the Index.

Since 2012, the Index has measured the extent to which customs authorities in the economies benchmarked in the Index have sufficient authority to effectively act against suspected counterfeit and pirated goods. Under Indicator 37: Effective Border Measures, the Index measures the extent to which customs authorities, border guards, and/or other designated officials have the *ex officio*

authority to seize suspected counterfeit and pirated goods, including goods in-transit, without a formal complaint from a given rightsholder. Unfortunately, few economies have these powers in place and thus deprive rightsholders (and consumers in these jurisdictions) an effective avenue for enforcing IP rights at the border and eliminating the health and safety risks of counterfeit and pirated goods.

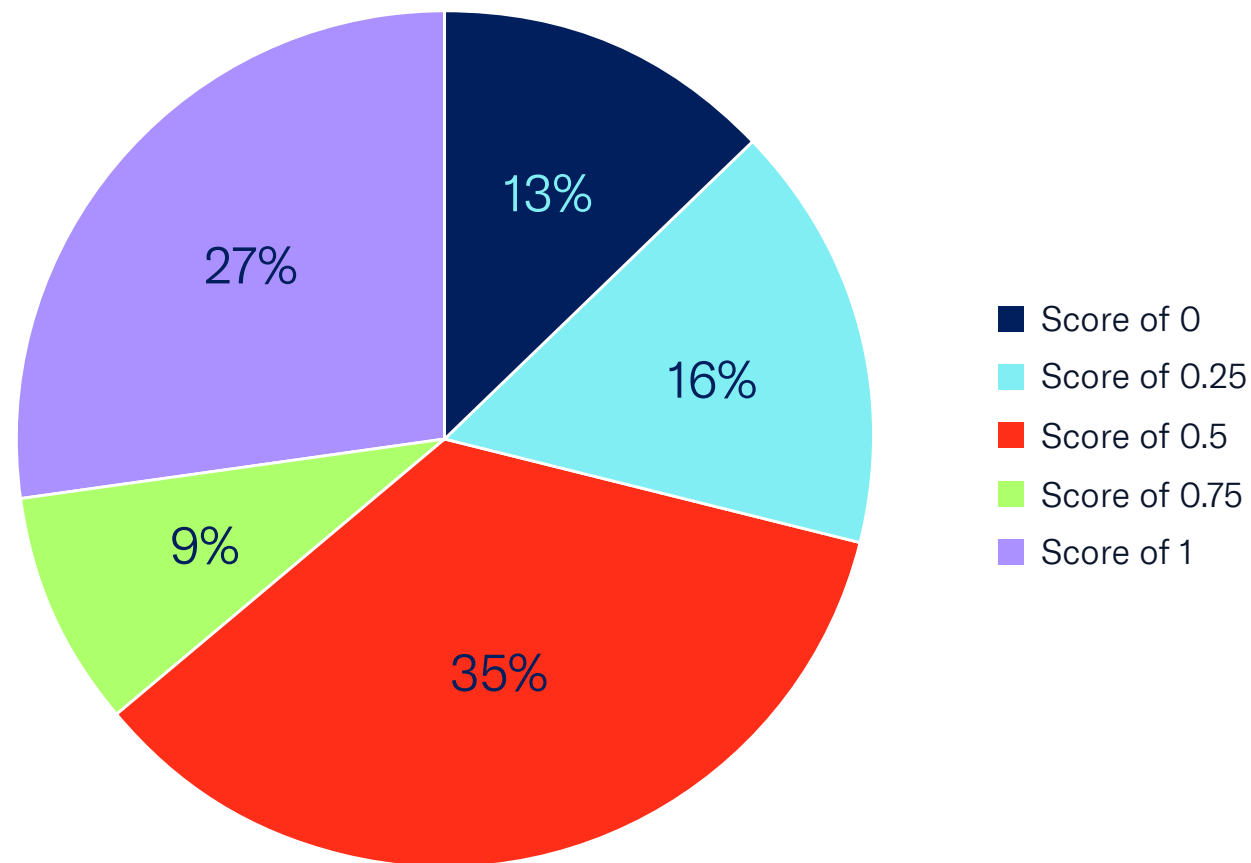
In many Index economies, customs officials are not given *ex officio* powers to seize suspected goods. In some cases in which they do have this power, in practice they do not use it or the power is restricted to only goods that are destined for the domestic



market and not those in-transit. Looking at the overall performance of the 55 sampled economies, less than one-third (27%) of the sample achieved a score of 1. In contrast, more economies (29% of

the entire sample) failed to achieve a score of 0.25 and seven economies received a score of zero. Below, Figure 7 shows the overall performance on this indicator in the tenth edition of the Index.

**Figure 7: Indicator 37: Effective Border Measures, Overall Scores, All Economies, Tenth Edition**

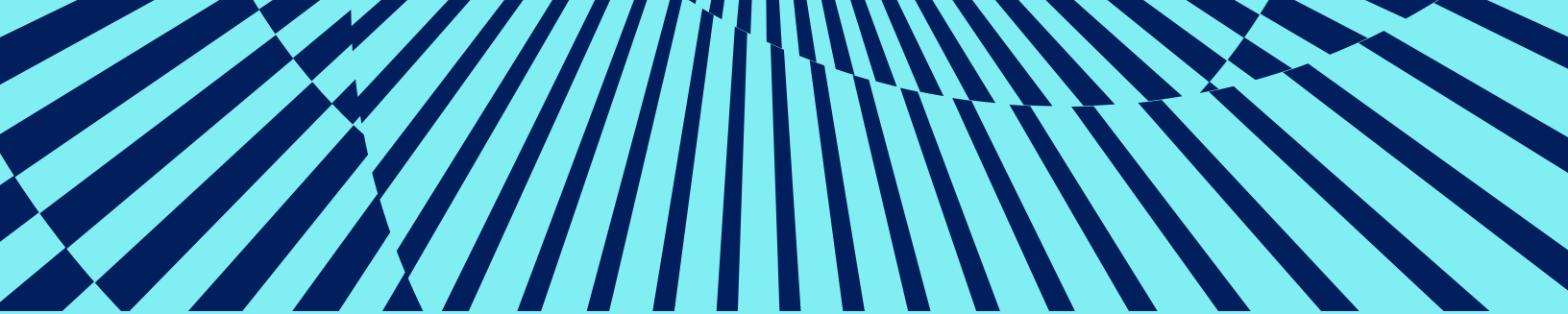


of any seized item. A surprisingly large number of economies—a full 29% of the 55 sampled economies—do not publish any statistics on actions taken by their customs authorities with respect to suspected IP-infringing goods. Only 16 of the 55 economies sampled in the Index regularly publish data on customs actions taken against suspected counterfeit goods. Another 23 economies publish some information; however, this may be on an ad hoc basis or fail to include relevant descriptive information such as countries of origin or volume and estimated value of the seized goods.

While important improvements have been made over time in the Index—for example, several economies have improved the legal framework granting *ex officio* authority to customs officials and the degree of transparency—the fact is that most economies benchmarked on the Index should be doing more. Counterfeiting and piracy are a direct threat to human welfare, and strong border enforcement is an effective tool in combatting this public safety menace. This remains as much of a challenge today as it was when the first edition of the Index was published in 2012.

Similarly, many economies do not measure or provide publicly available information on customs seizure activities with respect to IP-infringing goods. Since the fifth edition of the Index, under Indicator 38: Transparency and Public Reporting by Customs Authorities of Trade-Related IP Infringement, the Index has sought to measure the extent to which

customs authorities in a given economy publish statistics and data on trade-related IP infringement. Specifically, this indicator measures (1) the extent to which data are published on a regular and systematic basis and (2) the level of detail of these data, including, for example, whether the data lists important information such as countries of origin



# The Global IP Environment in 2021—Major Developments, Overall Index Scores, and Category-by-Category Results

## International Developments

In 2021, decades of development of a global IP rights architecture contributed to the rapid availability of life-saving vaccines and therapies and a host of other technological solutions that kept humans safe, connected, and productive to

a degree unimaginable in previous pandemics. In 2022, those same rights and architecture are under serious challenge from governmental and non-governmental activists who misrepresent the role of IP in innovation and the economy.

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

Even as COVID-19 continued to dominate world affairs in 2021, the global community began to avail itself of new and better tools to mitigate the health and socio-economic impact of the pandemic, especially including safe and effective vaccines being manufactured at global scale, as well, increasingly, as therapies.

Global estimates from the Johns Hopkins Coronavirus Resource Center suggest that at the end of the year, close to 9 billion total doses of COVID-19 vaccines had been administered and almost 50% (44.89%) of the global population was fully vaccinated.<sup>li</sup> Similarly, the IMF-WHO “COVID-19 Vaccine Supply Tracker” database suggests that most of the world’s economies have in place purchase and supply commitments to vaccinate 70% or more of their populations.<sup>liii</sup>

Global vaccine manufacturing output has also scaled up dramatically. Data from the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), released in conjunction

with the fall 2021 G-20 meeting in Rome, showed that global COVID-19 vaccination manufacturing capacity had reached just under 10 billion doses in October 2021, and was projected to reach 24 billion doses by June 2022.<sup>liiii</sup>

As the global community moves forward in 2022, 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 health and economic impact differently, with varying levels of severity experienced depending on the individual health and socio-economic circumstances of that economy. But two years into this pandemic, the critical takeaway is clear: the global community today is in a far better position to manage the socio-economic impact of the pandemic than it was at the beginning of this crisis. This is in large measure due to the extraordinary efforts of IP-intensive industries and, in particular, the research-based biopharmaceutical industry.



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

According to data from the Biotechnology Innovation Organization (BIO), within only three months of the publication of genetic sequencing data of SARS-CoV-2, the first human studies for COVID-19 vaccine candidates had begun.<sup>[iv]</sup> This compares to 20 months during the SARS outbreak in 2003.

At the time of research, data published by the Pharmaceutical Research and Manufacturers of America (PhRMA) at the end of 2021 showed that 1,659 active clinical trials were taking place globally to test treatments and potential vaccines for COVID-19.<sup>[v]</sup> Of these trials, 624 were testing unique COVID-19 treatments, with a total of 132 vaccines in clinical trials. Most important of all, several novel vaccines have been authorized or approved for use across the world and billions of people have been inoculated.

It is impossible to overstate the enormity of these accomplishments. The speed at which this research has taken place is unprecedented. It shows the extensive scientific capacity developed by the biopharmaceutical and biotech communities and their ability to understand and develop a treatment for a novel virus that was not present in human beings 24 months ago, and to scale up manufacturing quickly and decisively.

At a scientific, manufacturing, distribution, and organizational level, what the industry together with its partners in academia and the public sector has been able to achieve is remarkable. As many politicians, policymakers, and scientists pointed out when the first vaccine was authorized for emergency use by the FDA, this achievement truly amounts to a modern-day miracle.

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

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

International experience and the basic economics of the biopharmaceutical industry show how critical IP rights are to enable this massive investment in the research and development of new medical technologies and products.<sup>[ix]</sup> In particular, patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection (RDP) and special incentives for the protection and production of orphan drugs, enable research-based companies to make otherwise unsustainable investments in R&D toward the discovery of new drugs, medical devices, and therapies. And whereas public sector funding of early-stage scientific research is significant and critically important, the private sector, without any guarantee of a return on

investment, funds and performs the lion's share of the applied science that turns advances in knowledge into usable products that save lives.

Biopharmaceutical innovation is an extremely high-risk investment. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and 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. Generic competition from additional market entrants follows later, by design, precisely because these follow-on manufacturers bear none of the costs of early-stage investment, R&D, and product commercialization carried by the innovator.

## Taking a wrong turn: Proposals for a WTO TRIPS Waiver

In October 2020, before a single vaccine was fully tested, reviewed, and authorized as safe and effective by competent scientific and regulatory bodies, a group of WTO members led by India and South Africa put forth a proposal to waive the greater part of the international IP rights commitments that form the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement.<sup>[x]</sup> These countries offered no evidence that IP rights were or would become a barrier to an effective global response to the pandemic, merely their assertions that patents rights were inconsistent with their vision of global equity.

What waiver proponents appear to willfully mischaracterize is that undermining intellectual property rights for complex, hard to manufacture vaccines will not accelerate global production or increase local technical know-how—such capabilities are cultivated through sustained

The innovation, 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 allocation of resources, formation of partnerships, and transfer of technology on commercial terms. Without strong and clear IP rights, it is unlikely that any of the products and technologies—or the underlying science—that have been essential to keep societies functioning and fighting the COVID-19 pandemic, would exist.

As the Index and its accompanying *Statistical Annex* has sought to show over the last decade, the link between IP rights, innovation, and the commercialization of new products and technologies is clear and statistically significant.

education and investment. Rather, a waiver of IP rights will impede ongoing and successful efforts to license and scale global production of safe and effective vaccines. Indeed, as of May 2021, there were nearly 300 voluntary partnerships and collaborations among manufacturers facilitating the production of billions of doses of vaccines, all supported by the contractual licensing of IP rights, whether on commercial or not-for-profit terms.

Meanwhile, multiple media reports indicate that countries have asked manufacturers to suspend delivery of COVID-19 vaccines because they are unable to administer existing supply. This points to the genuine trade policy and supply chain challenges that experts warned would slow distribution and administration of life-saving vaccines and therapies once available. Overall, a waiver of IP rights commitments will undermine the global fight against COVID-19 and



it will diminish the world's ability to prepare for and respond effectively to the next pandemic.

Over the last year, considerable political discourse has focused on the need for global and local manufacturing capacity to address this pandemic and the next. These conversations have identified the right problem and, in the proposed IP waiver, the wrong solution. There is an existing architecture for building global capacity for both innovation and local production of the products of innovation. The ground floors of that architecture can be found in the WTO TRIPS Agreement, while many more critical elements can be found right here in this Index.

To date, too many countries have resisted the IP standards represented by TRIPS, which they have viewed as a cost rather than an investment. Consequently, and as this Index quantifies, the TRIPS Agreement has never been fully or faithfully implemented by most WTO member countries. Yet, for countries that wish to be on the front lines for solutions in the next pandemic, that very same IP architecture, where supported by a rule of law environment, provides all the tools necessary for full and effective participation in the innovation ecosystem: 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.

## Overall Results and Category-by-Category Scores

Up or down? How have economies fared in this edition of the Index? Below, Table 5 shows the overall results for the tenth edition of the Index and how it compares to last year's edition.

Table 5: Change in Overall Score, Ninth Edition Versus Tenth Edition

Country	Tenth Edition	Ninth Edition	Change in Overall Score
U.S.	95.48%	95.31%	0.17%
UK	94.14%	93.90%	0.24%
Germany	92.46%	92.27%	0.19%
Sweden	92.14%	90.92%	1.22%
France	92.10%	91.43%	0.67%
Japan	91.26%	91.12%	0.14%
The Netherlands	90.70%	90.02%	0.68%
Ireland	88.84%	88.86%	-0.02%
Switzerland	86.00%	85.82%	0.18%
Spain	85.94%	84.68%	1.26%
Singapore	84.44%	84.38%	0.06%
South Korea	83.94%	83.73%	0.21%
Italy	83.40%	83.15%	0.25%
Australia	80.70%	80.55%	0.15%
Hungary	76.90%	78.23%	-1.33%
Canada	75.24%	74.71%	0.53%
Israel	72.74%	72.57%	0.17%
Greece	70.92%	70.67%	0.25%
Poland	70.74%	70.50%	0.24%
New Zealand	69.28%	69.10%	0.18%
Taiwan	66.29%	66.18%	0.11%
Morocco	59.76%	59.62%	0.14%
Mexico	58.98%	58.25%	0.73%
China	55.86%	54.86%	1.00%
Costa Rica	54.56%	54.46%	0.10%
Dominican Republic	54.28%	54.32%	-0.04%
Malaysia	51.90%	51.61%	0.29%
Turkey	51.07%	51.07%	0.00%
Peru	49.32%	46.56%	2.76%
Colombia	48.84%	48.17%	0.67%
Chile	48.72%	46.20%	2.52%
Russia	46.64%	46.58%	0.06%
UAE	46.02%	41.98%	4.04%
Jordan	44.70%	44.53%	0.17%
Honduras	42.18%	NA	NA
Brazil	42.02%	42.32%	-0.30%
Philippines	41.58%	39.81%	1.77%



Country	Tenth Edition	Ninth Edition	Change in Overall Score
Saudi Arabia	41.38%	40.38%	1.00%
Brunei	41.08%	41.13%	-0.05%
Ghana	40.88%	NA	NA
Ukraine	39.74%	39.54%	0.20%
Vietnam	38.72%	37.49%	1.23%
India	38.64%	38.40%	0.24%
Kenya	37.38%	37.25%	0.13%
South Africa	37.28%	36.61%	0.67%
Argentina	37.02%	36.77%	0.25%
Thailand	35.78%	35.56%	0.22%
Egypt	32.82%	32.59%	0.23%
Nigeria	31.34%	27.43%	3.91%
Ecuador	30.70%	30.60%	0.10%
Indonesia	30.42%	30.16%	0.26%
Kuwait	27.92%	27.86%	0.06%
Pakistan	27.43%	26.43%	1.00%
Algeria	26.36%	26.45%	-0.09%
Venezuela	14.10%	14.10%	0.00%

Similar to the results of the ninth edition, the vast majority of economies sampled in the Index saw their IP environments improve in 2021. Out of the 53 economies included in both the ninth and tenth editions (Ghana and Honduras are new economies added to the tenth edition and cannot be compared to previous editions), 45 economies saw a net improvement in their scores. This compares to only six economies that saw their scores drop. Two economies saw their scores remain unchanged.

Compared with the large movements and changes seen over the seventh, eighth, and ninth editions of the Index, the results from the tenth edition are more muted. Only two economies, **UAE** and

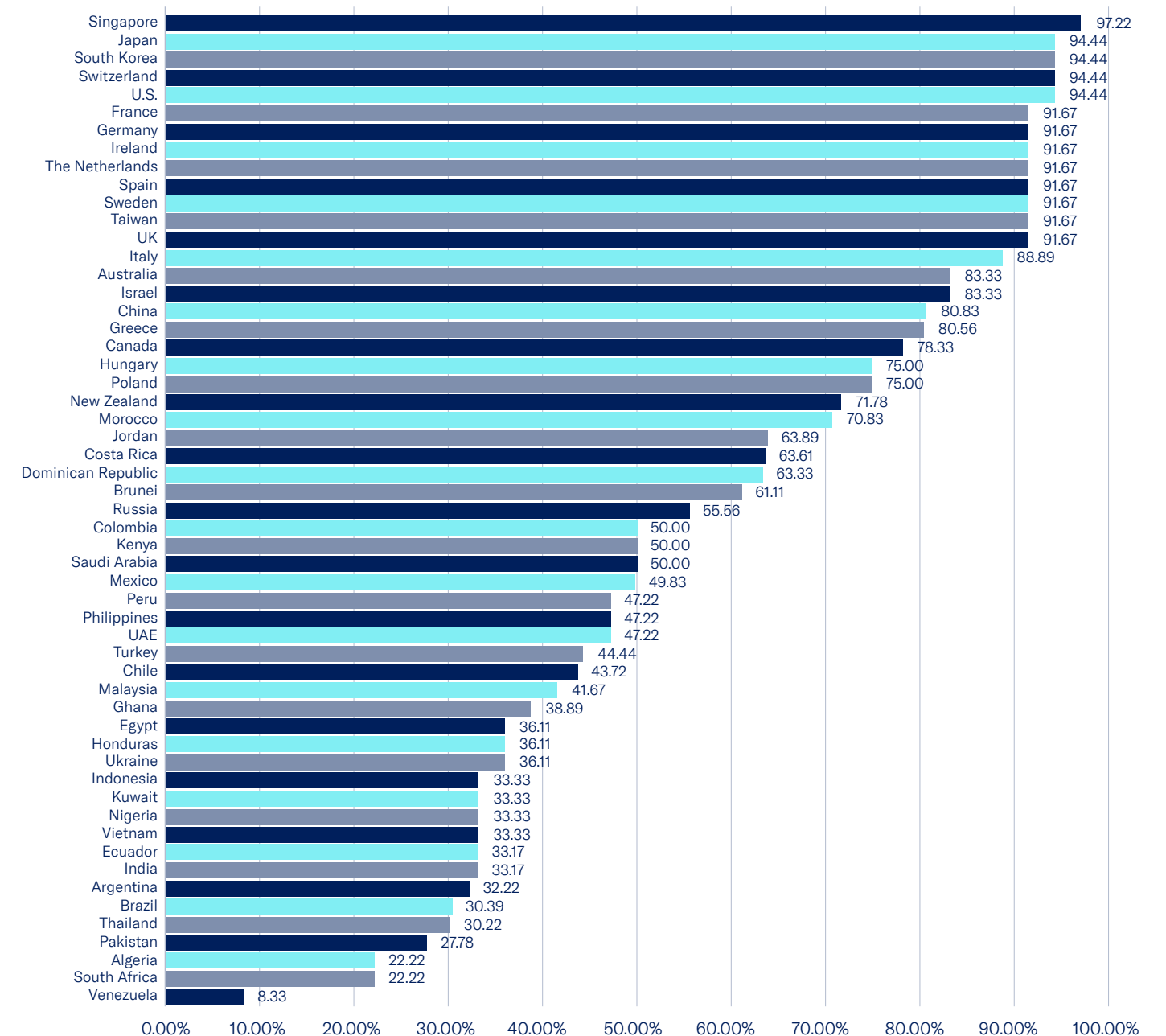
**Nigeria**, saw an increase of more than three percentage points, with increases of 4.04% and 3.91%, respectively. Conversely, of the economies that saw their scores drop, the largest recorded decrease was with **Hungary** at a fall of 1.33%. However, the lack of large movements in overall scores masks what amounted to rather substantial score swings within the individual Index categories. As the next few pages detail, many economies saw significant increases and, in many cases, decreases on individual category scores. In particular, many economies introduced fresh restrictions and limitations on the extent to which inventors can register and exercise their granted patent rights.

## Category 1: Patents, Related Rights, and Limitations

Below, Figure 8 summarizes the total scores for Category 1. This category measures the strength of an economy's environment for Patents, Related

Rights, and Limitations. The category consists of nine indicators, with a maximum possible score of 9.

Figure 8: Category 1: Patents, Related Rights, and Limitations, % Available Score







As in past editions, the overall results for Category 1 are still one of the strongest of all the categories included in the Index. Twenty-three economies achieved a score of 70% or more of the available score and 31 economies in total achieved a score of 50% or more. The average score on the category is 59.92%, which is the third highest scoring category on the Index. As in years past, **Singapore** is ranked number one, ahead of **Japan, South Korea, Switzerland,** and the **U.S.**

As noted in previous editions, the patenting environment in the **U.S.** continues to be held back by uncertainty over what constitutes patentable subject matter and patent nullity proceedings through the *inter partes review* (IPR), which occurs before the specialized Patent Trial and Appeals Board (PTAB) within the USPTO. Since the Supreme Court decisions in *the Bilski, Myriad, Mayo,* and *Alice* cases, there has been a high and sustained level of uncertainty as to which inventions are patentable in the U.S. Since 2014, the USPTO has issued and updated patent examination guidelines almost annually. Under the leadership of former Director Iancu, the USPTO recognized this dilemma and sought to re-formulate its position and the approach to be taken by its examiners.

In 2019, the USPTO released new guidance covering Section 101 patentability and Section 112 claims relating to computer inventions, the “2019 Revised Patent Subject Matter Eligibility Guidance” and “Examining Computer-Implemented Functional Claim Limitations for Compliance With 35 U.S.C. 112,” respectively. With respect to Section 101 patentability, the guidance provided more of a principle-based analysis of how patentability would be judged and described the stepwise approach examiners should follow to understand and apply the Supreme Court’s *Alice/Mayo* test. As the guidance rightly pointed out, the key challenge for USPTO examiners and courts has been to “consistently distinguish between

patent-eligible subject matter and subject matter falling within a judicial exception.”

The guidance recognized this and sought, to the extent that is possible without further statutory changes, to clarify with a revised procedure and process for examiners to follow. Unfortunately, as noted repeatedly by the Index, uncertainty over what constitutes patentable subject matter has crept into all facets of the American patent system: from initial application and examination to standards of review and invalidity proceedings, whether administratively through the PTAB or through the judiciary. This remains unchanged in 2021. For example, with respect to the influence and use of the USPTO’s 2019 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. More broadly, lower and circuit court decisions in patent infringement proceedings have not always been consistent. This level of uncertainty is further compounded by a sustained level of unpredictability with respect to post-grant opposition and patent nullity proceedings.

In an effort to provide a more cost-effective, efficient alternative to judicial proceedings, the 2011 America Invents Act (AIA) introduced new post-grant opposition and patent nullity proceedings. As has been noted in previous editions of the Index, despite the intentions of these new AIA mechanisms, the result has been a sustained level of uncertainty and unpredictability for many patent owners. This has been especially the case with the IPR, which occurs before the specialized PTAB within the USPTO. As noted over the last four editions of the Index, the U.S. government (chiefly through the USPTO) has recognized the unintended effects of the PTAB system and publicly pledged to work with all stakeholders

to address and remedy them. As a result, many important changes have since been introduced.

Examples of these reforms include (1) changing the patent claim construction standard used, moving away from the broadest reasonable interpretation (BRI) standard to the so-called “*Phillips* standard,” the latter which is the claim construction standard used in the judiciary since the mid-2000s; (2) a new Trial Practice Guide; and (3) Standard Operating Procedure (SOP) changes. Using the *Phillips* standard has aligned IPR proceedings with the same claim construction standards that are used in patent infringement proceedings at U.S. district courts. Similarly, the revised Trial Practice Guide provides greater clarity on the grounds on which a review may be initiated. And the changes to both SOP 1 and SOP 2 have sought to streamline how judges are assigned, the composition of panels, and the way precedent-setting opinions are set. Specifically, SOP 2 set up a “Precedential Opinion Panel” (POP), headed by the USPTO Director. Since its introduction, the POP has been active in shaping how the IPRs operate; several of the panel’s decisions have been of high procedural importance, addressing issues relating to the USPTO’s Director’s decisions to institute IPR proceedings (see, for example, *Valve Corp. v. Electronic Scripting Products, Inc.*) and procedural rules including the declaration of interested parties (*ProppantExpress Investments, LLC v. Oren Techs., LLC*).

The U.S. Supreme Court has also been active in shaping the manner in which PTAB proceedings take place; several important decisions have been rendered, including in *SAS Institute Inc. v. Iancu, Thryv, Inc. v. Click-to-Call Technologies, LP, et al.*, and, in 2021, *Arthrex, Inc. v. Smith & Nephew, Inc.* Although the judgment in the latter case provides more direction as to the technical categorization of judges serving on the PTAB, overall, rightsholders continue to face great uncertainty over how patent disputes will be adjudicated and how

decisions will be made and upheld within different fora. The net result is that, at a systemic level, rightsholders are left without a clear sense of how decisions on patent eligibility will be made and, 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.

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

As detailed over the course of the Index, there continues to be a high degree of uncertainty regarding the availability of patent term restoration in the **EU** and the **UK**. Regulation 2019/933 remains in force and the SPC export exemption is legal and operational in all EU Member States. In 2020, the Court of Justice of the European Union (CJEU) reversed earlier precedent from 2012 by disallowing the issuing of an SPC for new innovations relating to approved biopharmaceutical products and treatments. In earlier rulings, the CJEU had held that it was possible to obtain an SPC for the new use of a product for which a market authorization for the same active ingredient had already been granted. This decision has now, effectively, been overturned. The court’s verdict sets another unfortunate precedent and will likely further limit the availability of European incentives for biopharmaceutical innovation.

With respect to the **UK**, while the British government now has the sovereignty and power to effectively shelve Regulation 2019/933, it has instead chosen to maintain the EU SPC exemption. In 2020, the UK Intellectual Property Office (UKIPO) held a public consultation on a draft statutory instrument that would amend the existing exemption, making it more compatible with UK statute. Unfortunately, despite rightsholders calling for the government to reconsider its decision to retain the exemption, in its public



response to the consultation the government reiterated its position that the SPC exemption would be retained and be operable going forward.

Outside of Europe, Regulation 2019/933 continues to set a negative example and precedent for other economies to emulate. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU would be that the policy would be emulated by other economies. And that is exactly what is happening. Last year **Ukraine** introduced a similar set of provisions and, as detailed above, **Israel** has now proposed to do the same. As both the Ukrainian and Israeli examples show, instead of benefiting the European generics industry, the introduction of the EU's SPC exemption has simply ended up hurting Europe's research-based industry and has led to a global race toward the bottom in weakening global IP standards.

As detailed below under **Brazil's** "Economy Overview," rightsholders face many basic challenges in registering and protecting patent-eligible subject matter in Brazil, with patentability standards for both biopharmaceutical technologies and CIIIs outside international norms. The national IP office INPI has a long-standing backlog of patent applications ranging from 10 to 13 years depending on the field of technology; applications in the biopharmaceutical and ICT fields are traditionally the worst affected.

The past few years have seen a growing level of commitment and efforts by INPI to address this backlog. To some extent, these actions have had a positive impact and have reduced the number of pending applications. At the time of research, the estimated backlog of just under 150,000 applications, identified as constituting the backlog in 2019, had been reduced by roughly two-thirds, to around 50,000 applications. While a sizeable reduction, the bottom line is that even two years after significant reform efforts, around

50,000 applications are still subject to a backlog. Given that the INPI has struggled for decades to effectively address the extensive backlog and long delays in application processing, the Industrial Property Law has provided innovators in Brazil with a guaranteed minimum term of exclusivity and protection of 10 years from *grant* for standard patents. For years this has provided rightsholders with a proverbial floor of exclusivity and insurance against INPI's endemic delays.

In a series of decisions in the spring of 2021, the Brazilian Supreme Court has removed this floor. Not only did the court declare that Article 40 was unconstitutional and would no longer be available or applicable, but the court also stated that the ruling should be retroactively applied but only to granted patents in the biopharmaceutical and health-related fields. The ruling is a grave blow to Brazil's national IP environment and especially to biopharmaceutical rightsholders. Local legal estimates suggest that there are currently over 10,000 pending patent applications with a delay of over 10 years, which will, per definition, see their period of exclusivity cut short.

In a separate negative development, Brazilian policymakers continued the tradition of focusing on compulsory licensing as a public policy tool. Several amendments to the Industrial Property Law had been signed into law in late 2021, with many more under discussion. Passed amendments include provisions broadening the government's emergency powers and authority to issue compulsory licenses, setting the percentage of royalties to be paid in licensing fees, and expanding the compulsory licensing mechanism to also cover patent applications. At the time of research, additional provisions relating to technology transfer were still pending and being debated in the Brazilian Congress.

As in Brazil, in **Russia**, rightsholders face growing restrictions on their ability to protect

their inventions. As detailed below in Russia's "Economy Overview," the last few years have seen several negative developments with respect to the patentability of high-tech inventions in Russia, with new amendments to relevant sections of the Civil Code Part IV and guidelines used by the patent registration authorities. In addition, Russian authorities have come to view compulsory licensing for biopharmaceuticals as a legitimate policy tool for achieving industrial and public finance goals.

On December 31, 2020, the Russian government issued a compulsory license under Order 3718. The order authorized a local manufacturer to produce a generic version of remdesivir, an antiviral drug used in the treatment of COVID-19, overriding the existing Eurasian patents for the drug. In 2021 the

Russian Duma passed, and President Putin signed into law, fresh amendments to the Civil Code Part IV. These changes amended the relevant statute, inserting a further justification for the overriding of any granted rights relating to patents, utility models, and industrial designs. In addition to the existing broad national security powers, the Russian government can now justify the use of any invention on the basis of protecting "the life and health of citizens." This is another in a long succession of negative developments in Russia for biopharmaceutical innovators that fundamentally undermines the national IP environment.

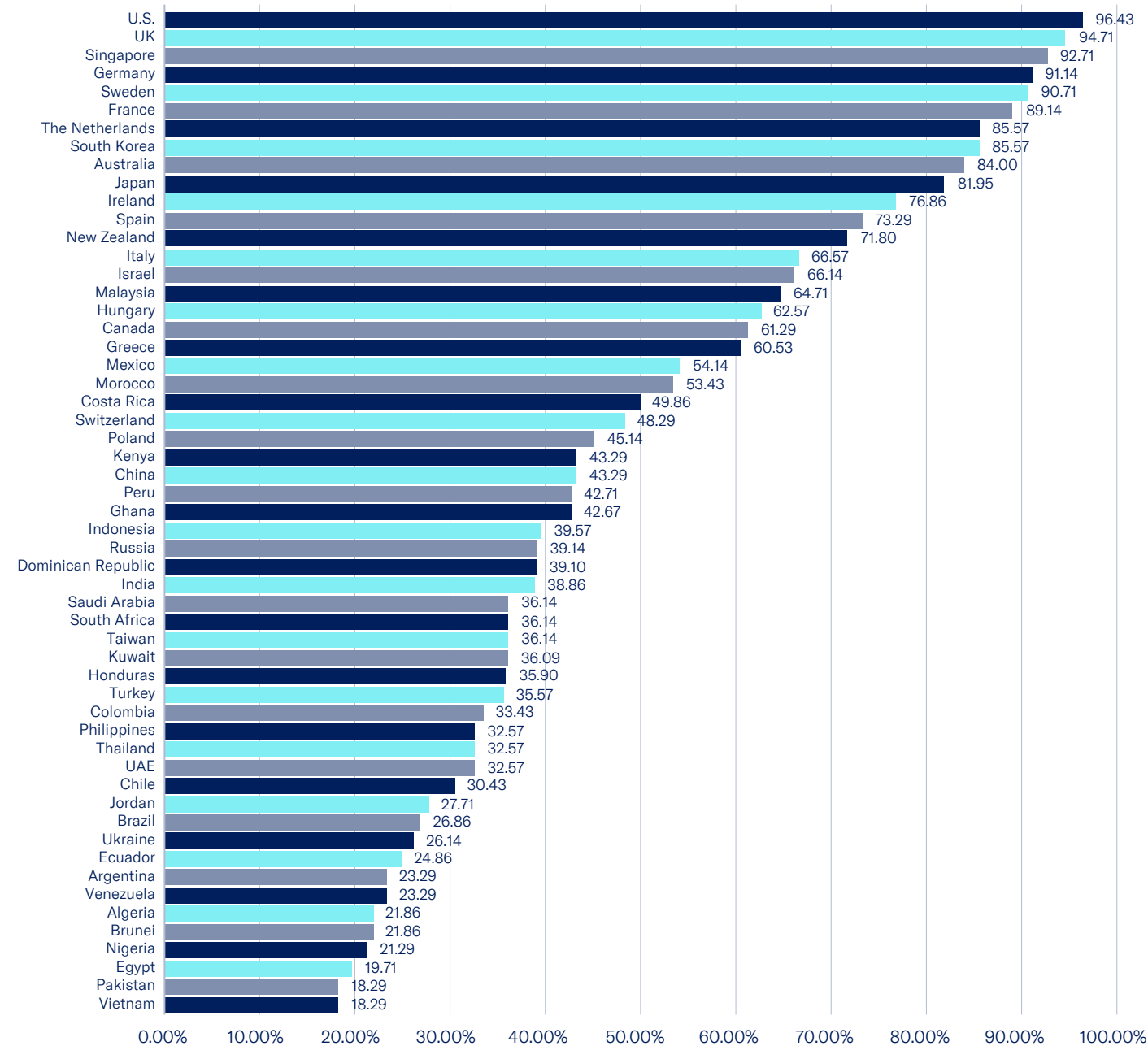


# Category 2: Copyrights, Related Rights, and Limitations

Figure 9 summarizes the total scores for Category 2. This category measures the strength of an economy's environment for

Copyrights, Related Rights, and Limitations. The category consists of seven indicators, with a maximum possible score of 7.

Figure 9: Category 2: Copyrights, Related Rights, and Limitations, % Available Score



As in years past, the results for Category 2 show how challenging the environment is for creators and copyright holders in the vast majority of sampled economies. Thirty-four of the 55 economies sampled failed to reach 50% of the available score. The average score on this category was 49.57%. Many economies have only the most basic forms of protection in place and enforcement remains wholly inadequate. Nevertheless, despite this aggregated weakness, there were some positive developments in 2021.

Many Latin American economies are adopting injunctive-style relief mechanisms to combat online piracy more effectively. In what could be an important new pathway for rightsholders to enforce their rights on the internet, in 2021 **Colombia's** national copyright office DNDA ordered local service providers to disable access to copyright-infringing material. At the time of research, the DNDA had ordered the disabling of access in two separate cases: the first case concerned the unauthorized publication of a scientific journal article, and the second case involved the unauthorized broadcasting and dissemination of copyrighted audiovisual content through a local company, IPTV Colombia Premium.

Similarly, over the past few years **Peru's** national IP office INDECOPI has acted against infringing websites and ordered the disabling of access to copyright-infringing materials. In 2017 INDECOPI ordered the suspension of access to the infringing website Foxmusica. Similarly, in 2019 the agency disabled access to six websites at the request of the Spanish football division *La Liga*. The same year, INDECOPI also ordered the e-commerce platform *Mercado Libre* to remove the links to 28 ads offering counterfeit products linked to the Pan American Games. This positive action continued in 2021. In May the agency announced that it had ordered the disabling of access to ten stream-ripping websites as well as several websites specializing in the unauthorized reproduction

and illegal streaming of live sporting events, including of professional soccer matches.

Even in **Ecuador**, where rightsholders have had little in the way of practical recourse against copyright infringement—copyright infringement had been decriminalized in 2013—relevant authorities have taken action against infringing websites. In June 2019, the Ecuadorian national IP authority SENADI ordered local ISPs to disable access to several websites hosting infringing and unlicensed content. The administrative order came following a request made by local rightsholders Fox Latin America and the Spanish national soccer league *Liga Nacional de Fútbol Profesional (La Liga)*.

There were also some notable positive developments in **Brazil**. Specifically, “Operation 404 against piracy” (*Operação 404 contra pirataria*) continued enforcement operations. Spearheaded by a special police enforcement unit (SEOPI) and the Ministry of Justice, along with international support from the U.S. Embassy and UK law enforcement officials, this special enforcement effort has had direct and tangible results: hundreds of websites and applications offering copyright-infringing content have been shut down; over 50 search and seizure warrants have been issued and executed across 12 Brazilian states; and several arrests have been made.

In **Canada** in May 2021, the Federal Court of Appeal upheld the granting of an injunction against websites hosting alleged infringing content. This marks the end of a long legal journey that began over two years ago. In November 2019, a court ordered a group of ISPs to disable access to websites hosting alleged infringing content. The case, *Bell Media Inc. v. GoldTV.Biz*, shows both the limitations and potential for this route of copyright enforcement in Canada. On the one hand, the granting of a permanent injunction shows that the possibility exists for rightsholders to access this type of relief under existing statute



in Canada. On the other hand, the injunction was only granted following unheeded initial complaints when preliminary injunctions were asked for and granted in the summer of 2019. In 2020 the case was appealed, and the final Federal Court of Appeal verdict was issued in May 2021. This ruling is of real significance to Canadian rightsholders, as not only did the court clearly affirm the right to injunctive relief and the disabling of access to infringing content online under existing Canadian statute, but it also affirmed, both in principle and in the specific circumstances of this case, that where there is clear *prima facie* evidence of infringement taking place, injunctive relief did not interfere with the principles of net neutrality or freedom of expression. Interestingly, both the Court of Appeal and lower court judgment recognized the possibility and need for amendments to the order with respect to relevant domain names and website addresses as the infringing parties seek to circumvent it.

There were also significant developments in **China** with legislative changes from 2020 coming into effect in June 2021. As noted in last year's edition of the Index, new important amendments to the Chinese Copyright Law finally passed in 2020. These include a strengthening of the legal framework in relation to sound and broadcasting. A revised Article 3 provides new

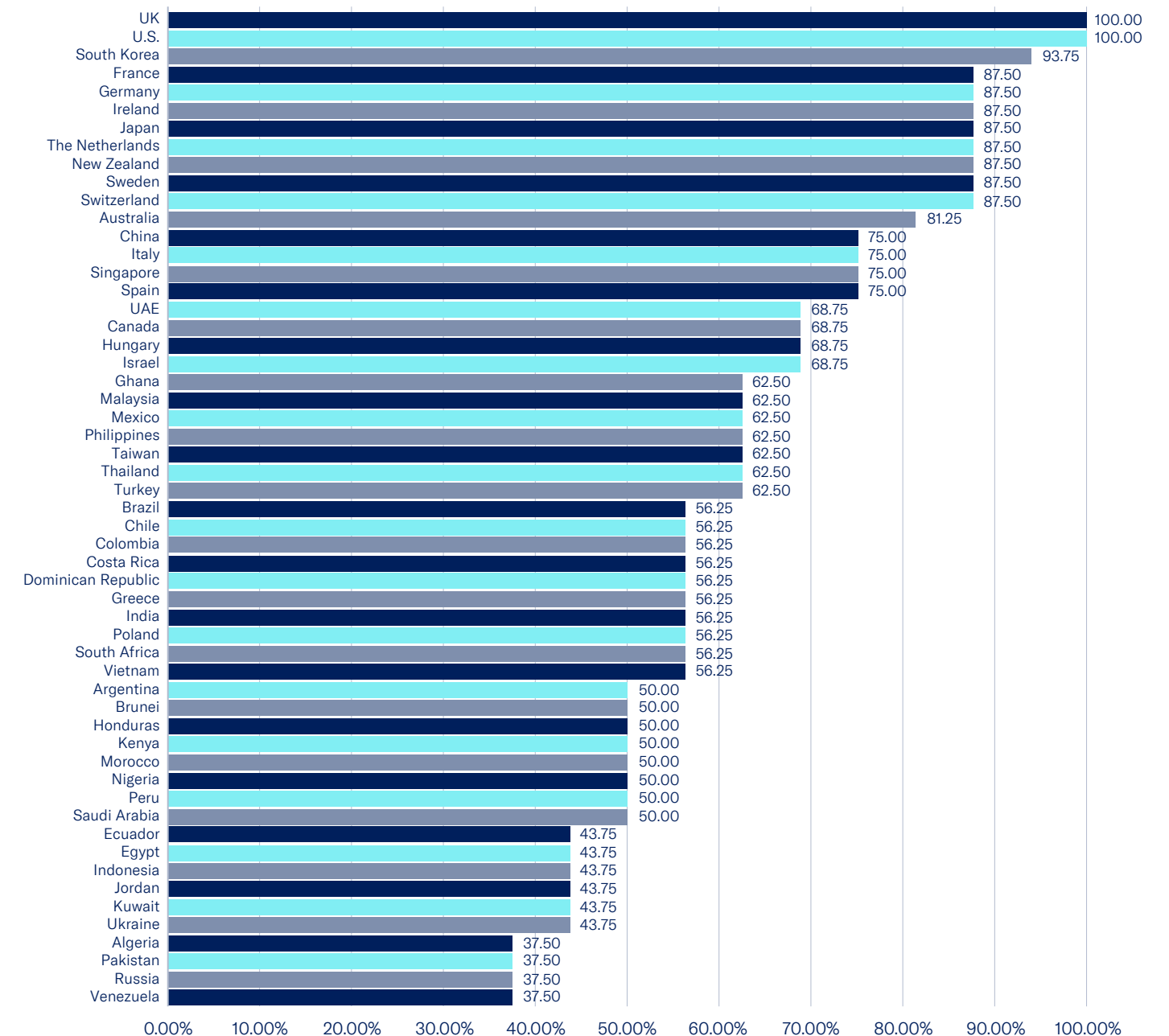
definitions of copyrightable material including for "audiovisual works" and a broad "other intellectual achievements that meet the characteristics of the work." Rights relating to performance rights, sound recording, and broadcasting have also been more clearly defined. Similarly, provisions relating to technological protection measures (TPM) and digital rights management (DRM) have been strengthened through Articles 49, 51, and 53, which now provide a broader definition of infringement—including for the manufacturing, importation, and offering of circumvention devices to the public. Statutory damages for copyright infringement have also been increased substantially following similar changes to the Patent Law and Trademark Law. These amendments are now in effect and in force in China. As mentioned at the time of passage, these positive changes could, in aggregate, amount to a significant improvement of the copyright environment in China. The Index will monitor how these legislative changes are applied in practice and the extent to which they improve the ability of rightsholders to enforce their copyrights in China over the next few years.

## Category 3: Trademarks, Related Rights, and Limitations

Figure 10 summarizes the total scores for Category 3. This category measures the strength of an economy's environment for Trademarks, Related

Rights, and Limitations. The category consists of four indicators, with a maximum possible score of 4.

Figure 10: Category 3: Trademarks, Related Rights, and Limitations, % Available Score





Most economies sampled in the Index offer basic forms of trademark protection. Only ten of the 55 sampled economies failed to score 50% or more on this category. Overall, the average score on this category was 62.95%.

An increasing share of trademark-infringing activity is taking place online through e-commerce platforms and online shopping. Some online third-party marketplaces and shopping platforms are working with brand owners and rightsholders extensively to adopt swift takedown procedures, pursue joint criminal actions, and encourage information sharing, among other efforts. Such practices offer improvements to a complex environment and work best as a collaborative effort involving brand owners, online marketplaces, and policymakers—as well as consumers. Still, this is an area where few economies have the appropriate resources, technology, or effective mechanisms in place to combat the increased sale of counterfeit goods online. There are some examples of jurisdictions where relevant legislation or case law has established an obligation on the part of online merchants to take down IP-infringing material upon notification by a rightsholder. However, overall, the mechanisms in place are outweighed by the sheer quantity of counterfeit goods available online. Still, there were some new positive developments in 2021.

As noted in previous editions of the Index, the past few years have seen the fight against online infringement intensify in the **Philippines**. At the time of research, draft anti-counterfeiting and anti-piracy legislation was still pending in the Congress. Specifically, the relevant legislative package—which was consolidated in 2021—would grant broader powers of enforcement to the national IP office IPOPHL, including the power to directly order the disabling of access to websites and online merchants offering IP rights-infringing goods or services. With respect to online violations of trademarks and copyrights, in parallel

to these legislative reforms, IPOPHL has actively pursued an enhanced online enforcement program based on existing powers to address the growing presence of counterfeit and pirated goods online.

In March 2021, IPOPHL adopted new rules through Memorandum Circular (MC) 2020-049. These changes explicitly recognize and include the electronic, online, or digital spheres within IPOPHL's enforcement remit. Upon receiving a complaint about potential infringement, IPOPHL now has the power to order the termination of the infringing activity and, in the case of infringement taking place online or through electronic means, refer the matter to the National Telecommunications Commission (NTC) for the disabling of access to the relevant online or electronic source. Instead of 60 days, alleged infringers now have 72 hours to comply with an IPOPHL enforcement order.

In a linked development, in April 2021, IPOPHL agreed on a new enforcement partnership with the NTC and a selection of the largest ISPs in the Philippines. IPOPHL described the aim of the partnership as enabling a “more streamlined and rapid blocking of pirated sites.” Similarly, an agreement was reached between rightsholders, the IPOPHL, and the leading Filipino e-commerce platforms Lazada and Shopee. Under a Memorandum of Understanding (MOU), all parties agreed to use a standardized notification process whereby access to links and advertisements to suspected infringing goods would be disabled. Finally, an IPOPHL referral to the National Bureau of Investigation (NBI) led to a physical raid and seizure of an estimated USD 1.8 million of counterfeit goods. The IPOPHL referral to the NBI came because of a complaint from a rightsholder.

Rightsholders have long faced difficulties in protecting their trademarks in **Thailand**. The availability of physical counterfeit goods is high, and as e-commerce grows an increasing proportion of the trade in counterfeits is moving online. The past

three years have seen major developments with respect to online enforcement against counterfeit goods. In 2019 the Thai government, through the national IP office, the DIP, held consultations with some of the major e-commerce platforms aimed at discussing tools and procedures to more effectively tackle online infringement and the sale of counterfeit goods. The two largest online shopping platforms in Thailand, Lazada and Shopee, reported on existing or recently enhanced systems to tackle online piracy. Lazada—a subsidiary of Alibaba—has begun implementing Alibaba's IP Protection Platform system, which enables customers to file a complaint directly with the platform either through the website or mobile application. Shopee reported on an online link and a call center line where rightsholders can submit their complaints. The same year, the DIP organized a workshop that brought together rightsholders, internet platforms, and national and foreign enforcement agencies to discuss the platforms' role in tackling online piracy. The DIP also created a dedicated unit for online violations tasked with furthering dialogue among relevant stakeholders, including online marketplaces.

As reported in the Index last year, these positive developments continued in 2020 with what could perhaps be a precedent-setting application of an injunctive-style relief mechanism introduced in

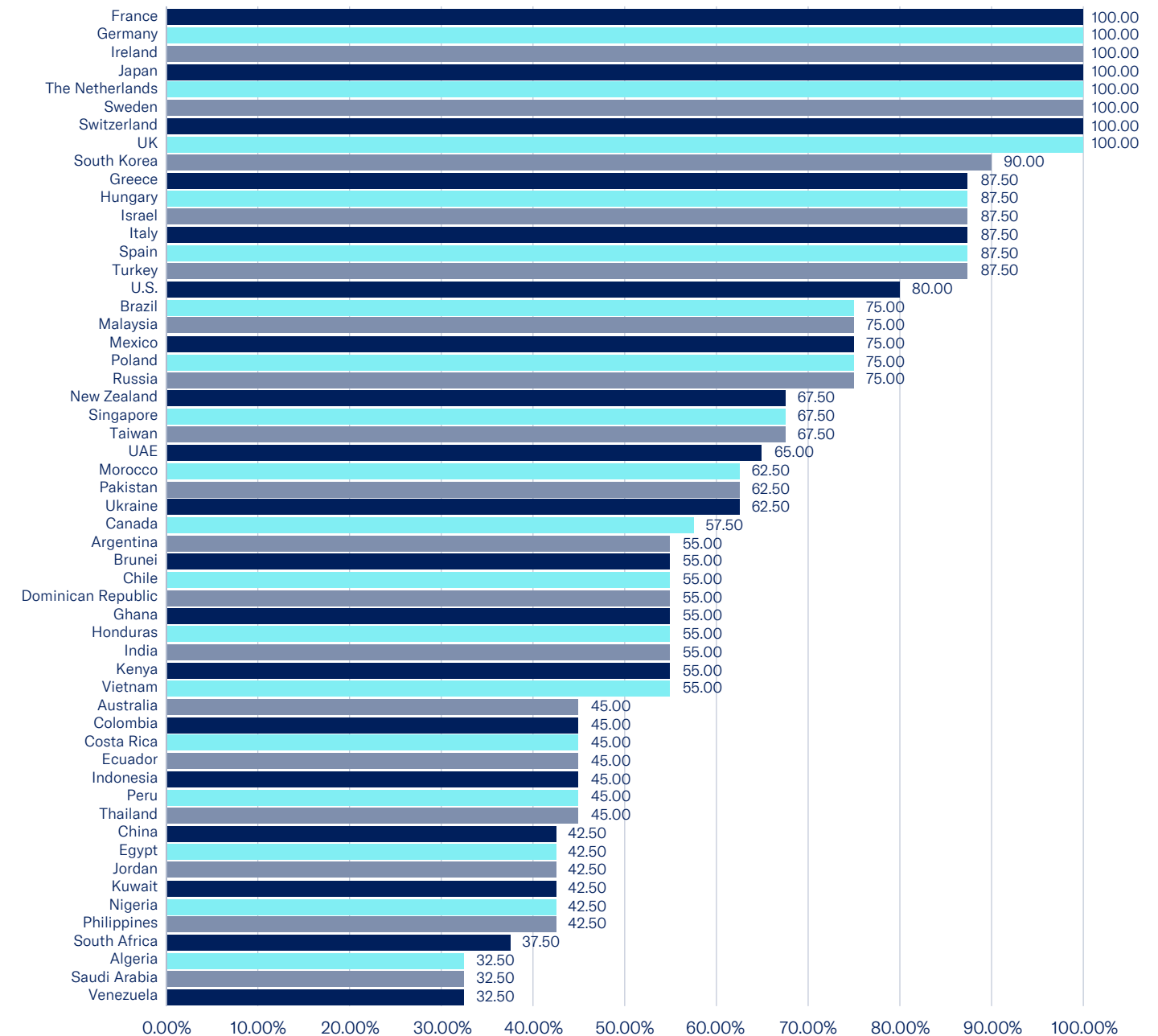
the 2016 Computer Crime Act. Specifically, these amendments provide a legal mechanism requiring ISPs to disable access to IP-infringing sites. Under the mechanism, the Ministry of Digital Economy and Society (MDES) may file a motion for a permanent injunction for disabling access to websites with IP-infringing content (defined as computer data that constitutes a criminal offense against IP). MDES is notified by IP owners of infringing content and then sends a request for injunctive relief to a court. If an injunction is granted by a court, MDES orders the ISP to disable access to the site. Up until 2020, this mechanism had exclusively been used by copyrights holders. This has now changed, and both the MDES and a relevant court approve and order ISPs to disable access to several websites on the basis of infringement of trademark rights. As noted in last year's Index, the decision marks a potential new and pivotal avenue whereby rightsholders can more effectively enforce their trademarks online. These positive efforts continued in 2021. In January the Deputy Prime Minister presided over the signing of an MOU between rightsholders, online retailers (including both Lazada and Shopee), and the Thai government. The purpose of the MOU is to facilitate stronger cooperation between online retailers, rightsholders, and relevant government ministries and agencies in eliminating counterfeiting and enforcing IP rights.



# Category 4: Design Rights, Related Rights, and Limitations

Figure 11 summarizes the total scores for Category 4. This category measures the strength of the environment for design rights. The category consists of two indicators, with a maximum possible score of 2. These indicators measure the maximum term of protection being offered (including renewable periods) for design rights and the extent to which economies have in place and apply laws and procedures that provide necessary exclusive rights.

Figure 11: Category 4: Design Rights, Related Rights, and Limitations, % Available Score



Most economies included in the Index have in place some form of statutory law defining design rights and a term of protection for registered design rights. More and more economies are recognizing the importance of design rights to their national economies. The average score on this category was 65.14%. Over the past few years,

many economies have reformed relevant laws and regulations and, in many cases, extended the term of protection. This continued in 2021.

Since the mid-2010s, **Chile's** National Congress has debated various iterations of the *Ley Corta de INAPI*, a package of reforms amending Law



19,309 on Industrial Property. In June 2021, this reform package was finally passed into law. The reforms include a revised Article 65 extending the term of protection for design rights to 15 years from the previous ten-year period.

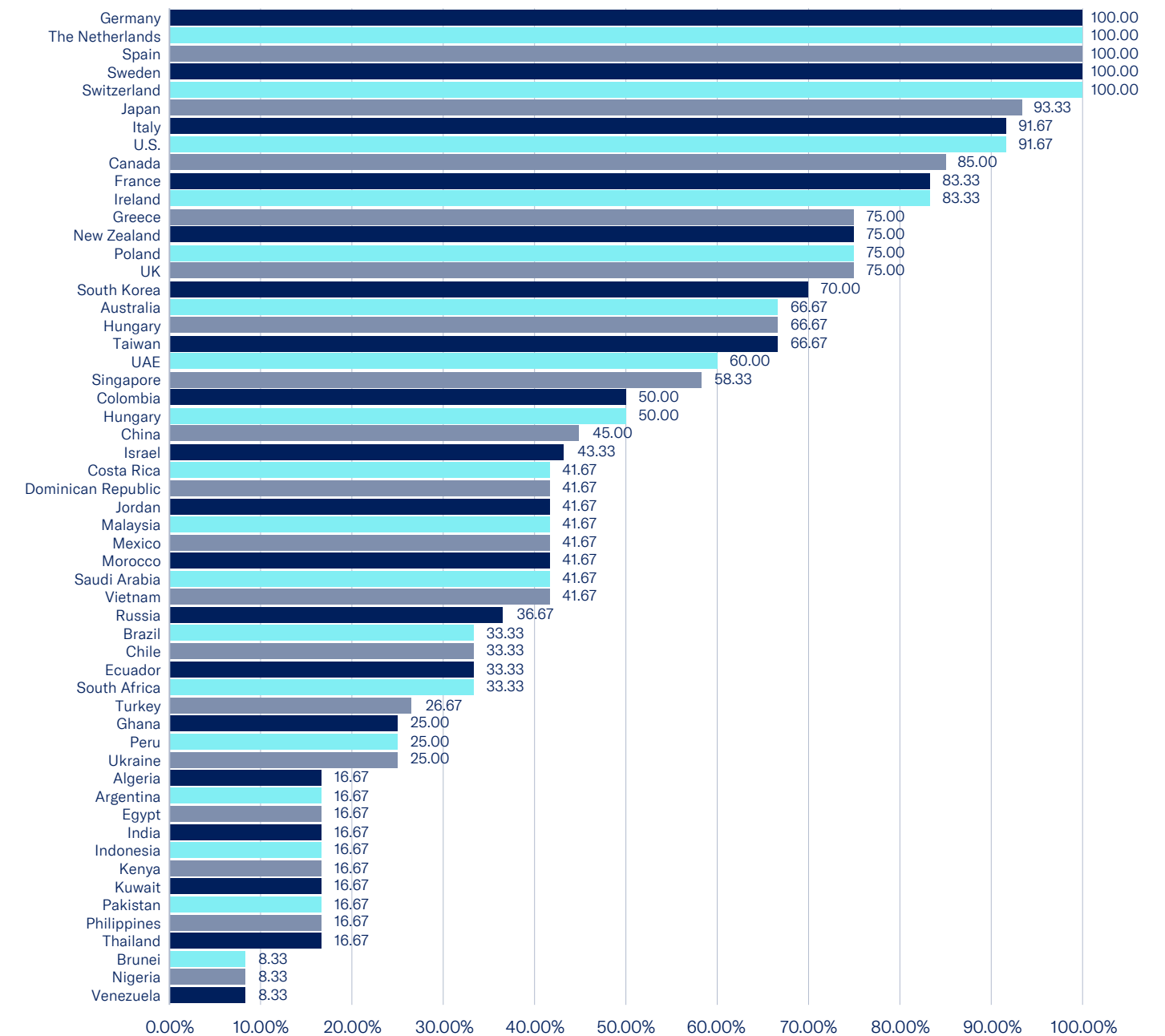
Similarly, a new industrial property law, Federal Law No. 11, was introduced and came into effect in the **UAE** in 2021. The new legislation replaces the old Patent Law and introduces some important changes to the UAE's national IP environment, including doubling the term of protection for design rights to 20 years.

## Category 5: Trade Secrets and the Protection of Confidential Information

Figure 12 summarizes the total scores for Category 5. This category measures the strength of the IP environment for trade secrets and confidential information. For trade secrets, the category includes two indicators measuring the availability of civil and criminal sanctions, respectively, in relation to the misappropriation, improper acquisition, use or disclosure of trade secrets or confidential business information, and the application of this legislation and effective access to these remedies. In addition to the protection of trade secrets,

this category also measures the existence of an RDP term of protection for biopharmaceuticals. In total, the category consists of three indicators, with a maximum possible score of 3. Overall, only 23 of the 55 economies included in the Index achieved a score of 50% or more on this category. A full 21 economies only achieved a score of 33.33%. The average score on this category is the weakest on the Index at 49.12%.

Figure 12: Category 5: Trade Secrets and the Protection of Confidential Information, % Available Score



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

Trade secrets are not adequately defined in relevant laws and regulations, and courts have limited experience ruling on cases involving the misappropriation, improper acquisition, use or disclosure of trade secrets, or confidential business information. This gap is especially pronounced with



respect to criminal sanctions. Many economies—including developed OECD members—do not have statutory criminal sanctions in place for the theft and misappropriation of trade secrets.

Likewise, many economies included in the Index do not provide RDP for biopharmaceutical test data submitted during market authorization. And of those that do, many limit or actively attempt to restrict the practical availability of this protection through various terms, conditions, and/or carve-outs. For example, one of the new economies included in this year's Index, **Honduras**, introduced a five-year term of RDP as part of its accession to the 2006 Dominican Republic–Central America Free Trade Agreement (CAFTA-DR) with the United States. The CAFTA-DR agreement contains a defined term of RDP for biopharmaceutical products of five years. However, in Honduras the implementing legislation (Decree-16 2006) contains some potential major caveats to this term of protection. This includes making the protection contingent on the marketing of a new biopharmaceutical product in Honduras within five years of global launch. Implementing regulations (*Acuerdo* No. 024-2018) released in 2018 introduced additional hurdles and caveats. These, too, condition access to RDP on the submission of a market authorization application in Honduras within 12 months of first global launch. The regulations also give health officials a right of cancellation on the grounds of a “public interest” defined broadly as encompassing a national emergency or relating to public health. It is unclear what would be defined or constitute such an emergency or basis for a public interest action.

Similar carve-outs and exceptions were introduced in **Ecuador** in December 2020 Implementing Regulations for the relevant underlying legislation, the 2016 *Código Ingenios*. Undermining IP-based incentives such as RDP that are needed to develop new life-saving products and technologies through various conditions and potential carve-outs is counterproductive. Over

time, such action will simply hollow out the national IP environment and incentives for future biopharmaceutical innovation. Critically, the negative effect will be the same on Honduran or Ecuadorian innovators as on foreign ones.

Nevertheless, despite the absence of trade secrets protection in many economies, there were some important developments, with some economies reforming their laws relating to trade secrets in 2021.

As noted in previous editions of the Index, **South African** law does not define or provide protection for trade secrets through a trade secrets-specific statutory law. Like many other common law jurisdictions, protection is primarily afforded through case law and other statutes. For instance, the Electronic Communications and Transactions Act, 2002, provides for a limited form of criminal liability in the case of the illicit access and misappropriation of any type of data, including an unspecified fine or maximum prison term of 12 months.

There were positive developments with respect to the protection of trade secrets and confidential information in South Africa in 2021. Under debate since 2017, in December 2020, the National Assembly finally passed the Cyber Crime Act 2020. The act was subsequently formally signed into law by President Ramaphosa in May 2021. The act strengthens the protection of trade secrets and confidential information in South Africa by providing a clear avenue for the criminal prosecution of the misappropriation and illicit accessing of trade secrets and confidential information. Chapter 2 of the act provides broad definitions of illegal access to and misappropriation of any type of data, including the breaching of existing protection measures to keep data secure. Penalties are up to 15 years' imprisonment and fines.

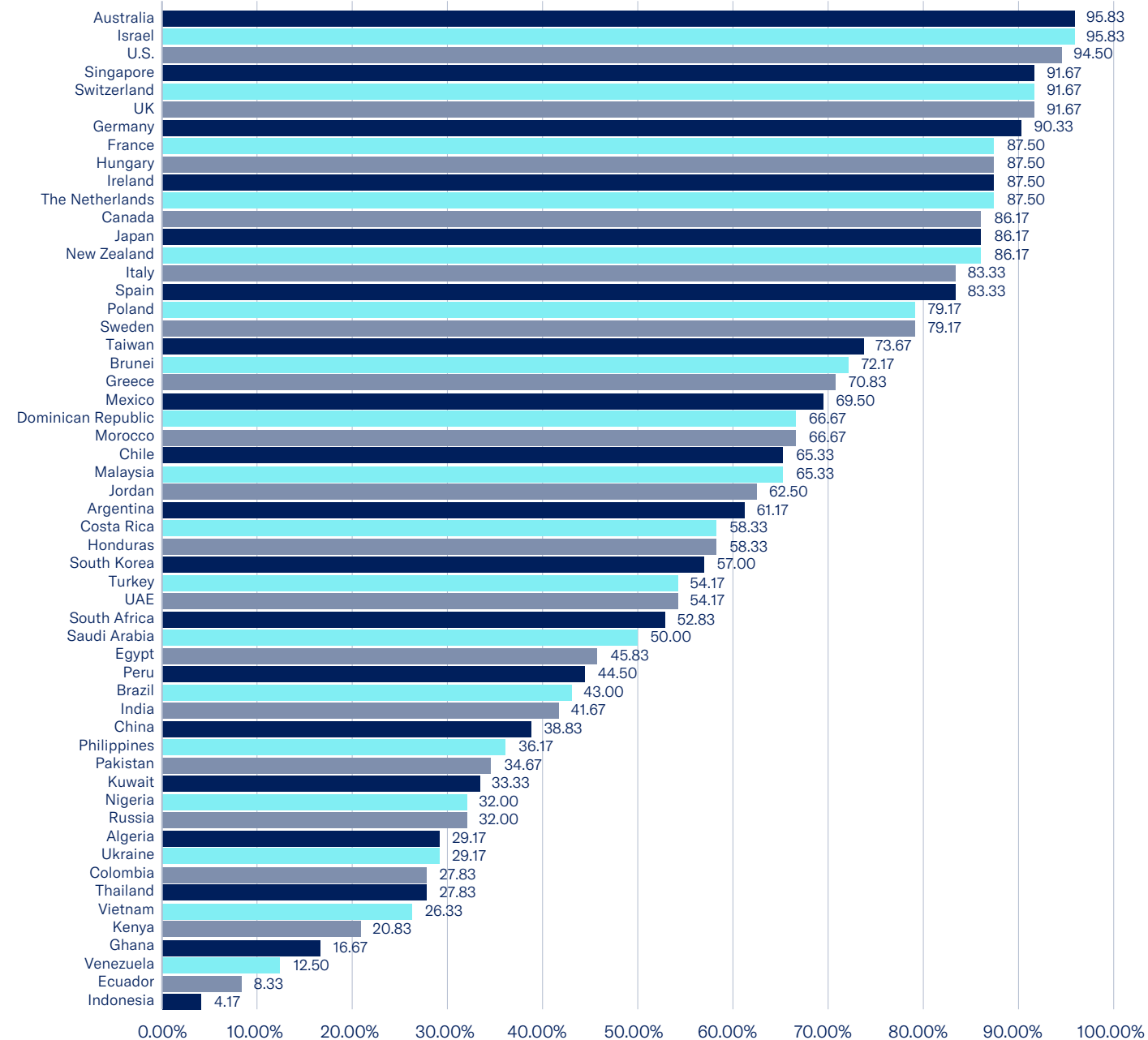
## Category 6: Commercialization of IP Assets

Figure 13 summarizes the total scores for Category 6. This category consists of six indicators, with a maximum possible score of 6. These indicators measure the presence of barriers and incentives in place for the commercialization and licensing of IP assets. This ranges from barriers to technology transfer, to registration and disclosure requirements of licensing agreements, to direct government intervention in setting licensing terms, to the existence of tax incentives for the creation and commercialization of IP assets.





Figure 13: Category 6: Commercialization of IP Assets, % Available Score



New technologies can only contribute to economic activity if they are successfully developed into real-life, useful products that can be commercialized in the marketplace. Technology transfer and licensing are critical mechanisms for commercializing and transferring research from public and governmental

bodies to private entities and private-to-private entities for the purpose of developing usable products and commercially available technologies. They also provide a significant and distinct contribution to the economic strength and well-being of the economies in which they take place.

For less developed economies, international licensing of technology can provide the basis for local technological development and building of a more sophisticated absorptive capacity. Global technology flows and the commercialization of IP assets are thus crucial drivers of innovation. However, licensing and technology transfer rely on a supportive and efficient regulatory environment and IP frameworks that minimize red tape, facilitate market-based partnerships, and uphold the integrity of partnerships.

Yet, in many respects, many economies included in the Index are failing to provide the necessary regulatory and IP-specific infrastructure to help incentivize and better facilitate domestic and cross-border licensing and technology transfer. One of the most significant barriers that affects and impedes all facets of licensing and technology transfer—domestic and cross-border—is direct government intervention and setting of licensing terms. As has been noted in previous editions of the Index, many of the economies benchmarked in the Index are introducing policies that make it more difficult to access their respective markets or commercialize IP assets. Of the 55 economies sampled, 20 failed to achieve a score of 50% or more, with a full 13 scoring 33.33% or less on the category. The average score on this category was 58.70%.

The collection and storage of data is one area in which a growing number of economies are putting in place barriers to trade and localization requirements. For rightsholders across many different industries and sectors, such barriers to digital trade raise serious concerns. The ICT and internet revolutions have fundamentally changed how human beings interact socially and economically. In virtually all industries, businesses and economic interaction is today being shaped by the collection of data and digital technologies. These technologies are allowing companies across all business sectors and public and private research organizations to collect and use greater levels of

data and information than ever before in so-called “big data.” Combined with increased computing capacity and the application of new technologies (such as artificial intelligence and machine learning) that allow us to analyze and better understand data collected, there is the possibility to make significant discoveries and breakthroughs in virtually any area of research and human socio-economic activity. Cross-border flows of data are ingrained in countless services relied on by consumers, with numerous digital, automated, and virtual services relying on the seamless movement and storage of data in various locations. Yet more economies are introducing restrictions on these flows. This negative trend continued in 2021.

In **Kenya**, the 2019 Data Protection Act includes potential restrictions on the movement of personal data accumulated in Kenya. Sections 48, 49, and 50 of the act outline a host of conditions that must be met for data to be transferred outside of Kenya. Personal data may only be transferred out of Kenya under specific circumstances and to jurisdictions “with commensurate data protection laws.” Under Section 49, the relevant Kenyan regulatory authorities (the Data Commissioner) has broad powers to examine and question the nature and necessity of any foreign data transfers. Likewise, Section 50 reserves broad powers to the Kenyan government to effectively force the localization of data in Kenya. Unfortunately, draft regulations released by the Office of the Data Protection Commissioner in 2021 do not fully address these concerns.

On a positive note, Section 40 of the Data Protection (General) Regulations 2021, states that any restrictions and requirements in relation to cross-border data transfers may not “impose a restriction on trade.” Yet other parts of the draft regulations affirm the localization requirements contained in the underlying statute. For example, Section 25 outlines a range of broad categories under which data processing must be carried out



in Kenya. In addition to data processing activities relating to “actualizing a public good,” this also includes processing in relation to electronic payments and “processing health data for any other purpose other than providing health care directly to a data subject.” Mandating the local storage and processing of data is likely to lead to fewer digital services being available in Kenya and less innovation in many critical sectors, including, for example, medical research. Public policies relating to national data management should recognize this reality and be formulated accordingly.

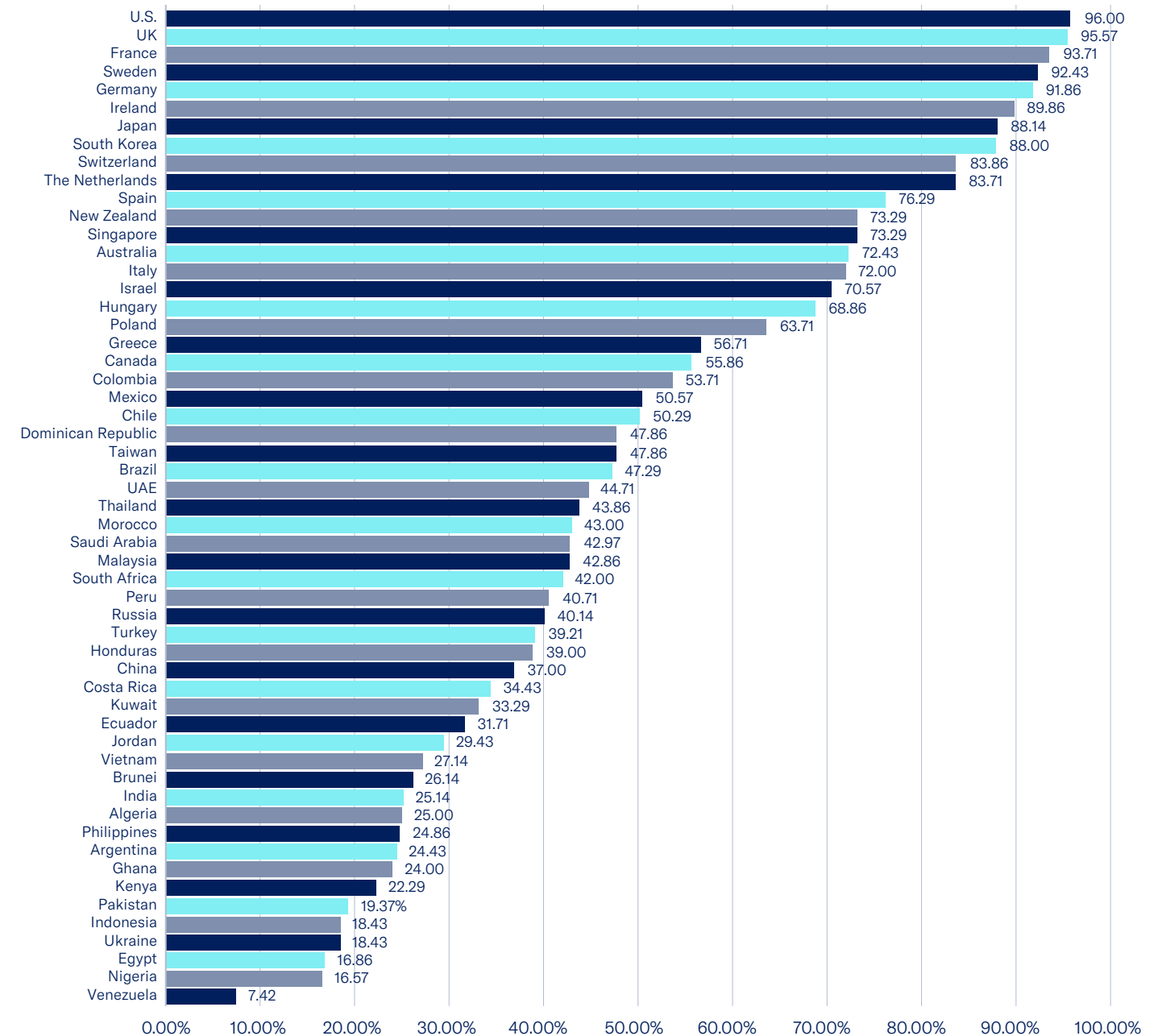
Similarly, and as noted in previous editions of the Index, rightsholders have over the years faced a growing number of regulatory and procedural barriers in **China** that impede technology flows, R&D cooperation, and digital trade. With respect to data localization requirements, these intensified in 2021 with the passage of the Personal Information Protection Law (PIPL) and Data Security Law. The laws include limits and conditions on cross-border transfers of data and impose local

storage requirements on both critical information infrastructure operators (CIIOs), important data handlers, and entities handling large volumes of personal information (PI) as defined by the Cyberspace Administration of China (CAC). Noncompliance with the new law may result in fines up to 5% of annual sales. Additional restrictions and compliance requirements are imposed on what is termed “large internet platforms.” The PIPL and DSL add to existing layers of restrictions and barriers to digital trade in China, including those contained in the National Security Law, Cybersecurity Law, Cybersecurity Review Measures, and Biosecurity Law. For rightsholders across many different industries and sectors, these barriers to digital trade raise serious questions and concerns. In order to support China’s innovation ecosystem, China’s national data management policies must recognize this reality and be formulated in a way that balances national security needs with commercial concerns.

## Category 7: Enforcement

Figure 14 summarizes the total scores for Category 7. This category measures the prevalence of IP rights infringement; the criminal and civil legal procedures available to rightsholders; and the authority of customs officials to carry out border controls and inspections. The category consists of seven indicators, with a maximum possible score of 7.

Figure 14: Category 7: Enforcement, % Available Score



As in years past, a clear majority of the sampled economies in the Index struggled in this category. Only 23 economies (41.89% of the sample) achieved a score of 50% or more on this category. And only 11 economies achieved a score of 75% or more. As with Category 2: Copyrights, Related Rights, and Limitations and

Category 5: Trade Secrets and the Protection of Confidential Information, the average score in this category is one of the weakest on the Index, at 50.26%. In many economies, effective enforcement options are not practically available. Judicial and/or administrative routes of enforcement are overloaded and/or under-



resourced. 2021 saw the exacerbation of this situation in many economies, including **India**.

Rightsholders have long faced real challenges in enforcing their IP rights in **India**. As has been detailed in previous editions of the Index, in many IP-intensive sectors (including both biopharmaceuticals and the copyright and creative industries), relevant legal rights are either not available or only partially available. Infringement is widespread with India, as both a global source of and home to high rates of substandard and counterfeit medicines, online and physical piracy, and counterfeiting. Using global customs data, the OECD and EUIPO found in the 2017 report *Mapping the Real Routes of Trade in Fake Goods* that India was the biggest source of counterfeit pharmaceuticals in the world at 55% of the global total. The study also found India to be a prominent provenance economy for counterfeit foodstuffs; perfumes and cosmetics; leather articles and handbags; and counterfeit clothing, footwear, and textile fabrics.

One long-standing area of concern has been the excessive pendency times in the Indian court system. In 2018 it was reported that over 30 million civil and criminal cases were pending, of which 40% were more than five years old. It was estimated that commercial disputes had risen from over 17,000 cases in 2015 to close to 40,000 in 2017. In the 2020 edition of the World Bank's *Doing Business* report, India ranked 163<sup>rd</sup> in the category "Enforcing contracts." It takes, on average, 1,445 days to enforce a contract—almost four years—and at a cost of 31% of the claim value. These long delays have persisted since 2014. The Indian government has long recognized this challenge and especially its negative impact on business disputes and IP rightsholders.

In 2015/16 the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015, was signed into law including

specific amendments to the Civil Procedure Code. Fundamentally, the purpose of the act was to improve the overall commercial environment in India by making it easier and quicker to resolve business-related disputes. Specific reforms included changes to the administration of justice, with an emphasis on solving disputes quickly and efficiently, streamlining commercial disputes, and ensuring a relevant level of expertise at the presiding court level. Also, new amendments were introduced in 2018 that aim to improve the legislation and cut down pendency rates. The amendments expand the types of case that can be heard and reduces the value threshold for commercial disputes and the introduction of mediation proceedings.

In parallel to the courts system, IP rightsholders have historically also been able to appeal administrative decisions taken by the relevant Indian registration authorities through the Intellectual Property Appellate Board (IPAB) system. The IPAB provided rightsholders for most major IP rights the ability to appeal directly to an IP specialist body to hear and resolve these disputes. However, under the Tribunal Reforms (Rationalisation and Conditions of Service) Ordinance 2021, the IPAB was dissolved and all pending cases before the board transferred to the judiciary, namely the High Courts and Commercial Courts. The dissolution of the IPAB, combined with the long-standing issue of an under-resourced and over-stretched judiciary, raises serious concerns about rightsholders' ability to enforce their IP rights in India and resolve IP-related disputes. The Parliamentary Standing Committee on Commerce, in its *Review of the Intellectual Property Rights Regime in India*, rightly recognized the negative impact the IPAB dissolution will have and called for the Board to be "re-established...and strengthened with more structural autonomy, infrastructural and administrative reforms." Whether through the judiciary, an administrative tribunal, or a combination of both, it is imperative that rightsholders are able to effectively have disputes heard and resolved

in a timely fashion. At the time of research, it was not clear what would happen to the IPAB or if additional capacity and resources would be provided to the judiciary to handle the additional case burden. On a positive note, in July 2021, the Delhi High Court stated it would be creating a specialized "Intellectual Property Division" to help the court meet this additional caseload.

Still, despite the overall poor performance on this category, there were some positive national developments in 2021.

In 2021 **Chile's** National Congress passed a package of reforms amending Law 19,309 on Industrial Property including important changes to the enforcement environment. To begin with, Article 108 has been amended and now provides for a form of statutory damages for trademark infringement. Up until now, Law 19,309 had not included any form of pre-established or statutory damages for any major IP right. Instead, damage calculations had been based on general rules of civil compensation that grant courts wide sway in assessing damages including loss of profits. With these amendments, it is now possible—in the case of proven trademark infringement—for the rightsholder to opt for a pre-established form of damages up to 2,000 monthly tax units per

infringement (circa USD 120,000). Furthermore, regarding criminal sanctions, the insertion of a new Article 28 Bis introduces a minimum prison sentence for trademark infringement and commercial counterfeiting; previously, such offences had only been subject to fines.

Similarly, in what is otherwise a highly challenging environment for the enforcement of all major IP rights, **Indonesia's** national IP office (the Directorate General of Intellectual Property [DGIP]) continues to work on improving the enforcement environment. The head of the office, Director General Freddy Harris, has in several public interviews described the need for stronger IP enforcement efforts and to more effectively work together with international rightsholders. In 2021 several new initiatives were launched and announced, including increased anti-counterfeiting activity at shopping malls and direct cooperation with international rightsholders and law enforcement, including the FBI; a dedicated interagency taskforce tasked with coordinating enforcement leading to the removal of Indonesia from the U.S. Trade Representative's (USTR) Priority Watch List; a dedicated anti-copyright piracy team within the IP office; and greater transparency through the creation of a dedicated web portal with data and statistics on cross-agency IP enforcement activity, including that of customs and police.

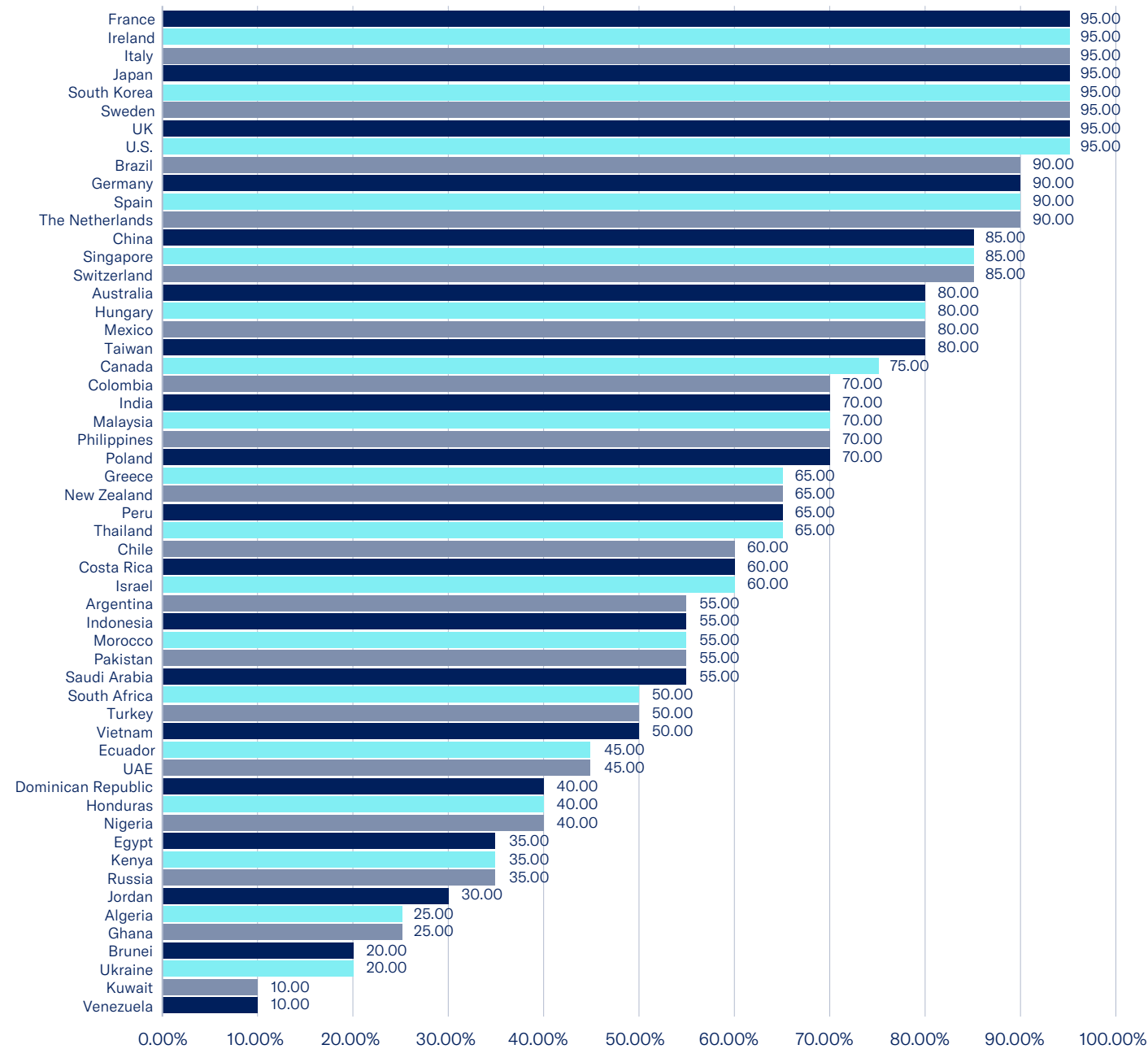
## Category 8: Systemic Efficiency

Figure 15 summarizes the total scores for Category 8. Indicators included in this category seek to measure national efforts at coordinating IP rights enforcement; the existence of stakeholder consultation mechanisms during the IP law and regulation-making process; existence of awareness raising and educational activities on the importance of IP rights and incentives; targeted

incentives for SMEs for the creation, registration, and use of IP assets; and the extent to which the relevant authorities in a given economy seek to map and measure the economic impact and importance of IP-intensive industries to their national economies. This category consists of five indicators, with a maximum possible score of 5.



Figure 15: Category 8: Systemic Efficiency, % Available Score



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

otherwise challenging national IP environments, such as **Colombia, India,** and the **Philippines,** none of which achieved an overall score of 50% or more. Yet on this category they all scored 70%. Overall, the average score on this category is one of the strongest on the Index at 62.55%.

In 2021, these positive efforts continued.

**Peru** made improvements with respect both to IP-based services for SMEs and procedures relating to public consultations. Peru provides a fairly large number of special programs and incentives for SMEs and individual inventors to develop, register, and commercialize their IP assets. Supreme Decree No. 092-2018-PCM provides for trademark registration at no cost and an accelerated, simplified three-month procedure for micro and small enterprises, business associations, cooperatives, and local organizations. While there is no similar mechanism for patent applications, in cooperation with the Innovate Peru Program of the Ministry of Production (*Ministerio de la Producción*), INDECOPI has been active in helping small businesses identify potentially patentable subject matter and thus add value to their business.

