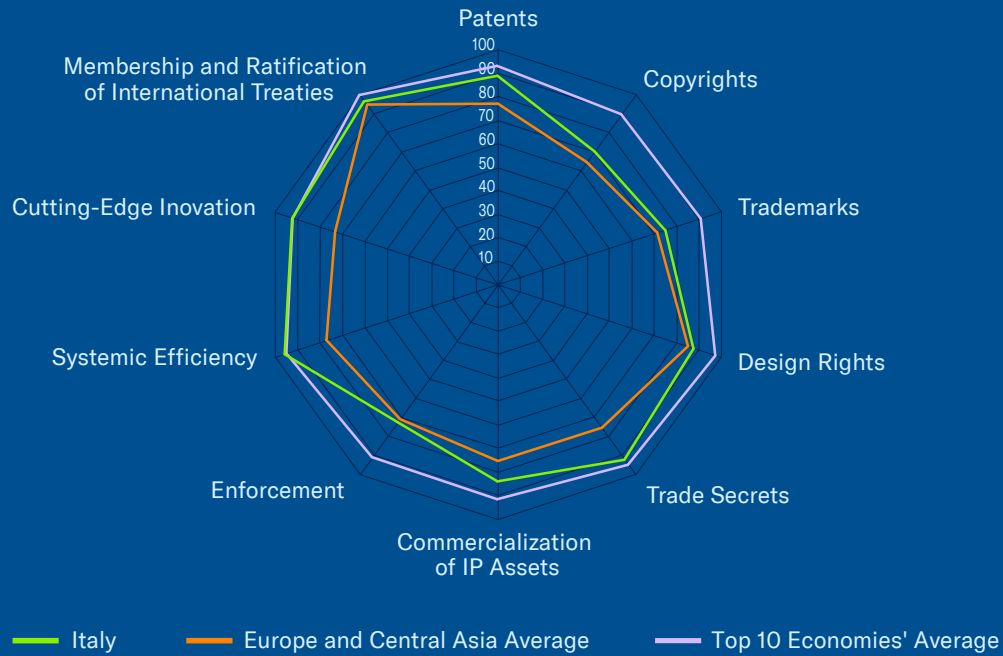




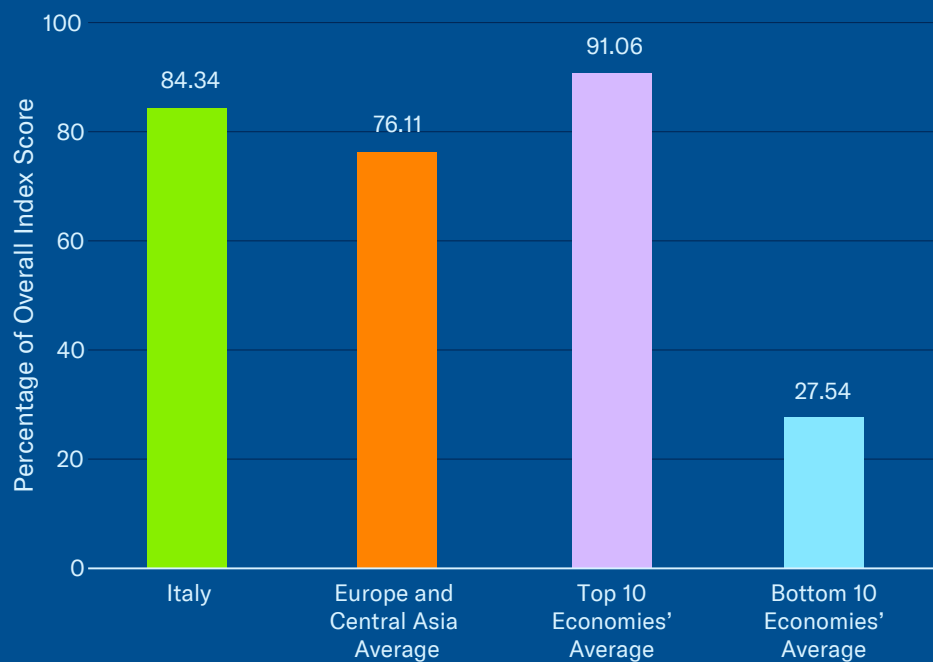
Italy

Rank
12/55

Category Scores



Overall Score in Comparison





Key Areas of Strength

- Since 2000, the orphan regulation has provided a world-leading 10-year term of orphan market exclusivity resulting in new biopharmaceutical R&D and the development of new treatments and medicines for rare diseases
- Transposed the EU Directive 2019/790 on Copyright and Related Rights CDSM Directive into law
- Generous R&D and IP-specific tax incentives are in place
- Fairly advanced national IP framework
- Major life sciences IP rights are in place
- Administrative and judicial mechanisms for addressing online copyright infringement
- Public consultation during policy formation and efforts to raise awareness of IP importance are present

Key Areas of Weakness

- The EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- The new EU-wide compulsory licensing regime would undermine patent rights in Europe
- The new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- Registration requirements for licensing agreements
- Regulation 2019/933 and the existing SPC exemption for exports of biopharmaceuticals pose significant risk to Italy's and the EU's research and IP-based biopharma industry

Indicator	Score	Indicator	Score
Category 1: Patents Rights and Limitations		Category 7: Enforcement	
1. Term of protection	1.00	29. Direct government intervention in setting licensing terms	1.00
2. Patentability requirements	0.75	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 8: Systemic Efficiency	
5. Pharmaceutical-related enforcement	0.50	32. Physical counterfeiting rates	0.72
6. Legislative criteria and use of compulsory licensing	1.00	33. Software piracy rates	0.57
7. Pharmaceutical patent term restoration	0.75	34. Civil and precedural remedies	0.75
8. Membership of a Patent Prosecution Highway	1.00	35. Pre-established damages	0.50
9. Patent opposition	1.00	36. Criminal standards	0.50
Category 2: Copyrights and Limitations		37. Effective border measures	1.00
10. Term of protection	0.66	38. Transparency and public reporting by customs	1.00
11. Exclusive rights	0.50	Category 9: Cutting-Edge Innovation	
12. Expeditious legal remedies disabling access to infringing content online	1.00	39. Coordination of IP rights enforcement	1.00
13. Cooperative action against online piracy	1.00	40. Consultation with stakeholders during IP policy formation	1.00
14. Limitations and exceptions	0.50	41. Educational campaigns and awareness raising	1.00
15. TPM and DRM	0.50	42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
16. Government use of licensed software	0.75	43. IP-intensive industries, national economic impact analysis	1.00
Category 3: Trademarks Rights and Limitations		Category 10: Membership and Ratification of International Treaties	
