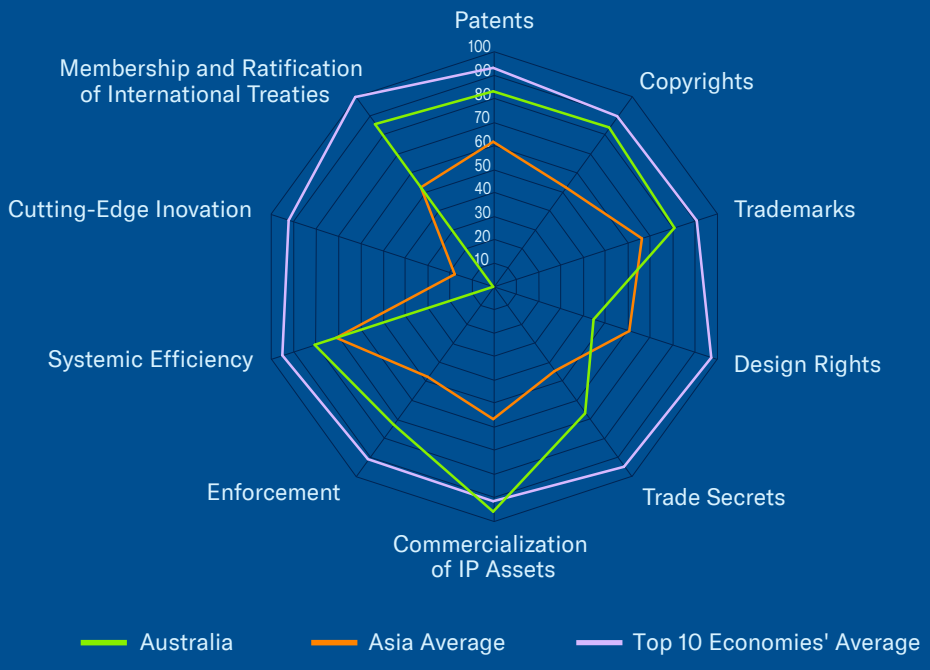
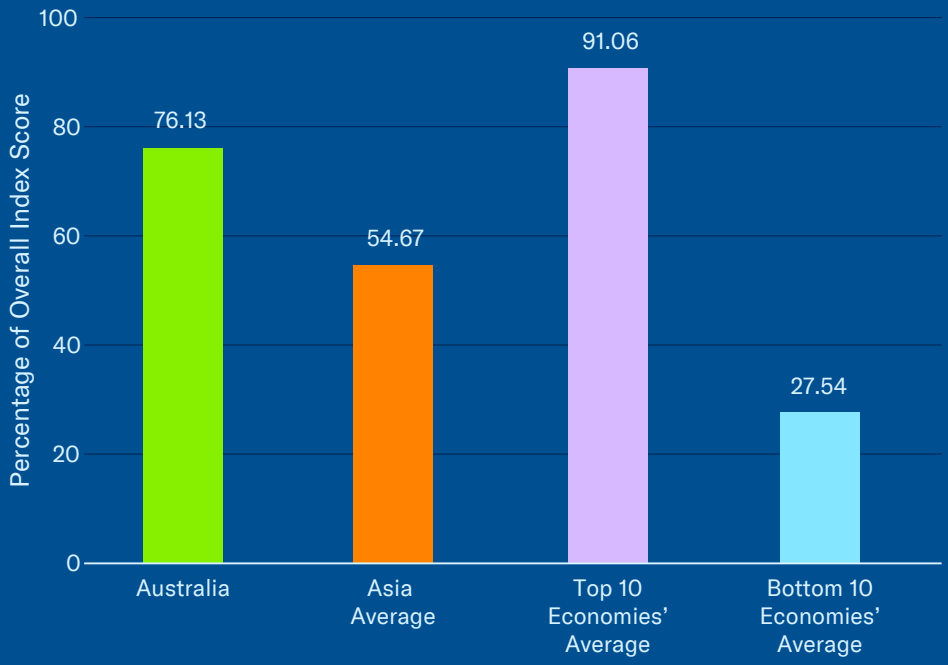
Australia