Technical assistance also takes place through the network of WIPO Technology and Innovation Support Center (TISC) offices around Peru. As of 2020, there were 19 active TISCs in place, most of which are primarily located in universities and public research organizations. INDECOPI also supports the “Peruvian Patent Marketplace,” a virtual service whereby Peruvian creators and inventors can advertise and attract foreign seed capital and investors. Over the last two years, these efforts—in particular targeted technical assistance and consulting—have intensified. In response to the COVID-19 pandemic, INDECOPI has launched a virtual platform, “IDENTI-PAT,” which helps entrepreneurs, SMEs, and inventors identify patentable subject matter; a virtual registry of works on copyright; and a new electronic reporting system of pharmaceutical and biotechnological patents.

In 2021 the President of INDECOPI, Hania Pérez de Cuéllar Lubienska, announced that the RUTA PI program would be reinstated. The purpose of this program is to provide SMEs with specific technical guidance and assistance in identifying, registering,

and managing IP assets. A specific emphasis would be placed on sectors and industries relating to copyright and trademarks. Similarly, for years Peru has had clear requirements that the public be notified and periods of public comments be offered in conjunction with proposed changes to primary and secondary legislation, including for IP-related laws and regulations. Most notably, under Decree No. 1 2009 (*Decreto Supremo N° 001-2009-JUS*) all relevant public agencies and departments must publish any draft regulations in the official government gazette *El Peruano*. Article 14 of the decree states that the regulations must be published for a minimum period of 30 days with exceptions only allowed in truly exceptional cases. However, there is no equivalent requirement for public bodies to acknowledge, consider, publish, or respond to any comments received during the public consultation period. To remedy this and provide greater levels of transparency and public accountability, in April 2021 the government of Peru introduced Decree 063-2021 (*Decreto Supremo N° 063-2021-PCM*). This decree clarifies the commitment of the government to a stronger regulatory review process, including enhancing public consultations and allowing the public’s participation in the regulatory process.

As has been noted in previous editions of the Index, there have been many important positive changes to the national IP environment in **Saudi Arabia** in the past five years. Many of these improvements result from the strengthening of national IP institutions and the creation of the Saudi Authority for Intellectual Property (SAIP). Over the last three years, SAIP has taken a central role in all matters relating to IP policy in the Kingdom, including the coordination of enforcement. Historically, the enforcement of IP rights has been spread out over various layers of the Saudi branches of government. The Kingdom has a dual law enforcement structure: administrative proceedings and judicial proceedings. Traditionally, judicial proceedings have taken place under the auspices



of Sharia Law, which is still the basis for the operation of the Saudi legal system. Commercial, business, and IP law are still evolving, and much of the enforcement and dispute settlement takes place through administrative mechanisms.

For initial disputes relating to patents, the governing administrative body has traditionally been “The Committee for Reviewing Patent Disputes” within the old Saudi Patent Office based in King Abdul Aziz City for Science & Technology (KACST). For trademarks, the main avenue of administrative enforcement has been the Ministry of Economy and Industry and the Anti-commercial Fraud Department. For copyright claims and administrative enforcement, the relevant administrative body has been the Ministry of Culture and Information’s Copyright Committee. For both trademarks and copyright, the Saudi Customs Authority carries out border enforcement. For judicial enforcement in civil and criminal claims, the relevant authority is the Board of Grievances. It is within this context that SAIP has emerged as taking a more prominent role in IP enforcement. To begin with, the authority includes enforcement as one of its core business areas and has taken several positive steps in coordinating and facilitating the enforcement of existing Saudi copyright statute, including by offering a portal through which rightsholders can directly communicate any suspected online infringement to the SAIP, which will then take enforcement action.

These positive efforts continued in 2021. In August the authority announced that it would also be providing a centralized role in the enforcement of trademark infringement, taking over the responsibilities and jurisdictional authority previously held by the Ministry of Commerce under Cabinet Resolution 496. Similarly, a new enforcement body, the National Committee for the Enforcement of Intellectual Property Rights, was announced in early 2021. The stated purpose of the committee is to guide and coordinate the enforcement of IP rights within the Kingdom. SAIP chairs the committee, which has representation from across the Saudi government, including the Ministries of Commerce, Justice, Communications, and Information Technology; the Public Prosecution Office; General Customs Authority; and Saudi FDA.

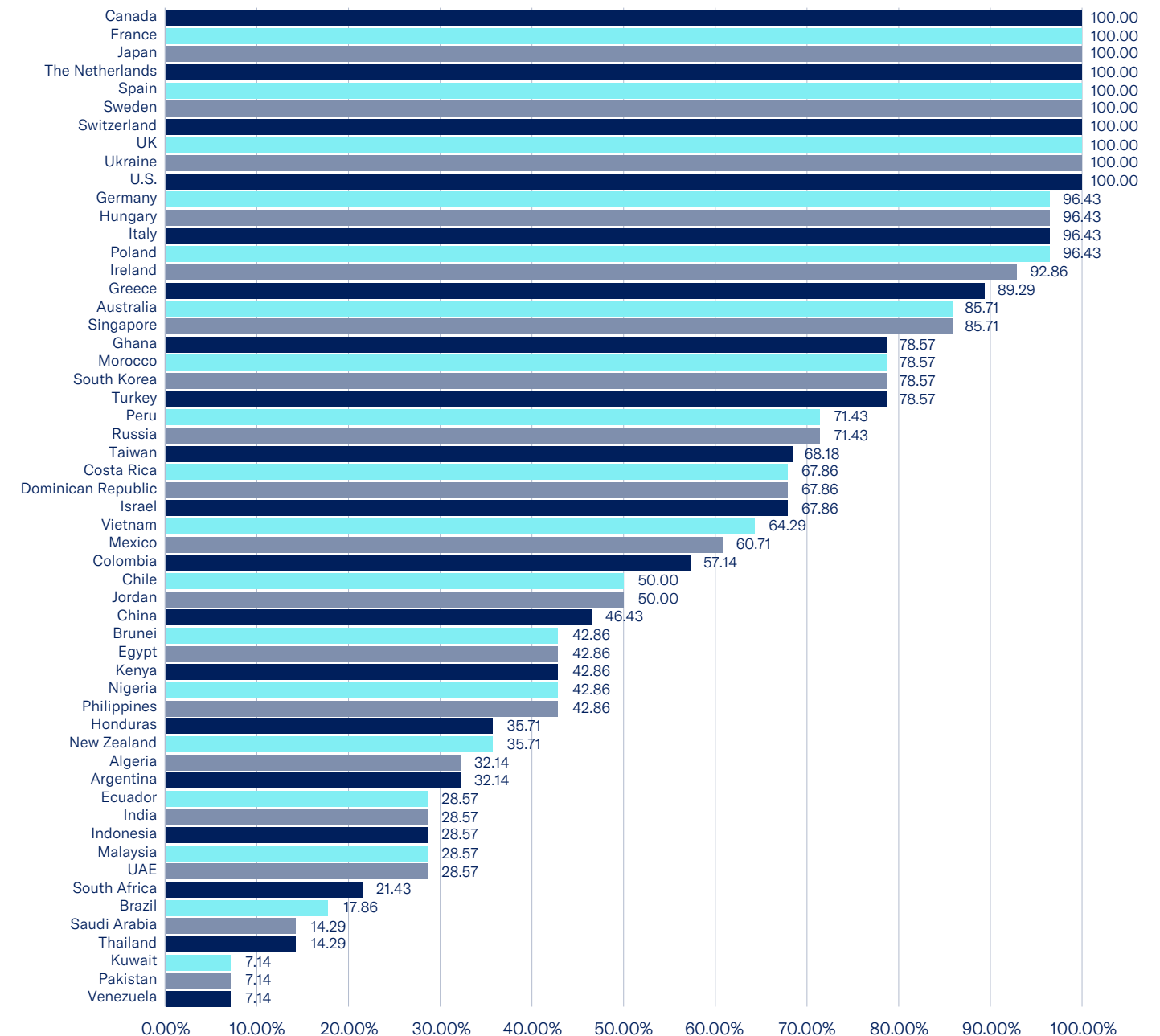
Finally, as detailed in the preceding section, several economies published the results of new studies measuring the economic impact of IP-intensive industries. This includes **Brazil, Mexico, and the UK**. Together, the results of these studies paint a clear and unambiguous picture: regardless of size, geographic location, structural composition, or level of development, IP-intensive industries are a critical and growing part of all national economies. Whatever the stage of development, IP-intensive industries are of increasing importance to all economies around the world. The first step in recognizing their importance is to actively seek to identify, categorize, and measure the size and economic impact of these industries domestically.

## Category 9: Membership and Ratification of International Treaties

Figure 16 summarizes the total scores for Category 9. This category measures whether an economy is (1) a signatory of and (2) has

ratified/acceded to international treaties on the protection of IP. The category consists of seven indicators, with a maximum possible score of 7.

**Figure 16: Category 9: Membership and Ratification of International Treaties, % Available Score**



Over the course of the Index, the number of treaties included in this category has expanded substantially; today, nine treaties are included. This category remains one of the stronger overall categories on the Index, achieving an average score of 61.43%. This is a notable improvement over time. As noted in the preceding section, many economies have over the course of the Index become contracting parties to international IP treaties and boosted the overall category score. A large number of economies achieved a high score on this category: 22 economies scored 75% or higher, with 14 economies achieving a score of over 96%. However, a surprisingly large number of high-income economies are not contracting parties to many international IP treaties included in the Index. **Kuwait, Saudi Arabia, UAE,** and **New Zealand** all achieved a score of 36% or less. Of note is Kuwait, which is a contracting party to only one out of the nine treaties measured in this category and achieved a total category score of 7.14%, the same as Venezuela.

In 2021, there were positive developments, with several emerging markets improving their score on this category.

Both **Nigeria** and **Ghana** acceded to the International Convention for the Protection of New Varieties of Plants (UPOV), Act of 1991 in 2021. Up until 2020-2021, neither economy had any relevant laws or regulations in place that provided plant variety protection.

Several economies also became contracting parties to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks. In February 2021, WIPO announced that **Pakistan** acceded to the protocol, which would become operational and available to rightsholders later in the year. Similarly, in September 2021, WIPO announced that the **UAE** had also acceded to the protocol.

Finally, in 2021 **Sweden** became a full contracting party to the Convention on Cybercrime. A signatory since 2001, the Swedish Parliament finally ratified the treaty in April 2021, and Sweden formally acceded with the treaty entering into force in August.

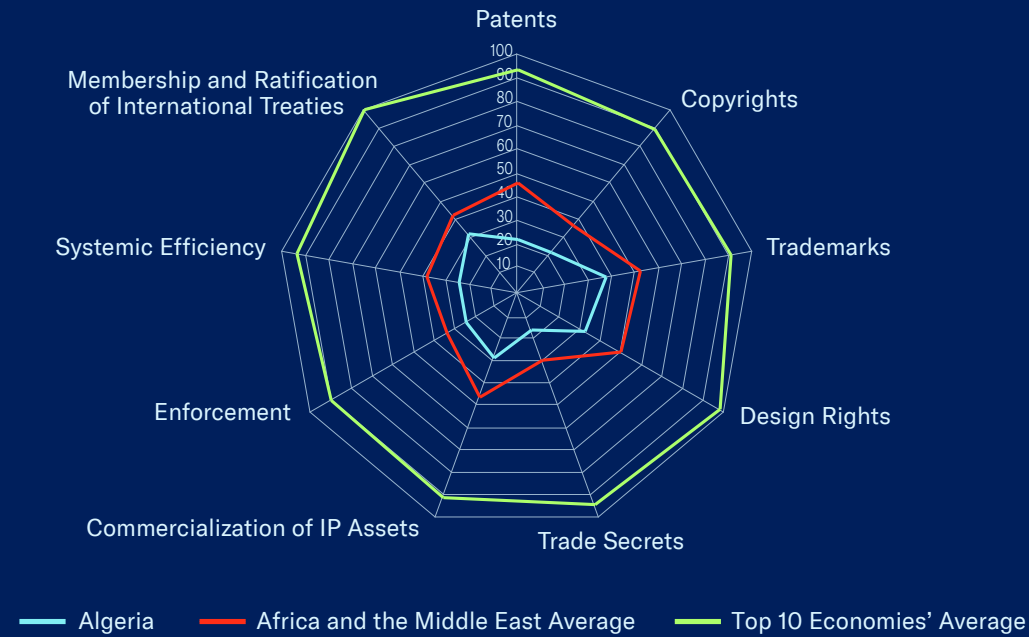
# Economy Overviews

## Introduction

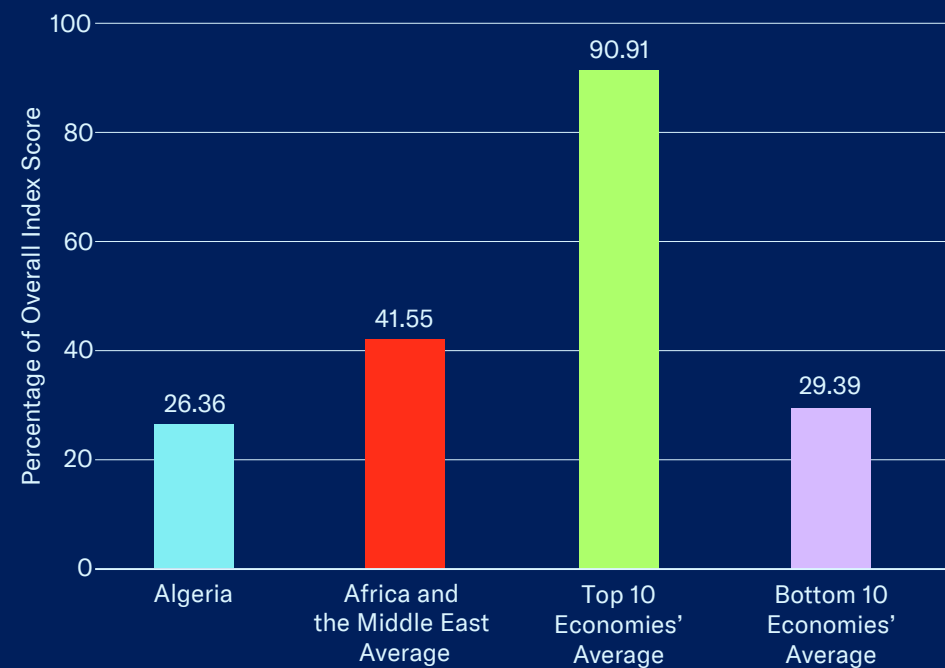
This section provides an overview and analysis of each individual economy's score on all 50 indicators.

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

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- Reforms in 2019 and 2020 removed the 51-49% local ownership rule and could amount to a sea-change in Algeria's openness to and relationship with foreign investment
- Basic framework for IP protection in place
- Contracting party to WIPO Internet Treaties Patent Cooperation Treaty, Patent Law Treaty, and Madrid Protocol

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>2.00</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of computer-implemented inventions (CIIs)	0.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.53</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.00
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.65</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

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

Total Score:  
**13.18**

## Spotlight on the National IP Environment

### Past Editions versus Current Score

Algeria's overall score has decreased from 26.45% (13.23 out of 50) in the ninth edition of the Index to 26.36% (13.18 out of 50) in the tenth edition. This reflects a score decrease on indicator 32.

### Commercialization of IP Assets and Market Access

**26. Barriers to market access; and 27. Barriers to technology transfer:** As noted over the course of the Index, the Algerian government has historically imposed localization rules for how foreign firms may participate in the market and has actively pursued an import substitution policy. The stated objective of these rules has been to reduce imports, encourage domestic production, and maximize technology transfer. These policies have run across various sectors. Key measures have included quantitative restrictions on imports when local production exists (for instance, on second-hand equipment for all sectors); a registration tax levied only on new imported vehicles as well as a requirement for car dealers to set up a domestic activity of an industrial nature on top of the dealership, such as production of car parts, in order to keep their import license; and local content requirements in procurement for office equipment of up to 15% of tenders.

Additional cross-sectoral policies in support of local sectors have included national public procurement rules. Specifically, access to tenders for foreign bidders has been greatly limited by Decree 10-36 (2010), which gives a 25% price preference to national producers. Foreign bidders have been able to qualify as local if they have partnered with national companies that are majority-owned by Algerian residents—but qualifying national companies are limited and determined by a government-generated list and/or (under the 2011 Decree 11-98) have provided an

investment plan cleared by the National Investment Development Agency. Moreover, some tenders have been statutorily restricted to domestic bidders with foreign firms invited to bid only if the contract is not awarded to a local producer.

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

Strict ownership limitations are one of the most onerous policies. Based on a pre-existing measure in the oil and gas sector, the 2009 Complementary Finance Law has limited foreign investment to a minority stake (49% or below) in any industrial sector. The 2014 Financial Law extended 2009 rules to companies only engaged in importation (and not domestic manufacturing activities), of which foreigners were previously allowed to own a 70% share. The rule was removed from the new Investment Law in August 2016 but was later reintroduced in the 2017 Finance Law. The government removed the 51-49% ownership requirement for non-strategic industries through the 2020 Finance Law. The Finance Law did not specify how the elimination of the local ownership requirement would be implemented or which industries would be considered non-strategic or strategic. In June 2020, a Supplemental Finance





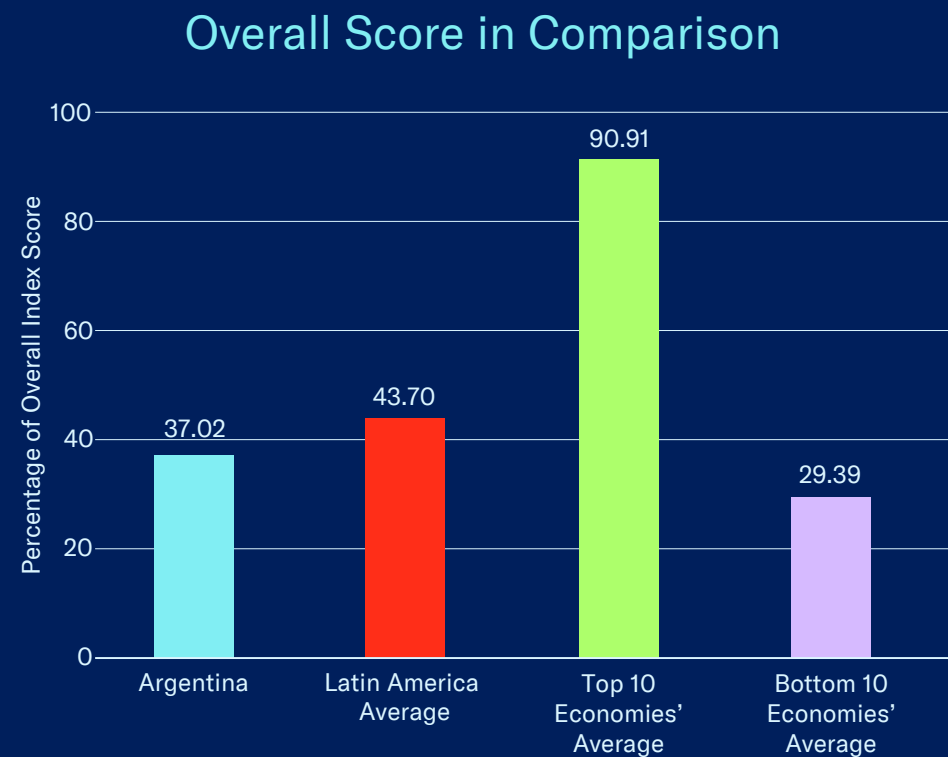
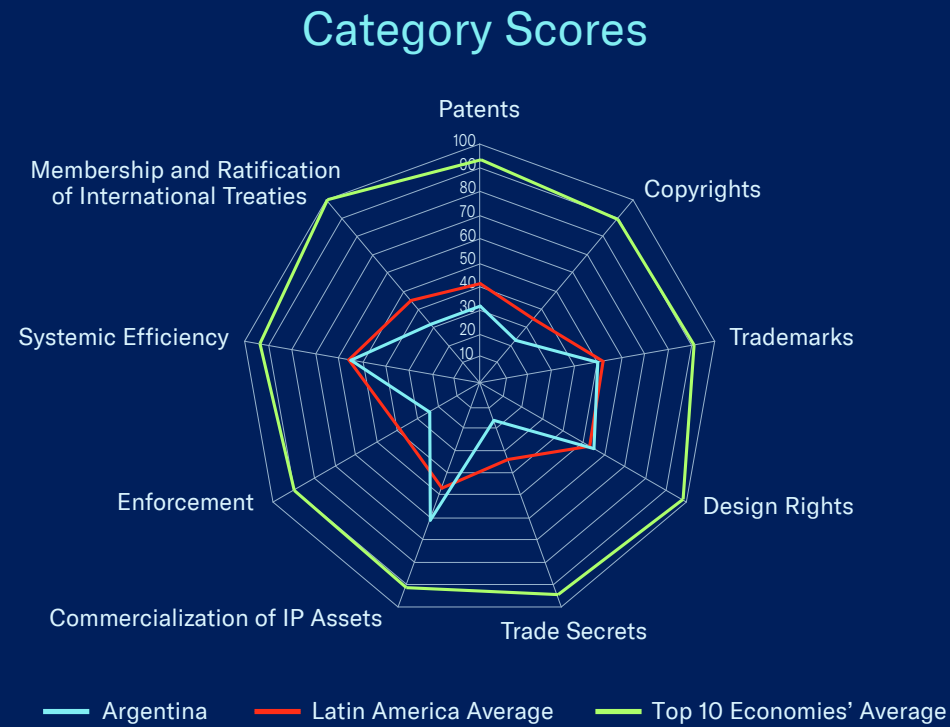
Law was enacted and published in the official gazette. Article 50 of this Law outlined which industries and sectors of the economy were to be considered as strategic and still subject to the 51-49% local ownership requirement. These included mining, hydrocarbons, industries relating to national defense,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

With regards to the biopharmaceutical industry, the law appeared to provide an exception to the local ownership requirement for the research-based industry. However, this exception was not entirely clear and appeared to be contingent on fulfilling several conditions, including a local production requirement. New Finance Laws were issued in December 2020 and June 2021. Both laws reiterate the conditions of the original Finance Law for the biopharmaceutical industry. There was no further clarification under what circumstances the local majority ownership requirements would not apply. Most economies around the world have in place foreign investment and ownership restrictions on strategic parts of the national economy related to defense and critical infrastructure. This includes industries and entities directly related to national security, defense suppliers and contractors, and infrastructure including ports, railways, telecommunications, utilities, and the like. It is unusual to have such requirements in place for the biopharmaceutical sector, which is, fundamentally, a truly global industry with new medical technologies discovered, developed, and manufactured all across the world.

The research-based biopharmaceutical industry is one of the world's leading sources of R&D investment. Data from the *EU's 2019 Industrial Investment Scoreboard* (which measures the total amount of corporate R&D spending by the top 2,500 companies in the world) shows how the biopharmaceutical sector spent EUR 153.8 billion in corporate R&D in 2018/19. This was well ahead of the second and third largest spenders

in the technology, hardware and equipment industry, and automotive industry. Similarly, aggregated (not just by the top companies) 2019 global life sciences R&D spending was estimated by Deloitte to be around \$177 billion. A substantial proportion of this expenditure comes from members of the Pharmaceutical Research and Manufacturers of America (PhRMA) trade association. In its annual 2020 membership survey, PhRMA estimated that R&D expenditure by member companies in 2019 totaled over USD 83 billion, the highest level on record. Most of this investment goes into clinical research.

Clinical trials represent one of the most important activities carried out by biopharmaceutical companies. Significantly, clinical research often takes place through multi-center trials in different jurisdictions and through partnerships between public and private institutions. It is this continuous and sustained R&D expenditure that has put in place the scientific knowledge and innovation ecosystem that has allowed the research-based industry to, in record time, develop vaccines and therapeutics to fight the COVID-19 pandemic. Without strong and clear IP rights, it is unlikely that any of those products and technologies—or the underlying science—that have been so essential to keep societies functioning and fighting the COVID-19 pandemic, would exist. Algeria's desire to build a greater local biopharmaceutical R&D, innovation, and manufacturing capacity should be applauded. More and more economies around the world are realizing the socio-economic benefits of having a strong and thriving research-based sector. The reforms to the 2020 Finance Law and elimination of the 51-49% local ownership requirement provide a real opportunity for change. These statutory changes should be followed by equally clear implementation of regulations that allow 100% foreign ownership for the research-based biopharmaceutical industry. The Index will continue to monitor these developments in 2022.



## Key Areas of Strength

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

## Key Areas of Weakness

- Key life sciences IP rights missing: RDP is not available, biopharmaceutical patentability standards remain outside international standards, and lack of enforcement of pharmaceutical patents persists
- Gaps in legal framework for enforcing copyright online, though some important instances of judicial action exist
- Persistently high rates of piracy, including physical counterfeiting
- Limited participation in international treaties—has not acceded to the Patent Cooperation Treaty



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>2.90</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	0.90
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.63</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.50
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.00</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>3.67</b>
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>1.71</b>
32. Physical counterfeiting rates	0.38
33. Software piracy rates	0.33
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.00
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>2.75</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>2.25</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.25
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
18.51**

## Spotlight on the National IP Environment

### Past Editions versus Current Score

Argentina's overall score has increased from 36.77% (18.38 out of 50) in the ninth edition of the Index to 37.02% (18.51 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Commercialization of IP Assets and Market Access

#### 31. Tax incentives for the creation of IP assets:

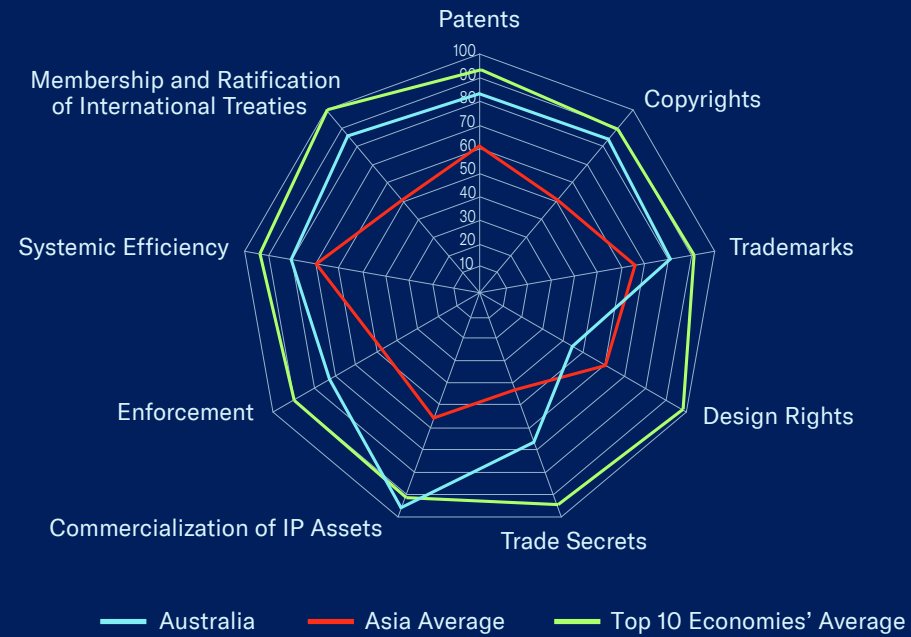
Although Argentinean tax law provides a range of incentives for knowledge-intensive and R&D-based activities, these tax incentives are convoluted and change frequently. All qualifying R&D expenses are, in principle, fully tax deductible and Law 23,877 provides tax credits on qualifying R&D expenditure. These credits are, however, subject to an annual cap set by the National Agency for Scientific and Technological Promotion (*Agencia Nacional de Promoción Científica y Tecnológica*). Historically, there have also been several sector- and industry-specific incentive schemes in place. For example, under Laws 25,922 and 26,692, there has been in place a "Software Promotional Regime" (*Ley de Promoción de la Industria del Software*). This regime has offered several incentives, including reduced payroll taxes, reduction in corporate income taxes, and exemption from value-added tax (VAT) withholding.

Separate incentive schemes have also been in place to promote the development of the biotechnology sector and professional development and training courses (*Promoción del Desarrollo y Producción de la Biotecnología Moderna and the Régimen de crédito fiscal para los establecimientos industriales que tengan organizados cursos de educación técnica*). Both the software and biotech incentive schemes have been subject to detailed requirements, registration with relevant government authorities, and evaluation on a case-by-case basis. In 2019 a new tax incentive scheme was introduced,

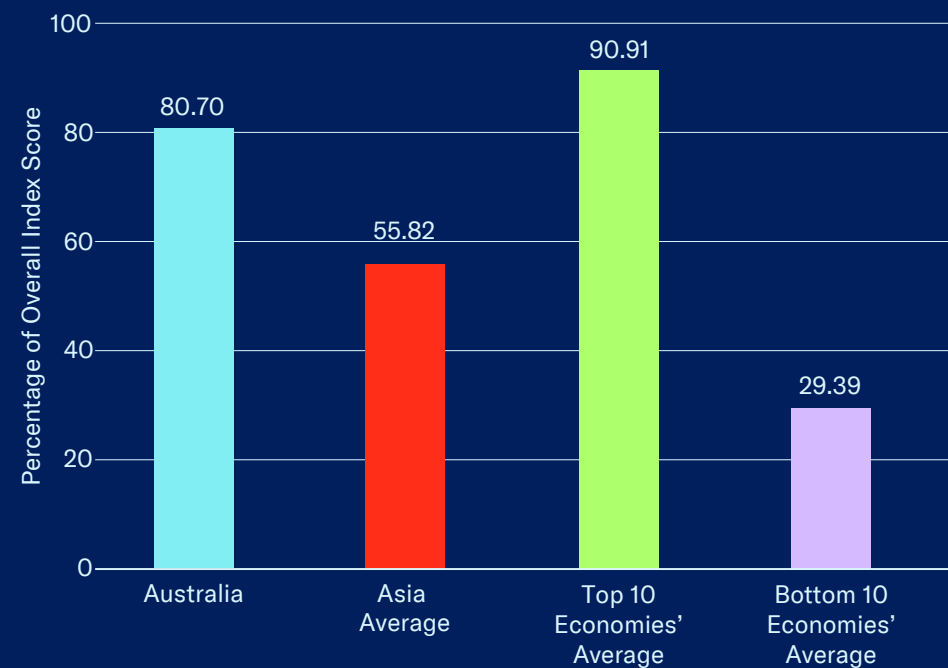
Law 27,506, the "Regime for the Promotion of the Knowledge Economy." The scheme broadened the basis of the "Software Promotional Regime," expanding the types of industries and sectors qualifying for relevant tax incentives, and was scheduled to come into effect in January 2021. However, under Resolution No. 30/2020 (published on January 21, 2021), this new tax regime was suspended by the new government of President Fernández. At the time it was not clear what, if anything, would replace the suspended regime. In February 2021, new implementing regulations were published under *Disposición 11/2021*. These regulations clarify the types of qualifying activities, clarify applicable rates of reduced tax liability, and set 2029 as the expiration date for the incentives.

Overall, it is a positive step that Argentina has recognized the economic value of IP-intensive industries and the knowledge economy to current and future economic activity. The government has also acknowledged how tax incentives can have a positive impact on promoting the development of these industries. However, as with other past tax incentives the new regime is not open-ended or available to any sector of the economy or type of R&D or IP-generating businesses. Unlike a growing number of economies around the world (including most recently Switzerland), these legislative changes did not include any IP-asset-specific innovation or patent box incentive.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- Global leader on copyright enforcement in the online space
- Established system of injunctive relief permitting the disabling of foreign-hosted infringing websites
- National Security Legislation Amendment (Espionage and Foreign Interference) 2018 introduces stiff penalties for industrial espionage on behalf of a foreign state entity
- No administrative or regulatory burdens in place hindering licensing activity
- 2019/20 case law clarified grounds for patentability of biotechnology inventions

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>7.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>5.88</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	1.00
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	1.00
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	1.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.75
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	1.00
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.90</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.00</b>
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.50

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

**Total Score:  
40.35**

## Spotlight on the National IP Environment

### Past Editions versus Current Score

Australia's overall score has increased from 80.55% (40.27 out of 50) in the ninth edition to 80.70% (40.35 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Patents, Related Rights, and Limitations

#### 5. Pharmaceutical-related patent enforcement and resolution mechanism:

As noted in previous editions of the Index, Australia's pharmaceutical linkage mechanism has several notable deficiencies. The system lacks an automatic stay (as provided by, for example, Hatch-Waxman in the U.S.) and instead gives patent holders interlocutory injunction relief through a court of competent jurisdiction. In an attempt to balance the interests of innovators and generic producers, the Australian system added both a certification from the generic producer (Section 26B) of invalidity and/or non-infringement, and a certification from the patent holder (Section 26C) that the infringement proceedings are in good faith, have reasonable prospects of success, and will be conducted without unreasonable delay. However, penalties for providing false or misleading information are disproportionately higher for a 26C Certificate (patent holder) than for a 26B Certificate (generic producer).

Another problem area is that patent holders are not made aware consistently and on a timely basis of potentially infringing follow-on products in advance of their approval by Australian drug regulators in the Therapeutic Goods Administration (TGA). Rather than notifying patent holders, generic manufacturers summarily certify their belief that their products do not infringe enforceable patents. In turn, patent holders are informed only after the follow-on products have been approved. In addition, there are also strong commercial incentives for generic manufacturers to launch

at risk due to the structure of the Australian health care system. Specifically, because Australia's Pharmaceutical Benefit Scheme (PBS) imposes automatic and irreversible price cuts on medicines as soon as competing versions enter the market, there is a strong incentive for generic companies to launch at risk and then innovator companies must pursue preliminary injunctions in order to resolve patent disputes. Furthermore, since 2012 Australia's Department of Health has pursued market-sized damages (on top of those sought by the generic company) aimed at compensating the PBS for any higher price paid for a patented medicine during the period of a provisional enforcement measure, but there is no corresponding mechanism to compensate innovators for the above-mentioned losses if an infringing product is launched prematurely.

In 2020, there was a potential precedent-setting decision in the long-running case *Commonwealth of Australia v Sanofi (No. 5) (2020) FCA 543*. The case revolves around the actual ability of the Australian government to claim damages and is the first time a court has made a judgment as opposed to the relevant parties reaching an agreement through a private settlement. In the April 2020 verdict, the court ruled against the government, dismissing its claims for damages. Local legal analysis suggests that the judgment sets a high bar for future claims because, although the court recognized the legitimacy of the claim, a successful claim will have to prove a direct link between the granted preliminary injunction and listing on the PBS. In October 2020, the TGA concluded an 18-month consultation on prescription medicines transparency measures. As a result of the consultation, the government announced its plan to introduce legislation to create an earlier patent notification framework. The legislation will require applicants for the first generic and biosimilar form of an originator product to notify the patent holder when their application is accepted for evaluation



by the TGA. The change was designed to create an opportunity for earlier negotiation and resolution of disputes on potential patent infringements before the follow-on product is listed in the PBS.

Additionally, the TGA announced it will publish a description of major innovative medicines applications that are under evaluation by the TGA. However, at the time of research, no new legislation had been proposed. The Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021—passed into law in early 2021—did not include any relevant references to a new patent notification framework, and no proposed legislation has been published by the TGA or presented to the Australian Parliament. 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 and biosimilar products. Linkage ensures that any disputes are resolved prior to the marketing of a follow-on product. This grants innovators a fair opportunity to secure a return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity. It also limits potential damages for follow-on manufacturers, as no potentially infringing product is ever launched or approved for market. Indeed, linkage provides **both** innovators and follow-on generic and biosimilar manufacturers with an opportunity of lower-risk challenges of validity or non-infringement, by largely taking the issue of damages out of the equation. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit.

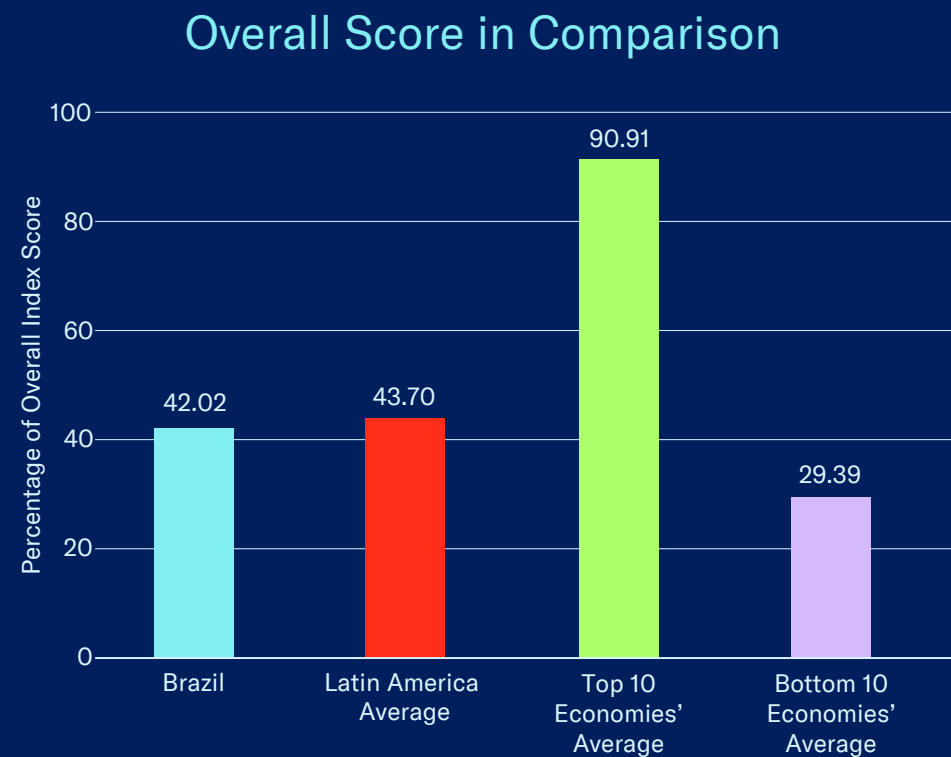
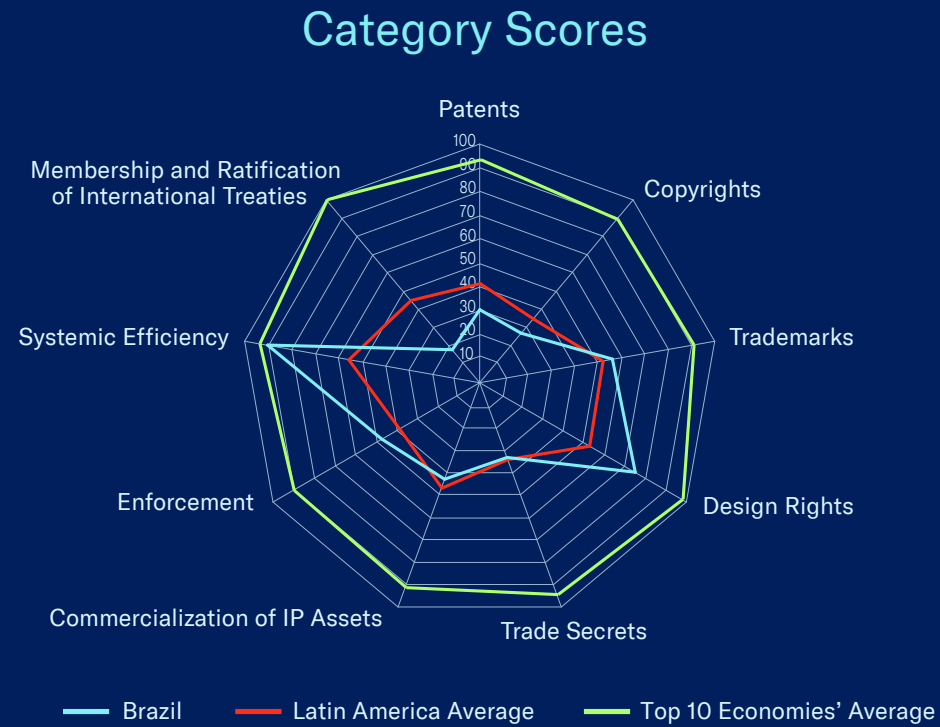
In sum, a well-balanced linkage system recognizes the crucial role of patent protection in promoting innovation, and the role of generic and biosimilar entry in providing patients access to lower cost

biopharmaceuticals. 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 Australia. The Index will continue to monitor these developments in 2022.

**7. Patent term restoration for pharmaceutical products:** A patent term restoration period of five years is allowed under the Australian Patent Act. There are currently no exemptions, waivers, or similar carve-outs on the full and effective use of the term of restoration offered. Australian policymakers have in the past considered the introduction of an export waiver of patent term exclusivity like that implemented in the EU in 2019. Specifically, the Australian Productivity Commission—an independent advisory board to the Australian government on economic and social affairs—in 2016 urged the government to pursue “the steps needed to explicitly allow the manufacture for export of pharmaceuticals in their patent extension period,” echoing the recommendation made by the Pharmaceutical Patents Review Panel (commissioned by the Australian government) in 2013. The idea was never pursued by the government, and Australia has received a full score of 1 on this indicator since the first edition of the Index. Still, rightsholders in Australia have historically faced some practical challenges to receiving the full maximum term of statutory restoration available. Under the Patent Act, an applicant who is within six months of the approval and listing of the relevant product—and corresponding patent claims—on the Australian Register of Therapeutic Goods is obliged to apply for term restoration to the granting authority (the Commissioner of Patents). Unlike other major jurisdictions, the Australian authorities have interpreted this six-month period as beginning not from when the applicant’s relevant product was licensed and duly listed by the drug registration

authorities, but instead from the time in which any product, regardless of it belonging to a third party, containing the substance falling under the relevant patent claim was registered. In effect, this has precluded rightsholders from accessing their full term of restoration.

In 2021, this long-standing practice was successfully challenged by Ono Pharmaceutical and E. R. Squibb & Sons, which brought suit against the commissioner for rejecting their application for term restoration relating to the oncology drug Opdivo. In his ruling, Justice Beach of the Federal Court stated that the commissioner’s interpretation of the relevant statute was “absurd” and “manifestly unreasonable.” This ruling addresses a long-standing area of concern for rightsholders and now better aligns Australian practices with those in other leading markets, including the U.S. At the time of research, the commissioner had announced that they would be appealing the ruling. The Index will continue to monitor these developments in 2022.



## Key Areas of Strength

- The Brazilian Patent Office's (INPI's) 2019 patent backlog plan "*Plano de Combate ao Backlog de Patentes*" seeks to eliminate long-standing registration backlogs
- Stronger criminal enforcement on copyright through "Operation Copyright" and "Operation 404 against piracy"
- INPI in 2021 released a first-ever study of IP-intensive industries' national economic impact in Brazil
- Law 14.195/2021 changed Brazil's IP Law so that the Brazilian National Health Surveillance Agency's (ANVISA's) prior consent on patent applications is no longer required

## Key Areas of Weakness

- Article 40 invalidation by Supreme Court in 2021: without an instrument to replace Article 40, the measure weakens Brazil's patenting standards and retroactively targets the biopharmaceutical industry
- Over 10,000 patent applications affected
- New compulsory licensing amendments for health emergency broadens existing emergency powers and authority and potentially generates legal uncertainty
- Key life sciences IP rights missing, including term restoration and RDP, and, overall, a challenging patentability environment
- Limited participant in international IP efforts—only a full contracting party to two out of nine treaties included in the Index



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>2.74</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of computer-implemented inventions (CIIs)	0.00
4. Plant variety protection, term of protection	0.74
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.50
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.88</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.50</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.00</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>2.58</b>
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.33
<b>Category 7: Enforcement</b>	<b>3.31</b>
32. Physical counterfeiting rates	0.53
33. Software piracy rates	0.53
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.75
<b>Category 8: Systemic Efficiency</b>	<b>4.25</b>
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>1.25</b>
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
21.01**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Brazil's overall score has decreased from 42.32% (21.16 out of 50) in the ninth edition to 42.02% (21.01 out of 50) in the tenth edition. This was primarily driven by a decrease on indicators 2 and 3.

### Patents, Related Rights, and Limitations

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

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

Furthermore, and as has been detailed in previous editions of the Index, up until 2021 Brazil was one of the few economies in the world in which drug regulatory authorities have a role in evaluating patent applications. Article 229-C of the Industrial Property Law 9.279 gave ANVISA a right to provide prior consent to biopharmaceutical patents that are being examined by INPI. Consequently, decisions on whether to grant a patent were based on examination not solely by patent specialists and officials at INPI, but also by ANVISA. This created a

requirement of dual examination. Despite numerous administrative efforts (including a 2017 Interagency Ordinance) and numerous court decisions, the exact meaning and nature of ANVISA's right to prior consent were never fully defined or curtailed. In a positive move, Chapter XIII of Law 14.195 has now eliminated this requirement by removing article 229-C altogether. At the time of research, INPI had released initial guidance indicating that all pending applications with ANVISA were to be returned to the patent office and subject to normal processing. If implemented and resulting in the full removal of ANVISA from the patent prosecution and examination process, this would be a remarkable and positive development in Brazil and potentially result in a score increase. However, the removal of this dual examination requirement is unlikely to have any immediate impact on the excessive patent application backlog.

Across all economic sectors and patent arts, INPI has a long-standing backlog of patent applications ranging from ten to 13 years depending on the field of technology; applications in the biopharmaceutical and information and communication technologies (ICT) fields are traditionally the worst affected. The past few years have seen a growing level of commitment and effort by INPI to address this backlog. In 2019 a new initiative was announced, the Backlog Fight Plan (*Plano de Combate ao Backlog de Patentes*). INPI has passed several administrative resolutions over the last few years, all aimed at accelerating the decision-making and patent prosecution process for applications with and without existing prior art searches and documentation. To some extent these actions have had a positive impact and reduced the number of pending applications. At the time of research, the estimated backlog of just under 150,000 applications identified as constituting the backlog in 2019 had been reduced by roughly two-thirds, to about 50,000 applications.





While a sizeable reduction, the bottom line is that even two years after significant reform efforts, about 50,000 applications are still subject to a backlog. Of these 50,000, almost 10,000 relate to biopharmaceutical technologies subject to review by ANVISA. An additional 24,000 are in the fields of mechanical and electrical engineering. Given that INPI has struggled for decades to effectively address the extensive backlog and long delays in application processing, the Industrial Property Law has provided innovators in Brazil with a guaranteed minimum term of exclusivity and protection of ten years from **grant** for standard patents.

Article 40 of the law states 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 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 has provided rightsholders with a proverbial floor of exclusivity and insurance against INPI’s endemic delays. In a series of decisions in the spring of 2021, the Brazilian Supreme Court has removed this floor. Not only did the court declare that Article 40 was unconstitutional and would no longer be available or applicable, but the court also stated that the ruling should be retroactively applied but only to granted patents in the biopharmaceutical and health-related fields. The ruling is a grave blow to Brazil’s national IP environment and especially to biopharmaceutical rightsholders.

Local legal estimates suggest that there are currently over 10,000 pending patent applications with a delay of over ten years, which will, per definition, see their period of exclusivity cut short. Through this decision and without a new instrument to serve as a remedy to the IP protection minimum term of exclusivity, the Brazilian Supreme Court weakened Brazil’s standards of patent protection. Furthermore, the selective retroactive

application of the ruling to one field of technology and innovation is a gross violation of Article 27(1) of the TRIPS Treaty and established international principles of non-discrimination. At the time of research, neither the Brazilian Congress nor the federal government had sought to effectively remedy this situation. No emergency legislation had been passed or proposed. The Index urges the Brazilian government and lawmakers to immediately address this issue. Large application backlogs and unreasonably long application processing times are not unique to Brazil or INPI, and there are a variety of mechanisms that can resolve those issues. Such mechanisms could include, for example, the introduction of a new statutory defined variable term of adjustment or a patent validation mechanism with other major IP offices. As a result of the weakening of the patenting environment and rightsholders’ inability to continue to secure even a ten-year minimum period of patent protection—let alone anything close to a TRIPS-defined term of 20 years—Brazil’s score on indicators 2 and 3 have been reduced. The Index will continue to monitor these developments in 2022.

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

As has been detailed in the Index, Brazilian health and pharmaceutical policy has historically had a strong focus on localizing industrial production, R&D, and cost controls through the overriding of IP rights. The relevant sections of the Industrial Property Law 9.279 provide a broad basis for compulsory licensing beyond the use of this mechanism solely for public health emergencies that do not involve commercial consideration. Moreover, this mechanism also includes a domestic manufacturing criterion that can form the basis for the issuing of a compulsory license. As noted in past editions of the Index, these sections have been used in the past during price negotiations with foreign biopharmaceutical innovators to reduce their prices in light of the threat of approving the manufacturing of local generic versions of patented

medicines. For example, the 2007 issuing of a compulsory license for the production of efavirenz by the Lula administration came one day after failed price negotiations with the manufacturer.

But compulsory licensing and the over-riding of property rights is not a cost-containment tool; cost is not a relevant justification or basis for compulsory licensing or equivalent declarations under the TRIPS agreement. TRIPS Article 31, the amendments introduced in the 2001 Doha Ministerial Declaration, and 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 suggests that compulsory licensing represents a “measure of last resort,” intended primarily for public health and humanitarian emergencies such as pandemics, and to be used only after all other options for negotiating pricing and supply have been exhausted.

The focus on compulsory licensing as a public policy tool in Brazil continued in 2021. Several amendments to the Industrial Property Law had been signed into law in late 2021, with many more under discussion. Passed amendments include provisions broadening the government’s emergency powers and authority to issue compulsory licenses, setting the percentage of royalties to be paid in licensing fees, and expanding the compulsory licensing mechanism to also cover patent applications. These provisions and other concerning provisions related to technology transfer were at the time of research still pending the presidential veto’s analysis by the Brazilian

Congress. The presidential veto removed these provisions from the law but the Brazilian Congress may overrule the veto. Together with the above discussed Supreme Court ruling and the lack of action on part of the Brazilian government and legislature to effectively address this ruling, these actions weaken a challenging environment for biopharmaceutical innovators. The Index will continue to monitor these developments in 2022.

**Copyrights, Related Rights, and Limitations; and Enforcement**

**11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 36. Criminal standards including minimum imprisonment and minimum fines:**

The Brazilian Copyright Act provides basic exclusive rights and protection with relatively limited provisions in place addressing the issue of online infringement. Brazil does not have a formalized and comprehensive notice-and-takedown system in place. Historically, there has been some cooperation between ISPs and rightsholders, but this is piecemeal, ad hoc, and not systematic. Having been debated and discussed for several years, the *Marco Civil da Internet* (Internet Bill of Rights, Law No. 12,965) was passed in 2014. Although primarily concerned with issues of data privacy and network neutrality, this law did contain some provisions relating to the protection of content and copyright online. Specifically, Section 3 and Articles 18–20 of the act provide a broad safe harbor provision for ISPs relating to third-party infringement, with ISPs required to act and make infringing content unavailable only once a court order has been issued unambiguously finding that the content is infringing.

Given that the Brazilian justice system generally suffers from long processing times and high costs of litigation, the need for a court order stands in the way of a practical and workable mechanism



ensuring the expeditious removal of infringing content. Similarly, there is no dedicated or defined administrative or judicial pathway in place to provide injunctive-style relief for copyright holders. As a result, and as has been noted over the course of the Index, industry data and consumer surveys all show that Brazil remains a central piracy hub in Latin America, with online infringement growing in the last few years as broadband penetration and the use of mobile technologies all grow. For example, 2019 data from the regional industry entertainment association ALIANZA (*Contra Piratería de Televisión Paga*) suggest that Brazil remains the largest market for online piracy in Latin America, with over 7 billion recorded web visits to online sources of piracy alone in the surveyed period. This was almost a 20% increase in traffic compared to 2017. Overall, Brazil was estimated to be the third largest consumer of pirated content in the world. This remains the case today. A news report published June 2, 2021, by *CNN Brasil* suggests that about one-third of Brazilian internet users access infringing content online.<sup>17</sup> Similarly, physical piracy remains a real challenge to rightsholders. For example, the video game industry has long noted that the trade in pirated and modified video games and devices remains a key piracy challenge in Brazil. Several markets in São Paulo have been included in the USTR's *Review of Notorious Markets for Counterfeiting and Piracy*, including in the latest edition. Unfortunately, copyright enforcement and an effective deterrence against piracy have historically been lacking. As mentioned, there are long backlogs in the Brazilian justice system, and the majority of those arrested on suspicion of criminal IP infringement never face criminal charges or prosecution; charges are either dropped or suspended.

There have been isolated areas of success—for example, against physical piracy in São Paulo through the “City Free of Piracy Project”—but overall, criminal copyright enforcement has

remained a challenge. As noted in previous editions of the Index, this has slowly begun to change with the launch of several dedicated special criminal enforcement operations against IP-infringing websites, vendors, and suspected criminals. For example, “Operation Copyright,” a new initiative by the Brazilian Federal Police to tackle copyright piracy, was launched in 2019. Reports suggest that the police took coordinated action in five Brazilian states, shutting down torrent sites and seizing equipment and suspected goods. In 2020 and 2021, “Operation 404 against piracy” (*Operação 404 contra pirataria*) was launched. Spearheaded by a special police enforcement unit (SEOPI) and the Ministry of Justice, with international support from the U.S. Embassy and UK law enforcement officials, this special enforcement effort has had direct and tangible results: hundreds of websites and applications offering copyright-infringing content have been shut down; over 50 search and seizure warrants have been issued and executed across 12 Brazilian states; and several arrests have been made. These are positive developments, and the Index will continue to monitor this activity in 2022.

### Commercialization of IP Assets and Market Access

**26. Barriers to market access:** As noted over the course of the Index, Brazilian industrial and economic policy actively limits access to its domestic market through various barriers, localization requirements, and procurement preferences. The divulging and sharing of IP and technology are sometimes part of these barriers and local preferences. Local content requirements have been a central part of Brazilian industrial policy with the automobile, oil and gas, telecommunications, and ICT industries, all historically subject to varying percentages of local production. Although some requirements have been reduced, the oil and gas sector still faces local content requirements for both offshore and onshore exploration and

development. Public procurement preferences are in place cross-sectorally, with varying rates of preferences depending on the industry and type of tender. Under the 2010 Law 12.349 (the “Buy Brazilian Act”), preferential margins of up to 25% were introduced for all public procurement.

There are additional incentives in place and local content requirements for telecommunications and the procurement of information technology goods and services. The biopharmaceutical sector has also been subject to indirect localization requirements through the “Partnerships for Productive Development” (PDPs). These public-private partnerships aim to further biopharmaceutical R&D and technology transfer into Brazil by offering exclusive market access to the Brazilian public health system *Sistema Único de Saúde* (SUS). These PDPs have in the past required private entities involved in a PDP to transfer a Drug Master File or the master cell bank (for small molecule and biological products, respectively). The SUS constitutes roughly 50% of purchasing power within the Brazilian health care market. Furthermore, the Brazilian government has historically, through burdensome regulatory and formal requirements, actively intervened and set the commercial terms of licensing activity and technology transfer within and into Brazil. For example, to become effective and binding on third parties, licensing agreements were required to be published in INPI's *Official Gazette*. Agreements were also required to be approved by INPI, with limitations on royalty fees and payments between the contracting parties. Exclusive licensing agreements were subject to more onerous publication requirements than non-exclusive licenses, making this process more time-consuming. This changed in 2017 when INPI announced through Rule 70 that the agency would no longer take an active role in framing and approving licensing agreements. Instead, the new rule suggested that the agency would operate as an agency of recording.

Unfortunately, the rules that accompanied the administration of INPI's new recording process remain bureaucratic and burdensome, with the government ultimately retaining the right to review sensitive aspects of all licensing agreements.

Regarding barriers to digital trade, 2020-21 saw the coming into force of the Brazilian Data Protection Law (LGPD). As part of the 2021 implementation of the law, a new administrative body—the Data Protection Authority (DPA)—has been established. Currently, Brazil's DPA is under the presidency body, but after two years from its creation, the agency will shift into an independent agency. The independency of Brazil's DPA is of great importance. However, uncertainty remains over how potential infringements and violations of the LGPD will be assessed and how the law will be enforced. While there are no direct requirements under the law for storing data locally, the potential size of the fines and damages in the event of a breach or infringement of the LGPD may work as a disincentive for entities either to process and collect data in Brazil or to store and transfer such data outside of Brazil.

For rightsholders across many different industries and sectors, any potential barrier to digital trade raises serious questions and concerns. The ICT and internet revolutions have fundamentally changed how human beings interact socially and economically. In virtually all industries, business and economic interaction is being shaped by the collection of data and digital technologies. These technologies are allowing companies across all business sectors and public and private research organizations to collect and use greater levels of data and information than ever before in so-called “big data.” Combined with increased computing capacity and the application of new technologies (such as artificial intelligence and machine learning) that allow us to analyze and better understand data collected, there is the possibility to make significant



discoveries and breakthroughs in virtually any area of research and human socio-economic activity. Cross-border flows of data are ingrained in countless services relied on by consumers, with numerous digital, automated, and virtual services relying on the seamless movement and storage of data in various locations. Public policies relating to national data management must recognize this reality and be formulated accordingly. The Index will continue to monitor these developments in 2022.

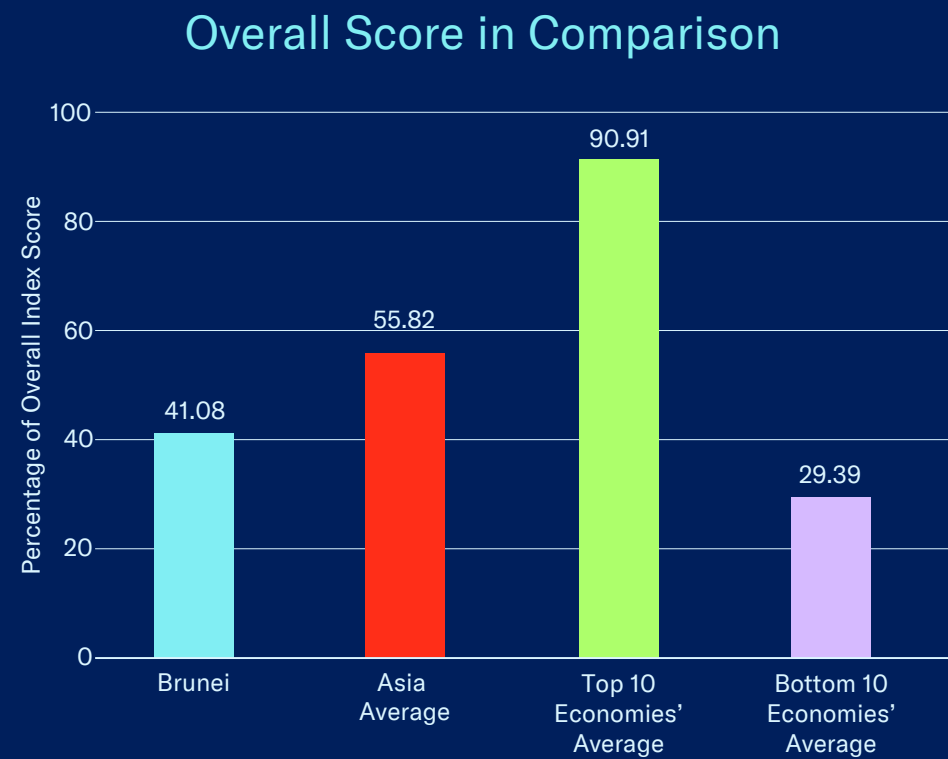
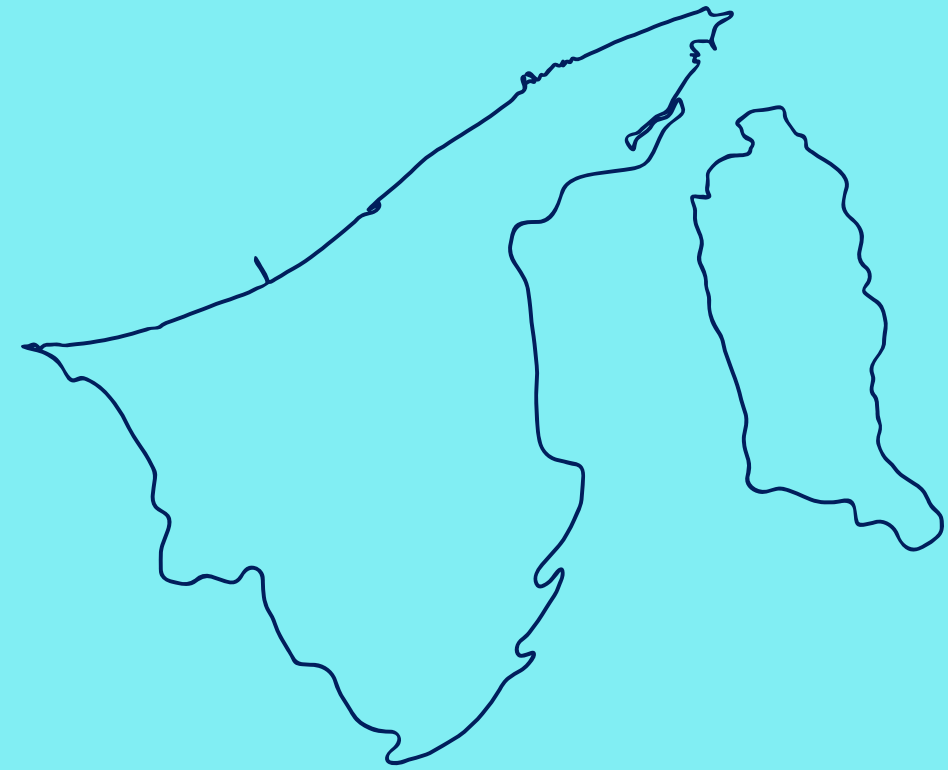
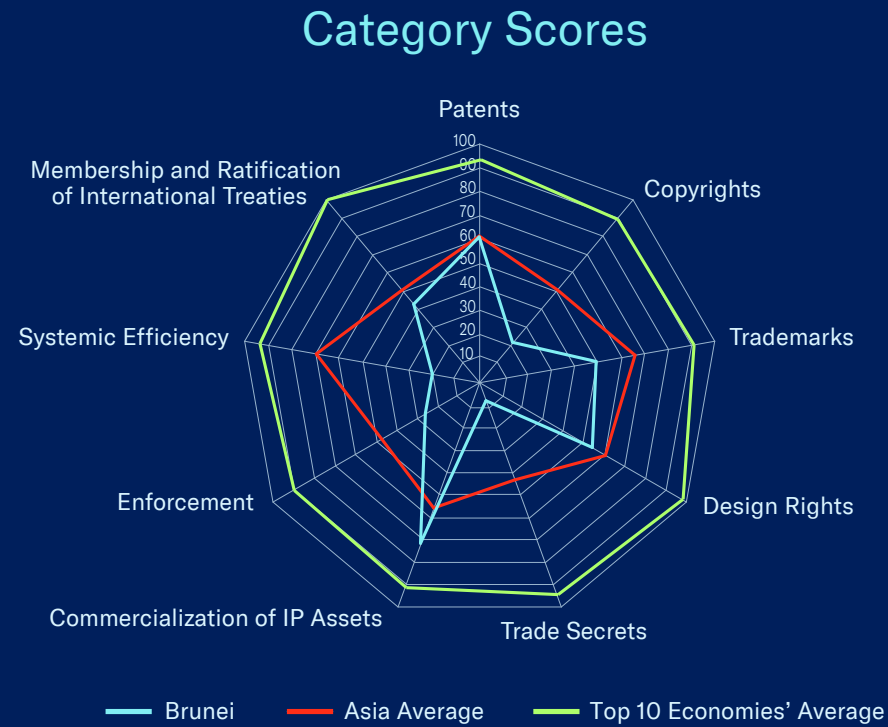
### Systemic Efficiency

**43. IP-intensive industries national economic impact analysis:** Several departments and agencies of the Brazilian government are actively studying the impact IP rights have on national economic development and output. For several years INPI, through INPI Academy (*Academia da Propriedade Intelectual*), has studied and commissioned research on the role of IP rights and their socio-economic impact. Since 2006 this academy has sponsored research and offered accredited postgraduate courses in various fields of IP rights and innovation. Furthermore, the main socio-economic research arm of the federal government, the Institute for Applied Economic Research (*Instituto de Pesquisa Econômica Aplicada; IPEA*) has commissioned and conducted several studies on the relationship between IP rights and economic activity. This includes the 2008 monograph *Incentive Policies for Technological Innovation in Brazil (Políticas de Incentivo à Inovação Tecnológica no Brasil)*. Chapter 12 of this book was dedicated to the economic impact that trademark and patent registration had on firm and labor productivity. The study found that although more empirical evidence was needed, “there is evidence that trademark and patent filing positively affects firm productivity, which reinforces the need for investments that make the operation of the intellectual property system more efficient.”

IPEA has also commissioned more recent studies,

including several technical notes (*Nota Técnica*) and sector-specific studies, such as a report on the creative economy. For the latter, see for example the 2013 *Panorama da Economia Criativa no Brasil*, which estimated that the creative economy generated between 1.2% and 2% of Brazilian GDP and employed 2% of the labor force. In 2021, this work was complemented by a new research project dedicated to mapping the national economic impact of all IP-intensive industries.

In May 2021, INPI released a comprehensive assessment 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 national output, employment, and trade. In the latest three-year period studied (2014-16), these industries were estimated to contribute an average 44.2% of total gross value added, and IP-intensive industries directly employed over 19 million people on average (36% of the workforce). The study was a joint effort between INPI and government departments and agencies including the Agency for Industrial Development, and it is the first of its kind in Brazil. This is a positive development, and INPI and its partnering agencies should be congratulated for putting the resources and time into understanding and measuring the positive economic impact IP rights have on the Brazilian economy and national economic output and employment. It would be good to see this exercise carried out at regular intervals using the latest available national statistics. As a result of this positive development, the score on this indicator has increased by 0.25.



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>5.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of computer-implemented inventions (CIIs)	0.75
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.50
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.53</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.00</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.00
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.25</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.00
25. Regulatory data protection term	0.00

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

**Total Score:  
20.54**

## Spotlight on the National IP Environment

### Past Editions versus Current Score

Brunei's overall score has decreased from 41.13% (20.57 out of 50) in the ninth edition to 41.08% (20.54 out of 50) in the tenth edition. This reflects a marginal decrease on indicator 32.

### Membership and Ratification of International Treaties

**45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; and 49. The Hague Agreement Concerning the International Registration of Industrial Designs:** Brunei has over the last decade taken tangible positive steps to improve its national IP environment. Reforms to patent and copyright laws; the introduction of a new dedicated IP office; and stronger enforcement against physical piracy are all noticeable improvements to the national IP environment. As a direct result of these steps, Brunei was removed from the USTR's *Special 301 Report* Watch List in 2013.

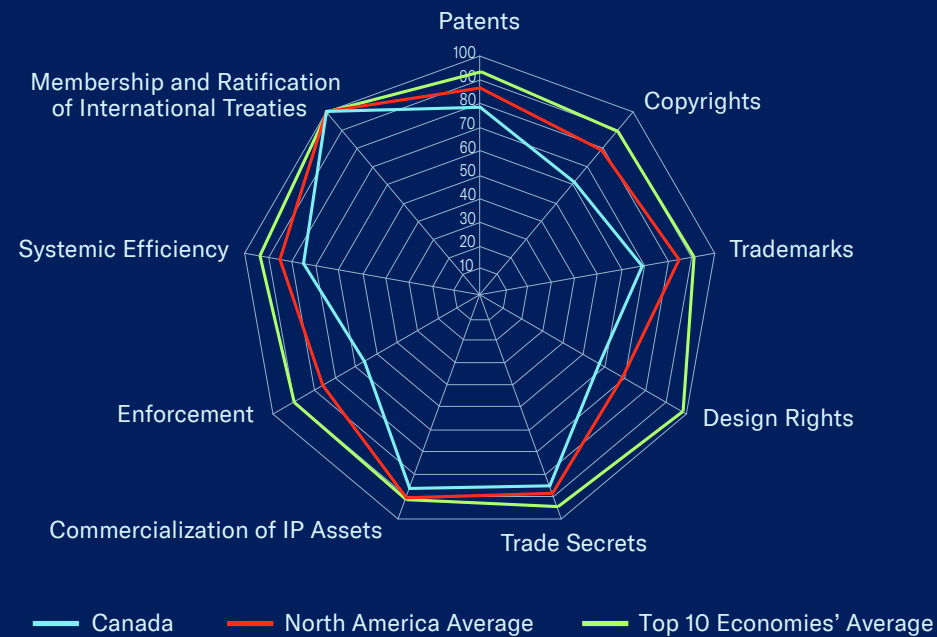
A key component of Brunei's IP reforms has been a dedicated effort to join several international IP treaties. Being a contracting party to key international IP treaties reflects a given economy's broader participation in the international IP community and embracing of the highest IP standards. As such, treaty participation is a strong signal of the extent to which an economy both chooses to participate in the international IP system and adheres to established standards and best practices. Brunei's score in this category of the Index has increased substantially from a score of 0 in the fourth edition of the Index (the first year Brunei was included) to now achieving a score of 3, or 42.86%, of the total available score. This is notably higher than many high-income economies, such as New Zealand and

the UAE, as well as some of the region's biggest economies like Malaysia and Indonesia.

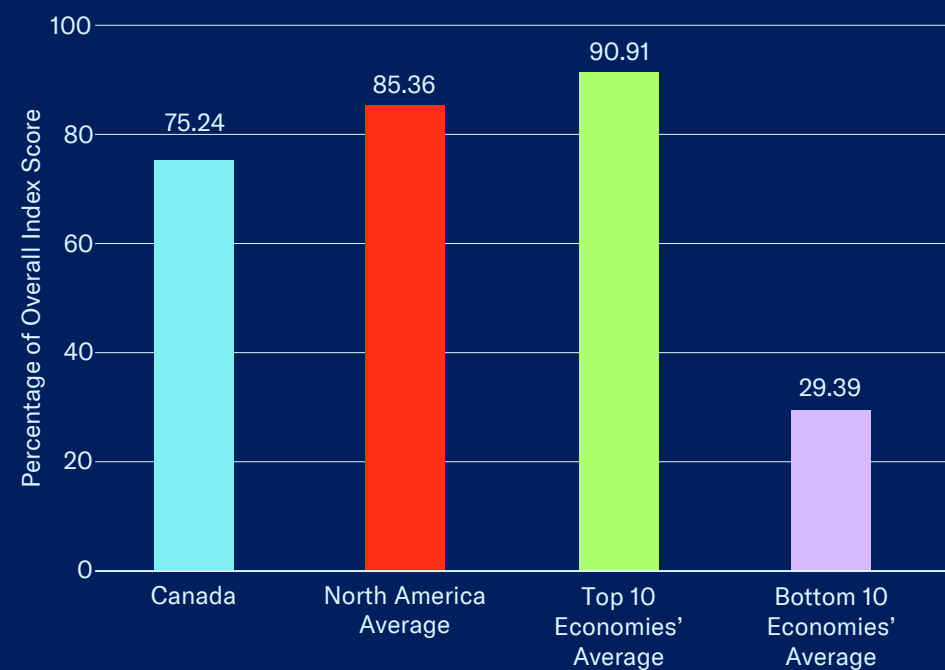
Notably, Brunei became a contracting party to the Hague Agreement in 2013 and the Madrid Protocol in 2017. Both treaties have better aligned Brunei's IP standards with international best practices and improved rightsholders' abilities to register and protect their rights across the world. The direct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

In the 15 years prior to joining the Madrid Protocol, Brunei had an average of 972 total trademark applications per year. That average has now almost doubled in the three-year period (2017-2019) for which data is available, to 1,876 applications per year. The number of applications for registering design rights has increased even more dramatically since Brunei became a contracting party to the Hague Agreement in 2013. In the 14-year time period for which data is available prior to the implementation of the agreement, there was an average of 13 total design applications per year. That average has now increased by more than 200% in the years for which data is available, to an average of 55.75 applications per year. The lesson is clear—for both Brunei and all other economies aspiring to improve their IP standards and the creation, registration, and use of IP assets—joining international treaties is a positive first step in reforming and strengthening national IP environments and reaping the economic rewards.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- 2020 Federal Court of Appeal case creates path for injunctive-style relief against online piracy
- U.S.-Mexico-Canada Agreement (USMCA) took effect in 2020, resulting in longer copyright term, new criminal sanctions for theft and misappropriation of trade secrets, and *ex officio* authority for border action against in-transit goods
- 2017 Supreme Court judgment on utility doctrine aligns Canada's patentability environment with international standards
- Implementing Comprehensive Economic and Trade Agreement (CETA) legislation in place in several areas, including patent term restoration
- Significant damages awarded in precedent-setting 2017 Federal Court case with regard to Canada's DRM provisions

## Key Areas of Weakness

- Continued uncertainty over existing interpretation of educational exceptions to copyright—2021 Supreme Court decision in *Access Copyright* case adds more layers of uncertainty and legal complexity
- CETA amendments to Patent Act introducing patent term restoration includes restrictive eligibility requirements as well as an export claw-out, which effectively undermines biopharmaceutical exclusivity
- Deficiencies regarding pharmaceutical patent enforcement remain unaddressed in Patented Medicines (Notice of Compliance) Regulations (PMNOC)



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>7.05</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.25
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.30
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	0.75
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>4.29</b>
10. Copyright (and related rights) term of protection	0.79
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.50
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	1.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	1.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.75
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.15</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.75
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.55</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.80

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>5.17</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>3.91</b>
32. Physical counterfeiting rates	0.63
33. Software piracy rates	0.78
34. Civil and precedural remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.50
37. Effective border measures	0.75
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.25
<b>Category 8: Systemic Efficiency</b>	<b>3.75</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.75
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>7.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
37.62**

## Spotlight on the National IP Environment

### Past Editions versus Current Score

Canada's overall score has increased from 74.71% (37.35 out of 50) in the ninth edition to 75.24% (37.62 out of 50) in the tenth edition. This reflects score increases on indicators 12 and 32.

### Area of Note

Biopharmaceutical rightsholders continue to face challenges in exercising their IP rights and granted periods of exclusivity in Canada. As has been noted over the last few editions of the Index, there is a growing focus on rigid cost control and minimizing overall biopharmaceutical spending within the Canadian health system. Over the last several years, Canadian authorities have been reforming how patented medicines are evaluated and priced through the Patented Medicine Prices Review Board's (PMPRB's) evaluation methodology. These changes will substantially lower the overall price comparisons and thus the overall biopharmaceutical price level in Canada while adding additional layers of complexity to the pricing and reimbursement process. Specifically, these reforms include changes to the basket of economies used for price comparisons. Most notably, the regulations expand the size of the basket and remove the U.S. and Switzerland. New comparator economies to be added are Australia, Belgium, Japan, the Netherlands, Norway, and Spain. Given the strict price controls in place in these new economies and the removal of the U.S. and Switzerland as comparator economies, these changes will substantially lower the overall price comparisons and thus the overall biopharmaceutical price level in Canada. The direct impact of the Canadian health system's strong focus on cost control has historically been a time lag in new products joining the market and patient access.

A 2019 study by Innovative Medicines Canada and the Pharmaceutical Research and Manufacturers of America (carried out by Ernst & Young) found that of 243 innovative drugs (new active substances) launched globally between January 2011 and June 2018, only 119 (49%) were launched in Canada. These findings are supported by additional studies. For example, a 2016 report conducted by IMS Health Canada, for Innovative Medicines Canada, shows how Canadian patients have access to fewer innovative treatments than in other OECD economies. The study finds that there are long lags between market authorization and inclusion for public reimbursement. On average for the period studied (2010-2014), it took 449 days from market authorization to reimbursement.

Looking at access across all Canadian provinces—formulary and reimbursement decisions are taken provincially in Canada—the study finds that only 37% of drugs were reimbursed and available to 80% or more of the population. There were particular gaps in availability for more advanced treatments including cancer medicines and biologic products. Only 59% of cancer medicines were available to 80% or more of the population. For new biologics, this ratio was even lower at 23%. The changes introduced by the PMPRB's package of regulatory reforms are very likely to exacerbate these gaps even further; as a result, Canadian patients will have to wait even longer to access new and innovative treatments.

The Canadian government rightly recognized the strategic nature of the research-based biopharmaceutical industry and in July 2021 launched a new *Biomanufacturing and Life Sciences Strategy*. Pillar 5 in this Strategy—“Enabling Innovation by Ensuring World Class Regulation”—seeks to make Canada a more “attractive destination for leading life sciences firms to establish and grow.” But 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. Compared to many other high-tech industries—for example, computer software—developing the next ground-breaking treatment for cancer or Alzheimer’s disease requires more than just a laptop and a great idea.

As medicines become more targeted and technically sophisticated, the cost of development rises dramatically. In 1979, the total cost of developing and approving a new drug stood at USD 138 million. Almost 25 years later, in 2003, this figure was estimated at USD 802 million. A 2012 estimate puts the total cost of drug development at approximately USD 1.5 billion. And 2016 research from Tufts University suggests that it costs USD 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 research and development of new medical technologies and products. In particular, patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection (RDP) and special exclusivity incentives for the protection and production of orphan drugs, enable research-based companies to invest vast sums in R&D and the discovery of new drugs, products, and therapies. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug.

IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market entrants who bore none of the costs of early-stage investment, research and development, and product commercialization. Many drugs and therapies may not have been discovered

without the legal rights provided to innovators through IP laws. As the Index has detailed over the last ten editions, the biopharmaceutical IP environment in Canada could in many respects be strengthened and aligned with best practices in the U.S., the European Union, and leading Asian economies. Similarly, recognizing and rewarding innovation in the Canadian health system through adequate pricing and reimbursement policies for biopharmaceuticals would also improve the competitiveness of the Canadian environment and allow innovators—domestic and international—to gain a fair reward for their innovation and creativity. At the time of research, the coming into force of the PMPRB’s new regulations had been postponed to January 1, 2022. The Index will continue to monitor these developments in 2022.

## Copyrights, Related Rights, and Limitations

**12. Expedient injunctive-style relief and disabling of infringing content online:** The Copyright Act does not include provisions for an injunctive-style relief mechanism, nor does it define an administrative or judicial route whereby rightsholders can petition a court of law or administrative body for injunctive relief akin to similar mechanisms in place in many economies in Europe and Southeast Asia. In January 2018, a group of rightsholders requested that the Canadian Radio-Television and Communications Commission (CRTC) establish such a regime for disabling infringing content online. The CRTC subsequently held a public consultation on the matter ending in May 2018, but no further action was taken on the proposal.

In November 2019, a court ordered a group of ISPs to disable access to websites hosting alleged infringing content. The case, *Bell Media Inc. v. GoldTV.Biz*, shows both the limitations and potential for this route of copyright enforcement in Canada. On the one hand, the granting of a permanent injunction shows that the possibility

does exist under existing statute in Canada for rightsholders to access this type of relief. On the other hand, the injunction was only granted following initial complaints that went unheeded when preliminary injunctions were asked for and granted in the summer of 2019. The case was appealed in 2020 and a final verdict was issued in May 2021 with the Federal Court of Appeal upholding the granted injunction. This ruling is of real significance to Canadian rightsholders as not only did the court clearly affirm the right to injunctive relief and the disabling of access to infringing content online under existing Canadian statute, but it also affirmed, both in principle and in the specific circumstances of this case, that where there is clear *prima facie* evidence of infringement taking place, injunctive relief did not interfere with the principles of net neutrality or freedom of expression. Interestingly, both the Court of Appeal and lower court judgment recognized the possibility and need for amendments to the order regarding relevant domain names and website addresses as the infringing parties seek to circumvent it. In response to such activity, many economies around the world are introducing so-called “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, the UK, and Russia. As a result of this Court of Appeal judgment, the score on this indicator has increased by 0.25.

**14. Scope of limitations and exceptions to copyrights and related rights:** As has been noted repeatedly in the Index, the 2012 amendments to the Copyright Act considerably broadened Canada’s framework for exceptions to copyright, including the expansion of education and personal-use exceptions. Canadian Supreme Court decisions of the 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. In 2017 a statutory review of the Copyright Act was initiated by the Canadian Parliament, and in 2019 two different committee reports were issued: one by the Standing Committee on Canadian Heritage (May 2019) and the other by the Standing Committee on Industry, Science, and Technology (July 2019). The reports differed sharply in their recommendations on the issue of educational exceptions. The Standing Committee on Canadian Heritage in its list of recommendations to the Canadian government called for amending the Copyright Act to “clarify that fair dealing [exceptions] should not apply to educational institutions when the work is commercially available.” The committee also recommended that the government “promote a return to licensing through collective societies.” In contrast, the Standing Committee on Industry, Science, and Technology’s list of recommendations did not ask for any substantive changes or legislative amendments. Instead, the committee simply recommended that the government “consider establishing facilitation between the educational sector and the copyright collectives to build consensus towards the future of educational fair dealing in Canada.” It also recommended that the committee should itself “resume its review of the implementation of educational fair dealing in the Canadian educational sector within three years, based on new and authoritative information as well as new legal developments.”

In April 2020, the Federal Court of Appeal released its judgment in the long-running case *York University v. The Canadian Copyright Licensing Agency (“Access Copyright”).* Running on for nearly ten years, the dispute centers on both the meaning of fair dealing within the context of educational institutions use of copyrighted content and the extent to which York University was bound by Access Copyright’s licensing terms (as a collective body representing many rightsholders)





and established royalty tariffs. A 2017 lower court decision had found that, first, York University's existing fair dealing guidelines and policy did not pass existing tests of fairness as defined and applied by the Canadian Supreme Court and, second, that the university was also bound to pay Access Copyright relevant licensing tariffs for the use of their work as defined and approved by the Canadian Copyright Board. In a departure from this decision, the Federal Court of Appeal held that York University was not bound by the existing tariff structure. Access Copyright's claims were dismissed with the court arguing that "tariffs do not bind non-licensees." On the other hand, the court did concur with the lower court's finding that York University's copyright guidelines did "not ensure that copying which comes within their terms is fair dealing." In October 2020, the Supreme Court of Canada granted leave for an appeal to proceed.

The appeal was heard in May 2021, with a final judgment rendered at the end of July 2021. Unfortunately, the Supreme Court's ruling leaves Canadian rightsholders with more questions than answers. Like the Court of Appeal ruling, the Supreme Court found that York University was not bound by Access Copyright's tariff structure as it was not a licensee. As such, any legal action to be taken should be centered on an infringement action. However, given that Access Copyright is a collective society with a non-exclusive license from its members, under Canadian law it does not have standing to sue for potential copyright infringement. Instead, any legal action needs to be taken by Access Copyright's members individually as individual rightsholders, which, practically speaking, means that after a decade in court, rightsholders are essentially back at square one and have to restart the litigation process.

