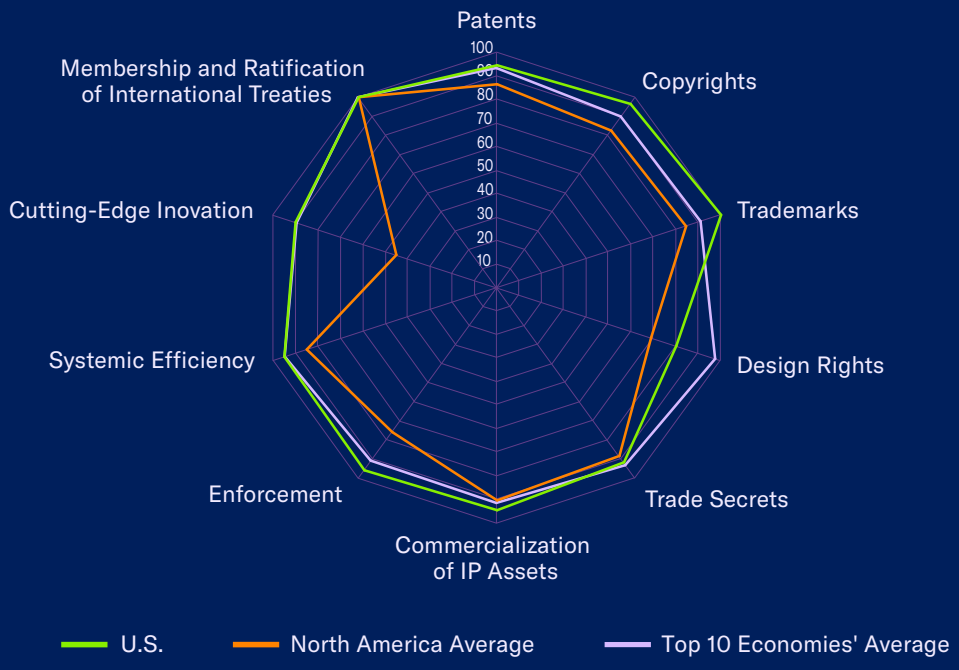
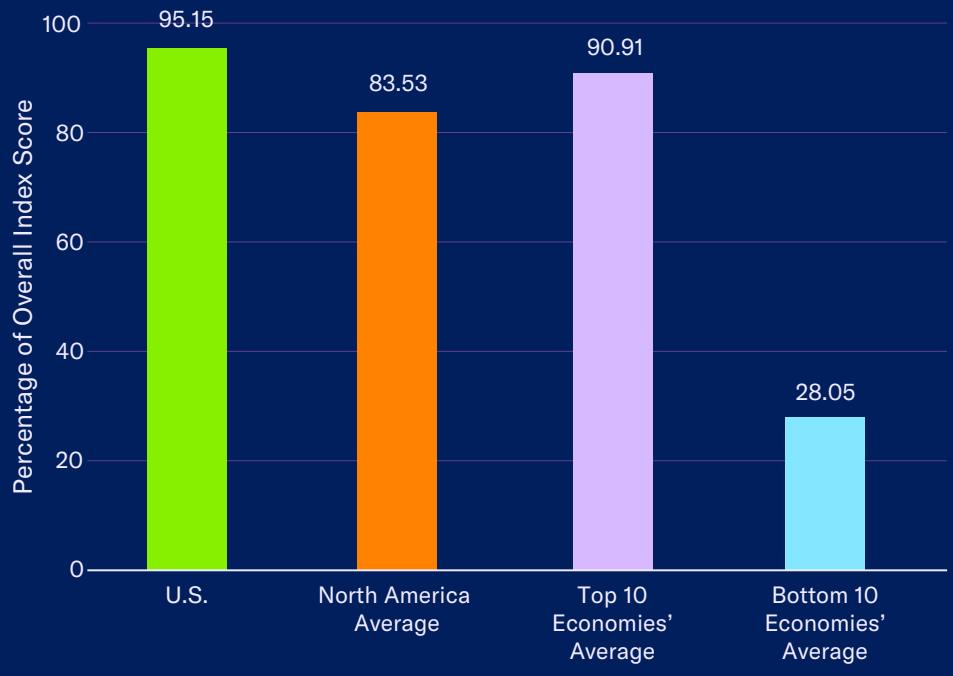
United States