17. Term of protection	1.00	44. IP incentives for orphan medicinal product development	1.00
18. Protection of well-known marks	0.75	45. IP incentives for orphan medicinal product development, term of protection	1.00
19. Exclusive rights, trademarks	0.75	46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.75
20. Frameworks against online sale of counterfeit goods	0.50	Category 5: Trade Secrets and the Protection of Confidential Information	
Category 4: Design Rights and Limitations		23. Protection of trade secrets (civil remedies)	1.00
21. Industrial design term of protection	1.00	24. Protection of trade secrets (criminal sanctions)	0.75
22. Exclusive rights, industrial design rights	0.75	25. Regulatory data protection term	1.00
Category 6: Commercialization of IP Assets		Category 10: Membership and Ratification of International Treaties	
26. Barriers to market access	1.00	47. WIPO Internet Treaties	1.00
27. Barriers to technology transfer	0.75	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	0.50	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

Percentage of Overall Score: 84.34%

Total Score: 44.70

Spotlight on the National IP Environment

Past Editions versus Current Score

Italy's overall Index score has increased from 41.95 out of 50 indicators in the twelfth edition to 44.70 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

6. Legislative criteria and use of compulsory licensing of patented products and technologies:

As noted in last year's Index, over the past two years, the European Commission has issued proposals to create a new cross-European compulsory licensing regime. However, as the COVID-19 pandemic and other crises illustrated, compulsory licenses are not necessary. The data does not support the European Commission's proposal to expand involuntary mechanisms for sharing IP through a more "effective" compulsory licensing mechanism. The Commission's impact assessment notes the downside of a compulsory licensing proposal, stating that patent owners will face an incremental loss of control of their patent rights. This, in turn, undermines the ecosystem for biopharmaceutical innovation in the EU. As part of the EU legislative process, in early 2024, the European Parliament provided its position on the Commission's proposed regulation. Although some of these amendments may limit the wide scope of the Commission's original proposals, Parliament has not rejected the draft legislation or fundamentally challenged the flawed premise on which it is based. More worryingly, Parliament's position proposes to explicitly violate the WTO TRIPS Agreement by including trade secrets and know-how in scope. The position of EU Member States in the legislative process appears to be more reasonable.