On the issue of fair dealing, both the lower courts' verdicts recognized that copyright had been infringed by York University and that the existing guidelines did not meet the relevant standards of

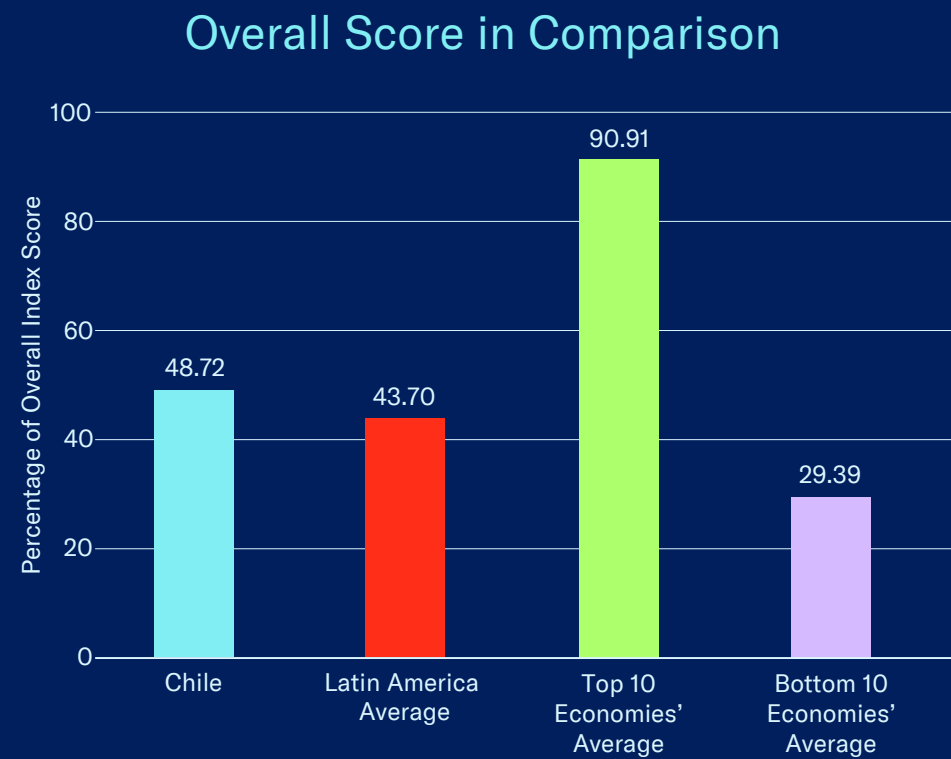
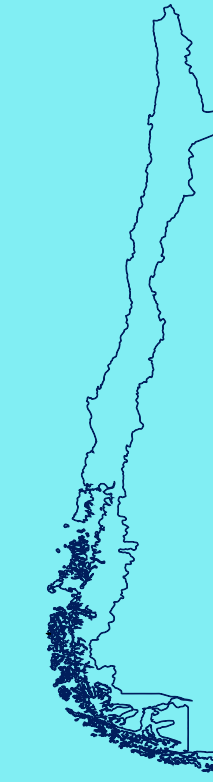
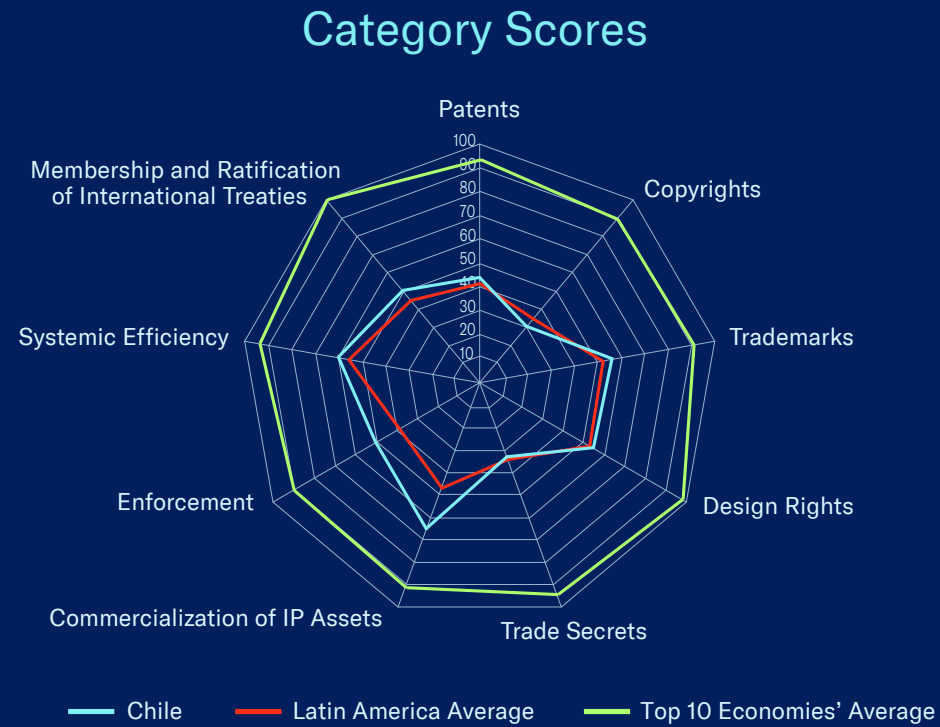
"fair dealing," and both courts refused to recognize York University's copyright guidelines as fair. While the Supreme Court also refused to formally grant a declaration that York University's guidelines were fair, unlike the lower courts it did so on the basis that there "was no live dispute between the parties" and not on an assessment of the guidelines themselves. Instead, muddying the waters even further, the court stated that there were "some significant jurisprudential problems" with the lower courts' interpretation and pronouncements on the issue of fair dealing. In the Supreme Court's view, the lower courts had misunderstood the meaning of fair dealing by focusing solely on the perspective of York University as an institution and not the actual end-user of the copyrighted materials, that is, the student population. By doing so, they had overlooked how the Supreme Court and Canadian jurisprudence on copyright was—both in the court's own view and in the words of academic scholarship cited in the ruling—moving "away from an earlier, author-centric view which focused on the exclusive right of authors and copyright owners to control how their works were used in the marketplace" and the court as an institution was "at the vanguard in interpreting copyright law as a balance between copyright rights and user rights."

In conclusion, the Supreme court stated that any analysis of a university's fair dealing practices should focus on "whether those practices actualize the students' right to receive course material for educational purposes in a fair manner, consistent with the underlying balance between users' rights and creators' rights in the Act." Yet it is unclear what this actually means outside the theoretical confines of a courtroom and in the real world of business and everyday commercial interactions. What is a "student's right" and "fair manner" in this context? Is it the "right" to largely free course materials? Instead of providing clarity and practical application of what fair dealing means within the context of education, the court simply punted on the issue, stating that "since we are not deciding the merits

of the fair dealing appeal brought by York, there is no reason to answer the question in this case."

Unfortunately, not only does the court's ruling not alter the long-standing negative dynamics and long-term consequences of the 2012 Copyright Act amendments and Supreme Court decisions, but it also adds even more layers of uncertainty and legal complexity to an already convoluted and tangled area of Canadian copyright law.

As the Index and others pointed out following Parliament's amendments to the Copyright Act and Supreme Court decisions in 2012, at best the changes to Canada's copyright regime would lead to a higher level of uncertainty for publishers and at worst a shrinking of their industry and business model. Today, it is clear that both have occurred: Industry figures from 2021 suggest that the Canadian publishing industry has suffered greatly over the last decade, with estimated uncompensated copying outside of fair dealing amounting to over CAD 150 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 substantially decreased publishing income. The bottom line is that after ten years of litigation and uncertainty, Canadian rightsholders have failed to achieve effective redress for the clear violation of their copyright, nor have they gained any further understanding of what does or does not constitute fair dealing within the context of education. That is a failure all around. The Index will continue to monitor these developments in 2022.



## Key Areas of Strength

- IP law amendment (Law 19,309) passed in 2021 extends term of protection for design rights and improves enforcement environment
- Joined global patent prosecution highway (GPPH) in July 2020
- Stronger efforts to increase transparency and public reporting of customs enforcement activities
- Commitment to improve IP environment through international trade agreements
- Efforts to streamline IP registration
- Promotion of IP commercialization

## Key Areas of Weakness

- Uncertainty on accessibility of term restoration with new IP law amendments (Law 19,309)
- Threat of compulsory licensing based on cost considerations for COVID-19 and HCV drugs persists
- Patchy patent protection for biopharmaceuticals, including obstacles to patentability and lack of effective patent enforcement
- High levels of counterfeiting and piracy for an OECD economy 55% estimated software piracy
- Lack of sufficient framework to tackle online piracy, though some success in disabling access to infringing websites



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.94</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of computer-implemented inventions (CIIs)	0.00
4. Plant variety protection, term of protection	0.74
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.70
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.13</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.50
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.00</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>3.92</b>
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	0.75
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>3.52</b>
32. Physical counterfeiting rates	0.57
33. Software piracy rates	0.45
34. Civil and precedural remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.50
37. Effective border measures	0.25
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.75
<b>Category 8: Systemic Efficiency</b>	<b>3.00</b>
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>3.50</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:**  
**24.36**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Chile's overall score has increased from 47.20% (23.60 out of 50) in the ninth edition to 48.72% (24.36 out of 50) in the tenth edition. This reflects score increases on indicators 21, 32, 35, and 36.

### Area of Note

As noted in previous editions of the Index, Chile's National Congress has since the mid-2010s debated various iterations of the *Ley Corta de INAPI*, a package of reforms amending Law 19,309 on Industrial Property. In June 2021, this reform package was finally passed into law and officially published in the national gazette, the *Diario Oficial de la República de Chile*. Implementing regulations are due to be published in the beginning of 2022, when the new law will come into effect. The legislative changes affect most major IP rights covered in the Index. While most of the amendments relate to the administration of IP laws and interaction between INAPI, applicants, and rightsholders, there are also some substantive changes relating to design rights and the enforcement of registered trademarks; these are discussed below under individual indicators.

One negative feature of the new legislation is the introduction of a much shorter period of time under which rightsholders can apply for “supplementary protection,” that is, a period of term restoration either due to delays on the part of INAPI in processing an application or, for biopharmaceutical products and technologies, due to the lengthy sanitary drug registration process.

Under the old law, rightsholders had to apply for supplementary protection within a period of six months after the grant of a patent and/or sanitary registration of the relevant biopharmaceutical product. Under an updated Article 53 Bis 1 and

53 Bis 2, the period has been reduced to 60 days. Similarly, the period under which rightsholders must pay any relevant fees for the restoration granted has now been changed from falling within a period of six months prior to the expiration of the original exclusivity period to, under the revised article, a period of 30 days. It is difficult to see why the Chilean authorities have shortened this time period so substantially, as it will only lead to the application process becoming more bureaucratic, convoluted, and, ultimately, inaccessible. The basic purpose of an IP right is to provide an incentive for innovation and creativity; it is self-defeating for the relevant granting authority to actively try to undermine the granting and practical availability of that right by introducing new layers of complexity. As with all negative changes to a national IP framework, the undermining of these incentives will hurt domestic Chilean innovators and creators just as much as it will hurt foreign ones. Finally, there are also some potential gray areas, including an updated Article 49 that defines a list of new exceptions to rights conferred by a granted patent. The Index will monitor the use and implementation of these new amendments in 2022.

### Design Rights, Related Rights, and Limitations

**21. Industrial design term of protection:** Article 65 of Law 19,309 provides a non-renewable 10-year term of protection for design rights. As noted in previous editions of the Index, proposed changes to the law as part of the *Ley Corta de INAPI* reform package would extend this term up to 15 years, also setting up a new abbreviated procedure for granting industrial design registrations without substantive examination. In June 2021, the reform package was passed into law with a revised Article 65 extending the term of protection to 15 years and officially published in the national gazette. As a result, the score on this indicator has increased.



## Enforcement

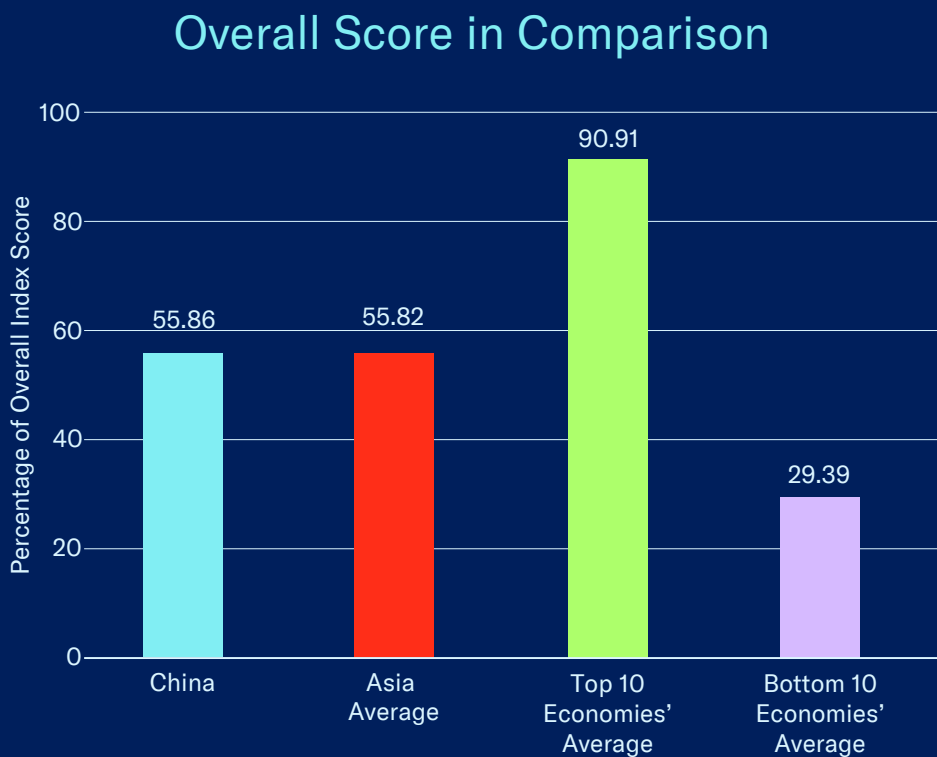
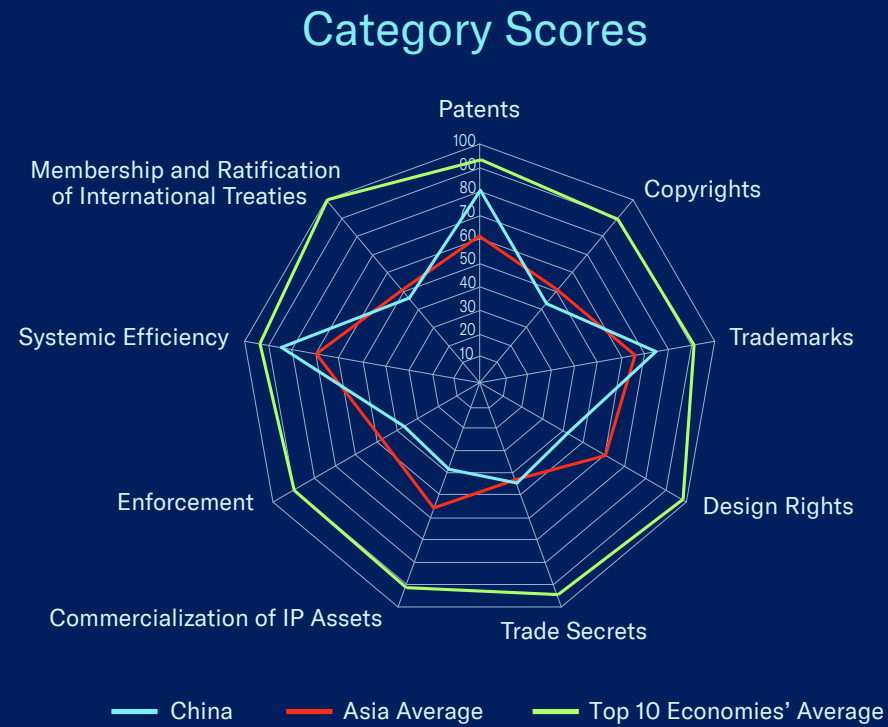
### **35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement; and 36. Criminal standards including minimum imprisonment and minimum fines:**

The IP reform package and changes to Law 19,309 described above also included changes to the enforcement environment. To begin with, Article 108 has been amended and now provides for a form of statutory damages for trademark infringement. Up until now, Law 19,309 had not included any form of preestablished or statutory damages for any major IP right. Instead, damage calculations have been based on general rules of civil compensation, which grant courts wide sway in assessing damages including loss of profits. With these amendments, it is now possible—in the case of proven trademark infringement—for the rightsholder to opt for a pre-established form of damages up to 2,000 monthly tax units per infringement (circa USD 120,000). Furthermore, with regard to criminal sanctions, the insertion of a new Article 28 Bis introduces a minimum prison sentence for trademark infringement and commercial counterfeiting; previously, such offences had only been subject to fines. As a result of these changes, the score on both these indicators has increased by 0.25, respectively.

### **Membership and Ratification of International Treaties**

Chile is a contracting party to the WIPO Internet Treaties; the Patent Cooperation Treaty; and the Convention on Cybercrime. Chile has also concluded a post-TRIPS FTA with substantive IP provisions through the United States-Chile FTA. Chile is not a contracting party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Singapore Treaty on the Law on Trademarks; the Patent Law Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991

(Chile is a contracting party to the Act of 1978); or the Hague Agreement Concerning the International Registration of Industrial Designs. In May 2021, the Chilean Senate approved Chile to join the Madrid Protocol. At the time of research, Chile had not acceded and had not yet been recognized by WIPO as a new contracting party to the protocol.



## Key Areas of Strength

- Continued reform of IP laws in 2021 following Phase One Agreement with the U.S.
- 2020 Patent Law amendment aims to improve the environment for biopharma and other patent-dependent industries and extends the term of protection for design patents
- 2020 Copyright Law amendments improve copyright environment
- 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

- Uncertainty over implementing rules for biopharmaceutical linkage mechanism and patent term restoration
- Despite improved enforcement efforts, levels of IP infringement remain high
- Interpretation of IP laws can be fragmented and out of sync with international standards
- Broader industrial and investment policies continue to undermine the investment and business environment



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>7.28</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	0.78
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>3.03</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.75
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.00</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.75
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.85</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.35</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.60

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>2.33</b>
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.33
<b>Category 7: Enforcement</b>	<b>2.59</b>
32. Physical counterfeiting rates	0.00
33. Software piracy rates	0.34
34. Civil and precedural remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	1.00
<b>Category 8: Systemic Efficiency</b>	<b>4.25</b>
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>3.25</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
27.93**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

China's overall score has increased from 54.86% (27.43 out of 50) in the ninth edition to 55.86% (27.93 out of 50). This reflects a score increase on indicator 50. Over the last three years, China has significantly reformed much of its national IP environment by amending and updating most major IP laws and regulations. This is in large measure a reflection of China implementing aspects of the Phase One Agreement it concluded with the U.S. in January 2020 as well as taking long-anticipated steps to strengthen IP protections to boost its domestic innovation ecosystem.

### Patents, Related Rights, and Limitations

**5. Pharmaceutical-related patent enforcement and resolution mechanism:** As noted in previous editions of the Index, Chinese regulatory authorities have committed to introducing a patent linkage mechanism for biopharmaceuticals. In October 2017, the central government issued the State Council Opinions on Deepening Regulatory Reforms to Encourage Drug and Medical Device Innovation, which confirmed the strengthening of the existing patent linkage mechanism in China (based on the existing Drug Registration Regulations) proposed earlier in 2017. Article 16 provided for the notification to patent holders of applications for relevant follow-on drugs (in comparison to the publishing of applications under the existing system) within a set period. It also specifically permitted the initiation of patent disputes once the patent holder was made aware of the application (instead of forcing patent holders to wait until the follow-on drug was marketed). Moreover, the measure indicated that the approval of any follow-on product would not take place if, "within a certain period of time," the corresponding patent dispute was not yet resolved.

Following that period, Chinese drug regulatory

authorities—the China National Medical Products Administration (NMPA), formerly known as the China FDA—could approve the product for marketing. These actions were recognized in the sixth edition of the Index as positive and important steps in strengthening China's biopharmaceutical IP environment and, as a result, the score on this indicator was increased by 0.5. However, the commitment to introduce a linkage regime was not implemented in 2018 and 2019. As noted last year, in 2020 China again committed in the Phase One Agreement (Article 1.11) to adopt a form of patent linkage. To this effect, a new set of patent amendments were passed into law in October 2020. Article 76 of this updated Patent Law outlined the new mechanism, including potential channels for both judicial enforcement via the Chinese court system and administrative enforcement through the China National IP Administration (CNIPA). In 2021, this new regime came into effect with implementing regulations published by the NMPA, the CNIPA, and a relevant judicial interpretation from the Supreme Court. The "Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial)" and State Intellectual Property Office Announcements 435 and 436 outline the administrative process and available remedies.

As discussed in previous editions of the Index, the mechanism introduced in China is, strictly speaking, not a "linkage mechanism," whereby a drug regulatory authority conditions the approval of a follow-on biopharmaceutical product on there being no relevant period of market exclusivity in place for the underlying reference product. Instead, China's early-resolution system places the emphasis of monitoring and early resolution on rightsholders and follow-on applicants. Specifically, under Articles 6 and 7 of the "Measures for the Implementation of Early Resolution Mechanisms for Drug Patent Disputes (Trial)," follow-on applicants must offer one of four declarations on the exclusivity status of the underlying reference



product. Rightsholders then have a 45-day period to initiate legal action on the basis that the follow-on applicant's declaration is objectionable. Such legal action may be filed either through judiciary and civil proceedings or through a new administrative trial process managed by the CNIPA. Under Article 8, an automatic nine-month waiting period is triggered with NMPA upon the initiation of a legal action and subsequent submission of a notification of acceptance from either the relevant judicial authorities or the CNIPA. While the drug regulatory technical review process of the follow-on applicant will continue during this time, no marketing approval will take place. Although the 45-day notice period for rightsholders lodging an objection is rather short, in principle this early resolution mechanism bears some promise.

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

months. Finally, it is unclear whether the nine-month waiting period will be available for all types of biopharmaceuticals including biologics—as specified under Article 1.11 of the Phase One Agreement. The Index will continue to monitor these developments in 2022 and the extent to which rightsholders for all forms of biopharmaceuticals can effectively and practically seek redress prior to the marketing of a follow-on product in a process that is fair and transparent to all parties.

**7. Patent term restoration for pharmaceutical products:** As noted in last year's Index, in October 2020 new draft amendments to the Patent Law were passed. Article 42 of these amendments states that a period of term restoration of up to five years for biopharmaceutical products may be made available by relevant Chinese authorities. As of late 2021, no final implementing regulations or further details had been provided regarding the specific circumstances that would be recognized or qualifying criteria for restoration to be granted, including, for example, the types of delays that would be recognized as justifying such restoration. In May 2021, CNIPA published Announcement 423, "Interim Measures for the Processing of Relevant Examination Services Related to the Implementation of the Revised Patent Law." These Interim Measures and the accompanying FAQ provide some guidance on how the term restoration process will be made available to rightsholders. Specifically, this guidance does not appear to make the term restoration contingent on a first global launch taking place in China. Instead, the FAQ refers to "new" biopharmaceutical products as those newly approved for market in China. This is positive and should be confirmed in any final implementing rules or regulations. The Index will continue to monitor these developments in 2022.

## Copyrights, Related Rights, and Limitations; and Enforcement

**11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 15. Technological protection measures and digital rights management legislation; and 35. Preestablished damages and/or mechanisms for determining the amount of damages generated by infringement:** As noted in last year's edition of the Index, 2020 saw important new amendments to the Copyright Law finally passed. These included important changes and a strengthening of the legal framework, notably in relation to sound and broadcasting. A revised Article 3 provides new definitions of copyrightable material, including for "audiovisual works" and a broadly defined "other intellectual achievements that meet the characteristics of the work." Rights relating to performance, sound recording, and broadcasting have also been more clearly defined. Provisions relating to TPM and DRM have been strengthened through Articles 49, 51, and 53, which now provide a broader definition of infringement, including for manufacturing, importing, and offering circumvention devices to the public. Statutory damages for copyright infringement have also been increased substantially following similar changes to the Patent Law and Trademark Law. These amendments came into effect in June 2021 and are now in force. As mentioned at the time, these are positive changes that could, in aggregate, amount to a significant improvement of the copyright environment in China. However, rightsholders in content industries continue to face challenges with respect to enforcement. The USTR has repeatedly highlighted these challenges facing rightsholders and the need for more effective action. The Index will over the next few years monitor how these legislative changes are applied in practice and the extent to which they improve the ability of rightsholders to enforce their copyrights in China.

## Commercialization of IP Assets and Market Access

**26. Barriers to market access:** As noted in previous editions of the Index, rightsholders have over the years faced a growing number of regulatory and procedural barriers in China that impede technology flows, R&D cooperation, and digital trade. With respect to data localization requirements, these barriers intensified in 2021 with the passage of the Personal Information Protection Law (PIPL) and Data Security Law (DSL). The laws include limits and conditions on cross-border transfers of data and impose local storage requirements on both critical information infrastructure operators, important data handlers, and entities handling large volumes of personal information (PI) as defined by the Cyberspace Administration of China. Non-compliance with the new law may result in fines up to 5% of annual sales.

Additional restrictions and compliance requirements are imposed on what is termed "large internet platforms." The PIPL and DSL add to existing layers of restrictions and barriers to digital trade in China including those contained in the National Security Law, Cybersecurity Law, Cybersecurity Review Measures, and Biosecurity Law. For rightsholders across many different industries and sectors, these barriers to digital trade raise serious questions and concerns. The ICT and internet revolutions have fundamentally changed how human beings interact socially and economically. In virtually all industries, commercial and economic interaction is now shaped by the collection of data and digital technologies. The cross-border flow and storages of data is essential to countless services relied on by consumers, including innovative, automated, and virtual services. In order to support China's innovation ecosystem, China's national data management policies must recognize this reality and be formulated in a way that balances national security



needs with commercial concerns. The Index will continue to monitor these developments in 2022.

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

As noted in previous editions of the Index, rightsholders have over the years faced a growing number of regulatory, procedural barriers, and inflexible terms to licensing in China that impede technology flows and R&D cooperation. China has imposed restrictions on the rights of foreign IP rights holders to freely negotiate market-based contractual terms in licensing and other technology-related contracts concerning the transfer of technology to China. The Technology Import/Export Regulations (TIER) historically included discriminatory conditions for foreign licensors, including indemnification of Chinese licensees against third-party infringement and transfer of ownership of future improvements on a licensed technology to the licensee, which restrict the ability of foreign companies to negotiate licensing and technology contracts on market terms and to fully commercialize their technology in China. Under the Joint Venture regime, licenses and tech transfer contracts could not last more than ten years, after which the licensee retained the right to use the transferred technology, although this might still be under a term of exclusivity.

Adopted in 2018, the Working Measures for Outbound Transfer of Intellectual Property Rights tightened the scrutiny on outbound transfer of technology and IP. More broadly, in the context of standards setting, there has also been a trend toward greater administrative involvement in determining patent licensing terms and the ability to secure relief from infringement. The National Security Law, Cybersecurity Law, Security Assessments for Network Products and Services, and other relevant standards all contain product reviews that require IP disclosure. These restrictions and the active discrimination against foreign entities have been at the heart of trade and market

access related bi- and pluri-lateral discussions with China for several years. Both the United States and the EU have filed their own complaints with the WTO against China over its technology licensing practices and this has been a central point of contention and negotiation in the trade dispute between the United States and China.

As detailed in previous editions of the Index, in 2019 and 2020, there were significant positive changes to China's technology transfer and licensing environment. Most importantly, both the Foreign Investment Law and the Technology Import and Export Regulations and Regulations for the Implementation of the Law of the People's Republic of China on Chinese-Foreign Equity Joint Ventures were changed with many of the most onerous provisions described above now removed. Specifically, article 22 of the Foreign Investment Law states explicitly that the IP rights of foreign entities and investors should be protected and there should be no coercion or forced technology transfer. Similarly, the revised TIER regulations have removed and/or amended provisions to indemnification and ownership and usage of improvements made to a licensed technology. In 2021, a new Civil Code came into effect. Although this sprawling piece of legislation touches upon all aspects of civil law, it also includes specific provisions relating to technology transfer and contract law in a dedicated chapter, Chapter 20. Of note is that, in general, although providing a legal framework and reference point for technology transfer and licensing contracts, the articles of this chapter place an emphasis on contractual terms being market driven and at the discretion of the contracting parties. For example, on the issue of ownership and rights related to any improvement of an existing technology or IP right transferred or licensed, articles 875 make clear that such benefits shall be agreed between the parties "in accordance with the principle of mutual benefit". As noted at the time, these changes hold the promise of fundamentally remodeling the nature in which licenses can be

drafted and executed between foreign and Chinese entities. As a result, China's score increased on indicators 26, 27 and 29 in the 2020 Index.

However, licensors and rightsholders continue to face substantive challenges to doing business in China on fair, non-discriminatory, and equal terms. The last two years has 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. Specifically, Chinese courts have increasingly claimed global jurisdiction to set global licensing rates for technologies protected by Standard and Essential Patents (SEPs), threatened exorbitant fines, and withheld access to the Chinese market to prevent foreign patent holders from asserting their rights (in both China and global jurisdictions). The outcomes of these cases have also been cited and referred to as "model" IPR cases by government authorities. Such actions seemingly 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. SEP-based technologies are central to future innovation and economic growth – both in China and globally. Many of the cutting-edge industries that are loosely labeled as making up the "Fourth Industrial Revolution" – the Internet of Things, artificial intelligence, robotics, and 3-D printing – will rely on SEPs to function. Indeed, the emergence and broader use of these new technologies is likely to result in an even greater utilization of SEPs as well as a concomitant increase in the number of potential legal disputes that could hold up the development and use of these new technologies and industries. However, disputes between licensors and licensees on what constitutes fair, reasonable, and non-discriminatory (FRAND) licensing terms are not new, nor are they unique to China. This is an evolving field of IP policy and jurisprudence for a subject matter that is deeply complex. As such, it

is critical that policymakers – whether in China or elsewhere – tread carefully and refrain from being overly prescriptive and restrictive. Each licensing negotiation is unique and should not be subject to prescriptive government action or intervention, whether through direct or indirect pressure. Should rightsholders continue to face challenges in asserting their rights on fair, non-discriminatory and equal terms this will result in a score decrease on relevant Index indicators. The Index will continue to monitor these developments in 2022.

**Membership and Ratification of International Treaties**

**50. At least one post-TRIPS FTA (or other types of bilateral or multilateral agreements) with substantive IP provisions and chapters in line with international best practices:**

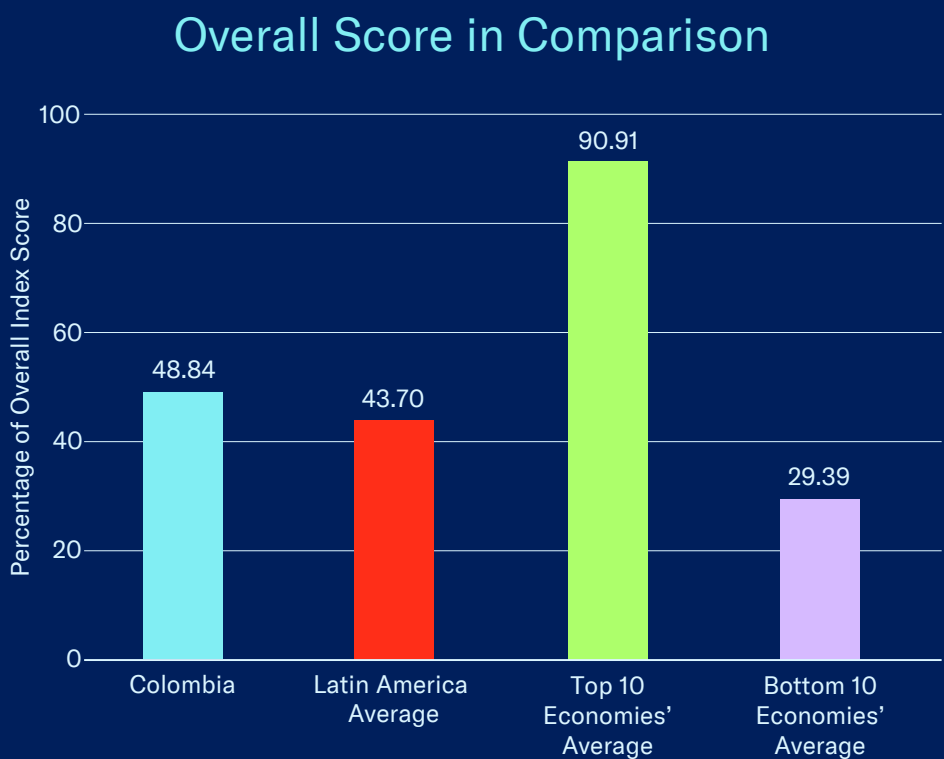
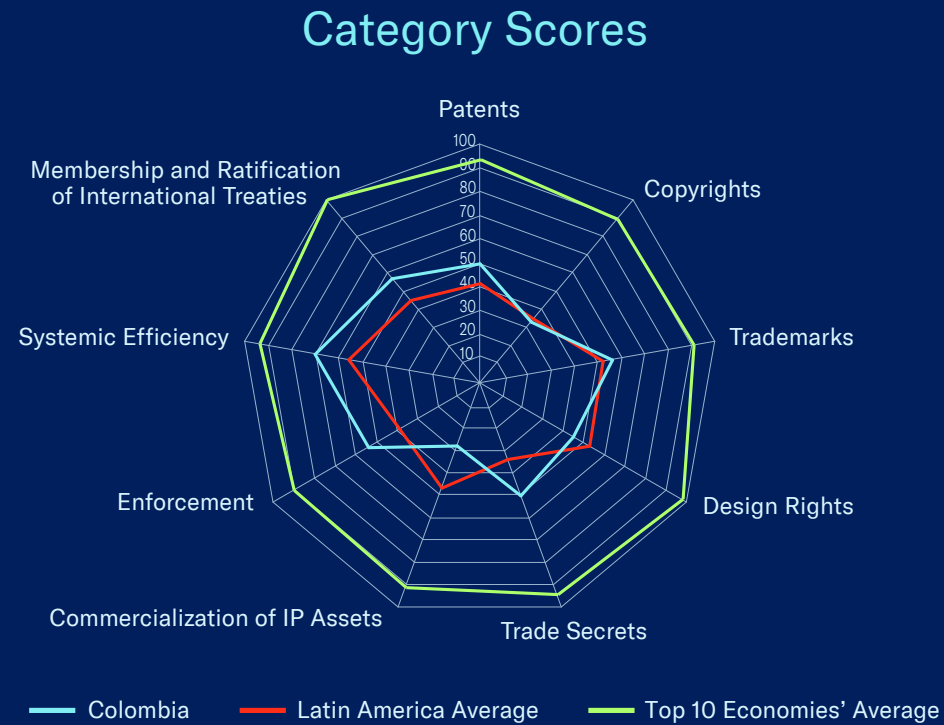
In January 2020, the U.S. and China signed the "Economic and Trade Agreement Between the Government of the United States and the Government of the People's Republic of China" (commonly known as the "Phase One Agreement"), a trade deal seeking to address imbalanced aspects across various sectors of the U.S.-China trading and economic relationship. The Phase One deal includes a dedicated chapter on IP (Chapter 1) and one on technology transfer and licensing (Chapter 2). The IP chapter covers most major IP rights, sector-specific rights, and enforcement, and addresses many of the challenges raised in the Index over the last nine editions. As noted in last year's Index, Article 1.35 states that within 30 days of the deal entering into force, China will "promulgate an Action Plan to strengthen intellectual property protection aimed at promoting its high-quality growth."

Following the signing of the Agreement, several IP reform initiatives were announced, including the "Opinions on Strengthening the Protection of Intellectual Property Promotion Plan" (the "Plan"), which was released in April 2020. The Plan included 133 action points and IP-related reforms,





ranging from substantive structural reforms, such as legislative amendments and the issuing of new judicial interpretation guidelines, to grassroots surveys of users of the national IP system. As noted in previous editions of the Index, many of these proposed changes have resulted in substantial statutory and regulatory changes, including a new Patent Law, Copyright Law, a new Civil Code, and new judicial interpretations issued by the Supreme People's Court on the application of civil and criminal law in IP proceedings. As detailed above, these reforms continued in 2021, with new implementing regulations and judicial opinions issued. While the Index will continue to monitor if these reforms will result in real practical changes to rightsholders' ability to register and effectively enforce their rights in a fair and transparent manner in China, for the purposes of this indicator and as a result of the above mentioned legislative and regulatory changes, the score has increased by 0.5.



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>4.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.50
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.25
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.34</b>
10. Copyright (and related rights) term of protection	0.84
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.90</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.50</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.50

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

**Total Score:  
24.42**

## Spotlight in the National IP Environment

### Past Editions versus Current Scores

Colombia's overall score increased from 48.17% (24.08 out of 50) in the ninth edition to 48.84% (24.42 out of 50) in the tenth edition. This reflects a score increase on indicators 12 and 32.

### Copyrights, Related Rights, and Limitations

**12. Expeditious injunctive-style relief and disabling of infringing content online:** As has been detailed in past editions of the Index, the copyright framework in Colombia remains rudimentary overall. 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 that is similar to the framework under the U.S. Digital Millennium Copyright Act. Despite Colombia's treaty obligations, no law introducing such a framework has been passed to date. Similarly, Colombian law does not provide for a defined and copyright-specific infringement injunctive-style relief mechanism as is being adopted in more and more economies across the world.

As a result, the piracy of audiovisual content represents a major challenge to rightsholders in Colombia. Local industry studies from 2015 estimated that around 50% of the time, cable TV services are accessed illegally or in an unauthorized manner, leading to economic losses of around USD 100 million per year. More recent estimates show that this situation has not improved. The Latin American industry association ALIANZA (*Alianza Contra la Piratería de Televisión Paga en América Latina*) in 2019 released the findings from a study of estimated rates of signal piracy and theft in Latin America.

The study found that the total pirated or unreported market in Colombia was between 26% and 45% of the total number of potential end-users.

There have been some positive changes over the last few years to counter this negative trend. Of note is a series of copyright amendments in 2017-18 through *Ley Lleras 6.0*. The law included updated language on copyright as well as online and rightsholders' exclusive rights. It also included new legal remedies against TPM and DRM violations. On the latter, these amendments introduced civil responsibility and interim relief to the copyright holder for violation of TPMs, as well as criminal sanctions with imprisonment from four to eight years. Up to the time of these amendments, TPM and DRM measures were mentioned only in the Criminal Code, and violations of the measures were punishable only by a fine. The legislative amendments also introduced the possibility of statutory damages for copyright infringement, including for the circumvention of TPMs, and strengthened provisions enabling courts to order the confiscation and destruction of infringing products, extending it also to circumvention devices.

These positive efforts have continued in 2021. In what could be an important new pathway for rightsholders to enforce their rights on the internet, the national copyright office *Dirección Nacional de Derecho de Autor* (DNDA) ordered the disabling of online access to copyright-infringing material. At the time of research, the DNDA had ordered the disabling of access in two separate cases: the first case concerned the unauthorized publication of a scientific journal article and the second case, the unauthorized broadcasting and dissemination of copyrighted audiovisual content through a local company, IPTV Colombia Premium. These cases are of real significance, particularly the action taken against IPTV Colombia Premium.

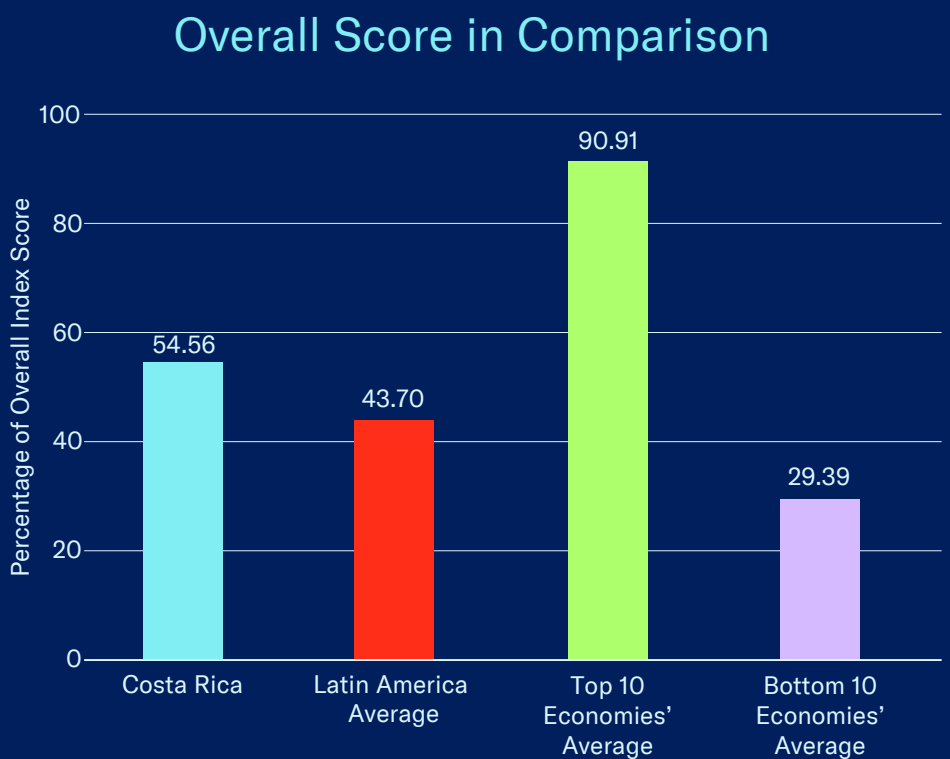
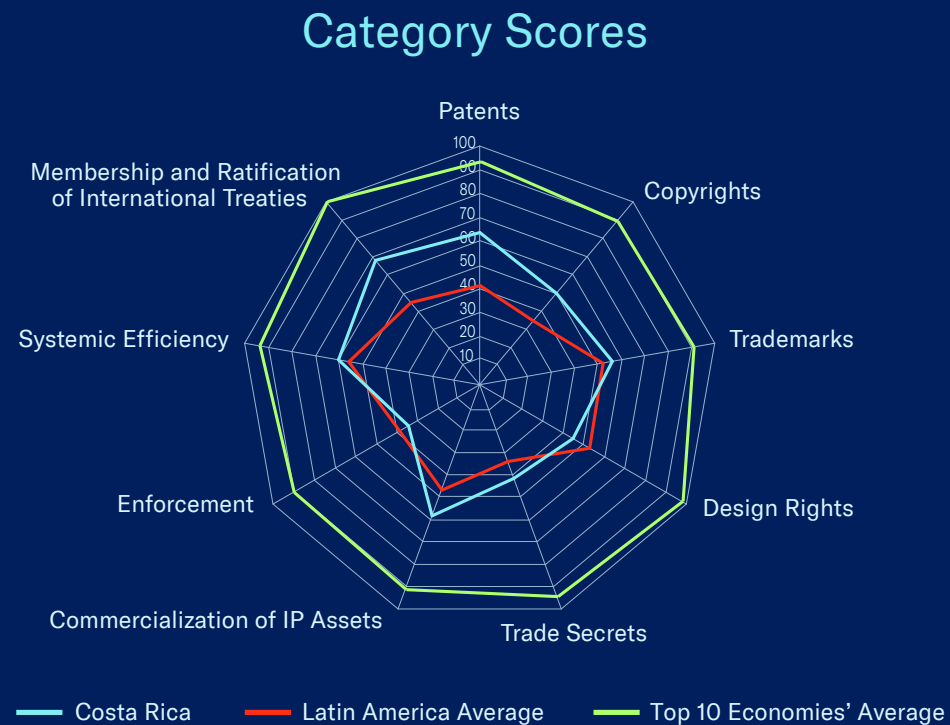


As a result of these positive enforcement actions, the score on this indicator has increased by 0.25.

### Trade Secrets and the Protection of Confidential Information

**25. Regulatory data protection (RDP) term:** As has been noted in previous editions of the Index, there has been a degree of uncertainty regarding the provision of RDP for submitted biopharmaceutical test data in Colombia. Decree 2085 of 2002 provides for a five-year period of RDP for both biopharmaceuticals and agrochemicals. Although less than international best practices and the benchmark 10-year period used in the Index, this is in line with Colombia's commitments under the U.S.-Colombia FTA. However, there have been reports that this protection is not fully available for all biopharmaceuticals. For example, Decree 1782, signed in September 2014, which modifies the registration process for biological medicines, does not discuss RDP for biologics. As a result, the legislation introduces ambiguity as to whether five years of protection will in fact be afforded to biologics under the new regime. Similarly, industry reports from 2020 and 2021 suggest that the Colombian drug regulatory agency INVIMA has changed its administrative standards and RDP is not being consistently granted to eligible products.

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. Undermining critical IP incentives such as RDP through various conditions and potential carve-outs is counterproductive. Over time, such action will simply hollow out the national IP environment and incentives for future biopharmaceutical innovation. Critically, the negative effect will be the same on Colombian as on foreign innovators. If rightsholders continue to face administrative barriers in accessing their statutory defined and granted term of RDP, the score on this indicator will be reduced to 0.



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>5.73</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.75
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.25
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.48
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>3.49</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	1.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.90</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.25</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>3.50</b>
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>2.41</b>
32. Physical counterfeiting rates	0.49
33. Software piracy rates	0.42
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>3.00</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>4.75</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
27.28**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Costa Rica's overall score has increased from 54.46% (27.23 out of 50) in the ninth edition to 54.56% (27.28 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Design Rights, Related Rights, and Limitations

**22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights:** Costa Rica's national IP office, the National Registry Office, has for many years been working toward modernizing and improving its capacities. The office is an active participant in the regional patent and trademark initiative PROSUR. It is also a regional leader in providing support services for academic researchers, research institutes, and SMEs, through its *Centro de Apoyo a la Tecnología y la Innovación* network of support centers. As has been noted in the Index, the number of centers and their activity levels have increased substantially over the last few years and, as of 2021, there were six such centers across the country. These positive efforts at harmonization and building technical support for rightsholders continued in 2021.

To begin, the office signed a Memorandum of Understanding with the USPTO. This memorandum seeks to deepen cooperation between the two IP offices, increase information sharing, and help build technical capacity within the registry—notably, the focus on educational programs and capacity-building within the registry on biotechnology patent claims and relevant patent registration applications. The registry has also expanded its support for the registration of design rights. Specifically, with support from EUIPO and within the broader work of the “IP KEY LA project,” the registry in 2021 published a *Practice Paper* for the registration of design rights. The *Paper* provides users with a comprehensive and detailed overview of graphic

representation and the standards and criteria the registry uses when evaluating design registration applications. This is an important development, as design rights are a growing field of registered IP rights around the world, including in Latin America.

Currently, design rights in Costa Rica are provided a term of protection of ten years, which is substantially below the 25-year benchmark period used in the Index. The Law on Invention Patents, Industrial Designs, and Utility Models defines exclusive rights for registered designs. These rights provide holders of an industrial design the right to prevent others from the manufacturing, sale, or importation of products embodying the design when carried out on a commercial scale. Standard IP rights enforcement measures are *de jure* available for design rights infringement, including seizure orders, injunctions, and the suspension of customs clearance of the allegedly infringing goods. While there are examples of rightsholders being able to seek redress for design rights infringement, overall, the enforcement environment in Costa Rica remains difficult. As noted by international observers (including the U.S. government) as well as domestic sources, the prevalence of counterfeit goods in Costa Rica remains high. In 2019, the Costa Rican Chamber of Commerce, through its *Observatorio de Comercio Ilegal*, published a report estimating the socio-economic impact of counterfeiting on the economy. The report found that the trade in counterfeit goods was an estimated CRC 700,000 million, or just under 7% of total household consumption. Of note is that design- and brand-related products, including clothing and footwear, were in the top items estimated as being most heavily counterfeited.

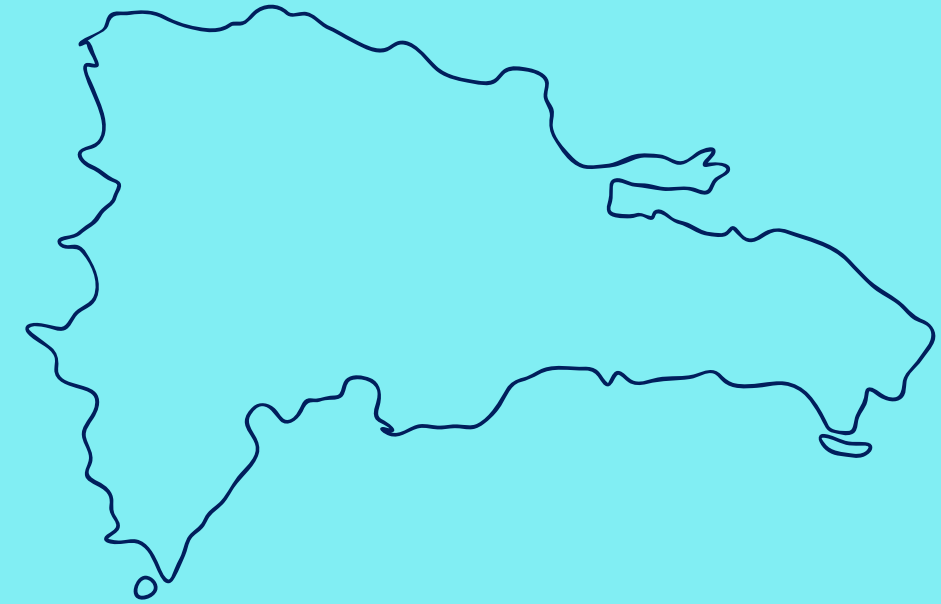
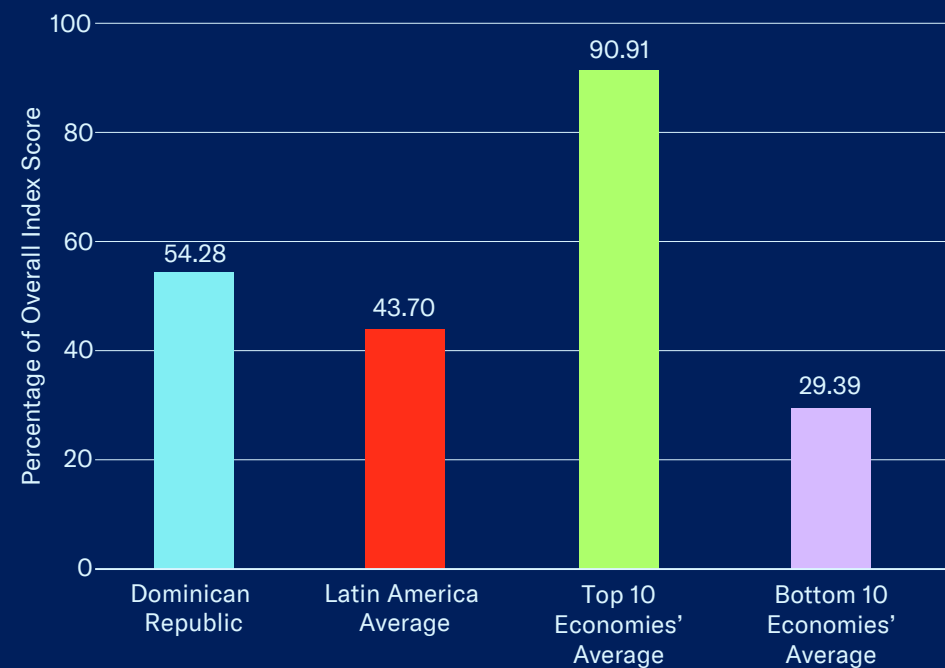
# Dominican Republic

Rank  
26/55

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

- Patentability standards outside international norms—no second use claims for biopharmaceuticals and virtually no patent protection for CIIIs
- RDP term not being granted although required by law
- Enforcement of copyright is highly challenging and is one of the main reasons the Dominican Republic has remained on the USTR's 301 Watch List for years
- Infringement of copyright through signal piracy, online, and web-based streaming is highly pervasive and constitutes a major source of illegal content—not effectively addressed by 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
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>5.70</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.70
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.50
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.74</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.25</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>4.00</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>3.35</b>
32. Physical counterfeiting rates	0.35
33. Software piracy rates	0.25
34. Civil and precedural remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.75
<b>Category 8: Systemic Efficiency</b>	<b>2.00</b>
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>4.75</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.25
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
27.14**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

The Dominican Republic's overall score has decreased from 54.32% (27.16 out of 50) in the ninth edition to 54.28% (27.14 out of 50) in the tenth edition. This reflects a score decrease on indicator 32.

### Area of Note

One of the flagship policy initiatives of the new government, led by President Abinader in 2021, is the "2030 Digital Agenda." Outlined in several presidential decrees and official announcements, the agenda is a set of ambitious programs and targets that seek to more fully incorporate digital technologies into Dominican society and the economy. The specific goals of the agenda are listed in Decree 527-21 and span everything from e-government reforms to new digitally focused policies on education, to the promotion of technology transfer and the development and creation of new technological goods and services. The Abinader administration should be congratulated for recognizing the massive socio-economic changes that the digital transformation is bringing to economies around the world.

The ICT and internet revolutions have fundamentally changed how human beings interact socially and economically. In virtually all industries and businesses, economic interaction is today being shaped by the collection of data and digital technologies. These technologies are allowing companies across all business sectors and public and private research organizations to collect and use greater levels of data and information than ever before in so-called "big data." Combined with increased computing capacity and the application of new technologies (such as artificial intelligence, machine learning, robotics, the Internet of Things, and 3-D printing) that allow us to analyze, better understand, and use

data collected, there is the possibility to make significant discoveries and breakthroughs in virtually any area of research and human socio-economic activity. Critically, IP-intensive industries and the protection of intellectual property are crucial drivers to this global transformation.

As the empirical evidence and economic data presented over the course of ten editions of the Index show, the successful development and use of digital technologies rely on the availability and effective use of IP rights. Simply put, the economies that are best placed to profit from the digital revolution and the technologies and industries of the future are those that have in place a strong and flexible national IP environment. While both Decree 527-21 and the agenda mention the strengthening of IP protection as part of the overall package of envisioned reforms, at the time of research there had been no further announcements on any proposed IP reform efforts in the Dominican Republic. As the Index has detailed, there are important gaps in the Dominican Republic's national IP environment, many of which relate directly to the creation and protection of digital technologies. For example, inventions relating to computer software are largely non-patentable because Article 2(1) of the Industrial Property Law excludes "computer software" from patentable subject matter.

Looking at patent statistics housed by WIPO for the Dominican Republic, a very small number of patent applications (patent publications by technology) were under the categories "Computer technology" and "IT methods for management." Between 1980 and 2017, a total of 14 patent applications were published under the categories "Computer technology" and "IT methods for management." This compares to a total number of 3,801 total applications during this time period, or 0.37% of the total number of applications published. Covering 50 indicators across nine separate





categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need to be able to fully develop and commercialize their ideas and products. As the Abinader administration pursues the “2030 Digital Agenda,” we would encourage them to utilize the findings of the Index and accompanying *Statistical Annex* as a guide to IP reforms in 2022 and beyond.

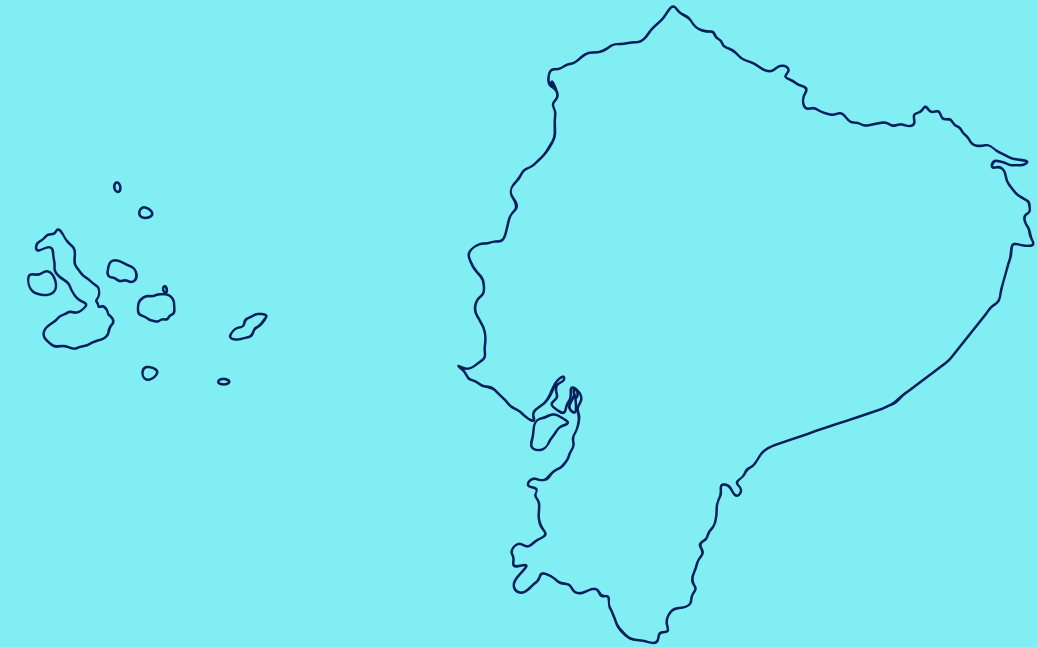
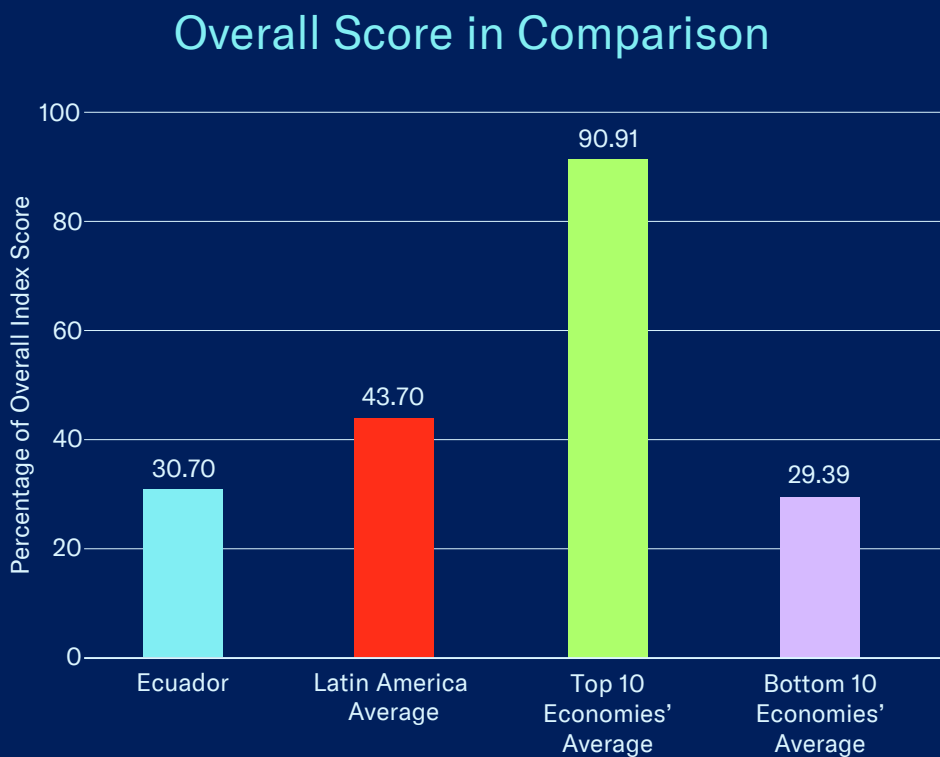
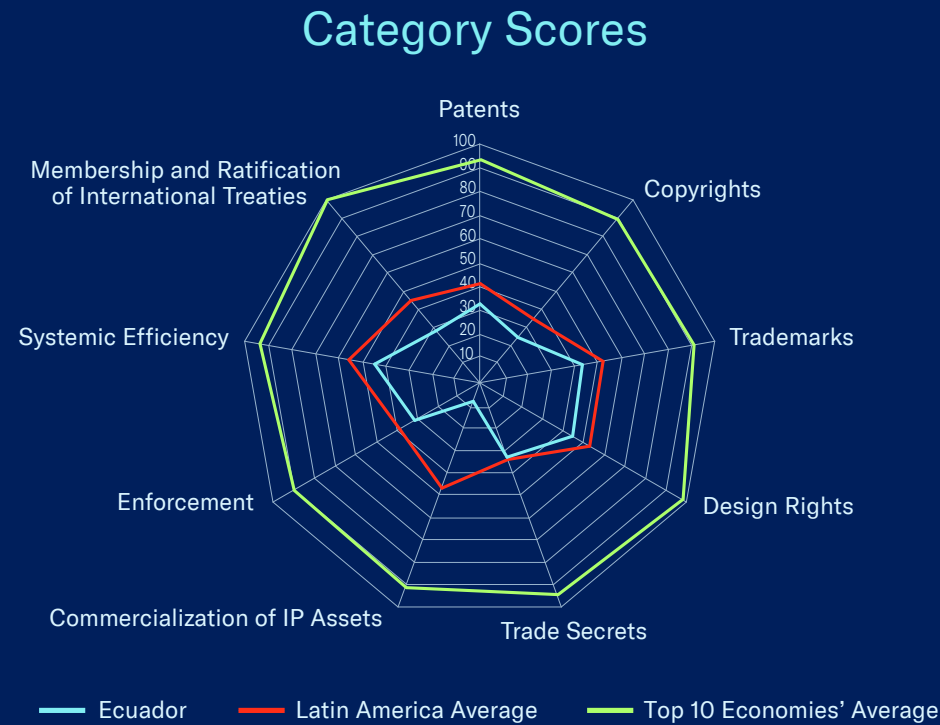
### Enforcement and Systemic Efficiency

#### **36. Criminal standards including minimum imprisonment and minimum fines; and 39.**

**Coordination of IP rights enforcement:** As has been noted in previous editions of the Index, rightsholders face significant challenges in enforcing their IP rights in the Dominican Republic. While many legal standards are in place, *de facto* protection and enforcement remain weak with rates of physical hard-goods piracy and counterfeiting high, particularly for alcohol and optical goods. Similarly, 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. Signal piracy has been brought up numerous times with the Dominican government by international rightsholders and the U.S. government. Authorities in the Dominican Republic have repeatedly made a commitment to better enforce copyright and address this issue but has thus far failed to do so. Such a commitment was, for example, made in a side letter between the U.S. and the Dominican Republic in 2004 during the conclusion of the Dominican Republic–Central America Free Trade Agreement. This has remained unchanged in 2021. The USTR, again, noted in the 2021 *Special 301 Report* the lack of action on this issue, stating that “the United States remains concerned with the Dominican Republic’s lack of political will to address long-standing IP issues, particularly against online and signal piracy.”

Part of the enforcement problem in the Dominican Republic has historically been a lack of coordination and cooperation between the relevant parts of the government involved in enforcement. No formal mechanism has been in place for inter-agency coordination of IP enforcement. There have been examples of joint public-private initiatives—including the “Campaign against Counterfeiting” (*Mesa Presidencial contra el Contrabando*), which brings together various agencies and departments from the government with representatives from the private sector—but this initiative is focused on educational activities and awareness raising, not the coordination of IP rights enforcement.

The last year saw what could amount to important improvements to the enforcement environment. To begin with, the Attorney General in 2021 reactivated a dedicated unit of prosecutors for IP infringement, the Intellectual Property Unit (UPI). To increase the criminal prosecution of copyright and trademark infringement, the UPI will provide dedicated resources and training to local prosecutors on IP rights infringement. In an August 2021 interview with the national newspaper *Diario Libre*, Assistant Attorney General and head of the UPI, Army Ferreira, emphasized the need for stronger enforcement efforts, especially against copyright infringement and signal piracy. Reports suggest that the UPI will also focus on promoting coordination of IP enforcement across the government and working more closely with other relevant agencies, including the National Copyright Office (ONDA). These are positive developments that, if implemented and carried out to full effect, will lead to an improved national IP environment in the Dominican Republic and score increases on relevant Index indicators. The Index will monitor these developments in 2022.



## Key Areas of Strength

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

## Key Areas of Weakness

- Use of compulsory license regime for biopharmaceuticals as basis for cost containment and industrial policy continued in 2021 with the issuing of a new license
- New implementing regulations potentially undermine *Código Ingenios* RDP term
- Plant variety protection term shorter than internationally accepted term
- Substantial barriers in place for licensing activities including direct government intervention and review of technology transfer and licensing agreements
- Key life sciences IP rights missing, including patent term restoration and mechanisms for early patent dispute resolution
- *Código Ingenios* imposes additional limits on patentability and amount of non-patentable subject matter
- Persistently high levels of piracy—estimated 68% software piracy rate
- Ecuador has a low score for its participation and ratification of international treaties



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>2.99</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.00
4. Plant variety protection, term of protection	0.74
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.74</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expedient injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.90</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.00</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>0.50</b>
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.25
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>2.22</b>
32. Physical counterfeiting rates	0.40
33. Software piracy rates	0.32
34. Civil and preceudural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.25
<b>Category 8: Systemic Efficiency</b>	<b>2.25</b>
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.25
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>2.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.50

**Total Score:  
15.35**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Ecuador's overall score increased from 30.60% (15.30 out of 50) in the ninth edition to 30.70% (15.35 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Patents, Related Rights, and Limitations

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

As has been noted over the course of the Index, successive Ecuadorian governments have issued compulsory licensing for biopharmaceutical products. Eleven licenses have been granted since 2010, with many more being considered. Most of these licenses were granted between 2010 and 2014 and largely justified on the basis of reducing the cost of medicines and as a policy to encourage domestic innovation. The cost containment grounds upon which these licenses have been issued stand in contrast to Ecuador's commitments under the WTO-TRIPS Agreement. Specifically, compulsory licensing and the over-riding of property rights is not a cost-containment tool; cost is not a relevant justification or basis for compulsory licensing or equivalent declarations under the TRIPS agreement.

TRIPS Article 31, the amendments introduced in the 2001 Doha Ministerial Declaration, and 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," intended

primarily for public health and humanitarian emergencies, and to be used only after all other options for negotiating pricing and supply have been exhausted. The Ecuadorian government's policy of using compulsory licenses as a non-emergency cost containment tool and the over-riding of duly granted IP rights continued in 2021.

Under a resolution issued by the national IP office SENADI (*Resolución No. LO-001-2021-DNPI-SENADI*), a compulsory license was issued on public interest grounds for the HIV/AIDS antiretroviral medicine Raltegravir (brand name Isentress). But it is not clear why this license was issued in the first place or what national public health crisis it was seeking to alleviate. As Article 22 of the resolution itself acknowledged, there was no shortage of Isentress in Ecuador or uncertainty as to current or future supply from the originator. In fact, Ecuador's national health service provider SERCOP (*El Servicio Nacional de Contratación Pública*) had pre-existing procurement contracts in place for the purchase of Isentress from the originator for 2021. Similarly, the cost savings from the granting of the license seem to be, at best, negligible. Article 20 of the resolution states that the per unit price of the originator's product is roughly the same as that proposed by the generic manufacturer at USD 3.48 versus USD 3.45. At the time of research and following an appeal, SENADI had revoked the original license. Although a positive development, the issuing of the license in the first place adds an additional layer of uncertainty to an already difficult business environment for biopharmaceutical rightsholders.

Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratory, research facilities, and researchers are high. Compared to many other high-tech industries—for example, computer software—developing the next ground-breaking treatment for cancer or Alzheimer's disease



requires more than just a laptop and a great idea. As medicines become more targeted and technically sophisticated, the cost of development rises dramatically. In 1979, the total cost of developing and approving a new drug stood at USD 138 million. Almost 25 years later, in 2003, this figure was estimated at USD 802 million. A 2012 estimate puts the total cost of drug development at approximately USD 1.5 billion. And 2016 research from Tufts University suggests that it costs USD 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 research and development of new medical technologies and products. In particular, patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection, enable research-based companies to invest vast sums in R&D and the discovery of new drugs, products, and therapies. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market entrants who bore none of the costs of early-stage investment, research and development, and product commercialization. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws. The *de facto* elimination of these incentives through the use of sweeping compulsory licenses—such as that issued for Raltegravir—is highly damaging and, ultimately, counterproductive. Over time, such action will simply hollow out Ecuador’s national IP environment and any incentives that research-based manufacturers have for future biopharmaceutical R&D.

Critically, the negative effect will be the same for Ecuadorian as for foreign innovators. If rightsholders cannot rely on Ecuador’s legal system to provide basic patent protection for their products and the underlying billions of dollars invested in the science and R&D necessary to develop them, then why should they invest in and develop these new products and technologies in the first place? The Index will continue to monitor Ecuador’s biopharmaceutical IP environment in 2022.

### Trade Secrets and the Protection of Confidential Information

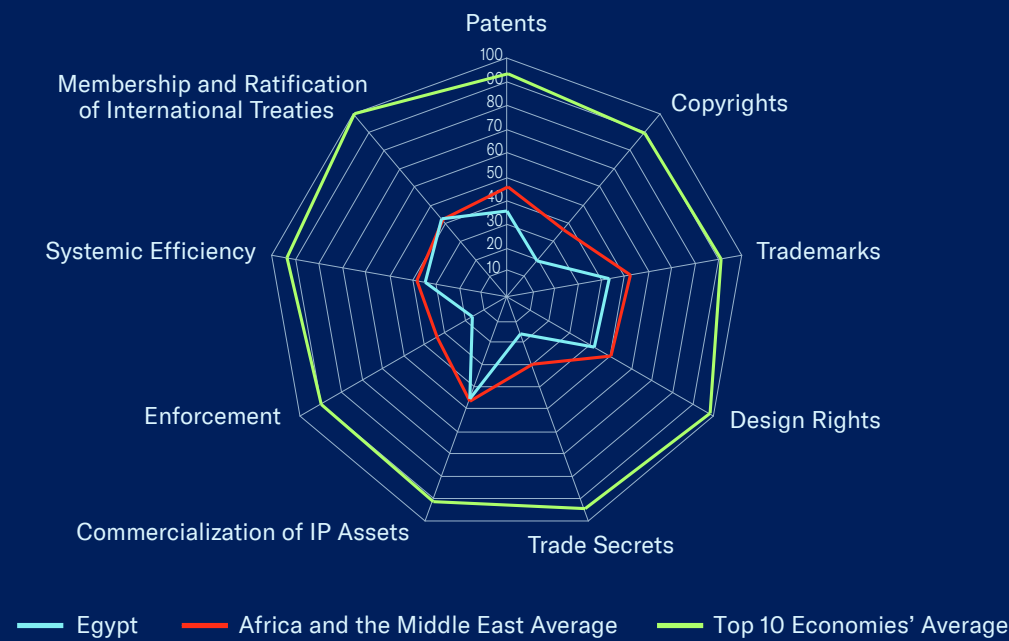
**25. Regulatory data protection (RDP) term:** As noted in the sixth edition of the Index, in a positive move, the 2016 innovation and IP law *Código Orgánico de Economía Social del Conocimiento, la Creatividad y la Innovación (Código Ingenios)* introduced a defined term of protection for submitted biopharmaceutical test data during the market authorization approval process. Until this time, Ecuador did not provide an effective term of regulatory data protection. Although Article 191 of the old Intellectual Property Law provided a basis for the protection of submitted biopharmaceutical test data, no term of protection was specified in this legislation. Now, Article 509 of the *Código Ingenios* clearly defines a five-year term of regulatory data protection. As a result, Ecuador’s score on this indicator increased in 2017.

In December 2020, Implementing Regulations for the *Código Ingenios* were released by the Ministry of Higher Education, Science, Technology and Innovation SENESCYT (*Secretaría de Educación Superior, Ciencia, Tecnología e Innovación*). These regulations provide further detail on how the RDP term of protection will be administered in Ecuador, including relevant terms and conditions. Unfortunately, Articles 364-374 of the regulations appear to provide considerable carve-outs and potential exceptions

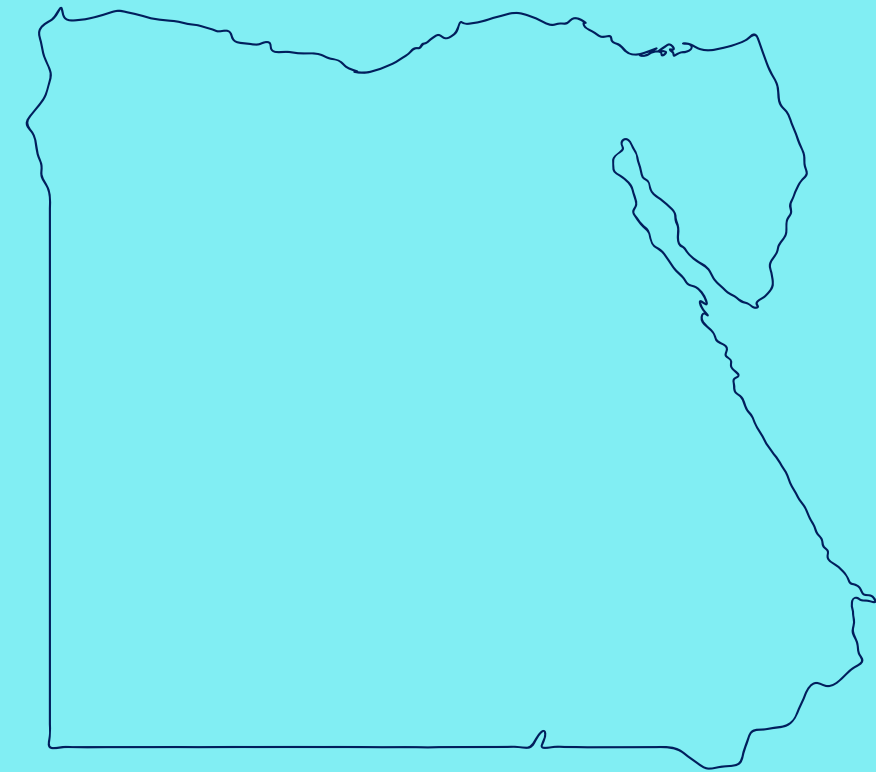
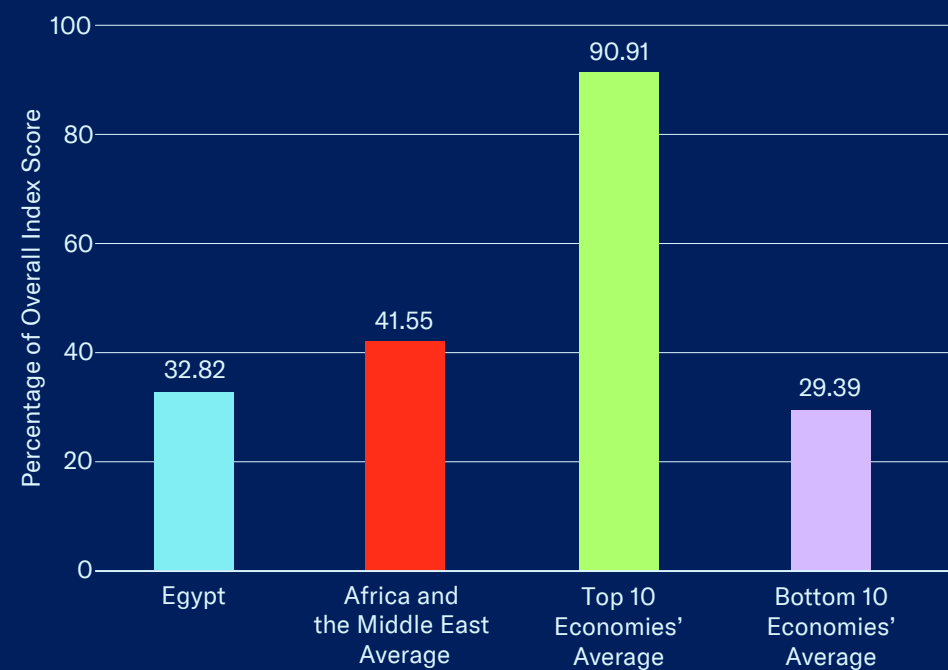
to the protection of undisclosed information. This includes a broad basis for authorizing access to undisclosed information to third parties on the basis of “public interest, national emergency situations or extreme urgency.” The regulations do not provide a definition of what such conditions would look like. As discussed above in relation to the recent granting of a compulsory license for the biopharmaceutical Raltegravir, Ecuadorian government authorities have a clear history of taking an expansive and interventionist view of the definition of “public interest.”

As the Index stated at the time of passing the *Código Ingenios* package in 2016, the government of Ecuador should be congratulated for adopting and clearly providing a defined term of regulatory data protection. This is a clear signal that policymakers in Ecuador understand the nature of biopharmaceutical R&D and the necessary incentives needed to develop new life-saving products and technologies, and that they wish to abide by international trade commitments made in the TRIPS Agreement and EU-Andean Community FTA. However, as with the expansive and non-emergency use of compulsory licensing, undermining regulatory data protection through various conditions and potential carve-outs is counterproductive and will simply reduce incentives for biopharmaceutical innovation and access to new medical products and technologies in Ecuador. The Index will continue to monitor these developments in 2022 and the extent to which rightsholders are effectively and practically able to obtain RDP. A failure to provide an effective term of protection in line with existing statutory law will result in a score decrease on this indicator.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of computer-implemented inventions (CIIs)	0.50
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.38</b>
10. Copyright (and related rights) term of protection	0.38
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.85</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>2.75</b>
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>1.18</b>
32. Physical counterfeiting rates	0.27
33. Software piracy rates	0.41
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.00
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>1.75</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.25
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>3.00</b>
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
16.41**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Egypt's overall score increased from 32.59% (16.30 out of 50) in the ninth edition to 32.82% (16.41 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

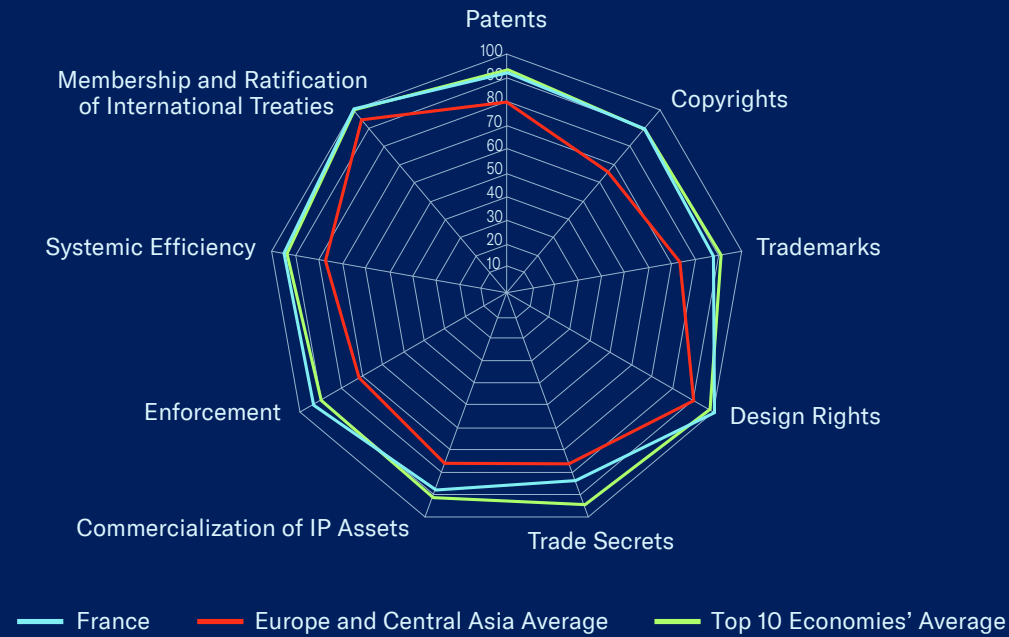
### Commercialization of IP Assets and Market Access

**26. Barriers to market access:** As noted in last year's edition of the Index, in August 2020 the Egyptian president signed into law the "Law on the Protection of Personal Data (Resolution No. 151 of 2020)." The law provides an entirely new legal framework and set of rules and requirements for the protection of personal data in Egypt and of data emanating from Egypt. At the time of promulgation, it was not clear what, if any, barriers to the cross-border transfer of data would be imposed by the law and its new administrative body, the Data Protection Authority. For example, Articles 14 and 15 of the law disallow the transfer of any data from Egypt to another legal jurisdiction unless, one, the level of data protection is at least equivalent in the host jurisdiction as under the Egyptian law, and, two, the transfer has been approved by a new Egyptian regulatory authority, the Data Protection Authority.

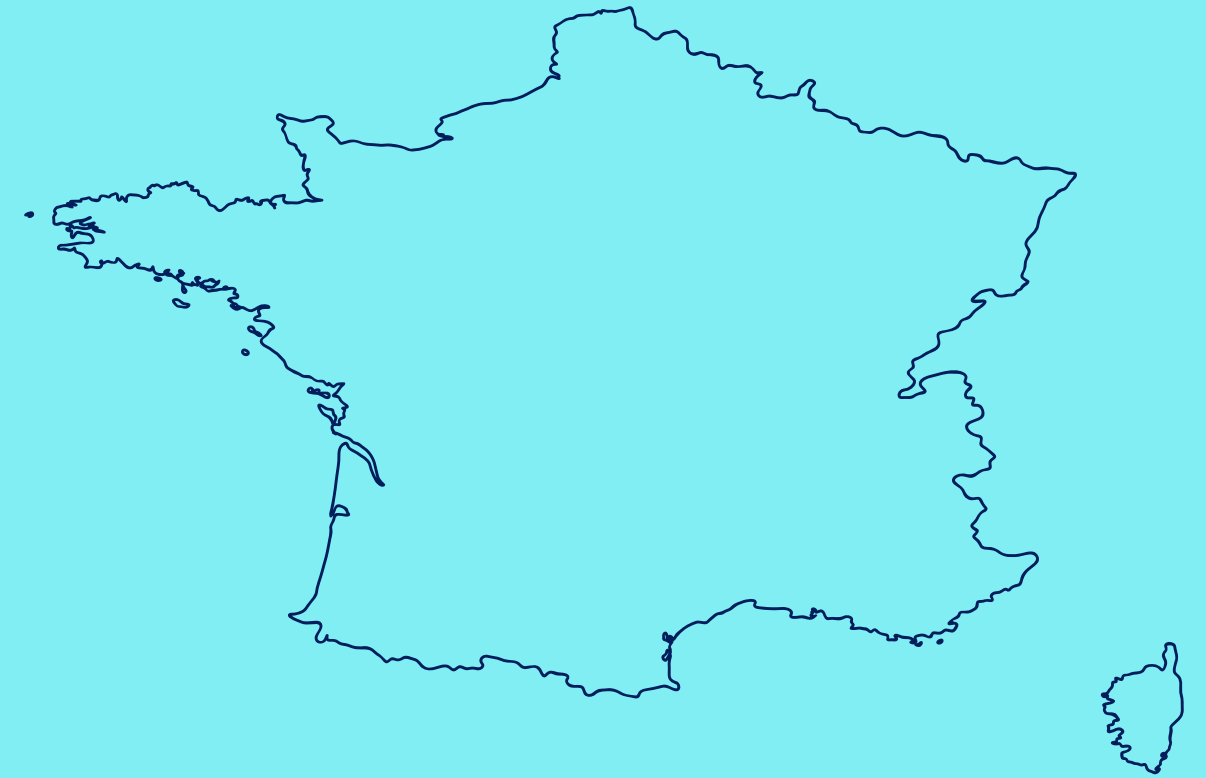
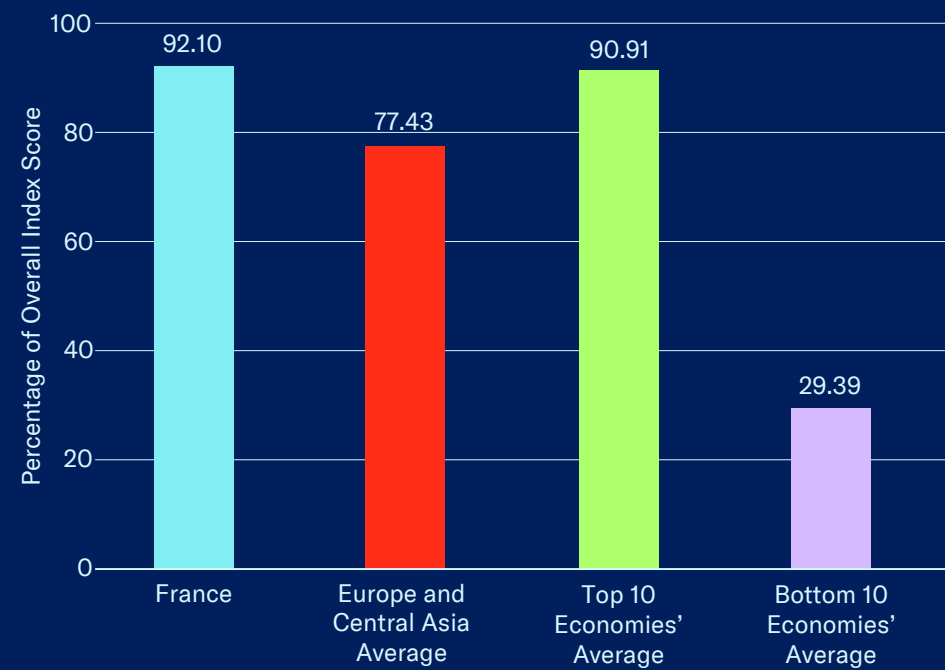
Cross-border flows of data are ingrained in countless services relied on by consumers, with numerous digital, automated, and virtual services relying on the seamless movement and storage of data in various locations. Impeding such free flows of data will inhibit digital trade and is likely to lead to fewer digital services being available in Egypt. At the time of research, no implementing regulations had been published for the law and it remained unclear how cross-border data flows would be managed. In a positive note, the 2021 Investment Climate Statement, published by the U.S. State Department, stated that the law "will not impose

any data localization requirements." This would be a positive development and benefit both Egyptian and international rightsholders. The Index will continue to monitor these developments in 2022.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>6.24</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.75
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	1.00
14. Scope of limitations and exceptions to copyrights and related rights	1.00
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	1.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.75
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	1.00
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	1.00
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>2.00</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1.00
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.50</b>
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	1.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>5.25</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
<b>Category 7: Enforcement</b>	<b>6.56</b>
32. Physical counterfeiting rates	0.88
33. Software piracy rates	0.68
34. Civil and preceudural remedies	1.00
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	1.00
36. Criminal standards including minimum imprisonment and minimum fines	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	1.00
<b>Category 8: Systemic Efficiency</b>	<b>4.75</b>
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>7.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
46.05**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

France's overall score has increased from 91.43% (45.71 out of 50) in the ninth edition to 92.10% (46.05 out of 50) in the tenth edition. This reflects a score increase on indicators 13 and 32.

### Copyrights, Related Rights, and Limitations

**13. Availability of frameworks that promote cooperative action against online piracy:** As has been detailed in previous editions of the Index, like all other EU Member States, France has for the past two years transposed and implemented EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive). Part of the directive was passed into Law 775, which amended the IP Code in 2019. This law established a neighboring right for press agencies and press publishers. This was followed up in 2021 with Ordinance 2021-580. This ordinance transposes additional articles of the CDSM Directive, including Article 17 of the directive. While maintaining existing exceptions and limitations provided under French and European copyright law and jurisprudence, Ordinance 2021-580 strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. It also provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability. As a result of this transposition, the score on this indicator has increased by 0.25.

