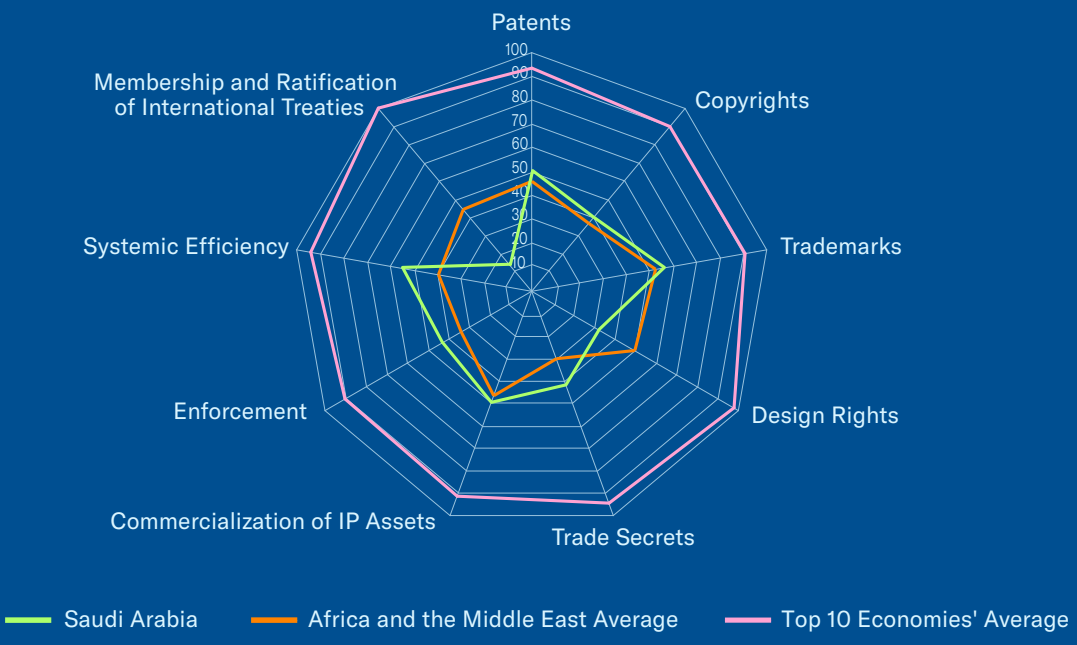
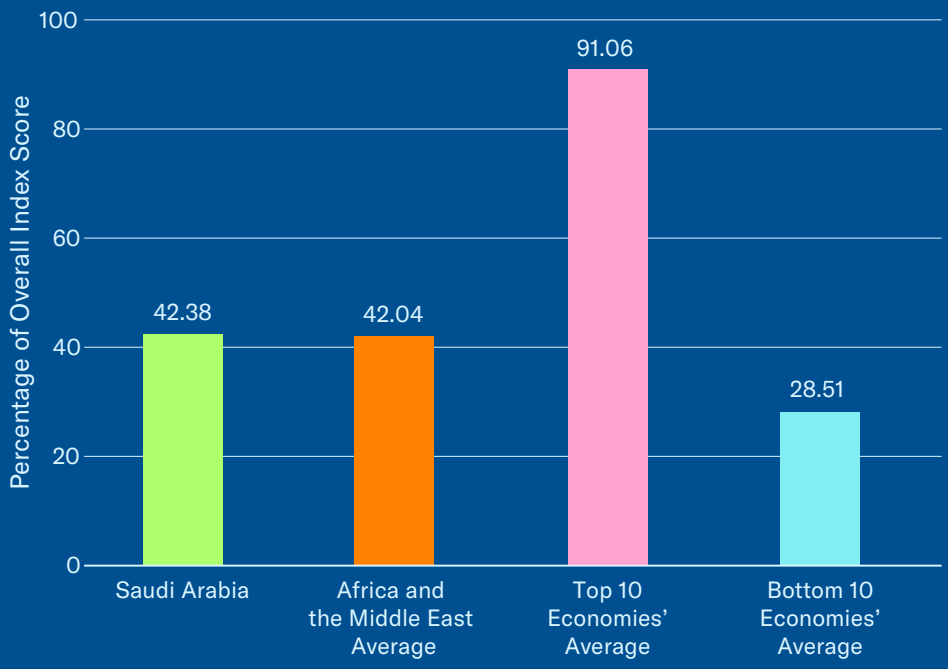
Saudi Arabia

