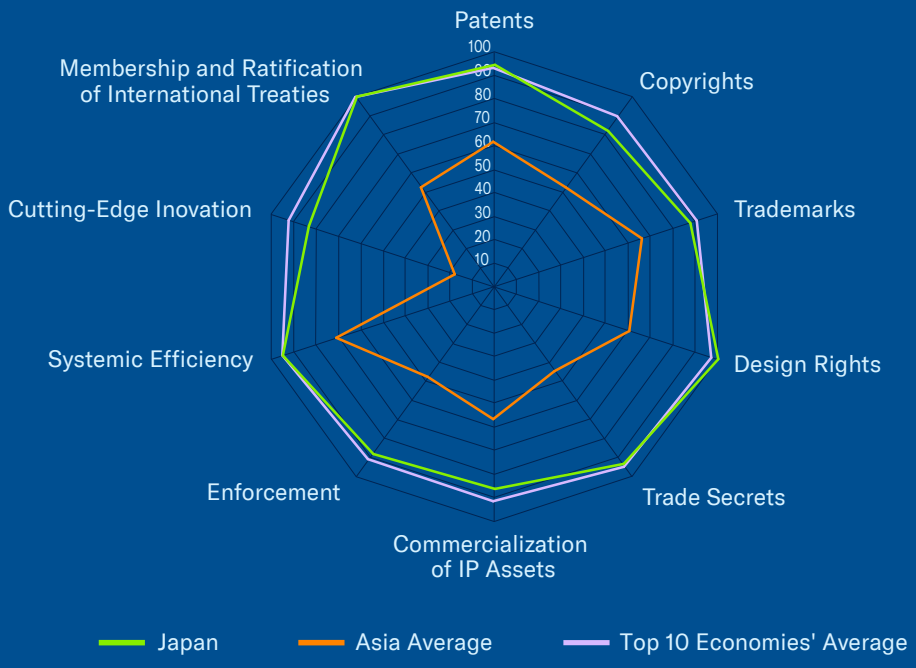
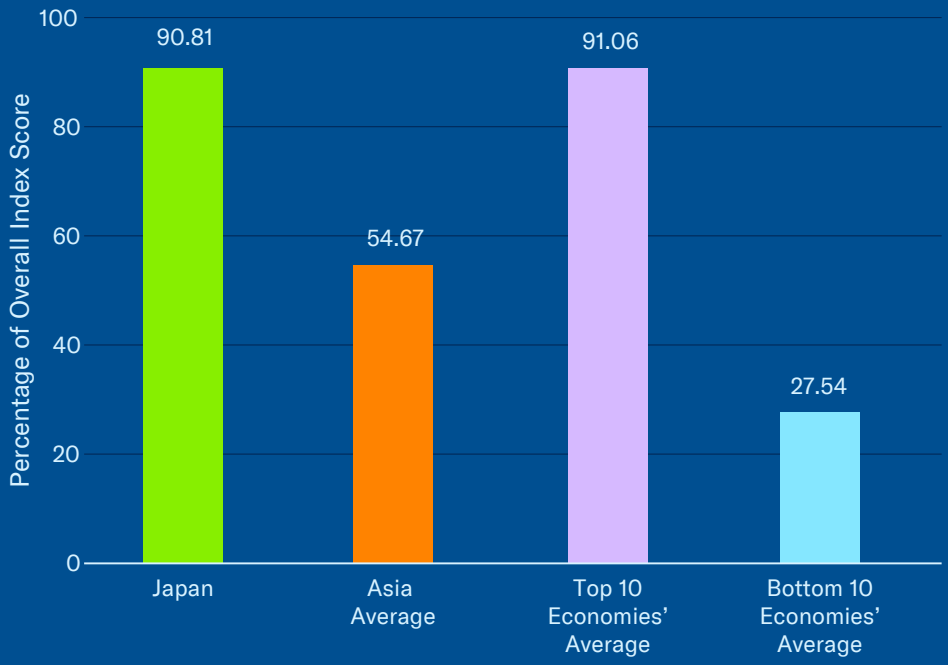
Japan