### Systemic Efficiency

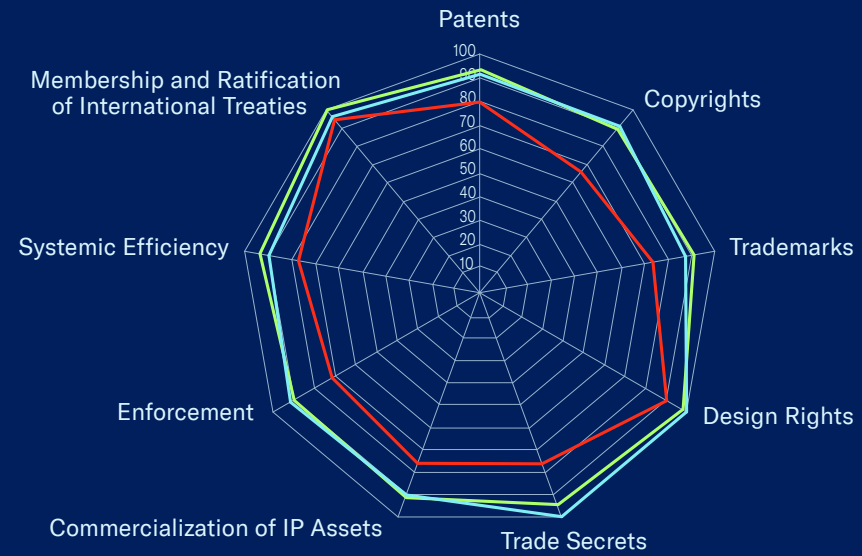
**43. IP-intensive industries national economic impact analysis:** As a Member State of the European Union and contracting party to the European Patent Convention, the French government also takes part in the multitude of research efforts conducted by European institutions. A whole swathe of EU institutions study

the economic impact of IP-intensive industries in Europe. Major institutions that publish studies and research on various aspects of the economics of IP-intensive industries include the European Patent Office (EPO), EUIPO, EUROSTAT, and the European Commission. The latest such study is the 2019 *IPR-Intensive Industries and Economic Performance in the European Union* published by the EUIPO and EPO. This study found that IP-intensive industries contributed an estimated 42.9% of French GDP, on average, in the time period 2014-16. Similarly, with respect to employment, an estimated 24.5% of the French labor force worked in IP-intensive industries.

Relevant institutions in France, such as the National Institute of Industrial Property (INPI), have a similar interest and research programs in place. For example, INPI has supported the research and publication of a study on the digital economy, innovation, economic activity, and IP rights (*La propriété intellectuelle & la transformation numérique de l'économie*) in 2015. WIPO has also supported the research and publication of a 2016 study of the economic impact of the copyright sector in France, *The Economic Contribution of Copyright Industries in France*. This important work continued in 2021 with the release of *Intellectual Property Rights and Firm Performance in the European Union*. Co-produced by the EPO and EUIPO, this report examines the relationship between IP rights and rates of economic activity at the firm level. Overall, the report finds that European businesses that own at least one registered form of IP right (patents, designs, or trademarks) have, on average, 20% higher revenues per employee than businesses with no registered IP portfolio. Similarly, the report found that firms with registered IP rights also pay higher wages; 19% higher, on average. The EPO and EUIPO should be congratulated for the production of this report and for their leadership on providing detailed statistical data and economic analysis of the socio-economic benefits of IP rights.

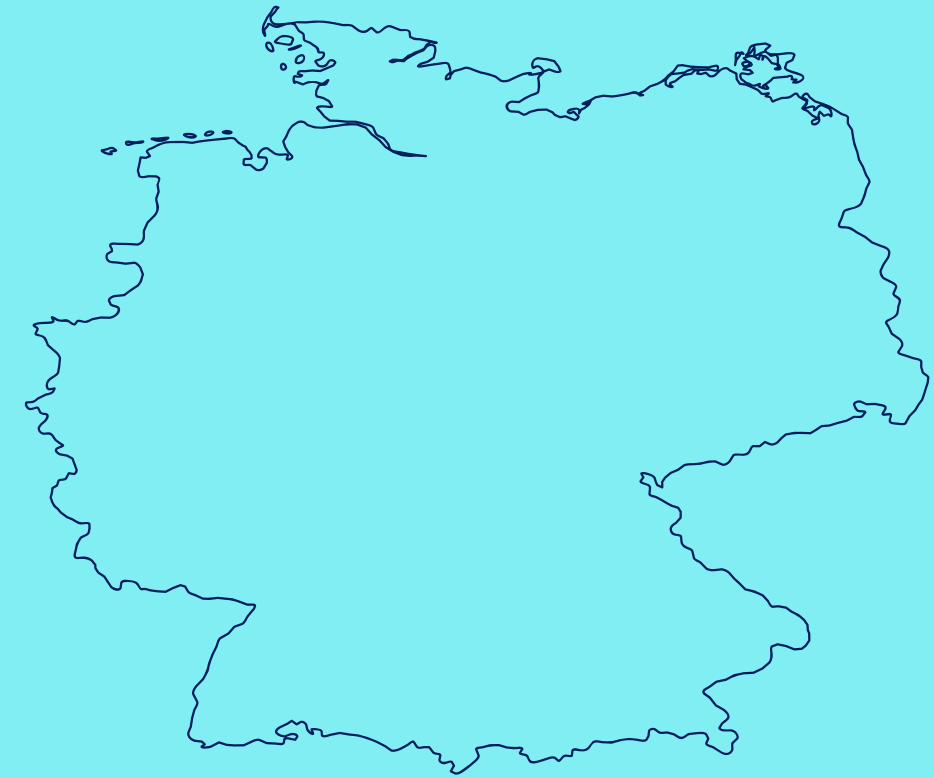
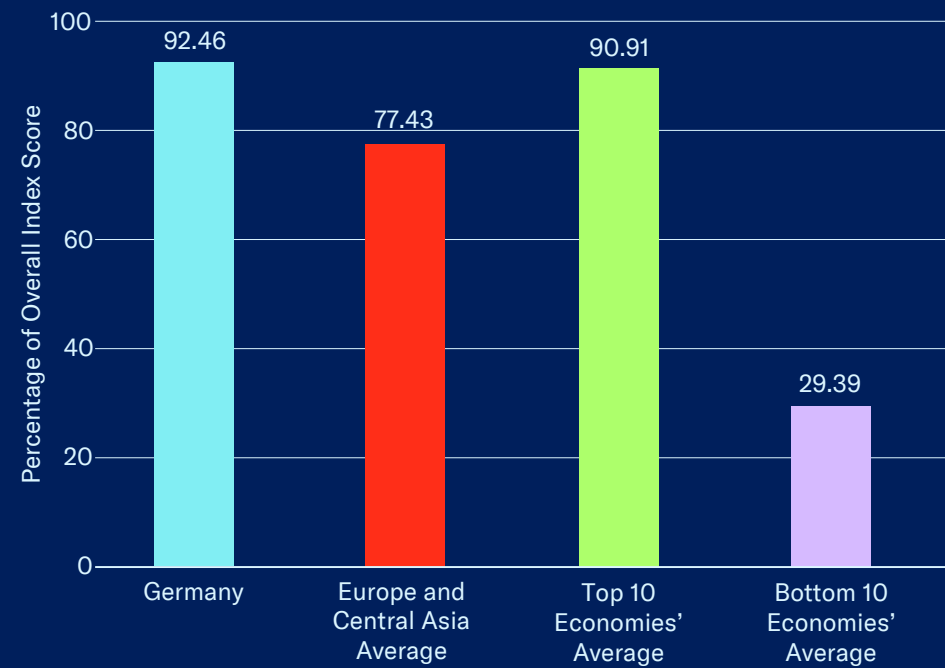


## Category Scores



Germany Europe and Central Asia Average Top 10 Economies' Average

## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>6.38</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	1.00
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	1.00
14. Scope of limitations and exceptions to copyrights and related rights	0.75
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	1.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	1.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	1.00
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	1.00
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>2.00</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1.00
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>3.00</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

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

**Total Score:  
46.23**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Germany's overall score has increased from 92.27% (46.13 out of 50) in the ninth edition to 92.46% (46.23 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Copyrights, Related Rights, and Limitations

**11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 13. Availability of frameworks that promote cooperative action against online piracy:** As has been detailed in previous editions of the Index, like all other EU Member States, Germany has for the past two years been in the process of transposing and implementing EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive). In June 2020, the Federal Ministry of Justice and Consumer Protection published a self-described draft discussion of a draft law transposing the CDSM (*Diskussionsentwurf des Bundesministeriums der Justiz und für Verbraucherschutz Entwurf eines Zweiten Gesetzes zur Anpassung des Urheberrechts an die Erfordernisse des digitalen Binnenmarktes*). This was followed up in May 2021 with the passing of a series of amendments and transposition of not only the CDSM but also Directive 2019/789, which complements the “Satellite and Cable Directive” from 1983. For purposes of transposing Article 17 of the CDSM and defining the responsibilities for online content-sharing platforms, the result is a new law, the “Law to adapt copyright law to the requirements of the digital single market” (*Gesetz zur Anpassung des Urheberrechts an die Erfordernisse des digitalen Binnenmarktes*). This law broadly follows the scope of the underlying directive, particularly regarding responsibilities and requirements under Article 17. While maintaining existing exceptions and

limitations provided under German and European copyright law and jurisprudence, the new law strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. It also provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability.

One further positive change in the law is a clarification on the extent to which text and data mining are allowed for research purposes. This is an important area of future economic activity, as advances in computational power and new technological advancements in artificial intelligence (AI) and machine learning allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. The German law adds a somewhat convoluted exception explicitly for short excerpts of content if they are for non-commercial purposes.

In what is now a moot matter given these changes to the German Copyright Act and EU law, 2021 did see a final verdict rendered by the European Court of Justice in the long-running court case between music producer Frank Peterson and YouTube. As has been detailed in preceding editions of the Index, the dispute began almost 15 years ago with Peterson (a music producer and rightsholder) alleging that 36 music clips he had produced and owned the rights to had been uploaded and viewed on YouTube. The gist of the dispute is the extent to which YouTube, and by extension other internet intermediaries, could be held liable for the posting of infringing content on its platform. Peterson argued that YouTube did have this responsibility and was liable for damages as it indirectly profited from the uploads through viewership, consequently depriving content creators and rightsholders, such as Peterson, from licensing income. The case initially ran through the lower German courts with two judgements



issued in 2010 and 2015 by the Hamburg District Court and Court of Appeal. In September 2018, the highest relevant court of law in Germany, the Federal Court of Justice (*Bundesgerichtshof*), was expected to issue a definitive ruling. Instead, the court asked the European Court of Justice to examine the issue pertaining to EU law, specifically the meaning of Directive 2001/29/EC On the Harmonization of Certain Aspects of Copyright and Related Rights in the Information Society, Directive 2000/31/EC On Electronic Commerce, and Directive 2004/48/EC On the Enforcement of Intellectual Property Rights. In July 2020, the CJEU's Advocate General, Henrik Saugmandsgaard Øe, issued a non-binding opinion on this case and the case *Elsevier Inc. v Cyando AG*. (The latter case touches on a similar set of legal principles, that is, the responsibilities and potential legal liabilities online service providers have for the content that is uploaded through and onto their platforms.)

In a long discussion on the particulars of the cases and pre-CDSM EU and German law, the opinion concluded that platforms could not be held directly liable for any potentially infringing content uploaded through their services. Regarding secondary liability, or any equivalent level of responsibility on part of the service providers, the Advocate General argued that this can only be maintained if the service provider has been served with “specific illegal information.” The opinion also raised concerns over service providers becoming *de facto* judges over the legality of uploaded content and “over-removing” content. In June 2021, the full CJEU gave its final judgment.

The verdict largely echoes the Advocate General's arguments. Overall, it finds that “the operator of a video-sharing platform or a file-hosting and sharing platform, on which users can illegally make protected content available to the public, **does not** make a ‘communication to the public’ of that content...unless it contributes, beyond merely making that platform available, to giving access to

such content to the public in breach of copyright” [Emphasis added]. As noted in last year's edition of the Index, it is remarkable that the rightsholders in question have been waiting for such a length of time to achieve redress for the alleged infringement: over a decade in the Peterson case and eight years in *Elsevier Inc. v Cyando AG*. While the CDSM and relevant changes to German copyright law should more effectively address this gap in legal protection than preceding statute under which the CJEU's judgment is based on, it is not acceptable that European rightsholders should have to wait so long to achieve a final verdict. The scale and speed of modern-day internet-based copyright infringement is such that new infringements take place by the hour. It is imperative that rightsholders can quickly and effectively achieve redress in cases in which their copyright is potentially being infringed. The Index will continue to monitor rightsholders' ability to practically enforce their copyrights in Germany in 2022.

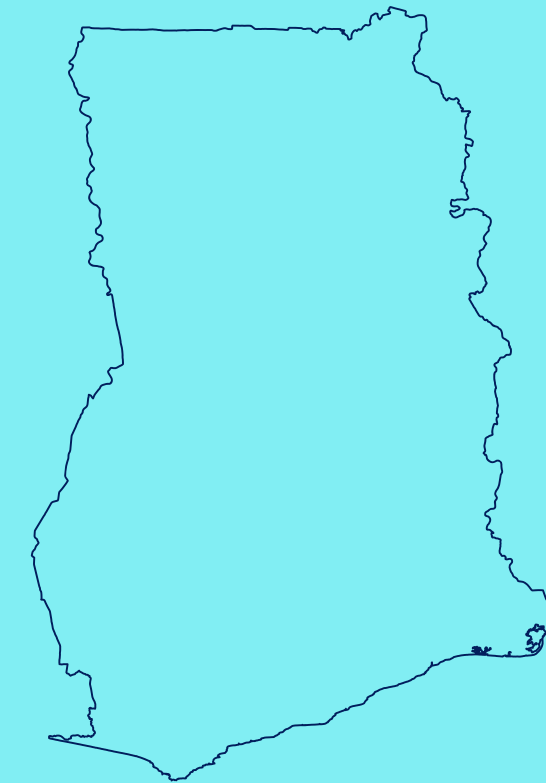
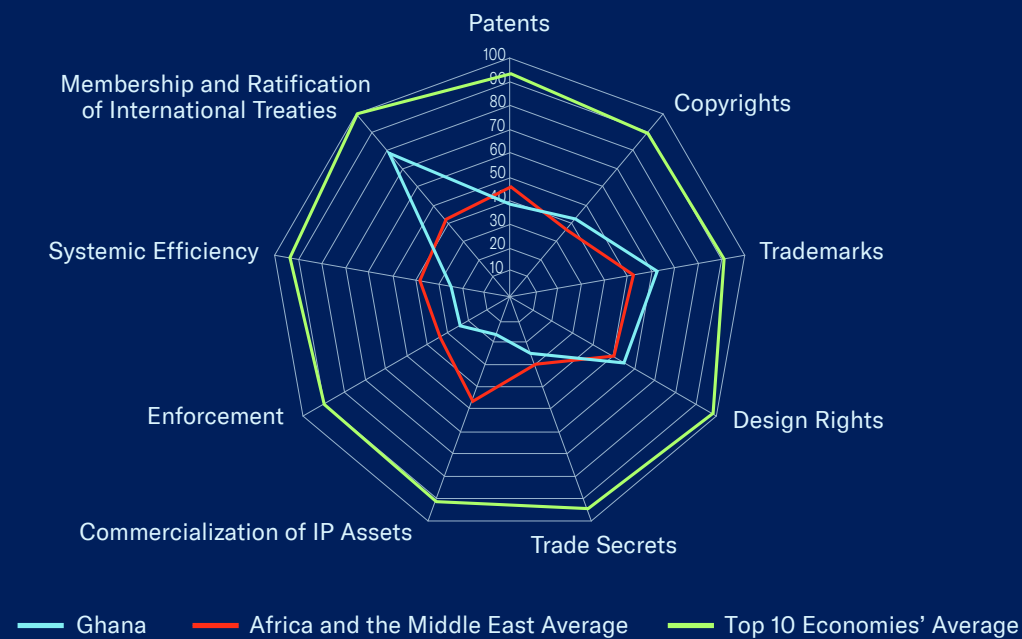
### Systemic Efficiency

**43. IP-intensive industries, national economic impact analysis:** As has been noted in previous editions of the Index, various German government departments and agencies are engaged in understanding and measuring the impact IP rights have on economic activity. For example, the Federal Ministry for Economic Affairs and Energy (*Bundesministeriums für Wirtschaft und Energie*) has a long-standing and strong research interest in understanding the drivers of the German economy. The ministry has sponsored several general and sector-specific studies measuring and examining the relationship between IP rights and economic impact. As a Member State of the European Union and contracting party to the European Patent Convention, the German government also takes part in the multitude of research efforts conducted by European institutions. A whole swathe of European institutions study the economic impact of IP-intensive industries in the EU and Europe. Major

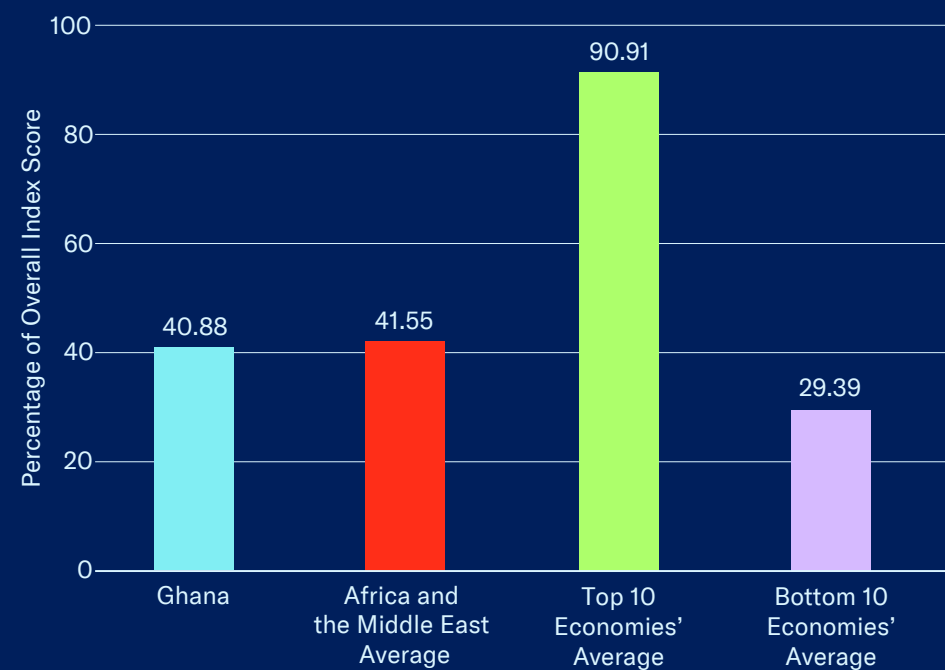
institutions that publish studies and research on various aspects of the economics of IP-intensive industries include the EPO, EUIPO, EUROSTAT, and the European Commission. The latest such study is the 2019 *IPR-Intensive Industries and Economic Performance in the European Union* published by the EUIPO and EPO. This study found that IP-intensive industries contributed an estimated 49.9% of German GDP, on average, in the time period 2014-16. Similarly, with respect to employment, an estimated 33.3% of the German labor force worked in IP-intensive industries.

This important work continued in 2021 with the release of *Intellectual Property Rights and Firm Performance in the European Union*. Co-produced by the EPO and EUIPO, this report examines the relationship between IP rights and rates of economic activity at the firm level. Overall, the report finds that European businesses that own at least one registered form of IP right (patents, designs, or trademarks) have, on average, 20% higher revenues per employee than businesses with no registered IP portfolio. Similarly, the report found that firms with registered IP rights also pay higher wages— 19% higher, on average. The EPO and EUIPO should be congratulated for the production of this report and for their leadership on providing detailed statistical data and economic analysis of the socio-economic benefits of IP rights.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- Contracting party to most international IP treaties included in the Index; joined UPOV 1991 in 2021
- Member of African Regional Intellectual Property Organization (ARIPO)
- ARIPO patentability guidelines allow high-tech claims (both Swiss-style biopharmaceutical claims and 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

- 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
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.75
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.99</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.75</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>1.00</b>
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.00
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>1.44</b>
32. Physical counterfeiting rates	0.44
33. Software piracy rates	NA
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>1.25</b>
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>5.50</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
20.03**

## Spotlight on the National IP Environment

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

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

Ghana's Patent Act provides fairly standard criteria for, and exclusions from, patentability. The Patent Act Section 3(1) provides a broad and internationally acceptable standard of patentable subject matter: "an invention is patentable if it is new, involves an inventive step and is industrially applicable." Sections 1, 2, and 3 define the types of inventions that are excluded. Neither high-tech inventions in the field of second use claims for biopharmaceuticals nor CIIs are explicitly excluded under the act. Ghana is also a member of the African Regional Intellectual Property Organization (ARIPO) and a contracting party to the Harare Protocol on Patents and Industrial Designs. The protocol, subsequent amendments, and patentability guidelines issued by the ARIPO ("Guidelines for Examination at the ARIPO Office") explicitly allow "Swiss-style" claims for biopharmaceuticals. With respect to CIIs there is less clarity. On the one hand, Section 3, Paragraph 10(h) of the Harare Protocol explicitly excludes "programs for computers." Conversely, ARIPO's examination guidelines clearly state that CIIs may be granted if there is a clear technical effect and a contribution to the prior art.

Patent statistics housed by WIPO for ARIPO (data is not available for Ghana specifically) suggest that only a small number of patent applications (patent publications by technology) are under the categories "Computer technology" and "IT methods for management." Between 1980 and 2017, a total of 320 patent applications were published under the categories "Computer technology" and "IT methods for management." This compares to a total number of 10,421 total applications during this time period, or 3.07% of the total

number of applications published. Statistics for the number of patents actually granted are not available by technology for ARIPO. But in most jurisdictions, not all patents published are granted.

#### 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:

The last two 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 a further positive development, in late 2021 Ghana acceded to the International Convention for the Protection of New Varieties of Plants, Act of 1991.

### Copyrights, Related Rights, and Limitations

#### 11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy:

The Copyright Act provides rightsholders with standard exclusive rights. Section 5 of the act defines economic rights, which include the right to distribution, communication to the public, and reproduction "of the work in any manner or form." Sections 41 through 47 outline offences under the act, criminal sanctions, civil remedies available to rightsholders, and the possibility of mediation and dispute settlement administratively through the Copyright Office. There is no reference to or recognition of the special challenges that



the internet and online infringement pose in the Copyright Act. The act does not include a notice-and-takedown and safe harbor system, nor does it refer to the possibility of an injunctive-style relief mechanism through which relief can be sought from a court of law or administratively. Having said that, the Electronic Transactions Act 2008 does include a fairly comprehensive definition and description of liability for service providers and intermediaries. Specifically, Sections 90-97 of the act define intermediaries' and service providers' responsibilities to avoid any potential legal liability, including the responsibility to act expeditiously upon notification by a concerned party of any infringing or illegal activity, including by removing or disabling access to any infringing information.

The Electronic Transactions Act also opens up the possibility for injunctive-style relief and a court-ordered disabling of access to infringing and illegal content. Section 97 states that the responsibilities and safe harbor mechanism outlined in the act do not affect intermediaries' and service providers' obligations to abide by any court order to "remove, block or deny of access to an electronic record." However, while defined under statute, there is no evidence that either of these mechanisms is successfully being accessed by rightsholders to enforce their rights online. As noted below under "Enforcement," overall, the enforcement environment for all IP rights—including copyright—remains challenging. Rates of physical piracy remain high, and there are substantial backlogs in the judiciary for both civil and criminal cases.

## Enforcement

### 34. Civil and procedural remedies; and 36.

**Criminal standards including minimum imprisonment and minimum fines:** Civil remedies and criminal sanctions are available for all major IP rights. Remedies and sanctions include injunctions, damages, and seizures as well as fines and imprisonment for criminal infringement. However,

overall, the enforcement environment remains highly fraught, with counterfeit and IP-infringing goods widely available. A 2019 OECD case study of counterfeiting found that Ghana "has a high prevalence of counterfeit, pirated and substandard goods." The study noted problem areas with respect to medicines and the high availability of counterfeit, substandard, and unregistered pharmaceuticals, which together were estimated by the Ghana FDA to constitute about 20-30% of the total market. More broadly, the study also noted the high prevalence of counterfeit consumer goods, textiles, copyright-infringing goods, and electronics. Other sources confirm these reports with, for example, the U.S. State Department in its latest 2021 *Investment Climate Statement* for Ghana stating that IP rights "enforcement remains weak, and piracy of intellectual property continues."

Judicial enforcement in Ghana is characterized by long delays. In the 2020 edition of the World Bank's *Doing Business* report, Ghana ranked 117<sup>th</sup> in the category "Enforcing contracts." It takes, on average, 710 days to enforce a contract—almost two years—and at a cost of 23% of the claim value. These long delays have actually increased by almost 50% over the last decade from an average of 487 days in the time period 2008-2013. Official statistics published by the Judicial Service of Ghana show a lengthy backlog at all instances, from district and circuit courts to the High Courts, the Court of Appeal and even to the Supreme Court. The latest available data covers the period July 2017 to June 2018. It shows that, in aggregate for both civil and criminal cases, the case backlog increased from 83,914 cases pending in July 2017 to 94,946 cases at the end of June 2018. During this period, 110,550 cases were filed and 99,518 cases were concluded.

### Membership and Ratification of International Treaties

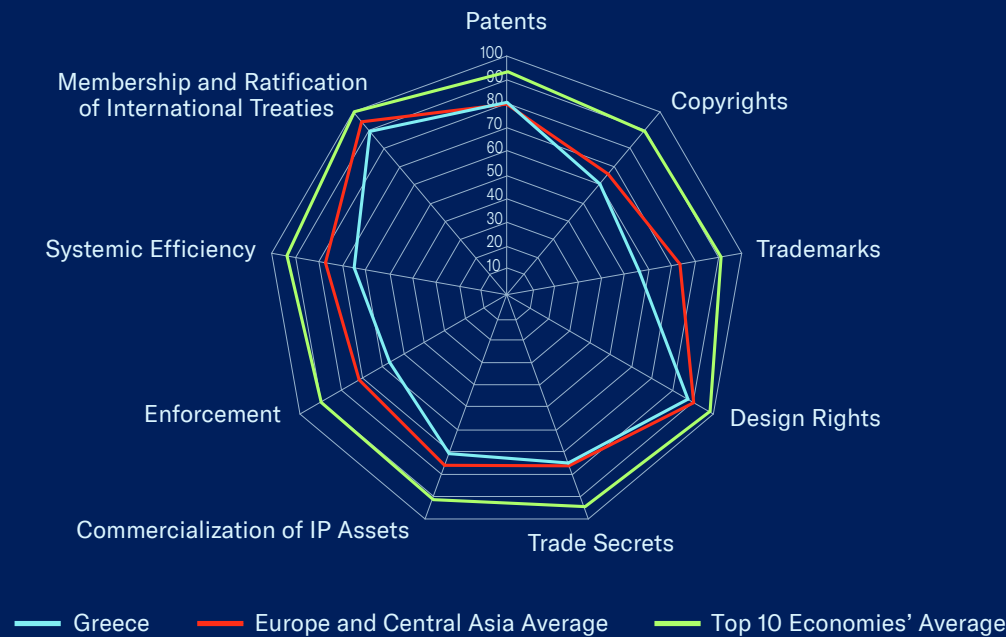
Ghana is a contracting party to the WIPO Internet Treaties; the Protocol Relating to the

Madrid Agreement Concerning the International Registration of Marks; the Patent Cooperation Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; the Convention on Cybercrime; and the Hague Agreement Concerning the International Registration of Industrial Designs. Ghana is a signatory but has not acceded to the Singapore Treaty on the Law on Trademarks or the Patent Law Treaty. Ghana has not concluded any post-TRIPS FTAs with substantial IP provisions. Neither the 2016 Framework Agreement for an Economic Partnership Agreement with the EU nor the 2021 Interim Trade Partnership Agreement with the UK contain provisions relating to IP rights. Both agreements do contain a commitment to conclude such an agreement at some point in the future. Ghana is a contracting party to the African Continental Free Trade Area, signed by 44 African nations in 2018. The agreement could fundamentally revolutionize economic activity in Africa by reducing barriers to trade and economic interaction across the entire continent, including with respect to IP rights. Parts of the Free Trade Area (Phase I of the agreement) came into force in June 2019 and have been operational across the continent since January 1, 2021. Phase II of the agreement, which is to include a "Protocol on Intellectual Property," was still being negotiated. At the time of research, no timetable for completion had been announced.

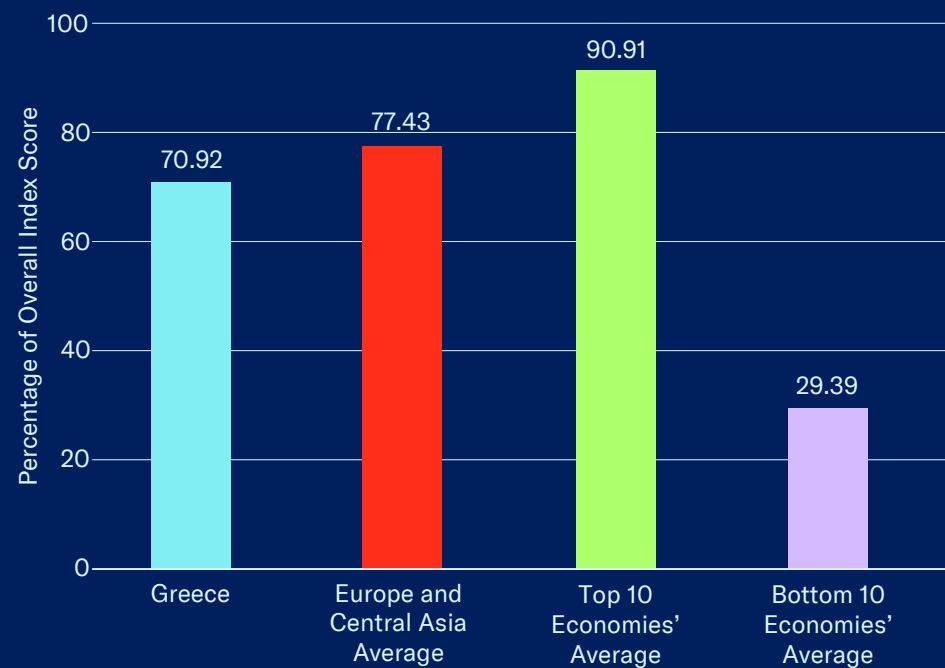
Overall, Ghana achieves a total score of 5.5 on this category of the Index or 78.57% of the total available score. This is notably higher than many high-income economies, such as New Zealand and the UAE, and more than double some of the biggest emerging markets included in the Index, including Brazil, China, and India. It is also more than three times the score of other major economies from Sub-Saharan Africa included in the Index, such as South Africa and Nigeria. Being a contracting party to key international IP treaties reflects a given economy's broader

participation in the international IP community and embrace of the highest IP standards. 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.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

- 2019 changes to compulsory licensing regime were 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 since 2011, Greece has had a remarkably high rate of software piracy for an EU and OECD Member State
- Software piracy rate has consistently stayed between 61% and 63% (in 2018 it was an estimated 61%)—compared to an average estimated rate of 26% for the rest of Western Europe
- Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals poses significant risk to Greece's and the EU's research and IP-based biopharma industry
- Registration requirement for licensing deals in Greece



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>7.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>4.24</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	0.75
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.75</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.75
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.25</b>
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

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

**Total Score:  
35.46**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Greece's overall score has increased from 70.67% (35.33 out of 50) in the ninth edition to 70.92% (35.46 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Systemic Efficiency

**43. IP-intensive industries, national economic impact analysis:** There is growing interest among relevant government institutions in Greece to better understand and map the contribution of IP-intensive industries to the national economy. Subsequent to the Greek sovereign debt crisis, the Hellenic Industrial Property Organisation (OBI) recognized the importance of expanding IP-intensive industries' contribution to national economic output. Several campaigns aimed at facilitating the use of IP rights within the broader economy and supporting the growth of IP-intensive industries have been initiated. For example, the OBI has launched a "Smart IP" program that will focus on commercialization and the creation of IP assets. Additionally, as a Member State of the European Union and contracting party to the European Patent Convention, the Greek government also takes part in the multitude of research efforts conducted by European institutions. A whole swathe of 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 economics of IP-intensive industries include the EPO, EUIPO, EUROSTAT, and the European Commission. The latest such study is the 2019 *IPR-Intensive Industries and Economic Performance in the European Union* published by the EUIPO and EPO. This study found that IP-intensive industries contributed an estimated 35.9% of Greek GDP, on average, in the time period 2014-16. Similarly, with respect to employment, an estimated 27.2% of the Greek labor force worked in IP-intensive industries.

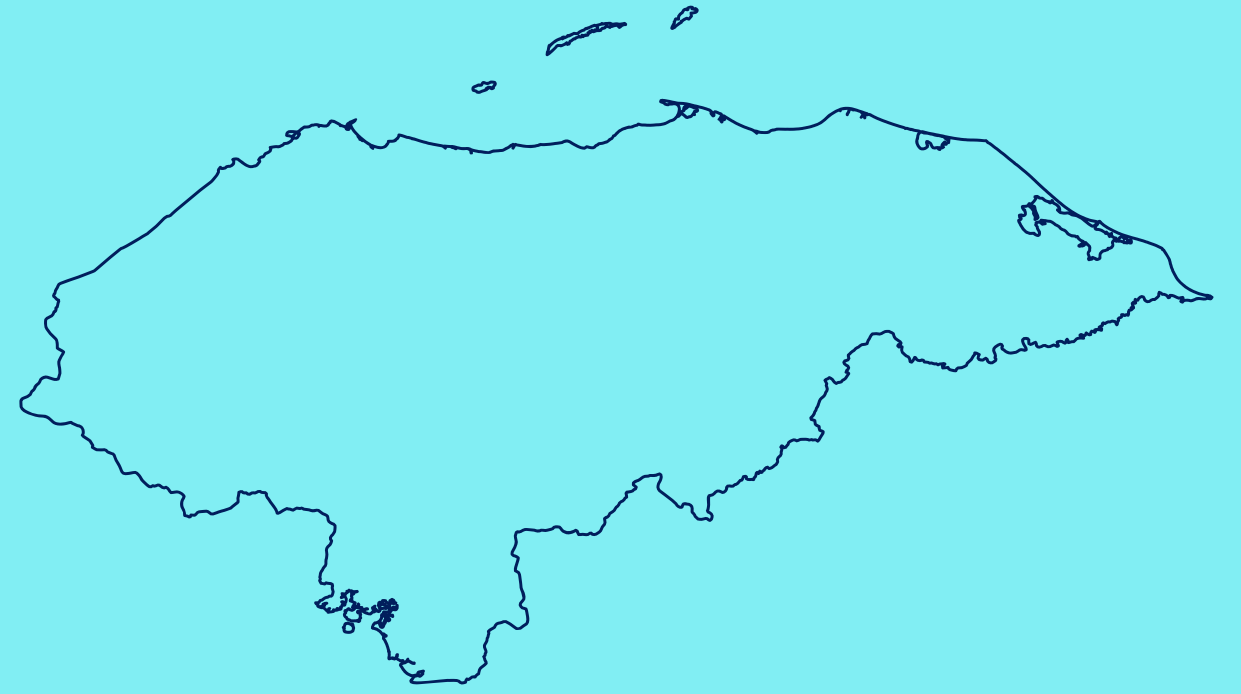
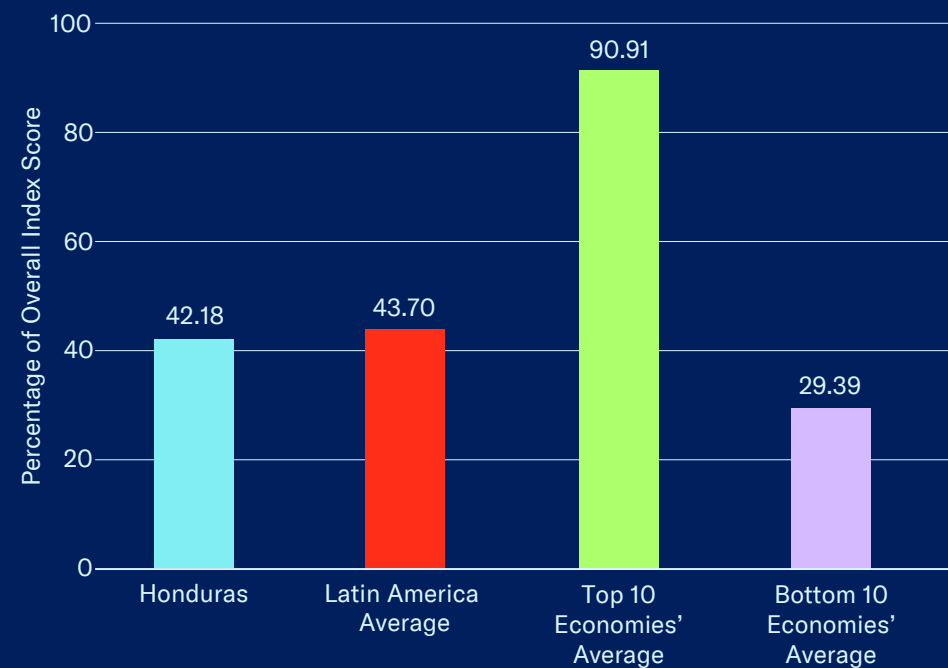
This important work continued in 2021 with the release of *Intellectual Property Rights and Firm Performance in the European Union*. Co-produced by the EPO and EUIPO, this report examines the relationship between IP rights and rates of economic activity at the firm level. Overall, the report finds that European businesses that own at least one registered form of IP right (patents, designs, or trademarks) have, on average, 20% higher revenues per employee than businesses with no registered IP portfolio. Similarly, the report found that firms with registered IP rights also pay higher wages—19% higher, on average. The EPO and EUIPO should be congratulated for the production of this report and for their leadership on providing detailed statistical data and economic analysis of the socio-economic benefits of IP rights.



## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

- Patentability standards outside international norms—key problem areas include second use claims for biopharmaceuticals and patent protection for CIIIs
- Uncertainty over access to statutory period of RDP: 2018 implementing regulations (*Acuerdo No. 024-2018*) provide a broad basis for overriding exclusivity
- Challenging enforcement environment—particularly regarding online and digital content
- Infringement of copyright through signal piracy, online, and web-based streaming is highly pervasive and constitutes a major source of illegal content—not effectively addressed by government
- BSA's estimated rates of software piracy are among highest in the region at 75%
- Signal piracy and theft are among the highest in Latin America: total pirated or unreported market in Honduras estimated at 50% of total number of potential end-users



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.51</b>
10. Copyright (and related rights) term of protection	0.76
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.00</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.50</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>3.50</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>2.73</b>
32. Physical counterfeiting rates	0.48
33. Software piracy rates	0.25
34. Civil and precedural remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>2.00</b>
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>2.50</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
21.09**

## Spotlight on the National IP Environment

### Copyrights, Related Rights, and Limitations

**11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 15. Technological protection measures (TPM) and Digital rights management (DRM) legislation:** The Honduran Copyright Law (Decree-4-99) provides rightsholders with standard exclusive rights. Article 39 of the law defines economic rights, which include the right to distribution, communication to the public, and reproduction with authors having the “exclusive right to authorize or prohibit the use of their works by any means, form or process.” Articles 156-180 outline offences under the act, criminal sanctions, and civil remedies available to rightsholders, and the possibility of administrative enforcement measures through the Honduran Directorate of Intellectual Property within the National Registry (*Instituto de la Propiedad*).

Historically, there had been no reference to or recognition of the special challenges that the internet and online infringement posed in the Copyright Law or relevant supplementary legislation. This changed with Honduras’ accession to the 2006 Dominican Republic–Central America Free Trade Agreement (CAFTA-DR). The agreement contains several important standards and measures relating to copyright enforcement on the internet and digital realm, including a defined notice-and-takedown mechanism for communication service providers (Article 15.10, Subsection 27); extensive TPM and DRM protection provisions (Article 15.5); definitions of obligations pertaining to related rights (Article 15.7); protection against satellite piracy (Article 15.8); and general civil and criminal enforcement procedures for all IP rights, including copyrights (Article 15.11). CAFTA-DR was adopted and implemented in Honduras through Decree-16 2006, the “Law on the Implementation of the Free Trade Agreement, Dominican Republic,

Central America and United States.” Decree-16 reflects many of the provisions listed above. For instance, under Title IV and Articles 31-39, TPM and DRM protection provisions are outlined and prohibited infringing activities are clearly defined. This includes not only the actual evasion of TPM and DRM technologies and use of circumvention devices, but also the “manufacture, import, distribution, offering to the public, providing or otherwise trafficking (trafficking) devices, products, or components, or offering to the public or providing services” of circumvention devices or enabling services. However, the challenge in Honduras has always been in the effective enforcement of IP rights, including copyright. Rates of infringement remain high, with both physical counterfeiting and online piracy rates growing.

The U.S. State Department noted in the 2021 *Investment Climate Statement*, “The legislative framework for the protection of intellectual property rights (IPR)...is generally adequate but often poorly implemented” and that with respect to copyright infringement “digital piracy is widespread and frequently ignored in Honduras, especially by telecommunications companies.” Similarly, the BSA estimates that 75% of software in Honduras is unlicensed; this is one of the highest rates in the Latin America region and substantially higher than the regional average of 52%. Critically, the rate of software piracy has virtually stood still for over a decade, with no decline measured despite the updated legal framework and general commitment from the authorities to fighting piracy. In 2007 BSA estimated that unlicensed software usage stood at 74%—a 1% difference from the latest report.

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 2016 the USTR and the government of Honduras agreed on an “Intellectual Property Work Plan.” This followed an *Out-of-Cycle Review* in 2015.



Looking at estimated rates of signal piracy, these remain high. For example, the Latin American industry association ALIANZA (*Alianza Contra la Piratería de Televisión Paga en América Latina*) in 2019 released the findings from a study of estimated rates of signal piracy and theft in Latin America. The study found that the total pirated or unreported market in Honduras was an estimated 50% of the total number of potential end-users. Of the 19 Latin American economies sampled, Honduras estimated that the 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.

### Trade Secrets and the Protection of Confidential Information

**25. Regulatory data protection term:** Under Article 77 of the Industrial Property Law, Honduras had provided a general commitment to the protection of undisclosed biopharmaceutical test data submitted during sanitary registration. No term of protection had been defined. Article 15.10 of the CAFTA-DR agreement contains a defined term of RDP for biopharmaceutical products of five years. Decree-16 2006 implemented these relevant sections of the CAFTA-DR through Articles 19-24. Specifically, Article 19 provides a defined term of RDP of five years. Unlike the CAFTA-DR, Decree-16 also contains some potential major caveats to this term of protection. For example, Article 20 appears to make protection contingent on the marketing of a new biopharmaceutical product in Honduras within five years of global launch. Furthermore, implementing regulations (*Acuerdo* No. 024-2018) released in 2018 by the national drug regulatory authority ARSA (*Agencia de Regulación Sanitaria*) introduces additional hurdles and caveats.

Like Decree-16, Article 3 of this *Acuerdo* seems also to condition access to RDP on the submission of a market authorization application in Honduras within

12 months of first global launch. Articles 15 and 16 also provide ARSA and health officials with the right of cancellation on the basis of the existence of a “public interest” defined broadly as encompassing a national emergency or relating to public health. It is unclear what would be defined or constitute such an emergency or basis for a public interest action. Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratory, research facilities, and researchers are high. Compared to many other high-tech industries—for example, computer software—developing the next ground-breaking treatment for cancer or Alzheimer’s disease requires more than just a laptop and a great idea.

As medicines become more targeted and technically sophisticated, the cost of development rises dramatically. In 1979, the total cost of developing and approving a new drug stood at USD 138 million. Almost 25 years later, in 2003, this figure was estimated at USD 802 million. A 2012 estimate puts the total cost of drug development at approximately USD 1.5 billion. And 2016 research from Tufts University suggests that it costs USD 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 research and development of new medical technologies and products. In particular, patents and other forms of exclusivity for biopharmaceuticals, such as regulatory data protection, enable research-based companies to invest vast sums in R&D and the discovery of new drugs, products, and therapies. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market

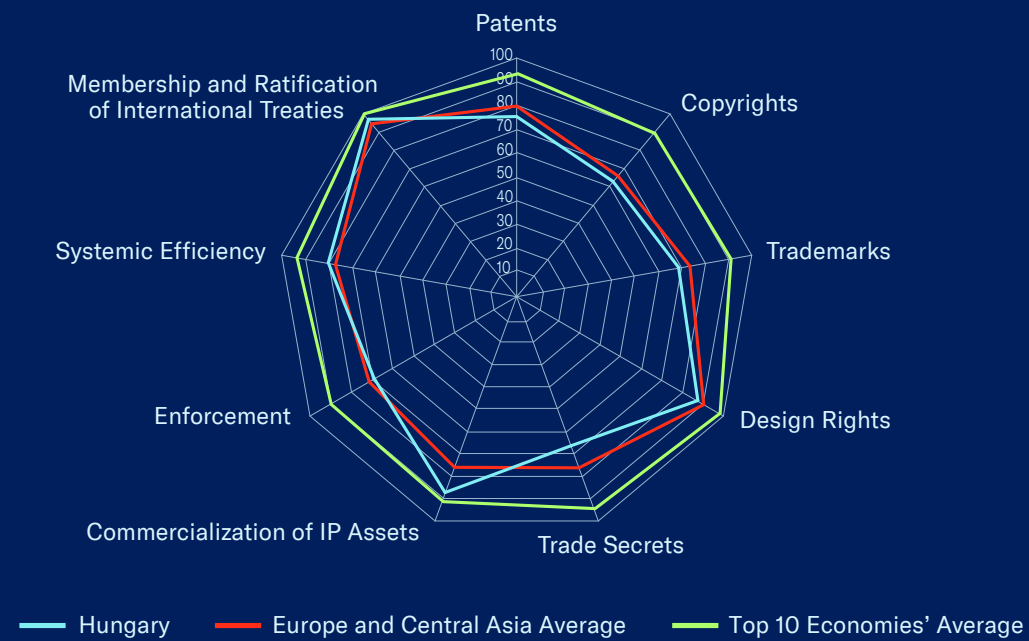
entrants who bore none of the costs of early-stage investment, research and development, and product commercialization. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws.

The government of Honduras should be congratulated for adopting and clearly providing a defined term of regulatory data protection. This is a clear signal that policymakers in Honduras understand the nature of biopharmaceutical R&D and the necessary incentives needed to develop new life-saving products and technologies, and also wish to abide by its international trade commitments made in the CAFTA-DR. Undermining these incentives through various conditions and potential carve-outs is counterproductive. Over time, such action will simply hollow out the national IP environment and incentives for future biopharmaceutical innovation. Critically, the negative effect will be the same on Honduran as on foreign innovators.

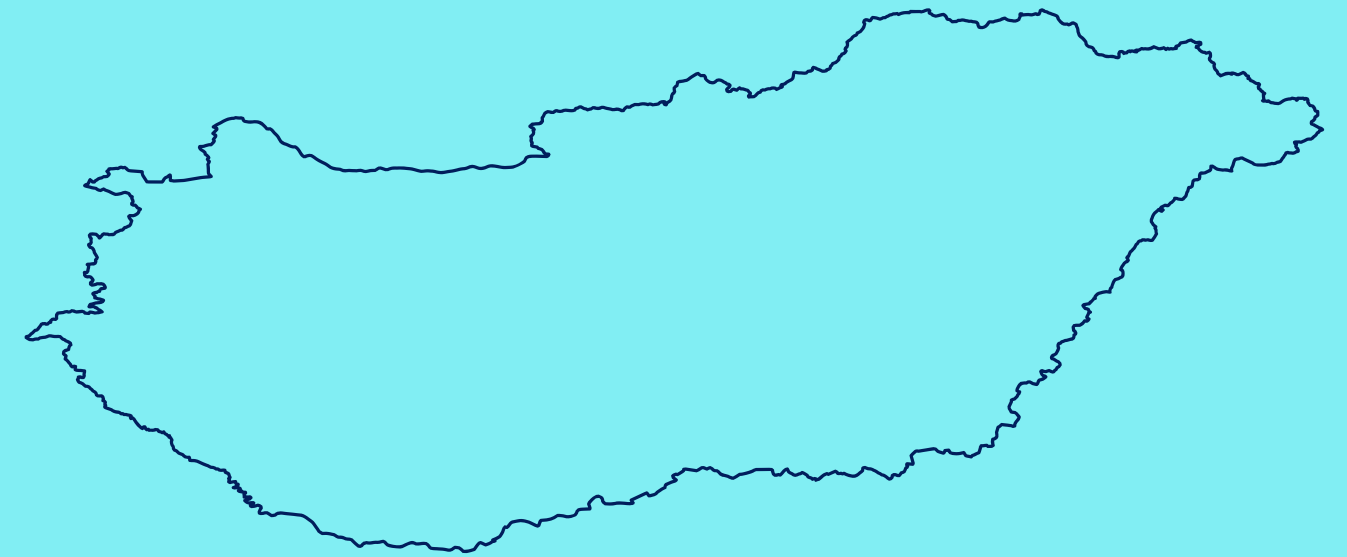
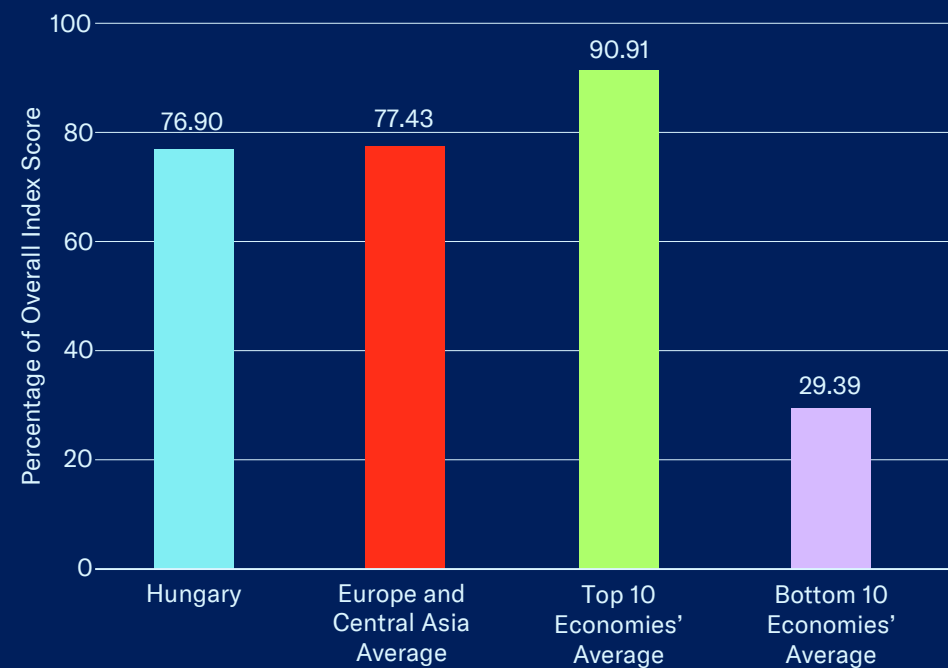
### Membership and Ratification of International Treaties

Honduras is a contracting party to the WIPO Internet Treaties and the Patent Cooperation Treaty. Honduras is not a contracting party to the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Singapore Treaty on the Law on Trademarks; the Patent Law Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; the Convention on Cybercrime; or the Hague Agreement Concerning the International Registration of Industrial Designs. Honduras concluded a post-TRIPS FTA with substantial IP provisions in 2006 with the coming into effect of the CAFTA-DR.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>6.75</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of computer-implemented inventions (CIIs)	0.75
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>4.38</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.75
13. Availability of frameworks that promote cooperative action against online piracy	0.75
14. Scope of limitations and exceptions to copyrights and related rights	0.75
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.75</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.75
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.00</b>
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	1.00

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

**Total Score:  
38.45**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Hungary's overall score has decreased from 78.23% (39.12 out of 50) in the ninth edition to 76.90% (38.45 out of 50) in the tenth edition. This reflects a score decrease on indicator 6, but an increase on indicators 13 and 32.

### Patents, Related Rights, and Limitations

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

In response to the COVID-19 pandemic, in May 2020, the Hungarian government issued Decree 212/2020, introducing an expedited compulsory licensing mechanism for biopharmaceuticals. This decree follows Act XII and the government's emergency powers to deal with the pandemic. The decree gives the Hungarian Intellectual Property Office (HIPO) the right to issue compulsory licenses to ensure the supply of any and all medical products (including biopharmaceuticals) needed to protect public health during the pandemic. The emergency nature of Decree 212 resulted in it effectively being repealed just over a month after it was issued on the basis that there was no longer a national emergency, as the pandemic was viewed as being under control. However, the powers of granting a public health compulsory license as outlined in the decree were not eliminated. Instead, a new law, Act LVIII of 2020 on Transitional Rules Related to the Termination of State of Danger and on Epidemiological Preparedness, amended the Patent Act and, virtually verbatim, inserted the relevant compulsory license provisions of Decree 212 into the act.

In a separate development, in October 2020, a Hungarian manufacturer began producing a local version of the drug remdesivir for use in a local clinical trial. Registration data in the European Union Clinical Trials Register shows the trial is

supported by the Hungarian government (the Ministry of Innovation and Technology through a consortium). As noted in last year's edition of the Index, it was unclear on what legal basis this research, manufacturing, and clinical trial is taking place. That remains the case to date. Industry sources suggest that a compulsory license was granted by the Hungarian authorities in November 2020. The basis of this license has, at the time of research, still not been made public or official by the Hungarian government. As both TRIPS Article 31 and the Doha Declaration make clear, the issuing of a compulsory license represents a "measure of last resort." It is not clear that this was the situation in Hungary in late 2020 and it is certainly not the case today. At the time of research, the rightsholder in question had unsuccessfully challenged the issuing of the license in court. The issuing of the license and the lack of effective appeal and redress—either through the judiciary or through the executive branch—raises serious questions and concerns about the protection of biopharmaceutical IP rights in Hungary. As a result of this action—and the lack of transparency and communication on part of the Hungarian authorities—the score on this indicator has been reduced to 0.

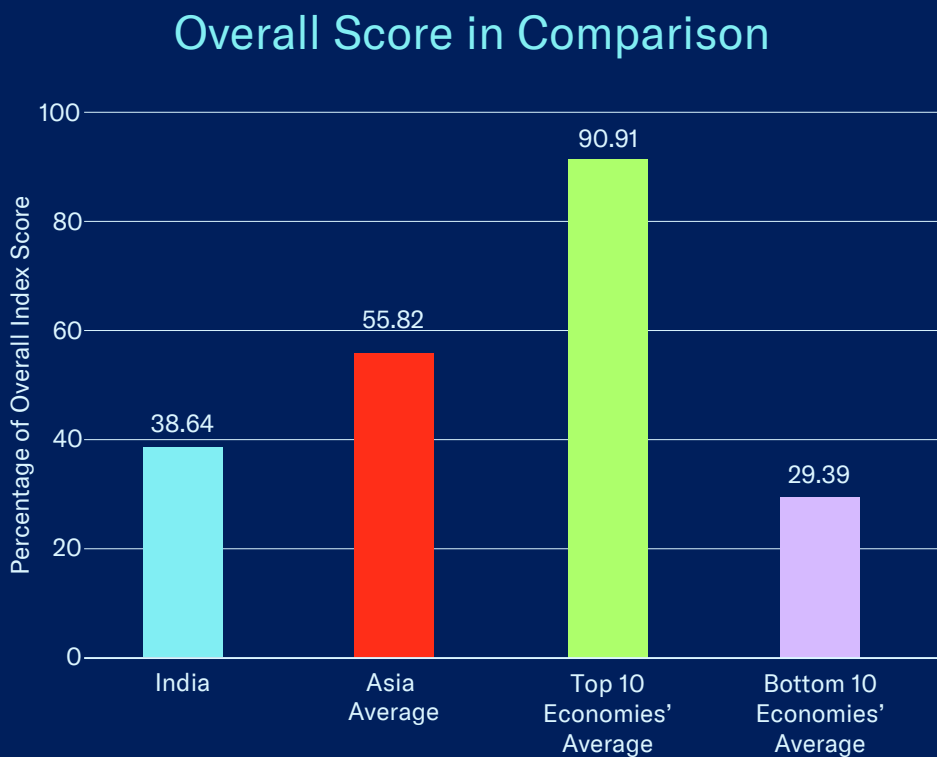
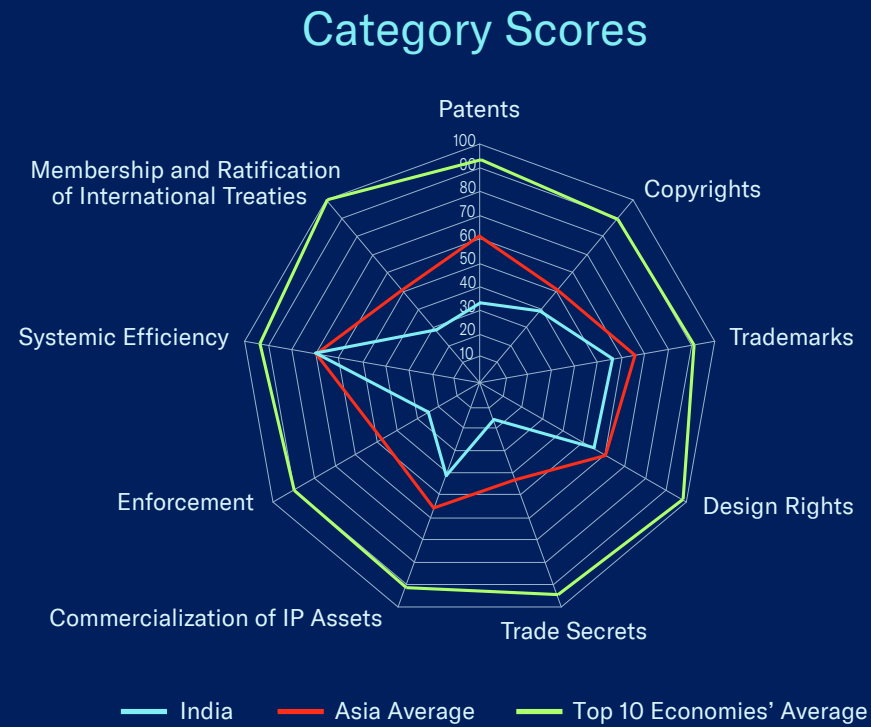
### Copyrights, Related Rights, and Limitations

#### 11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 13. Availability of frameworks that promote cooperative action against online piracy:

As has been detailed in previous editions of the Index, like all other EU Member States, Hungary has for the past two years been in the process of transposing and implementing EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive). As mentioned last year, parts of the CDSM were transposed into Hungarian



law in 2020. Specifically, new exceptions relating to digital media usage in education were adopted through Copyright Act amendments passed in June. This transposition was completed in May 2021 with a further set of amendments passed through the adoption of Law XXXVII. In addition to the adoption of relevant provisions of the CDSM—including Article 17—these amendments also contain clarifications on existing exceptions and limitations to copyrighted material. This law broadly follows the scope of the underlying directive, particularly regarding responsibilities and requirements under Article 17. While maintaining existing exceptions and limitations provided under Hungarian and European copyright law and jurisprudence, the new law strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. It also provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability. One positive change in the law is a clarification on the extent to which text and data mining are allowed for research purposes. This is an important area of future economic activity, as advances in computational power and new technological advancements in AI and machine learning allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. As a result of these positive changes, the score on indicator 13 has increased by 0.25.



## Key Areas of Strength

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

## Key Areas of Weakness

- 2021 dissolution of the Intellectual Property Appellate Board combined with the long-standing issue of an under-resourced and over-stretched judiciary raises serious concerns about rightsholders’ ability to enforce their IP rights in India and 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 are available
- Lengthy pre-grant opposition proceedings
- Previously used compulsory licensing for commercial and non-emergency situations
- Limited participation in international treaties



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>2.99</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of computer-implemented inventions (CIIs)	0.75
4. Plant variety protection, term of protection	0.74
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.72</b>
10. Copyright (and related rights) term of protection	0.47
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.00
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

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

**Total Score:  
19.32**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

India's overall score has increased from 38.40% (19.20 out of 50) in the ninth edition to 38.64% (19.32 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Area of Note

In July 2021, the Parliamentary Standing Committee on Commerce released a *Review of the Intellectual Property Rights Regime in India*. This Review is a welcome development and offers a comprehensive and detailed study of the strengths and weaknesses of India's national IP environment. It is the first major attempt at assessing the state of India's IP policy regime since 2016 and the *National Intellectual Property Rights Policy*. The 2016 *Policy* sought to address several important gaps in India's national IP environment, including the need for stronger enforcement of existing IP rights by building new state-level IP cells and investing more resources in existing enforcement agencies; strengthening administrative capacities at India's IP offices by reducing processing times for patent and trademark applications; and the need to introduce a legislative framework for the protection of trade secrets.

Much has been achieved in the time since the *Policy* was released. For example, there has been a marked uptick in educational activities and awareness-raising campaigns on the importance of IP protection. The Indian government has also made a concerted effort to sign up to some international IP standards through establishing a PPH agreement with the Japanese Patent Office and joining the WIPO Internet Treaties.

However, overall, many critical gaps remain in India's national IP environment. Indian statutory law still does not provide specific protection for trade secrets or confidential information for civil or

criminal infringement. Similarly, there has been no recognition of the need to address the challenges and uncertainties rightsholders face regarding protecting their patent rights (particularly in the biopharmaceutical sector), modernizing existing copyright laws, or introducing international best practices and new sector-specific IP rights such as regulatory data protection for submitted biopharmaceutical test data. Refreshingly, the Committee on Commerce's *Review* acknowledges many of these existing limitations. Specifically, the *Review* recognizes the need for both continuing the work of strengthening the administration of India's national IP system with more staff and resources, as well as carrying out major legislative changes. In fact, the *Review* makes several important recommendations on legislative changes, including adopting a new anti-counterfeiting law; introducing a trade secrets law; limiting existing educational copyright exceptions; creating legislation specific to the financing of IP assets; and developing rights relating to AI inventions.

Overall, the proposed reforms are significant and would substantially improve India's national IP environment and also lead to a score increase on the Index. In what marks a welcome shift in policymakers' views of the purpose of IP rights, the *Review* acknowledges the strong link between economic activity, innovation, and the protection of IP rights, and the centrality of this nexus to the Indian economy: "[The Parliamentary Committee] is of the opinion that strengthening IPRs in India would also spur economic development by encouraging foreign exchange inflow thereby increasing productivity and generation of employment opportunities in the country." The committee should be congratulated for adopting such a forward-looking view on the importance of IP rights to India's economic development.

Unfortunately, the *Review* does not apply this logic to all industries and sectors of the economy.





This disconnect is most noteworthy with respect to the research-based biopharmaceutical industry. The committee has rightly recognized that although a world leader in the production of generic and follow-on medicines, India lags far behind in the development of novel and innovative biopharmaceuticals. Yet while urging the government to more effectively address this through the introduction of more R&D- friendly policies, the committee fails to see that the primary reason for this lack of activity in India is the weak IP environment. Instead of recognizing how detrimental existing limitations on biopharmaceutical IP rights are (such as, restrictions on biopharmaceutical patentability) and the lack of critical IP rights (such as patent term restoration, regulatory data protection, and market exclusivity incentives for the development of orphan drugs), the committee **recommends** maintaining some of the largest existing barriers, including, patentability restrictions imposed through Section 3(d) of the Patent Act. This is not the right way forward.

Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratory, research facilities, and researchers are high. Compared to many other high-tech industries, developing the next ground-breaking treatment for cancer or Alzheimer’s disease requires more than just a laptop and a great idea. As medicines become more targeted and technically sophisticated, the cost of development rises dramatically. In 1979, the total cost of developing and approving a new drug stood at USD 138 million. Close to four decades later, in 2016, this figure was estimated to be USD 2.6 billion. International experience and the basic economics of the biopharmaceutical industry show how critical IP rights are to incentivize and support this research and development. IP rights enable research-based companies to invest vast sums in R&D and the discovery of new drugs, products, and therapies. On average, only one to two of every 10,000

synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market entrants who bore none of the costs of early-stage investment, research and development, and product commercialization. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws. Since 2014 the Index has included a dedicated *Statistical Annex* exploring the relationship between national IP environments and the development of innovative and competitive economies by comparing Index scores with a wide range of economic variables using correlation analysis (statistical measures of the likelihood of two elements occurring together). The latest *Statistical Annex* includes four relevant correlations relating to biopharmaceutical innovation:

1. Clinical trials
2. Early-phase clinical research
3. Development of biologic therapies
4. Biotechnological innovation (as measured by Scientific American’s *Worldview Scorecard*)

These correlations measure the relationship between IP rights specific to the biopharmaceutical sector and rates of biopharmaceutical innovation and R&D for the economies included in the Index. Overall, the results are clear: there is a strong correlation between the availability of biopharmaceutical IP rights and levels of biopharmaceutical research and innovation, as all correlations for the above variables achieved a score of between 0.74 and 0.81. As the committee and relevant ministries and agencies of the Indian government continue to develop and work on the reform proposals put forward in the *Review*, we urge

them to carefully examine this data and evidence. Like any IP-dependent industry, the research-based biopharmaceutical sector cannot exist and thrive in the absence of strong and clear IP incentives.

### Copyrights, Related Rights, and Limitations; and Enforcement

**11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 36. Criminal standards including minimum imprisonment and minimum fines:** The infringement of copyright through piracy, online, and web-based streaming is highly pervasive and constitutes a major source of illegal content in India. The pirating of film and audio-visual content has historically been a major challenge to both domestic and international rightsholders. Much of this has taken place through illicit camcording. To provide a greater level of deterrence to this type of behavior, a Cinematograph (Amendment) Bill was introduced by the Indian government in 2019. This draft legislation has now been updated with new draft language and criminal sanctions including potential imprisonment of up to three years and a fine. Strengthening existing legal sanctions would mark an improvement in India’s copyright enforcement environment. The Index will continue to monitor these developments in 2022.

### Enforcement

**34. Civil and procedural remedies:** Rightsholders have long faced real challenges in enforcing their IP rights in India. As has been detailed in previous editions of the Index, in many IP-intensive sectors (including both biopharmaceuticals and the copyright and creative industries) relevant legal rights are either not available or only partially available. Infringement is widespread: India is both a global source of and home to high rates of substandard and counterfeit medicines, online

and physical piracy, and counterfeiting. Using global customs data, the OECD and EUIPO found in the 2017 *Mapping the Real Routes of Trade in Fake Goods* that India was the biggest source of counterfeit pharmaceuticals in the world at 55% of the global total. The study also found India to be a prominent provenance economy for counterfeit foodstuffs; perfumes and cosmetics; leather articles and handbags; and counterfeit clothing, footwear, and textile fabrics.

One long-standing area of concern has been the excessive pendency times in the Indian court system. In June 2018, it was reported that over 30 million civil and criminal cases were pending (3.3 crore), of which 40% were more than five years old. Commercial disputes were estimated to have risen from over 17,000 cases in 2015 to close to 40,000 in 2017. In the 2020 edition of the World Bank’s *Doing Business* report, India ranked 163<sup>rd</sup> in the category “Enforcing contracts.” It takes, on average, 1,445 days to enforce a contract—almost four years—and at a cost of 31% of the claim value. These long delays have stood still since 2014. The Indian government has long recognized this challenge and especially its negative impact on business disputes and IP rightsholders. In 2015/16 the Commercial Courts, Commercial Division and Commercial Appellate Division of High Courts Act, 2015 was signed into law; it included specific amendments to the Civil Procedure Code. Fundamentally, the purpose of the act was to improve the overall commercial environment in India by making it easier and quicker to solve business-related disputes. Specific reforms included changes to the administration of justice with an emphasis on solving disputes quickly and efficiently, streamlining commercial disputes, and ensuring a relevant level of expertise at the presiding court level.

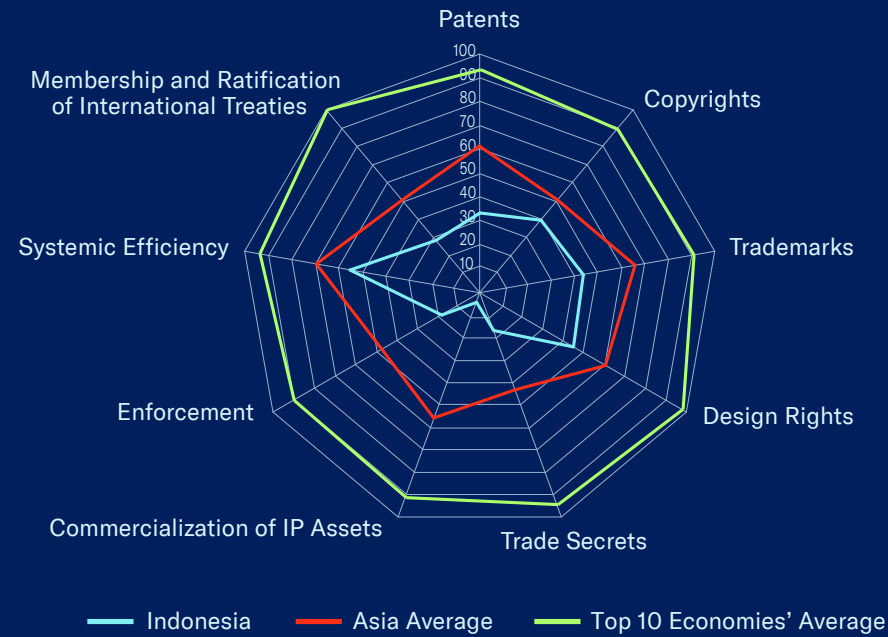
New amendments were also introduced in 2018 that aimed to improve the legislation by cutting down pendency rates through the expansion of the types of case that can be heard, reducing the



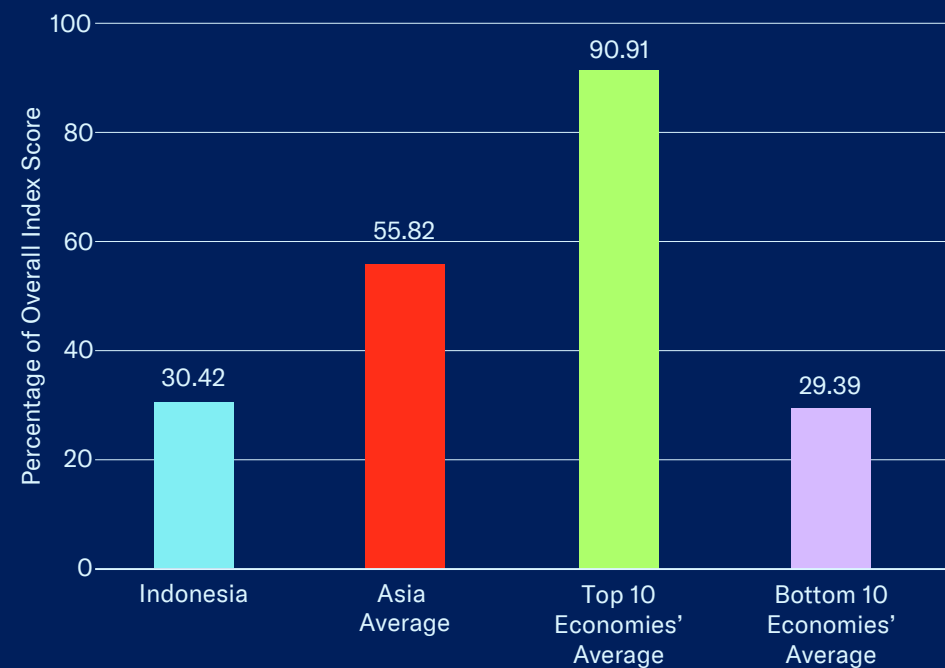
value threshold for commercial disputes, and introducing mediation proceedings. In parallel to the courts system, IP rightsholders have historically also been able to appeal administrative decisions taken by the relevant Indian registration authorities through the Intellectual Property Appellate Board (IPAB) system. The IPAB provided rightsholders for most major IP rights the ability to appeal directly to an IP specialist body to hear and resolve these disputes. Under the “Tribunal Reforms (Rationalisation and Conditions of Service) Ordinance 2021,” the IPAB was dissolved and all pending cases before the board transferred to the judiciary, namely the High Courts and Commercial Courts. The dissolution of the IPAB, combined with the long-standing issue of an under-resourced and over-stretched judiciary, raises serious concerns about rightsholders’ ability to enforce their IP rights in India and resolve IP-related disputes.

The Parliamentary Standing Committee on Commerce in its *Review of the Intellectual Property Rights Regime in India* rightly recognized the negative impact the IPAB dissolution will have and called for the Board to be “re-established... and strengthened with more structural autonomy, infrastructural and administrative reforms.” Whether through the judiciary, an administrative tribunal, or a combination of both, it is imperative that rightsholders are able to effectively have disputes heard and resolved in a timely fashion. At the time of research, it was not clear what would happen to the IPAB or if additional capacity and resources would be provided to the judiciary to handle the additional case burden. On a positive note, the Delhi High Court in July 2021 stated it would be creating a specialized “Intellectual Property Division” to help the court meet this additional case load. The Index will continue to monitor these developments in 2022.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

- Significant barriers in place for licensing and commercialization of IP assets, including technology transfer
- Biopharmaceutical patentability standards outside international norms
- History of using compulsory licensing for commercial and non-emergency situations, 2018/19; Regulations go beyond the stated goals and circumstances for the issuing of compulsory licenses under the TRIPS Agreement
- 2020 Presidential Regulation, Number 77 expands compulsory licensing and emergency use provisions further
- Challenging copyright environment with high levels of piracy, as administrative measures do not address mirror and linking sites
- Limited participation in international IP treaties



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.00</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.77</b>
10. Copyright (and related rights) term of protection	0.52
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.75
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.90</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>0.25</b>
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.00
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.25
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>1.29</b>
32. Physical counterfeiting rates	0.37
33. Software piracy rates	0.17
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.00
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>2.75</b>
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.25
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>2.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
15.21**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Indonesia's overall score has increased from 30.16% (15.08 out of 50) in the ninth edition to 30.42% (15.21 out of 50) in the tenth edition. This reflects an increase on indicator 32.

### Patents, Related Rights, and Limitations

**2. Patentability requirements:** Indonesia's patenting environment has been marred by deep uncertainty and several negative legislative developments over the last half-decade. In 2016 the Indonesian Parliament (People's Representative Council) passed a new wide-ranging patent law (Law 13 2016). While aiming to strengthen Indonesia's innovation infrastructure and encourage more high-tech economic development through the creation and use of new technologies, overall, the law did not improve what was already a challenging patenting environment. To begin with, Article 4 inserted a new heightened efficacy requirement targeting biopharmaceutical products and outlawed second use claims. The new efficacy standard was never comprehensively defined; the sole example cited was for antibiotics. In a further effort to target biopharmaceutical innovation, Article 167 allowed the parallel importation of follow-on products under patent protection in Indonesia but approved for consumption in other markets. The law explained that this importation was to target the cost of medicines and in particular where prices in Indonesia are judged to be higher than the "international market." No details were provided as to what constituted a "higher price" or the "international market."

More broadly, Article 20 of the law seemed to make the granting of a patent conditional on localizing manufacturing and/or R&D in Indonesia. Specifically, it mandated that all patent rightsholders "make" the patented product or process within Indonesia. Subsection (2) of

this article stated that this production should support Indonesia's industrial and development policies, specifically the "transfer of technology, investment absorption and/or employment." No further details were provided as to the meaning or legal definition of "make" in this context.

Indonesia has for many years had in place several mandatory localization requirements targeting certain industrial sectors (most notably the biopharmaceutical sector), but this new requirement broadened this to any patented technology. In July 2018, long-awaited Patent Regulations were published aiming to provide clarity on what Article 20 meant in practice. On the one hand, the regulations affirmed the meaning and intent of the original act that the "making" of a patent was an obligation on part of a given rightsholder to make products or use processes in Indonesia, and that this must support technology transfer, investment, and/or employment. Upholding the sweeping localization requirements of the original law was not only firmly outside international standards, but was likely to do little to encourage and incentivize the transfer of new technologies or foreign direct investment into Indonesia.

On a more positive note, the regulations did provide the possibility of indefinitely postponing these requirements. Article 3 of the regulations allowed patent holders to apply to "postpone" the production or use of the patent in Indonesia for up to five years. Article 6 also provided that this five-year postponement may be extended "with reasons."

In 2019 the government announced that it would be issuing new regulations. However, instead of revised regulations, the Indonesian government, in February 2020, proposed fresh amendments to the Patent Act. In a reversal from its previous stance, the proposed amendments—as part of a sprawling legislative package, the Omnibus Job Creation Bill (*Undang-Undang (RUU) Omnibus*



*Cipta Kerja*)—simply deleted Article 20 of the 2016 Patent Act. As noted in last year’s edition, although unexpected, the removal of this article would have been a positive step and help alleviate some of the uncertainty with respect to Indonesia’s patenting environment. Although the final passed version of the law did not eliminate the working requirement, Article 107(2) defines the use and “implementation” of patents in Indonesia as including domestic creation, importation, or the licensing of the relevant invention. Local reports suggest that the government is considering further amendments to the patent law. Some of these reportedly include potential onerous patent use reporting requirements and restrictions on foreign rightsholders’ ability to choose a legal proxy. The Index will continue to monitor these developments in 2022.

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

The Indonesian government has since the mid-2000s issued nine “government use” compulsory licenses overriding existing biopharmaceutical patents primarily for hepatitis and HIV drugs. These licenses allowed the government to exploit existing patent-protected products in the event of threats to national security or an urgent public need. Both the manner in which these licenses were issued and their justification were in contradiction of Article 31 of the TRIPS Agreement. TRIPS Article 31, including the amendments introduced in the 2001 Doha Ministerial Declaration, and subsequent General Council decision allowing the export of medicines produced under a compulsory license (outlined in Paragraph 6), form the legal grounds for compulsory licensing for medicines. The chairman’s statement accompanying the General Council decision (concerning Paragraph 6 of the Doha Declaration) underscores that these provisions are not in any way intended for industrial or commercial objectives, and if used, it is expected that they would solely be aimed at protecting public health. In addition, Article 31 and the Doha

Declaration suggest that compulsory licensing represents a “measure of last resort,” intended primarily for public health and humanitarian emergencies such as pandemics, and to be used only after all other options for negotiating pricing and supply have been exhausted.

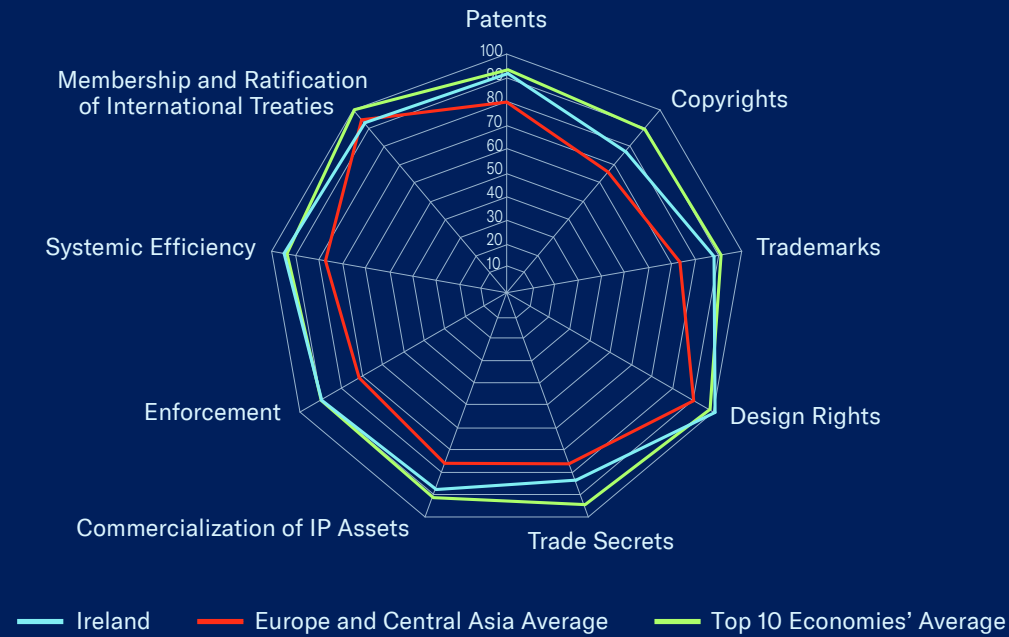
The 2016 amendments to the Patent Act (see above discussion under Indicator 2) included changes with respect to compulsory licensing, expanding a regime that was already outside international standards and highly permissive. Subsequent implementing regulations and presidential decrees have further expanded the basis on which involuntary licenses can be issued. In November 2021, the government issued a government-use license for patents related to remdesivir—Gilead Sciences’ COVID-19 treatment. While the license cites the urgent need to access the medicine, there is no evidence of existing IP rights or supply being a barrier to access remdesivir given. The Indonesian government continues to source generic remdesivir from Gilead’s voluntary licensing partners in Indonesia to meet patient need. This development further weakens what was already a highly challenging national IP environment for biopharmaceutical rightsholders.

#### **Enforcement**

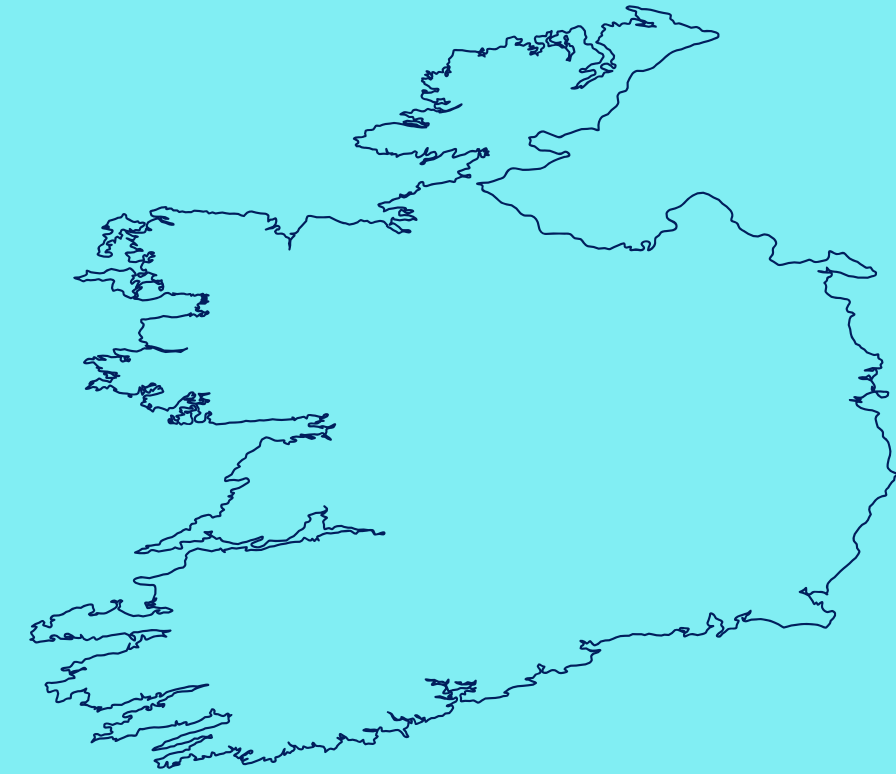
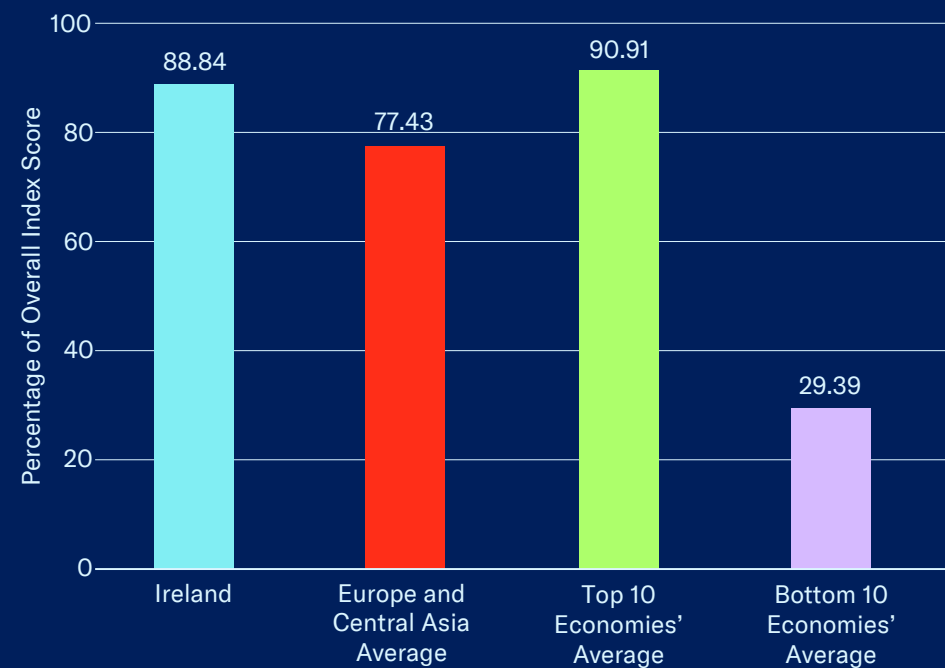
In what is otherwise a highly challenging environment for the enforcement of all major IP rights, Indonesia’s national IP office (the Directorate General of Intellectual Property [DGIP]) continues to work on improving the enforcement environment. The head of the office, Director General Freddy Harris, has in several public interviews described the need for stronger enforcement efforts and of more effectively working together with international rightsholders. In 2021 several new initiatives were launched and announced, including increased anti-counterfeiting activity at shopping malls and direct cooperation with international rightsholders and law enforcement, including the FBI; a dedicated

interagency taskforce tasked with coordinating enforcement leading to the removal of Indonesia from the USTR’s Priority Watch List; a dedicated anti-copyright piracy team within the IP office; and greater transparency through the creation in 2022 of a dedicated web portal with data and statistics on cross-agency IP enforcement activity including that of customs and police. The DGIP and its leadership team should be congratulated on these efforts. Implementation of these new measures should lead to a marked improvement in the enforcement environment in Indonesia and a commensurate score increase on relevant Index indicators. The Index will monitor the application and success of these new initiatives in 2022.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>5.38</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.75
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	0.75
14. Scope of limitations and exceptions to copyrights and related rights	0.75
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.75
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.75
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	1.00
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	1.00
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>2.00</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1.00
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.50</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>5.25</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
<b>Category 7: Enforcement</b>	<b>6.29</b>
32. Physical counterfeiting rates	0.83
33. Software piracy rates	0.71
34. Civil and precedural remedies	1.00
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	1.00
36. Criminal standards including minimum imprisonment and minimum fines	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	1.00
<b>Category 8: Systemic Efficiency</b>	<b>4.75</b>
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>6.50</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
44.42**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Ireland's overall score has decreased from 88.86% (44.43 out of 50) in the ninth edition to 88.84% (44.42 out of 50) in the tenth edition. This reflects a score decrease on indicator 32.