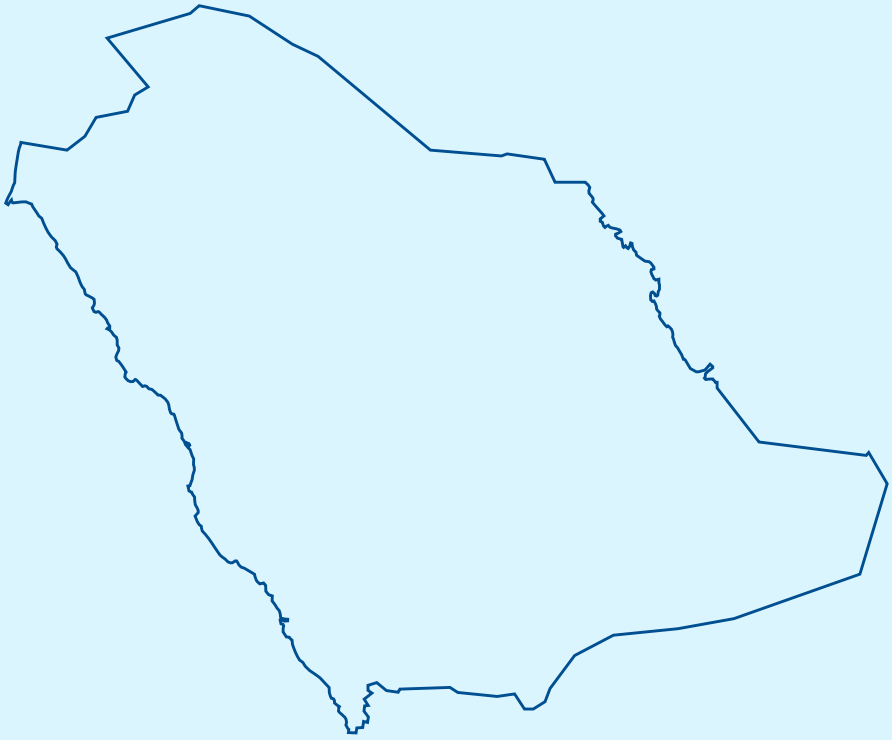
Rank
34/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- SAIP continues to assume leadership on IP policy and enforcement; marked increase in online copyright and trademark enforcement in 2021-2022
- SAIP has put in place an ambitious reform agenda and is revamping the administration of the Kingdom's national IP environment
- SAIP is leading and coordinating IP enforcement on 2021 National Committee for the Enforcement of Intellectual Property Rights
- Joined multiple PPHs in 2019-2020
- Increased consultation and awareness-raising activities in 2019
- Strong and sustained focus by Saudi authorities and institutions to encourage IP commercialization and technology transfer
- *Ex officio* authority in place for customs officials

Key Areas of Weakness

- Pharmaceutical patent protection and linkage mechanism in effect suspended through SFDA actions in 2017
- Significant gaps in copyright legal framework, chiefly relating to protections online
- Increasing number of localization requirements
- Industry reports of a lack of practical availability of RDP—indirect reliance has been allowed when reviewing follow-on products

Indicator	Score
Category 1: Patents, Related Rights and Limitations	**4.50**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.75
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	0.50
9. Patent opposition	0.75
Category 2: Copyrights, Related Rights, and Limitations	**2.78**
10. Term of protection	0.53
11. Exclusive rights	0.50
12. Injunctive-type relief	0.75
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.50
15. TPM and DRM	0.25
16. Government use of licensed software	0.25
Category 3: Trademarks, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.25
19. Exclusive rights and trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights, Related Rights, and Limitations	**0.65**
21. Industrial design term of protection	0.40
22. Exclusive rights and industrial design rights	0.25
Category 5: Trade Secrets and the Protection of Confidential Information	**1.25**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.25
25. Regulatory data protection term	0.50

Indicator	Score
Category 6: Commercialization of IP Assets	**3.00**
26. Barriers to market access	0.50
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
29. Direct government intervention in setting licensing terms	0.50
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	0.00
Category 7: Enforcement	**3.01**
32. Physical counterfeiting rates	0.48
33. Software piracy rates	0.53
34. Civil and precedural remedies	0.50
35. Preestablished damages	0.00
36. Criminal standards	0.50
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**2.75**
39. Coordination of IP rights enforcement	1.00
40. Consultation with stakeholders during IP policy formation	0.50
41. Educational campaigns and awareness raising	0.50
42. Targeted incentives for the creation and use of IP assets for SMEs	0.25
43. IP-intensive industries, national economic impact analysis	0.50
Category 9: Membership and Ratification of International Treaties	**1.00**
44. WIPO Internet Treaties	0.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.00
46. Patent Law Treaty and Patent Cooperation Treaty	1.00
47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	0.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	0.00

