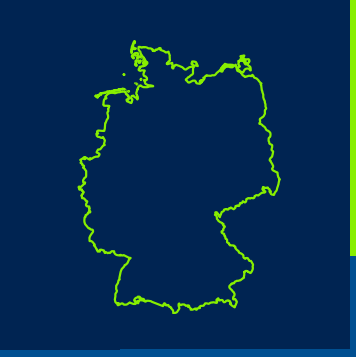
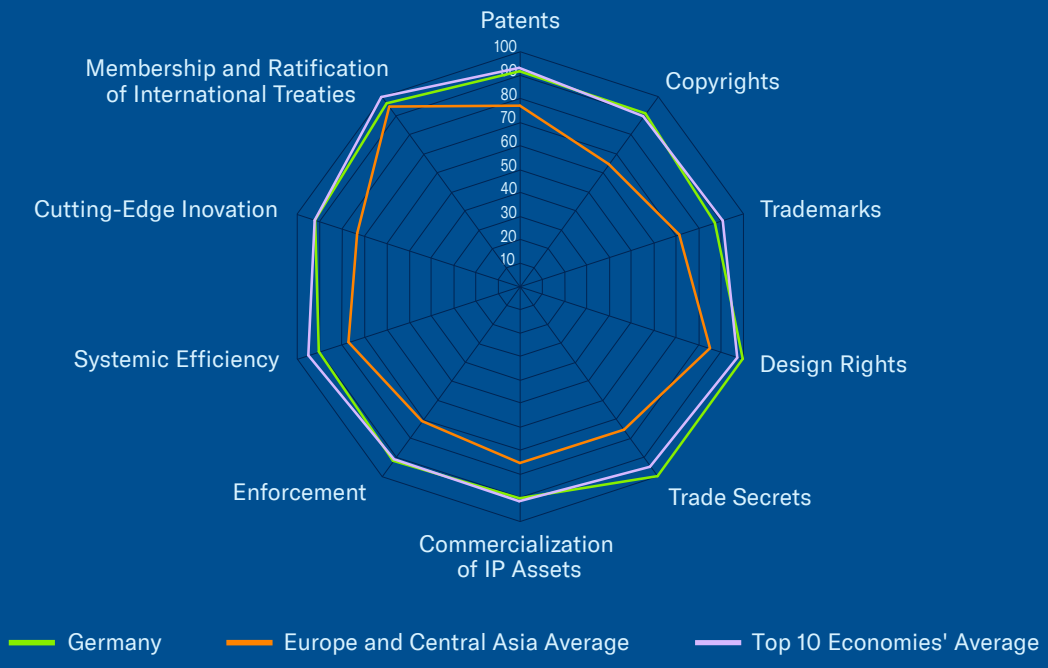