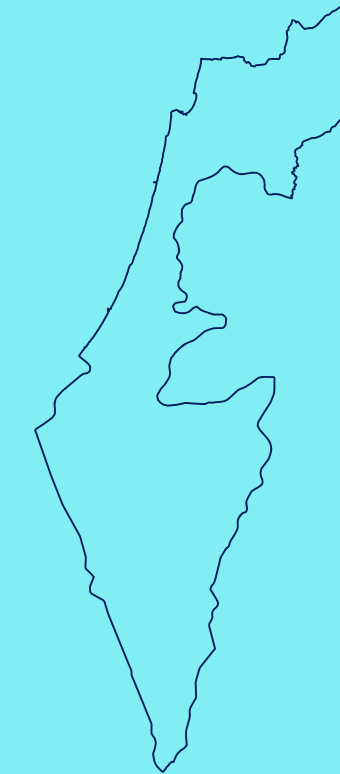
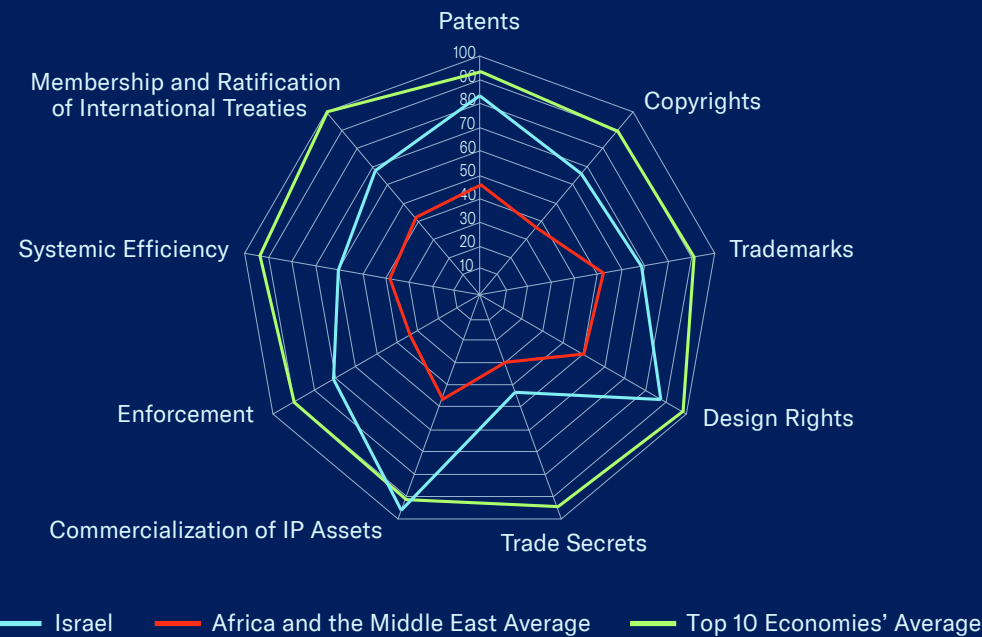
### Systemic Efficiency

**43. IP-intensive industries, national economic impact analysis:** As has been noted in previous editions of the Index, the Irish economy is built on high-tech, IP-intensive industries. The government has through various initiatives sought to incentivize the creation, registration, and use of IP assets to spur economic growth and development. In terms of macro and micro studies examining the relationship between IP rights and economic activity, Enterprise Ireland and Knowledge Transfer Ireland have been at the forefront. In 2012 the former published *Inventions & Innovations, the Positive Impact of Ideas from Research on Irish Industry and Society*, a study of the real-life socio-economic impact technology transfer and commercialization have had on the Irish economy.

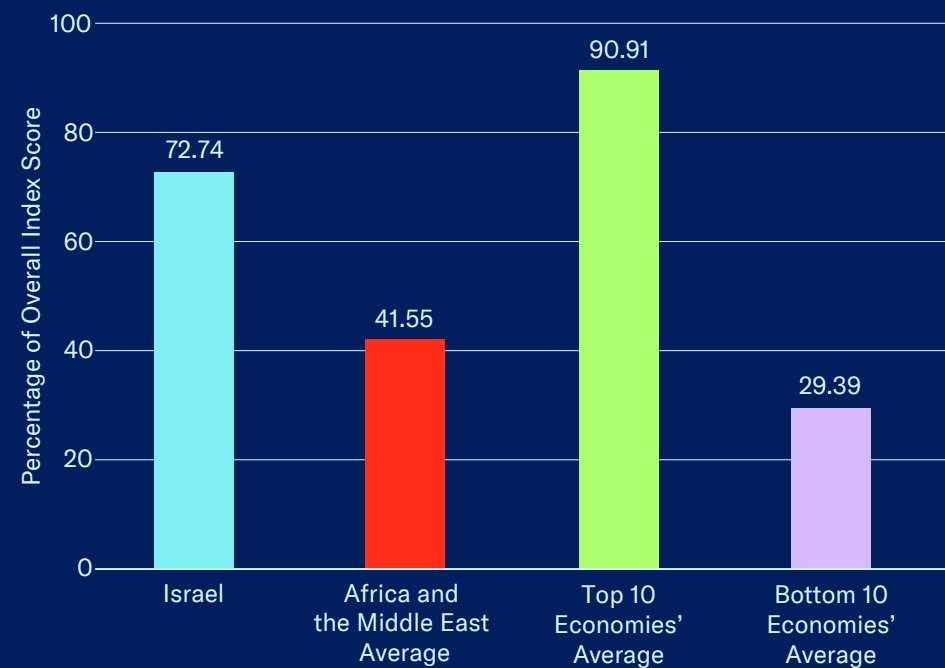
As a Member State of the European Union and contracting party to the European Patent Convention, the Irish government also takes part in the multitude of research efforts conducted by European institutions. A whole swathe of European institutions study the economic impact of IP-intensive industries in the EU and Europe. Major institutions that publish studies and research on various aspects of the economics of IP-intensive industries include the EPO, EUIPO, EUROSTAT, and the European Commission. The latest such study is the 2019 *IPR-Intensive Industries and Economic Performance in the European Union* published by the EUIPO and EPO. This study found that IP-intensive industries contributed an estimated 65% of Irish GDP, on average, in the time period 2014-16. Similarly, with respect to employment, an estimated

27.1% of the Irish labor force worked in IP-intensive industries. This important work continued in 2021 with the release of *Intellectual Property Rights and Firm Performance in the European Union*. Co-produced by the EPO and EUIPO, this report examines the relationship between IP rights and rates of economic activity at the firm level. Overall, the report finds that European businesses that own at least one registered form of IP right (patents, designs, or trademarks) have, on average, 20% higher revenues per employee than businesses with no registered IP portfolio. Similarly, the report found that firms with registered IP rights also pay higher wages; 19% higher, on average. The EPO and EUIPO should be congratulated for the production of this report and for their leadership on providing detailed statistical data and economic analysis of the socio-economic benefits of IP rights.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

- 2021 proposed amendments to Patent Law introducing a manufacturing, export, and stockpiling exemption to the current patent term restoration regime
- Government issued compulsory license in response to COVID-19 pandemic in 2020
- Current pre-grant patent opposition proceedings are characterized by long delays to patent prosecution
- Unclear the extent to which current RDP applies to large molecule products





Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>7.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>4.63</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.75
12. Expeditious injunctive-style relief and disabling of infringing content online	0.75
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	1.00
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	1.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.75
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.75</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.75
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.30</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.00
25. Regulatory data protection term	0.30

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

**Total Score:  
36.37**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Israel's overall score has increased from 72.57% (36.29 out of 50) in the ninth edition to 72.74% (36.37 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Patents, Related Rights, and Limitations

**7. Patent term restoration for pharmaceutical products:** Up until 2014, Israel did not offer patent restoration for pharmaceutical products. In 2014, following long discussions with the USTR regarding Israel's *Special 301* status and the development of a Memorandum of Understanding with the U.S. government, the Israeli Knesset amended the Patent Law, introducing a 5-year maximum term of restoration. In August 2021, the Israeli Ministry of Justice published draft amendments to the Patent Law, "The Patents Law (Amendment No. 14) (Increasing the Competitiveness of the Israeli Economy), 5721-2021." The proposed amendments seek to introduce a manufacturing, export, and stockpiling exemption to the current term restoration regime. The law refers to and is explicitly modelled on a similar carve-out introduced by the European Commission through Regulation 2019/933, which has been operational in the EU since 2019. As the Index has repeatedly pointed out, the most obvious side effect of the overriding of IP rights in the EU would be that the policy would be emulated by other economies. And that is exactly what is happening.

Last year Ukraine introduced a similar set of provisions and now Israel is set to do the same.

As these two examples show, instead of benefiting the European generics industry, the introduction of the EU's SPC exemption has simply ended up hurting Europe's research-based industry and has led to a global race toward the bottom in weakening global IP standards. In the Israeli case, the

exemption allows for the manufacture and export of a product for which a term of restoration has been granted. Manufacturing for the purposes of stockpiling is also allowed beginning within a period of six months of any granted patent term restoration expiring. This is a highly negative development and comes on the heels of the Israeli government's March 2020 authorization of a compulsory license for the antiviral drug lopinavir/ritonavir. As noted in last year's Index, when the license was issued, there was limited clinical evidence that lopinavir/ritonavir would be an effective treatment against COVID-19 and justify the use of such an extreme measure. Subsequent to the issuing of the license and importation of the generic product from India, there is also no publicly available information that suggests the generic product was ever distributed to Israeli COVID-19 patients.

Israel has made substantive progress over the last decade in strengthening its national IP environment for biopharmaceuticals and has become a model for other economies seeking to build their research-based industries. Following the 2010 Memorandum of Understanding with the U.S. government, Israel carried out significant improvements in key areas of biopharmaceutical IP protection, including in relation to regulatory data protection, patent term restoration, and legal remedies for infringement. As a result, Israel has become a global leader in biopharmaceutical R&D. Twenty years ago the innovative research-based biopharmaceutical sector consisted mainly of research organizations and early-stage companies focused on licensing out technologies, with little development and commercialization of biopharmaceuticals and biomedical technologies in Israel. Since the IP policy reform efforts, biopharmaceutical foreign direct investment into Israel has surged, growing over 250% between 2010 and 2014. As importantly, the IP reforms have not had a negative impact on the domestic generics industry. Contrary to common perceptions and received wisdom,



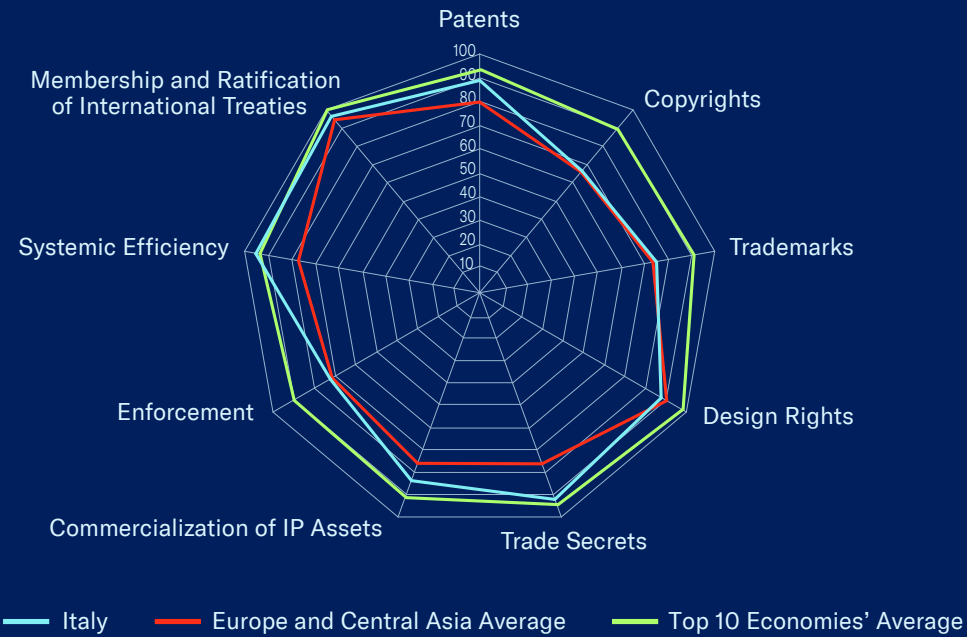
providing a supportive environment for innovative activities in the life sciences (including a robust IP regime) has not hurt Israel's generic drugs industry, including its national champion Teva.

Israel has fought hard to strengthen its national IP environment over the last ten years. The introduction of a manufacturing and export exemption to the existing patent term restoration regime would be a significant setback. Beginning in last year's Index, the methodology used to calculate the score on this indicator has changed. This indicator now consists of two distinct variables: first, the existence of a term of patent restoration for pharmaceutical products due to the prolonged research, development, and regulatory approval periods for such products; and second the existence of any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. Of the available score for this indicator, 0.75 is allocated to the existing term of protection compared to the current baseline rate of five years term restoration used in the U.S., EU, and Japan. The remaining 0.25 is allocated on the basis of a given economy providing any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. At the time of research, the proposed Israeli Patent Law amendments had not been passed into law. Should these legislative changes take place, Israel's score on this indicator will be reduced from 1 to 0.75.

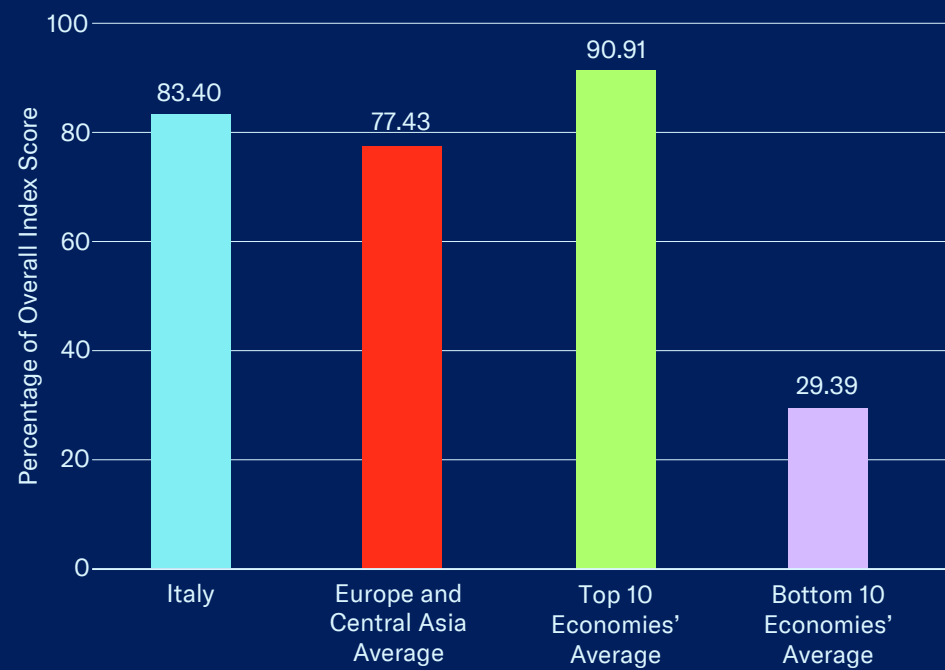
**9. Patent opposition:** Israeli patent law provides for a pre-grant form of opposition to pending patent applications. The examination of a patent application's eligibility for registration is conducted by the Israeli Patent Office within a time frame of 18 months from the filing date, upon which the application is published online for public scrutiny. Once published, a period of three months is granted during which third parties are permitted to file an opposition to the patent application.

Upon filing of a notification of opposition, a period of 13 months is granted to the opposing party to submit the causes, arguments, and supporting evidence for the opposition, and for responses by both parties. Thus, the examination of a patent application can be extended by an additional 16 months, not including the process of reexamination and/or judicial hearings. Regardless of the merits of any opposition filing, these generous timelines add a significant burden and delay to the patent prosecution process in Israel. Recognizing these deficiencies, in late 2016 the Ministry of Justice and Patent Office published a public call for comments and suggestions regarding its intention to review the existing pre-grant system and curtail these generous timelines. As noted at the time in the Index, this would be a very positive development and mark a potential shift and recognition by Israeli policymakers of the costs the pre-grant system imposes on inventors and Israeli consumers. In June 2021, a follow-up consultation to this proposal was published with new proposed regulatory amendments. While not in final draft regulatory form, overall, these proposed amendments recognize the excessive time taken in Israeli patent opposition proceedings and the need for clearer procedural demarcations and limits on the length of these proceedings. Instituting such changes would result in a score increase on this indicator. The Index will continue to monitor these developments in 2022.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.00</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>4.66</b>
10. Copyright (and related rights) term of protection	0.66
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	0.75
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.75
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.00</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.75
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.75</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.75
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.75</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	1.00

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

**Total Score:  
41.70**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Italy's overall score has increased from 83.15% (41.57 out of 50) in the ninth edition to 83.40% (41.70 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Copyrights, Related Rights, and Limitations

**11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking) and 12. Expeditious injunctive-style relief and disabling of infringing content online:** As noted over the course of the Index, Italy has historically been one of the more challenging EU Member States for rightsholders to effectively enforce their copyrights. The Italian Copyright Law, No. 633, provides for general exclusive copyrights and neighboring rights, and Decree 70/2003 on Electronic Commerce introduced rights and penalties specific to the online sphere. Law 67/2014 and Decree 28/2015 reduced or removed penalties for crimes that were punishable by five years' imprisonment or less, including the majority of copyright violations. Although exceptions were identified, the language on these was ambiguous and thus introduced uncertainty as to the penalties applicable for copyright infringement. As a result, online piracy has been a major problem in Italy, with wide access to illegal cyberlockers and linking sites operated outside Italy.

Estimates on copyright piracy have traditionally been high—estimates from the mid-2010s by the Sturza Institute placed music piracy at around 50% and film piracy at just under 40%—with enforcement efforts generally having lagged behind other European economies. While there are still significant challenges facing rightsholders in Italy, the last few years has seen a significant increase in enforcement activity through the introduction and

active use of injunctive-style relief mechanisms.

The EU's E-Commerce Directive (2000/31/EC), Articles 12-14, combined with the Copyright Directive (2001/29/EC), Article 8(3), enable a court or administrative authority to require ISPs to terminate or prevent copyright infringement by third parties using their services, and lay the basis for injunctive-style relief against infringing websites in all EU Member States (while still providing a safe harbor for ISPs). Several years' worth of case law from the CJEU (including Case C-610/15, Brien/Ziggo) suggests that this provision extends to disabling access to torrent websites, which are perceived by the CJEU as under the umbrella of a "communication to the public" per EU copyright law. Similarly, in Italy the Italian Communications Regulatory Authority (AGCOM) is empowered to receive complaints from rightsholders and order ISPs to remove or prevent access to illegally published content. The agency's legal remit has been strengthened over the course of the Index. Rule 490/13/CONS, adopted in October 2018, strengthens the agency's power to fight the most damaging online violations. The rule has allowed AGCOM to ask ISPs to implement notice and stay-down measures, and to issue preliminary injunctions that disable access to infringing websites within three days upon receiving notification from the rightsholder, including "dynamic injunctions" that address alias sites.

The necessity of these types of stay-down mechanisms have also been supported through several court rulings. For instance, in April 2018 (in a case involving Mondadori SPA and the main national ISPs), the Court of Milan defined the requirement to disable access to current and future domain names as "the most appropriate technical measures" to prevent copyright infringement. In addition, jurisprudence from Italian courts has established the responsibility of ISPs to remove access to copyright-infringing content



online when made aware of it (including the 2016 Court of Rome decision in *Break Media v. Reti Televisive Italiane*). Similarly, Article 195 of Decree Law 34 of May 2020 (*Decreto Rilancio*) expands AGCOM's powers to protect copyrighted works through social platforms and telephone or instant messaging platforms—violations that up until now had escaped the authority's jurisdiction.

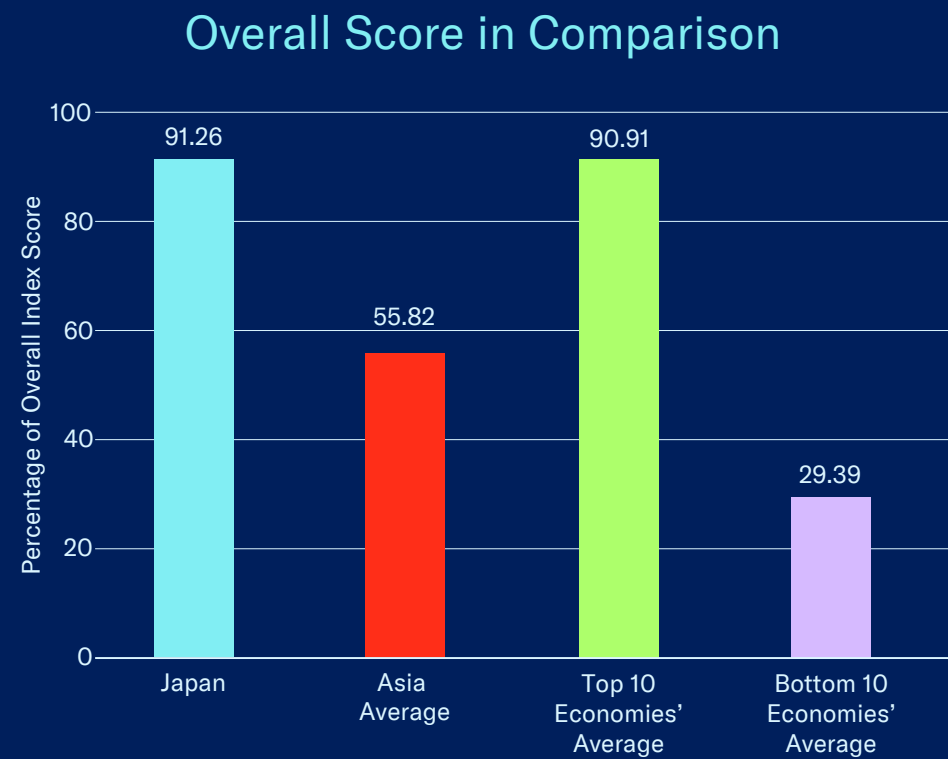
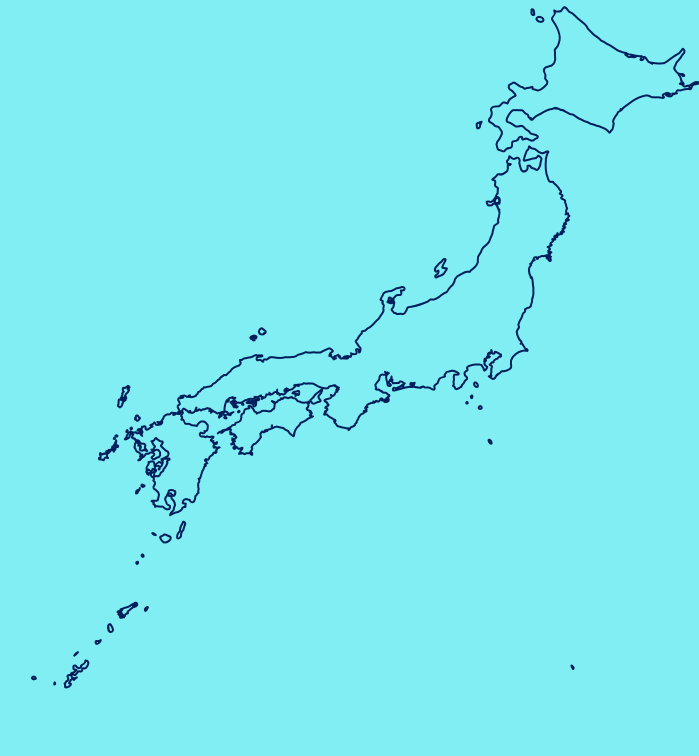
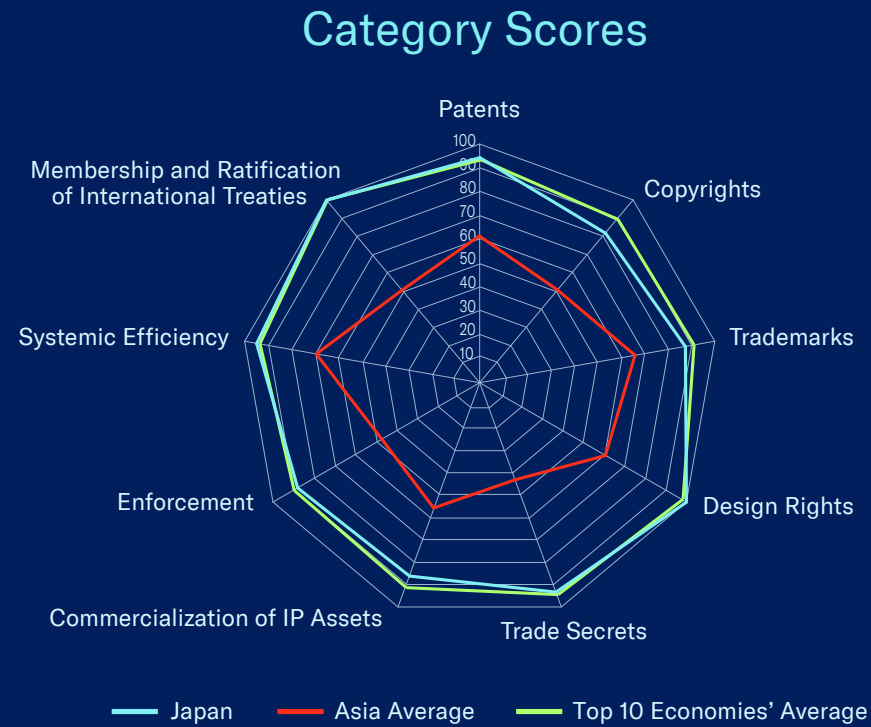
In the event of non-compliance with AGCOM's orders, an administrative fine can be issued worth from EUR10,000 up to 2% of the turnover achieved in the financial year closed prior to notification of the dispute. AGCOM has been an active user of these powers. As of October 2019, AGCOM had launched 1,123 compliance procedures; of these, 723 resulted in a compliance order and most of the others resulted in spontaneous removal of the disputed content. With respect to foreign-hosted sites, AGCOM has ordered the relevant domestic ISP ("conduit provider") to disable Italian users' access to infringing sites. The result has been a steady improvement in the Italian copyright environment. In a separate development, like many other EU Member States, Italy is currently in the process of transposing Directive 2019/790 on copyright and related rights in the Digital Single Market. In the fall of 2020, the Italian Senate (European Affairs Chamber) had approved a draft version of the law and transmitted it back to the government with comments. This was followed up in April 2021 with the promulgation of Law 53, 2021 (*Legge di delegazione europea 2019-2020*) delegating power to the government to issue implementing legislation for relevant EU laws, including legislative changes relating to the adoption of Directive 2019/790. Article 9 of this law provides fairly detailed instructions on what areas implementing legislation should focus on and define, including with respect to Article 17, the so-called "upload filter." At the time of research, no draft implementing legislative decree had been issued by the government.

### Systemic Efficiency

**43. IP-intensive industries, national economic impact analysis:** As has been noted in previous editions of the Index, various Italian government departments and agencies are engaged in understanding and measuring the impact IP rights have on economic activity. For example, the Italian Patent and Trademark Office (*Ufficio Italiano Brevetti e Marchi*) has sponsored several studies on the negative impact of counterfeiting. The Italian Senate and police have also looked at specific IP rights and sectors, attempting to quantify the negative impact of counterfeiting and piracy. This has been done for the counterfeiting of agricultural and foodstuff products.

As a Member State of the European Union and contracting party to the European Patent Convention, the Italian government also takes part in the multitude of research efforts conducted by European institutions. A whole swathe of 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 economics of IP-intensive industries include the EPO, EUIPO, EUROSTAT, and the European Commission. The latest such study is the 2019 *IPR-Intensive Industries and Economic Performance in the European Union* published by the EUIPO and EPO. This study found that IP-intensive industries contributed an estimated 46.9% of Italian GDP, on average, in the time period 2014-16. Similarly, with respect to employment, an estimated 31.5% of the Italian labor force worked in IP-intensive industries. This important work continued in 2021 with the release of *Intellectual Property Rights and Firm Performance in the European Union*. Co-produced by the EPO and EUIPO, this report examines the relationship between IP rights and rates of economic activity at the firm level. Overall, the report finds that European businesses that own at least one registered form of IP right (patents,

designs, or trademarks) have, on average, 20% higher revenues per employee than businesses with no registered IP portfolio. Similarly, the report found that firms with registered IP rights also pay higher wages—19% higher, on average. The EPO and EUIPO should be congratulated for the production of this report and for their leadership on providing detailed statistical data and economic analysis of the socio-economic benefits of IP rights.



## Key Areas of Strength

- Continued strong copyright enforcement efforts in 2021
- 2020 amendments to Copyright Act continue to strengthen copyright environment
- Design Act amendments came into effect in 2020, increasing term of protection
- 2019 copyright amendments strengthen TPM laws and increase term of protection
- Global leader with respect to targeted administrative incentives for the creation and use of IP assets for SMEs
- Economic Partnership Agreement with EU—agreement includes a substantial IP chapter
- Japan has signed and acceded to all international IP treaties included in the Index
- Strong, sophisticated national IP environment in place with relevant IP rights and protection available for all major IP rights categories

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>5.74</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	1.00
12. Expeditious injunctive-style relief and disabling of infringing content online	0.50
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	1.00
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	1.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	1.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	1.00
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	1.00
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>2.00</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1.00
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.80</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	0.80

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

**Total Score:  
45.63**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Japan's overall score has increased from 91.12% (45.56 out of 50) in the ninth edition to 91.26% (45.63 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Copyrights, Related Rights, and Limitations

**11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights:** As has been noted in previous editions of the Index, online piracy and copyright infringement (in particular of Manga and Anime) are of growing concern in Japan. Over the last decade, the Japanese government has recognized this growing threat and implemented a range of important reforms, with many copyright laws strengthened and greater resources put into enforcement and educational activities. Examples include the Manga-Anime Guardians Project (an anti-piracy enforcement and educational coalition of industry, content creators, and the Japanese Ministry of Economy, Trade, and Industry, [METI]); criminal enforcement against online infringement; and legislative amendments in 2020, which, first, introduced criminal penalties and sanctions for the hosting, operation, and linking of “leech” websites and, second, made downloading all forms of copyright infringing content, not just audio and film, an offence. These positive efforts continued in 2021. Most notably, Japanese police made several arrests in relation to the infringement of copyright through so-called “fast movie” editing. These “fast movies” are condensed versions of feature films that have been edited to a shorter format of about 10-15 minutes in length. This editing and the subsequent

sharing online and commercial exploitation of this content is done without the consent, knowledge, or approval of the relevant rightsholders of the original content. It is a growing area of infringement in Japan, and the Japanese authorities should be commended for taking such decisive action. The Index will continue to monitor these efforts in 2022.

### Commercialization of IP Assets and Market Access

**29. Direct government intervention in setting licensing terms:** As discussed in previous editions of the Index, an area of growing interest to Japanese industrial and competition policy has been the centrality of Standard and Essential Patents (SEPs) to future innovation and economic growth. In 2017, METI issued *The Intellectual Property System for the Fourth Industrial Revolution*. This report examined future challenges and proposed potential adjustments to the IP framework for technological developments that include the Internet of Things, artificial intelligence, robotics, and other cutting-edge industries that are loosely labeled as a “Fourth Industrial Revolution.” One key area discussed in the report was licensing terms and conditions for SEPs. Specifically, the report identified that the emergence and broader use of these new technologies will result in a greater utilization of SEPs as well as a concomitant increase in the number of potential legal disputes that could hold up the development and use of these new technologies and industries. The report rightly noted that the complexities and costs of negotiations and potential legal battles will increase as more fields utilize and depend on these SEPs and the underlying technologies. Addressing this issue, the report proposed the implementation of two new types of administrative procedures aimed at expediting resolutions and reducing litigation costs in patent disputes. Under the first procedure, in cases where no agreement between the parties was reached, the amount of royalties would be



determined by an administrative committee appointed by the Japanese Patent Office (JPO). Under the second pathway for private companies, a dedicated organization would manage the disputes where the parties could not reach an agreement, although the specifics for this process were unclear.

Many rightsholders expressed deep concern over this policy and its potential for direct government intervention and management of this negotiating process. To address these concerns and settle on a finalized comprehensive government policy on the issue, the JPO released the document *Guide to Licensing Negotiations Involving Standard Essential Patents* in 2018. This *Guide* is a thorough and detailed discussion of the complexities of the negotiation process and the legitimate challenges that face both the implementer and the SEP holder. Critically, the *Guide* is not prescriptive and does not provide a set formula for how negotiations should proceed or how fair, reasonable, and non-discriminatory (FRAND) terms and royalty rates should be set: “This *Guide* is not intended to be prescriptive, is in no way legally binding, and does not forejudge future judicial rulings. It is intended to summarize issues concerning licensing negotiations as objectively as possible based on the current state of court rulings, the judgment of competition authorities, and licensing practices, etc.” Specifically, with respect to determining FRAND rates, the *Guide* wisely recognizes that there is no magic formula and each negotiation is separate and unique: “This *Guide* presents factors to be considered when determining a reasonable royalty, not ‘recipes’ which can be used to automatically calculate an appropriate royalty... Given the diversity of SEP licensing negotiations and of the circumstances in which the parties to such negotiations are placed, a solution has to be worked out in each particular case.”

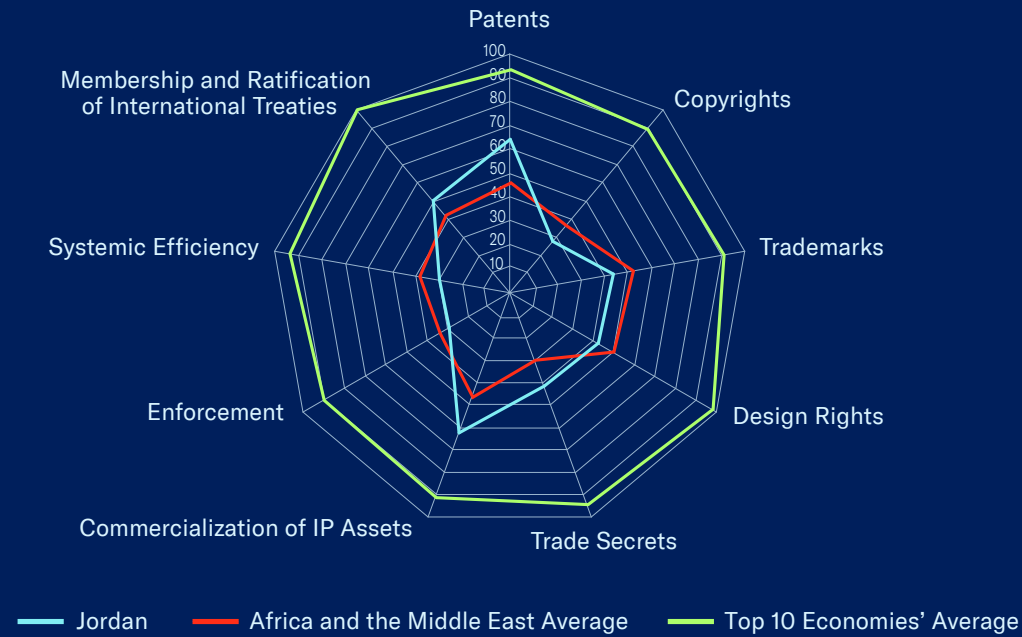
The Japanese government's work in this field continued in 2021. Beginning in March, METI's Competition Enhancement Office and the

Intellectual Property Policy Office convened a “Study Group on Licensing Environment of Standard Essential Patents” consisting of external experts and industry representatives who met for a series of meetings. In July, the group published the results of these discussions in an interim report. Like the preceding work by the JPO, this report rightly points out the growing importance of SEPs to future economic activity—both globally and in Japan. The report also reiterates the view that as increasing numbers of products and services are based around technologies, such as the Internet of Things, they will increasingly rely on SEPs to function. With this growth in use, the number of disputes is also likely to rise. Given this reality, the report calls for greater transparency in SEP negotiations, the provision of pre-set negotiation frameworks (termed “rules on good faith negotiations”), the potential use of patent pools, and greater use of joint licensing.

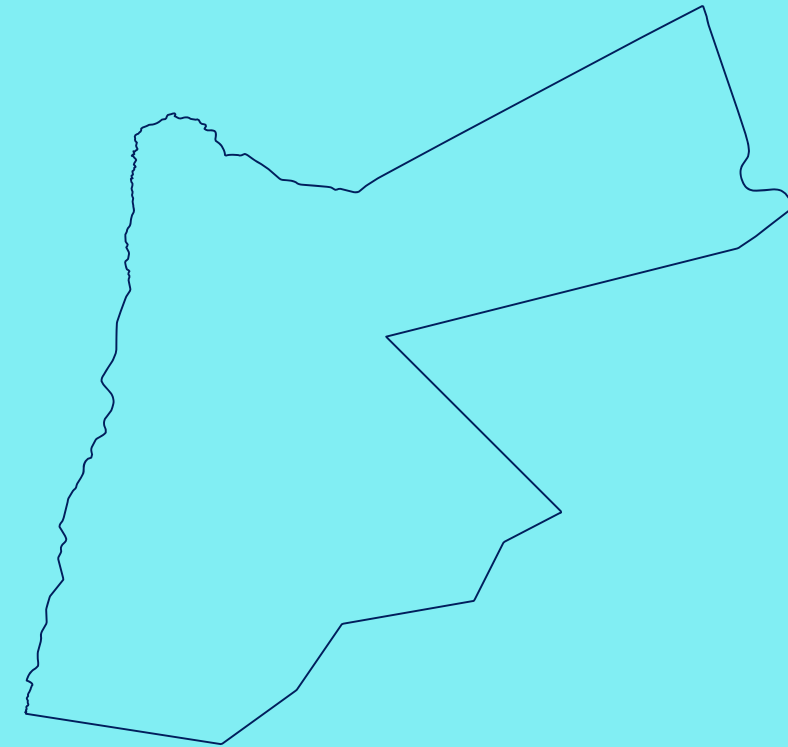
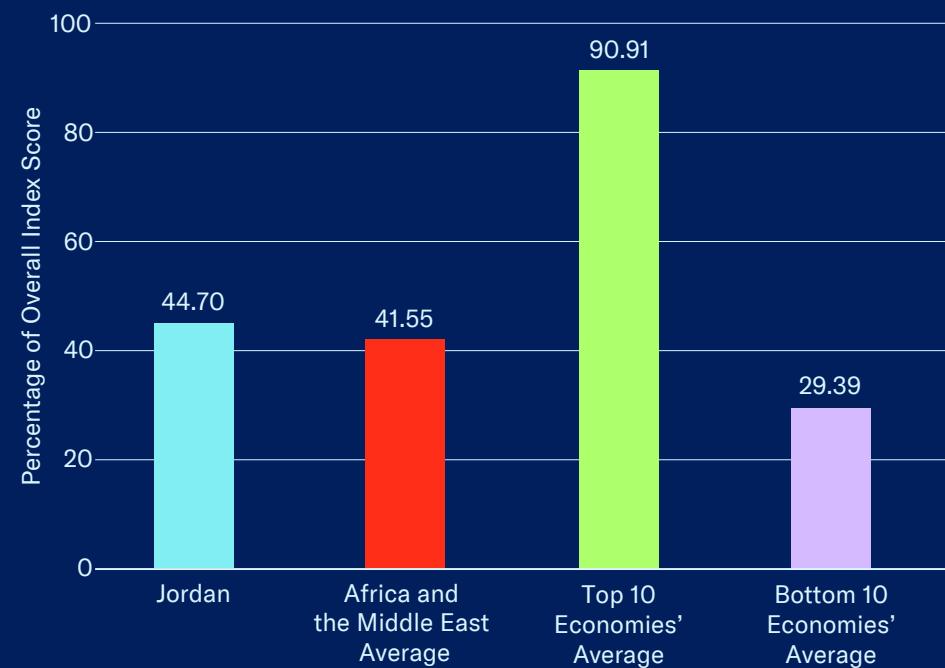
As the Index noted in 2018 in connection with the JPO's publication of the *Guide to Licensing Negotiations Involving Standard Essential Patents*, METI and the JPO should be commended for rightly identifying the importance of SEPs to future economic activity, global growth, and innovation. However, this is an evolving field of IP policy and jurisprudence for a subject matter that is deeply complex. As such, it is critical that policymakers—whether in Japan or elsewhere—tread carefully and refrain from being overly prescriptive. It is clear that there are real challenges to the SEP licensing process and that it is likely these challenges will only intensify in the years to come. The right solutions are less clear. The Index will continue to monitor these developments in 2022.



## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>5.75</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	1.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.94</b>
10. Copyright (and related rights) term of protection	0.44
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.85</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.25</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

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

**Total Score:  
22.35**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Jordan's overall score has increased from 44.53% (22.26 out of 50) in the ninth edition to 44.70% (22.35 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

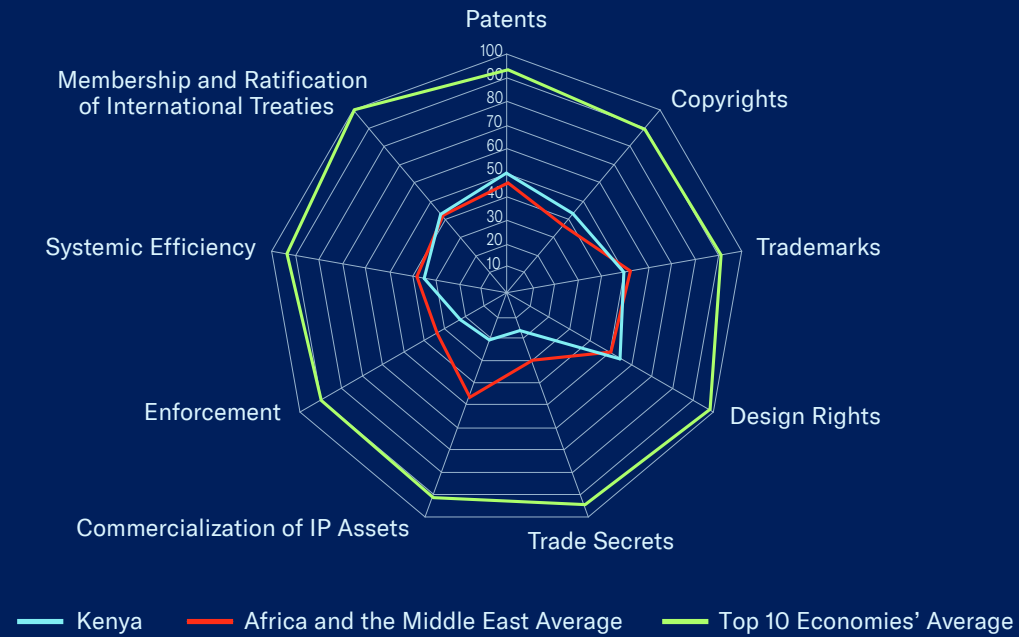
### Commercialization of IP Assets and Market Access

**27. Barriers to technology transfer:** As noted in past editions of the Index, while technology transfer activities in Jordan remain fairly rudimentary, there have been notable efforts in the last few years to improve both the capacity for technological development and commercialization. For instance, there are some positive examples of transfer activities taking place through EU-supported initiatives, such as the ongoing "Support to Research, Technological Development, and Innovation program" (now in its second phase). The program seeks to increase the "contribution of Jordan's research and technological development and innovation sectors to Jordan's economic growth and employment." It focuses on four key areas: water, energy, health, and food. Reports suggest the program has had a positive impact on technology transfer and commercialization, with increased patenting activity as a result of the program.

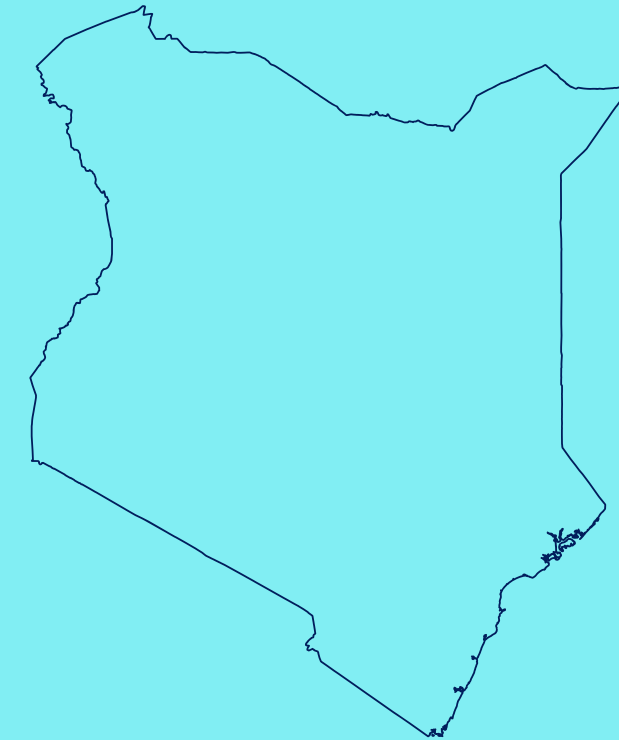
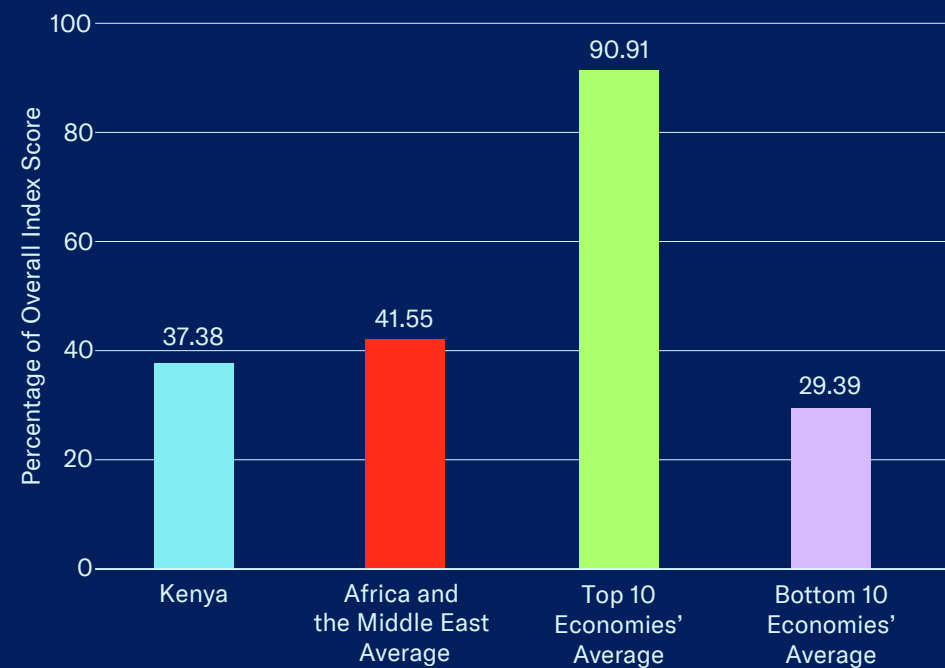
There has also been an increase in the number of universities and research institutes with functioning technology transfer offices (TTOs). This includes a network of TTOs including the University of Jordan, Jordan University for Science and Technology, Yarmouk University, Mut'ah University, Jerash University, and the National Centre for Agricultural Research and Extension. There are also 16 WIPO Technology and Innovation Support Centers operational in Jordan. These centers provide support services and advice to prospective inventors and creators, often within a university setting.

These positive developments continued in 2021. To begin with, the Jordanian government is in the process of a wholesale digitalization effort encompassing both private sector reforms and institutional changes within the manner in which public services and policies are developed and delivered. The Ministry of Digital Economy and Entrepreneurship has launched several reform programs under the umbrella of the "Jordan's Growth Incentives Program." Major programs include the "Youth, Technology and Jobs Project" and the "Jordanian Digital Transformation Strategy 2020." Improving the technology transfer and commercialization environment is a key component of these programs. As part of the reform effort, in 2021 the ministry supported the creation of several technology incubators, partnering with local non-governmental organizations (NGOs) and private sector companies. The Index will continue to monitor these developments in 2022.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>4.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.75
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>3.03</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.00</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>1.25</b>
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>1.56</b>
32. Physical counterfeiting rates	0.30
33. Software piracy rates	0.26
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.00
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.25
<b>Category 8: Systemic Efficiency</b>	<b>1.75</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.50
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>3.00</b>
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
18.69**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Kenya's overall score has increased from 37.25% (18.62 out of 50) in the ninth edition to 37.38% (18.69 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Area of Note

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

### Commercialization of IP Assets and Market Access

**26. Barriers to market access:** The Kenyan economy is generally free, non-discriminatory, and open to foreign investment. There are no general restrictions on foreign ownership or localization and local content requirements. There are foreign ownership restrictions in the telecommunications, mining, and construction sectors of the economy that indirectly erect a localization barrier through a local partnership requirement, but more broadly, the sharing or divulging of IP and transfer of proprietary technology in exchange for market access are not part of the general policy environment or required by Kenyan law.

With respect to data localization, there has historically not been a general data protection

or localization policy in place. This may now be changing. To begin with, the 2019 Data Protection Act included potential restrictions on the movement of personal data accumulated in Kenya. Sections 48, 49, and 50 of the act outline a host of conditions that must be met for data to be transferred outside of Kenya. Personal data may only be transferred out of Kenya under specific circumstances and to jurisdictions "with commensurate data protection laws." Under Section 49, the relevant Kenyan regulatory authority (the "Data Commissioner") has broad powers to examine and question the nature and necessity of any foreign data transfers. Likewise, Section 50 reserves broad powers to the Kenyan government to effectively force the localization of data in Kenya: "The Cabinet Secretary may prescribe, based on grounds of strategic interests of the state or protection of revenue, certain nature of processing that shall only be effected through a server or a data centre located in Kenya." For rightsholders across many different industries and sectors, these barriers to digital trade raise serious questions and concerns.

The ICT and internet revolutions have fundamentally changed how human beings interact socially and economically. In virtually all industries, business and economic interaction is today being shaped by the collection of data and digital technologies. These technologies are allowing companies across all business sectors and public and private research organizations to collect and use greater levels of data and information than ever before in so-called "big data." Combined with increased computing capacity and the application of new technologies (such as artificial intelligence and machine learning) that allow us to analyze and better understand data collected, it is possible to make significant discoveries and breakthroughs in virtually any area of research and human socio-economic activity. Cross-border flows of data are ingrained in countless services relied on by consumers, with numerous digital,



automated, and virtual services relying on the seamless movement and storage of data in various locations. Unfortunately, draft regulations released by the Office of the Data Protection Commissioner in 2021 do not fully address these concerns.

On a positive note, Section 40 of the Data Protection (General) Regulations 2021 states that any restrictions and requirements in relation to cross-border data transfers may not “impose a restriction on trade.” Yet other parts of the draft regulations affirm the localization requirements contained in the primary statute. For example, Section 25 outlines a range of broad categories under which data processing must be carried out in Kenya. In addition to data processing activities in relation to “actualizing a public good,” this also includes processing in relation to electronic payments and “processing health data for any other purpose other than providing health care directly to a data subject.” Mandating the local storage and processing of data is likely to lead to fewer digital services being available in Kenya and less innovation in many critical sectors, including, for example, medical research. Public policies relating to national data management should recognize this reality and be formulated accordingly. The Index will monitor these developments and the extent to which these proposed regulations seek to mandate the localization of data and act as a barrier to international data transfers.

## Enforcement

**37. Effective border measures:** As has been noted in previous editions of the Index, rightsholders have historically faced significant challenges in enforcing their rights at the border in Kenya. On the legislative side, there are several layers of national and regional law and enforcement organs that govern customs and anti-counterfeiting activities in Kenya. Specifically, Kenya has its own national laws, regulations, and levels of application, but anti-counterfeiting and customs activities are also

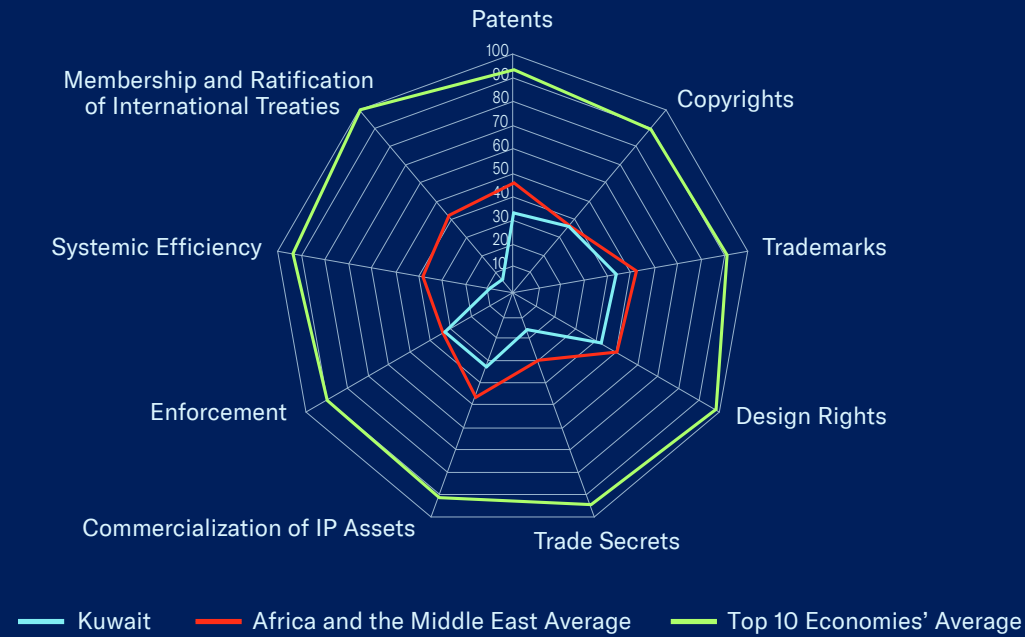
governed by its regional commitments. Kenya is a party to the East African Community (EAC), a regional group consisting of six East African states. Since 2005, the EAC has had a Customs Union in place that is guided by the East African Community Customs Management Act. The end result has been a level of uncertainty and lack of clarity on how relevant statute and enforcement agencies interact.

Since 2019, effective authority on all anti-counterfeiting activities in Kenya has, for all intents and purposes, been transferred to the Anti-Counterfeit Authority (ACA). The ACA has broad authority over anti-counterfeiting enforcement activity throughout Kenya, including border enforcement. Section 23 of the Anti-Counterfeit Act gives designated inspectors broad and strong executive powers, including powers of seizure, inspection, and detainment of any suspected goods or activity pertaining to counterfeiting. Section 32 of the act outlines what constitutes an offence. Sub-section (f) states that it is an offence to “import into, transit through, tranship within or export from Kenya, except for private and domestic use of the importer or exporter as the case may be, any counterfeit goods.” The 2019 legislative amendments to the Anti-Counterfeit Act—the ACA’s governing legislation—clarifies the powers that inspectors will be able to exert within the context of border enforcement and importation, provides the power of *ex officio* authority, and aligns Kenya’s statute with the East African Community Customs Management Act.

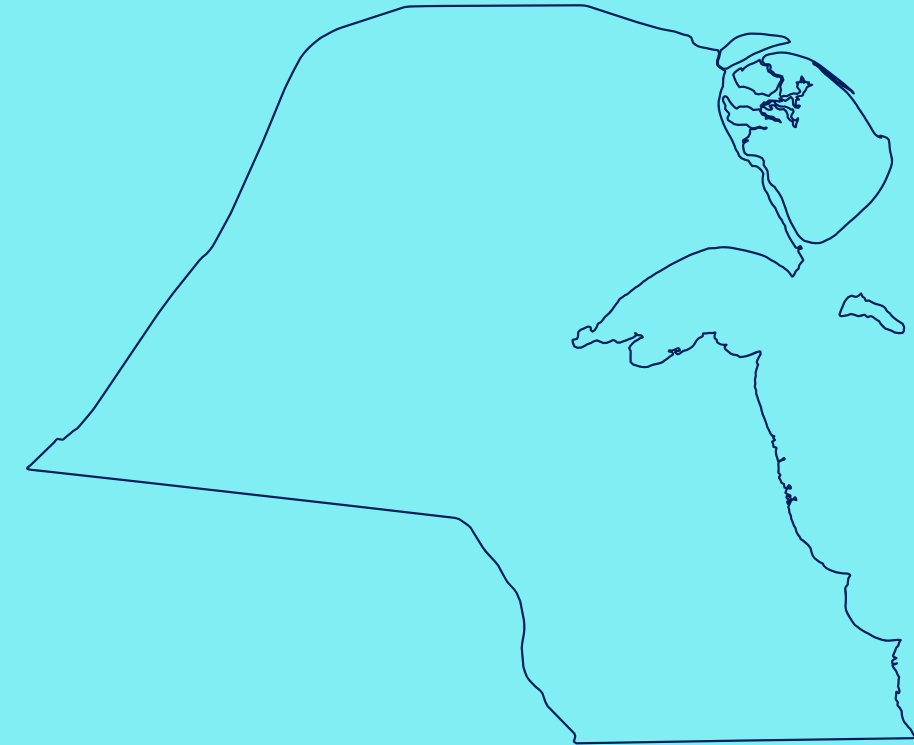
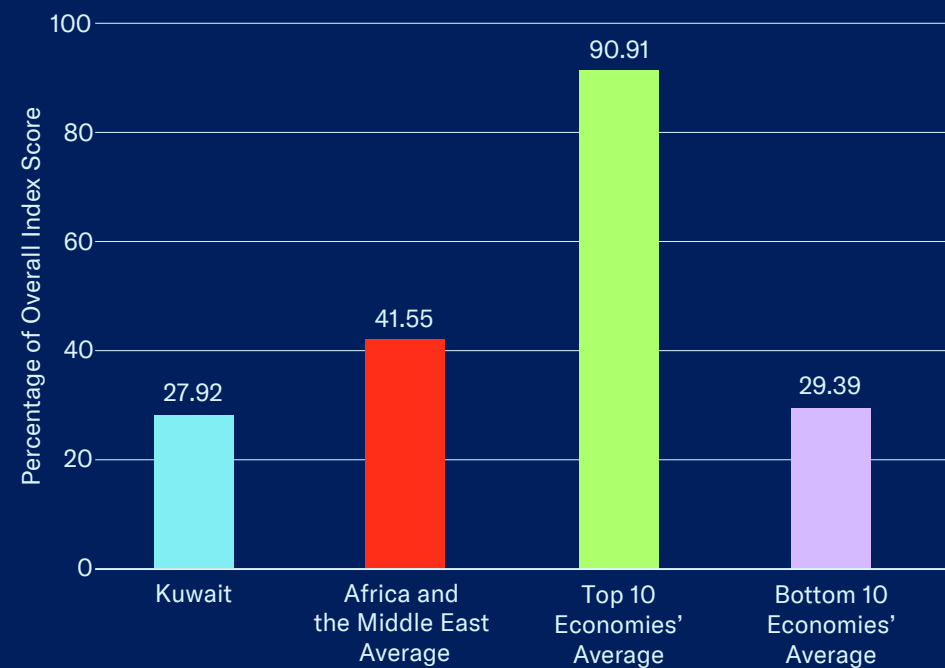
The 2019 amendments also allowed for the recording of IP rights with the ACA. In 2021, implementing regulations were published that outline the process and responsibilities that come with these rights. Specifically, under the Anti-Counterfeit Amendment Regulations (2021), legal notices 117 and 118, relevant IP rights in relation to imported goods shall be recorded with the ACA. It is a positive development that rightsholders are now able to record their relevant IP rights

with Kenyan anti-counterfeiting authorities. It remains to be seen whether the enforcement of these rights will become more effective. As noted in past editions of the Index, the Anti-Counterfeit Act and Authority as in the past been criticized for a lack of effective implementation and action of its anti-counterfeiting mandate. The Index will continue to monitor these developments in 2022.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- Basic IP framework in place
- Participant in regional patent and trademark harmonization efforts through the Gulf Cooperation Council (GCC)

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.00</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	0.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.53</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.85</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

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

**Total Score:  
13.96**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Kuwait's overall score has increased from 27.86% (13.93 out of 50) in the ninth edition to 27.92% (13.96 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Area of Note

As noted last year, in January 2021, the Gulf Cooperation Council (GCC) Patent Office announced that following the 41<sup>st</sup> Session of the Supreme Council and amendments to the Patent Regulation, the Patent Office would no longer accept patent applications. The announcement was unexpected, as the GCC patent application route had been operational for more than two decades. This was followed up with an announcement by the GCC Secretariat in April 2021. Under this announcement, new amendments to the GCC Patent Regulation were issued whereby a new regional application pathway would replace the old Regulation. Under this new proposed system, the regional GCC patent appears to have been abolished. Instead, future patent applications will be routed through individual GCC member states. At the time of research, no further announcements had been made and it remained unclear, first, what would happen to applications filed prior to 2021, and, second, how this new system would work in practice. Statistics on patents granted, published on the GCC Patent Office's website, suggest that no patents had been granted by the Office in 2021. The Index will continue to monitor these developments in 2022.

In 2016 the Kuwaiti Patent Office stopped accepting national patent applications. This followed the implementation of Law No. 71 2013 through implementing Regulations 115/2016. The two pieces of legislation in effect repealed the old patent law and replaced it with the patent regime in place under the GCC. With the changes to the

GCC Patent Office, news reports suggest that the Kuwaiti Patent Office (under the Trademark Control Department, Ministry of Commerce) has resumed operations and is processing new applications, and several patents were granted in 2021. The Index will continue to monitor these developments in 2022.

### Copyrights, Related Rights, and Limitations

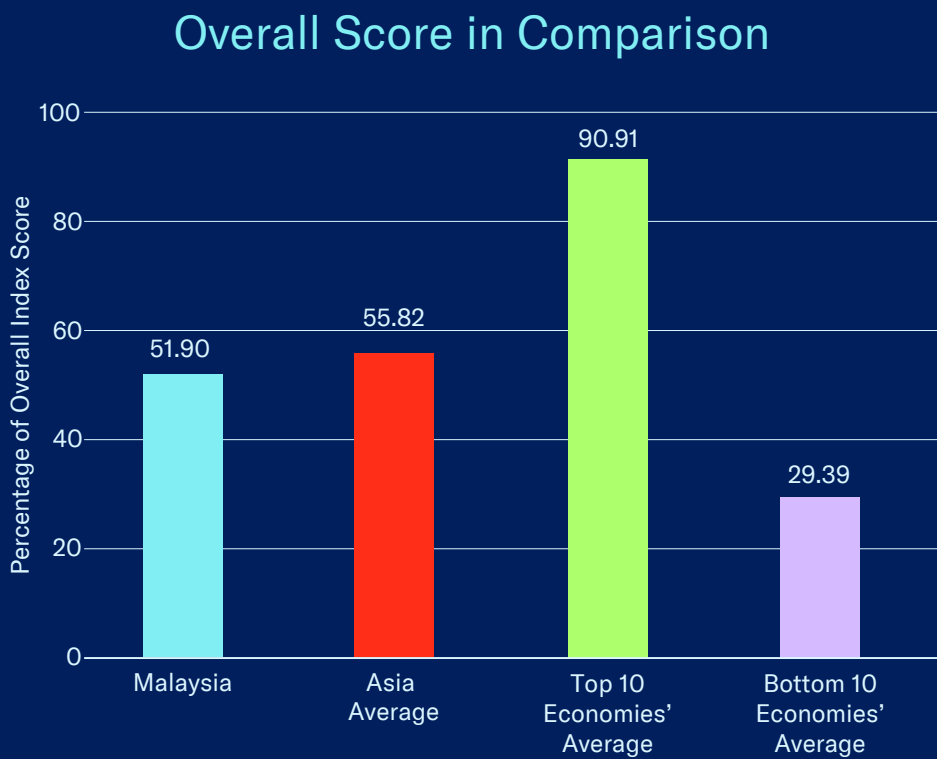
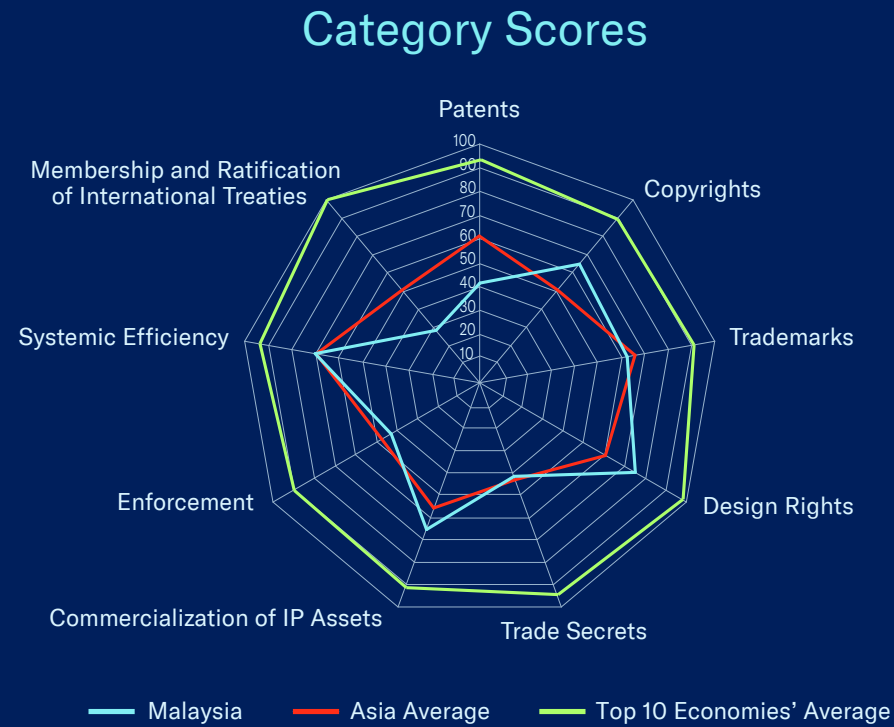
**11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 12. Expeditious injunctive-style relief and disabling of infringing content online:** As noted in previous editions of the Index, in 2019 a new copyright law, Law 75 on Copyright and Related Rights, was passed. Law 75 makes some potentially important changes to Kuwait's copyright regime with potential new avenues for enforcement. Specifically, Article 36 grants a broader type of administrative enforcement authority to designated officials compared with the provisions in the older Copyright Law. No implementing regulations have been published, and it remains unclear how these enforcement powers will be administered and applied.

Kuwait's National Library administers the national system of copyright and now also offers rightsholders the option of filing copyright infringement complaints directly with the library. This administrative enforcement option comes on top of the existing mechanism through the Communications and Information Technology Authority (CITRA). Since 2014-15 new laws relating to telecommunications and cybercrime have invested vast powers in CITRA to oversee and regulate the online space. Under Law No. 37 of 2014 on the "Establishment of Communication and Information Technology Regulatory Authority," CITRA has the power to suspend operating licenses and individual accounts. CITRA offers



a dedicated web portal where online requests for the disabling of websites can be requested, including on the basis of IP infringement. There is no publicly available information showing the amount of infringing website access that has been disabled or the extent to which these enforcement mechanisms act as a deterrent against copyright infringement. News reporting and published reports by the U.S. State Department suggest that the Kuwaiti authorities have disabled access to a variety of web content, including sites that link or provide access to copyright-infringing material. The next step would be for relevant Kuwaiti authorities to institutionalize this route of administrative enforcement through the issuing of more detailed guidelines or a process note. The Index will continue to monitor these developments in 2022. Should the option of administrative enforcement through the National Library and CITRA become a practical and effective way for rightsholders to enforce their copyrights, it would result in a potential score increase on indicators 11 and 12.





## Key Areas of Strength

- Strong enforcement efforts against infringing set-top boxes in 2021, including a landmark court ruling by Intellectual Property High Court
- 2020 Trademark Act amendments strengthen enforcement environment
- Generous R&D and IP-specific tax incentives in place
- Intellectual Property Corporation of Malaysia has PPH agreements in place with both the EPO and JPO
- Strong focus by Malaysian government on IP as a commercial asset and technology transfer

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.75</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>4.53</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.75
12. Expeditious injunctive-style relief and disabling of infringing content online	0.75
13. Availability of frameworks that promote cooperative action against online piracy	0.75
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.75
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.50</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.25</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>3.92</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>3.00</b>
32. Physical counterfeiting rates	0.51
33. Software piracy rates	0.49
34. Civil and precedural remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>3.50</b>
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.75
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>2.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
25.95**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Malaysia's overall score has increased from 51.61% (25.80 out of 50) in the ninth edition to 51.90% (25.95 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Area of Note

In February 2021, the Malaysian government announced the *Malaysia Digital Economy Blueprint*, the “MyDigital” program. This ambitious roadmap for reforms touches on all facets of the Malaysian economy and society. The government has rightly recognized the massive socio-economic changes that the digital transformation is bringing to economies around the world, including Malaysia. The ICT and internet revolutions have fundamentally changed how human beings interact socially and economically. In virtually all industries, business and economic interaction is today being shaped by the collection of data and digital technologies. These technologies are allowing companies across all business sectors and public and private research organizations to collect and use greater levels of data and information than ever before in so-called “big data.” Combined with increased computing capacity and the application of new technologies (such as artificial intelligence, machine learning, robotics, the Internet of Things, and 3-D printing) that allow us to analyze, better understand, and use data collected, there is the possibility to make significant discoveries and breakthroughs in virtually any area of research and human socio-economic activity. This is a societal transformation that was already underway before the pandemic. As the “MyDigital” program correctly notes, the effect of the COVID-19 pandemic and the accompanying changes in socio-economic behavior have led to an acceleration of this digital transformation.

### Copyrights, Related Rights, and Limitations

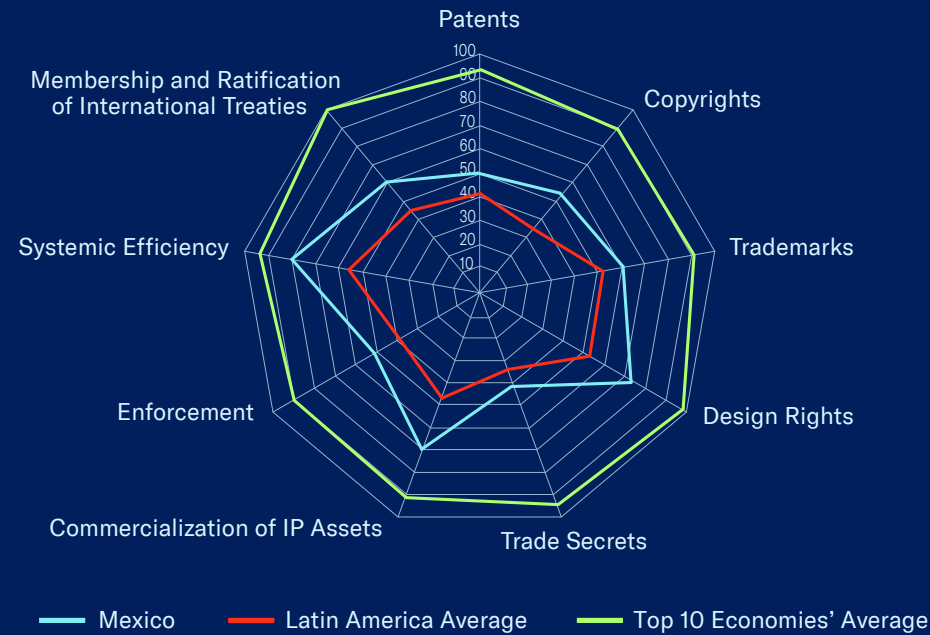
**11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 12. Expeditious injunctive-style relief and disabling of infringing content online:** As in many other economies benchmarked in the Index, there has been an explosion in the growth and use of internet-based applications providing infringing content to set-top boxes in Malaysia. A 2019 survey commissioned by the Asia Video Industry Association's Coalition Against Piracy (CAP) found that a quarter of those surveyed owned a set-top box that could be used to access and stream illegal content. The survey also found that 60% of those who purchased the set-top box with the intent of streaming illicit content cancelled all or some of their legally purchased content and television subscriptions. In response, Malay rightsholders and policymakers have acted in different for a. The disabling of access to infringing content has played a key part in the government's response.

Both the Malaysian Communications and Multimedia Commission (MCMC) and the Ministry of Domestic Trade and Consumer Affairs have broad authority to censor all manner of content in Malaysia, including that suspected of infringing copyright. Data released by the MCMC suggests that between 2008 and 2016, access to close to 12,000 websites (11,684) had been disabled. Most of these sites were pornographic in nature, with a minority relating to other offences, including copyright infringement. In 2019 the MCMC began targeting websites that provide infringing content through set-top boxes and disabled access to 246 such websites. These positive efforts continued in 2021. To begin with, criminal enforcement has increased against the sales and promotion of

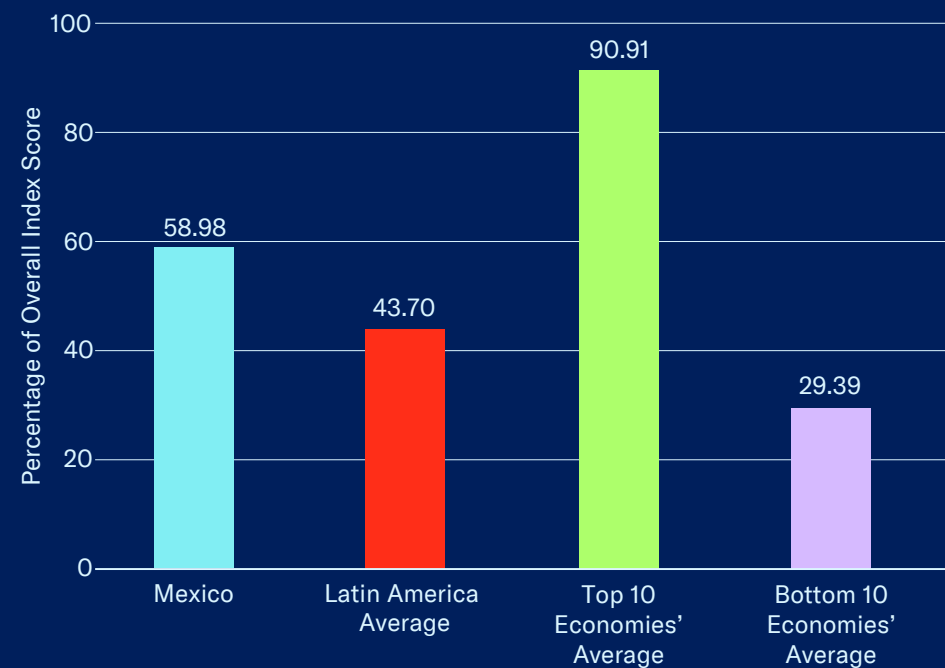


illicit set-top boxes, with the first ever successful criminal prosecution taking place in February 2021. Moreover, in May 2021, in a civil ruling, the specialist Intellectual Property High Court in Kuala Lumpur held that the sale, promotion, or dissemination of set-top boxes that allow users to illicitly stream infringing content was a violation of copyright. The case is a potential landmark decision, as it may pave the way for further legal action and allow rightsholders to enforce their copyright more effectively. The Index will continue to monitor these developments in 2022.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>4.49</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.00
4. Plant variety protection, term of protection	0.74
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.25
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.50
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>3.79</b>
10. Copyright (and related rights) term of protection	0.79
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.75
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.50</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.25</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.25

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>4.17</b>
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>3.54</b>
32. Physical counterfeiting rates	0.53
33. Software piracy rates	0.51
34. Civil and precedural remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	1.00
36. Criminal standards including minimum imprisonment and minimum fines	0.75
37. Effective border measures	0.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.25
<b>Category 8: Systemic Efficiency</b>	<b>4.00</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>4.25</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
29.49**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Mexico's overall score has increased from 58.25% (29.13 out of 50) in the ninth edition to 58.98% (29.49 out of 50) in the tenth edition. This reflects score increases on indicators 32 and 43.

### Patents, Related Rights, and Limitations

**5. Pharmaceutical-related patent enforcement and resolution mechanism:** While a 2003 Presidential Decree introduced a basic system for early adjudication of disputes relating to biopharmaceutical patent infringement and the marketing of a follow-on product, as noted over the course of the past ten editions of the Index, this has never represented an effective or transparent pathway because the patent holder receives no notification of infringing issues and is not formally involved in the adjudication process. Furthermore, the regulatory enforcement pathway has historically been limited to substance and formulation patents only; use patents have not been included. In practice, resolution of patent disputes is delayed and often ineffective, whether through administrative or judicial routes. Industry sources suggest that historically where cases of infringement have been brought, substantial delays at both the administrative and judicial levels have hindered rightsholders' ability to secure damages effectively (reaching a total of around ten years on average). Some reform proposals have been introduced over the course of the Index, but they have failed to sufficiently address the shortcomings of the existing system with some instead compounding the existing deficiencies.

In 2019 modifications to the Health Law were proposed by the Mexican Senate. Under the proposed system, only one patent could be listed per each new chemical entity, and patents for biologics would not be considered. If adopted, this reform would be a highly negative move by the

Mexican authorities that would further devalue the existing linkage regime and rightsholders' ability to enforce their patents. Mexico is both through the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) and the USMCA bound to introduce a more comprehensive and practical system of biopharmaceutical patent enforcement. Article 20.50 of the USMCA provides a clear requirement that the contracting parties provide "a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use...[and] adequate time and sufficient opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies."

As noted last year, Mexico's revised Industrial Property Law, which implements the USMCA, does not contain any legal provisions relating to the existing linkage regime. Transitional paragraph (5) of the law simply states that the Mexican IP authority, IMPI, shall "participate" with the Mexican drug regulatory authority COFEPRIS "in the establishment of the corresponding technical collaboration mechanism for inventions in the field of allopathic drugs." At the time of research, no new regulations or laws had been passed. Local reports suggest that relevant Mexican authorities are considering introducing new secondary legislation. Any enacted changes to Mexico's biopharmaceutical IP environment should incorporate the requirements of the USMCA and address the deficiencies in the current system, including uncertainty with respect to which method of use patents have been covered. The USMCA's language on the requirements for an effective pharmaceutical-related patent enforcement and resolution mechanism is quite clear. Full implementation and application of these



requirements in Mexican law and practice will result in a score increase on this indicator. The Index will continue to monitor these developments in 2022.

### 7. Patent term restoration for pharmaceutical products:

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

Early 2021 saw what may become an important and precedent-setting development for rightsholders. In January, the Mexican Supreme Court held that under the provisions of North American Free Trade Agreement (NAFTA) and the old Industrial Property Law, patent rightsholders are eligible to a minimum period of protection of 17 years from the granting of a patent. Under this ruling, rightsholders should be compensated for undue delays by the relevant administrative authorities. This is a potentially positive development and would help ensure rightsholders are able to in practice benefit from their statutorily granted period of exclusivity. This ruling aside, as noted

last year, the USMCA is clear on the requirement that contracting parties should make available a period of restoration due to delays caused by the market review process for biopharmaceuticals. Full implementation and application of these requirements in Mexican law and practice will result in a score increase on this indicator. The Index will continue to monitor these developments in 2022.

### Systemic Efficiency

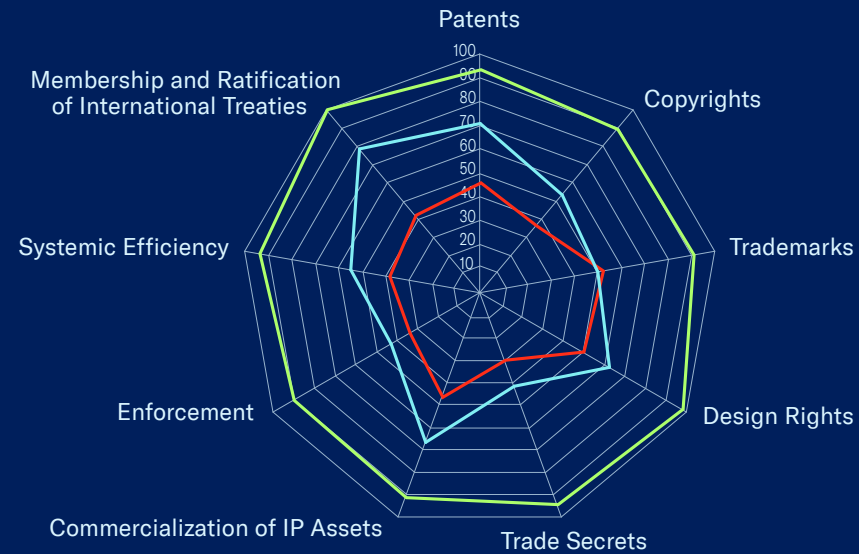
#### 43. IP-intensive industries, national economic impact analysis:

As noted in previous editions of the Index, several Mexican government agencies measure and examine the relationship between IP rights and economic activity. For example, since 2013 the Mexican National Institute of Statistics and Geography (INEGI) has issued an annual bulletin estimating the value of IP products in the Mexican economy looking at gross fixed capital formation (GFCF). As part of Mexican GFCF, IP products were valued at 176,099 million pesos in 2017, or 3.6% of the total. This represents a decrease from 2016, when IP products were valued at 4.12% of total investment. There have also been more sector-specific studies published that examine the economic contribution of IP-intensive industries. For example, in 2006 WIPO commissioned a study carried out by a local consultancy, on the economic impact of the creative industries in Mexico. The report, *The Economic Contribution of Copyright-Based Industries in Mexico*, found that in 2003, the copyright-based industries generated economic output equivalent to 4.77% of GDP and employed about 11% of total workers.

More broadly, the IMPI regularly hosts conferences and workshops on the creation and commercialization of IP assets. Other governmental bodies also measure levels of innovation-related activities. In 2014 INEGI, in collaboration with the National Council of Science and Technology, published the latest available biennial “Survey on Innovation and Technological Development.”

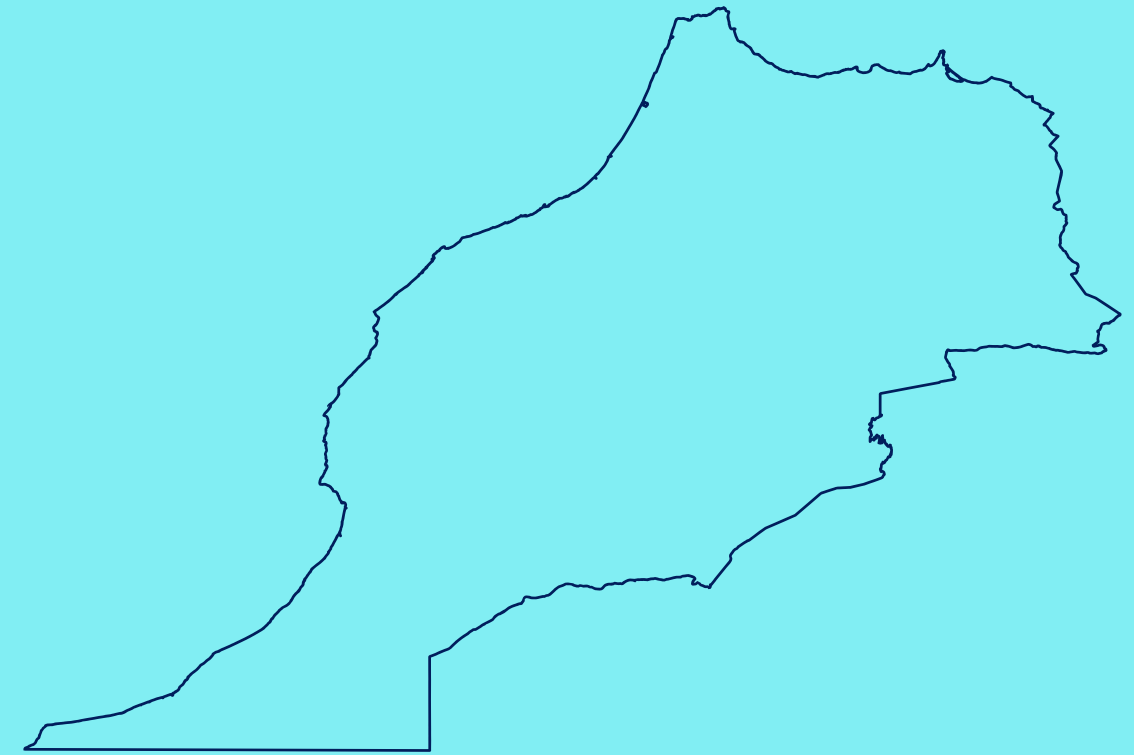
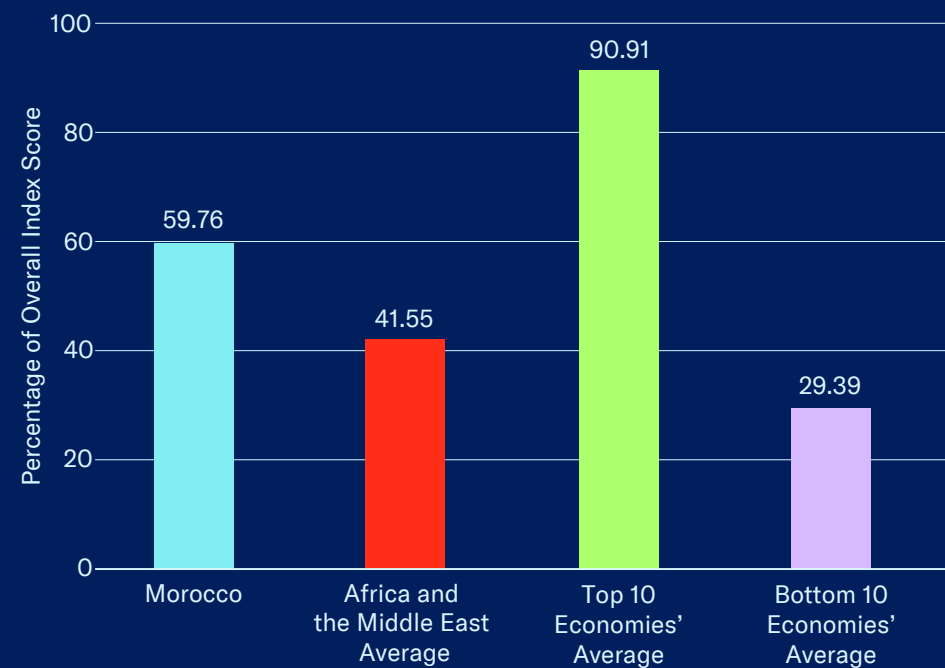
First launched in 2006, the survey captures information related to human and financial resources allocated to research and technological development activities in the private, non-profit, higher education, and government sectors. The survey includes information on tech transfer such as income from royalties and other IP-related transactions. However, up until now there has been no government program that seeks to categorize and regularly measure the aggregate contributions of the IP-intensive industries to national economic output and employment. This changed in 2021. In partnership with the European Commission, EUIPO, and under the umbrella of the “IP Key Latin America” project, the IMPI in March 2021 presented the results of *La contribución económica de la Propiedad Intelectual en México*. The first of its kind in Mexico and modelled on existing studies in the U.S. and EU, this study measures the economic contribution of IP-intensive industries to the Mexican economy. Overall, the report finds 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). This is a positive development and the IMPI and EU Commission should be congratulated for putting the resources and time into understanding and measuring the positive economic impact IP rights have on the Mexican economy and national economic output and employment. It would be good to see this exercise carried out at regular intervals using the latest available statistics. As a result of this development, the score on this indicator has increased by 0.25.

