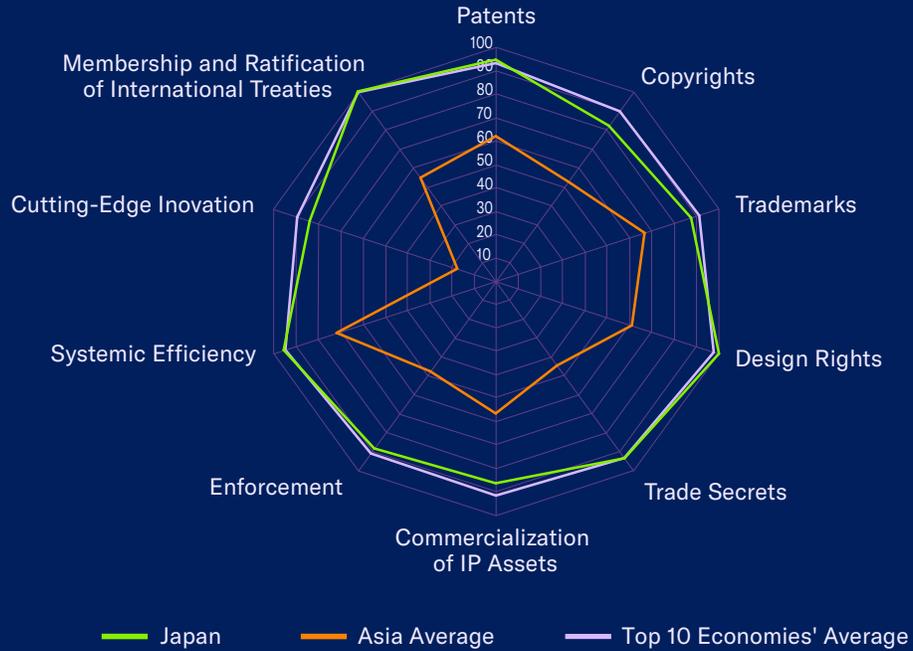
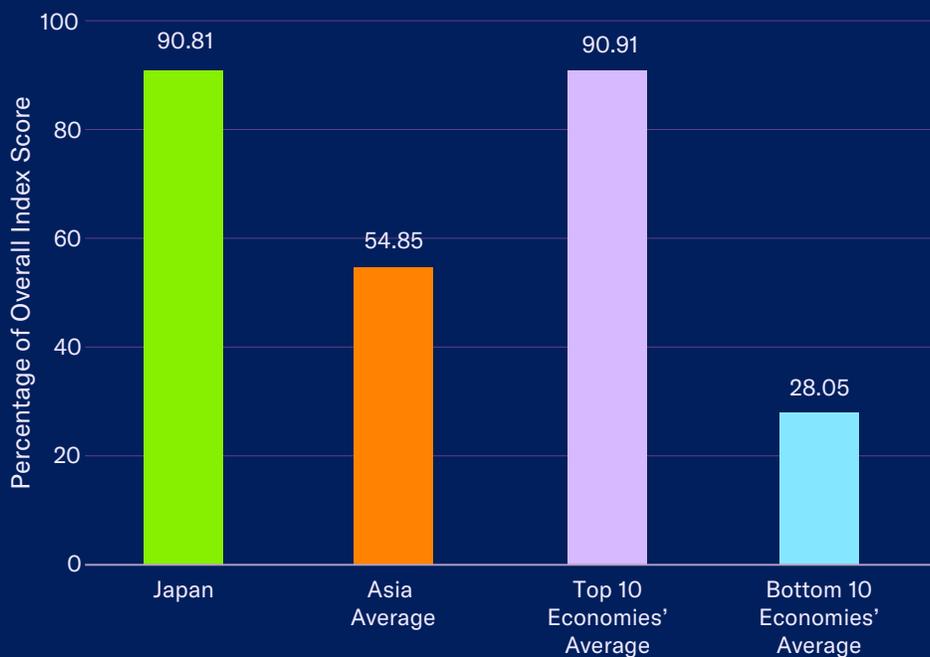


## Category Scores



## Overall Score in Comparison





## Key Areas of Strength

- 2019 and 2020 copyright amendments increase term of protections and strengthen TPM laws, copyright environment, and enforcement
- Design Act amendments came into effect in 2020, which included an increase in 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
- Since mid-2010s, Japan has provided an extended data exclusivity period (referred to as 're-examination' period) of 10 years for designated orphan drugs
- Japan has signed and acceded to all international IP treaties included in the Index
- Strong, sophisticated national IP environment 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 following approval of several follow-on drugs in 2020 by the Japanese drug regulatory authority
- No IP specific tax incentives in place such as a patent box regime
- Remedies against online copyright infringement remain under-developed compared to other OECD economies

