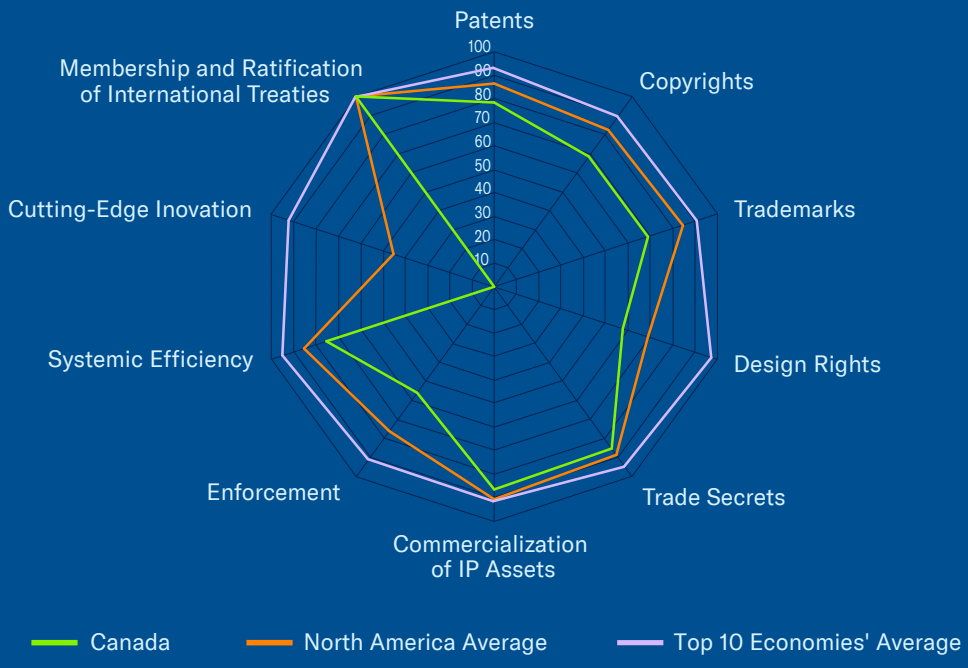
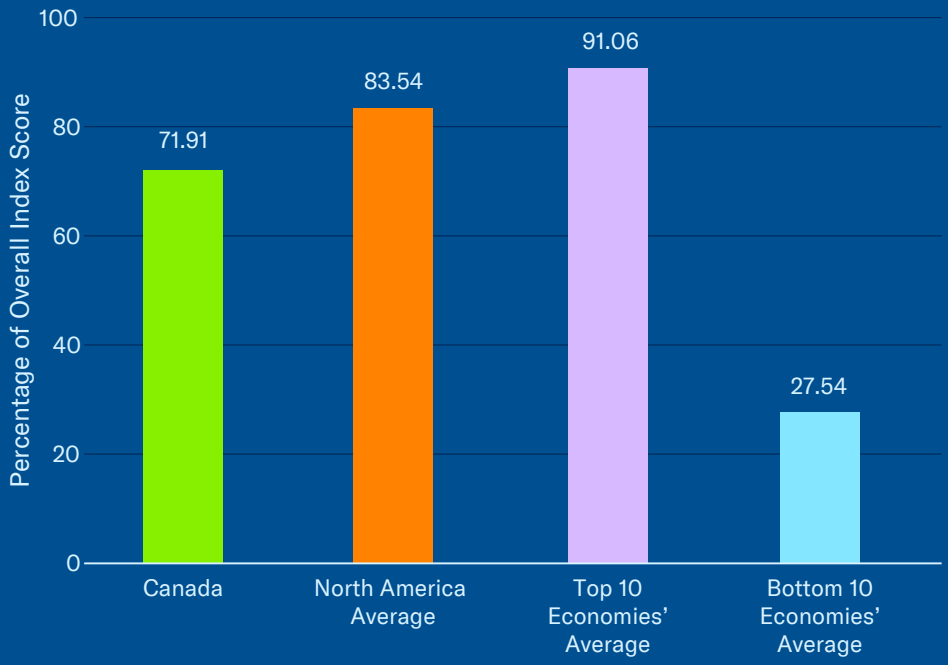
Canada

Rank
17/55

Category Scores



Overall Score in Comparison



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Key Areas of Strength

- Continued issuing of dynamic injunction orders in 2023 further strengthened copyright enforcement in Canada
- USMCA took effect in 2020, resulting in longer copyright terms, new criminal sanctions for theft and misappropriation of trade secrets, and *ex officio* authority for border action against in-transit goods
- The 2017 Supreme Court judgment on utility doctrine aligns Canada's patentability environment with international standards
- CETA-implementing legislation is in place, which strengthened some rights
- Significant damages were awarded in precedent-setting 2017 federal court case with regard to Canada's DRM provisions

Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Continued uncertainty over existing interpretation of educational exceptions to copyright; 2021 Supreme Court decision in Access Copyright case added more layers of uncertainty and legal complexity
- CETA amendments to Patent Act introducing patent term restoration includes restrictive eligibility requirements and an export claw-out, which effectively undermines biopharmaceutical exclusivity
- Deficiencies exist with respect to pharmaceutical patent enforcement and remain unaddressed in PMNOC regulations