## Category Scores



— Morocco — Africa and the Middle East Average — Top 10 Economies' Average

## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>6.38</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of computer-implemented inventions (CIIs)	0.50
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	1.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.63
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>3.74</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.50
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.00</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.25</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.25</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>4.00</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>3.01</b>
32. Physical counterfeiting rates	0.40
33. Software piracy rates	0.36
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.75
<b>Category 8: Systemic Efficiency</b>	<b>2.75</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>5.50</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.50
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
29.88**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Morocco's overall score has increased from 59.62% (29.81 out of 50) in the ninth edition to 59.76% (29.88 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Patents, Related Rights, and Limitations

As has been noted over the course of the Index, the Moroccan Office of Industrial and Commercial Property (OMPIC) has deliberately sought to align Moroccan patenting standards with those used by major European IP offices and particularly those of the EPO. Most notably, since 2015, the OMPIC has offered a validation service of European patents. Under this agreement between the EPO and the OMPIC, all qualifying patents filed directly with the EPO or through the Patent Cooperation Treaty (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. This cooperation deepened in 2021 with OMPIC and the EPO signing a Memorandum of Understanding and OMPIC becoming the 31<sup>st</sup> IP office to join the Cooperative Patent Classification (CPC). The CPC is a standardized patent classification scheme used and supported by the USPTO and EPO.

**8. Membership of a Patent Prosecution Highway (PPH):** Although Morocco is not a member of either the Global Patent Prosecution Highway or the IP5 PPH, the 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. PPH initiatives and

increased cooperation between IP offices—like the patent validation scheme described above with the EPO—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, Related Rights, and Limitations

**11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and Digital rights management (DRM) legislation:** As has been noted in past editions of the Index, Morocco has a fairly strong statutory copyright framework in place. Article 10 of the Law on Copyright and Related Rights provides definitions of exclusive rights of exploitation, and standard civil remedies are available. Furthermore, Article 65.12 provides the possibility of seeking an injunction and a court order for the disabling of access to infringing content with respect to foreign hosts, and Law 34-2005 amended Article 60 and introduced a notice-and-takedown regime. Moroccan law also has in place robust provisions relating to digital rights management and technological protection measures. The 2005 copyright amendments made acts of circumvention and related activities (including manufacturing, sale, importation, offering for sale, and distribution to the public) infringements of copyright. However, the key challenge to rightsholders in Morocco has long been the lack of effective enforcement and application of the existing legal framework. Levels of copyright infringement remain high.





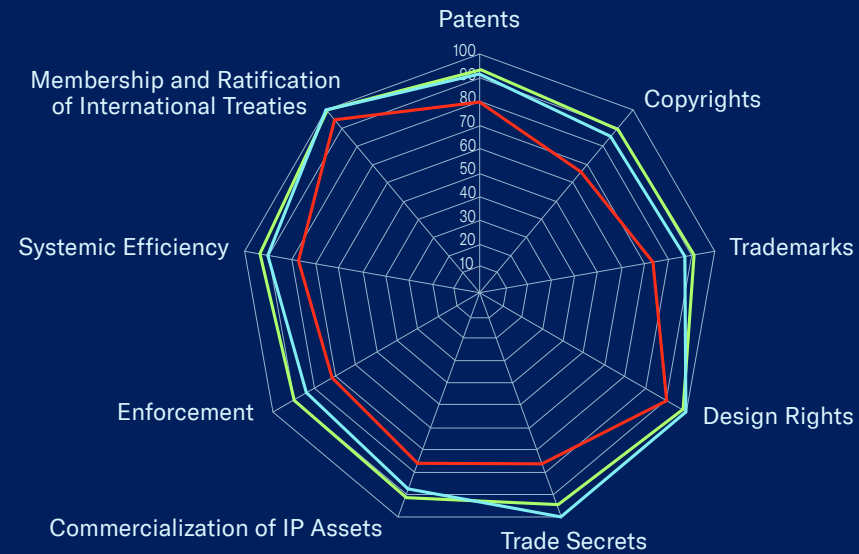
Historically, rightsholders in North Africa and Morocco have faced significant problems with satellite decoding and broadcasting signal piracy. Decoders have been readily available and used across North Africa to illegally access copyrighted content. In 2011 the French satellite and content provider *Canal+* withdrew from the Moroccan and Algerian markets, citing widespread piracy as the main reason. The latest trend has seen a migration from physical decoders and satellite piracy to the use of set-top boxes and the accessing of infringing content over the internet through streaming.

2021 saw some positive developments. Specifically, in October an international rightsholders' coalition, the Alliance for Creativity and Entertainment, announced that it had successfully disabled access to a significant source of pirated content in Morocco and North Africa, Electro TV Sat. The provider sold illicit streaming devices and illegal access to thousands of television channels, film, and audiovisual content, including French-speaking content created and supported by *Canal+*. This is a positive development for both domestic Moroccan creators and international rightsholders. Unfortunately, the action was not led by local law enforcement or the Moroccan authorities but was instead an initiative spearheaded by rightsholders themselves. The enforcement of copyright should be led by both rightsholders and relevant government authorities. This is of particular importance today when, because of the internet, infringement is more widespread and extensive than ever before. The Index will continue to monitor these developments in 2022.

# The Netherlands

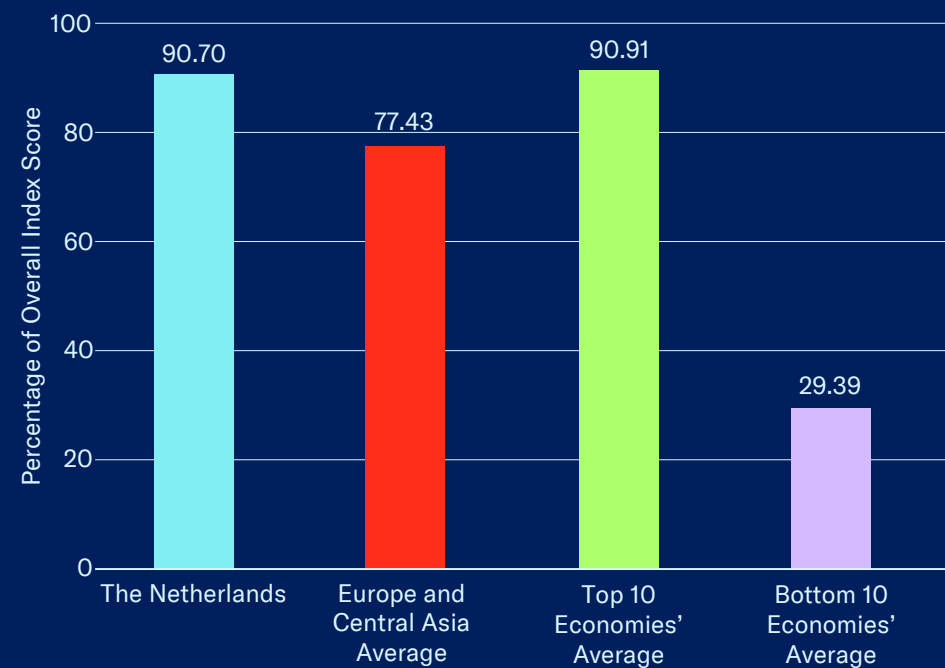
Rank  
7/55

## Category Scores



— The Netherlands — Europe and Central Asia Average — Top 10 Economies' Average

## Overall Score in Comparison



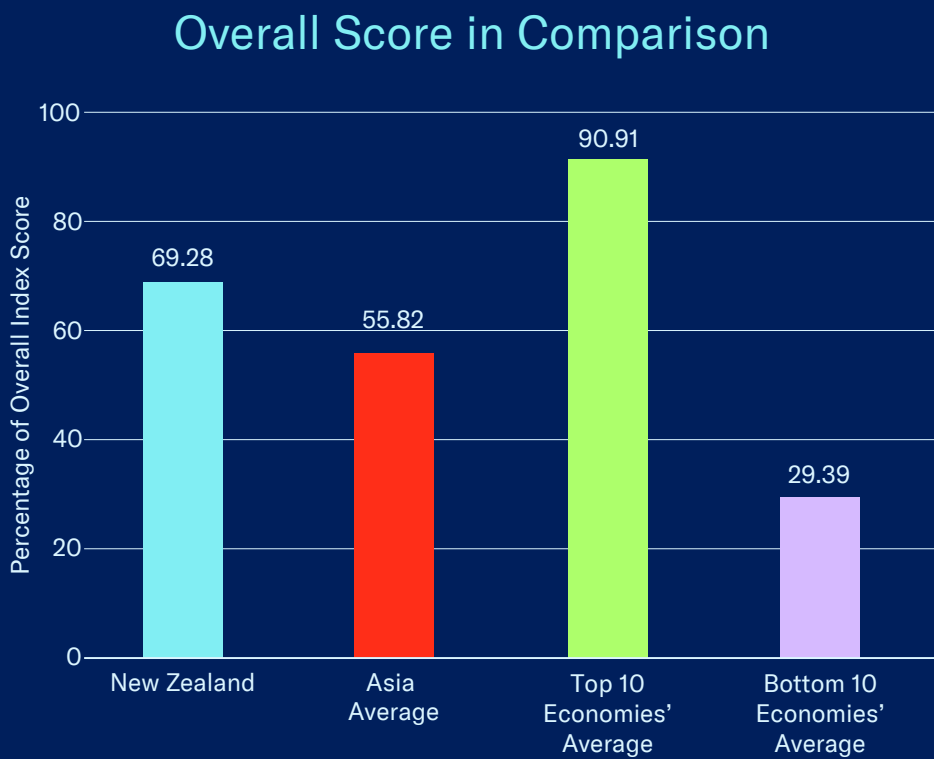
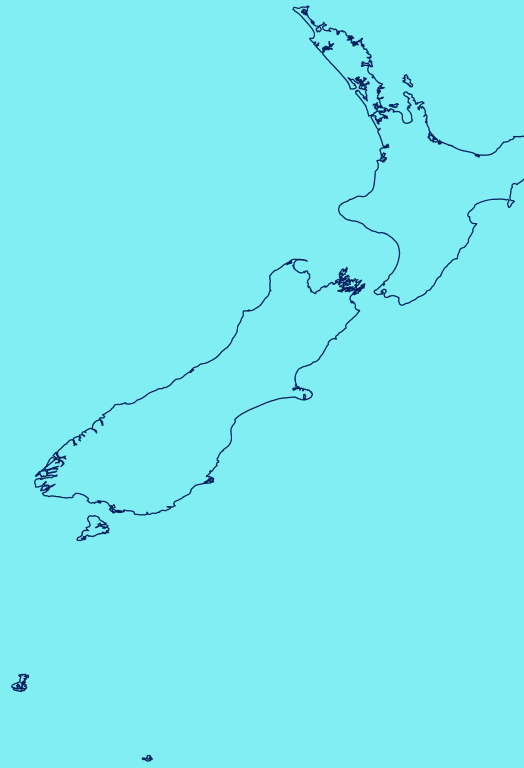
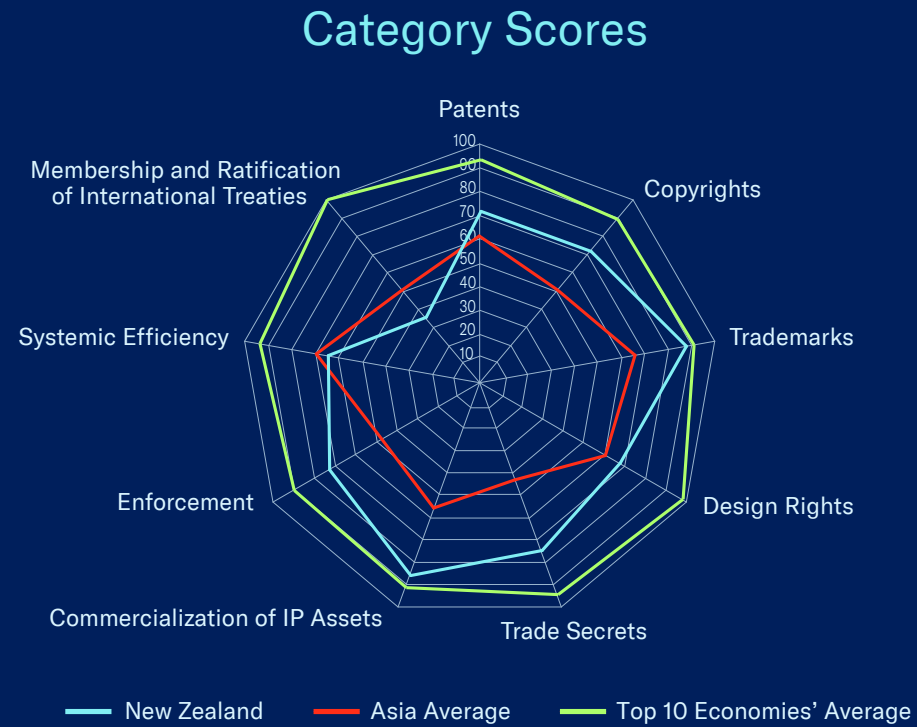
## Key Areas of Strength

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

## Key Areas of Weakness

- Registration requirements in place for licensing agreements
- Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals poses 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





## Key Areas of Strength

- R&D tax incentives passed in 2019
- Legislative amendments following ratification of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (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

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

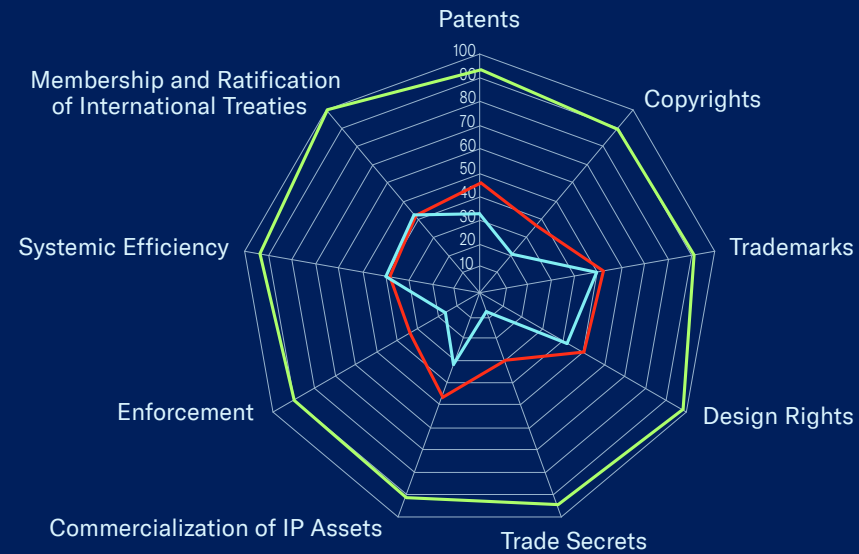




to New Zealand customs officers to detain and seize suspected infringing goods. With respect to copyright-infringing goods, the act states, “Any item in the control of the Customs may be detained in the custody of the chief executive or a Customs officer if a Customs officer has reasonable cause to suspect that the item is a pirated copy.” The act provides similar language for suspected trademark infringing goods. Still, as noted in the Index at the time the legislation was passed, it remains unclear if these new powers also apply to goods that are in transit and not intended for the domestic New Zealand market.

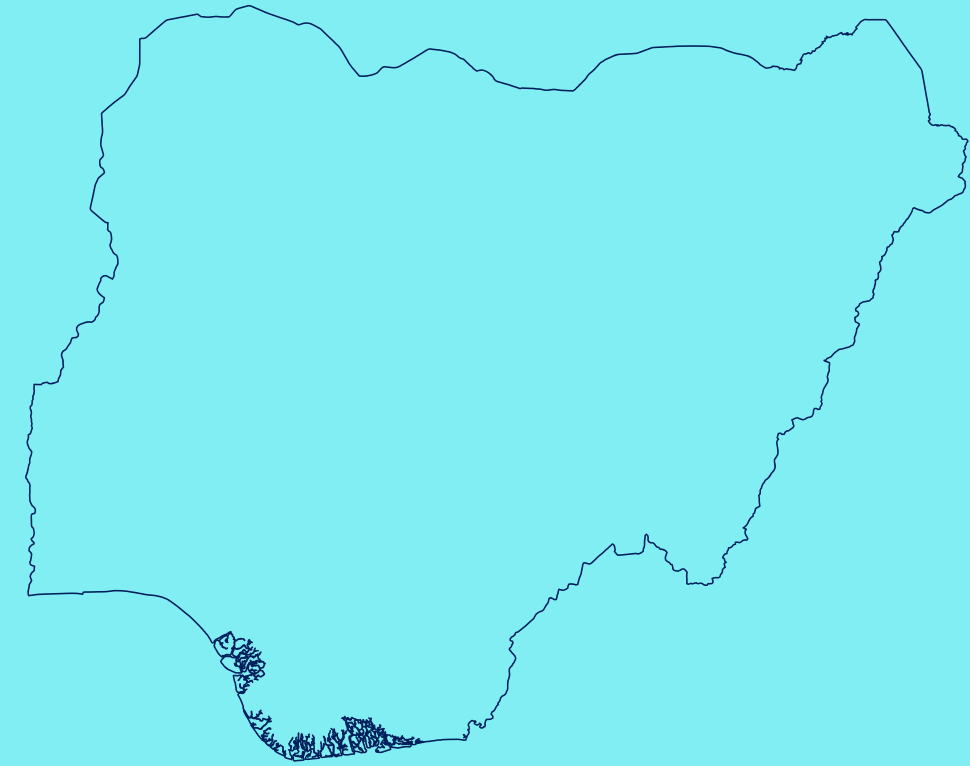
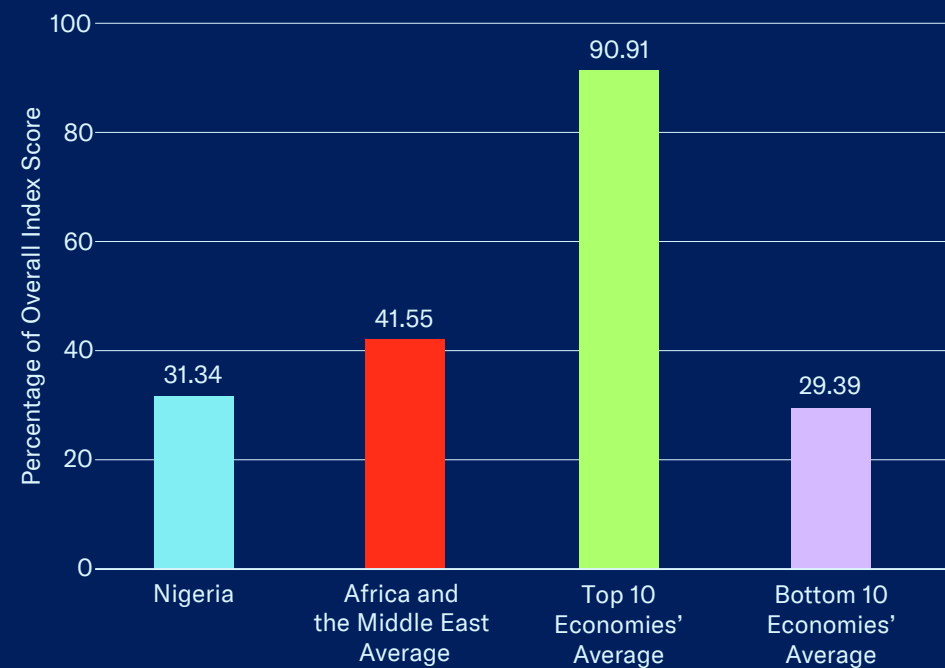
In late 2020, 15 economies—including New Zealand—signed the Regional Comprehensive Economic Partnership (RCEP) agreement. While notably weaker than many other post-TRIPS FTAs, just like the CPTPP, the RCEP contains some important provisions relating to the protection of IP. Specifically, Articles 11.69 and 11.70 require contracting parties to give *ex officio* authority to relevant customs and border officials to take action against suspected infringing goods. These articles do not refer to or exclude transshipped goods or goods in-transit. At the time of research, New Zealand was in the process of ratifying this treaty. In October 2021, Parliament passed the “Regional Comprehensive Economic Partnership (RCEP) Bill.” This law did not contain any reference to border measures or whether New Zealand border officials have the authority to act against suspected goods in-transit. Providing customs officials with clear and unambiguous authority to act against suspected IP-infringing goods that are in transit would lead to a score increase on this indicator. The Index will continue to monitor these developments in 2022.

## Category Scores



— Nigeria — Africa and the Middle East Average — Top 10 Economies' Average

## Overall Score in Comparison



## Key Areas of Strength

- New Plant Variety Protection Act 2021
- Joined UPOV 1991 in 2021
- Ratified the WIPO Internet Treaties in 2017
- Despite overall challenging environment, ongoing enforcement efforts by the Nigerian Copyright Commission are encouraging

## Key Areas of Weakness

- Overall, weak and limited legal and regulatory framework, with no major forms of IP rights in place
- Enforcement challenges persist—no national coordination, only ad hoc efforts
- Persistently high rates of physical and growing online piracy
- Software piracy estimated at 80% by BSA
- Localization barriers and restrictions in place on technology transfer and licensing activities intensified in 2020
- National Office for Technology Acquisition and Promotion (NOTAP) oversees all technology transfer and licensing between Nigerian entities and foreign licensors and has the power to evaluate and approve or disapprove technology transfer agreements, including evaluating royalty amounts





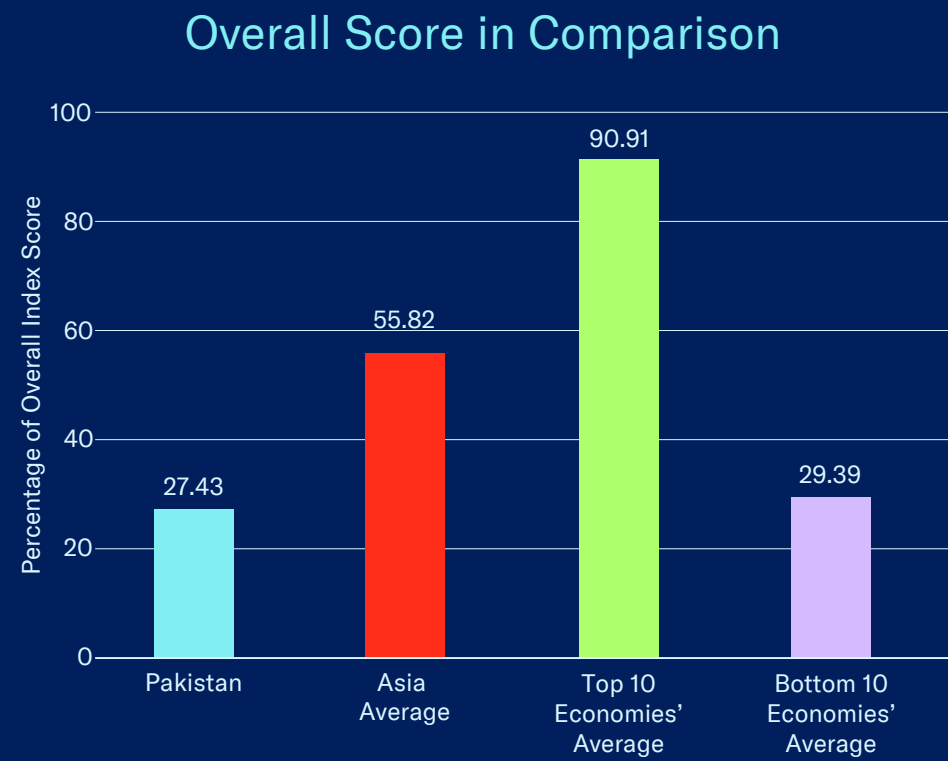
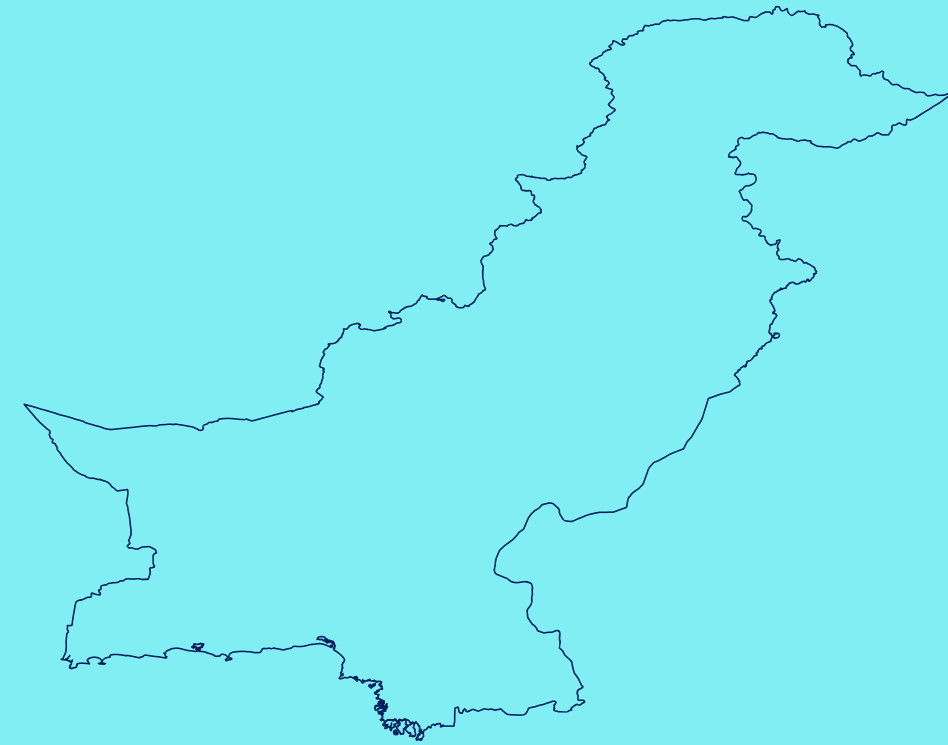
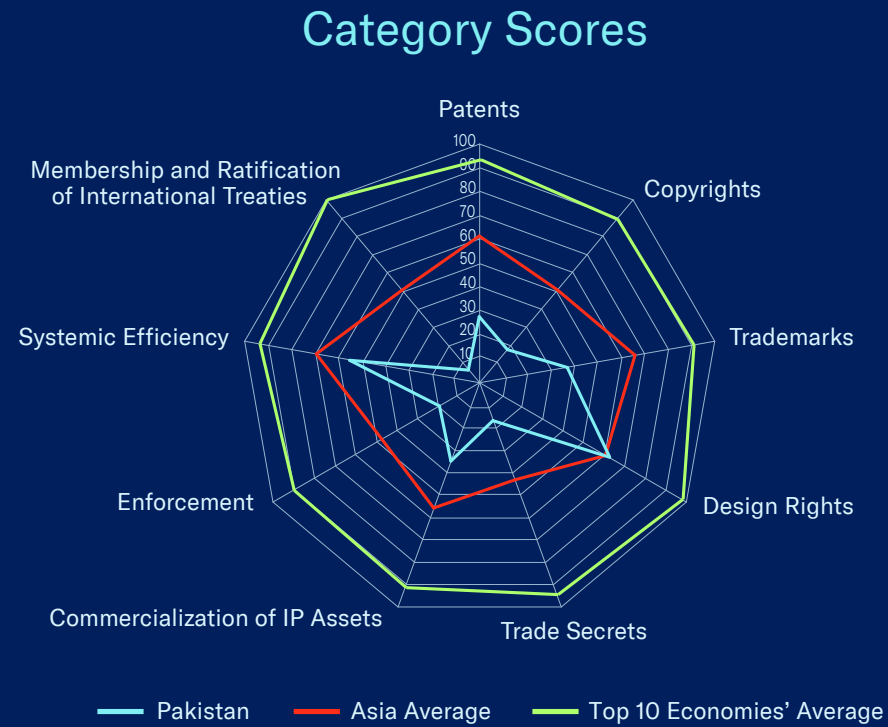


amend Nigeria's copyright laws to bring them in line with Nigeria's international obligations. In June 2018, the Federal Executive Council (Nigeria's Cabinet) approved a draft copyright bill that was subsequently sent for review to Nigeria's Parliament, the National Assembly. Draft versions of this bill available for public review included only limited reference to copyright protection extending to the internet as well as a rudimentary notification and safe harbor regime for internet service providers.

2021 saw some potential positive developments with the release of a new, updated bill in the Nigerian Senate. Senate Bill 688 contains many important updates and reforms. Specifically, the draft legislation includes explicit references to copyright protection online; new copyright-specific provisions relating to TPM and DRM; an injunctive-style relief mechanism by which access to infringing content can be disabled upon application; and a fairly comprehensive notice-and-takedown mechanism that includes clearly defined safe harbors and circumstances under which legal liability arises. If enacted and enforced, these proposed changes would substantially improve the copyright environment in Nigeria and result in score increases on indicators 11, 12, 13, and 15. It is particularly noteworthy that proposed Section 36 of the Bill provides clear and unambiguous powers to the NCC to disable access to infringing content online.

The last half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today EU Member States, the UK, India, Singapore, Russia, India, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called "dynamic" injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain

by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, the UK, and Russia. While mentioned in relation to the proposed notice-and-takedown regime, Section 30(5) of the draft Senate bill recognizes the need for these types of dynamic actions and includes a so-called "stay-down" responsibility on the part of service providers to ensure that any infringing content that has been removed or access that has been disabled shall not be reloaded. Unfortunately, it is less clear that other provisions of the draft legislation would improve Nigeria's copyright environment. Most notably are a long list of provisions relating to copyright exceptions. These provisions contain limited references to the Berne three-step test and some potentially broad exceptions for educational, private, and research use. The Index will continue to monitor these developments in 2022.



## Key Areas of Strength

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

## Key Areas of Weakness

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





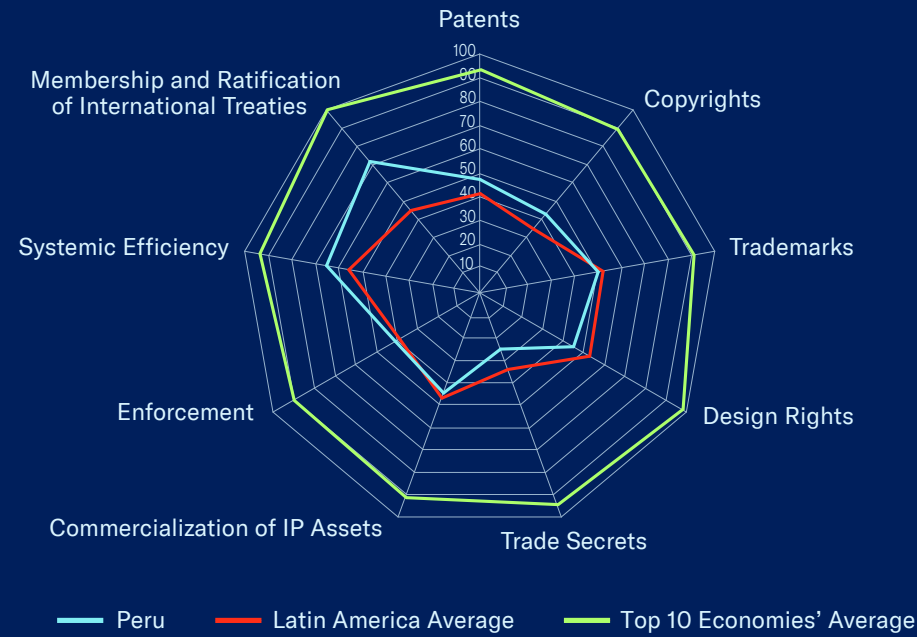
with the Government of Pakistan over several years seeking resolution of long-standing software licensing and IP infringements committed by offices within the Government of Pakistan which undermine Pakistan's credibility with respect to IP enforcement." Furthermore, as of 2021 Pakistan remained on the *Special 301* Watch List, with the USTR noting that "sales of counterfeit and pirated goods remain widespread, including with respect to pharmaceuticals, printed works, digital content, and software." In light of these challenges, amendments to the Copyright Ordinance aimed at modernizing protection have been under review for the past few years. At the time of research, these efforts had not progressed to a legislative stage. The Index will continue to monitor Pakistan's efforts to improve its copyright environment in 2022.

### Membership and Ratification of International Treaties

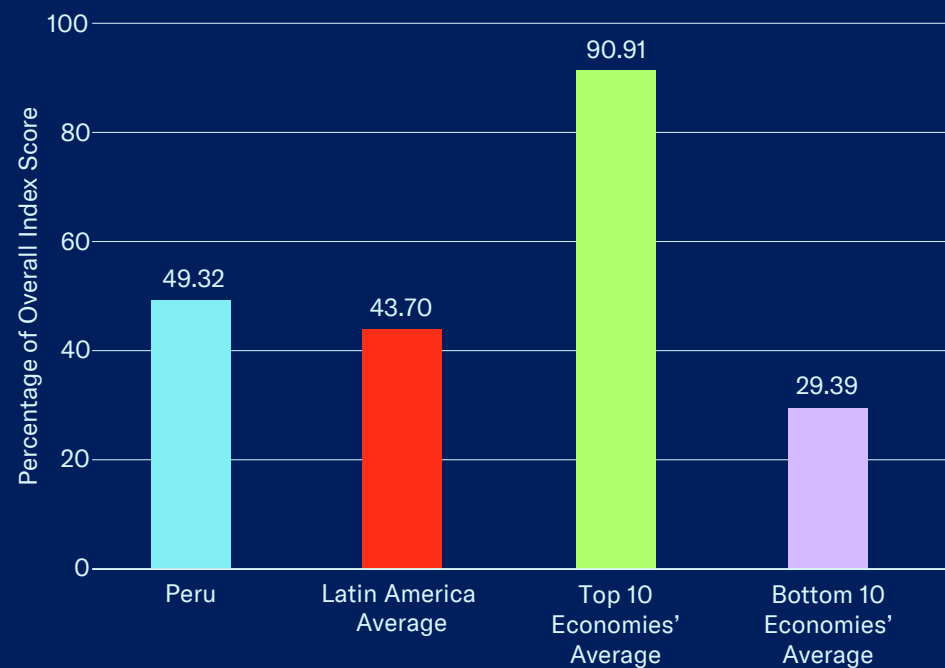
#### **45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of**

**Marks:** As mentioned in previous editions of the Index, IPO-Pakistan has stated its plans to accede to various international IP treaties, including the Protocol Relating to the Madrid Agreement. In February 2021, WIPO announced that Pakistan acceded to the treaty, which would become operational and available to rightsholders later in the year. Pakistan's accession to the Madrid Protocol is a positive development and the government of Pakistan should be congratulated. Pakistan's accession has resulted in a score increase on this indicator.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- Continued injunctive-style relief copyright enforcement by national IP office INDECOPI in 2021
- 2021 Decree 063-2021 strengthens public consultation and stakeholder participation in law and regulatory making process
- INDECOPI support for SMEs strengthened in 2021: new technical assistance and IP asset identification programs
- Peru in 2019 joined the Global Patent Prosecution Highway
- INDECOPI in 2019 continued suspending access to copyright infringing websites
- Basic IP protections available
- Legislation provides border measures to counter IP infringement
- Efforts to coordinate IP rights enforcement across government agencies and to raise awareness on the importance of IP protection

## Key Areas of Weakness

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





technical evaluation. As a result of these legislative changes, over the past few years more information has become available about government agencies' software procurement practices, with examples of individual ministries and agencies regularly publishing these technical evaluations and making them available to the public. Together this suggests that licensing requirements are part of the general central government procurement process for software. As a result, the score on this indicator has increased by 0.25.

### Systemic Efficiency

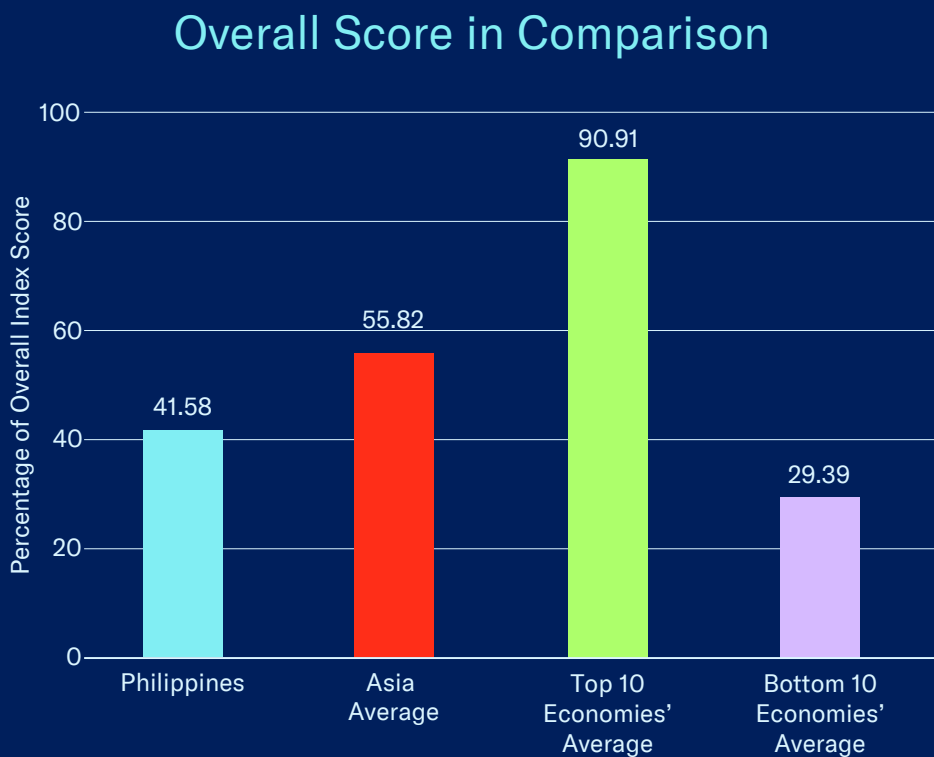
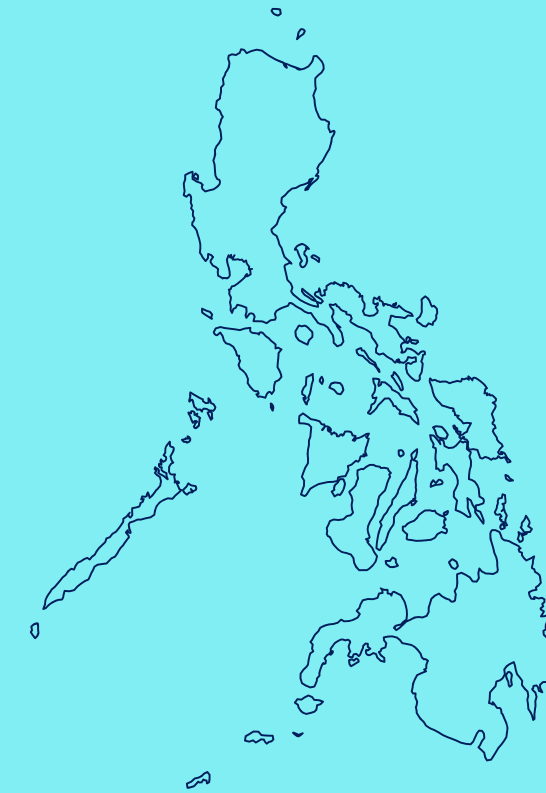
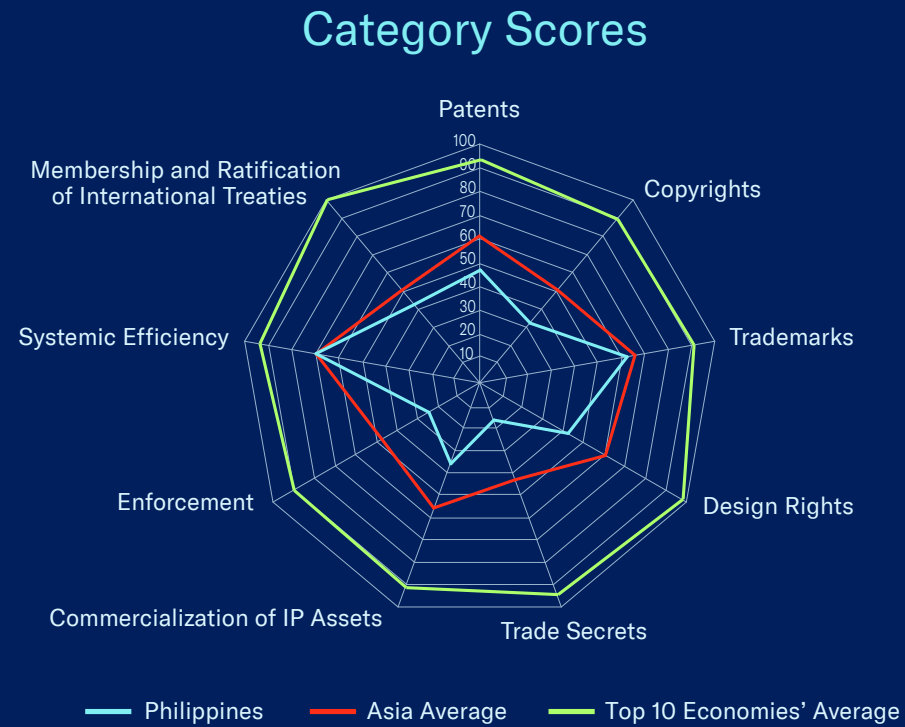
**40. Consultation with stakeholders during IP policy formation:** For years Peru has had clear requirements that the public be notified, and periods of public comments be offered in conjunction with, proposed changes to primary and secondary legislation. Most notably, under Decree No. 1 2009 (*Decreto Supremo N°001-2009-JUS*), all relevant public agencies and departments must publish any draft regulations in the official government gazette *El Peruano*. Article 14 of the decree states that the regulations must be public for a minimum period of 30 days, with exceptions only allowed in truly exceptional cases. However, there is no equivalent requirement for public bodies to acknowledge, take into account, publish, or respond to any comments received during the public consultation period. The OECD in 2019 published *Implementing Regulatory Impact Analysis in the Central Government of Peru, Case Studies 2014-16*, an in-depth review of Peru's legal framework for public administration and the regulation-making process. With respect to the use of public consultations, the study noted that government "ministries are not obliged to publish the comments or to reply to them" and such practice varied from agency to agency. To remedy this and provide greater levels of transparency and public accountability, the government of Peru, in April 2021, introduced Decree 063-2021 (*Decreto Supremo N°063-2021-PCM*). This decree clarifies

the commitment of the government to a stronger regulatory review process, including enhancing public consultations and the participation of the public in the regulatory process. Specifically, Article 4 of the decree states, "The process for the regulatory decision adopted by public entities must...guarantee that the regulatory production process is open and transparent for which, said process **contains mechanisms for public consultation, coordination and permanent cooperation that allow the early participation of stakeholders and public entities involved in the implementation of the provisions that are subject regulation.**" Article 11 further enhances this obligation by stating clearly that the relevant public agency is required to "program, organize, develop, evaluate, monitor and publish the results of the public consultation and the tool used, taking into account its objective." The exact standards and processes to be used are further defined under Article 14. As a result of this positive change in Peru's public consultation framework, the score on this indicator has increased by 0.25.

**42. Targeted incentives for the creation and use of IP assets for SMEs:** Peru provides a fairly large number of special programs and incentives for SMEs and individual inventors to develop, register, and commercialize their IP assets. Supreme Decree No. 092-2018-PCM provides for trademark registration at no cost and through an accelerated, simplified three-month procedure for micro and small enterprises, business associations, cooperatives, and local organizations. While there is no similar mechanism for patent applications, in cooperation with the Innovate Peru Program of the Ministry of Production (*Ministerio de la Producción*), INDECOPI has been active in helping small businesses identify potentially patentable subject matter and thus add value to their business.

Technical assistance also takes place through the network of WIPO Technology and Innovation Support Center (TISC) offices around Peru. As

of 2020, 19 active TISCs are in place, most of which are primarily located in universities and public research organizations. INDECOPI also supports the "Peruvian Patent Marketplace," a virtual service whereby Peruvian creators and inventors can advertise and attract foreign seed capital and investors. Over the last two years, these efforts—in particular, targeted technical assistance and consulting—have intensified. In response to the COVID-19 pandemic, INDECOPI has launched a virtual platform, "IDENTI-PAT," with which it helps entrepreneurs, SMEs, and inventors identify patentable matter; a virtual registry of works on copyright; and a new electronic reporting system of pharmaceutical and biotechnological patents. In 2021 the President of INDECOPI, Hania Pérez de Cuéllar Lubienska, announced that the RUTA PI program would be reinstated. The purpose of this program is to provide SMEs with specific technical guidance and assistance in identifying, registering, and managing IP assets. A specific emphasis would be placed on sectors and industries relating to copyright and trademarks. As a result of these positive efforts, the score on this indicator has increased by 0.25.



## Key Areas of Strength

- The national IP office (IPOP HL) continued stronger IP enforcement efforts online in 2021
- Draft amendments to IP Code would strengthen IP environment
- R&D tax incentives in place
- Most basic IP rights provided for in existing legislation
- Growing specialization and capacity building, such as in administrative IP courts

## Key Areas of Weakness

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





Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>4.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.50
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.25
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.50
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.28</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.85</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

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

**Total Score:  
20.79**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

The Philippines' overall score has increased from 39.81% (19.91 out of 50) in the ninth edition to 41.58% (20.79 out of 50) in the tenth edition. This reflects a score increase on indicators 12, 13, 20, and 32.

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

**12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 20. Availability of frameworks that promote cooperative private action against online sale of counterfeit goods:** As noted in previous editions of the Index, the last few years have seen the fight against online infringement intensify in the Philippines. At the time of research, draft anti-counterfeiting and anti-piracy legislation was still pending in the Congress. Specifically, the relevant legislative package, which was consolidated in 2021, would grant broader powers of enforcement to the national IP office (IPOP HL), including the power to directly order the disabling of access to websites and online merchants offering IP rights infringing on goods or services. With respect to online violations of trademarks and copyrights, IPOP HL has actively pursued an enhanced online enforcement program based on existing powers to address the growing presence of counterfeit and pirated goods online. In 2019 IPOP HL launched a focus group discussion with online platforms to address how to more effectively respond to violation notices and how to preemptively intervene to preclude online access to counterfeit goods. In 2020 proposed amendments to IPOP HL's "Rules and Regulations in the Exercise of Enforcement Functions and Visitorial Power" were submitted.

These revisions would expand the agency's powers to explicitly cover online IP-infringing activities. This would allow IPOP HL to take stronger action based on rightsholders' complaints, including ordering the takedown of infringing goods and, ultimately, disabling access to infringing sites.

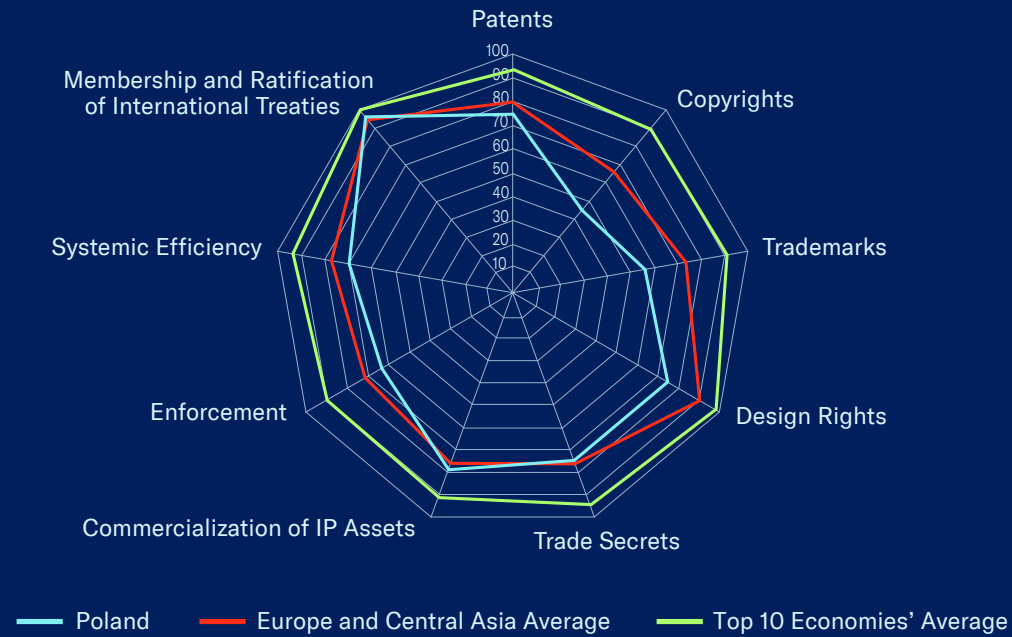
Citing the increased level of infringement and presence of counterfeit goods online during the COVID-19 pandemic, in November 2020 IPOP HL's Director General pointed out the necessity of changing the agency's enforcement functions, saying this would "strengthen our enforcement mandate in the area of e-commerce, allowing us to request the take down and blocking of websites by rightful authorities." These efforts continued in 2021. To begin with, IPOP HL adopted new rules through Memorandum Circular (MC) 2020-049 in March 2021. These changes explicitly recognize and include the electronic, online, or digital spheres within IPOP HL's enforcement remit. Upon receiving a complaint about potential infringement, IPOP HL now has the legal basis to order the termination of the infringing activity and, in the case of infringement taking place online or through electronic means, refer the matter to the National Telecommunications Commission (NTC) for the disabling of access to the relevant online or electronic source. Instead of 60 days, alleged infringers now have 72 hours to comply with an IPOP HL enforcement order. In a linked development, in April 2021 IPOP HL agreed on a new enforcement partnership with the NTC and a selection of the largest ISPs in the Philippines. IPOP HL described the aim of the partnership as enabling a "more streamlined and rapid blocking of pirated sites."

Similarly, an agreement was reached between rightsholders, the IPOP HL, and the leading Filipino e-commerce platforms Lazada and

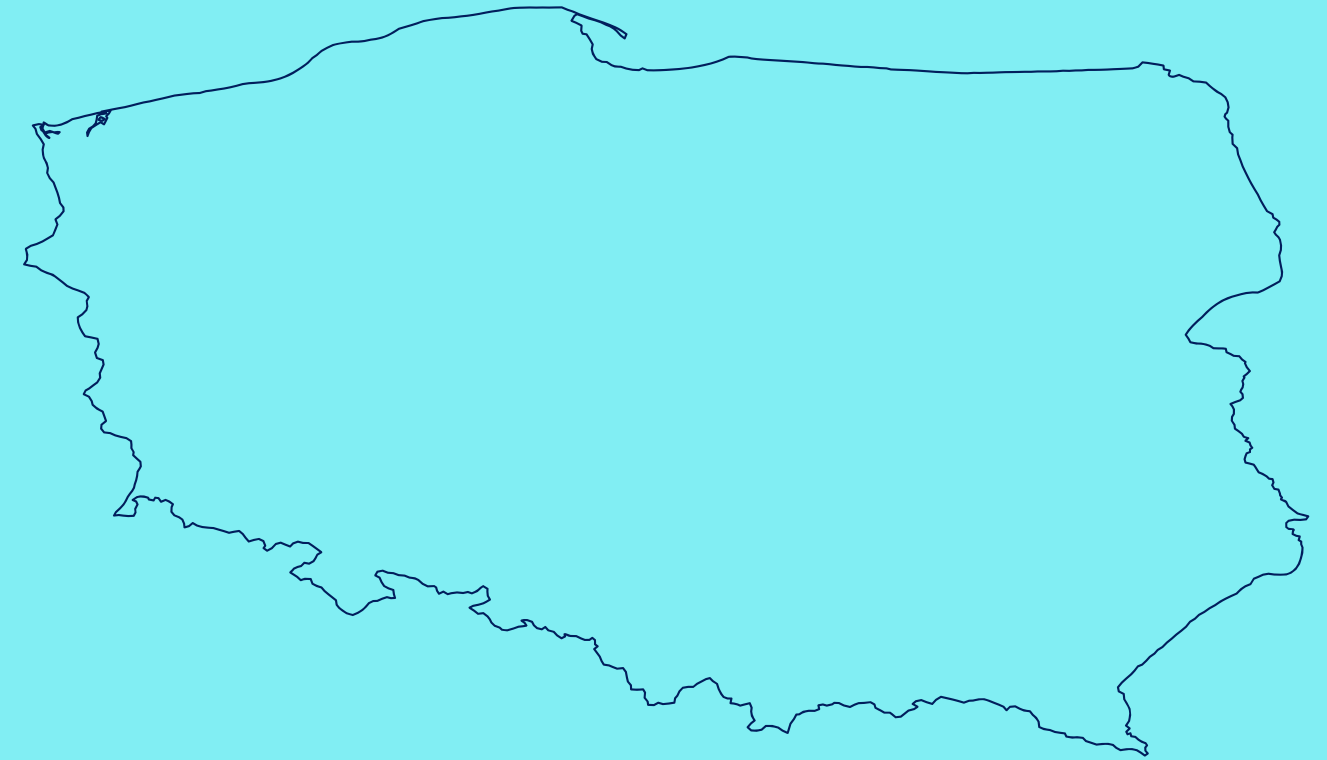
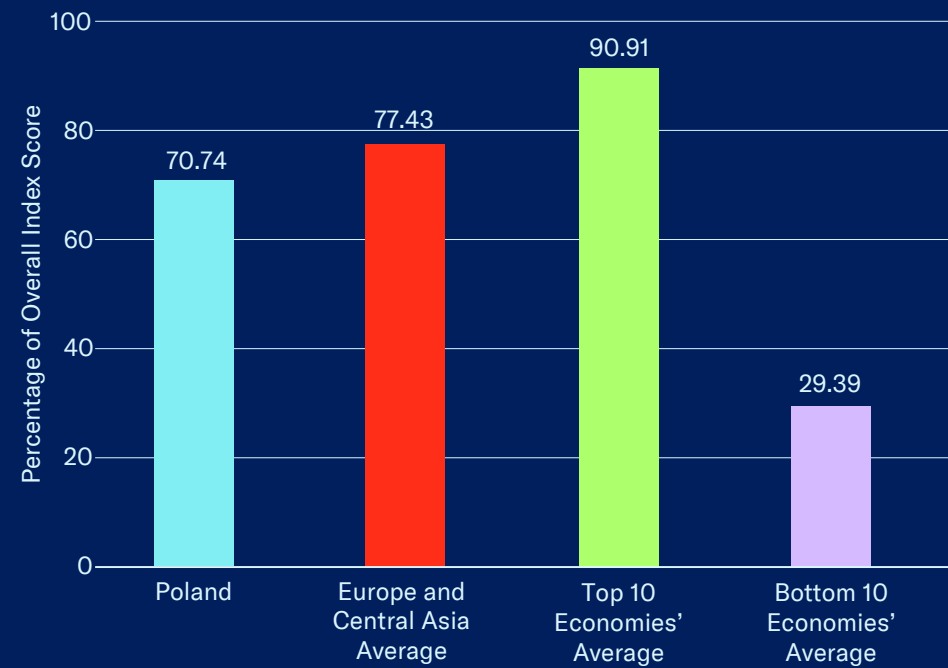


Shopee. Under a Memorandum of Understanding (MOU), all parties agreed to use a standardized notification process whereby access to links and advertisements to suspected infringing goods would be disabled. As of date, there are 16 signatories to the MOU, including the online platform Zalora. Finally, an IPOP HL referral to the National Bureau of Investigation (NBI) led to a physical raid and seizure of an estimated USD 1.8 million of counterfeit goods in March 2021. The IPOP HL referral to the NBI occurred because of a complaint from a rightsholder. The IPOP HL and other relevant authorities should be congratulated for these efforts and the resulting clear improvement to the IP rights enforcement environment in the Philippines. As a result, scores have increased on indicators 12, 13, and 20.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>6.75</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.25
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>3.16</b>
10. Copyright (and related rights) term of protection	0.66
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.75
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.50</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.25</b>
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	1.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>4.75</b>
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
<b>Category 7: Enforcement</b>	<b>4.46</b>
32. Physical counterfeiting rates	0.67
33. Software piracy rates	0.54
34. Civil and precedural remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	1.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	1.00
<b>Category 8: Systemic Efficiency</b>	<b>3.50</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>6.75</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
35.37**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Poland's overall score has increased from 70.50% (35.25 out of 50) in the ninth edition to 70.74% (35.37 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

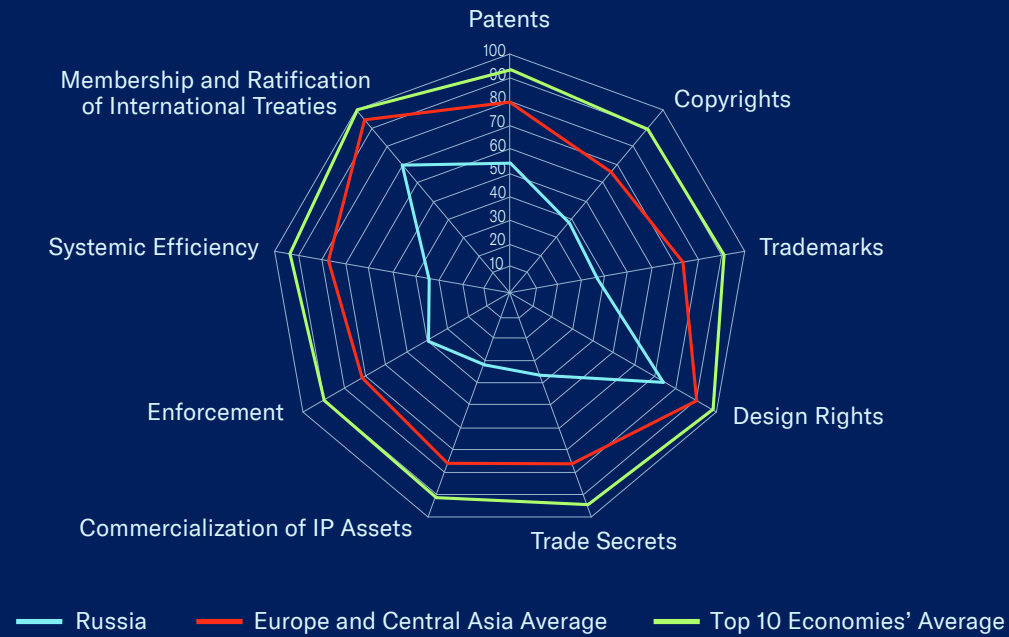
### Systemic Efficiency

**42. Targeted incentives for the creation and use of IP assets for SMEs:** The Patent Office of the Republic of Poland (PPO) provides relatively few incentives or special assistance for SMEs. The PPO does not offer reduced filing fees or expedited review of applications from SMEs, and there is no systematic educational or technical assistance program specifically targeting SMEs and entrepreneurs. Because Poland is a member of the EPO, Polish rightsholders and inventors can access the full suite of EPO educational programs, technical assistance, and special incentives. The EPO provides a 30% reduction in fees to SMEs, individuals, and universities for patent filing and examination. A broad range of technical assistance and IP education is available for SMEs and businesses. For example, the European Patent Academy provides expert speakers and advice, including in relation to portfolio management and IP valuation, and a range of online training materials, webinars, and educational tools.

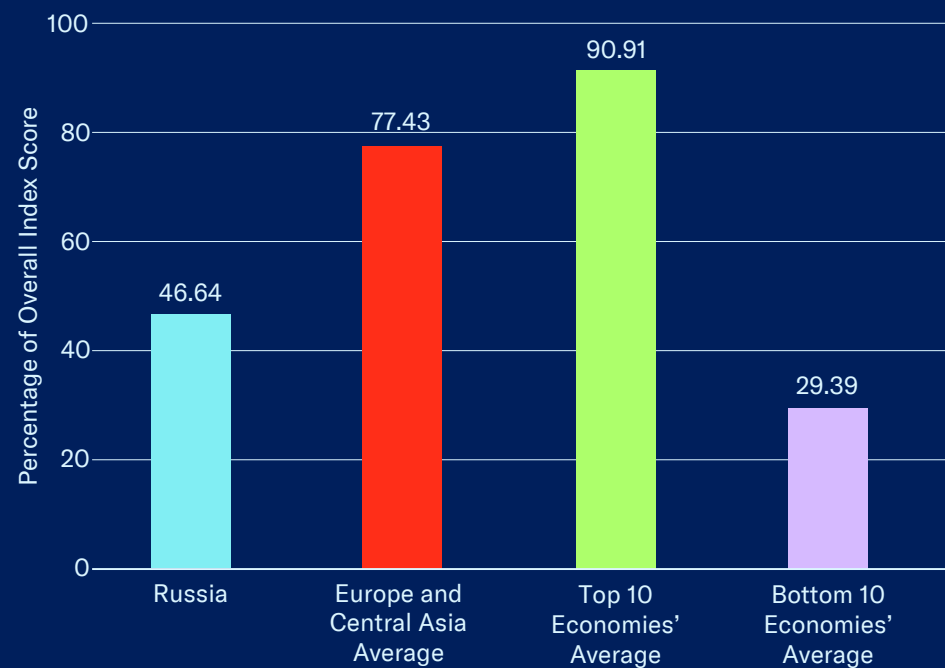
Since 2016, the EPO has also offered a revised accelerated prosecution procedure (PACE). The PACE program does not target SMEs specifically but is open to all applicants. In response to the COVID-19 pandemic, 2021 saw a new initiative launched by the EUIPO—The Ideas Powered for Business SME Fund. The EUR 20 million fund will provide individual grants to SMEs to help defray the cost of assessing potential IP assets and registering these assets with relevant

national or EU authorities. Grants were, at the time of research, limited to the registration of trademarks and industrial design. In Poland the fund is operational and supported by the PPO.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- Last few years have seen new copyright laws passed, strengthening rightsholders' ability to request the disabling of access to infringing material online
- The Patent Office, ROSPATENT, has in place numerous PPHs and is a full participant in the GPPH
- Full participant in international IP treaties

## Key Areas of Weakness

- Continued weakening of the life sciences environment through new administrative barriers for patentability and term restoration
- Use and threat of compulsory licenses and the overriding of IP rights as public health policy: compulsory license issued in 2020 and new 2021 amendments to Civil Code Part IV broaden existing basis for action
- Administrative and regulatory barriers in place for licensing activities—including direct government intervention
- Increasingly punitive localization requirements targeting ICT and the biopharmaceutical sector
- Data localization requirements for technology companies have been in place for a long time and have intensified over the last 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
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>5.00</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	0.50
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.74</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.75
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	0.00
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.00
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.50</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.10</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.60

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>1.92</b>
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.25
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>2.81</b>
32. Physical counterfeiting rates	0.40
33. Software piracy rates	0.38
34. Civil and preceudral remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.50
<b>Category 8: Systemic Efficiency</b>	<b>1.75</b>
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>5.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

Total Score:  
**23.32**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Russia's overall score has increased from 46.58% (23.29 out of 50) in the ninth edition to 46.64% (23.32 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Patents, Related Rights, and Limitations; Commercialization of IP Assets and Market Access

**2. Patentability requirements:** The last few years have seen several negative developments with respect to the patentability of high-tech inventions in Russia. New amendments to relevant sections of the Civil Code Part IV and the practice notes of the Russian Patent Office, ROSPATENT, were issued in 2018 (Order 527). As noted in the Index at the time, these amendments inserted new claim restrictions on second use patent claims for medicines and effectively reduced the number of eligible applications and scope of available patent protection. Further restrictions on incremental innovation have been introduced in 2021 through both negative precedential decisions and new additional amendments to relevant patent rules and regulations.

In June 2021, the Ministry of Economic Development (the parent agency for ROSPATENT) amended Order 316, 2016, which outlines the formal registration process for industrial property applications, including for patents. Article 77—which outlines inventions that are not to be considered in compliance with the inventive step requirement of Russian patent law—now includes potential restrictions on incremental biopharmaceutical innovation, including changes to form and application of a known substance. This is a curious change, as incremental innovation is an essential part of the biopharmaceutical R&D process. Follow-on medications and incrementally

improved or altered therapies frequently reduce side effects, improve upon existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. Without incremental innovation—and the IP incentives that drive investment and resources into developing them—the world would not have access to the latest generations of some of the most used medicines and medical devices. This includes insulin, beta-blockers, ACE inhibitors, contraceptives, insulin pumps, statins, zoledronic acid, and countless other commonly used biopharmaceutical products and devices.

The development of HIV/AIDS treatment is a concrete example of how incremental improvements to existing technologies over time amount to what in effect becomes a radical innovation whereby the latest technology is barely recognizable compared to its first-generation predecessor. The first generation of HIV/AIDS antiretrovirals had both serious side effects and were combination therapies requiring the consumption of large volumes of medication several times per day. Side effects included explosive diarrhea, severe nausea, the loss of sense of taste, skin problems, and painful nerve injury. The development of the second-generation of drugs, centering on the concept of highly active antiretroviral therapy, saw improved treatment options and reduced side effects. Still, treatment centered around the administration and consumption of several medicines per day. It is only in recent years that new therapies have been introduced based on incremental innovations that allow for combination pills. Instead of an array of pills taken every few hours, these products require only that the patient take a single pill once daily. This new ease of medication has led to increased adherence which has, in turn, increased efficacy significantly with little to no significant change in lifestyle. This allows patients to live socio-economically



productive lives with what had been a debilitating and often fatal disease. In the long term, this has also caused a significant decrease in costs for treating side effects, thus reducing the cost burden on a given health system. Given the many benefits of incremental innovation, it is critical that this type of innovation is eligible for patent protection both in Russia and elsewhere. The Index will continue to monitor these developments in 2022.

**5. Pharmaceutical-related patent enforcement and resolution mechanism:** Biopharmaceutical rightsholders have long faced the challenge of protecting their granted periods of exclusivity and enforcing their patent rights against the premature early market entry of follow-on products in Russia. Preliminary injunctions in cases of patent infringement are difficult to obtain and historically there has not been any type of administrative “linkage mechanism” in place 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. As noted in previous editions of the Index, in 2019 the Ministry of Health published draft legislative proposals for changes to Law No. 61-3 On the Circulation of Medicines. The proposed changes included the introduction of a new administrative mechanism linking the approval of a follow-on medicine with the expiration of the exclusivity of a reference product. Specifically, the draft law included a requirement that a follow-on applicant submit written documentation stating that the prospective registration did not violate any existing IP exclusivity. ROSPATENT was also to house a register of the current exclusivity status of registered products. In 2021 an outline of what this register was to look like was published by the Ministry of Economic Development and ROSPATENT announced that it had developed a pilot program whereby rightsholders could on a test basis register their existing rights. Although a positive development, at the time of

research there was still no primary or secondary legislation outlining what the pre-marketing patent enforcement mechanism would look like.

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 biopharmaceutical exclusivity (usually but not always through patent protection) and stimulating early market entry of follow-on products. Linkage ensures that any disputes are resolved prior to the marketing of a follow-on product. This grants innovators a fair opportunity to secure a return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity. It also limits potential damages for generic manufacturers, as no potentially infringing product is ever launched or approved for market. Indeed, linkage also provides both innovators and generic companies with an opportunity of lower-risk challenges of validity or non-infringement, by largely taking the issue of damages out of the equation. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit. In sum, a well-balanced linkage system recognizes the crucial role of IP protection in promoting innovation, and the role of generic entry in providing patients access to lower cost biopharmaceuticals. Given the broader deterioration in Russia’s biopharmaceutical IP environment—as detailed below and in previous editions of the Index—the introduction of a functioning linkage regime that provides rightsholders with a meaningful and real ability to stop follow-on products from being launched when a granted term of exclusivity is in place, would be a substantial improvement to the biopharmaceutical IP environment in Russia and result in a score increase on this indicator.

**6. Legislative criteria and use of compulsory licensing of patented products and technologies; 26. Barriers to market access:** As has been detailed in the Index, Russian industrial and economic policy over the last decade has increasingly been driven by an effort to localize industrial production and R&D. Key policy initiatives include the Strategy for Innovative Development of the Russian Federation 2020 (2020 Strategy), the State Coordination Program for the Development of Biotechnology (BIO 2020), the Strategy of Development of the Pharmaceutical and Medical Industries (Pharma 2020), the New Digital Society Strategy 2017–30, and the National Economic Security Strategy, 2017. A major part of these efforts has been localization and import substitution policies that actively discriminate against foreign entities and favor domestic Russian companies. While covering most parts of the economy, high-tech sectors such as aerospace and nuclear energy, nanotechnology, medical technologies, ICT, and alternative fuels have been targeted. The requirements and intensity of these policies have varied from sector to sector. But both the ICT and biopharmaceutical sectors have been especially targeted. Data localization requirements for technology companies have been in place for a long time and have intensified over the last few years. For biopharmaceuticals, industrial localization policies have fused together with IP policy and broader health policy on the pricing and procurement of medicines. The result is a highly challenging environment that targets high-tech, innovation-based industries with a mix of requirements for local manufacturing; procurement preferences for locally produced products; local clinical trials and R&D requirements; and the use and threat of compulsory licenses and the overriding of IP rights as public policy. Russian authorities have come to view compulsory licensing for biopharmaceuticals as a legitimate policy tool for achieving industrial and public finance goals.

In 2016 the Russian Federal Antimonopoly Service proposed a compulsory license scheme as a

method of reducing prices of certain high-cost specialty medicines. In 2018 the first court-ordered biopharmaceutical compulsory license was issued. In July of that year, the Moscow Arbitration Court granted a compulsory license to local manufacturer Nativa for Celgene’s Revlimid. The compulsory license was for Celgene to license one of its granted patents for the production of a product in which a dependent patent was to be used by Nativa. Without a license, the use of this patent would constitute infringement of Celgene’s patent. Critically, the lower cost of the product by Nativa was considered by the court to be economically advantageous and a deciding factor in granting the license. In 2019 another compulsory license was issued to Nativa on largely similar grounds.

In a separate development, on December 31, 2020, the Russian government issued a compulsory license under Order 3718. The order authorized a local manufacturer to produce a generic version of remdesivir, an antiviral drug used in the treatment of COVID-19, and the overriding of existing Eurasian patents for the drug. The order was based on Article 1360 of the Civil Code Part IV, which grants the government broad powers to act “in the interest of national security” and override any existing granted rights relating to patents, utility models, and industrial designs. News reports suggest that the order followed a request made by the local manufacturer to the government in November 2020, which was most recently extended by one more year. In 2021 the Russian Duma passed, and President Putin signed into law fresh amendments to the Civil Code Part IV. These changes amended Article 1360, inserting a further justification for the overriding of any granted rights relating to patents, utility models, and industrial designs.

In addition to the broad national security powers described above, the Russian government can now justify the use of any invention on the basis of protecting “the life and health of citizens.” This is another in a long succession of negative



developments in Russia for biopharmaceutical innovators and fundamentally undermines the national IP environment. Compulsory licensing as an actively used tool in Russian industrial and health policy is not only outside international norms but is self-defeating: over time, it will hollow out Russia’s national IP environment and incentives for future innovation, biopharmaceutical and otherwise. Critically, the negative effect will be the same on Russian as on foreign innovators.

### Copyrights, Related Rights, and Limitations

**11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expedient injunctive-style relief and disabling of infringing content online; and 13. Availability of frameworks that promote cooperative action against online piracy:**

As noted in previous editions of the IP Index, over the last decade Russia has introduced and implemented a range of new laws and regulations to help combat the country’s high level of online infringement. Over the past ten editions as a percentage of the available score, Russia’s score on this category has almost doubled, rising from 20.67% on the first edition of the Index to 39.14% in this year’s edition. This positive trend began in 2013, which saw the passing of several amendments to the Civil Code Part IV, including a notice-and-takedown provision regarding the responsibilities of “information intermediaries” with an obligation to act upon a notice of infringement from a rightsholder. These amendments also included the introduction of interim judicial measures designating the Moscow City Court as the first instance of such application and with the power to issue temporary injunctions. Furthermore, a rightsholder could also apply to the Federal Service for Supervision in the Sphere of Telecom, Information Technologies, and Mass Communication (the ROSKOMNADZOR) for the enforcement of these provisions. Specifically,

ROSKOMNADZOR was given the power to issue notices to the hosting service provider requiring (1) notification to the alleged infringer and (2) if no action was taken, the restriction of access to the alleged infringing material.

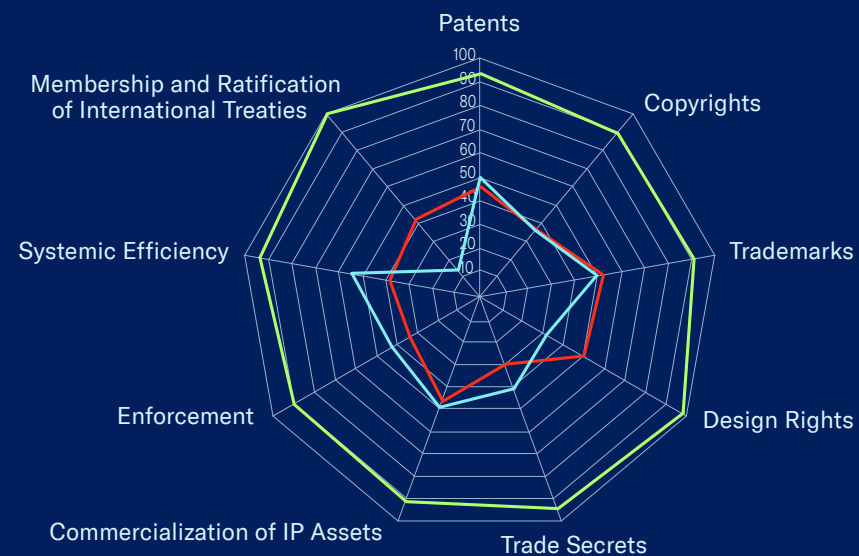
In 2017 further legislative changes were introduced to strengthen rightsholders’ ability to request the disabling of access to infringing material online. Specifically, several important amendments were added to the “Law on Information, Information Technologies and Information Protection.” These amendments included a ban on so-called mirror sites that infringe copyrighted content. These mirror websites are essentially replicas of sites that have been taken down or to which access has been disabled. Rightsholders now have the option of notifying the Ministry of Communications, which has two days to order the hosting provider to disable access to the site. Internet mediators (including search engines) are obliged to remove links to sites that have been found to host illegal content. ROSKOMNADZOR actively monitors online infringement and has developed a database of infringing content. Furthermore, a “Counter-Piracy Memorandum of Understanding” between creators and internet mediators was agreed on and signed in late 2018. This agreement—which was set to expire in early 2021—has now been extended, with ROSKOMNADZOR announcing that it had effectively mediated an extension of the agreement. It was also announced that this voluntary agreement could form the basis for new national legislation. At the time of research, no new law had been passed.

The aggregated result of these efforts has been positive with a decrease in online infringement. Nevertheless, in some areas piracy and infringement remain stubbornly high. For example, with respect to the infringement of video games and videogaming content, industry sources suggest that for almost a decade Russia has had the highest population-adjusted rates of infringement

through peer-to-peer (P2P) software. For 2020, IP addresses from Russia are reported to have accounted for over 30% of all global video game infringement on a P2P network. 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 USD 90 billion in total economic output supporting close to half a million jobs in the U.S. Given the growing importance of video game and computer game technology to young people all around the world, it is vital that this industry is better protected both in Russia and globally. The Index will continue to monitor these developments in 2022.

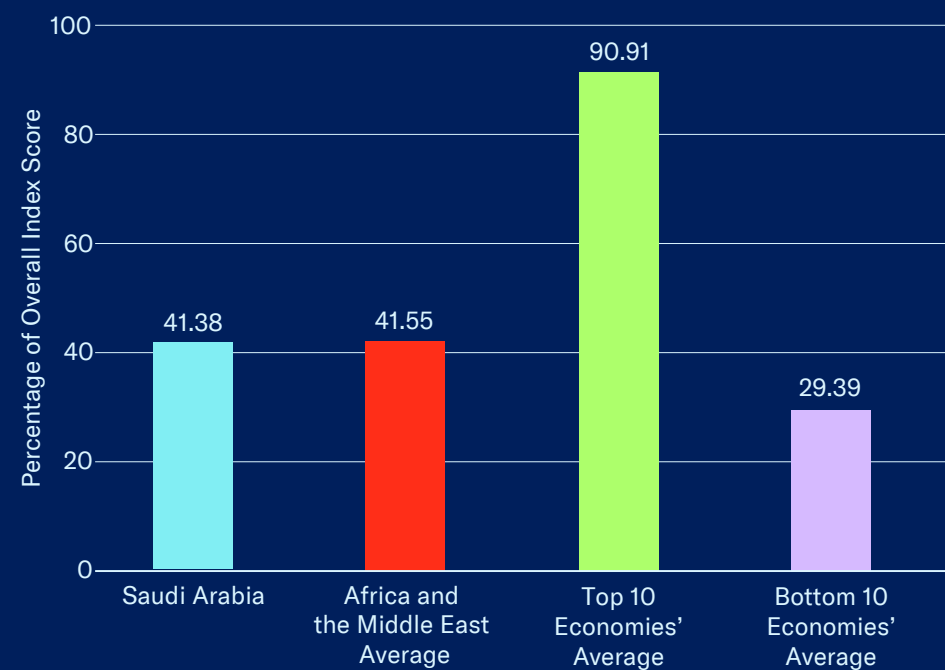


## Category Scores



— Saudi Arabia — Africa and the Middle East Average — Top 10 Economies' Average

## Overall Score in Comparison



## Key Areas of Strength

- Saudi IP authority (SAIP) has put in place an ambitious reform agenda that continued in 2021
- SAIP is leading and coordinating IP enforcement on new 2021 National Committee for the Enforcement of Intellectual Property Rights
- Joined multiple PPHs in 2019/20
- Increased consultation and awareness-raising activities in 2019
- Stronger copyright enforcement through Saudi IP Authority
- Strong and sustained focus by Saudi authorities and institutions to encourage IP commercialization and technology transfer
- *Ex officio* authority in place for customs officials

## Key Areas of Weakness

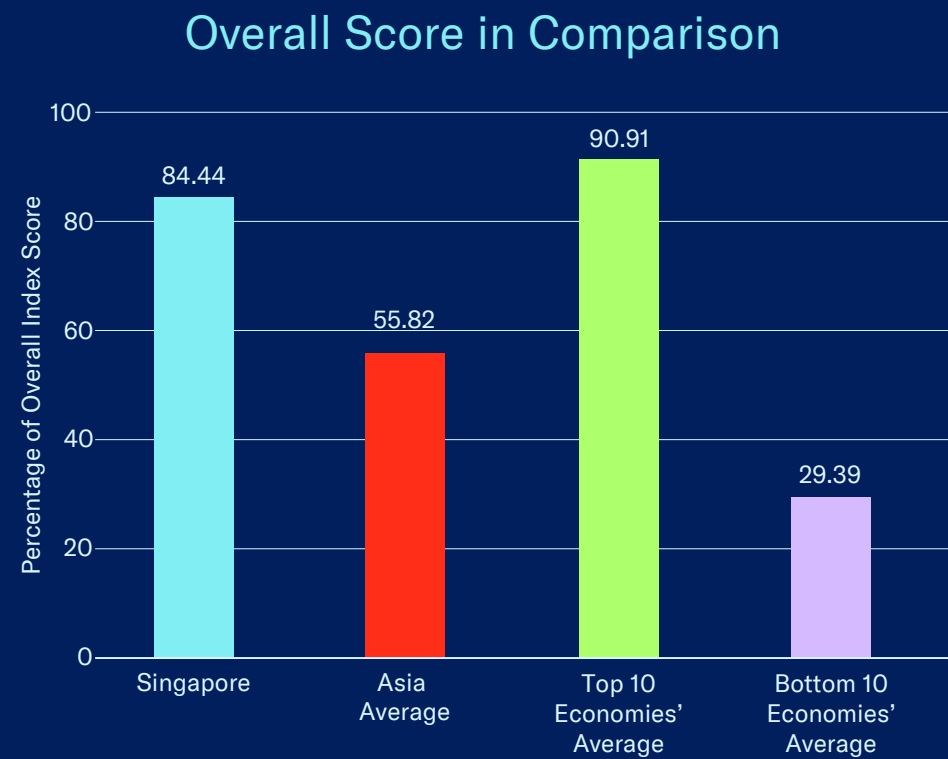
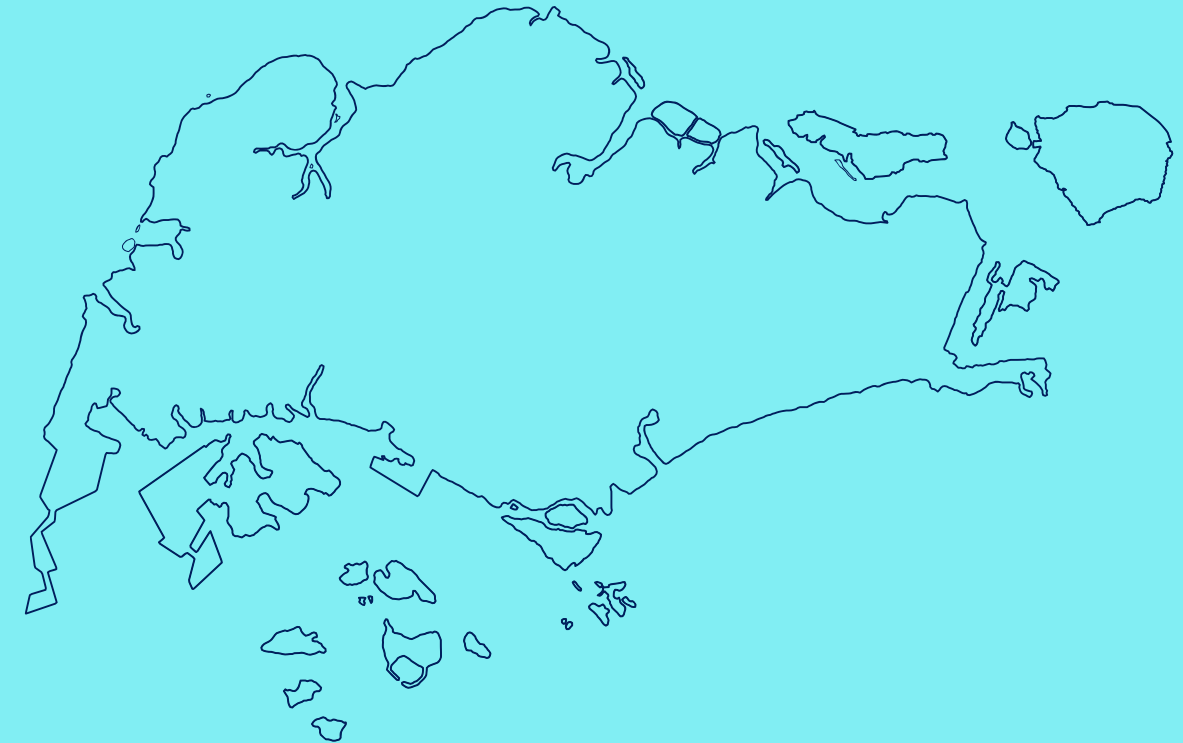
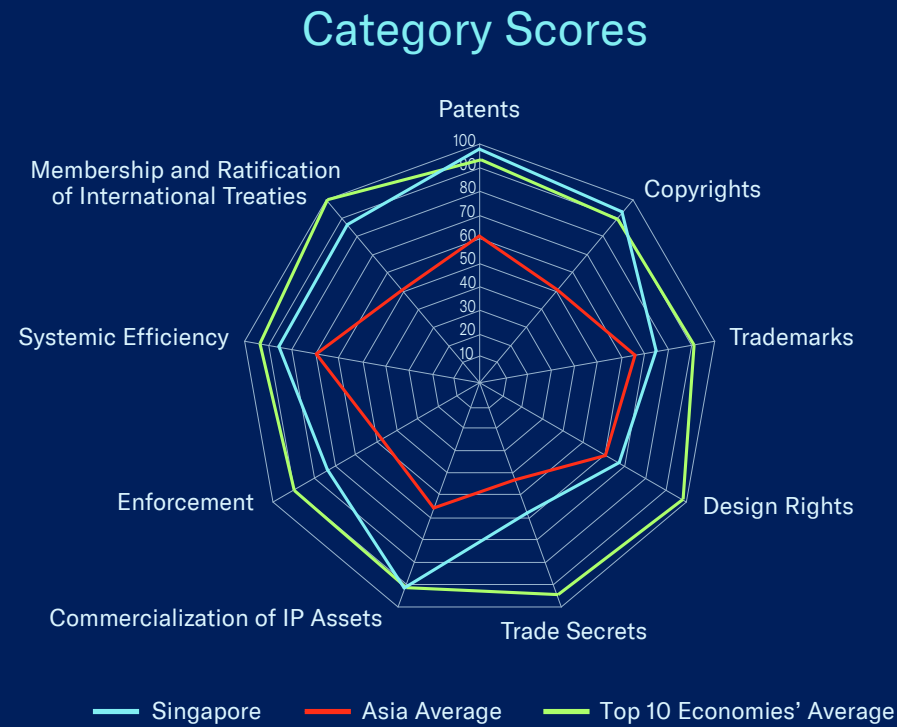
- Pharmaceutical patent protection and linkage mechanism in effect suspended through Saudi FDA (SFDA) actions in 2017
- Significant gaps in copyright framework—chiefly relating to protection online
- Increasing number of localization requirements
- Industry reports of a lack of practical availability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





For trademarks, the main avenue of administrative enforcement has been the Ministry of Economy and Industry and the Anti-commercial Fraud Department. For copyright claims and administrative enforcement, the relevant administrative body has been the Ministry of Culture and Information's Copyright Committee. For both trademarks and copyright, the Saudi customs authority carries out border enforcement. For judicial enforcement in civil and criminal claims, the relevant authority is the Board of Grievances. It is within this context that SAIP has emerged over the last five years, taking a more prominent role in IP enforcement. To begin with, the authority includes enforcement as one of its core business areas and has taken several positive steps in coordinating and facilitating the enforcement of existing Saudi copyright statute, including through offering a portal through which rightsholders can directly communicate any suspected online infringement to the SAIP, which will then take enforcement action.

