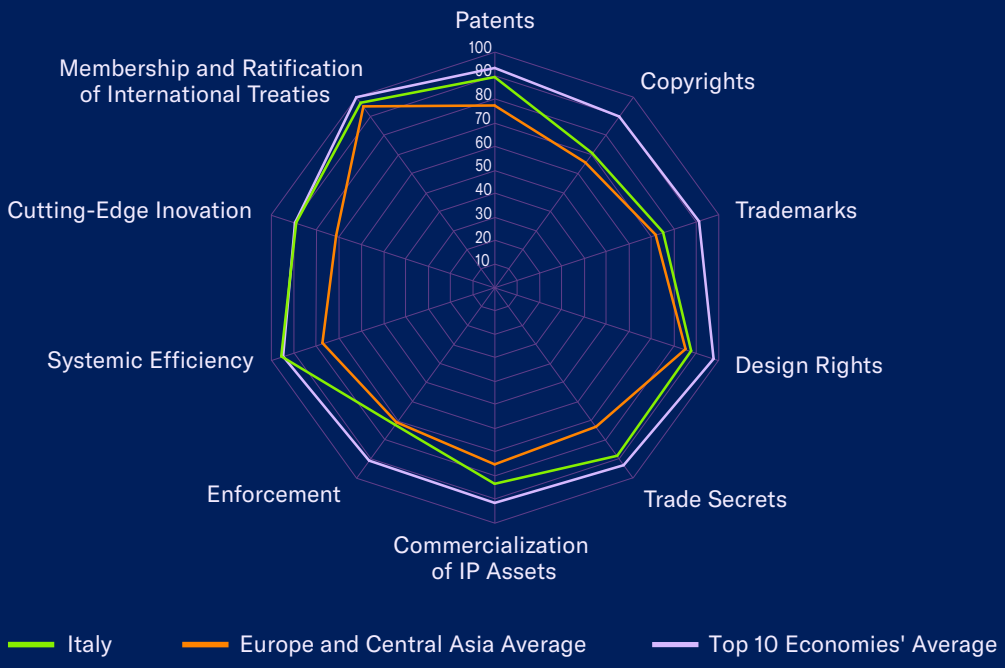
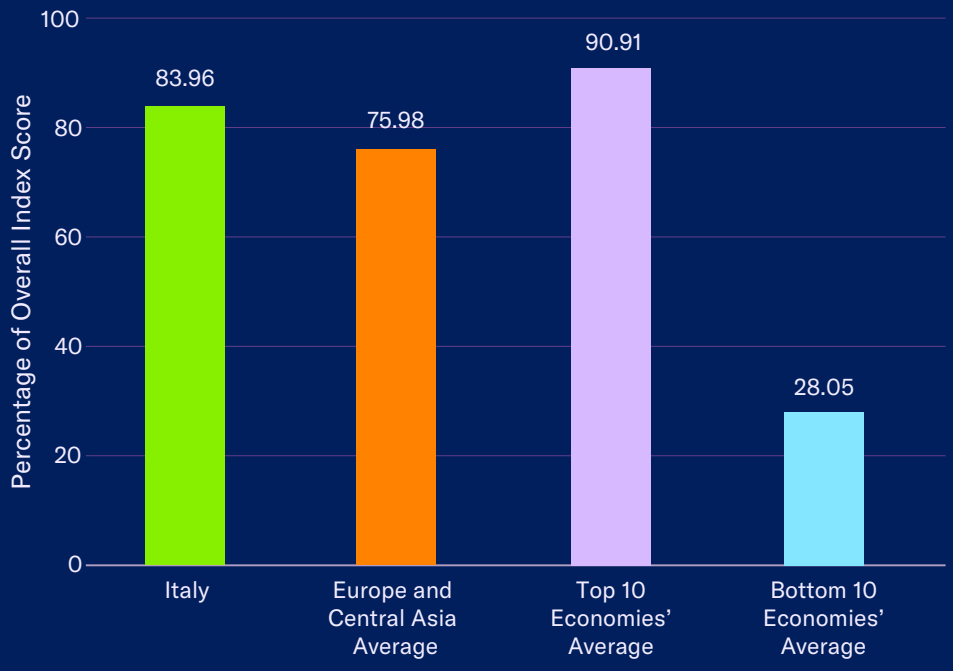
Italy

Rank
12/55

Category Scores



Overall Score in Comparison



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Key Areas of Strength

- Transposed EU Directive 2019/790 on Copyright and Related Rights CDSM Directive into law
- Generous R&D and IP specific tax incentives in place
- 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
- Major life sciences IP rights in place
- Administrative and judicial mechanisms for addressing online copyright infringement
- Public consultation during policy formation and efforts to raise awareness of IP importance present
- Fairly advanced national IP framework

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
- Licensing agreements include registration requirements
- Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals poses significant risk to Italy's and EU's research and IP based biopharma industry

