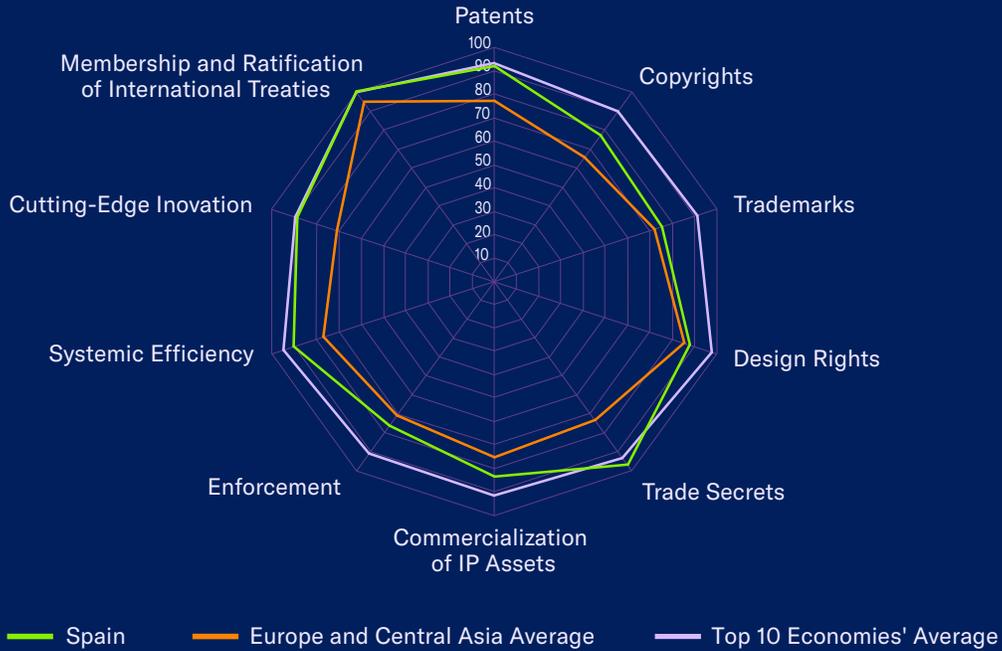




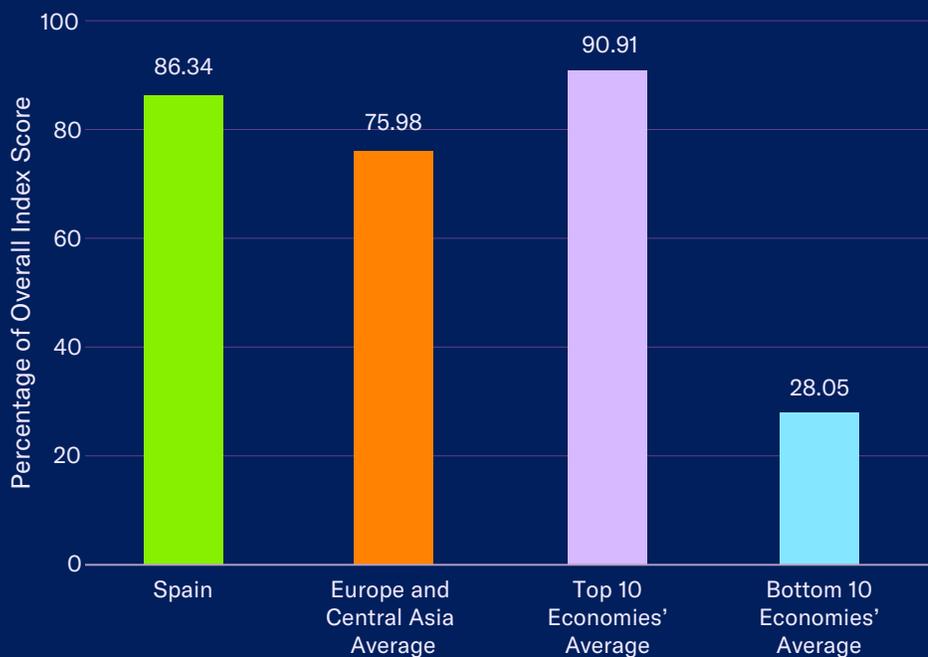
Spain

Rank
9/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Royal Decree-Law 24/2021 transposed EU Directive 2019/790 on Copyright and Related Rights in the CDSM Directive into law
- 2021 Protocol to Strengthen the Protection of Intellectual Property Rights further strengthens Spanish enforcement efforts
- Stronger copyright enforcement measures in place through Royal Decree Law 2/2018; continued enforcement efforts through Ministry of Culture
- Since 2000, Orphan Regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and development of new treatments and medicines for rare diseases
- As an EU Member State, Spain has in place an advanced IP system

Key Areas of Weakness

- EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights including RDP and orphan incentives
- New EU-wide compulsory licensing regime risks undermining patent rights in Europe
- Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals poses significant risk to Spain's and EU's research and IP based biopharma industry
- Counterfeiting and piracy levels remain high compared to other EU economies with software piracy estimated at 42%

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		8.25	
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	1.00
4. Plant variety protection	1.00	Category 7: Enforcement	
5. Pharmaceutical-related enforcement	0.50	5.33	
6. Legislative criteria and active use of compulsory licensing	1.00	32. Physical counterfeiting rates	0.75
7. Pharmaceutical patent term restoration	0.75	33. Software piracy rates	0.58
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	0.50
Category 2: Copyrights and Limitations		4.50	
5.38		36. Criminal standards	0.75
10. Term of protection	0.63	37. Effective border measures	1.00
11. Exclusive rights	0.75	38. Transparency and public reporting by Customs	1.00
12. Expeditious legal remedies disabling access to infringing content online	1.00	Category 8: Systemic Efficiency	
13. Cooperative action against online piracy	1.00	4.50	