These positive efforts continued in 2021. In August the authority announced that it would also be providing a centralized role in the enforcement of trademark infringement, taking over the responsibilities and jurisdictional authority previously held by the Ministry of Commerce under Cabinet Resolution 496. Similarly, a new enforcement body, the National Committee for the Enforcement of Intellectual Property Rights, was announced in early 2021. The stated purpose of the committee is to guide and coordinate the enforcement of IP rights within the Kingdom. SAIP chairs the committee, which has representation from across the Saudi government, including the Ministries of Commerce, Justice, Communications, and Information Technology; the public prosecution office; General Customs Authority; and Saudi FDA. This positive development has resulted in a score increase of 0.5.



## Key Areas of Strength

- Implementation of new 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 2020
- Singapore is an active participant in efforts to accelerate patent prosecution—the Intellectual Property Office of Singapore has several PPHs in place and is a member of the GPPH

## Key Areas of Weakness

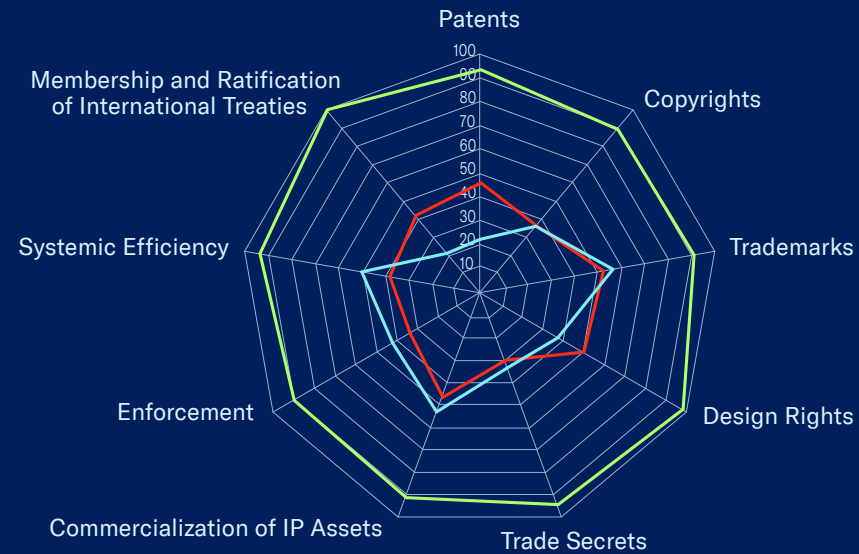
- Estimated software piracy has decreased from 35% in 2009 to 27% today—but is still high for developed high-income economy
- Lack of transparency and data on customs seizures of IP-infringing goods



# South Africa

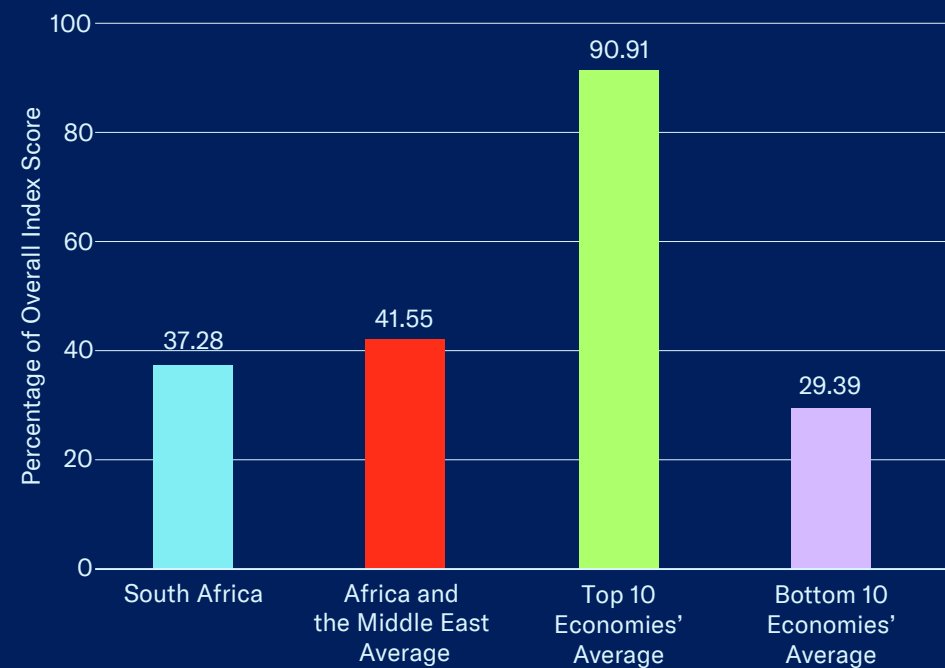
Rank  
45/55

## Category Scores



— South Africa — Africa and the Middle East Average — Top 10 Economies' Average

## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

- Growing emphasis on localization and local content requirements in economic and industrial policy—intensified in 2020
- *IP Policy Phase I* does not fundamentally address South Africa's gaps in IP protection—focus is not on innovation and development of new IP in South Africa but of use of existing developed IP through compulsory licenses, parallel imports, and restricting patentability of pharmaceuticals
- Proposed copyright amendments create uncertainty for rightsholders through expansive “fair use” definitions
- Major gaps in laws and enforcement across all categories of the Index





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.

The proposed amendments would strengthen and reinforce important aspects of South Africa's legal framework, including the protection for DRM and TPMs. There is no current provision in the existing Copyright Act with regards to DRM or TPMs. The proposed amendments contained a fairly robust set of draft sections corresponding with those already contained in the Electronic Communications and Transactions Act. Yet, overall, the proposed amendments did 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 did not consider additional enforcement measures such as the disabling of access through an injunctive-style relief program.

The last half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today EU Member States, the UK, India, Singapore, Russia, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called "dynamic" injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, the UK, and Russia. As the National Assembly and government move forward with the drafting of a new Copyright Act, they should consider adding equivalent provisions to South African law. In a

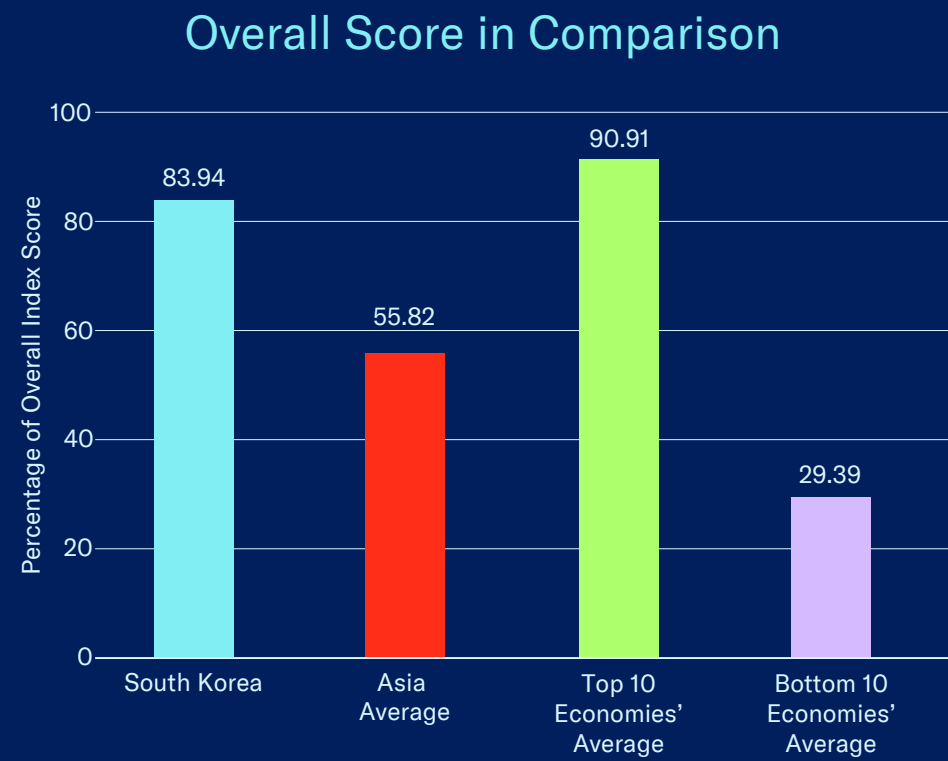
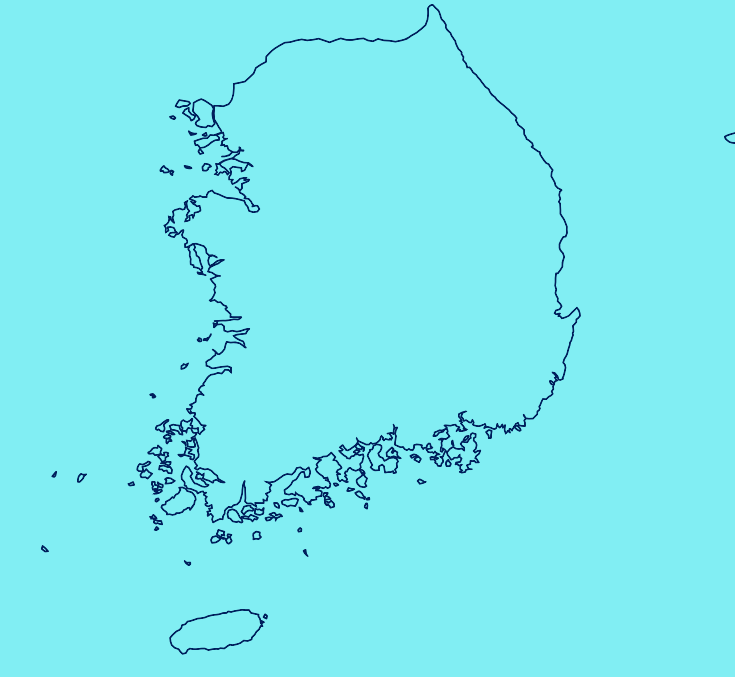
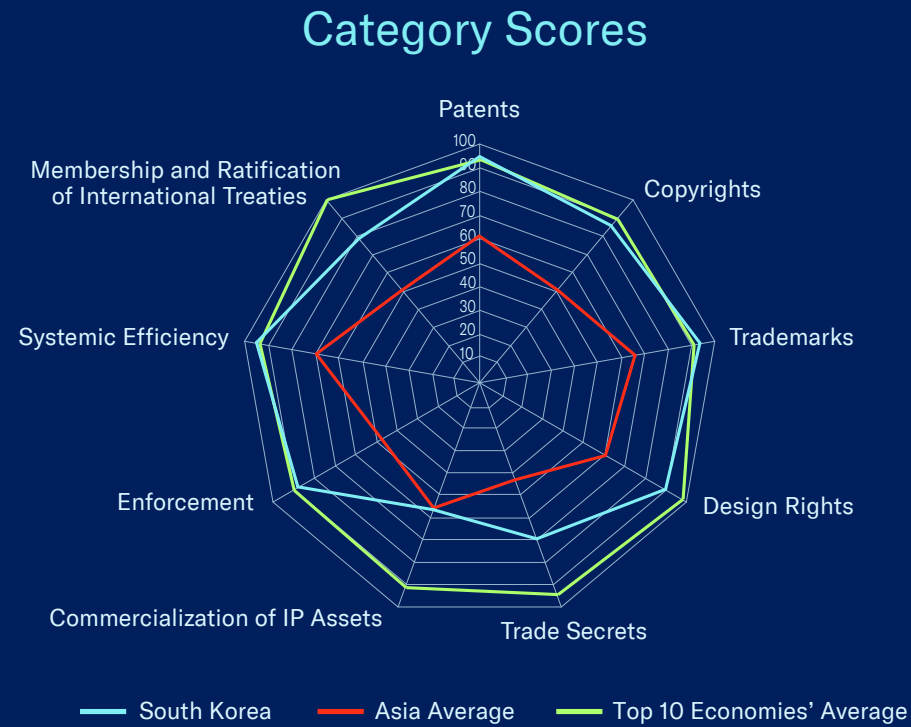
related development, the Cyber Crime Act 2020 (passed by the National Assembly in late 2020) was signed into law by President Ramaphosa in May 2021. The act may potentially improve the copyright enforcement environment. Although not specific to copyright (the act includes only a single reference to the protection of intangible assets, referred to as "incorporeal property"), the act does include a mandatory requirement that electronic service providers report any potential illicit behavior on or through their networks to the relevant authorities. The Index will continue to monitor these developments in 2021.

### Trade Secrets and the Protection of Confidential Information

**24. Protection of trade secrets (criminal sanctions):** As noted in previous editions of the Index, South African law does not define or provide protection for trade secrets through a trade secrets-specific statutory law. Like many other common law jurisdictions, protection is primarily afforded through case law and other statutes. For instance, the Electronic Communications and Transactions Act, 2002, provides for a limited form of criminal liability in the case of the illicit access and misappropriation of any type of data including an unspecified fine or maximum prison term of 12 months. 2021 saw positive developments in the protection of trade secrets and confidential information in South Africa. Having been debated since 2017, in December 2020 the National Assembly finally passed the Cyber Crime Act 2020, which was subsequently formally signed into law by President Ramaphosa in May 2021. The act strengthens the protection of trade secrets and confidential information in South Africa by providing a clear avenue for the criminal prosecution of the misappropriation and illicit accessing of trade secrets and confidential information. Chapter 2 of the act provides broad definitions of illegal access to and misappropriation of any type of data, including the breaching of

existing protection measures to keep data secure. Penalties are up to 15 years' imprisonment and fines. As a result of this positive development, the score on this indicator has increased by 0.25.





## Key Areas of Strength

- Amendments to the Unfair Competition Prevention and Trade Secret Protection Act in 2020 strengthened criminal sanctions for trade secret theft
- Amendments to the Patent Act and Unfair Competition Prevention and Trade Secret Protection Act in 2020 strengthened the basis for which damages can be awarded for patent and trade secret infringement
- Patenting standards are generally in line with international best practices
- Generally strong online/digital copyright protection (with important exceptions, including software)
- Relatively robust legal framework for trademark and design protection
- Membership in Global PPH and IP5 and new post-grant patent opposition mechanism streamline the patent office
- Korean Intellectual Property Office (KIPO) provides SMEs with a variety of educational and technical assistance programs as well as right to reduced filing fees

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>5.99</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	1.00
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	1.00
14. Scope of limitations and exceptions to copyrights and related rights	0.75
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	1.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	1.00
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	1.00
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.80</b>
21. Industrial design term of protection	0.80
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1.00
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.10</b>
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.60

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>3.42</b>
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>6.16</b>
32. Physical counterfeiting rates	0.73
33. Software piracy rates	0.68
34. Civil and precedural remedies	0.75
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	1.00
36. Criminal standards including minimum imprisonment and minimum fines	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	1.00
<b>Category 8: Systemic Efficiency</b>	<b>4.75</b>
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>5.50</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:**  
**41.97**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

South Korea's overall score has increased from 83.73% (41.86 out of 50) in the ninth edition to 83.94% (41.97 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

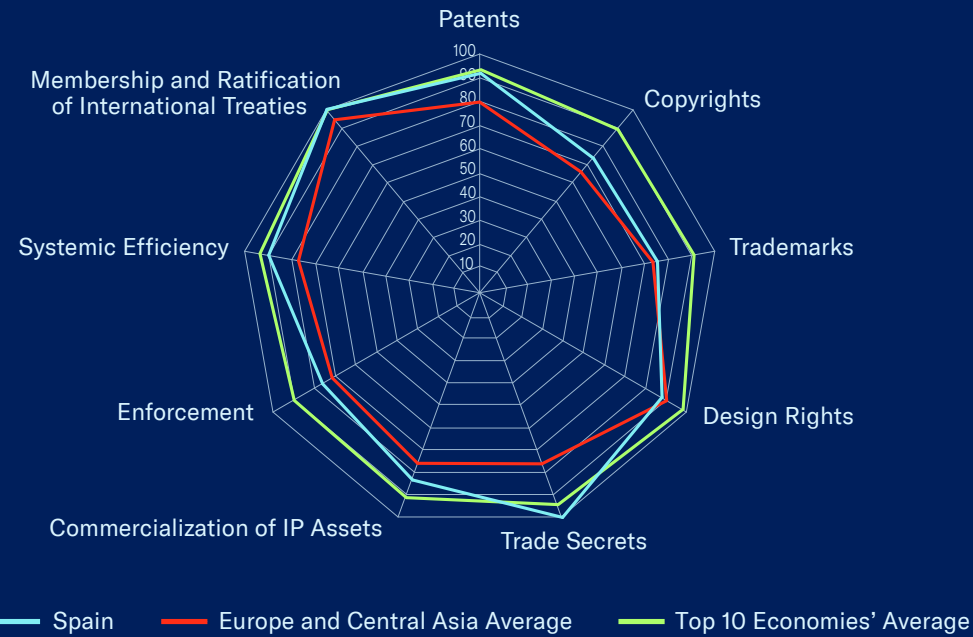
### Copyrights, Related Rights, and Limitations

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

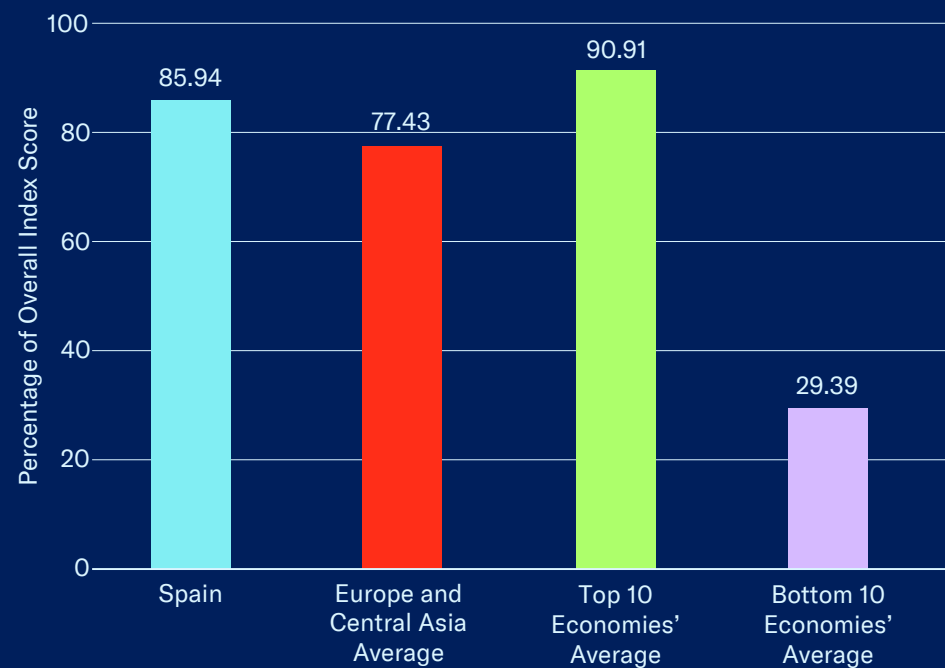
The result of these reforms has been that copyright piracy in Korea has decreased substantially. This has been achieved while internet connectivity

and speed have increased manifold with more Koreans than ever accessing content online. At the same time, the creative sector in Korea has flourished. For example, the 2012 WIPO-commissioned study, *The Economic Contribution of Copyright-Based Industries in the Republic of Korea*, found that the copyright industries made a substantial contribution to both national economic output and employment. The report found that copyright-intensive industries constituted 9.89% of total national economic output (GDP) in Korea and 6.24% of total employment. More recent research suggests that the economic impact of Korea's cultural industries and the creative economy were substantial and valued at over USD12 billion in exports in 2019. As such, Korea stands as an example to southeast Asia and emerging markets around the world of what strong and consistent protection of copyright can achieve in terms of stimulating innovation, cultural production, and income-generating economic activity. In January 2021, the Ministry of Culture, Sports, and Tourism proposed amendments to the Copyright Act to allow the reproduction of copyrighted works for information analysis, offer authors the right to claim additional remuneration, provide a "right of publicity" for people who are the object of a portrait, and extend the collective management organizations that can represent rightsholders. The Index will continue to monitor these developments in 2022.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- 2021 Protocol to Strengthen the Protection of Intellectual Property Rights further strengthens Spanish enforcement efforts
- 2019 trade secret law operational—Business Secrets Act entered into force in March 2019
- Stronger copyright enforcement measures in place through Royal Decree Law 2/2018—continued enforcement efforts through Ministry of Culture
- As an EU Member State, Spain has in place an advanced IP system
- Sector-specific rights in place and enforced
- Efforts to strengthen and modernize patent and copyright frameworks, including with respect to online copyright enforcement
- Civil and criminal reforms enhance remedies available for IP infringement
- Active public awareness campaigns and engagement efforts

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>5.13</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.75
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	0.75
14. Scope of limitations and exceptions to copyrights and related rights	0.75
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.75
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.00</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.75
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.75</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.75
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>3.00</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>5.00</b>
26. Barriers to market access	0.75
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
<b>Category 7: Enforcement</b>	<b>5.34</b>
32. Physical counterfeiting rates	0.76
33. Software piracy rates	0.58
34. Civil and precedural remedies	0.75
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.50
36. Criminal standards including minimum imprisonment and minimum fines	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	1.00
<b>Category 8: Systemic Efficiency</b>	<b>4.50</b>
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>7.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
42.97**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Spain's overall score has increased from 84.68% (42.34 out of 50) in the ninth edition to 85.94% (42.97 out of 50) in the tenth edition. This reflects a score increase on indicators 12, 13, and 32.

### Copyrights, Related Rights, and Limitations

**11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and 12. Expeditious injunctive-style relief and disabling of infringing content online:** For many years, the protection of copyrighted material online has been a serious challenge for rightsholders in Spain. Historically, most digital content accessed has been infringing, with the consumption of unauthorized content particularly visible in the areas of TV, gaming, and sports. Industry reports from 2015 suggested that almost 90% of creative content online consumed in Spain was pirated. Similarly, a 2016 study from the consultancy IDC suggested a rate of 45% of illegal software use in businesses. Estimates from the BSA on the total use of unlicensed software echo these findings: Since 2011 the estimated rate of unlicensed software usage has hovered between 42% and 45% of total software used. This compares to an average estimated rate of 26% for the rest of Western Europe.

Unlicensed software in Spain is more comparable to economies outside of the EU in Asia, Latin America, and the MENA region, where average rates of unlicensed software are often over 50% of the total. In light of these challenges, the Spanish government has since the early 2010s embarked on a series of copyright reform efforts, including significant legislative changes and stronger enforcement at both the administrative and judicial levels. Key changes include amendments to the Intellectual Property Act and the Criminal

Code in 2014-15, introduction of the Sinde Act of 2012, and several royal decrees. The Sinde Act created a notification regime whereby the Spanish Intellectual Property Commission may receive notices from copyright owners and determine which should be sent on to relevant ISPs, who then should either disable access to the identified content within 72 hours of the notice or have the case brought before a court of law. These administrative cases are initiated by the Second Section of the Intellectual Property Commission that considers the websites' audience share, number of works, or business model. From its creation in 2012 until 2018 (included), the commission's work has resulted in 114 websites being closed and 466 websites removing content from their pages. Of these, over 90% did so without a court order. As a result, there has been a substantial reduction in pirate page audiences in Spain: In 2018 there were 13 pirate websites among the 250 most visited in the country, down from 19 in 2017. The commission has also worked directly with the private sector and used new anti-piracy software provided by the Spanish soccer association *La Liga*. The powers of the commission and of this administrative enforcement route have since been expanded.

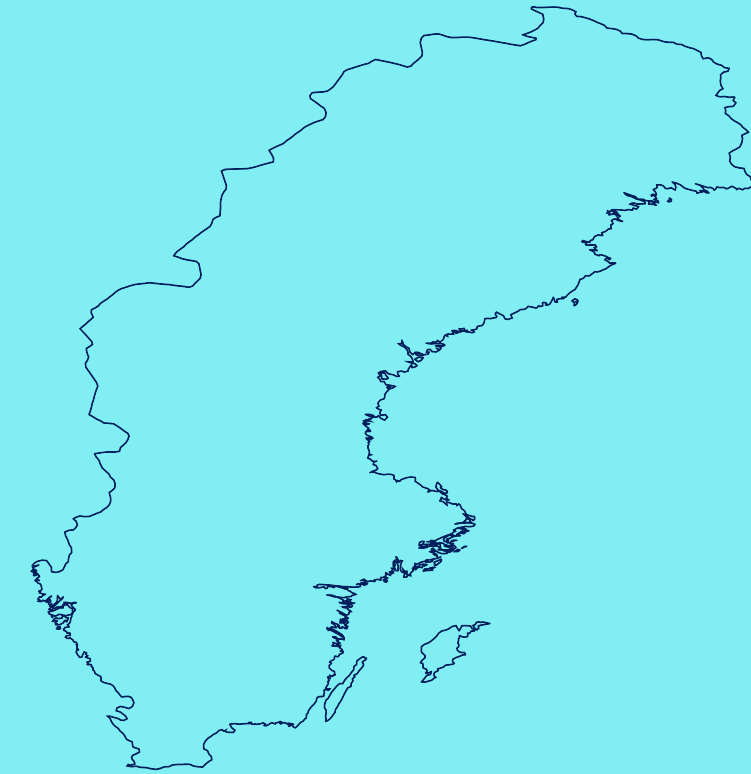
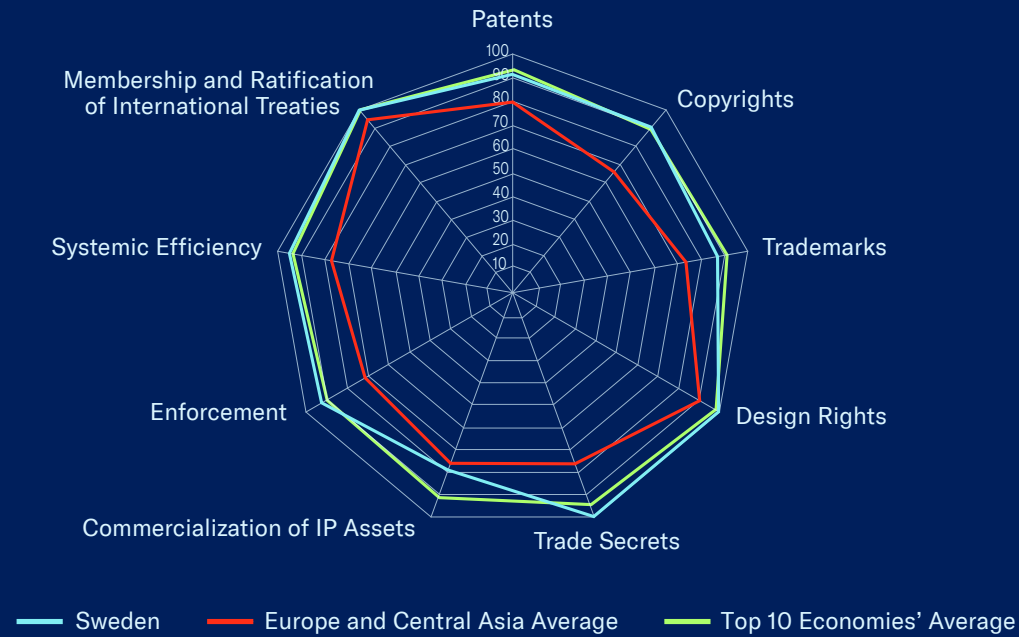
In 2019 amendments to the revised Intellectual Property Law came into force, incorporating measures outlined in Royal Decree Law 2/2018. These amendments further strengthen available tools in the fight against online crime, including copyright infringement. Among the major updates to the text is the capacity granted to the Second Section to close a webpage for up to one year without a judicial order in case of a reiteration of non-compliance (Article 195.6). Reiteration of non-compliance is also punishable with an administrative sanction of between EUR 150,000 and EUR 600,000 (the first such fine was issued by the commission in 2018). At the same time as the commission has expanded its remit and enforcement efforts, there have also been stronger



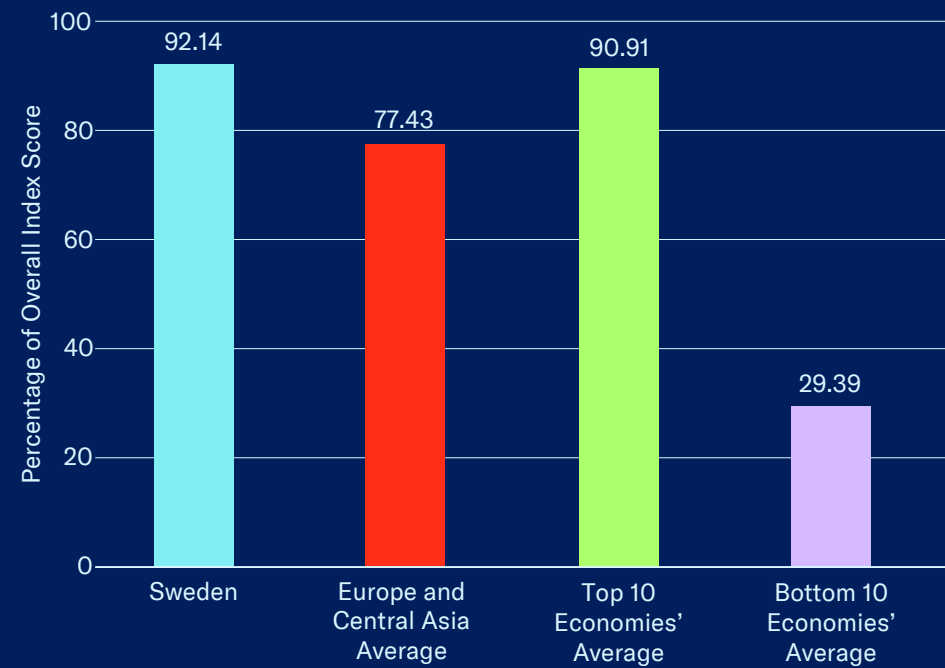
enforcement efforts through the Spanish courts and police. Like in many other EU Member States, rightsholders in Spain are now able to effectively seek redress through the judiciary.

Over the past few years, Spanish courts have issued several orders to ISPs in relation to sites linking to pirated content, including The Pirate Bay. For example, in a 2017 case (STC No. 24/2017), the Commercial Court of La Coruña granted an order against the owner of the linking site Rojadirecta.es, which provided unauthorized access to sports events broadcast by Movistar (a domestic TV distributor). In 2018 another court ordered ISPs to disable access to two major piracy websites with audiences across most Spanish-speaking countries (HDFull and Repelis—the latter was labeled a “Notorious Market” by the USTR). Similarly, the national police force *Guardia Civil* has carried out notable enforcement efforts. In 2018 the Guard’s Department of Telematic Crimes disabled access to 23 websites dealing with pirated movies, TV shows, music, and video games under the framework of operation *Cascada*. The guard’s operations led to the disabling of access to 49 highly-frequented piracy websites and to the arrest of three of their administrators. One of the main Spanish-speaking piracy organizations (linked to the domain descargasmix.com) was dismantled in cooperation with Argentine authorities. These positive efforts continued in 2021. Specifically, in April a new “Protocol to Strengthen the Protection of Intellectual Property Rights” was signed by representatives of the content industry and representatives for the largest telecommunications service providers in Spain. The protocol was developed through the active support of the Ministry of Culture and Sports, which had been hosting a technical Working Group. The purpose of the protocol is to improve existing enforcement procedures and, specifically, address the issue of mirror sites. As a result of these positive actions, the score on indicators 12 and 13 have increased by 0.25, respectively.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- 2021 accession to Convention on Cybercrime
- Strong and sophisticated national IP environment
- Online copyright enforcement improving over the last few years with stronger police enforcement and precedent-setting court decisions on ISP responsibility
- New case law in 2020 creates more certainty as to under what circumstances Swedish ISPs and internet mediators will be ordered to disable access to infringing content

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>6.35</b>
10. Copyright (and related rights) term of protection	0.60
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	1.00
12. Expeditious injunctive-style relief and disabling of infringing content online	1.00
13. Availability of frameworks that promote cooperative action against online piracy	0.75
14. Scope of limitations and exceptions to copyrights and related rights	1.00
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	1.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	1.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	1.00
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	1.00
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>2.00</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1.00
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>3.00</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>4.75</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>6.47</b>
32. Physical counterfeiting rates	0.91
33. Software piracy rates	0.81
34. Civil and precedural remedies	0.75
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	1.00
36. Criminal standards including minimum imprisonment and minimum fines	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	1.00
<b>Category 8: Systemic Efficiency</b>	<b>4.75</b>
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	1.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>7.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
46.07**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Sweden's overall score has increased from 90.92% (45.46 out of 50) in the ninth edition to 92.14% (46.07 out of 50) in the tenth edition. This reflects a score increase on indicators 32 and 48.

### Copyrights, Related Rights, and Limitations

**13. Availability of frameworks that promote cooperative action against online piracy:** As has been detailed in previous editions of the Index, like all other EU Member States, Sweden has for the past two years been in the process of transposing EU Directive 2019/790 on copyright and related rights in the Digital Single Market (CDSM Directive). A first draft of the implementing law was published in October 2021 by the Ministry of Justice. The draft law broadly follows the scope of the underlying directive, particularly regarding responsibilities and requirements under Article 17. While maintaining existing exceptions and limitations provided under Swedish and European copyright law and jurisprudence, the law strengthens protections for creators online by providing clear definitions of what constitutes secondary liability for communication to the public of a protected work. It also provides a clear definition and safe harbor mechanism for content-sharing platforms to avoid any direct liability. One positive change in the proposed law is a clarification on the extent to which text and data mining are allowed for research purposes. This is an important area of future economic activity, as advances in computational power and new technological advancements in AI and machine learning allow for scientific advances and innovation to take place through the analysis of large volumes of data and information. The Index will continue to monitor these developments in 2022.

### Systemic Efficiency

**43. IP-intensive industries, national economic impact analysis:** Both the Swedish government and relevant institutions, including the Swedish Patent and Registration Office (*Patent- och registreringsverket*) and innovation agency Vinnova, are placing a stronger emphasis on understanding the link between IP rights and economic activity and the economic contribution these industries make to the Swedish economy. For example, in 2016 the Swedish government, in its strategic overview for higher education and research (*Regeringens proposition 2016/17:50, Kunskap i samverkan—för samhällets utmaningar och stärkt konkurrenskraft*), stated clearly that there should be more government-commissioned research into the relationship between economic activity and IP assets: "The Government therefore sees a need for a broad knowledge increase in the area of intellectual property law in business, universities and colleges and other public activities." Similarly, in a 2015 policy report, the Ministry of Enterprise and Innovation (*Näringsdepartementet*) recommended that more resources and a dedicated research program be put in place to strengthen the study of the relationship between IP assets, innovation, and economic growth in Sweden.

As a Member State of the European Union and contracting party to the European Patent Convention, the Swedish government also takes part in the multitude of research efforts conducted by European institutions. A swathe of 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 economics of IP-intensive industries include the EPO, EUIPO, EUROSTAT, and European Commission. The latest such research is the 2019 *IPR-Intensive Industries and Economic Performance in the European Union* published by



the EUIPO and EPO. This study found that IP-intensive industries contributed an estimated 42.9% of Swedish GDP, on average, in the period 2014-16. Similarly, regarding employment, an estimated 32.1% of the Swedish labor force worked in IP-intensive industries. This important work continued in 2021 with the release of Intellectual Property Rights and Firm Performance in the European Union. Co-produced by the EPO and EUIPO, this report examines the relationship between IP rights and rates of economic activity at the firm level. Overall, the report finds that European businesses that own at least one registered form of IP right (patents, designs, or trademarks) have, on average, 20% higher revenues per employee than businesses with no registered IP portfolio. Similarly, the report found that firms with registered IP rights also pay higher wages—19% higher, on average. The EPO and EUIPO should be congratulated for the production of this report and for their leadership on providing detailed statistical data and economic analysis of the socio-economic benefits of IP rights.

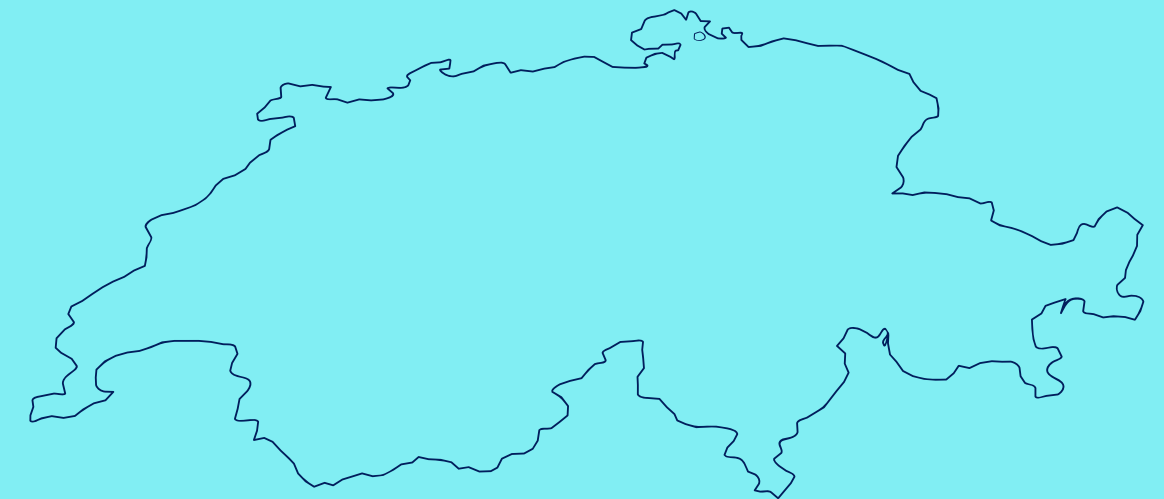
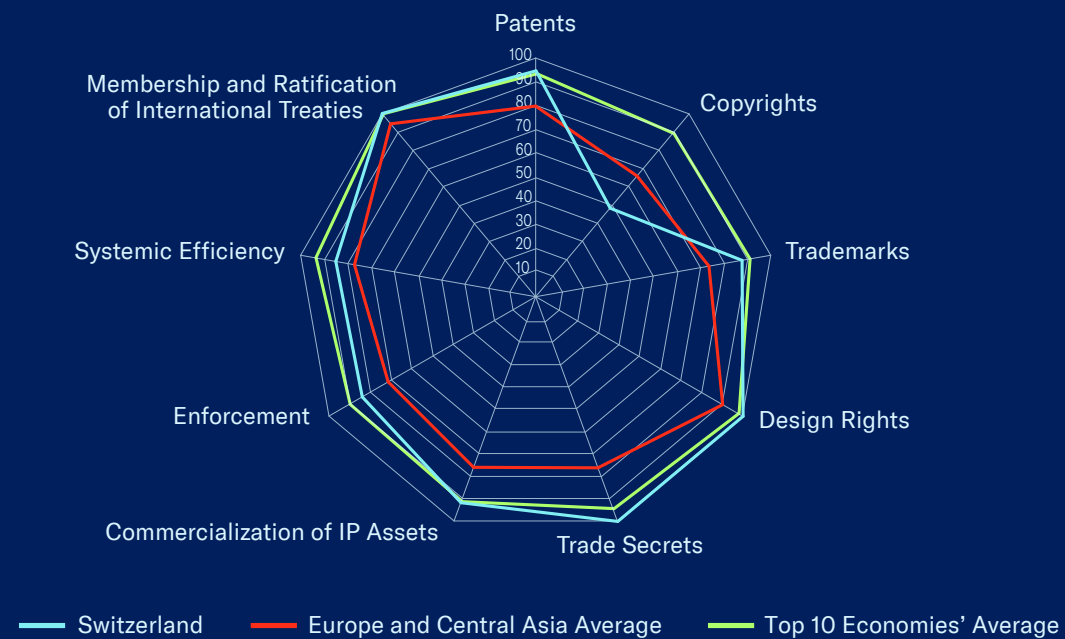
### Membership and Ratification of International Treaties

#### 48. Membership of the Convention on

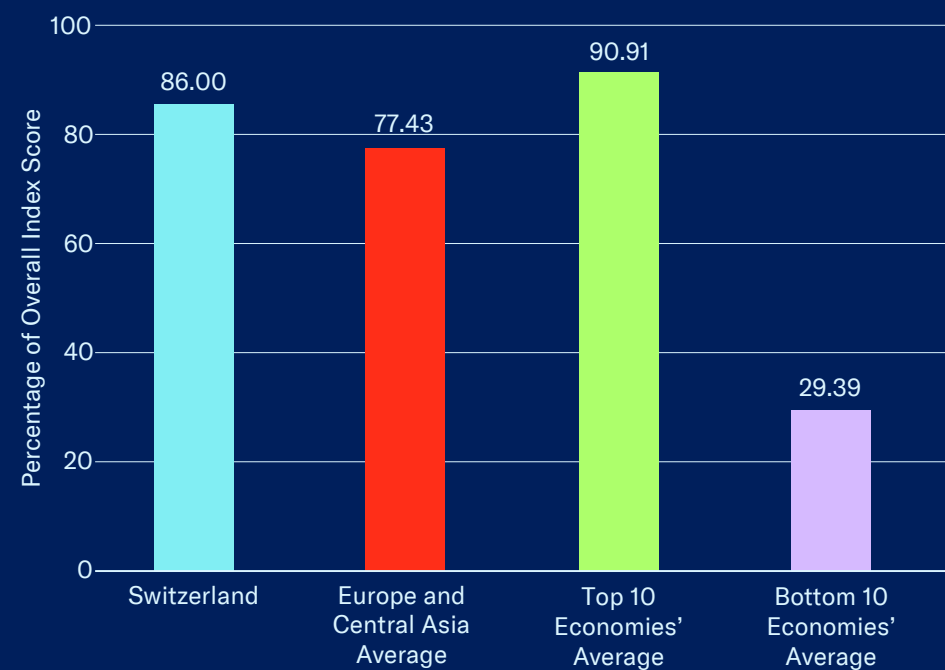
**Cybercrime, 2001:** In April 2021, Sweden became a full contracting party to the Convention on Cybercrime. A signatory since 2001, the Swedish Parliament (*Riksdag*) finally ratified the treaty in April 2021 and Sweden formally acceded with the treaty entering into force in August. As a result, the score on this indicator has increased by 0.5. Sweden is now a full contracting party to all international treaties included in the Index.



## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.50</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.50
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	1.00
9. Patent opposition	1.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>3.38</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.50
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	1.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>3.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	1.00
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	1.00
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>2.00</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	1.00
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>3.00</b>
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>5.50</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
<b>Category 7: Enforcement</b>	<b>5.87</b>
32. Physical counterfeiting rates	0.83
33. Software piracy rates	0.79
34. Civil and preceudural remedies	0.75
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.75
36. Criminal standards including minimum imprisonment and minimum fines	0.75
37. Effective border measures	1.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	1.00
<b>Category 8: Systemic Efficiency</b>	<b>4.25</b>
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.75
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>7.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
43.00**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Switzerland's overall score has increased from 85.82% (42.91 out of 50) in the ninth edition to 86.00% (43.00 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Copyrights, Related Rights, and Limitations

**11. Legal measures that provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights:** As noted in previous editions of the Index, online piracy in Switzerland is a long-standing issue and a departure from Switzerland's otherwise gold-standard IP regime. Broad precedent established in the landmark 2010 Federal Supreme Court decision *Federal Data Protection and Information Commissioner v. Logistep AG*—in which IP addresses were viewed as constituting “personal data”—has severely limited the ability to identify and build cases against infringing users. This development has discouraged Swiss prosecutors from taking on such cases. While there are some examples of cases where rightsholders have successfully been able to defend their rights, overall, enforcement has been difficult. For example, while a 2014 judgment in the Zurich Canton High Court (*Obergericht Zürich, Case UE130087*) on illegal file-sharing did recommend the prosecution of the alleged infringing activity, the case also re-affirmed that the monitoring of the activity of the alleged infringer was a violation of the individual's privacy. Without a legal tool for targeting infringing users or the platforms on which they operate, digital and online piracy has remained widespread and Switzerland has become a hub for sites hosting infringing content.

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 in 2014 announced an ambitious reform plan following the recommendations by the Swiss Working Group on Copyright (AGUR12). A draft copyright law was presented for public discussion in December 2015 but, given the more than 1,200 contributions received, underwent further review by a new multi-stakeholder group (AGUR12 II).

In late 2017, the Swiss Federal Department of Justice and Police (*Eidgenössische Justiz- und Polizeidepartement*) published new draft amendments and announced that copyright reforms would finally go ahead. These amendments were approved by the Swiss Federal Council (*Bundesrat*) in November 2017, the Federal Assembly (*Schweizer Parlament*) in 2019, and 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. On the one hand, the final amendments did introduce 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, critically 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.

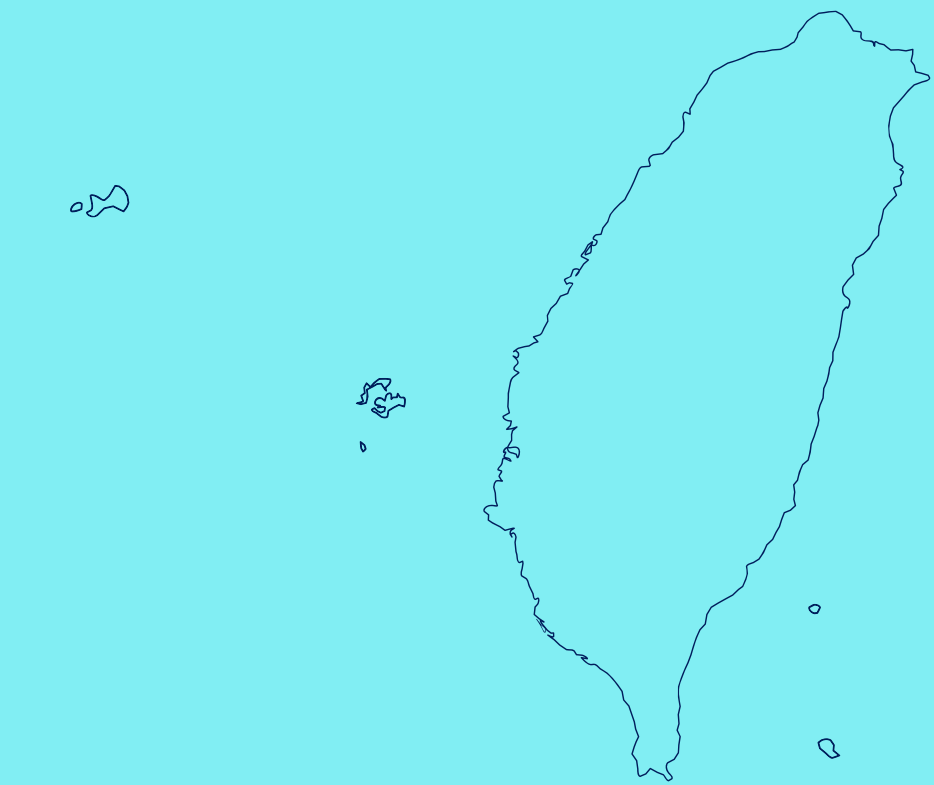
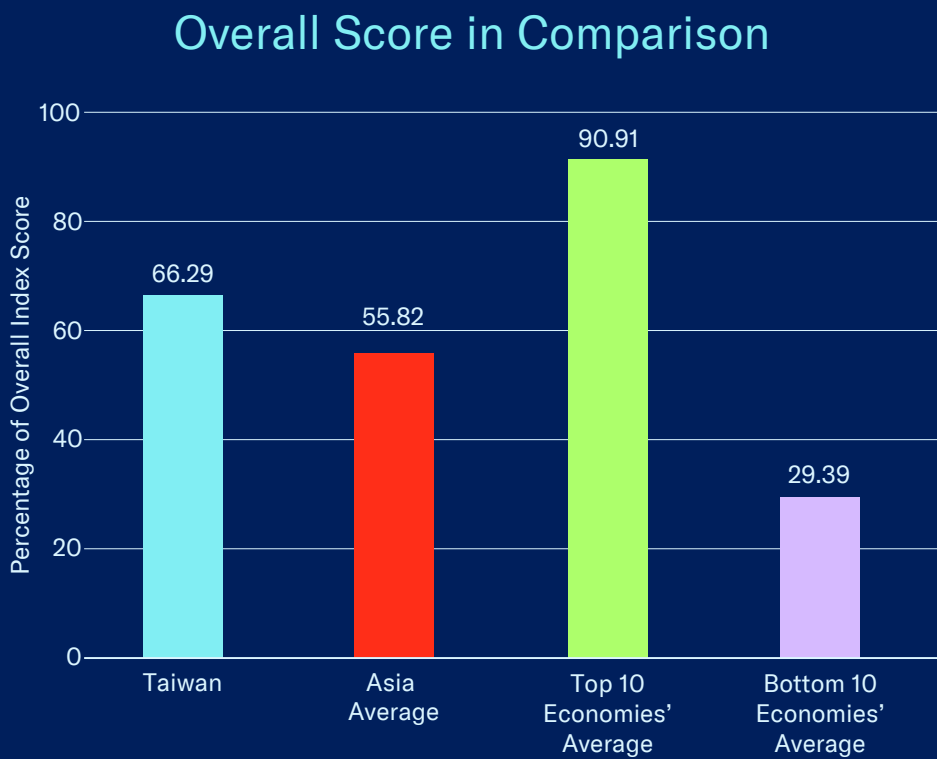
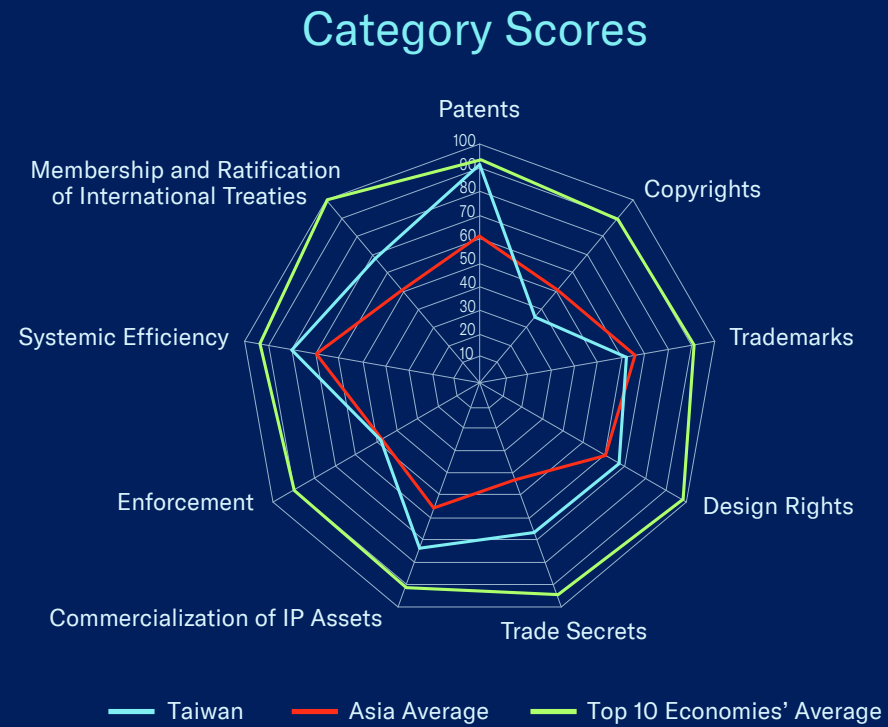
Historically, Switzerland’s private use exception has been interpreted broadly and has been confirmed by the Swiss government and existing case law to include the downloading and sharing of infringing content. Article 19 of the Copyright Act asserts that the downloading of content (other than software) 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, there is no distinction made between whether the downloaded copy is itself a legal version. In other words, even if the material has been made available in an illegal manner, the private use exception still applies in Switzerland. This remains unchanged to this day. Indeed, the Federal Institute of Intellectual Property clearly stated at the time of enactment of the 2020 amendments that the changes to Swiss copyright law did **not** affect existing personal use exceptions: “Nothing changes for consumers of illegal content. They are allowed, for example, to continue downloading music which was published online without the permission of the rightsholder for private use.” Finally, it remains unclear what

the legal consequences, if any, will be for internet hosts that fail to comply with the conditions of Article 39d or under what circumstances a refusal to comply with the law is acceptable. In sum, the reforms remain a real missed opportunity for rightsholders in Switzerland and internationally.

While addressing some of the shortcomings in the existing legal framework, the amendments did not fundamentally change the dynamics of copyright enforcement and online piracy in Switzerland. Of note is how 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 last half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today, EU Member States, the UK, India, Singapore, Russia, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called “dynamic” injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, the UK, and Russia. Only this past year has seen Canada added to this list of economies with a Federal Court of Appeal ruling affirming the right to injunctive relief and the disabling of access to infringing content online under existing Canadian statute.

These limitations and questions about the ultimate effectiveness of the Swiss amendments remained unaddressed in 2021. On the one hand, some examples of positive copyright enforcement efforts were reported. For instance, in late 2020, *Canal+* and the Kudelski Group (a cybersecurity

organization) announced that, working closely with local law enforcement, they had successfully disabled access to a significant source of pirated content globally operated out of Switzerland. The provider, KBoxServ, sold illicit streaming devices and illegal access to thousands of television shows, film, and audiovisual content including French-speaking content created and supported by *Canal+*. This operation was reportedly based on a criminal complaint made to local Swiss police. Still, industry sources continue to suggest that Switzerland and Swiss entities are linked to the dissemination of copyright-infringing materials. The Index will continue to monitor these developments in 2022.



## Key Areas of Strength

- Continued strong support for SMEs developing IP assets through 2021 TIPO fast-track examination procedure and expanded technical assistance
- Amendments to trade secrets law improved IP environment in 2020
- Pharmaceutical linkage regime operational—strengthens protection and enforcement of biopharmaceutical IP rights
- Term of protection for industrial design rights extended from 12 to 15 years
- Patent framework in line with international standards
- Though facing political hurdles to becoming a contracting party, Taiwan has in many cases implemented the provisions of several international IP treaties

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>8.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of computer-implemented inventions (CIIs)	1.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	1.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	1.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.75
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.53</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.35</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.75
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>2.00</b>
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>4.42</b>
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>3.35</b>
32. Physical counterfeiting rates	0.44
33. Software piracy rates	0.66
34. Civil and preceudal remedies	0.50
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.75
<b>Category 8: Systemic Efficiency</b>	<b>4.00</b>
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.75
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>3.75</b>
44. WIPO Internet Treaties	0.75
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.50
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.50
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
32.15**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Taiwan's overall score has increased from 66.18% (32.10 out of 48.5) in the ninth edition to 66.29% (32.15 out of 48.5) in the tenth edition. This reflects a score increase on indicator 32.

### Area of Note

Taiwan is currently in the process of reforming various parts of its national IP environment. As detailed below, copyright reforms have been ongoing for the past decade, and the last few years have also seen several draft versions for legislative changes to the Patent Act (and corresponding implementing regulations and rules) as well as relevant trademark statute and rules. Some of these proposals and changes would improve the national IP environment. For example, the new rules on the submission of third-party observations during patent prosecution formalize the process and provide applicants and third parties with more procedural transparency and clarity. The positive impact of other proposals is less clear. Proposed changes to the patent examination process could potentially preclude applicants in high-technology fields, including biotechnology and biopharmaceuticals, from supplementing their applications with post-filing data.

At the time of research, a lack of clarity remained regarding what final legislative changes would look like. In a related development, in late 2021 the Taiwanese government (the Executive Yuan) announced that a formal application to join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) had been submitted. News reports suggest that because of this application, additional, fresh proposals for changes to relevant IP laws and regulations were being considered within the government and parliament (Legislative Yuan). Covering 50 indicators across nine separate categories the

Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need in order to fully develop and commercialize their ideas and products. As the government and Legislative Yuan pursue a program of national IP rights reforms, we would encourage them to utilize the findings of the Index and accompanying *Statistical Annex* as a guide in 2022 and beyond.

### Copyrights, Related Rights, and Limitations

**11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); 12. Expeditious injunctive-style relief and disabling of infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights:** As has been noted over the course of the Index, rightsholders face significant challenges in protecting their content in Taiwan. Major gaps exist in the existing legal framework and enforcement remains inadequate. The Copyright Act provides for standard exclusive rights, including reproduction and performance. In 2009, amendments to the Copyright Act introduced a notice-and-takedown mechanism including safe harbors for ISPs that remove access to infringing sites or forward notices from rightsholders to infringing users. However, there was a great deal of ambiguity regarding how the mechanism should be implemented. For instance, it was not clearly defined what infringements ISPs should take action against, nor was it explained how ISPs should handle or respond to notices. In practice, although evidence suggests that local ISPs frequently respond to rightsholder notices, the law does not provide a mechanism for addressing foreign content, which has become a major source of online piracy.



There have been efforts on the ground to improve levels of enforcement, and relevant Taiwanese authorities have been fairly active. A special IPR Police Force has been created and the Taiwanese Intellectual Property Office (TIPO) has recognized copyright infringement as a major challenge. TIPO regularly publishes enforcement statistics on raids, arrests, and prosecutions. Still, digital and online piracy remain major problems in Taiwan. File-sharing, streaming, and deep-linking sites, particularly from abroad, represent the top platforms for illegal content. In 2020, the U.S. State Department noted the continued high levels of copyright infringement, including with respect to online piracy, academic book piracy, and illegal access to content through set-top boxes. In light of these challenges, amendments to the Copyright Act aimed at modernizing protection have been under review for close to a decade. In 2014, draft amendments were proposed that introduced the concept of a right of distribution and public communication and revised the definition of public transmission and broadcast to include aspects applicable in the digital and online arenas. The amendments also sought to further clarify exceptions to copyright provided under its fair use doctrine for education, libraries, software, and antenna systems. The proposed amendments also expanded criminal liabilities beyond possession or distribution of physical goods specifically to work more broadly (which can thereby include digital works). The proposed revisions were never acted upon by the Legislative Yuan and have remained dormant.

In 2019, smaller reforms were passed by the Yuan. Amendments to Articles 87 and 93 strengthen existing DRM and TPM provisions by punishing manufactures, importers, and distributors of pirated TV boxes with up to two years imprisonment and/or a fine. In 2020 and 2021, this piecemeal reform effort continued with TIPO releasing for public comment a new batch of draft amendments and a finalized draft Copyright Act approved by the

Executive Yuan and submitted to the Legislative Yuan. As noted in previous editions of the Index, while there are some provisions that strengthen the enforcement framework, overall, the proposed amendments do not fundamentally change the dynamics of copyright enforcement and online piracy in Taiwan. The proposed changes include only some aspects of the 2014 amendments, including an adjustment to the definition of public broadcasting and distribution, as well as changes to the existing framework on exceptions and limitations. At the time of research, it remained unclear exactly what the final package of changes would look like. The Legislative Yuan was reviewing the proposed amendments, and local news reports suggest that the legislation may be changed again as part of Taiwan's application to join the CPTPP.

As documented in the Index, Taiwan continues to lack many of the fundamental building blocks for effective copyright enforcement. None of the publicly available proposed changes to the Copyright Act have included any requirement or option for the disabling of access to illegal content whether through the judiciary or an administrative mechanism. The last half-decade has seen a sharp increase in the number of economies that are using judicial or administrative mechanisms to effectively disable access to infringing content. Today EU Member States, the UK, India, Singapore, Russia, and a host of other economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing so-called "dynamic" injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These types of dynamic injunction orders are becoming more commonplace, with similar mechanisms available in, for example, the Netherlands, Greece, Singapore, India, the UK, and Russia. Critically, they 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 2022.

### Systemic Efficiency

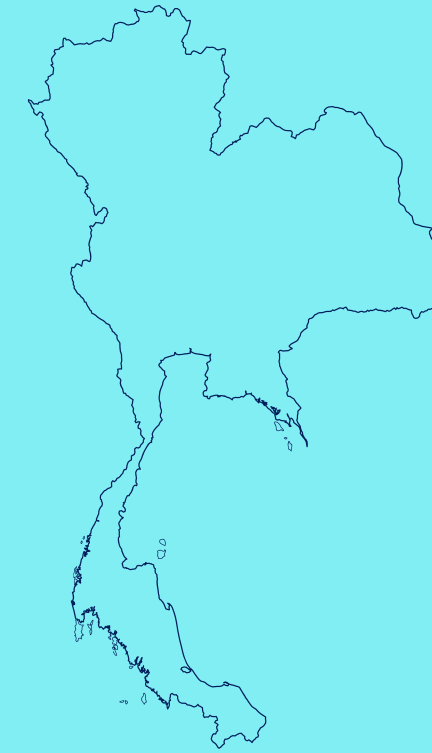
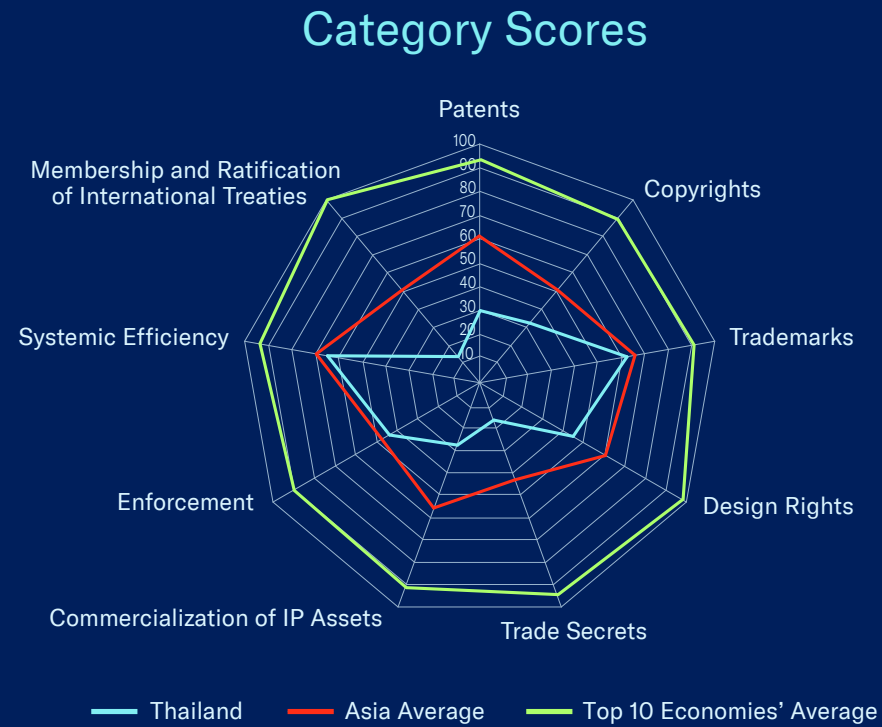
**42. Targeted incentives for the creation and use of IP assets for SMEs:** As has been noted over the course of the Index, Taiwan is one of the regional leaders in technology development, transfer, and IP commercialization activities. The Basic Law on Science and Technology introduced in 1999 establishes a Bayh-Dole style framework for tech transfer such that publicly funded IP rights and technologies are fully owned by public institutions. Taiwanese universities and research institutes are known for strong patenting rates as well as generating substantial income from royalties and license fees. Significant resources are dedicated to training IP management and commercialization for universities and SMEs. Since 2005, the Taiwan Intellectual Property Training Academy (TIPA), led by TIPO and the National Taiwan University, has provided training to IP professionals at several universities across Taiwan. TIPA targets SMEs and R&D institutions as well as academic, technology transfer, and legal professionals. Courses include IP management practice and commercialization strategies for all major types of IP rights. IP awareness classes are organized by TIPO and held at individual SMEs as well as industrial parks.

In terms of direct support, TIPO offers reduced fees and technical assistance to SMEs through various programs, including for patent commercialization, the "SME IP Zone," and bespoke consulting services for the identification and registration of IP assets. These efforts have been expanded considerably over the last two years and in response to the COVID-19 pandemic. TIPO has also created a new dedicated consulting service for SMEs to help them apply for patent registration outside of Taiwan in foreign jurisdictions. In January 2021, TIPO launched a new fast-track examination

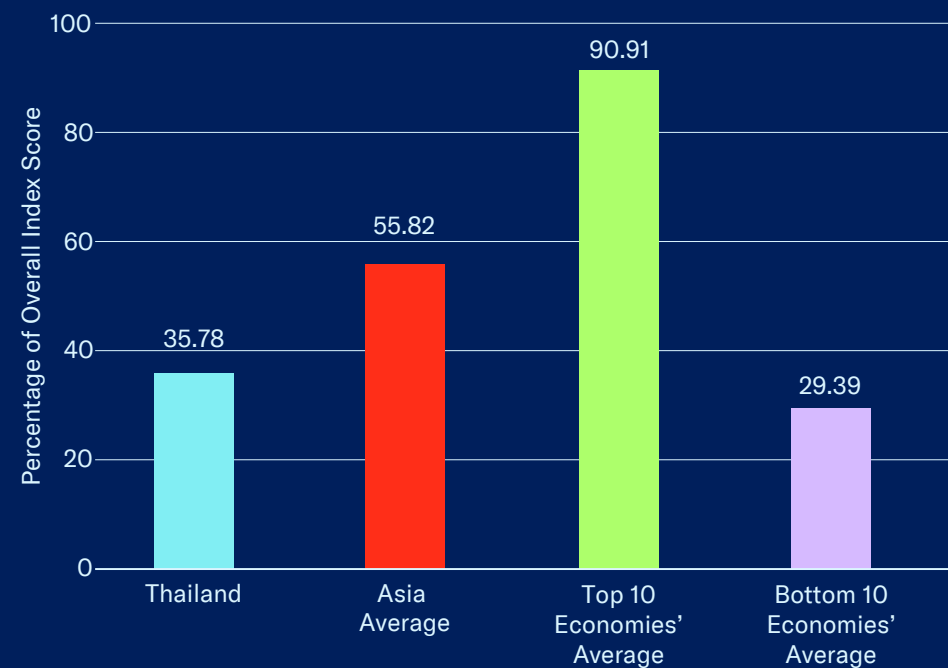
program for patent applications submitted by start-ups, the "Positive Patent Examination Pilot Program for Startup Companies." At the time of research, the program was only a pilot initiative and had not been made permanent. Should this program stay in place and become a permanent fixture, the score on this indicator will increase.

### Membership and Ratification of International Treaties

Taiwan is a full member of the WTO but is not eligible for membership in the UN or affiliated institutions including WIPO. Taiwan is therefore unable to join and become a contracting party to any WIPO-administered treaty. Taking into consideration these political hurdles to Taiwan becoming a contracting party to many of the treaties included in the Index, Taiwan has since the fifth edition of the Index not been scored on whether it is a signatory to and has acceded to these treaties. Instead, the Index has measured the extent to which core elements of the treaties included in the Index are present in equivalent Taiwanese domestic legislation. This is, however, not possible to do with all the treaties included in the Index. For example, those treaties whose primary goal is to establish and harmonize administrative and operational procedures for the international registration of IP rights cannot be wholly scored for Taiwan. Such treaties measured in the Index include the Patent Cooperation Treaty, Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks, and parts of the Hague Agreement Concerning the International Registration of Industrial Designs. Consequently, the score for Taiwan on this category is 5.5 and not 7. Overall, Taiwan's maximum available score on the Index is therefore 48.5 not 50.



### Overall Score in Comparison



### Key Areas of Strength

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

### Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>2.72</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	0.72
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.28</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.50
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.75
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.90</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.50</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>1.67</b>
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.67
<b>Category 7: Enforcement</b>	<b>3.07</b>
32. Physical counterfeiting rates	0.48
33. Software piracy rates	0.34
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.75
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.75
<b>Category 8: Systemic Efficiency</b>	<b>3.25</b>
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>1.00</b>
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:**  
**17.89**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Thailand's overall score has increased from 35.56% (17.78 out of 50) in the ninth edition to 35.78% (17.89 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Area of Note

Thailand is currently in the process of reforming various parts of its national IP environment, including statutory law, implementing regulations, and IP office examination manuals. As detailed over the course of the Index, in anticipation of Thailand's accession to the WIPO Internet Treaties, copyright reforms through both proposed direct amendments to the Copyright Act as well as changes to the Computer Crime Act have been put forward. Some of these proposed changes have been passed into law, but many more remain at a review stage. The latest draft Copyright Act from late 2020 builds on earlier proposals and would improve some aspects of Thailand's copyright environment. For example, the amendments include the creation of a notice-and-takedown scheme, the definition of liability for service providers, and some additional remedies for the circumvention of technological protection measures including the manufacture, sale, rental, or importation of circumvention devices. With respect to the proposed notice-and-takedown mechanism, it is critical that any final Copyright Act includes clear provisions on what constitutes secondary liability and the extent to which ISPs and online intermediaries must act in an expeditious fashion upon receiving a notice of alleged infringement.

Revisions to the Patent Act have also been ongoing for years, with several iterations of draft proposals put forward since 2018. At the time of research, it was still unclear what a final draft law would look like. On a positive note, early indications are 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 ten years. Covering 50 indicators across nine separate categories, the Index has for a decade provided a clear model for the type and strength of IP rights that international innovators, creators, and rightsholders need in order to fully develop and commercialize their ideas and products. As the Thai government and the National Assembly pursue a program of national IP rights reforms, we would encourage them to utilize the findings of the Index and accompanying *Statistical Annex* as a guide in 2022 and beyond.

### Trademarks, Related Rights, and Limitations

**19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks; and 20. Availability of frameworks that promote action against online sale of counterfeit goods:** As discussed in previous editions of the Index, rightsholders have long faced difficulties in protecting their trademarks in Thailand. The availability of physical counterfeit goods is high and as e-commerce grows, a growing proportion of the trade in counterfeits is moving online. The past three years have seen major developments with respect to online enforcement against counterfeit goods. In 2019 the Thai government through the national IP office, the DIP, held consultations with some of the major e-commerce platforms to discuss tools and procedures to more effectively tackle online infringement and the sale of counterfeit goods. The two largest online shopping platforms in Thailand, Lazada and Shopee, reported on existing or recently enhanced systems to tackle online piracy. Lazada—a subsidiary of Alibaba—has begun implementing Alibaba's IP Protection Platform system, which enables customers to file a complaint directly with the platform through either the website or the mobile application. Shopee reported on an





online link and a call center line where rightsholders can submit their complaints. The same year, the DIP organized a workshop bringing together rightsholders, internet platforms, and national and foreign enforcement agencies to discuss the platforms' role in tackling online piracy. The DIP also created a dedicated unit for online violations tasked with furthering dialogue among relevant stakeholders, including online marketplaces.

As reported in the Index last year, these positive developments continued in 2020 with what could perhaps be a precedent-setting application of an injunctive-style relief mechanism introduced in the 2016 Computer Crime Act. Specifically, these amendments provide a legal mechanism requiring ISPs to disable access to IP-infringing sites. Under the mechanism, the Ministry of Digital Economy and Society (MDES) may file a motion for a permanent injunction for disabling access to websites with IP-infringing content (defined as computer data that are a criminal offense against IP). MDES is notified by IP owners of infringing content and then sends a request for injunctive relief to a court. If an injunction is granted by a court, MDES orders the ISP to disable access to the site. Up until 2020, this mechanism had exclusively been used by copyright rightsholders. This has now changed, and both the MDES and a relevant court approve and order ISPs to disable access to several websites on the basis of infringement of trademark rights. As noted in last year's Index, the decision marks a potential new and pivotal avenue whereby rightsholders can more effectively enforce their trademarks online.

These positive efforts continued in 2021. In January the Deputy Prime Minister presided over the signing of an MOU between rightsholders, online retailers (including both Lazada and Shopee), and the Thai government. The purpose of the MOU is to facilitate stronger cooperation between online retailers, rightsholders, and relevant government ministries and agencies in eliminating

counterfeiting and strengthen the enforcement of IP rights. The Index commends the Thai government and, in particular, the DIP for the leading role it has played in these positive developments.

### Systemic Efficiency

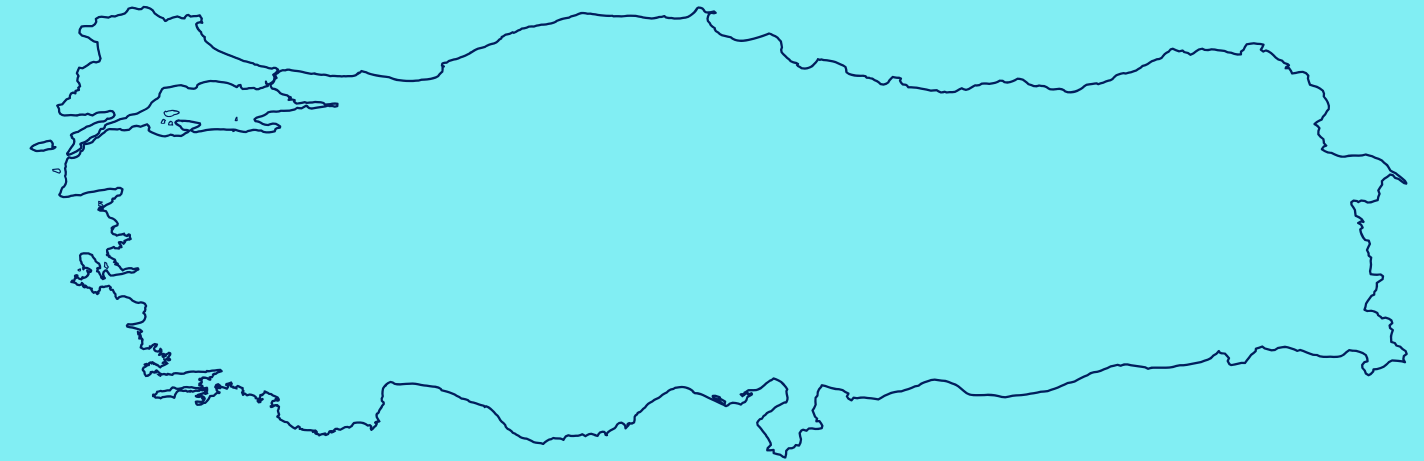
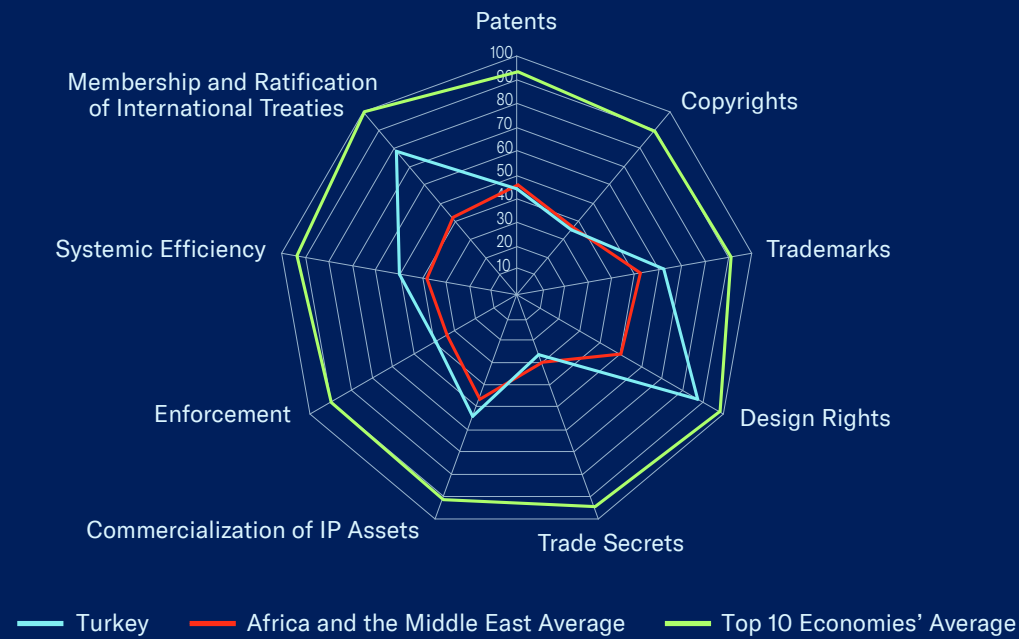
As has been noted over the course of the Index, Thailand is a leader among emerging markets with respect to the indicators in Category 8: Systemic Efficiency. Thailand achieves a score of 65% (3.25 out of 5) in this category. This compares to an overall Index score of 35.78%. This is also considerably higher than its performance in other Index categories. Thailand's score in this category is higher than many high-income markets—including both Kuwait and the UAE—and comparable to OECD members like Greece, New Zealand, and Israel. Since 2013 Thailand has had in place the National IP Center for Enforcement (NICE), a body created to promote cooperation across government agencies that covers enforcement of IP rights. Led by the DIP, the NICE focuses on operations aimed at serious offenders.

In 2016, Thailand introduced a follow-on platform, the Subcommittee on IPR Enforcement, which brings together 16 government agencies as well as industry groups, including the Thai FDA, National Science and Technology Development Agency, Pharmaceutical Research and Manufacturers Association, IP Association of Thailand, Fair Trade Area Watch, and Thai Pharmaceutical Manufacturers Association. Led by the Internal Security Operations Command, the subcommittee focuses on IP policy and enforcement. Similarly, relevant Thai authorities have historically and are currently supporting awareness-raising and educational activities on the socio-economic benefits of IP rights and the harm that counterfeiting does. Also, technical support programs are in place for inventors and creators. Specifically, the DIP has introduced a wide range of programs intended to educate SMEs about

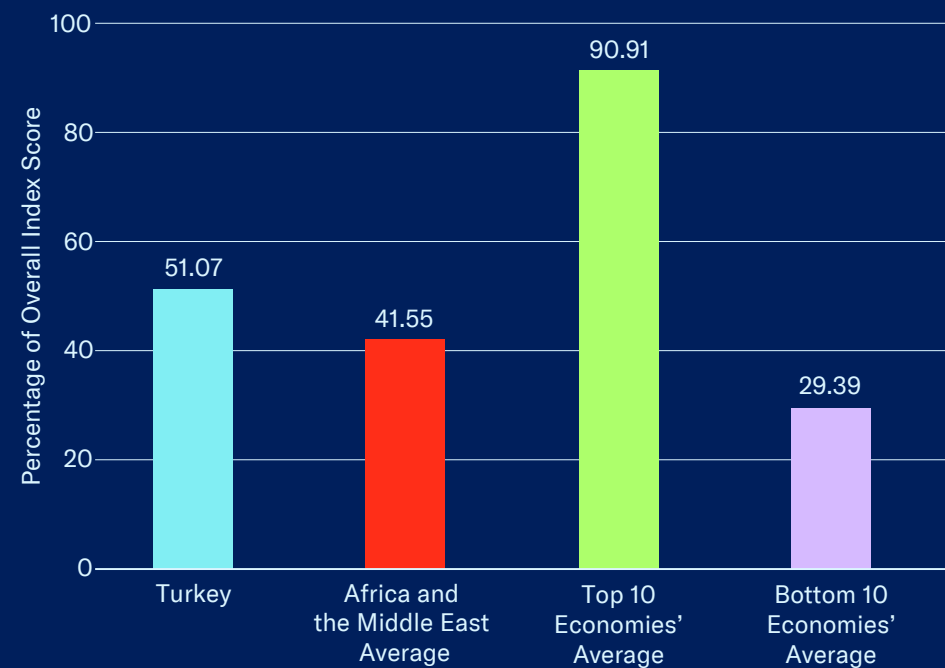
IP and enhance the role of IP in their business. It also has a unit dedicated to guide businesses to understand how to file an application.

The National Science and Technology Development Agency also has a program to assist SMEs in drafting patent specifications at a low cost. Several studies have also been commissioned or supported by the Thai government that examine the relationship between IP rights and economic activity. This includes the 2012 *The Economic Contribution of Copyright-Based Industries in Thailand*, commissioned by WIPO. This report found that the total contribution of copyright-related industries to the Thai economy was substantial, amounting to a value added of the equivalent of 4.48% of GDP and 2.85% of total employment. These efforts have continued over the last few years and, specifically, in response to the COVID-19 pandemic. The DIP has launched several additional support programs and policies, including deadline extensions and greater adoption of electronic and virtual services. The latter initiative includes the 2020-21 program "Smart DIP," which includes a dedicated e-platform for IP registration; an online dispute resolution process; and a growing database of patent and technology trends. Thailand's positive and sustained efforts in building its institutional capacity have been widely recognized. In 2018, Thailand was moved from the Priority Watch List to the Watch List on the United States Trade Representative's *Special 301 Report Out-of-Cycle Review*. When describing why it made this decision, the USTR rightly emphasized Thailand's sustained and systematic efforts on cross-governmental coordination and enforcement. Thailand stands as an example to other middle-income economies and emerging markets of how their national IP environments can be improved at an institutional level.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>4.00</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.50
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.50
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.49</b>
10. Copyright (and related rights) term of protection	0.74
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.50
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.75
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.75</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.75
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.80</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.30

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>3.25</b>
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
<b>Category 7: Enforcement</b>	<b>2.74</b>
32. Physical counterfeiting rates	0.30
33. Software piracy rates	0.44
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.75
<b>Category 8: Systemic Efficiency</b>	<b>2.50</b>
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>5.50</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.75
46. Patent Law Treaty and Patent Cooperation Treaty	0.75
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:**  
**25.53**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Turkey's overall score remains unchanged at 51.07% (25.53 out of 50).

### Commercialization of IP Assets and Market Access

**26. Barriers to market access:** Over the last 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. These policies have to a large extent targeted the research-based biopharmaceutical and ICT industries. In November 2014, the Turkish Prime Minister presented the objectives of covering 60% of national demand for pharmaceuticals and 20% for medical devices with local production, as well as increasing clinical research by 25%. In 2016 the Turkish Medicines and Medical Devices Agency began implementing an import substitution plan whereby drugs that have at least one local generic or therapeutic equivalent are required to localize their production by 2018 or be excluded from public reimbursement. An Import and Transfer Commission was set up to manage the process and evaluate commitments by drug producers. Industry reports suggest that close to 200 products were delisted in 2018, of which 71 medicines were identified and delisted from reimbursement in early 2018 by the Turkish Social Security Institution.

In 2019 the European Union filed a complaint before the WTO alleging that Turkey's localization policies were in violation of fundamental provisions of the General Agreement on Tariffs and Trade (GATT), the Agreement on Trade-Related Investment Measures (TRIMS), TRIPS, and the Agreement on Subsidies and Countervailing Measures (SCM) agreements. In September 2020, the WTO announced that due

to the COVID-19 pandemic, no final report would be issued on this dispute until the second half of 2021. As the time of research—late 2021—no report had been published by the WTO. More broadly, the Turkish government actively uses public procurement policies as a form of incentivizing localization and discriminating against foreign bidders. Since 2002, under Article 63 of the Procurement Law, domestically manufactured products are afforded a 15% price advantage in tenders. For several years, there was some uncertainty as to what constituted a “local” product. In 2014 the threshold for being considered a local product was explicitly defined and raised as part of Decree 2014/35. In order to obtain a Domestic Goods Certificate, and in so doing qualify for the price preference, all companies operating in Turkey, including foreign firms, must make domestic investments of at least 51% of the contract value. This investment must include major parts of the production process and not just the final stages. Also, any certificate applicants operating under a joint venture must be comprised of only domestic partners. Since 2015 all government ministries have the possibility to apply Industrial Cooperation (civil offset) clauses for public procurement contracts. Regarding the ICT sector, Turkish laws place onerous requirements (including local data storage) on ICT companies and digital service providers.