After elections to a new European Parliament in the summer of 2024 and the election of a new European Commission, Trilogue negotiations are underway among the three EU institutions on a final legal text, which may be expected by the second half of 2025. It was unclear what would happen to the current proposals. The Index will continue to monitor these developments in 2025.

7. Patent term restoration for pharmaceutical products:

As noted over the course of the Index, 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 during the last six months of the validity of the SPC for the domestic market. Because of this action, the score for this indicator was reduced by 0.25 for 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 IP environment in the EU.

As part of the introduction of the Unitary Patent system and Patent Court, in 2022, the European Commission outlined several options for reforming the SPC system, including the introduction of a new centralized system of SPC protection and application. 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 the Commission's proposal.

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 SPC opposition mechanism. 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 duly granted and in-force patent either regionally through the EPO or nationally in a manner defined in each Member State. As such, it seems unnecessary to add a novel layer of potential opposition. The most likely outcome of this is additional delays in the application process and additional costs imposed on applicants. At the time of research, the European Parliament had adopted its position, and the Council of the EU was debating the proposal. The Index will continue to monitor these developments in 2025.

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 legal remedies disabling access to infringing content online:

As noted over the course of the Index, Italy has historically been one of the more challenging EU Member States for effective copyright enforcement. Estimates on copyright piracy have traditionally been high. An analysis from the mid-2010s by the Sturza Institute placed music piracy at around 50% and film piracy at just under 40%. Although rightsholders in Italy still face significant challenges, as noted in the Index, the past five years have seen a significant increase in enforcement activity through the introduction and active use of injunctive-style relief mechanisms. Through both legislative changes and a strong body of case law at the EU level and in Italy, the Italian Communications Regulatory Authority (AGCOM) is today empowered to receive complaints from rightsholders and to order ISPs to remove or prevent access to illegally published content. In fact, the agency's legal remit has been strengthened over the course of the Index and now includes the power to ask ISPs to implement notice-and-takedown measures, issuing of preliminary injunctions that disable access to infringing websites within three days upon receiving notification from the rightsholder (including dynamic injunctions that address alias sites), enforcement on social platforms and telephone or instant messaging platforms, and the issuing of administrative fines from EUR10,000 up to 2% of an accused entity's prior year turnover. Furthermore, in 2023, AGCOM's remit was further expanded with the enactment of a new anti-piracy law (Law 93/2023). The primary purpose of this new legislation was to enhance AGCOM's ability to fight online piracy of live broadcasts, including sporting events.

Overall, AGCOM's and Italy's antipiracy efforts have proven to be highly effective. Italy's overall score in 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.

At the same time, rates of online piracy have also decreased. For example, in 2023, EUIPO found in the study *Online Copyright Infringement in the European Union: Films, Music, Publications, Software and TV (2017–2022)* that 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. Although this bounced back slightly to over five accesses at the end of 2022, this is still a substantive long-term reduction in overall piracy levels.

In 2024, AGCOM launched a new antipiracy tool, the "Piracy Shield," specifically targeting IPTV content. Figures from AGCOM suggest that thousands of online access points had successfully been disabled. However, reports also suggest that access had been disabled to several content delivery networks. Subsequent public testimony by the head of AGCOM, Giacomo Lasorella, explained that this had occurred because both illicit and legal content was hosted through the same online access point. The Index will continue to monitor these developments in 2025.

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

As noted in the Index, the European Commission and Parliament have for the past several years been working on an "Artificial Intelligence Act." In late 2023, the European Council and Parliament announced a provisional agreement, with the finalized version of the legislation made public in early 2024. The publication of the new law marks a turning point in the regulation of AI-based technologies in the EU and internationally.