Rank
7/55

Category Scores



Overall Score in Comparison



Japan

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Key Areas of Strength

- Since the mid-2010s, Japan has provided an extended data exclusivity period (referred to as a “re-examination” period) of 10 years for designated orphan drugs
- Continued strong copyright enforcement efforts
- 2020 amendments to the Copyright Act continued to strengthen the copyright environment
- Design Act amendments came into effect in 2020, which included an increase in the term of protection
- 2019 copyright amendments strengthen TPM laws and increase the 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 includes a substantial IP chapter
- Japan has signed and acceded to all international IP treaties included in the Index
- Strong, sophisticated national IP environment is in place with relevant IP rights and protection available for all major IP rights categories

Key Areas of Weakness

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

Indicator	Score
Category 1: Patents Rights and Limitations	**8.50**
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	1.00
Category 2: Copyrights and Limitations	**5.74**
10. Term of protection	0.74
11. Exclusive rights	1.00
12. Expeditious legal remedies disabling access to infringing content online	0.50
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	1.00
Category 3: Trademarks Rights and Limitations	**3.50**
17. Term of protection	1.00
18. Protection of well-known marks	1.00
19. Exclusive rights, trademarks	1.00
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights and Limitations	**2.00**
21. Industrial design term of protection	1.00
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.80**
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
Category 6: Commercialization of IP Assets	**5.17**
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
Category 7: Enforcement	**6.17**
32. Physical counterfeiting rates	0.83
33. Software piracy rates	0.84
34. Civil and precedural remedies	0.75
35. Pre-established damages	0.75
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by customs	1.00
Category 8: Systemic Efficiency	**4.75**
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
Category 9: Cutting-Edge Innovation	**2.50**
44. IP incentives for orphan medicinal product development	1.00
45. IP incentives for orphan medicinal product development, term of protection	0.50
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	**7.00**
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	1.00
53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 90.81% • Total Score: 48.13

Spotlight on the National IP Environment

Past Editions versus Current Score

Japan's overall Index score has increased from 45.63 out of 50 indicators in the twelfth edition to 48.13 out of 53 indicators. This reflects 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, after the conclusion of a patent invalidation action lodged in 2019 with the Japan Patent Office (JPO), in 2020, the Japanese Ministry of Health, Labour and Welfare (MHLW) approved several generic follow-on products for a reference product. This occurred even though the JPO had upheld several of the innovator's claims and rights in the patent invalidation action. After the approval, the rightsholder initiated patent infringement proceedings against the approved generic products. Industry reports suggest that this was not an isolated example but that the MHLW has subsequently approved several more follow-on products despite the reference products in question being under a term of IP exclusivity. Once a follow-on product has been approved for market, it is automatically eligible for inclusion in Japan's national formulary and, by extension, Japanese patients. There is a potential high cost to any national IP system that is unable to effectively resolve any biopharmaceutical patent infringement dispute before the marketing of a product and to provide effective interim relief. In this respect, biopharmaceutical products are unique because they involve not only the potential infringing party and the rightsholder but also patients whose health and well-being depend on the products in question. Consequently, the introduction of a potentially infringing product onto the marketplace puts both patients and the follow-on manufacturers at risk. In short, this situation creates significant uncertainty for innovators and generic manufacturers alike and could result in products being prescribed to Japanese patients that ultimately have to be withdrawn from the market based on the outcome of the pending litigation. Reports suggest that in 2024, the MHLW was considering introducing a more formalized patent and IP exclusivity review process.

As this Index has consistently argued, 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. Such linkage ensures that any disputes are resolved before 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—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 postmarketing lawsuit. The introduction of a clearly defined and formalized linkage mechanism in Japan would constitute an improvement to Japan's biopharmaceutical IP environment and would result in a potential score increase for this indicator. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:
As noted in the Index, the Japanese Agency for Cultural Affairs Copyright Division (part of the Ministry of Education, Culture, Sports, Science and Technology) has been actively discussing the interaction between copyright protection and the use and application of AI and machine learning for the past few years. In 2023, the agency held a seminar and released a presentation setting out its views. This work continued in 2024 with the agency making several important policy contributions—most notably the publication of a concept paper "Thoughts on AI and Copyright" in March 2024—and hosting an additional stakeholder seminar. The paper provides an in-depth technical analysis of AI and related technologies and Japan's copyright law and exceptions regime. By and large, the analysis follows the same reasoning as the 2023 agency presentation by drawing a distinction between what is termed an "AI development/learning stage" and a "Generation/Usage stage." A detailed analysis of existing Japanese copyright exceptions and the meaning and application of Section 30(4) is provided. The concept paper rightly notes that this is a novel and challenging area of copyright law requiring much nuance and a case-by-case analysis of the type of technologies used, the purpose of the AI application, the extent to which any copyrighted works have been studied, how these works have been used (and what proportion of the works have been used), and how these works were acquired. Based on a close reading of Article 30(4), the paper draws a distinction between the "enjoyment" of a copyrighted work in question and its "non-enjoyment."