Sector-specific data storage requirements are in place on payment service providers and banking and financial services institutions. As with other localization measures, the requirements for data providers have intensified in the last few years. In 2020 the Turkish Parliament passed amendments to Law No. 5651 (the Regulation of Internet Broadcasts and Prevention of Crimes Committed through Such Broadcasts). These amendments require social media service providers with over 1 million visits per day to store any user data locally in Turkey, appoint a legal representative in Turkey, and report regularly on their activities and requirements under



these amendments. Non-compliance is potentially subject to substantial fines. While cross-border transfers are technically allowed under the Law on the Protection of Personal Data, such transfers can only take place after explicit consent has been obtained from the data subject or the country to which data is being transferred to provide an equivalent level of protection as in Turkey. These conditions have not improved in 2021. The Index will continue to monitor these developments in 2022.

## Enforcement

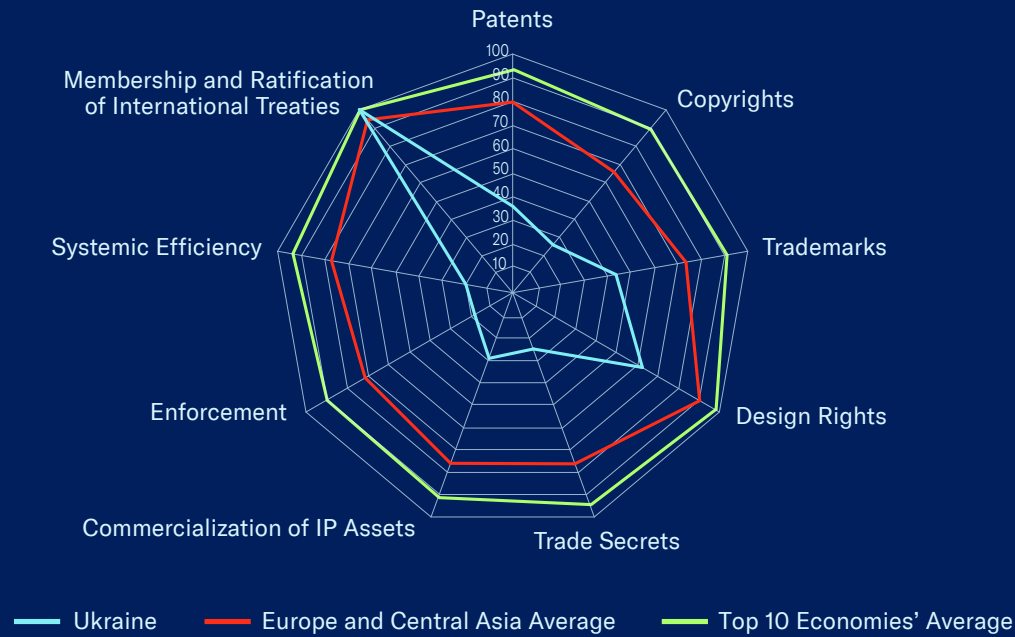
### 34. Civil and procedural remedies; and 35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement:

IP laws in Turkey generally provide for basic civil remedies, which include injunctions, damage awards, and, for patents and trademarks, the confiscation of goods and equipment used to produce infringing material. However, with respect to practical enforcement in Turkey, this is characterized by long delays. In the 2020 edition of the World Bank's *Doing Business* report, Turkey ranked 24<sup>th</sup> in the category "Enforcing contracts." Although a good overall ranking, it takes, on average, 623 days to enforce a contract—almost 2 years—and at an estimated cost of 24.9% of the claim value. These long delays have actually increased by almost 200 days over the last decade from an average of 449 days in the time period 2004-2015. More broadly, there remains a general dearth of IP expertise and experience on the part of the judiciary and public prosecutors and, in addition to the difficulty in obtaining preliminary injunctions, many sentences are reversed on appeal.

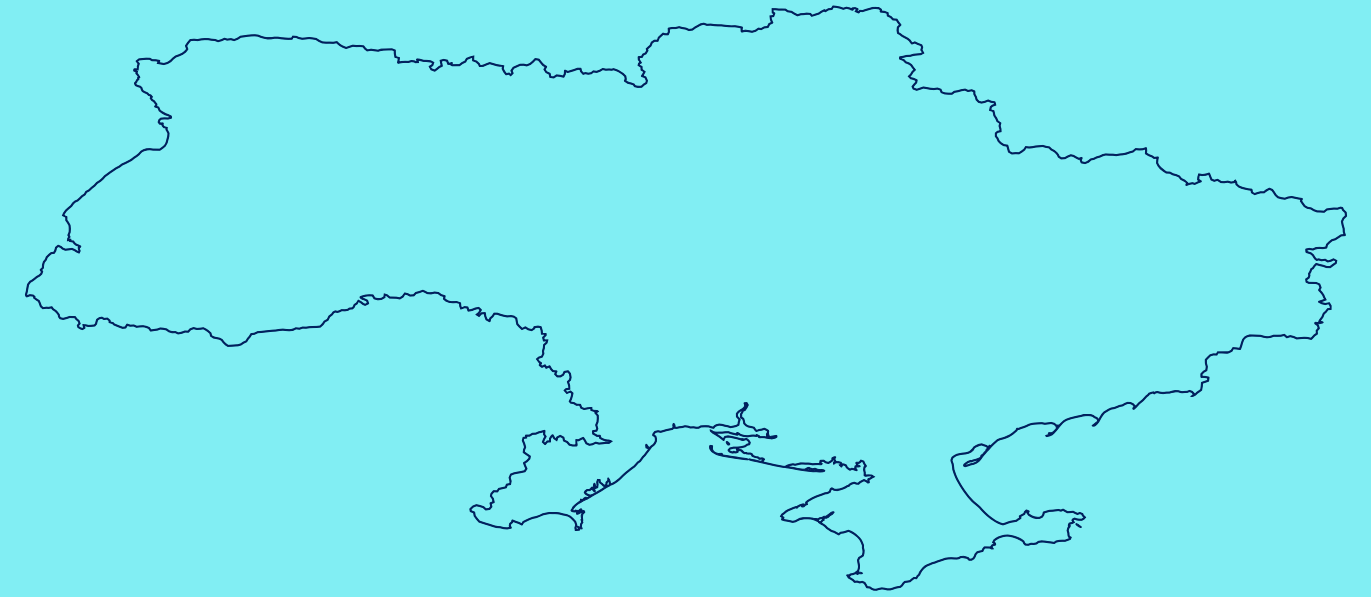
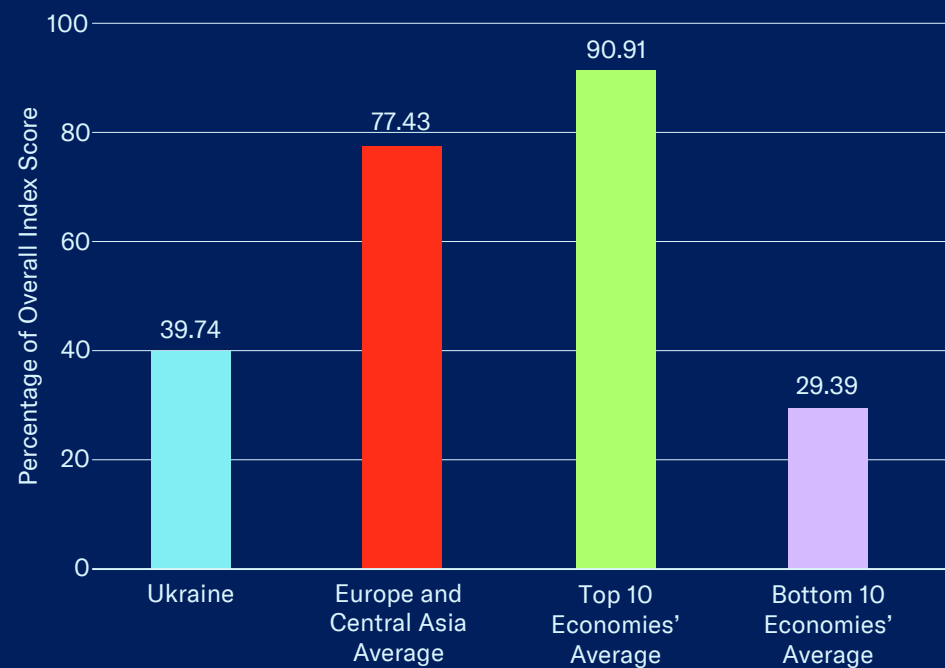
As noted over the course of the Index, there have been some positive developments over the last decade in Turkey, the most prominent being the introduction of specialized IP courts in select cities and the establishment of a special prosecutor's agency responsible for IP rights investigations. However, industry reports suggest

that the specialist courts are over-burdened and rightsholders continue to face difficulties in gaining redress through the judiciary. With respect to damages, while there are mechanisms in place in the IP Code to estimate damages for most major IP rights, historically, damages awarded have been fairly low and non-deterrent. In a positive development, local legal analysis suggests a record amount of damages have been awarded in a long-running copyright infringement case. The case, first filed in 2008, finally saw a judgment in late 2020 with the plaintiff receiving compensatory damages of three times the amount of its standard licensing fee. It would be a marked improvement in the enforcement environment if this case sets an example for future awards in IP disputes. The Index will monitor these developments in 2022.

## 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 Customs Code strengthens enforcement capacity
- Efforts 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”) set up in 2017—should help improve consistency and expertise within judiciary
- Contracting party to all international IP treaties included in the Index

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.00
3. Patentability of computer-implemented inventions (CIIs)	0.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.25
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.75
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.83</b>
10. Copyright (and related rights) term of protection	0.58
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.50
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.00
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.25</b>
21. Industrial design term of protection	1.00
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.75</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.00
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>1.75</b>
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.25
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>1.29</b>
32. Physical counterfeiting rates	0.34
33. Software piracy rates	0.20
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.00
36. Criminal standards including minimum imprisonment and minimum fines	0.25
37. Effective border measures	0.25
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>1.00</b>
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.25
41. Educational campaigns and awareness raising	0.25
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.25
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>7.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:**  
**19.87**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Ukraine's overall score has increased from 39.54% (19.77 out of 50) in the ninth edition to 39.74% (19.87 out of 50) in the tenth edition. This reflects a score increase on indicator 32.

### Patents, Related Rights, and Limitations

**2. Patentability requirements; and 3. Patentability of computer-implemented inventions (CIIs):** As noted over the course of the Index, the protection of patents in the Ukraine has long been problematic. Patentability standards have stood firmly outside international best practices, with restrictions in place on many innovation-based and high-tech industries. This situation did not improve in 2020 with the signing into law of new amendments to the Law on Protection of Rights to Inventions and Utility Models. While these legislative changes were meant to better align Ukraine's national IP environment with that of the EU as part of the 2017 Ukraine–European Union Association Agreement, they have had the opposite effect.

To begin with, these changes substantially weakened the eligibility for biopharmaceutical patentable subject matter. Second use claims and follow-on products are now defined, under an expanded Article 7, as ineligible patent matter. This is firmly outside international standards and practice. Similarly, with respect to CIIs, the Law on Protection of Rights to Inventions and Utility Models has historically excluded computer programs from patentable subject matter. While there have been examples of patents granted for CIIs, these are a small minority of the total number of patents filed and granted. For example, looking at patent statistics housed by WIPO in the IP Statistics Data Center for Ukraine, the data shows only a small number of patent applications (patent publications by technology) were under the categories “Computer technology” and

“IT methods for management.” Between 1980 and 2018, a total of 740 such applications were published. This compares to a total number of 58,845 applications during this time, or 1.26% of the total number of applications published.

As noted last year, the amendments did not address the existing deficiencies with respect to CIIs, and there have been no changes in 2021. This is surprising given the launch of the “Diia City” economic free zone and passing of the supporting legal framework “On Stimulating the Development of the Digital Economy in Ukraine” in late 2021. The initiative seeks to position the Ukraine at the forefront of the ICT industry and digital innovation. While a range of tax and economic reforms have been introduced as part of this legal framework—all seeking to incentivize the growth and development of the sector—no changes were introduced to patentability standards. Ukraine is one of a growing number of economies seeking to develop their high-tech and capacity for innovation-driven economic growth. Since being elected in 2019, President Zelensky has repeatedly emphasized the need to promote innovation and the digital transformation of the Ukrainian economy and public sector. In this light, strengthening Ukraine's national IP environment and improving the ability of innovators and inventors to protect their innovations should be at the forefront of the government's policy platform.

The economic data and analysis in the Index, its accompanying sister publication the Statistical Annex, and the experiences of other economies strongly suggest that IP rights and incentives are the fundamental building blocks for innovation and developing high-tech industries. For all economies—emerging and developed alike—what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP. Unfortunately, the changes introduced in the Ukraine's patent laws over



the last few years are unlikely to help it achieve its economic objectives and will, instead, make creating, protecting, and commercializing IP assets in high-tech industries more difficult.

**7. Patent term restoration for pharmaceutical products:** Term restoration of up to five years for delays caused by market authorization and regulatory approval for biopharmaceuticals has historically been made available to rightsholders under the Law on Protection of Rights to Inventions and Utility Models. Amendments to the law, which were passed in July 2020, do not remove the possibility for rightsholders to apply for and receive a period of term restoration, but they have introduced both new procedural barriers to obtaining the additional protection and an export and stockpiling exemption. The latter exemption appears to be modelled on a similar carve-out introduced by the European Commission through Regulation 2019/933, which has been operational in the EU since 2019. In the Ukrainian case, the exemption allows for the manufacture and export of a product for which a term of restoration has been granted. Manufacturing for the purposes of stockpiling is also allowed beginning within a period of six months of any granted patent term restoration expiring. Beginning in last year's Index, the methodology used to calculate the score on this indicator has changed. This indicator now consists of two distinct variables: first, the existence of a term of patent restoration for pharmaceutical products due to the prolonged research, development, and regulatory approval periods for such products; and second, the existence of any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. Of the available score for this indicator, 0.75 is allocated to the existing term of protection, compared to the current baseline rate of five years' term restoration used in the U.S., EU, and Japan. The remaining 0.25 is allocated on the basis of a given economy providing any

exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. Given the introduction of this export and manufacturing exemption in the Ukraine, the score on this indicator was reduced from 1 to 0.75 in last year's Index. This issue remained unaddressed in 2021.

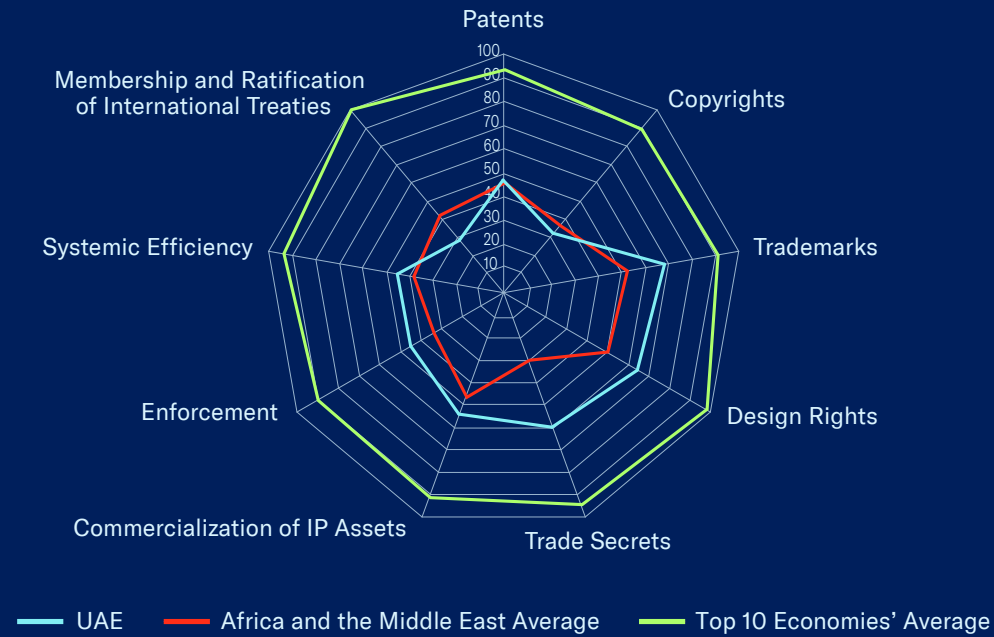
### Copyrights, Related Rights, and Limitations

**16. Clear implementation of policies and guidelines requiring any proprietary software used on government ICT systems to be licensed software:** As noted since Ukraine was first included in the Index in 2014, the use of unlicensed software by the Ukrainian government and public sector entities is a long-standing challenge. Rightsholders and the U.S. government have for many years pointed to the need for fundamental reform and the effective application and implementation of existing requirements that any software used by government agencies should be properly and fully licensed. A Cabinet regulation from 2003 banned the use of unlicensed software by government agencies and established procedures for legal access to software. Recent reports suggest that centralized public procurement could be used by the Ukrainian government to ensure the use of licensed software. Still, as the USTR reiterated in 2021, there continues to be "use of unlicensed software by Ukrainian government agencies." As part of the Tenth Meeting of The United States-Ukraine Trade and Investment Council in November 2021, the USTR announced the establishment of an "Intellectual Property (IP) Work Plan" with the government of Ukraine. The issue of use of unlicensed software was cited as an area of needed improvement in the USTR press release accompanying this announcement. The Index will continue to monitor these developments in 2022.

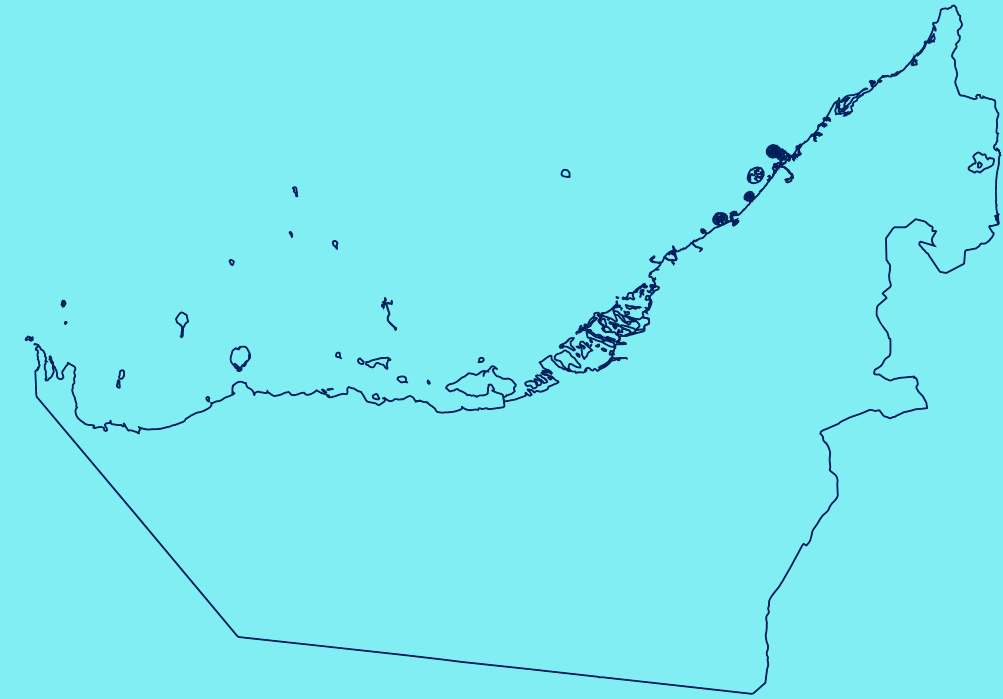
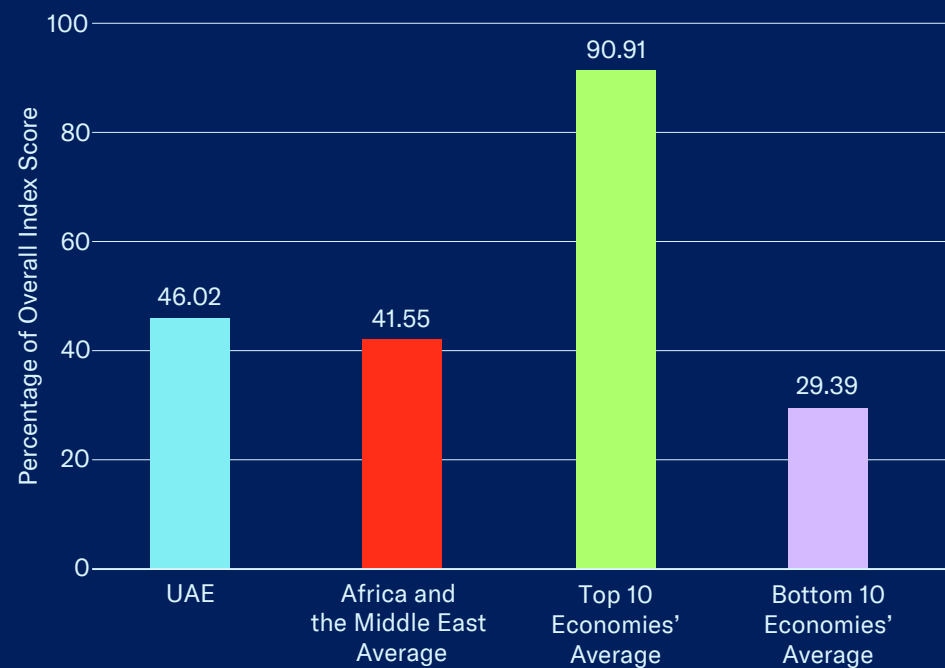
# United Arab Emirates

Rank  
33/55

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- Term of protection for design rights extended in 2021
- Acceded to Madrid Protocol in 2021
- New Trademark Law improves environment for well-known marks and raises potential damages
- New Trademark Law provides stronger border measures against counterfeit goods
- Defined RDP term introduced in 2020
- New 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 holding a minimum of 51% of a company's shares
- Basic IP protections in place
- Enhanced anti-counterfeiting efforts, including criminal penalties
- Awareness-raising and capacity-building efforts on importance and value of IP rights

## Key Areas of Weakness

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





Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>4.25</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of computer-implemented inventions (CIIs)	0.50
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	1.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>2.28</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.50
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.50
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.50
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.75</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.75
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.75
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.25
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.30</b>
21. Industrial design term of protection	0.80
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.80</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.80

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>3.25</b>
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.50
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	1.00
<b>Category 7: Enforcement</b>	<b>3.13</b>
32. Physical counterfeiting rates	0.45
33. Software piracy rates	0.68
34. Civil and preceudural remedies	0.75
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>2.25</b>
39. Coordination of IP rights enforcement	0.25
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.25
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>2.00</b>
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
23.01**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

The UAE's overall score has increased from 41.98% (20.99 out of 50) in the ninth edition to 46.02% (23.01 out of 50) in the tenth edition. This reflects a score increase on indicators 18, 21, 28, 32, 35, 37, and 45.

### Area of Note

As noted last year, in January 2021, the Gulf Cooperation Council (GCC) Patent Office announced that following the 41<sup>st</sup> Session of the Supreme Council and amendments to the Patent Regulation, the Patent Office would no longer be accepting patent applications. The announcement was unexpected, as the GCC patent application route had been operational for more than two decades. This was followed up with an announcement by the GCC Secretariat in April 2021. Under this announcement, new amendments to the GCC Patent Regulation were issued whereby a new patent application pathway had been introduced replacing the old regulation. Under this new proposed system, the regional GCC patent appears to have been abolished. Instead, future patent applications will be routed through individual GCC member states. At the time of research, no further announcements had been made and it remained unclear, first, what would happen to applications filed prior to 2021 and, second, how this new system would work in practice and how/if individual applications would be validated in all GCC member states. Statistics on patents granted, published on the GCC Patent Office's website, suggest that no patents had been granted by the office in 2021. The Index will continue to monitor these developments in 2022.

### Patents, Related Rights, and Limitations

#### **2. Patentability requirements; 3. Patentability of computer-implemented inventions (CIIs); and 6. Legislative criteria and use of compulsory licensing of patented products and technologies:**

In 2021, a new industrial property law, Federal Law No. 11, was introduced and came into effect. The new legislation replaces the old Patent Law and introduces some important changes to the UAE's national IP environment; see indicator 21 for details relating to the protection of design rights. With respect to patents, up until 2021, patent registration in the UAE was available through a traditional domestic/national route as well as through the filing of a GCC patent application. Given the suspension of the GCC regional route (described above), rightsholders wishing to obtain patent protection for their inventions in the UAE must now apply directly to the relevant Emirati registration authorities.

Historically, there have been some differences between patentable subject matter in the UAE compared to the GCC. For example, with respect to CIIs, while computer programs and software have been excluded as such, patents have been granted for CIIs in the UAE if the invention was linked to hardware and the claims were drafted as a technical solution to a technical problem, provided that the other criteria for patentability were satisfied. The data bear this out. According to international patenting statistics from WIPO, since 2000 a relatively large number (about 7%) of patent applications in the UAE have been in the field of computer technology. The situation is different under the old GCC route where few CII patents have been granted.

Unlike the UAE, statistics published by the GCC on the scientific fields with the highest number of patents granted do not include ICT and computer-related grants. It is not expected that the new



industrial property law will fundamentally change practices relating to CII, but the Index will monitor the extent to which Emirati examination guidelines and practice change and do become more restrictive. In contrast, for other high-tech fields, the new law appears to impose new restrictions. For example, patentable subject matter appears to have been somewhat restricted with additional exclusions added for biological research activities. Similarly, the basis for overriding granted rights through the issuing of a compulsory license and the use of patented technologies in biopharmaceutical combination therapies appear to have been broadened and patent rights weakened. At the time of research, no implementing regulations had been published and it was not clear if these changes would amount to substantially different examination and grant criteria, particularly for biopharmaceutical inventions. On this basis, the UAE's score on these indicators remains unchanged in this edition of the Index. The Index will continue to monitor these developments in 2022 and the extent to which rightsholders are able to continue to obtain and maintain patent protection for their inventions.

### Trademarks, Related Rights, and Limitations

**18. Protection of well-known marks:** In 2021 a new trademarks law, Federal Decree-Law No. 36/2021 On Trademarks, was introduced and came into effect. The new law replaces the old trademark law and introduces several improvements to the legal environment for trademark. As detailed below under indicators 28, 35, and 37, the new law eliminates registration requirements for trademark licensing agreements, increases potential damages for trademark infringement, and clarifies the extent to which customs officials may take *ex officio* action against suspected goods. In addition, the new law also improves the protection of well-known marks. Under articles 4 and 5, the definition of well-known marks is now clearer, and protection is better defined with regard to likelihood for confusion even for products in different classes of

goods. As a result of these positive developments, the score on this indicator has increased by 0.25.

### Design Rights, Related Rights, and Limitations

**21. Industrial design term of protection:** Under article 49 of Federal Law No. 31 of 2006, registered design rights were granted a non-renewable 10-year term of protection. The new industrial property law, Federal Law No. 11, has doubled this term of protection to 20 years. As a result of this positive development, the score on this indicator has increased.

### Trade Secrets and the Protection of Confidential Information

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

follow-on manufacturers to conduct research and necessary scientific studies to meet regulatory safety and quality requirements in preparation for market approval. Due to the long timelines involved in the drug approval process, the primary goal of these types of exemptions is to ensure that there is no undue delay for the launch of a generic follow-on product once the reference product's exclusivity has expired. In the case of the UAE, Article 3 of the resolution does not specify or outline what type of activities follow-on manufacturers are allowed to engage in, and there is no assurance that the reference product's full eight-year period of data exclusivity will be maintained.

There is also a degree of uncertainty regarding the meaning and purpose of Article 5 of the decree. The article states that the relevant drug regulatory authorities may, under "exceptional" circumstances, including "for the purpose of protecting public health," override or disregard an existing term of RDP and approve a follow-on product. New developments in 2021 add to the uncertainty over whether a full eight-year period of data exclusivity will be available to rightsholders. Article 62(2) of the new industrial property law, Federal Law No. 11, states that the period of protection for confidential information submitted to government agencies will be protected for "a period not exceeding (5) five years." This is less than the eight-year term in Resolution 321. At the time of research, it was not clear how the conflicting provisions of Federal Law No. 11 and Resolution 321 would interact, and which would take precedence.

As the Index stated last year, the introduction of a defined term of RDP was a positive step and a clear improvement in the biopharmaceutical IP environment in the UAE. Providing rightsholders with a full, uninterrupted eight-year term of protection would position the UAE as one of the leaders on biopharmaceutical RDP in the MENA region. Should the term of RDP be reduced from eight years to five years of protection, in line with

the new provisions of Federal Law No. 11, the score on this indicator will be reduced. The Index will continue to monitor these developments in 2022.

### Commercialization of IP Assets and Market Access

**28. Registration and disclosure requirements of licensing deals:** Emirati law has historically required licensing agreements to be registered with the relevant authorities. Under both national law and the GCC Patent Regulation, a licensing contract must have been recorded in order to have legal effect against third parties. For GCC patents, licensing agreements were required to be registered with the GCC Patent Office. Agreements were to be registered, reviewed, and approved by the Patent Office as outlined in Article 54 of the Implementing Bylaws. The registration application included a requirement of submitting the licensing contract, which must be translated into Arabic. Details of an agreement that shall be listed on a register include the legal names of the contracting parties, the legal domicile of the parties, and "contract subject and term." The UAE's new industrial property law, Federal Law No. 11, does not fundamentally change this. Under Article 50, patents and industrial design rightsholders must continue to register the relevant licensing agreement with the register. In contrast, and in a positive development, the new trademark law (Federal Decree-Law No. 36/2021 On Trademarks) has eliminated this requirement for trademarks. Specifically, Article 31 of the law states explicitly that licensing agreements do not need to be registered. As a result, the score on this indicator has increased by 0.25.

### Enforcement

**35. Preestablished damages and/or mechanisms for determining the amount of damages generated by infringement:** Both the new industrial property law (Federal Law No. 11) and the new trademark law (Federal Decree-Law No. 36/2021 On Trademarks)



have increased the potential damages available to rightsholders in the event of infringement of relevant IP rights. Both laws now provide potential penalties of between AED 100,000 and AED 1 million (circa USD 27,000-270,000). As a result, the score on this indicator has increased by 0.25.

**37. Effective border measures:** Article 45 of the new trademark law (Federal Decree-Law No. 36/2021 On Trademarks) provides UAE customs officers with *ex officio* authority to suspend the release of suspected trademark-infringing goods up to a maximum period of 20 days. This is a positive development, as the UAE has long been identified as a central hub for the transshipment of counterfeit goods and the global trade of physical counterfeit goods. For example, in the 2021 publication *Global Trade in Fakes: A Worrying Threat*, the OECD and EUIPO found that the UAE was one of the top provenance economies for counterfeit products in the world. As a result, the score on this indicator has increased by 0.25.

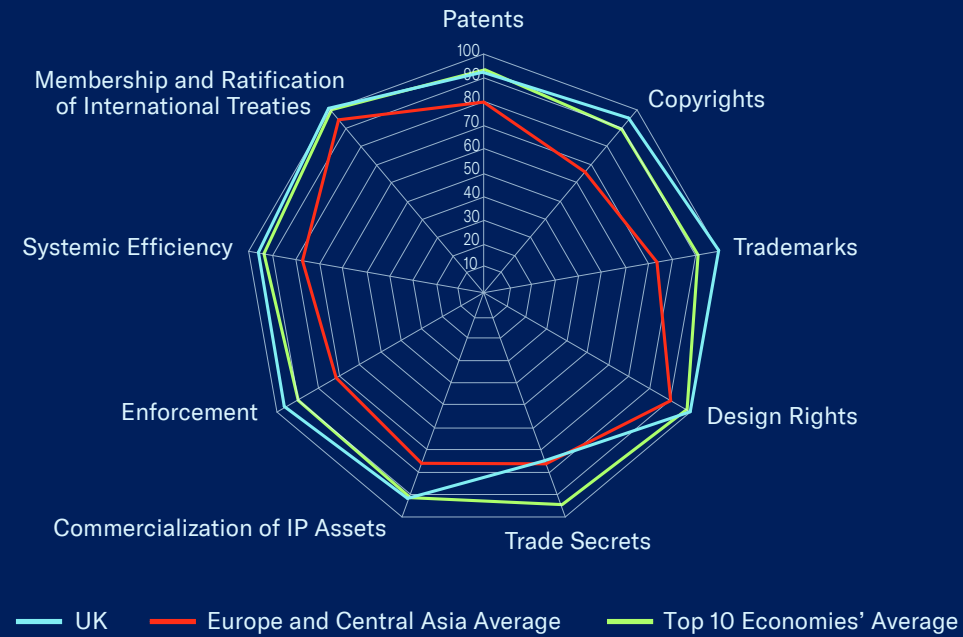
#### Membership and Ratification of International Treaties

**45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks:** In September 2021, WIPO announced that the UAE had acceded to the Protocol Relating to the Madrid Agreement. The UAE's accession to the protocol is a positive development and has resulted in a score increase on this indicator.

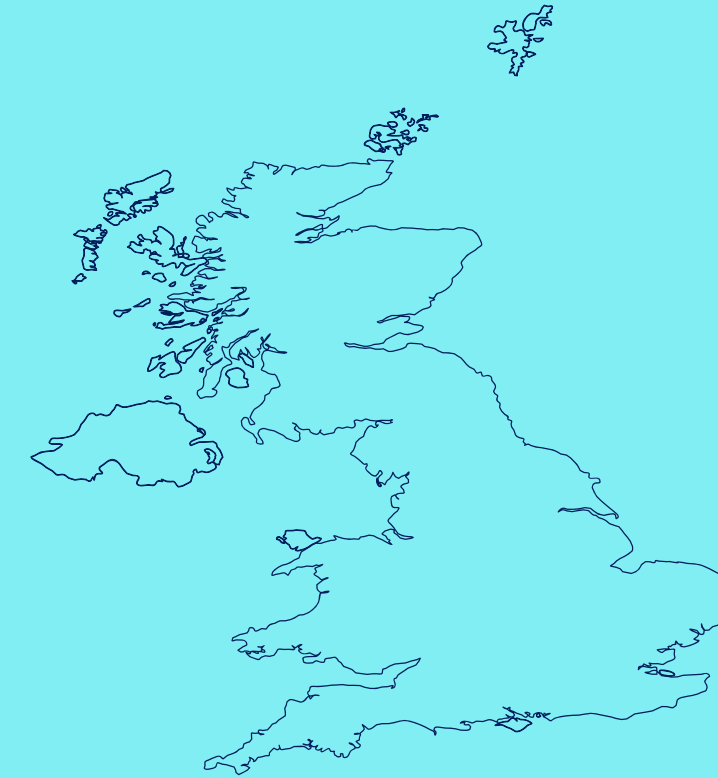
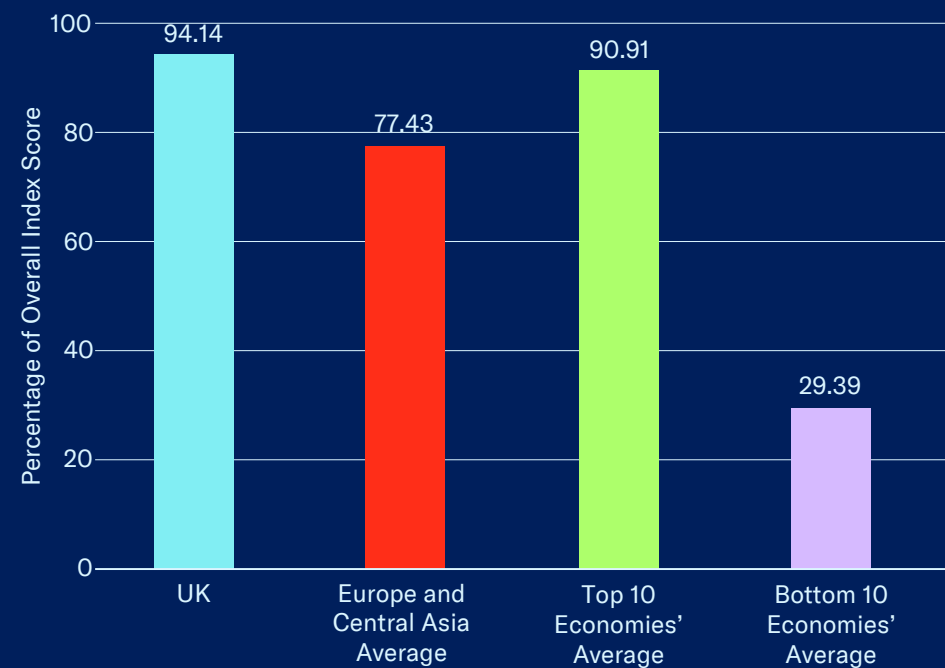
# United Kingdom

Rank  
2/55

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

- UK government chose to retain EU SPC exemption for exports of biopharmaceuticals—remains a significant risk to the UK's research and IP-based biopharma industry
- Limited criminal sanctions available for the theft and misappropriation of trade secrets

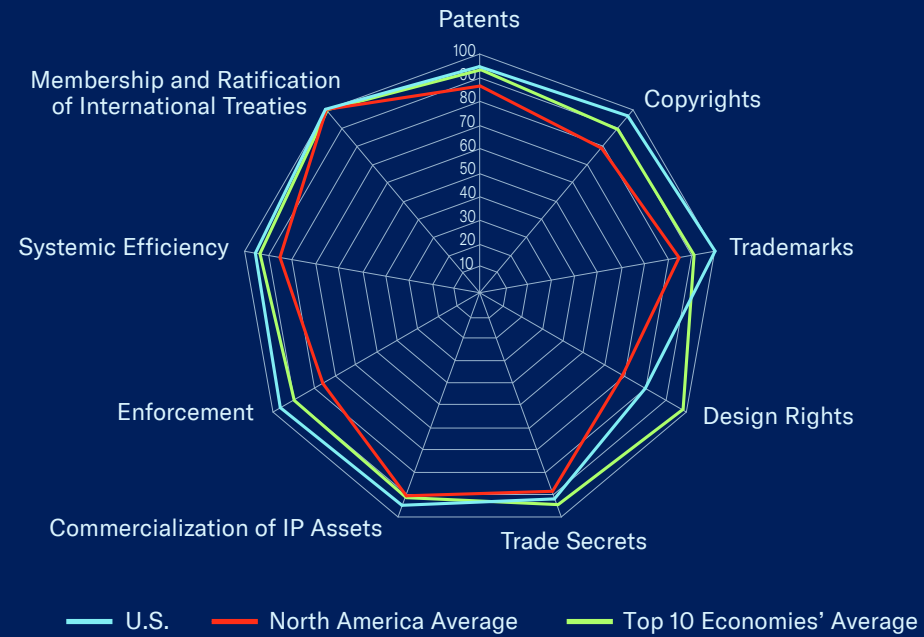




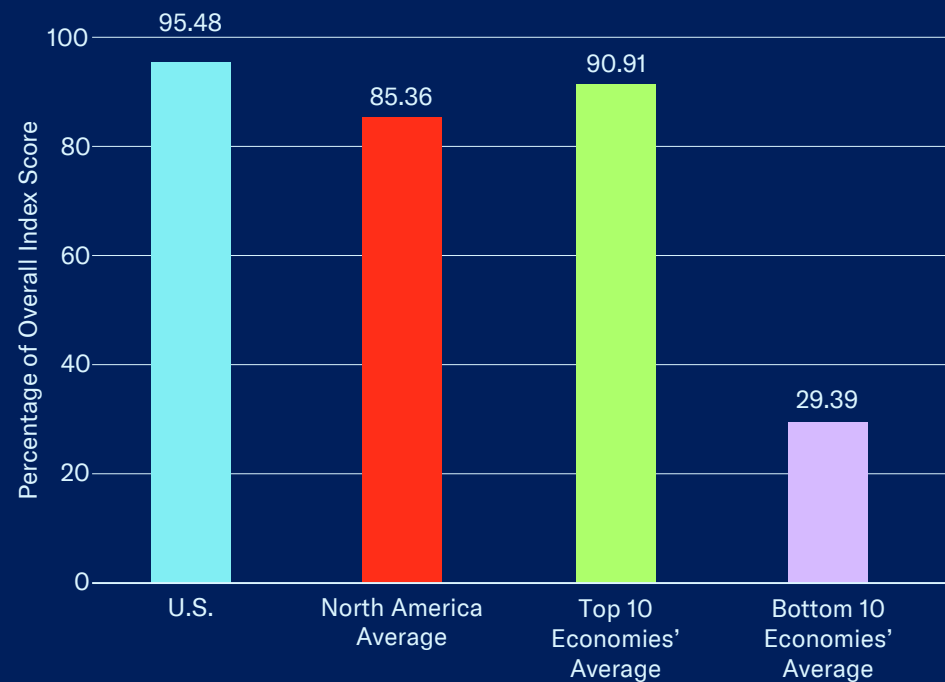
regular updates to the British Parliament on the extent to which the agency's activities have "contributed to the promotion of innovation and of economic growth" and "legislation relating to intellectual property has been effective in facilitating innovation and economic growth." These reports, *Promoting Innovation and Growth: The Intellectual Property Office at Work*, provide a good overview of the importance intangible assets and IP-intensive industries play in the British economy. The UK IPO also regularly commissions and publishes a range of free-standing research reports on the positive relationship between IP rights and economic activity. This includes, for instance, the 2016 *UK Intangible Investment and Growth: New Measures of UK Investment in Knowledge Assets and Intellectual Property Rights*. However, and as noted in previous editions of the Index, neither the IP or any other British public institution have carried out a regular assessment akin to the USPTO's and EPO's work on the national economic impact of IP-intensive industries. This has now changed. In late 2020, the IPO published *Use of Intellectual Property Rights across UK Industries*. The study provides a detailed overview of IP-intensive industries, the types of rights they use, and their contribution to British economic activity. Specifically, the study employs a stratified research approach examining the intensity of IP rights usage rate both by different industries and by type of IP right (both registered and unregistered). Overall, the study echoes the results of the EPO and finds that IP-intensive industries make a substantial contribution to national economic output and employment. Industries with an above average (defined as "high" and "medium") IP usage rate and intensity accounted for an estimated 15.5% of UK employment and approximately 27% of gross value added to the non-financial business part of the national economy; the latter of which is estimated at about two-thirds of the entire British economy. The IPO should be congratulated for this important research

contribution on the links between IP-intensive industries and economic activity in the UK.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

- 2020 Copyright Office report on Section 512 recognizes need for copyright reform
- USPTO released new guidance in 2019 covering Section 101 patentability and Section 112 claims relating to computer inventions—seeks to address uncertainty in patenting system
- Sector-specific rights and protections in place across all categories of the Index
- Reform efforts to patent opposition proceedings by USPTO continued in 2021—agency should be commended for its efforts to provide a greater balance and address concerns over unpredictability and uncertainty within the Patent Trial and Appeals Board (PTAB) process

## Key Areas of Weakness

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







controlling factor in any patentability analysis carried out by the court. The Index will continue to monitor these developments in 2022.

**9. Patent opposition:** In an effort to provide a more cost-effective, efficient alternative to judicial proceedings, the 2011 America Invents Act (AIA) introduced new post-grant opposition and patent nullity proceedings. As has been noted in previous editions of the Index, despite the intentions of these new AIA mechanisms, the result has been a sustained level of uncertainty and unpredictability for many patent owners. This has been especially the case with the *inter partes* review (IPR), which occurs before the specialized Patent Trial and Appeals Board (PTAB) within the USPTO. As noted over the last four editions of the Index, the U.S. government (chiefly through the USPTO) has recognized the unintended effects of the PTAB system and publicly pledged to work with all stakeholders to address and remedy them. As a result, many important changes have since been introduced. Examples of these reforms include (1) changing the patent claim construction standard used, moving away from the broadest reasonable interpretation (BRI) standard to the so-called *Phillips* standard, the latter which is the claim construction standard used in the judiciary since the mid-2000s; (2) creating a new Trial Practice Guide; and (3) issuing Standard Operating Procedure (SOP) changes. Using the *Phillips* standard has aligned IPR proceedings with the same claim construction standards that are used in patent infringement proceedings at U.S. district courts. Similarly, the revised Trial Practice Guide provides greater clarity on the grounds on which a review may be initiated. And the changes to both SOP 1 and SOP 2 have sought to streamline how judges are assigned, how the panels are composed, and how precedent-setting opinions are set. Specifically, SOP 2 sets up a Precedential Opinion Panel (POP), headed by the USPTO Director. Since its introduction, the POP has been active in shaping how the IPRs operate; several of the panel's

decisions have been of high procedural importance, addressing issues relating to the USPTO Director's decisions to institute IPR proceedings (see, for example, *Valve Corp. v. Electronic Scripting Products, Inc.*) and procedural rules including the declaration of interested parties (*Proppant Express Investments, LLC v. Oren Techs., LLC*).

The U.S. Supreme Court has also been active in shaping the manner in which PTAB proceedings take place; several important decisions have been rendered, including in *SAS Institute Inc. v. Iancu*, *Thryv, Inc. v. Click-to-Call Technologies, LP, et al*, and, in 2021, in the case *Arthrex, Inc. v. Smith & Nephew, Inc.* Although the judgment in the latter case provides more direction as to the technical categorization of judges serving on the PTAB, overall, rightsholders continue to face great uncertainty over how patent disputes will be adjudicated and how decisions will be made and upheld within different fora. The Index will continue to monitor these developments in 2022.

### Commercialization of IP Assets and Market Access

**27. Barriers to technology transfer:** The U.S. is a global leader in technology creation, transfer, and commercialization activities. The Patent and Trademark Law Amendments Act of 1984 and 1986—commonly referred to as the Bayh-Dole Act—and the Stevenson-Wydler Technology Innovation Act (later amended by the Federal Technology Transfer Act of 1986 and the Technology Transfer Commercialization Act in 2003) have all been instrumental in incentivizing technology transfer in the U.S. These laws gave institutions that received federal support (such as American universities, small businesses, and non-profits) control and the rights to any resulting intellectual property of their inventions or research. Studies have found a significant correlation between increased patenting activities at American universities following the legislation.

For example, a 2004 study found that university share of total patenting in the U.S. increased from 0.69% of total patents at the time of legislation to just under 5% in 1996. Moreover, in a range of 117 industries, the increase was from 87% in 1969 to 1,648% in 1996. Similarly, using 18 years of data from the Association of University Technology Managers (AUTM) annual university technology licensing survey, a 2015 study estimating the economic contribution of licensing activity by American academic institutions, found that the contribution of academic licensing to gross industrial output in the U.S. ranged from USD 282 billion to USD 1,180 billion (measured in 2009 USD). Contributions to national GDP were equally significant, estimated at between USD 130 billion and USD 518 billion (measured in 2009 USD). In addition, the study found that this licensing activity was also a major contributor to the American jobs market, responsible for between 1.1 million and 3.8 million person years of employment.

More recent figures from the AUTM survey show how licensing revenue and technology transfer is continuing to grow in the U.S. and presents an important income stream for higher education institutions. Results from pre-COVID-19 surveys show that executed licenses grew by 4.5% year on year, almost 1,000 new commercial products were created (representing an increase of over 34% from the previous year), and over 6,000 new patents were issued. IP-intensive industries including software and ICT as well as the life sciences and biotechnology have thrived as a result. An instructive example is the biopharmaceutical industry, which has developed extensive R&D partnerships and cooperation with universities, higher education, and research institutes since the 1980s. From the perspective of universities and technology development, the life sciences play a critical role for universities' commercial activities and account for most of the licensing income at American universities. For instance, figures calculated by *Nature* magazine for a sample of the

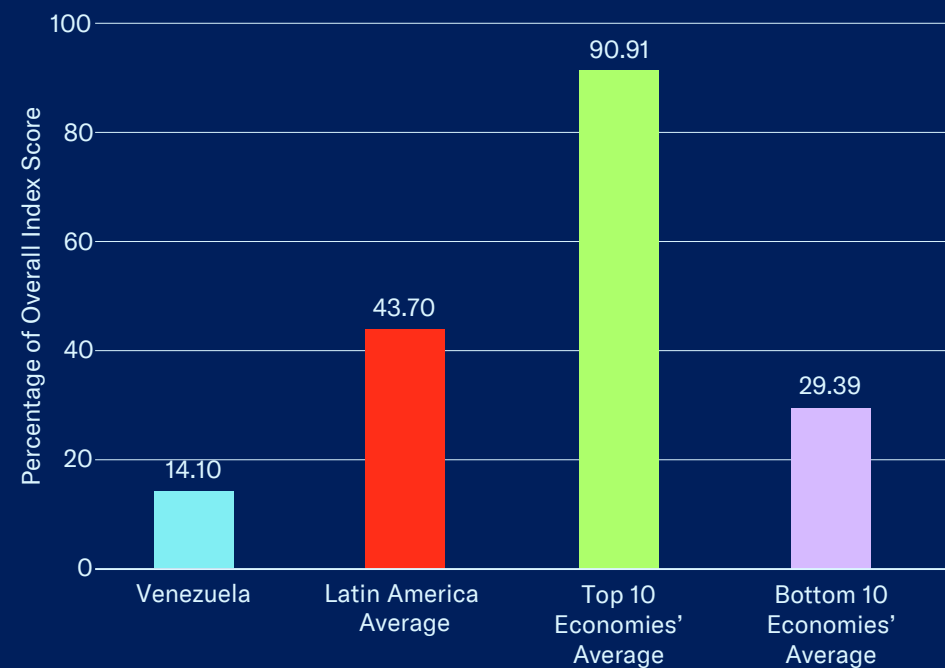
major research institutions in the U.S. showed how, out of the USD 860 million of licensing income received in 2014, USD 734 million came from the life sciences. Also, two-thirds of total licenses executed, and startups created, were related to life sciences.

Other more recent initiatives to promote tech transfer include the National Science Foundation's Innovation Corps (I-Corps) program, specifically mentioned in the revised the Strategy for American Innovation. The program, which includes a dedicated biomedical pilot program, provides entrepreneurship training for federally funded scientists and engineers. In January 2021, the Department of Commerce and the National Institute of Standards and Technology requested comments for potential changes to the way technologies developed or supported with federally funded are transferred and licensed. Part of the discussion around the proposed rule changes related to the issue of so-called "march-in-rights." Such rights grant the federal government a mechanism to access a given technology under very specific circumstances. These march-in-rights are not meant to be used as a lever to reduce the cost of commercialization of a given technology or abrogate an existing licensing agreement on the basis of cost—an idea that has been suggested by some. It is vital to all high-tech sectors, industries, and their publicly funded partners that have close partnerships and R&D, that the concept of march-in-rights are not misconstrued or presented as a basis for introducing price controls with regard to, for example, biopharmaceutical products and technologies. The final accepted rule changes emphasize this and make clear that march-in-rights are not meant to do this and were never intended to do so.

## Category Scores



## Overall Score in Comparison



## Key Areas of Strength

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

## Key Areas of Weakness

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



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>0.75</b>
1. Patent term of protection	0.50
2. Patentability requirements	0.00
3. Patentability of computer-implemented inventions (CIIs)	0.25
4. Plant variety protection, term of protection	0.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.00
9. Patent opposition	0.00
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.63</b>
10. Copyright (and related rights) term of protection	0.63
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.00
13. Availability of frameworks that promote cooperative action against online piracy	0.25
14. Scope of limitations and exceptions to copyrights and related rights	0.25
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.00
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.25
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>1.50</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.25
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.00
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>0.65</b>
21. Industrial design term of protection	0.40
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.25
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>0.25</b>
23. Protection of trade secrets (civil remedies)	0.25
24. Protection of trade secrets (criminal sanctions)	0.00
25. Regulatory data protection term	0.00

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>0.75</b>
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.00
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.00
<b>Category 7: Enforcement</b>	<b>0.52</b>
32. Physical counterfeiting rates	0.16
33. Software piracy rates	0.11
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.00
36. Criminal standards including minimum imprisonment and minimum fines	0.00
37. Effective border measures	0.00
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>0.50</b>
39. Coordination of IP rights enforcement	0.00
40. Consultation with stakeholders during IP policy formation	0.00
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.00
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>0.50</b>
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	0.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	0.00

**Total Score:  
7.05**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

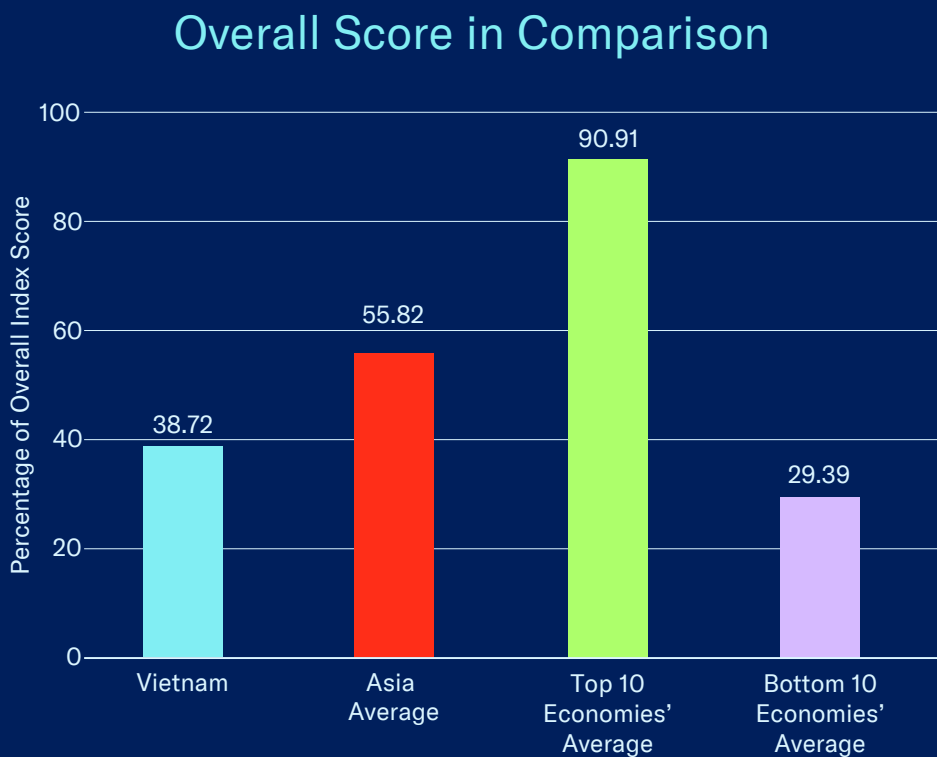
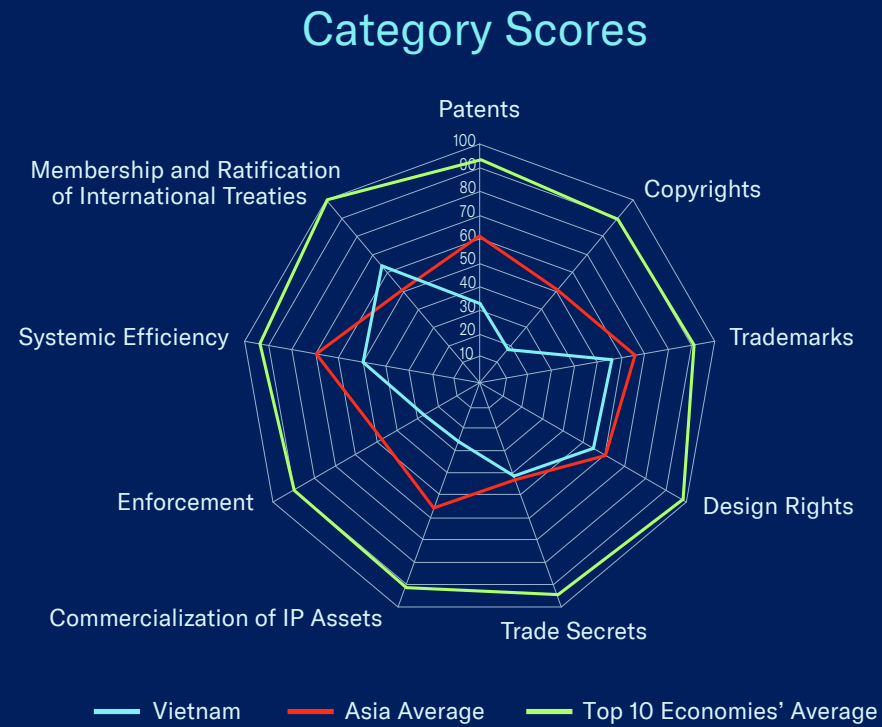
Venezuela's overall score remains unchanged at 14.10% (7.05 out of 50) in the tenth edition.

### Systemic Efficiency

**42. Targeted incentives for the creation and use of IP assets for SMEs:** In addition to basic issues pertaining to the availability and enforcement of IP rights, rightsholders in Venezuela have long faced the challenge of a lack of supportive institutions. To begin with, the overall business environment has, and remains, a challenge with rightsholders in Venezuela facing a highly uncertain and evolving business environment. Politically, the environment remains fraught, with portions of the Venezuelan government ceasing to function amid a continued stand-off between the government and the opposition. The Venezuelan economy has contracted substantially over the last decade, and inflation was estimated by Reuters to be running at close to 3,000% in 2021. The World Bank's *Doing Business* report has ranked Venezuela in the bottom of its overall "Ease of Doing Business" scores for the last decade.

In 2010, Venezuela ranked 177<sup>th</sup> out of 183 economies; in 2020, it was 188<sup>th</sup> out of 190 economies. With respect to the national IP framework, the Venezuelan IP office (the Autonomous Service of Intellectual Property, SAPI) has over the last few years intermittently operated. In 2018, SAPI suspended its services and ceased operations for months. Fees were dramatically increased the same year for most registration and office procedures, making IP protection *de facto* inaccessible to Venezuelan businesses, in particular SMEs. Given this difficult background, the SAPI should be commended for introducing new measures to reach SMEs and assist them to identify and register their rights more effectively.

Specific measures include the *El SAPI va a la calle* direct outreach campaign targeting SMEs; the launch of a new interactive IP portal; and the suspension of all IP registration fees through the end of 2021 for all newly formed SMEs. If these changes and the focus on SMEs is made a permanent part of SAPI's remit, the score on this indicator will rise in future editions. The Index will continue to monitor these developments in 2022.



## Key Areas of Strength

- Acceded to WIPO Copyright Treaty in 2021
- Ratified EU-Vietnam FTA in 2020
- Basic IP protections and enforcement framework in place
- Growing integration into international IP platforms—e.g., through EU-Vietnam FTA
- Long-standing effort to coordinate IP enforcement

## Key Areas of Weakness

- Inadequate protection of life science patents, with challenging enforcement environment
- Gaps in copyright protection, including lack of measures to address online infringements
- High physical counterfeiting rates and online infringement—BSA estimates a software piracy rate of 74%
- Restrictions in place on digital trade and cross-border data transfers through Law on Cybersecurity
- Enforcement generally poor; penalties insufficient in practice; administrative inaction



Indicator	Score
<b>Category 1: Patents, Related Rights and Limitations</b>	<b>3.00</b>
1. Patent term of protection	1.00
2. Patentability requirements	0.25
3. Patentability of computer-implemented inventions (CIIs)	0.00
4. Plant variety protection, term of protection	1.00
5. Pharmaceutical-related patent enforcement and resolution mechanism	0.00
6. Legislative criteria and use of compulsory licensing of patented products and technologies	0.00
7. Patent term restoration for pharmaceutical products	0.00
8. Membership of a Patent Prosecution Highway (PPH)	0.50
9. Patent opposition	0.25
<b>Category 2: Copyrights, Related Rights, and Limitations</b>	<b>1.28</b>
10. Copyright (and related rights) term of protection	0.53
11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)	0.25
12. Expeditious injunctive-style relief and disabling of infringing content online	0.25
13. Availability of frameworks that promote cooperative action against online piracy	0.00
14. Scope of limitations and exceptions to copyrights and related rights	0.00
15. Technological protection measures (TPM) and digital rights management (DRM) legislation	0.25
16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software	0.00
<b>Category 3: Trademarks, Related Rights, and Limitations</b>	<b>2.25</b>
17. Trademarks term of protection (renewal periods)	1.00
18. Protection of well-known marks	0.25
19. Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks	0.50
20. Availability of frameworks that promote action against online sale of counterfeit goods	0.50
<b>Category 4: Design Rights, Related Rights, and Limitations</b>	<b>1.10</b>
21. Industrial design term of protection	0.60
22. Legal measures available that provide necessary exclusive rights to redress unauthorized use of industrial design rights	0.50
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>	<b>1.25</b>
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
<b>Category 6: Commercialization of IP Assets and Market Access</b>	<b>1.58</b>
26. Barriers to market access	0.00
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.25
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.33
<b>Category 7: Enforcement</b>	<b>1.90</b>
32. Physical counterfeiting rates	0.39
33. Software piracy rates	0.26
34. Civil and precedural remedies	0.25
35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement	0.25
36. Criminal standards including minimum imprisonment and minimum fines	0.50
37. Effective border measures	0.25
38. Transparency and public reporting by customs authorities of trade-related IP infringement	0.00
<b>Category 8: Systemic Efficiency</b>	<b>2.50</b>
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.00
43. IP-intensive industries, national economic impact analysis	0.50
<b>Category 9: Membership and Ratification of International Treaties</b>	<b>4.50</b>
44. WIPO Internet Treaties	0.50
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991	1.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
50. At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices	1.00

**Total Score:  
19.36**

## Spotlight on the National IP Environment

### Past Editions versus Current Scores

Vietnam’s overall score has increased from 37.49% (18.74 out of 50) in the ninth edition to 38.72% (19.36 out of 50) in the tenth edition. This reflects a score increase on indicators 32 and 44.

### Area of Note

As noted last year, in late 2020, the Ministry of Science and Technology published a set of draft amendments to the 2005 Law on Intellectual Property (IP Law). The amendments seek to align Vietnam’s IP Law with both the EU FTA and CPTPP and fulfill its treaty obligations under both. It is a positive step that the Vietnamese government is so actively engaging with stakeholders in the reform efforts. The draft IP Law does contain some positive features. For example, draft provisions relating to copyright would potentially strengthen the protection of copyright online as well as improve the TPM and DRM environment. However, in other aspects the draft, articles are more problematic. For example, with respect to patent rights, articles 112 and 112a—including the various “options” listed under the articles—would, first, institutionalize a pre-grant opposition system and, second, introduce a long list of potential grounds for patent opposition and invalidation including everything from substantive objections to procedural errors.

With respect to patent term restoration, the main thrust of the legislative interpretation of article 12.40 under the EU FTA (including the draft IP Law) is to provide compensation to a rightsholder in the form of a reduction in annual patent renewal fees for any relevant period of delay. Draft article 131a, Option 2, appears to provide a potential period of term restoration of up to two years. However, Subsection 2 of the draft article appears to also condition this term restoration on a minimum of a two-year delay in the relevant Vietnamese

drug regulatory authorities’ first response to a market authorization application. Conditioning the availability of restoration on such conditions would in effect mean that, for all practical intents and purposes, term restoration would not be made available to rightsholders in any meaningful way. At the time of research, no finalized draft had been published or presented for public comment. The Ministry of Science and Technology and relevant Vietnamese authorities were continuing to hold meetings and consultations with key stakeholders on the draft legislation, and the draft law was said to be subject to further revisions. Specifically, during a briefing session with the National Assembly in October 2021, the Minister of Science and Technology, Huynh Thanh Dat, stated that comments made during the session would be incorporated into continued consultations and discussions between the Ministry and National Assembly delegates. As has been noted over the course of the Index, Vietnam’s IP Law needs reform and modernization. Adopting the IP provisions of the EU FTA and the CPTPP would help strengthen Vietnam’s national IP environment. The Index will continue to monitor these developments in 2022.

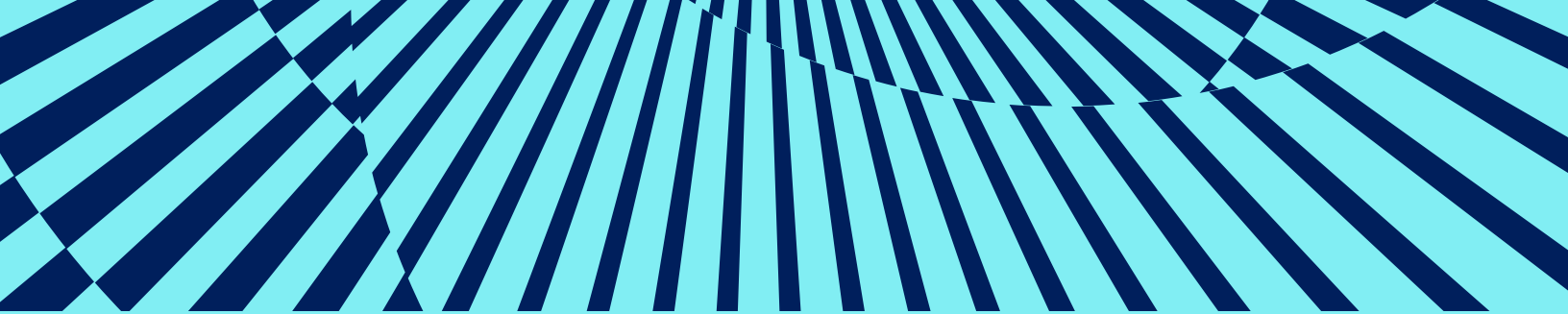
### Membership and Ratification of International Treaties

Vietnam’s overall score on this category continues to improve with Vietnam acceding to the WIPO Copyright Treaty in 2021. As a result, the score on this category has increased by 0.5. At the time of research, it was not clear if Vietnam would also be acceding to the WIPO Performances and Phonograms Treaty. Vietnam is now a contacting party to the WIPO Copyright Treaty; the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks; the Patent Cooperation Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991; and the Hague Agreement Concerning



the International Registration of Industrial Designs. Vietnam is not a contracting party to the WIPO Performances and Phonograms Treaty; the Singapore Treaty on the Law on Trademarks; the Patent Law Treaty; or the Convention on Cybercrime. As noted, last year saw the ratification and coming into force of the EU-Vietnam FTA, a post-TRIPS FTA with substantive IP provisions.

Being a contracting party to key international IP treaties reflects a given economy's broader participation in the international IP community and embrace of the highest IP standards. 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. Vietnam's score on this category of the Index has increased substantially from a score of 0 in the second edition of the Index (the first year Vietnam was included) to now achieving a score of 4.5, or 64.29% of the total available score. This is notably higher than many high-income economies included in the Index, such as New Zealand and the UAE, as well as some of the biggest economies in Southeast Asia, such as Malaysia and Indonesia.



# Appendix: Methodology, Sources, and Indicators Explained

The Index consists of 50 indicators across nine separate categories:

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

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

## Scoring Methodology

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

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

Numerical indicators are those indicators that, for example, measure terms of exclusivity or are based on a quantitative source. Terms of exclusivity are calculated by dividing the actual term of exclusivity of each relevant indicator by a standard baseline. For example, the standard baseline used for the copyright term is that of 95 years provided in the U.S. to orphan works.<sup>18</sup> If an

economy has a copyright term of 95 years, the value it scores in this indicator is 1. If it has a copyright term of less than 95 years, then the value is less than 1. Details of the individual baselines used for different types of IP rights are provided below.

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

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

Mixed indicators are the majority of indicators used in the Index. The use of mixed indicators



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

Finally, there are also a few instances in which rather than the *de jure* and *de facto* existence of a single element, a mixed indicator is split between two separate elements. For example, in Category 9: Membership and Ratification of International Treaties, the indicators are measured by the signature and ratification or accession to a given international treaty. Thus, 0.5 is given

for being a signatory of a treaty and 0.5 for ratifying or acceding to that treaty. This is also the case for Indicator 7: 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. For this indicator, 0.75 of the available score is allocated to the existing term of protection compared to the current baseline rate of five years’ term restoration used in the U.S., EU, and Japan. The remaining 0.25 is allocated on the basis of a given economy providing any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes.

## Baselines Used

When possible, the Index uses baseline values, measures, and models. These values are based on best practices regarding terms of protection, enforcement mechanisms (*de jure* and *de facto*), and/or model pieces of primary or secondary legislation that can be found at

the national and international level. Where no adequate baselines are found in international law or treaties, the baselines and values used are based on what rightsholders view as an appropriate environment and level of protection.

### IP Rights Baselines

Baselines	Baseline in Years	Legislation Model
Basic patent protection	20	TRIPS
Copyrights	95	U.S.
Trademarks	10	WIPO
Regulatory data protection	10	EU
Patent term restoration	5	EU/U.S./Japan
Design rights	25	EU

## Measuring Counterfeiting and Piracy

Indicators 32 and 33 of the Index measure rates of physical counterfeiting and software piracy, respectively. Attempting to measure piracy and counterfeiting presents 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 piracy and counterfeiting are often either specific to one or a handful of economies, or global and not providing data at an individual economy level. The result is a relative paucity in the number of studies that measure and compare levels of piracy and counterfeiting with a sample of economies sufficient enough to make large-scale comparisons empirically robust.

Finally, because measures of piracy and counterfeiting are inexact, estimates of their economic impact can vary widely depending on the methodology and data samples used.<sup>19</sup>

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

- The OECD’s General Trade-Related Index of Counterfeiting of Economies (GTRIC-e), which measures the relative rates of physical counterfeiting<sup>20</sup>
- Software piracy rates compiled by the Business Software Alliance (BSA) (2018 was the most recently published survey)

These sources are both robust and internationally recognized measures. Furthermore, they cover

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

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

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

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

The measure provides a total and per economy estimate of rates of physical trade-related counterfeiting for each of the economies included in the Index. The full details of the building of the model, methodology, sources used, and an assessment of the wider threat





of physical counterfeiting is provided in the report *Measuring the Magnitude of Global Physical Counterfeiting* available on the GIPC's and U.S. Chamber of Commerce's website.

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

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

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

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

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

The third factor used is the rate of perceived corruption within an economy, as measured by Transparency 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 on the Index. For example, if economy X has an estimated software piracy rate of 90% according to the BSA, it receives a score of 0.10 for indicator 33 within the Index.

## Sources

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

### Government

Sources from government branches and agencies include:

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

### Legal

Sources from judicial authorities and legal practitioners include:

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

### International Institutions and Third Parties

These sources include:

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

### Academic

Academic sources include:

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

### News

News sources include:

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

In addition to the above listed resources, over the last few years more and more governments and economies have started making submissions directly to the GIPC and U.S. Chamber of



Commerce. These submissions include everything from updates on legislative and regulatory initiatives to details of various government policies such as anti-piracy initiatives as well as data and statistics on anti-counterfeiting and activities to fight online piracy.

We welcome these submissions and endeavor to use them together with all other available information to provide the most accurate as

possible depiction of the national IP environment in each of the economies sampled.

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

to the marketing of a generic or biosimilar product. This score is evenly divided between the existence of a relevant mechanism and its application/enforcement. If no mechanisms is in place, the maximum score that can be achieved is 0.5. Such a score is based on the extent to which de facto practices (such as expeditious preliminary injunctive relief) are in place that achieve a similar result. This is a mixed indicator.

term of protection compared to the current baseline rate of five years' term restoration used in the U.S., EU, and Japan. The remaining 0.25 is allocated on the basis of a given economy providing any exemptions, waivers, or similar carve-outs on the full and effective use of such a term of restoration, including for industrial policy purposes. This indicator does not include other forms of patent term restoration that are granted on the basis of prolonged examination periods, including for the granting of patents. This is a mixed indicator.

## Indicators Explained

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

### Category 1: Patents, Related Rights, and Limitations

The indicators included in this category relate to patent protection, 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.<sup>21</sup> Measured by (1) existing de jure patentability guidelines and regulations and (2) de facto standards established through the application of these guidelines and regulations through the examination process and judicial review. This is a mixed indicator.
3. **Patentability of computer-implemented inventions (CIIs)**—Measured by the extent to

which primary and/or secondary legislation explicitly allows for the patentability of CIIs. This is a mixed indicator.

4. **Plant variety protection, term of protection**—Measured by the maximum term of protection 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.<sup>22</sup> This is a numerical indicator.
5. **Pharmaceutical-related patent enforcement and resolution mechanism**—Measured by the existence of primary and/or secondary legislation (such as a regulatory and/or administrative mechanism) that provides a transparent pathway for adjudication of patent validity and infringing issues prior

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

7. **Patent term restoration for pharmaceutical products**—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. For this indicator, 0.75 of the available score is allocated to the existing

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 in the different tracks. Economies that are members of either (or both) the Global Patent Prosecution Highway or IP5 Patent Prosecution Highway will receive a full score of 1. Economies that are members of a PPH and have bilateral and multilateral agreements to this effect will receive a score of 0.5.
9. **Patent opposition**—Measured by the availability of mechanisms for opposing patents in a manner that does not unduly delay the granting of a patent (in contrast to a right of opposition before the patent is granted) and ensures fair, transparent, and expeditious opposition proceedings. This is a mixed indicator.



## Category 2: Copyrights, Related Rights, and Limitations

The indicators included in this category relate to copyright protection, 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 U.S. of 95 years. Terms of protection are measured as the minimum term allowed by copyright law. Where different minimum terms of protection are defined for different forms of copyright, all major terms are added together and divided by 95. This is a numerical indicator.
- 11. **Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking)**—Measured by the extent to which economies (1) have in place laws and procedures that provide necessary exclusive rights and (2) apply these laws to prevent, deter, and remedy online infringement of copyright and related rights. This is a mixed indicator.
- 12. **Expeditious injunctive-style relief and disabling of infringing content online**—This indicator measures the existence and extent of an official national government administrative or judicial injunctive relief mechanism available to rightsholders. The mechanism should provide for the effective and timely disabling of access to websites that seem to exist solely to offer or make available infringing content online. Such a mechanism should be based on a clear, transparent, expeditious, and standardized procedure and 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).<sup>23</sup> The score for this indicator is evenly divided between legislation and application in the court system. This is a mixed indicator.
- 15. **Technological protection measures (TPM) and digital rights management (DRM) legislation**—Measured by the extent to which economies have (1) 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: Trademarks, Related Rights, and Limitations

The indicators in this category relate to trademark protection, design rights, and related rights and limitations.

- 17. **Trademarks term of protection (renewal periods)**—Measured by the renewal term of protection being offered, with the baseline term of ten years as provided by the Singapore Treaty on the Law of Trademarks. This is a numerical indicator.
- 18. **Protection of well-known marks**—Measured by the extent to which existing laws and regulations and/or *de facto* practices allow for trademark protection through use of the mark, regardless of whether the trademark owner registers the mark. This is a mixed indicator.
- 19. **Legal measures available that provide necessary exclusive rights to redress unauthorized uses of trademarks**—Measured by the extent to which economies (1) have in place laws and procedures that provide necessary causes of action to address violations of a trademark owner's rights (such as infringement of registered trademarks, unfair competition, false designation of origin, false advertising, dilution of famous trademarks, cybersquatting, and violation of

rights associated with a corresponding trade dress), 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/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.<sup>24</sup>

## Category 4: Design Rights, Related Rights, and Limitations

The indicators in this category relate to design rights and related rights and limitations.

- 21. **Industrial design term of protection**—Measured by the maximum term of protection being offered (including renewable periods), with the baseline term of 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.<sup>25</sup> 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/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 that achieve a similar effect. This is a mixed indicator.

- 27. **Barriers to technology transfer**—The extent to which laws and regulations or *de facto* practices act as barriers to technology transfer and commercialization activities of publicly funded and supported research. This is a mixed indicator.
- 28. **Registration and disclosure requirements**

**of licensing deals**—The extent to which licensing agreements must be registered and/or disclosed with relevant authorities to carry legal effect. This is a mixed indicator.

- 29. **Direct government intervention in setting licensing terms**—The extent to which relevant government authorities directly intervene and set licensing terms between licensee and licensor.<sup>26</sup> This can be done through, for example, governmental pre-approval for any licensing agreement between two parties as well as government intervention in the setting of licensing terms, including royalty rates. This is a mixed indicator.
- 30. **IP as an economic asset**—The extent to which relevant institutions (including, for example, public and private institutions for higher education as well as national IP offices) in a given economy are actively engaged in capacity building and training on how to use IP as a commercial and economic asset. Examples of capacity building include academic (university/ tertiary level) courses on the commercialization and use of IP as an economic and financial asset as well as the extent to which national

IP offices host and/or engage in similar training programs. This is a mixed indicator.

- 31. **Tax incentives for the creation of IP assets**—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 the above described incentives are not hampered by onerous localization and/or administrative requirements linked to the availability and use of the tax incentive or mechanism.

## Category 7: Enforcement

The indicators in this category measure the prevalence of IP rights infringement, the criminal and civil legal procedures available to rightsholders, the authority of customs officials to carry out border controls, and inspections and transparency of customs authorities’ actions.

- 32. **Physical counterfeiting rates**—Measured by estimated rates of general trade-related physical counterfeiting using the U.S. Chamber’s Global Measure of Physical Counterfeiting. This is a numerical indicator.

- 33. **Software piracy rates**—Measured by rates of software piracy. This is a numerical indicator.
- 34. **Civil and procedural remedies**—Measured by (1) the existence of civil and procedural remedies, including injunctions, damages for injuries, and destruction of infringing and counterfeit goods, as well as (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.

counterfeit and pirated goods, including goods in-transit, without complaint from the rightsholder. 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.

38. **Transparency and public reporting by customs authorities of trade-related IP infringement**—The extent to which customs authorities in a given economy publish statistics and data on trade-related IP infringement. This indicator measures (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.

37. **Effective border measures**—Measured by the extent to which border guards have the *ex officio* authority to seize suspected

**impact analysis**—The extent to which the relevant authorities in a given economy seek to map and measure the economic impact and importance of IP-intensive industries to their national economies. Economies are scored on the basis of (1) whether the mapping

and measuring of the economic impact and importance of IP-intensive industries to national economic activity are taking place; and (2) the extent to which such mapping and measuring are systematic and occur on a periodic and recurring basis. This is a mixed indicator.

## Category 8: Systemic Efficiency

The indicators in this category seek to measure the manner in which a national IP system actually works.

39. **Coordination of IP rights enforcement efforts**—The existence of coordinated efforts at IP rights enforcement at the national government level. This indicator measures the extent to which a national government institution or formalized structure is in place providing cross-governmental coordination to national IP enforcement efforts. This is a mixed indicator.

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 socio-economic impact of IP rights and the negative impact the infringement of these rights has on creators, innovators, and the national economy; and (2) the extent to which these campaigns and awareness raising efforts (if in place) are systematic and sustained over time. This is a mixed indicator.

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.

42. **Targeted incentives for the creation and use of IP assets for SMEs**—This indicator measures the extent to which a given economy's national IP system provides special incentives for SMEs for the creation, registration, and use of IP assets. Examples of such incentives include fast-track registration procedures, reduced filing fees, and technical assistance targeting SMEs. This is a mixed indicator.

43. **IP-intensive industries, national economic**

## Category 9: Membership and Ratification of International Treaties

Generally, the indicators in this category are mixed and measure whether an economy is (1) a signatory of and (2) has ratified or acceded to international treaties on the protection of IP; some international treaties only allow for 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:

44. **WIPO Internet Treaties**—These consist of the WIPO Copyright Treaty and the WIPO Performances and Phonograms Treaty. Respectively, they cover and clarify the use of copyright in a digital environment and the moral and economic rights of performers and producers of phonograms. This is a mixed indicator.

47. **Membership of the International Convention for the Protection of New Varieties of Plants, Act of 1991**—This is a binary indicator.

48. **Membership of the Convention on Cybercrime, 2001**—This is a mixed indicator.

49. **The Hague Agreement Concerning the International Registration of Industrial Designs**—This is a mixed indicator.<sup>27</sup>

50. **At least one post-TRIPS FTA with substantive IP provisions and chapters in line with international best practices**—This is a mixed indicator.

45. **Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks**—This is a mixed indicator with half of the score allocated for membership and ratification of each individual treaty.

46. **Patent Law Treaty and Patent Cooperation Treaty**—This is a mixed indicator, with half of the score allocated for membership and ratification of each individual treaty.



# 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 (2021), "Country and Lending Groups."
2. The Index has evolved over time and been reconstructed several times with new categories and indicators being added. Consequently, this heatmap only offers a comparison over time for those categories in place in each edition of the Index. When a category has not been available, the relevant table box has been defined as "NA."
3. World Bank Data Bank, Trade, Merchandise exports (current US\$).
4. Ibid.
5. TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
6. Ibid.
7. WHO (2004), *The World Medicines Situation*, Geneva, pp. 34-35.
8. United States Pharmacopeia (2004), *Drug Quality and Information Program, A Review of Drug Quality in Asia with Focus on Anti-Infectives*, Washington D.C.
9. Roger Cockburn et al. (2005), "The Global Threat of Counterfeit Drugs: Why Industry and Governments Must Communicate the Dangers," *PLoS Medicine*, 2(4), March 2005.
10. O. Shakoor, R.B. Taylor, & R.H. Behrens (1997), "Assessment of the Incidence of Substandard Drugs in Developing Countries," *Tropical Medicine and International Health*, 2(9), pp. 839-845, Sep. 1997.
11. Ibid.
12. Ibid.
13. H. Miao (2021), "WHO Warns Against Sales of Counterfeit COVID Vaccines on the Dark Web," CNBC, March 26, 2021.
14. K. Srivastava (2021), "Fake COVID vaccines boost the black market for counterfeit medicines," *BMJ*, November 2021.
15. OECD (2009), "Magnitude of Counterfeiting and Piracy of Tangible Products: An Update," November 2009, OECD Publishing.
16. OECD/EUIPO (2021), *Global Trade in Fakes: A Worrying Threat*, Illicit Trade, OECD Publishing, Paris. See also: OECD/EUIPO (2019), *Trends in Trade in Counterfeit and Pirated Goods, Illicit Trade*, OECD Publishing, Paris/European Union Intellectual Property Office.
17. D. Mendes, K. Chaves, & T Santoro (2021), "Pirataria Digital: Só as TVs por Assinatura Perdem Mais de R\$ 15 Bilhões por Ano", CNN Brasil, June 2, 2021. Accessed August 2021: <https://www.cnnbrasil.com.br/business/pirataria-digital-so-as-tvs-por-assinatura-perdem-mais-de-r-15-bilhoes-por-ano/>
18. Many economies have a copyright term that is measured by the life of an author plus an additional number of years. Given the difficulties in measuring and estimating an average life of an author, and thus an average term of protection, this indicator only uses minimum terms that are applied in lieu of the life of 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.
19. These difficulties of measuring piracy are particularly pronounced for online piracy. No comprehensive studies exist that measure and compare rates of online piracy for a large sample of economies. Because of this, the indicators measuring piracy and counterfeiting in the Index are primarily based on physical piracy and counterfeiting, with the data from BSA being based on both physical and digital software piracy. Nevertheless, a number of academic and industry-supported studies measure rates of online piracy and its economic impact either on a global basis or for a few large economies. For example, a 2011 study commissioned by NBCUniversal and produced by Envisional found that 23% of global internet traffic was estimated to be infringing in nature. Similarly, a 2011 report by Frontier Economics estimated the total value of counterfeit and pirated products in 2008 and forecast for 2015 to be \$455-\$650 billion and \$1,220-\$1,770 billion, respectively. Out of this total, digitally pirated products were estimated at \$30-75 billion in 2008 and forecast to be \$80-240 billion in 2015. Furthermore, this report found that online piracy in the U.S. made up a large share of this digital piracy figure. For 2008, the report estimated that \$7-\$20 billion worth of digitally pirated recorded music was consumed in the U.S., with an additional \$1.4-\$2 billion of digitally pirated movies also consumed. Finally, the vast majority of academic papers and economic analyses have found that online piracy and file sharing has had a negative impact on media sales, including music. For details, see: Envisional (2011), *Technical Report: An Estimate of Infringing Use of the Internet* (Cambridge 2011), p. 2; Frontier Economics (2011), *Estimating the Global Economic and Social Impacts of Counterfeiting and Piracy* (London 2011), pp. 56-58; and M.D. Smith & R. Telang (2012), *Assessing the Academic Literature Regarding the Impact of Media Piracy on Sales* (Social Science Research Network).
20. OECD (2016), *Trade in Counterfeit and Pirated Goods*, pp.110-111.
21. 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."
22. Act of 1991, International Convention for the Protection of New Varieties of Plants, Article 19, Duration of the Breeder's Right.
23. The Berne three-step test generally requires that limitations and exceptions to copyrights should be (1) confined to special cases; (2) which do not conflict with a normal exploitation of the work; and (3) do not unreasonably prejudice the legitimate interests of the rightsholder. (TRIPS Agreement, Article 13)
24. Examples of voluntary and industry-based standards include those standards and policies used in the U.S. and elsewhere by providers such as eBay. The latter has a system in place—the Verified Rights Owner (VeRO) Program—which allows rightsholders

to protect their intellectual property through a process of notification and takedown in which eBay is notified of the infringement and promptly removes the material from its website. Full details of the system are available at: <http://pages.ebay.com/vero/intro/index.html>.

25. Half (0.5) of the available score is based on the term available for biologics or large molecule compounds. If a country's relevant legislation/regulation either *de jure* or *de facto* does not cover such compounds, then the maximum score that can be achieved in this indicator is 0.5. The baseline numerical term used is that by the EU of 10 years (8+2) of marketing exclusivity.
26. This indicator is not concerned with commercial litigation brought by private parties and settled by an independent judiciary.
27. 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.