Total: 21.19

Spotlight on the National IP Environment

Past Editions versus Current Score

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

Area of Note

In January 2021, the Gulf Cooperation Council (GCC) Patent Office announced that following the 41st Session of the Supreme Council and amendments to the Patent Regulation, the Patent Office would no longer accept patent applications. The announcement was unexpected because the GCC patent application route had been operational for more than two decades. This was followed up with an announcement by the GCC Secretariat in April 2021. Under this announcement, new amendments to the GCC Patent Regulation were issued whereby a new regional application pathway would replace the old regulation. Under this system, the regional GCC patent was abolished. Instead, future patent applications will be routed through individual GCC member states. Once granted by the GCC Patent Office, relevant patents will be valid only in the underlying national jurisdiction. This system was formalized in late 2021 with the issuing of new Implementing Regulations. The Index will continue to monitor these developments in 2023.

Additionally, in December 2022, Saudi's Crown Prince launched a new National Intellectual Property Strategy for the Kingdom. The Strategy includes four pillars: IP creation, IP administration, IP commercialization, and IP protection. The Strategy notes the importance of effective IP standards to spurring innovation and creativity, fostering economic growth, and attracting great investment in the Kingdom. Through the Strategy, the Saudi government seeks to achieve the goals included in Vision 2030, including improving the Kingdom's position in the Global Competitiveness Index by 2030. The Index will monitor the implementation of the Strategy in 2023.

Patents, Related Rights, and Limitations

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

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

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

of achieving a balance between the protection of pharmaceutical exclusivity (usually but not always through patent protection) and stimulating early market entry of follow-on generic products. Linkage ensures that any disputes are resolved before the marketing of a follow-on product. This grants innovators a fair opportunity to secure return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity. It also limits potential damages for generic manufacturers, as no potentially infringing product is ever launched or approved for market. Indeed, linkage also provides both innovators and generic companies with an opportunity of lower-risk challenges of validity or non-infringement by largely taking the issue of damages out of the equation. Patients also benefit from the increased certainty because they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit.

In sum, a well-balanced linkage system recognizes the crucial role of patent protection in promoting innovation and the role of generic entry in providing patients access to lower cost biopharmaceuticals. Having in place a functioning linkage regime that provides rightsholders with a meaningful and real ability to stop follow-on products from being launched when a granted term of exclusivity is in place would be a substantial improvement to the biopharmaceutical IP environment in Saudi Arabia. The Index will monitor these developments in 2023.

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

12. Expeditious disabling of infringing content online; and 20. Availability of frameworks that promote action against online sale of counterfeit goods: As noted over the course of the Index, rightsholders have historically faced significant challenges in protecting their copyrighted content and trademarks in Saudi Arabia. Relevant laws and regulations are not well developed, and the illicit use of IP-infringing material has remained high. With respect to copyright, current Saudi law provides for only basic exclusive rights and protection of creative works. Although Article 9 of the Copyright Law Royal Decree No. M/41 includes a reference to the exclusive right to communication of a given work to the public "via any possible means," no specific law or regulation is in place that provides a notification-and-takedown mechanism for infringing online content, nor is any similar legal framework in place to more specifically address the issue of online infringement.

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

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

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

Trade Secrets and the Protection of Confidential Information

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

In 2020, SAIP released new draft implementing regulations on how confidential commercial information will be protected in Saudi Arabia. Although SAIP should be applauded for publishing these draft regulations, holding a public consultation, and inviting stakeholder feedback on the matter, as noted in the Index at the time, the regulations themselves were deeply flawed and stood outside established international standards of RDP. Specifically, Article 4(1) of the regulations stated that any term of protection offered in Saudi Arabia would begin on "the date of the first registration of the preparation *in another country.* [Emphasis added]" If applied in practice, this would dramatically rewrite existing regulations and significantly curtail rightsholders' effective RDP term. The introduction of such a definition and the linking of the exclusivity period in Saudi Arabia to a product's first global launch would severely limit the availability of RDP in Saudi Arabia and undermine the incentives for innovation and investment such exclusivity provides. Moreover, the draft regulations did not allow a period of RDP for new indications. As noted in the Index, when the draft regulations were published, the implementation of this regulation and application of the existing provisions in relation to RDP would result in a reduction of the score to 0 for this indicator. In a positive step, the U.S. State Department's 2022 *Investment Climate Statement* noted that SAIP and SFDA have reaffirmed their support for the availability of regulatory data protection in the Kingdom. The Index will continue to monitor these developments in 2023.

Commercialization of IP Assets and Market Access

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

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