Essentially, the agency argues that the use of copyrighted material is allowed in cases whereby the training of the AI application (the "developmental/learning stage") falls under the category of "non-enjoyment" of the work "when a work is used for information analysis, including for the purposes of AI training, it is considered to fall under the provision of Article 30-4 of the Act, which states that 'the work does not aim to enjoy for oneself or to allow others to enjoy the ideas or emotions expressed in the work.'" Yet this reasoning fails to account for the fact that any application using a copyrighted work for learning and developmental purposes is, by definition, an "enjoyment" of the work. Regardless of the extent to which an eventual AI output resembles the copyrighted work used or the quantity of copyrighted works used during the AI developmental process, the copyrighted work in question constitutes part of the technology's learning and, hence, "enjoyment." Without access to materials to learn from, the AI-based application would not be able to learn and, consequently, not be able to produce any desired output. More broadly, this logic holds true for any type of learning or developmental activity whether for machines or human beings. For example, human beings who want to learn and develop from copyrighted works must acquire them lawfully to be able to make use of and, potentially, "enjoy" them. There is no reason why this logic should not be applied to computer software and the development of AI applications. More broadly, and as noted last year, the narrow exceptions to copyright protection defined under Article 30(4) are all prefaced by such usage only being allowed if it does not "unreasonably prejudice the interests of the copyright owner in light of the nature or purpose of the work or the circumstances of its exploitation." Similarly, this article—and other copyright exceptions defined in the Act—do not allow for the unlawful appropriation of or access to copyrighted works.

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 Japan and around the world. The concept paper acknowledges that the existence, dissemination and, potential use of pirated content in AI development is a problem: "The damage caused by pirated copies to Japan's content industry is enormous, and it goes without saying that we must take measures against pirated copies, including regulating reach sites." But overall, the paper seems to suggest that the responsibility for enforcement lies with rightsholders and that, in contrast, AI developers have only a relatively limited duty of care:

> *Whether data on the Internet is a pirated or other infringing copy is ultimately difficult for anyone other than the copyright holder of the work to which the copy pertains, and it is likely to be difficult in practice to ask those who are trying to collect learning data for AI training to make this judgment. In addition, infringing copies include a wide range of things, from those posted on pirate sites that upload a large number of original manga and other works without permission, to those posted by individual users on SNS and other sites that do not meet the requirements of the rights restriction provisions for citations, etc. For this reason, when collecting training data on the internet for AI training, the data to be collected may contain pirated copies or other copies that have been uploaded in violation of copyright...*
>
> *AI development businesses and AI service providers are required to take sufficient care when collecting training data from websites that host pirated copies to ensure that such actions do not encourage infringement of rights, such as an increase in new pirated copies, by making it easier to access such websites or generating advertising revenues or other financial benefits for those who operate such websites. In this regard, it is desirable for rights holders to provide relevant parties such as these businesses with information about known websites that host pirated copies in advance to an appropriate extent, so that businesses can recognize websites that host pirated copies and take measures such as excluding them from the collection of training data, thereby realizing a situation that does not encourage infringement of rights through pirated copies.*

After the agency's seminar and publications, the Japan Newspaper Publishers and Editors Association released a statement demanding, as described by *The Japan Times*, "consent and accuracy from generative AI." This follows a similar 2023 statement issued by a collection of Japanese publishers and rightsholders calling for more clarity on the interpretation of existing copyright statute and the need for the government to engage rightsholders in this issue. The Index will 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 the 1970s, Japan has had a dedicated policy program in place for rare diseases. Today, the 2014 Act on Medical Care for Patients with Rare/Intractable Diseases (Act No. 50 of 2014) and relevant sections of the drug regulatory framework provide the legal definitions and policies related to rare diseases and orphan drugs. Specifically, these laws 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 diseases.

With respect to incentives to R&D and the development of new treatments and technologies, designated orphan drugs benefit from an extended data exclusivity period (referred to as "re-examination" period) of 10 years (against eight years for new chemical entities and four years for new indications of drugs already approved).