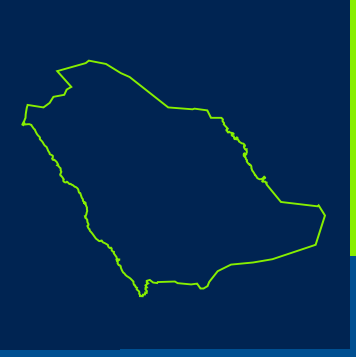
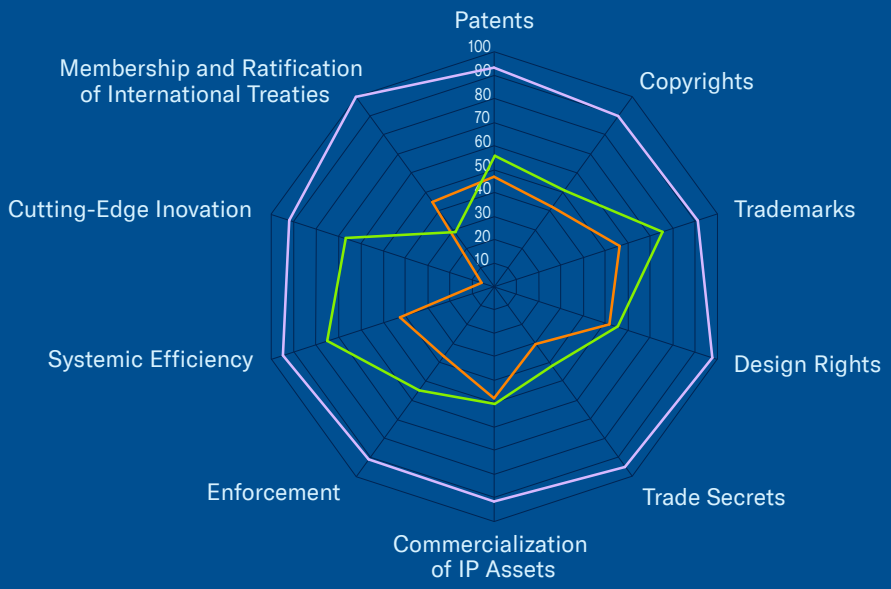