Rank
1/55

Category Scores



Overall Score in Comparison



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Key Areas of Strength

- U.S. national IP system continues to provide international leadership
- Sector specific rights and protections in place across all categories of the Index
- Since mid-1980s, Orphan Drugs Act has provided a world leading seven-year term of orphan market exclusivity, resulting in new biopharmaceutical R&D and development of new treatments and medicines for rare diseases

Key Areas of Weakness

- Congressional bills seek to limit the number of patents a rights holder may assert in an infringement action; specifically targets biopharmaceuticals
- 2025 NIH changes to Intramural Research Program puts U.S. innovation and economic growth at risk
- 2023 NIST proposals for exerting “march-in rights” fundamentally undermines patent rights
- Long-standing uncertainty over patentability standards for high-tech sectors
- Long-standing uncertainty over PTAB proceedings
- No targeted legal basis for addressing online piracy along the lines of other global leaders

Indicator	Score
Category 1: Patents Rights and Limitations	**8.50**
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	1.00
6. Legislative criteria and active use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	1.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent Opposition	0.75
Category 2: Copyrights and Limitations	**6.75**
10. Term of protection	1.00
11. Exclusive rights	1.00
12. Expeditious legal remedies disabling access to infringing content online	0.75
13. Cooperative action against online piracy	1.00
14. Limitations and exceptions	1.00
15. TPM and DRM	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks Rights and Limitations	**4.00**
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	1.00
Category 4: Design Rights and Limitations	**1.60**
21. Industrial Design Term of Protection	0.60
22. Exclusive rights, industrial design rights	1.00
Category 5: Trade Secrets and the Protection of Confidential Information	**2.75**
23. Protection of trade secrets (Civil Remedies)	1.00
24. Protection of trade secrets (Criminal Sanctions)	1.00
25. Regulatory data protection term	0.75
Category 6: Commercialization of IP Assets	**5.67**
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	1.00
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**6.71**
32. Physical counterfeiting rates	0.86
33. Software piracy rates	0.85
34. Civil and procedural remedies	1.00
35. Pre-established damages	1.00
36. Criminal standards	1.00
37. Effective border measures	1.00
38. Transparency and public reporting by Customs	1.00
Category 8: Systemic Efficiency	**4.75**
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	**2.70**
44. IP incentives for orphan medicinal product development	1.00
45. IP incentives for orphan medicinal product development, term of protection	0.70
46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	1.00
Category 10: Membership and Ratification of International Treaties	**7.00**
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	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: 50.43

Spotlight on the National IP Environment

Past Editions versus Current Score

The United States' overall score has decreased from 50.44 out of 53 indicators in the 13th edition to 50.43. This reflects a score decrease on indicator 32.

Area of Note

Unlike many other high-income OECD economies, the U.S. federal government has not historically imposed national price controls or other restrictions or market-access barriers on health technologies, including life sciences and medical devices. This changed with the passage of the 2022 Inflation Reduction Act (IRA), which marks a sharp departure in U.S. health and life sciences policy. The law includes a series of fundamental changes to the pricing framework for medicines covered under Medicare Part B and Part D.

The law was presented as a way to grant the Department of Health and Human Services (HHS) and the Centers for Medicare and Medicaid Services (CMS) greater authority to negotiate the prices of a specific number of medicines covered under Medicare that do not have generic or biosimilar competition. However, it granted such sweeping powers to the Secretary of Health and Human Services and imposes such punitive damages on manufacturers that fail to agree or abide by the price setting mechanism, that it is a *de facto* expenditure and price control.

Efforts to introduce national price controls preceded the IRA. In 2025, the Trump administration announced the Executive Order "Delivering Most-Favored-Nation (MFN) Prescription Drug Pricing to American Patients." Under this Order, the President authorized the CMS to impose most-favored-nation pricing through a "rule-making plan to impose most-favored-nation pricing." At the time of the research, CMS announced a new national drug-pricing model for Medicaid called the GENEROUS (GENErating cost Reductions fOr U.S. Medicaid) Model.