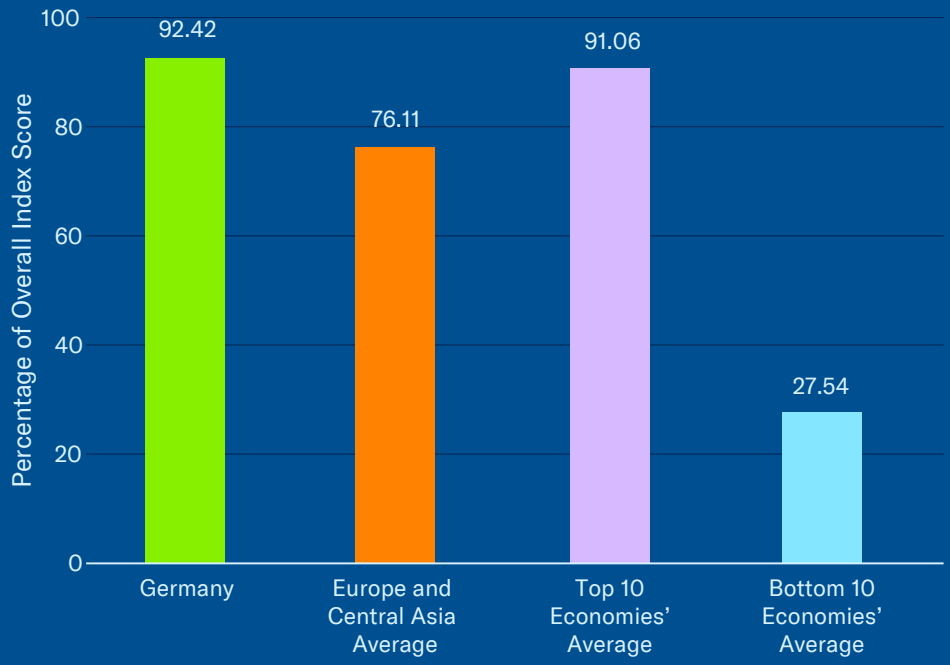
Germany

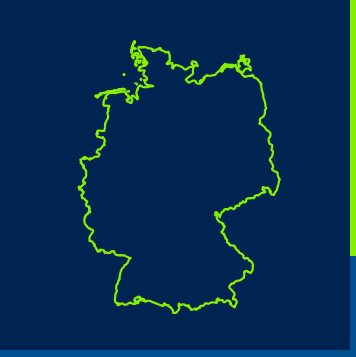
Rank
4/55

Category Scores



Overall Score in Comparison





Germany

Rank
4/55

Key Areas of Strength

- 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
- Additional R&D tax credits were introduced in 2020
- Advanced and sophisticated national IP environment
- Sector-specific IP rights are in place
- Member of all major international PPH tracks through the national patent office and EPO

Key Areas of Weakness

- EU package of new pharmaceutical laws fundamentally weakens biopharmaceutical IP rights, including RDP and orphan incentives
- A new EU-wide compulsory licensing regime would undermine patent rights in Europe
- A new EU-wide centralized SEP licensing authority would change practice related to licensing negotiations
- Regulation 2019/933 and existing SPC exemption for exports of biopharmaceuticals pose significant risk to France's and the EU's research and IP-based biopharma industry
- The Patent Law Treaty was signed but not ratified

Indicator	Score
Category 1: Patents Rights and Limitations	**8.25**
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	0.75
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	1.00
Category 2: Copyrights and Limitations	**6.38**
10. Term of protection	0.63
11. Exclusive rights	1.00
12. Expeditious legal remedies disabling access to infringing content online	1.00
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	0.75
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	**3.00**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	1.00
25. Regulatory data protection term	1.00
Category 6: Commercialization of IP Assets	**5.42**
26. Barriers to market access	1.00
27. Barriers to technology transfer	1.00
28. Registration and disclosure requirements of licensing deals	1.00
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	**6.43**
32. Physical counterfeiting rates	0.88
33. Software piracy rates	0.80
34. Civil and precedural remedies	1.00
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	**4.50**
39. Coordination of IP rights enforcement	0.75
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	**2.75**
44. IP incentives for orphan medicinal product development	1.00
45. IP incentives for orphan medicinal product development, term of protection	1.00
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

Percentage of Overall Score: 92.42% • Total Score: 48.98

Spotlight on the National IP Environment

Past Editions versus Current Score

Germany's overall Index score has increased from 46.23 out of 50 indicators in the twelfth edition to 48.98 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, the 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 Regulation2019/933 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

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 (1) required to 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.

In a separate development, 2024 saw the first instance judgment in the case *Kneschke v. LAION*, a legal dispute concerning the extent to which AI training models can use copyrighted content for training purposes. To this the effect, the Hamburg Regional Court found that the use by LAION—a nonprofit research entity—of images that it had accessed on the internet, without the explicit permission or consent from the author, fell under existing text and data mining exceptions for scientific research. The judgment argued that given how LAION did not have a direct commercial interest in the research—the relevant datasets were published and distributed free of charge—the research, per definition, qualified as scientific and noncommercial. Yet, as the judgment itself concedes, it is not at all clear that the end research product distributed by LAION would not be used by commercial entities. Somewhat confusingly, the judgment acknowledges both this reality and the potential illegality of such use but claims it is not pertinent to this dispute: "Whether the data set—as the plaintiff claims with regard to the services… is also used by commercial companies to train or further develop their AI systems is irrelevant because research by commercial companies is still research—even if not privileged as such under Sections 60c et seq. of the Copyright Act."

This is an important judgment because it constitutes one of the first European court cases on the interaction between copyright protection and the use and application of AI. It remains to be seen whether its interpretation of the relevant statute will be upheld in any future appeals procedure or shared by other European courts. 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.