Indicator	Score	Indicator	Score
<b>Category 1: Patents Rights and Limitations</b>		<b>8.50</b>	
1. Term of protection	1.00	29. Direct Government intervention in setting licensing terms	1.00
2. Patentability requirements	1.00	30. IP as an economic asset	0.75
3. Patentability of CII	1.00	31. Tax incentives for the creation of IP assets	0.67
4. Plant variety protection	1.00	<b>Category 7: Enforcement</b>	
5. Pharmaceutical-related enforcement	0.50	<b>6.17</b>	
6. Legislative criteria and active use of compulsory licensing	1.00	32. Physical counterfeiting rates	0.83
7. Pharmaceutical patent term restoration	1.00	33. Software piracy rates	0.84
8. Membership of a Patent Prosecution Highway	1.00	34. Civil and procedural remedies	0.75
9. Patent Opposition	1.00	35. Pre-established damages	0.75
<b>Category 2: Copyrights and Limitations</b>		<b>5.74</b>	
10. Term of protection	0.74	36. Criminal standards	1.00
11. Exclusive rights	1.00	37. Effective border measures	1.00
12. Expeditious legal remedies disabling access to infringing content online	0.50	38. Transparency and public reporting by Customs	1.00
13. Cooperative action against online piracy	0.50	<b>Category 8: Systemic Efficiency</b>	
14. Limitations and exceptions	1.00	<b>4.75</b>	
15. TPM and DRM	1.00	39. Coordination of IP rights enforcement	1.00
16. Government use of licensed software	1.00	40. Consultation with stakeholders during IP policy formation	1.00
<b>Category 3: Trademarks Rights and Limitations</b>		<b>3.50</b>	
17. Term of protection	1.00	41. Educational campaigns and awareness raising	1.00
18. Protection of well-known marks	1.00	42. Targeted incentives for the creation and use of IP assets for SMEs	1.00
19. Exclusive rights, trademarks	1.00	43. IP-intensive industries, national economic impact analysis	0.75
20. Frameworks against online sale of counterfeit goods	0.50	<b>Category 9: Cutting-Edge Innovation</b>	
<b>Category 4: Design Rights and Limitations</b>		<b>2.00</b>	
21. Industrial Design Term of Protection	1.00	<b>2.50</b>	
22. Exclusive rights, industrial design rights	1.00	44. IP incentives for orphan medicinal product development	1.00
<b>Category 5: Trade Secrets and the Protection of Confidential Information</b>		<b>2.80</b>	
23. Protection of trade secrets (Civil Remedies)	1.00	45. IP incentives for orphan medicinal product development, term of protection	0.50
24. Protection of trade secrets (Criminal Sanctions)	1.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	1.00
25. Regulatory data protection term	0.80	<b>Category 10: Membership and Ratification of International Treaties</b>	
<b>Category 6: Commercialization of IP Assets</b>		<b>7.00</b>	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	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
28. Registration and disclosure requirements of licensing deals	0.75	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

**Total Score: 48.13**

# Spotlight on the National IP Environment

## Past Editions versus Current Score

Japan's overall score remains unchanged at 48.13 out of 53 indicators.

## Patent Rights and Limitations

### *5. Pharmaceutical-related patent enforcement and resolution mechanism:*

As reported last year, the Japanese Ministry of Health, Labour and Welfare (MHLW) is considering introducing a more formalized review process for patents and intellectual property (IP) exclusivity as part of the market registration for medicines. At the time of research, the MHLW had not publicly released a formal proposal, and the details of said proposed process remain unclear.

Based on the conclusions of a study group convened in 2024, the Ministry of Health, Labor and Welfare is considering setting up an expert committee to assist the ministry in determining whether a follow-on product approval application infringes any valid patent in force. While they have not yet put forward a formal proposal, such a system would not support the early judicial resolution of patent disputes. As this Index has stated, linking the approval of follow-on biopharmaceutical products to the exclusivity status of a reference product is an effective way to balance the protection of pharmaceutical exclusivity with the 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.

Still, it also limits potential damages for generic manufacturers, as 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.

In the last five years, pharmaceutical rights holders have faced growing uncertainty about how effectively they can enforce their exclusivity and IP rights in Japan. Specifically, following the conclusion of a patent invalidation action filed with the Japan Patent Office (JPO) in 2019, the MHLW approved several generic follow-on products in 2020 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. Following the approval, the rights holder-initiated patent infringement proceedings against the approved generic products. Industry reports suggest that this was not an isolated example and that the MHLW has, in the intervening years, approved several more follow-on products despite the reference products being under IP exclusivity. Once a follow-on product has been approved for market, it is automatically eligible for inclusion in Japan's national pharmaceutical formulary and, by extension, available to Japanese patients.

There is a high potential cost to any national IP system that is unable to resolve biopharmaceutical patent infringement disputes before a product is marketed and to provide effective interim relief. In this respect, biopharmaceutical products are unique as they involve not only the potential infringing party and the rights holder, 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 follow-on manufacturers at risk. In short, such a situation creates significant uncertainty for innovators and generic manufacturers alike and could result in products prescribed to Japanese patients that must ultimately be withdrawn from the market based on the outcome of any pending litigation. As the MHLW moves forward with developing its reform proposals, the Index suggests considering the introduction of a modern patent enforcement and resolution mechanism. The introduction of a clearly defined and formalized linkage mechanism in Japan would improve the biopharmaceutical IP environment and could increase the score on this indicator. The Index will continue to monitor these developments in 2026.

## Commercialization of IP Assets and Market Access

*31. Tax incentives for the creation of IP assets:* Japan offers a range of general R&D tax credits and additional incentives for specific industries and areas of technology development, including the Internet of Things and 5G cellular networks. The credit ranges from 25% to 45% of the qualifying tax liability. Unlike a growing number of economies around the world, Japan has historically not offered IP-asset-specific innovation or patent box incentives. This has now changed. In 2025, the government introduced a new “Innovation Box Tax System” incentive for IP-derived income, offering a 30% income deduction on qualifying IP income. However, this is not a general incentive available to IP income from all technologies and patent arts, as it is limited to income from patents and copyrights related to AI technologies. While AI technologies, computational advancements, and machine learning are essential for future economic growth, to maximize any intellectual property (IP) incentives’ positive economic impact, they must be accessible to all technologies and inventions. As a result, no additional score for Japan has been allocated under this indicator.