14. Limitations and exceptions	0.75	39. Coordination of IP rights enforcement	0.75
15. TPM and DRM	0.75	40. Consultation with stakeholders during IP policy formation	1.00
16. Government use of licensed software	0.50	41. Educational campaigns and awareness raising	1.00
Category 3: Trademarks Rights and Limitations		2.65	
3.00		42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
17. Term of protection	1.00	43. IP-intensive industries, national economic impact analysis	1.00
18. Protection of well-known marks	0.75	Category 9: Cutting-Edge Innovation	
19. Exclusive rights, trademarks	0.75	2.65	
20. Frameworks against online sale of counterfeit goods	0.50	44. IP incentives for orphan medicinal product development	1.00
Category 4: Design Rights and Limitations		7.00	
1.75		45. IP incentives for orphan medicinal product development, term of protection	0.90
21. Industrial Design Term of Protection	1.00	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
22. Exclusive rights, industrial design rights	0.75	Category 10: Membership and Ratification of International Treaties	
Category 5: Trade Secrets and the Protection of Confidential Information		7.00	
2.90		47. WIPO Internet Treaties	1.00
23. Protection of trade secrets (Civil Remedies)	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
24. Protection of trade secrets (Criminal Sanctions)	1.00	49. Patent Law Treaty and Patent Cooperation Treaty	1.00
25. Regulatory data protection term	0.90	50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991	1.00
Category 6: Commercialization of IP Assets		5.00	
5.00		51. Membership of the Convention on Cybercrime, 2001	1.00
26. Barriers to market access	0.75	52. The Hague Agreement Concerning the International Registration of Industrial Designs	1.00
27. Barriers to technology transfer	0.75	53. Post-TRIPS FTA	1.00
28. Registration and disclosure requirements of licensing deals	0.75		

Total Score: 45.76

Spotlight on the National IP Environment

Past Editions versus Current Score

Spain's overall score has decreased from 45.97 out of 53 indicators to 45.76. This reflects a score decrease on indicators 25, 32, and 45.

