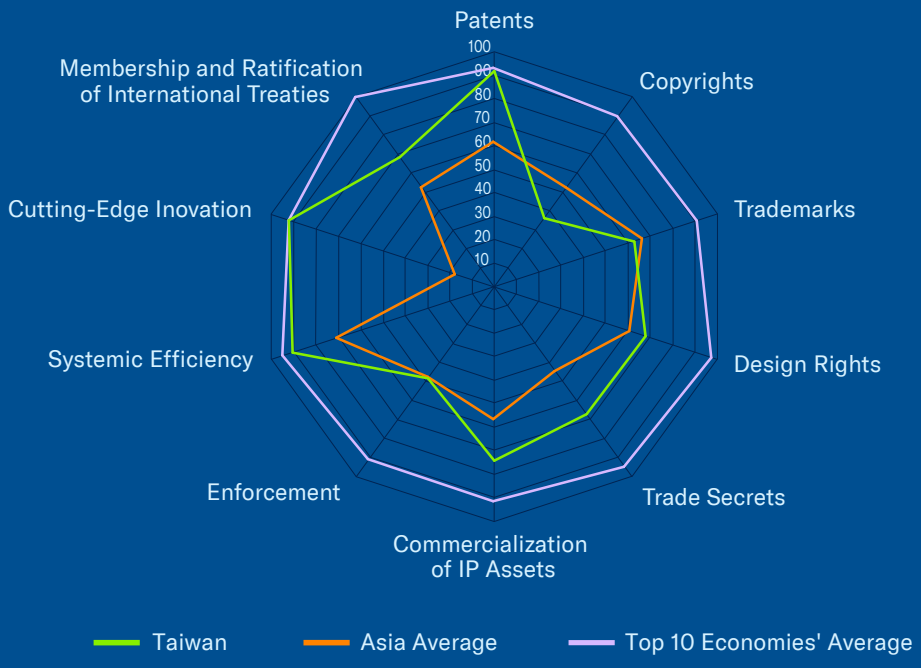
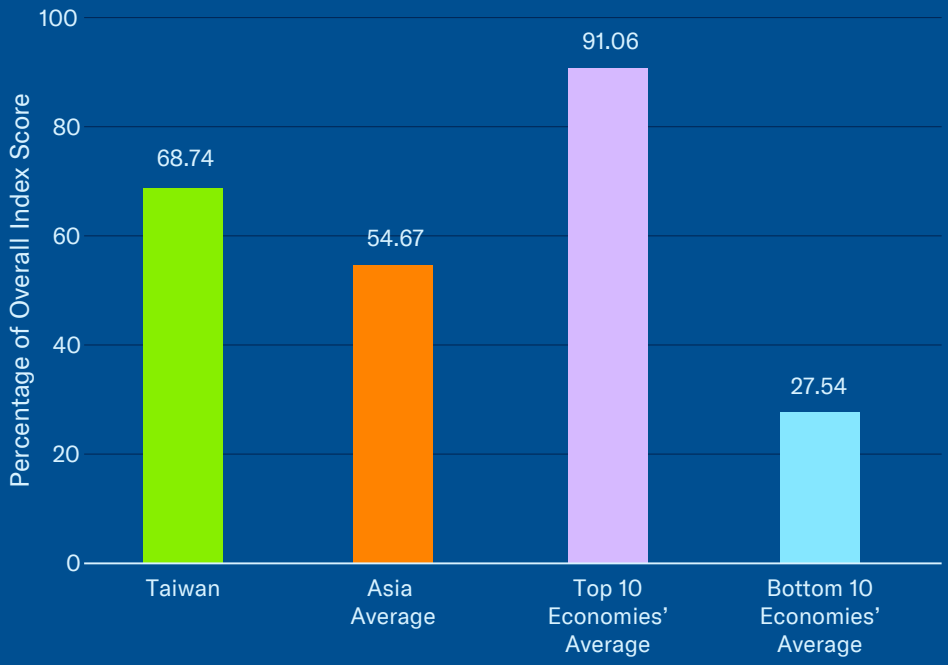
Taiwan