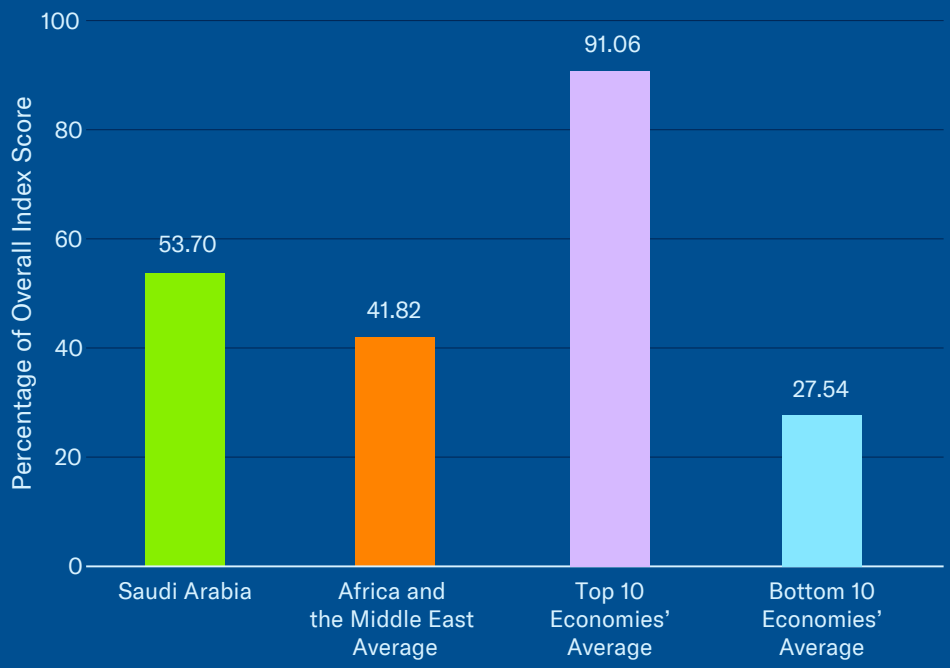
Saudi Arabia

Rank
25/55

Category Scores



Overall Score in Comparison



Saudi Arabia

Rank
25/55

Key Areas of Strength

- Royal Decree M/45 extends design rights term of protection from 10 to 15 years
- IP incentives for orphan medicinal development are in place through Saudi FDA
- Saudi Authority for Intellectual Property (SAIP) continues to assume leadership on IP policy and enforcement with a marked increase in online copyright and trademark enforcement since 2022
- SAIP has put in place an ambitious reform agenda and is revamping the administration of the Kingdom's national IP environment; these positive efforts continued in 2023
- SAIP is leading and coordinating IP enforcement in the 2021 National Committee for the Enforcement of Intellectual Property Rights
- SAIP joined multiple PPHs in 2019–2020
- Increased consultation and awareness-raising activities occurred in 2019
- Strong and sustained focus by Saudi authorities and institutions to encourage IP commercialization and technology transfer
- *Ex officio* authority is in place for customs officials

Key Areas of Weakness

- Pharmaceutical patent protection and linkage mechanism were suspended through SFDA actions in 2017
- Significant gaps exist in the copyright legal framework, chiefly related to protection online
- Increasing number of localization requirements
- Industry reports a lack of practical availability of RDP; the government has allowed indirect reliance on innovators' data when reviewing follow-on products

Indicator	Score
Category 1: Patents Rights and Limitations	**5.00**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.75
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.00
6. Legislative criteria and use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights and Limitations	**3.53**
10. Term of protection	0.53
11. Exclusive rights	0.50
12. Expeditious legal remedies disabling access to infringing content online	1.00
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. TPM and DRM	0.50
16. Government use of licensed software	0.50
Category 3: Trademarks Rights and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.75
Category 4: Design Rights and Limitations	**1.10**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets	**3.00**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**3.83**
32. Physical counterfeiting rates	0.55
33. Software piracy rates	0.53
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.75
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**3.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.75
41. Educational campaigns and awareness raising	1.00
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Cutting-Edge Innovation	**2.00**
44. IP incentives for orphan medicinal product development	1.00
45. IP incentives for orphan medicinal product development, term of protection	0.00
46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	1.00
Category 10: Membership and Ratification of International Treaties	**2.00**
47. WIPO Internet Treaties	0.00
48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
49. Patent Law Treaty and Patent Cooperation Treaty	1.00
50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	0.00
51. Membership of the Convention on Cybercrime, 2001	0.00
52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
53. Post-TRIPS FTA	0.00

Percentage of Overall Score: 53.70% • **Total Score: 28.46**

Spotlight on the National IP Environment

Past Editions versus Current Score

Saudi Arabia's overall Index score has increased from 24.21 out of 50 indicators in the twelfth edition to 28.46 out of 53 indicators. This reflects score increases for indicators 16, 21, 32, 35, 36, 42, and 52 as well as a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation.

Patent Rights and Limitations

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

As noted by the Index at the time of publication, the release of this procedure is a positive move by the Saudi FDA. However, the new procedure does not, strictly speaking, introduce a "linkage" regime, whereby a drug regulatory authority conditions the approval of a follow-on biopharmaceutical product on there being no relevant period of market exclusivity in place for the underlying reference product. For example, the procedure does not contain a notification mechanism to the relevant rightsholder or an automatic stay period ensuring that any dispute can be resolved before the approval and launch of the follow-on product.