Area of Note

In 2023, the European Commission published a package of proposed legislative changes to almost all facets of the biopharmaceutical market authorization process and related incentives. The Commission, Parliament, and Council have introduced multiple proposals. Although the proposed reforms are intended to create a 21st-century life sciences landscape that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe's competitiveness, many of the proposed changes would do the opposite by fundamentally weakening the EU's legal framework governing biopharmaceutical IP rights. At the time of research, European institutions had agreed on a final package, and a legislative text was being finalized and expected to take effect soon after Index publication. Under this finalized deal, IP rights related to regulatory data protection (RDP), orphan drugs, and patent protection — through an expansion of existing Bolar exemptions — would all be negatively affected. The impact of these proposals on specific Index indicator scores is detailed below. Some of these changes affect several categories of the Index and could affect multiple indicators, including, for example, changes to Bolar exemptions.

A Bolar exemption (or exception) allows biopharmaceutical follow-on applicants to begin testing and regulatory approval for their follow-on products without obtaining consent from a rights holder, in this case, the market authorization holder of a biopharmaceutical reference product. This type of exception originates in the United States, specifically in the 1984 Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act). The rationale for these exclusivity exemptions is to ensure there is no undue delay in the market supply of follow-on products once the reference product's exclusivity expires. These exceptions are not intended to shorten or undermine rights holders' legitimately granted exclusivity periods. The expansion of existing EU Bolar exemptions risks weakening IP exclusivity periods at the level of each EU Member State — including, for example, duly granted patent protection — by prematurely launching IP-rights-infringing generic or biosimilar products. The exact impact of this expansion will depend on the individual national characteristics of each EU Member State. The Index will continue to monitor these developments at the Member State level as the pharmaceutical package is nationally implemented.

Patent Rights and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In December 2025, the European Council and European Parliament formally adopted, as regulation, a new cross-European compulsory licensing regime. While this agreement constitutes an improvement over preceding drafts — this includes, for instance, the exclusion of trade secrets and know-how — it remains unclear why the EU needs a cross-European compulsory licensing regime.

The proposals are fundamentally based on the notion that the COVID-19 pandemic highlighted the need for a clearer and more effective pan-European compulsory licensing mechanism. However, as indicated by this Index and rights holders, the actual evidence and experiences from the pandemic suggest otherwise. Together with the proposed rollback of IP protections in the pharmaceutical reform package discussed above, this new compulsory licensing regime will further undermine biopharmaceutical IP rights in the EU. At the time of research, no finalized legal text had been published. The Index will continue to monitor these developments.

7. Patent term restoration for pharmaceutical products:

Since 2015, the European Commission has sought to recalibrate certain elements of patent term restoration for biopharmaceuticals, namely the Supplementary Protection Certificates (SPCs). Notably, Regulation 2019/933 created an SPC manufacturing and export exemption. The exemption allows companies to manufacture generic and biosimilar products in the EU during the SPC period for export to third (non-EU) economies and to stockpile them during the last six months of the SPC's validity for the domestic market. As a result of this action, the score for this indicator was reduced by 0.25 across all EU Member States in the eighth edition of the Index. Unlike Regulation 2019/933 and the SPC exemption, proposals for a new centralized process for granting and administering SPCs would be a positive addition to the EU's IP environment.

In 2022, as part of the introduction of the Unitary Patent system and the Patent Court, the European Commission outlined several options for reforming the SPC system, including a new centralized system for SPC protection and applications. In 2023, the Commission released a formal legislative proposal for both a unitary SPC and a new centralized procedure for other applications, and the European Parliament subsequently responded to it.

The Commission and Parliament should be congratulated for recognizing that a potential centralized procedure for SPC protection would provide legal, administrative, and financial efficiencies to all affected parties. In this sense, the proposed legislation fills a gap and is a net positive.

Unfortunately, fundamental aspects of the proposed procedure would insert a new level of uncertainty and potential delay into the patent term restoration process. For example, both the Commission's proposal and Parliament's response include a novel mechanism for SPC opposition. The purpose of the SPC system is to restore patent term lost due to the unique and lengthy sanitary registration requirements for biopharmaceutical products. This restoration applies to an existing, valid, and in-force patent. By the time an SPC (Supplementary Protection Certificate) application is submitted, there will have already been numerous opportunities for relevant parties to challenge the validity of the underlying patent. These challenges can occur administratively or judicially, either regionally through the European Patent Office (EPO), nationally as defined by each Member State, or through the Unified Patent Court. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome is simply additional delays, bureaucracy, and costs imposed on applicants. At the time of research, no finalized legal text had been published. The Index will continue to monitor these developments.