These initiatives build on policy proposals from the first Trump administration. In late 2018, the administration announced plans to build an International Pricing Index and develop an MFN model for use by Medicare Part B. This plan was formalized in late 2020 by HHS and CMS. The MFN model would benchmark the price of a basket of 50 biopharmaceutical products against the prices of the same products in a sample of OECD economies. The comparator economies were chosen based on OECD membership and per capita gross domestic product (GDP) at purchasing power parity (PPP) of 60% or more than that of the United States. After several court rulings in late 2021, the CMS formally rescinded the proposed MFN model.

The imposition of national price controls and life sciences expenditure controls is not cost-free. Price controls and life sciences cost-containment policies directly affect the availability of new, innovative medicines and medical technologies for patients and consumers in the affected market. Economies that impose price controls and life sciences cost-containment policies tend to see fewer medicines introduced to the market, and patients generally must wait longer to access new, innovative medicines and medical technologies. But beyond access to new medicines and life sciences technologies, such policies also directly undermine future R&D investment and the development of new medicines.

With fewer resources, it stands to reason that life sciences manufacturers will invest less in R&D and be less likely to develop new life sciences products and services at the same rate as in the past. This logic holds true whether a new medicine was developed by a public or private research entity.

The U.S. has historically been the global leader in all types of clinical research, with particular strengths in cutting-edge, higher-risk early-phase trials and research on cancer, Alzheimer's Disease, diabetes, obesity, cardiovascular diseases, and biologics. While this leadership in life sciences innovation is a result of many different enabling factors — including scientific capacity, R&D infrastructure, human capital, strong IP protection, and a sophisticated technology transfer framework — one of the strongest drivers of life sciences innovation has been the existence of a relatively free market in the pricing of life sciences. The imposition of biopharmaceutical price controls through the IRA and MFN jeopardizes much of this research leadership and the future innovation that comes with it.

Patent Rights and Limitations

Press reports in 2025 suggest that the Commerce Department has been investigating the feasibility of introducing a new fee structure on the commercial value of granted U.S. patents, ranging from 1-5%. It is unclear how such a proposal would continue to stimulate R&D and innovation in the United States. The most likely outcome of introducing such a policy is a steep contraction in patenting activity (through a drop in both new applications and maintenance of granted patents), in domestic U.S. inventive activity, and in the wholesale offshoring of R&D investment across most major patent arts and technologies. At a Congressional hearing in February, Commerce Secretary Howard Lutnick stated that the Department does not plan to move forward with a valuation fee or tax on patents. At the time of research, no formal proposal had been published by the administration or presented to the public. The Index will continue to monitor these developments in 2026.

2. Patentability requirements; and
9. Patent opposition:
As noted in previous editions, there remains uncertainty about the patenting environment in the United States. Since the Supreme Court decisions in the *Bilski, Myriad, Mayo*, and *Alice* cases, there has been uncertainty about which inventions are patent-eligible in the United States. In 2025, efforts to address this continued in both Congress and at the USPTO. Similarly, discussions continued in both the executive and legislative branches about how to reform post-grant opposition and patent nullity proceedings, which were originally introduced under the 2011 America Invents Act (AIA).

In Congress, several bills were also under consideration to limit the number of patents a rights holder may assert in an infringement action. Not only do these bills discriminate and selectively target the life sciences sector with these restrictions, but they also embrace a fundamentally anti-IP and anti-innovation logic whereby the restriction of IP rights will lead to lower prices and greater access to a given product, in this case, biopharmaceutical treatments. At the time of research, the proposed laws had not been passed by Congress or signed into law. The Index will continue to monitor these developments in 2026.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:
Like many other advanced economies, the United States recognizes the importance of artificial intelligence (AI) and machine learning as key areas for technological development and future economic growth. Both the Federal Government and Congress are actively working on policy reforms related to these technologies.

In early 2025, President Trump signed Executive Order 14179, "Removing Barriers to American Leadership in Artificial Intelligence." This was followed up in July with the presentation of "Winning the AI Race: America's AI Action Plan."