The Act defines different levels of AI deployment with some activities prohibited and other forms of deployment and systems categorized according to the perceived level of risk. As such, the development, application and usage of AI-based technologies and systems will all have varying levels of legal and compliance requirements. Different parts of the legislation will come into force at varying points in time over the next two years depending on the AI in question, type of deployment, and usage.

With respect to the interaction between copyright protection and the use and application of AI, the Act imposes several specific obligations. First, the Act restates the requirements under Directive 2019/790 on Copyright and Related Rights in the Digital Single Market (CDSM Directive). The Act also reiterates the existing EU framework for text and data mining, stating that the act of copying or communicating for computational analysis can only be carried out on works that have been lawfully obtained or accessed. Furthermore, new and specific transparency requirements are in place. For example, general purpose AI models that use vast quantities of information for training purposes—such as those that can generate new content—are required to (1) make public summaries of the main sources used for such educational purposes and (2) ensure they comply with existing copyright law. Some positive features of the Act include its enforcement provisions. For example, Chapter XII and Article 99 provide for the possibility of administrative fines and sanctions upon noncompliance with the Act.

AI and machine learning are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific advances and innovation to take place through the analysis of large volumes of data and information.

However, 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 enforce their rights, both in the EU and around the world. It remains to be seen whether the AI Act and its subsequent implementation will provide rightsholders with such a practical recourse mechanism. The Index will continue to monitor these developments in 2025.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term:

RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). Before 2004, the EU’s RDP regime was not harmonized among EU members, and the term of protection varied from 6 to 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula, new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic and follow-on applicants are allowed to apply for marketing authorization), and potentially an additional year of protection for approval of a significant new indication of an existing product. This period of protection applies to chemical entities and biologics. On this basis, until now, all EU Member States have achieved the maximum available score of 1 for this indicator.

In 2023, the European Commission published a package of proposed legislative changes to the RDP regime and many facets of the biopharmaceutical market authorization process and related incentives, including for orphan and pediatric drugs, detailed under Category 9.

Although the proposed reforms are intended to create a 21st-century life sciences landscape in Europe that fosters innovation, enhances access to innovative therapies for patients, and elevates Europe’s competitiveness, the proposed legislative changes will likely do the opposite. The Commission’s proposal would replace the current RDP regime and 8+2+1 formula with a baseline formula of 6+2 with a defined data exclusivity term of protection of six years and a two-year market exclusivity window. Although Article 81(2) of the Commission’s draft directive includes the possibility of extending this exclusivity to the existing 10-year period (or even, under unique circumstances, 12 years), the conditions that must be fulfilled to gain these additional periods of exclusivity are so complex that it is unlikely that many research entities will be able to access them in practice. The draft directive also conditions the extension of the term of exclusivity on external factors, such as market access. For example, under Article 82, the possibility of a 24-month extension of the term of data exclusivity is contingent on the relevant product being “continuously supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorization is valid.”

Each Member State, through its broader health and biopharmaceutical policies, decides on biopharmaceutical market access policies and how to control the cost of medicines. Some EU Member States and health systems seek to eliminate barriers to patient access and the introduction and use of new products and technologies. Others focus solely on expenditure and cost containment and do not prioritize patient access to new products and innovation. Consequently, substantial differences exist among Member States with respect to both the number of products publicly reimbursed and the average time it takes for patients to gain effective access to them within a health system. Within this context, IP rights play no part.

Yet the European Commission's proposal will end up further damaging the research-based biopharmaceutical industry in Europe and beyond. The EU's share of global biopharmaceutical R&D, clinical research, and new medicines developed will continue to shrink. As less R&D is conducted in the EU, high-paying R&D and manufacturing jobs will be lost, and a long-standing global competitive advantage built on over a century of scientific excellence and tradition will cease to exist.