The linking of the approval of follow-on biopharmaceutical products to the exclusivity status of a reference product is an effective way of achieving a balance between the protection of pharmaceutical exclusivity and stimulating early market entry of follow-on products. Linkage ensures that any disputes are resolved before the marketing of a follow-on product. This grants innovators a fair opportunity to secure return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity. It also limits potential damages for follow-on manufacturers because no potentially infringing product is ever launched or approved for market. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit. In summary, a well-balanced linkage system recognizes the crucial role of IP protection in promoting innovation and the role of follow-on products in providing patients access to lower cost biopharmaceuticals. The introduction of a functioning linkage regime that provides rightsholders with the ability to stop follow-on products from being launched when a granted term of exclusivity is in place would be a substantial improvement to the biopharmaceutical IP environment in Saudi Arabia. The Index will monitor these developments in 2025.

Copyrights and Limitations

16. Clear implementation of policies and guidelines requiring that any proprietary software used on government ICT systems should be licensed software:
As noted in past editions of the Index, rightsholders have historically faced challenges in ensuring the use of licensed software by Saudi government ICT systems. The U.S. government has in the past noted the use of unlicensed or "underlicensed" software by public sector entities. In 2012, a Royal Decree was issued requiring the use of licensed software on all government ICT systems, but to date, internal auditing and compliance efforts have been limited. Since 2020, SAIP has built a dedicated program—the "IP Respect Officer Initiative"—to raise awareness of and compliance with IP rights in public and private sector organizations. The authority provides a training and certification program, and, upon completion, officers are dispatched to their respective organizational entity. The initiative consists of six separate tracks, including compliance and self-assessment. To date, close to 150 officers have been certified, and over 80% are working in public sector entities. As a result of this dedicated effort to raise IP compliance in the public sector, the score for this indicator has increased by 0.25.

Design Rights and Limitations

21. Industrial design term of protection:
In 2024, some significant changes were made to the protection of design rights in Saudi Arabia. In late 2023, Royal Decree M/45, increased the term of protection for design rights from 10 years to 15 years. Although this is still less than the 25-year term benchmark used by the Index, this is still a positive development. As a result, the score for this indicator has increased.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection term:
The 2005 Minister of Commerce and Industry's decision No. 3218, "Regulations for the Protection of Confidential Commercial Information," provides specific protection for submitted clinical research data as part of a biopharmaceutical market registration application. Article 5 of the regulations provides a clear and unambiguous protection term of five years from the date of approval and states that relevant Saudi authorities "shall undertake to protect such information against unfair commercial use, for a minimum period of five years from the date of obtaining the approval." The existence of this RDP is a positive feature of Saudi Arabia's national IP environment. However, as noted over the course of the Index, a level of uncertainty exists about the actual availability of this protection. Industry reports have suggested that follow-on products have been approved through the use of "indirect reliance" on submitted clinical research data. International standards and best practices for RDP are clear on this subject: neither direct nor indirect reliance on submitted clinical test data should be used to approve follow-on products within any specified and granted term of exclusivity.

In 2020, SAIP released new draft implementing regulations on how confidential commercial information would be protected in Saudi Arabia. Although SAIP should be applauded for publishing these draft regulations, holding a public consultation, and inviting stakeholder feedback on the matter, as noted in the Index at the time, the regulations themselves were deeply flawed and stood outside established international standards of RDP. Specifically, Article 4(1) of the regulations stated that any term of protection offered in Saudi Arabia would begin "the date of the first registration of the preparation in another country".

The introduction of such a definition and the linking of the exclusivity period in Saudi Arabia to a product's first global launch would severely limit the availability of RDP in Saudi Arabia and would undermine the incentives for innovation and investment such exclusivity provides. Moreover, the draft regulations did not allow a period of RDP for new indications. As noted in the Index, when the draft regulations were published, the implementation of this regulation and application of the existing provisions in relation to RDP would result in a reduction of the score to 0 for this indicator. In a positive step, in 2022, SAIP and Saudi FDA released a statement reaffirming their support for the availability of regulatory data protection in the Kingdom. The U.S. State Department in its *2022 Investment Climate Statement* noted the publication of this statement and, through it, SAIP's "commitment to regulatory data protection." The Index will continue to monitor these developments in 2025.