Rank
15/55

Category Scores



Overall Score in Comparison



Australia

Rank
15/55

Key Areas of Strength

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

Key Areas of Weakness

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

Indicator	Score
Category 1: Patents Rights and Limitations	**7.50**
1. Term of protection	1.00
2. Patentability requirements	1.00
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.00
Category 2: Copyrights and Limitations	**5.88**
10. Term of protection	0.63
11. Exclusive rights	1.00
12. Expeditious legal remedies disabling access to infringing content online	1.00
13. Cooperative action against online piracy	0.50
14. Limitations and exceptions	1.00
15. TPM and DRM	1.00
16. Government use of licensed software	0.75
Category 3: Trademarks Rights and Limitations	**3.25**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**2.00**
23. Protection of trade secrets (civil remedies)	0.75
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets	**5.75**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
29. Direct government intervention in setting licensing terms	1.00
30. IP as an economic asset	0.75
31. Tax incentives for the creation of IP assets	1.00
Category 7: Enforcement	**5.07**
32. Physical counterfeiting rates	0.75
33. Software piracy rates	0.82
34. Civil and precedural remedies	1.00
35. Pre-established damages	0.75
36. Criminal standards	0.75
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.50
Category 8: Systemic Efficiency	**4.00**
39. Coordination of IP rights enforcement	0.75
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Cutting-Edge Innovation	**0.00**
44. IP incentives for orphan medicinal product development	0.00
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	0.00
Category 10: Membership and Ratification of International Treaties	**6.00**
47. WIPO Internet Treaties	1.00
48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	1.00
49. Patent Law Treaty and Patent Cooperation Treaty	1.00
50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
51. Membership of the Convention on Cybercrime, 2001	1.00
52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 76.13% • Total Score: 40.35

Spotlight on the National IP Environment

Past Editions versus Current Score

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

Patents and Related Rights and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism:
As noted in previous editions of the Index, Australia's pharmaceutical linkage mechanism has several notable deficiencies: the absence of an automatic stay, the certification requirements for both generic producers and innovative patent holders, the absence of a mechanism to notify patent holders of potentially infringing follow-on products, and the historical application of market-sized damages. In 2020, the Australian drug regulatory authority, the Therapeutic Goods Administration (TGA), concluded an 18-month consultation on prescription medicines transparency measures. As a result of the consultation, the government announced a plan to introduce legislation to create a timelier patent notification framework. The plan would require that applicants for the first generic and biosimilar form of an originator product notify the patent holder at an earlier stage of the market approval process, namely, when their application is accepted for evaluation by the TGA. This change would create an opportunity for earlier negotiation and resolution of disputes on potential patent infringements before the follow-on product was listed in the Pharmaceutical Benefits Scheme, the national drug formulary. Additionally, the TGA announced it would publish a description of major innovative medicines applications that were under evaluation by the TGA. As noted in past editions of the Index, the Therapeutic Goods Amendment (2020 Measures No. 2) Act 2021—passed into law in early 2021—did not include any relevant references to this new patent notification framework, and no proposed legislation has been published by the TGA or presented to the Australian Parliament since.

In early 2023, the TGA published an update on the timetable and the outlines of an implementation plan on a new patent notification framework. As stated, under this proposed framework, first follow-on applicants would be required to notify the relevant rightsholder when an application has been submitted to the TGA but before the agency begins its review process. As the Index has noted repeatedly regarding this issue, the introduction of such an early notification requirement in this process would constitute a considerable improvement to Australia's existing patent linkage mechanism and would resolve some of the long-standing issues. However, it now seems that these proposals have been shelved. In an update on its website in December 2023, the TGA stated that the agency would not be moving forward with any of its proposals: "Views were mixed regarding earlier notification of generic and biosimilar medicine applications to the innovator. None of the options canvassed during consultation received consensus support and therefore the proposed measure was not progressed." The linking of the approval of follow-on biopharmaceutical products to the exclusivity status of a reference product is an effective way of achieving a balance between the protection of pharmaceutical exclusivity and stimulating early market entry of follow-on generic products. Linkage ensures that any disputes are resolved before the marketing of a follow-on product. This grants innovators a fair opportunity to secure return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity, but it also limits potential damages for generic manufacturers because no potentially infringing product is ever launched or approved for market.

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

Copyrights, Related Rights, and Limitations

11. Legal measures, which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including web hosting, streaming, and linking); 12. Expeditious legal remedies disabling access to infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 14. Scope of limitations and exceptions to copyrights and related rights:
As noted in previous editions, the attorney general has over the past few years initiated several reviews of various aspects of Australia's copyright environment. In 2022, a "copyright enforcement review" was announced with an "Issues Paper" published together with a 12-week public consultation. The purpose of the review was to examine the state of copyright protection in Australia and the extent to which "there is any need to supplement or strengthen existing enforcement mechanisms." At the time of research, the government had announced that it would develop options "reducing barriers for Australians to use of the legal system to enforce copyright" and, more generally, to improve public understanding and awareness of copyright.

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

Incentives for Cutting-Edge Innovation

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

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