In important respects, this trend can already be seen today. For example, the 2024 report *The Future of European Competitiveness*—authored by former European Central Bank President and Prime Minister of Italy Mario Draghi—identified a growing “competitiveness gap” for the EU in the life sciences. Specifically, the report found that the EU was falling behind in the development and commercialization of cutting-edge medicines, including biologics, orphan drugs, and advanced therapy medicinal products. At the time of research, the European Parliament had proposed a modified version of the pharmaceutical package, including with respect to both the term of RDP offered and the conditioning of extensions to this term of protection on levels of market access. For example, under Parliament's proposals, the baseline term of RDP would be lowered but only by six months. Similarly, there would be no conditioning of exclusivity on levels of market access. Although constituting an improvement over the Commission's proposed baseline terms, Parliament's draft nevertheless results in a weakening of RDP standards compared to the current term of protection. The Council of the EU is currently considering a draft proposal before Trilogue negotiations begin among the three EU institutions. From the Index's perspective, moving forward with the draft changes to the EU's RDP regime would result in all EU Member States seeing a score reduction for this indicator. The Index will continue to monitor these developments in 2025.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer; and 29. Direct government intervention in setting licensing terms: Over the past two years, the European Commission has proposed wide-ranging reforms to the SEP negotiation process in the EU, including draft legislation that would significantly change current practices related to SEPs and licensing negotiations. These proposals would lead to a centralization of the licensing process in the EU and would introduce the potential for direct government intervention and management of the SEP negotiating process. Under the proposal, EUIPO would become an SEP “competence center” tasked with not only overseeing and maintaining a register of SEPs but also functioning as an arbiter and evaluator of essentiality and various forms of “royalty determination.” The Commission's proposals would also require SEP holders to register their essential patents with EUIPO. A failure to do so may jeopardize an SEP holder's ability to collect royalties and/or claim damages during the period of nonregistration.

In early 2024, the European Parliament responded to the Commission's ideas with a set of proposed amendments. SEP-based technologies are central to future innovation and economic growth; many of the cutting-edge industries loosely labeled as making up the “Fourth Industrial Revolution”—the Internet of Things, AI, robotics, and 3-D printing—will rely on SEPs to function. However, disputes between licensors and licensees on what constitutes fair, reasonable, and nondiscriminatory licensing terms are not new or unique to the EU. This is an evolving field of IP policy and jurisprudence for a subject matter that is deeply complex. Each licensing negotiation is unique and should not be subject to prescriptive government action or intervention, whether through direct or indirect pressure.

As such, it is critical that EU policymakers tread carefully and refrain from being overly prescriptive or restrictive through the creation of a new centralized SEP licensing authority. At the time of research, reports suggest that the European Commission had withdrawn its proposal. 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. In 1999, the EU introduced Regulation (EC) No. 141/2000 (the “EU Orphan Regulation”), which entered into force in January 2000. The purpose of the EU Orphan Regulation was to “lay down a Community procedure for the designation of medicinal products as orphan medicinal products and to provide incentives for the research, development and placing on the market of designated orphan medicinal products.” The incentives offered under the orphan regulation aim to mitigate the challenges across all phases of orphan medicine development, from defraying some of the costs and regulatory fees to providing market exclusivity that ensures that orphan medicinal products’ developers will have a sufficient time frame for recouping the high costs of development. Of the incentives offered in the EU, market exclusivity for orphan medicines is usually regarded as having been the most consequential.

Article 8 defines the nature of this exclusivity, which consists of a baseline 10-year term of marketing exclusivity, which can potentially be expanded by two years upon completion of additional pediatric studies. However, this baseline 10-year term of exclusivity can also be reduced by four years under specific circumstances. Article 8(2) states, “This period may however be reduced to six years if, at the end of the fifth year, it is established, in respect of the medicinal product concerned, that the criteria laid down in Article 3 are no longer met, *inter alia*, where it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. To that end, a Member State shall inform the Agency that the criterion on the basis of which market exclusivity was granted may not be met and the Agency shall then initiate the procedure laid down in Article 5.” Subsequent guidelines on the meaning of this subclause were published in 2008.

Academic research published in the past few years suggests that only a small number of products have had their orphan designation removed since the regulation was introduced. Notably, the orphan regulation has been under review for an extended period as part of a larger initiative to reform the EU’s pharmaceutical legal framework described under indicator 25. At the time of research, no new regulation had been passed into law. Worryingly, under all published proposals, including the European Parliament’s response to the Commission’s proposals in early 2024, the current term and scope of protection for orphan products would be restricted or reduced. Moving forward with such changes to the EU’s orphan drug regime would result in all EU member states included in the Index seeing a score reduction for indicators 45 and 46.