Rank
20/55

Category Scores



Overall Score in Comparison



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Key Areas of Strength

- A 10-year exclusivity period for designated orphan drugs has been in place since 2000
- TIPO offers support for SMEs developing IP assets through a fast-track examination procedure and expanded technical assistance
- 2020 amendments to the trade secrets law improved the IP environment
- The pharmaceutical linkage regime strengthens the protection and enforcement of biopharmaceutical IP rights
- The term of protection for industrial design rights has been extended from 12 to 15 years
- The patent framework is in line with international standards
- Although it has faced political hurdles to becoming a contracting party, Taiwan has in many cases implemented the provisions of several international IP treaties

Key Areas of Weakness

- Important gaps in the digital copyright regime are not addressed by the 2022 Copyright Act amendments
- The new Copyright Act introduces an unprecedentedly broad exceptions regime related to educational, personal use, and nonprofit copyright exceptions
- Relatively high rates of online piracy and physical counterfeiting

Indicator	Score
Category 1: Patents Rights and Limitations	**8.25**
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	1.00
6. Legislative criteria and use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	0.50
9. Patent opposition	0.75
Category 2: Copyrights and Limitations	**2.53**
10. Term of protection	0.53
11. Exclusive rights	0.25
12. Expeditious legal remedies disabling access to infringing content online	0.25
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.50
15. TPM and DRM	0.50
16. Government use of licensed software	0.25
Category 3: Trademarks Rights and Limitations	**2.50**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights, trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights and Limitations	**1.35**
21. Industrial design term of protection	0.60
22. Exclusive rights, industrial design rights	0.75
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	**4.42**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.75
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
Category 7: Enforcement	**3.35**
32. Physical counterfeiting rates	0.44
33. Software piracy rates	0.66
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.25
36. Criminal standards	0.25
37. Effective border measures	0.50
38. Transparency and public reporting by customs	0.75
Category 8: Systemic Efficiency	**4.50**
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	1.00
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Cutting-Edge Innovation	**2.75**
44. IP incentives for orphan medicinal product development	1.00
45. IP incentives for orphan medicinal product development, term of protection	1.00
46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
Category 10: Membership and Ratification of International Treaties	**3.75**
47. WIPO Internet Treaties	0.75
48. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
49. Patent Law Treaty and Patent Cooperation Treaty	0.50
50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
51. Membership of the Convention on Cybercrime, 2001	0.50
52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.50
53. Post-TRIPS FTA	0.00

Percentage of Overall Score: 68.74% • Total Score: 35.40

Spotlight on the National IP Environment

Past Editions versus Current Score

Taiwan's overall Index score has increased from 32.66 out of 48.50 indicators in the twelfth edition to 35.40 out of 51.50 indicators. This reflects a strong performance for the new indicators added under Category 9: Incentives for Cutting-Edge Innovation but a score decrease for indicator 32.

Patent Rights and Limitations

5. Pharmaceutical-related patent enforcement and resolution mechanism:
First announced by the Taiwanese authorities in 2017, a patent linkage system came into effect in 2019 covering both chemical and biologic products. This system allows rightsholders to record their patent information on a list housed by the Taiwan Food and Drug Authority (TFDA). In conjunction with sanitary registration, follow-on manufacturers must declare that their product does not infringe on any listed patent and must notify the patent holder. As noted at the time in the Index, the introduction of this linkage system by Taiwan was a positive development and was awarded with a score increase for this indicator. However, since the introduction of the linkage mechanism, there has been uncertainty about what constitutes a "new" medicine. Specifically, TFDA has taken the view that changes to a product's dosage or strength do not qualify as "new" and, consequently, are not eligible for inclusion in the mechanism. This view has been challenged in several lawsuits by rightsholders who have had their products removed from TFDA's linkage registration system. In 2023, final verdicts were issued in several of these cases by both lower and higher courts. Unfortunately, these judgments were not consistent. The Taipei High Administrative Court found that in two cases pertaining to challenges from Novartis and Cima Labs, TFDA had erred in its interpretation. However, in two other cases, the same court found the opposite, that is, TFDA's interpretation was the correct one. Appeals were subsequently filed in all four cases with the final verdict issued by the superior court—the Taiwan Supreme Administrative Court—being in favor of TFDA in all four cases. This is a regrettable outcome for the rightsholders in question and for Taiwan's national IP environment.