Enforcement

35. Pre-established damages and/or mechanisms for determining the amount of damages generated by infringement:
As noted last year, SAIP has aimed to strengthen the enforcement of IP rights in Saudi Arabia through both institutional improvements and increased levels of transparency and engagement with rightsholders over the past three years. In 2024, SAIP continued to publish judgments reached by standing committees related to copyright and patent infringement (the "Committee for Review of Violations of the Copyright Protection System" and "Committee for Consideration of Patent Claims"). As stated last year, the publication of these decisions shows that, first, the number of cases considered for IP violations continues to increase and, second, damages are more consistently awarded. As a result, the score for this indicator has increased by 0.25 for the second consecutive year.

36. Criminal standards, including minimum imprisonment and minimum fines:
Historically, criminal enforcement against IP violations has been relatively rare with limited dedicated resources and focus among Saudi law enforcement. Like the efforts taken by SAIP since 2020 related to administrative enforcement, this may now also change with relevant Saudi authorities introducing institutional reforms to strengthen criminal enforcement of IP rights. Specifically, in February 2024, the Public Prosecution Council announced that it had established a dedicated prosecution office for IP offenses. This office will work on investigating and filing criminal charges in cases concerning the violation of IP rights. As a result of these positive efforts, the score for this indicator has increased by 0.25.

Systemic Efficiency

42. Targeted incentives for the creation and use of IP assets for SMEs:
Historically, Saudi and GCC IP authorities have not offered any special IP incentives targeting SMEs. No reduced fees or expedited approval process has been on offer for SMEs nor has much technical assistance been offered. The GCC Patent Office has offered wider support programs for IP practitioners and inventors, but these have not been targeted at SMEs. Although the King Abdullah University of Science and Technology and King Abdulaziz City for Science and Technology provides several programs and support for innovators, including SMEs, this support is not within the specific context of IP development but more broadly in terms of economic development and innovation. This includes, for example, the SMEs Support Initiative run by King Abdulaziz City for Science and Technology. However, in the past few years, there has been a substantial expansion of support, training, and educational programs available through SAIP. These programs often target SMEs and start-ups. For example, in 2020, SAIP launched the "Intellectual Property Advisory Clinics Program."

This program seeks to help SMEs develop, register, and commercialize IP assets. In 2020, SAIP also released an "Intellectual Property Policies Manual" to assist SMEs, academic institutions, and individual inventors. Similarly, since 2020, SAIP has opened over 50 technology and innovation support centers as part of a national network of IP centers often in partnership with WIPO. The authority has more recently developed a comprehensive suite of online training and educational programs on all aspects of IP development, protection, and commercialization, many of which have been developed specifically for SMEs and entrepreneurs. As a result of these continued positive efforts, the score for this indicator has increased by 0.25.

Incentives for Cutting-Edge Innovation

44. Special market exclusivity incentives for orphan medicinal product development; 45. Special market exclusivity incentives for orphan medicinal product development, term of protection; and 46. Restrictions on the effective use of existing market exclusivity incentives for orphan medicinal product development:
Interest in rare diseases has grown in the Middle East and North Africa region. In 2003, the Centre for Arab Genomic Studies was established to map and improve the state of care for patients with genetic diseases in the Arab world.
Today, the Center has become the leading research point on rare diseases in the region.

Moreover, several Index economies in the region, including Saudi Arabia, have introduced a defined regulatory sanitary registration pathway and special incentives for orphan products. Since 2023, the Saudi FDA has had in place a dedicated rules document on orphan drug registration and relevant requirements and incentives, the "Guidance for Orphan Drug Designation." Section 4 of this document includes the provision of a marketing exclusivity incentive for drugs qualifying for orphan designation. However, no further details have been made available as to the length of this exclusivity period.

Membership and Ratification of International Treaties

52. The Hague Agreement Concerning the International Registration of Industrial Designs
January 2025, Saudi Arabia acceded to the full Hague Agreement, including the Geneva Act. As a result, the score for this indicator has increased by 1.00.