Together, these initiatives aim to increase AI innovation, domestic AI-supporting infrastructure, and the production, commercialization, and export of American-made AI-based and derived products.

Separately, the Copyright Office issued two new reports examining copyright within the context of the development and application of AI and machine learning tools. The third report, Copyright and Artificial Intelligence Part 3: Generative AI Training, addresses IP rights within the context of AI development and language training models. The Copyright Office released this report with a disclaimer that reads, "The Office is releasing this pre-publication version of Part 3 in response to congressional inquiries and expressions of interest from stakeholders. A final version will be published in the near future, without any substantive changes expected in the analysis or conclusions." As of publication, no further editions of this report have been issued. 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.

Throughout 2025, Congress continued to examine several bills relating to AI and copyright, some of which would seek to strengthen existing legal protections. At the time of research, no new legislation had been voted on or signed into law by the President. There were also significant judicial developments in 2025. While the jurisprudence is still evolving, with only a handful of verdicts handed down, the USD 1.5 billion settlement in Bartz v. Anthropic is likely to set an important precedent for this type of dispute going forward. Under the terms of the settlement, Anthropic will, according to the suing rights holders, pay "the largest publicly reported copyright recovery in history, larger than any other copyright class action settlement or any individual copyright case litigated to final judgment." The Index will continue to monitor these developments in 2026.

Commercialization of IP Assets and Market Access

27. Barriers to technology transfer:
In 2025, several potentially negative developments affected the U.S. technology transfer environment. To begin with, the NIH's proposed new policy on patent licensing — the Intramural Research Program (IRP) Access Planning Policy — came into effect. As discussed in the Index when this was first proposed, the NIH would require licensees to submit plans for how successfully developed and commercialized medicinal products would be accessed by patients.

While the final policy applies only to NIH-owned inventions and research conducted at NIH, the NIH seems to have fundamentally misunderstood its own role and that of the private sector in the technology transfer process. The overwhelming majority of publicly funded research — whether through the NIH, academic institutions, or other parts of the federal government — does not produce, or even aim to produce, a finalized, commercially available product. The translation of basic research into new products, services, and technologies is achieved through partnerships with the private sector, which invests resources and bears all accompanying financial risk of the commercialization process.

In this respect, while critical, basic research — no matter how pathbreaking — is almost never in itself enough to lead to a final product or service. And while the commercialization process for each licensed technology and invention is itself unique — and the exact amount of expenditure and commercialization spending ratio between licensee and licensor varies from technology to technology and transaction to transaction — practical experience and research suggest that the overwhelming majority of investment needed in the development and bringing to market of a commercial product is done by the private sector entity to which the invention has been licensed.

For example, the Congressional Research Service, in a 2012 study, stated that: “Although research is often important to innovation, it appears that, on average, it constitutes approximately 25% of the cost of commercializing a new technology or technique, thus requiring the expenditure of a substantial amount of additional resources to bring most products or processes to the marketplace [emphasis added].”

Separately, the Commerce Department declared it was investigating Harvard University’s compliance under the Bayh-Dole Act, with the possibility of initiating the Federal Government’s right to exercise march-in rights. As the Index has noted in the past, when the Federal Government has announced plans to adopt a more expansionist view of march-in rights — most notably in 2023 and the National Institute of Standards and Technology’s proposal — adopting such an interventionist mindset on march-in rights and the public-private licensing process would stand in marked contrast to the intended goals of the Bayh-Dole Act.

Bayh-Dole has, over the last 40 years, provided federal laboratories, small businesses, universities, and other entities that use federal funds with the incentives needed to work with the private sector to translate early-stage research into usable products in the marketplace for the benefit of the wider public. The importance of the Bayh-Dole framework to U.S. innovation cannot be overstated. In 2002, the Economist magazine called the law the “most inspired piece of legislation to be enacted in America in the last half-century.”

Indeed, if such a flawed misinterpretation of Bayh-Dole and the Federal Government’s role in the licensing process were adopted, it would likely lead to a significant contraction of the current U.S. R&D ecosystem, putting tens of thousands of future patents and accompanying innovation and economic growth at risk. That is not a risk worth taking.