Indicator	Score
Category 1: Patents Rights and Limitations	**8.00**
1. Term of protection	1.00
2. Patentability requirements	0.75
3. Patentability of CIIs	1.00
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.50
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent Opposition	1.00
Category 2: Copyrights and Limitations	**4.91**
10. Term of protection	0.66
11. Exclusive rights	0.50
12. Expeditious legal remedies disabling access to infringing content online	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.50
15. TPM and DRM	0.50
16. Government use of licensed software	0.75
Category 3: Trademarks Rights and Limitations	**3.00**
17. Term of protection	1.00
18. Protection of well-known marks	0.75
19. Exclusive rights, trademarks	0.75
20. Frameworks against online sale of counterfeit goods	0.50
Category 4: Design Rights and Limitations	**1.75**
21. Industrial Design Term of Protection	1.00
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.65**
23. Protection of trade secrets (Civil Remedies)	1.00
24. Protection of trade secrets (Criminal Sanctions)	0.75
25. Regulatory data protection term	0.90
Category 6: Commercialization of IP Assets	**5.00**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
28. Registration and disclosure requirements of licensing deals	0.50
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	**5.04**
32. Physical counterfeiting rates	0.72
33. Software piracy rates	0.57
34. Civil and procedural remedies	0.75
35. Pre-established damages	0.50
36. Criminal standards	0.50
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	0.75
43. IP-intensive industries, national economic impact analysis	1.00
Category 9: Cutting-Edge Innovation	**2.65**
44. IP incentives for orphan medicinal product development	1.00
45. IP incentives for orphan medicinal product development, term of protection	0.90
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	**6.75**
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	0.75
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: 44.50

Spotlight on the National IP Environment

Past Editions versus Current Score

Italy's overall score has decreased from 44.70 out of 53 indicators in the 13th edition to 44.50. This reflects a score decrease on indicators 25 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 put forward 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.

During the research, European institutions reached an agreement on a final package and finalized a legislative text, which was expected to take effect soon after the Index's 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 the testing and regulatory approval processes for their follow-on products without acquiring 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 purpose of these exclusivity exemptions is to prevent delays in the market availability of follow-on products after the reference product's exclusivity period ends; these exceptions are not designed to shorten or undermine the exclusivity periods that are legitimately granted to rights holders.

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. Fundamentally, the proposals are based on the idea that the COVID-19 pandemic showed the need for a clearer and more 'effective' pan-EU compulsory licensing mechanism. But as this Index and rights holders argued, if anything, the actual evidence and experience from the pandemic show the complete opposite. 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 is for an already existing, duly granted, valid, and in-force patent. Consequently, by the time an SPC application is lodged, there will have already been plenty of opportunities for related parties to administratively or judicially challenge the validity of the underlying patent either regionally through the EPO, nationally (in a manner defined in 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

11. Legal measures which provide necessary exclusive rights that prevent infringement of copyrights and related rights (including Web hosting, streaming, and linking); and
12. Expeditious injunctive-style relief and disabling of infringing content online:
In 2025, Italy expanded the use of its "Piracy Shield" program. The program seeks to disable access to copyright-infringing content within 30 minutes of a processed request. As noted in last year's Index, the Italian Communications Regulatory Authority (AGCOM) first launched the "Piracy Shield" program in 2024 in response to live sports piracy and copyright infringement via IPTV set-top boxes. That year, media reports suggested that access to several content delivery networks had been disabled. Subsequent public testimony by Giacomo Lasorella, head of AGCOM, explained that this occurred because both illicit and legal content were hosted through the same online access point.

As noted throughout the Index, Italy has historically been among the weakest EU Member States in terms of effective copyright enforcement. Estimates on copyright piracy have traditionally been high. An analysis from the mid-2010s by the Sturza Institute estimated that music piracy was around 50% and film piracy was just under 40%. In response, there has been a significant increase in enforcement activities in the past five years due to the introduction and active use of injunctive-style relief mechanisms. Legislative changes and a strong body of EU- and Italy-level case law now empower AGCOM to receive complaints from rights holders and to order the removal of copyright-infringing content. The agency's legal remit now includes the power to ask ISPs to implement notice and stay-down measures; the issuing of preliminary injunctions that disable access to infringing websites within three days upon receiving notification from the rights holder (including 'dynamic injunctions' that address alias sites); enforcement on social platforms and telephone or instant messaging platforms; and the issuing of administrative fines worth from EUR10,000 up to 2% of an accused entity's prior year turnover.

At the same time, rates of online piracy have also decreased. For example, in 2023 the EUIPO found in the study *Online copyright infringement in the European Union: films, music, publications, software and TV (2017-2022)* — which measured on a standardized basis the total number of pirated accesses per internet user for film, music and TV — online piracy had dropped in Italy from almost 10 accesses per Internet user in March 2017 to four accesses in late 2022. While this bounced back slightly to over five accesses at the end of 2022, it is still a substantial long-term reduction in overall piracy levels. Italy's overall score on this category of the Index has increased from 56.83% of the total available score in 2016 (the fourth edition of the Index) to 70.14% in this edition. That is a notable and significant achievement. The Index will continue to monitor these developments in 2026.

14. Scope of limitations and exceptions o copyrights and related rights:
As noted last year, the EU 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 levels of risk. In 2025, the European AI Office was established to coordinate and oversee the implementation and enforcement of copyright protections for the use and application of AI.

Furthermore, new guidance documents are being released by the European Commission, the AI Office, and the EUIPO. 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. Considering 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. This ensures that rights holders can effectively 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.

In a separate development, in early 2025, the Italian Senate approved Bill 1146/2024 "Provisions and Delegations to the Government Concerning Artificial Intelligence." While the bill reflects the principles of the EU AI Act, it also includes additional details and regulations for specific economic sectors. This includes health care, scientific research, professional services, law, and public administration, among others. With respect to copyright exceptions, a draft Article 70-septies (amending the Copyright Law) explicitly allows AI systems to utilize text and data mining exceptions transposed from the 2019 CDSM in relation to "reproductions and extractions from works or other materials contained on the Internet or in databases to which one has legitimate access." At the time of the research, it remained unclear whether the purpose of this draft legislation was to expand the existing text and data mining exceptions framework. The bill is currently being debated in the Italian Parliament's lower house, the Chamber of Deputies.

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 11 years 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.