Copyrights and Limitations

14. *Scope of limitations and exceptions to copyrights and related rights:*

As noted last year, the AI Act now provides a legislative framework governing the development and deployment of AI-based technologies in the EU. The first of its kind in the world, the Act defines different levels and types of AI deployment, with some activities prohibited and other forms of deployment and systems regulated based on perceived level of risk. The European Commission established the European AI Office to coordinate and oversee the implementation and enforcement of the Act.

In 2025, further developments occurred in the interaction between copyright protection and AI, with the European Commission, AI Office, and EUIPO all releasing new guidance documents. While these documents address some of the key challenges creators and rights holders face — most notably the *AI Code of Practice* and the EUIPO's *The Development of Generative Artificial Intelligence from a Copyright Perspective* — none of them carry any legal weight or impose any additional regulatory requirements on AI developers and platforms.

AI and machine learning are important areas of future economic activity, as advances in computational power and new technologies enable scientific research and innovation through the analysis of large volumes of data. However, given the existing dynamics of the Internet and the volume of infringing content available online, it is essential that safeguards be adhered to, and that rights holders can appropriately enforce their rights. It remains to be seen whether the AI Act and its subsequent implementation will provide rights holders with a meaningful avenue of enforcing their copyrights. The Index will continue to monitor these developments in 2026.

Trade Secrets and the Protection of Confidential Information

25. *Regulatory data protection (RDP) term:*

As noted in previous editions, in 2023, the European Commission published proposed legislative changes to the EU's RDP regime. In December 2025, the Council and the European Parliament agreed on the final General Pharmaceutical Legislation. Article 10 of Directive 2004/27/EC (amending 2001/83/EC) has historically provided new pharmaceutical products with eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to submit bio-equivalence studies), and one additional year of protection for significant new indications of existing products.

On this basis, all EU Member States have, up until this edition of the Index, achieved the maximum available score of 1.00 on this indicator. The General Pharmaceutical Legislation has weakened this term of protection. The final legislation provides eight years of data protection and one year of market protection, for a baseline of eight+ one years. This reduces market protection from two years to one year, weakening the EU's RDP framework. The agreement also conditions the restoration of lost RDP terms on criteria such as conducting clinical trials in multiple EU Member States or seeking EU marketing authorization within 90 days of the first global submission. The deal includes an 11-year cap on the combined RDP. As a result, the score on this indicator has been reduced for all EU Member States included in the Index. The Index will continue to monitor these developments in 2026.

Incentives for Cutting-edge Innovation

45. Special market exclusivity incentives for orphan medicinal product development, term of protection:

Since coming into force in 2000, Regulation (EC) No 141/2000 (the “EU Orphan Regulation”) has provided innovators with a strong term of IP exclusivity. Specifically, Article 8 of the Regulation defines exclusivity as a baseline 10-year marketing exclusivity term, which may be extended by two years upon completion of additional pediatric studies. For over a quarter of a century, this Regulation has stood as an international example of how strong IP incentives can incentivize the R&D and innovation necessary to tackle some of the toughest health challenges in the world. The Regulation has directly resulted in more clinical research, product development, and medicines available to patients with rare diseases in the EU and beyond.

Despite this track record of success, the Regulation has been under review for an extended period, most recently as part of the pharmaceutical package. Like the term of protection relating to RDP, the finalized agreement between the Parliament, Council, and Commission has weakened the term of protection offered to innovators. While it is possible to obtain an 11-year period of protection for products “addressing a high unmet medical need,” the baseline term of protection has been reduced from 10 to nine years. As a result, the score on this indicator has been reduced for all EU Member States included in the Index. The Index will continue to monitor these developments in 2026.