Changes in form and application of a known substance are some of the most important forms of biopharmaceutical innovation. This type of "incremental innovation," which results in new follow-on medications and incrementally improved or altered therapies, frequently reduce side effects, improve on existing delivery systems or the administration of a medicine, increase effectiveness, and reduce dosages required. At the time of research, it was unclear how, or if, the Taiwanese Government would respond with any potential legislative changes and broader definitions of what constitutes a new drug under the Pharmaceutical Affairs Act. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:
In a positive feature of Taiwan's national IP environment, Section 53 of the Patent Act provides a clear and unambiguous five-year maximum period of patent term restoration for pharmaceuticals or agrochemicals. However, rightsholders report that, since 2018, uncertainty surrounds how current regulatory practices recognize and assess the period of exclusivity to be restored. Specifically, the current Patent Examination Guidelines no longer align with international best practices. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

In a positive development, 2024 saw the continued criminal prosecution of operators of piracy websites in Taiwan. Early in the year, the responsible parties for the GimyTV website and online portals received significant prison sentences. This follows the successful prosecution and sentencing of a major online piracy network in 2023—the 8maple network. As documented in the Index, despite being in the process of reforming its copyright laws for the past decade, Taiwan continues to lack many of the fundamental building blocks for effective copyright enforcement. The Copyright Act includes digital piracy as an actionable criminal offense that does not require a formal complaint provided certain thresholds of estimated economic damages are met. However, the Act does not include a defined and copyright-specific mechanism of injunctive-style relief and the option to give ISPs the ability to disable access to illegal content whether through a court order or an administrative mechanism.

The past decade has seen a sharp increase in the number of economies that use judicial or administrative mechanisms to effectively disable access to infringing content. Today, India, Singapore, Brazil, Malaysia, and other Index economies have introduced measures that allow rightsholders to seek and gain effective relief against copyright infringement online. Many of these economies are also introducing dynamic injunctions. Such an injunction addresses the issue of mirror sites and disables infringing content that re-enters the public domain by simply being moved to a different access point online. These have proven to be effective in reducing the availability of copyright-infringing content within these jurisdictions. The Index will continue to monitor Taiwan's efforts to improve its copyright environment in 2025.

14. Scope of limitations and exceptions to copyrights and related rights:
In mid-2024, the National Science and Technology Commission released a draft version of the "Basic Law on Artificial Intelligence." This is the first legislative initiative in Taiwan that seeks to establish a framework for the national development and application of AI and machine learning technologies. These technologies are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific breakthroughs and innovation to take place through the analysis of large volumes of data and information. As such, the draft bill is instructive in that it recognizes the dilemma posed by AI and machine learning technologies to copyright holders and the risk for widespread infringement and use of illicit content. Specifically, Article 15 of the bill states that the "government should strive to improve the quality and quantity of artificial intelligence use materials in our country to ensure that training results maintain the country's multicultural values and protect intellectual property rights." Given the existing dynamics of the internet and the volume of infringing content available online—much of it made available without rightsholders' permission or even their knowledge—as well as the ability of scraping technologies to access rightsholders' content without their permission, it is essential that traditional safeguards enshrined in decades of copyright law and legal practice be strictly adhered to and that rightsholders can practically enforce their rights, both in Taiwan and around the world. At the time of research, the bill had not been enacted. The Index will continue to monitor these developments in 2025.

Incentives for Cutting-Edge Innovation

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

Acknowledging the challenges in developing new medicines for rare diseases, many Index economies have developed legislation and special programs to encourage the development of orphan medicines. Since 2000, Taiwan has had in place a dedicated legal framework for rare diseases and orphan drugs. The Rare Diseases Control and Orphan Drugs Act of 2000 provides the legal definitions and policies related to rare diseases and orphan drugs in Taiwan. This law and related programs provide an expedited market approval pathway for new drugs as well as protocol assistance and dedicated funding mechanisms for patients with rare diseases.

With respect to incentives for R&D and the development of new treatments and technologies, designated orphan drugs benefit from a 10-year market exclusivity period. During these 10 years, requests to register drugs "of the same kind" will not be accepted by the national drug regulatory authorities (Article 17) unless—as in the United States and the EU—the second drug complies with three conditions: (1) it is clinically superior, (2) it is insufficiently supplied, and (3) the first drug manufacturer agrees to allow market entry to a competing product. However, unlike the United States and EU, Article 18 of the Act also adds a fourth condition that allows for the approval of a similar product during the 10-year exclusivity period if the price of the drug is deemed "unreasonable."