Indicator	Score
Category 1: Patents Rights and Limitations	**7.05**
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	0.25
6. Legislative criteria and use of compulsory licensing	1.00
7. Pharmaceutical patent term restoration	0.30
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.75
Category 2: Copyrights and Limitations	**4.79**
10. Term of protection	0.79
11. Exclusive rights	0.50
12. Expeditious legal remedies disabling access to infringing content online	1.00
13. Cooperative action against online piracy	0.25
14. Limitations and exceptions	0.25
15. TPM and DRM	1.00
16. Government use of licensed software	1.00
Category 3: Trademarks Rights and Limitations	**2.75**
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	0.25
Category 4: Design Rights and Limitations	**1.15**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.75
Category 5: Trade Secrets and the Protection of Confidential Information	**2.55**
23. Protection of trade secrets (civil remedies)	1.00
24. Protection of trade secrets (criminal sanctions)	0.75
25. Regulatory data protection term	0.80
Category 6: Commercialization of IP Assets	**5.17**
26. Barriers to market access	1.00
27. Barriers to technology transfer	0.75
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	**3.90**
32. Physical counterfeiting rates	0.62
33. Software piracy rates	0.78
34. Civil and precedural remedies	0.50
35. Pre-established damages	0.50
36. Criminal standards	0.50
37. Effective border measures	0.75
38. Transparency and public reporting by customs	0.25
Category 8: Systemic Efficiency	**3.75**
39. Coordination of IP rights enforcement	0.50
40. Consultation with stakeholders during IP policy formation	1.00
41. Educational campaigns and awareness raising	0.75
42. Targeted incentives for the creation and use of IP assets for SMEs	0.75
43. IP-intensive industries, national economic impact analysis	0.75
Category 9: Cutting-Edge Innovation	**0.00**
44. IP incentives for orphan medicinal product development	0.00
45. IP incentives for orphan medicinal product development, term of protection	0.00
46. Restrictions on the effective use of existing IP incentives for orphan medicinal product development	0.00
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

Percentage of Overall Score: 71.91% • Total Score: 38.11

Spotlight on the National IP Environment

Past Editions versus Current Score

Canada's overall score remains unchanged at 38.11 out of 53 indicators.

Area of Note

Biopharmaceutical rightsholders continue to face challenges in exercising their IP rights and granted periods of exclusivity in Canada. A growing focus on rigid cost control and minimizing overall biopharmaceutical spending exists within the Canadian health system. Over the past several years, Canadian authorities have reformed how patented medicines are evaluated and priced through the Patented Medicine Prices Review Board's (PMPRB) evaluation methodology. These reform efforts have focused almost exclusively on cost and expenditure reduction. Although successful legal challenges have limited the scope of some of these proposals, the changes to the basket of economies the PMPRB uses for international price comparisons have been retained and are now in effect. Specifically, the reforms have expanded the size of the basket and have removed the United States and Switzerland as comparator economies. New economies added include Australia, Belgium, Japan, the Netherlands, Norway, and Spain. Given the strict price controls in place in many of these new economies and the removal of the United States and Switzerland as comparator economies, these changes will substantially lower the overall price comparisons and thus the overall biopharmaceutical price level in Canada while adding layers of complexity to the pricing and reimbursement process. These changes came into force on July 1, 2022.

At the time of research, the PMPRB was still in the process of updating and finalizing a new "Guidance" document with a new "Discussion Guide," and a series of consultations were held in 2024. Although both the guide and consultations touched on a range of important regulatory issues, a pivotal issue to rightsholders remains the way price comparisons are made and what is judged as "excessive." The PMPRB has developed options ranging from a "median international price" assessment to a "highest international price" assessment. Given that the in-force changes to the basket of economies used for international price comparisons has been changed to reduce average price comparisons, it would be illogical to apply the median international price rather than the highest international price to judge whether a given price in Canada was excessive. At the time of research, no final regulations had been published, and the "Interim Guidance" remains in effect.

The direct impact of the Canadian health system's strong focus on cost control has historically been a time lag in new products on the market and patient access. Data shows that, on average, it takes 52 months from global launch of a product to reimbursement listing in Canada. Almost two-thirds of this time (34 months) is spent in review after a product has been launched locally. Compared with other OECD peers, many innovative products are not launched or listed in Canada. For example, evidence collected by IQVIA on the availability of new medicines launched in the 10-year period between 2012 and 2021 and published by PhRMA shows that of the 460 new medicines launched between 2012 and 2021, Canadian patients had access to only 207, or 45%. This compares to 391 of the 460 products available in the United States (85%).

The changes introduced by the PMPRB's package of regulatory reforms are likely to exacerbate this, the result being Canadian patients waiting even longer for access to new and innovative treatments.

In response to the COVID-19 pandemic, Canadian policymakers at all levels of government have rightly recognized the strategic nature of the research-based biopharmaceutical industry and the socioeconomic value it brings to Canada. At the federal level, the government in 2021 launched the *Biomanufacturing and Life Sciences Strategy*. Significantly, the strategy seeks explicitly to make Canada a more "attractive destination for leading life sciences firms to establish and grow." Similarly, in 2022, Canada's largest provinces—Ontario and Quebec—released new life sciences strategy documents and plans to encourage local biopharmaceutical R&D and innovation. But developing new medicines is a long-term, high-risk, resource-intensive process. Many drugs and therapies may not have been discovered without the legal rights provided to innovators through IP laws. As the Index has detailed over the past decade, the biopharmaceutical IP environment in Canada could be strengthened and aligned with best practices in the United States, the EU, and leading Asian economies in many respects. Similarly, recognizing innovation in the Canadian health system through adequate pricing and reimbursement policies for biopharmaceuticals would also improve the competitiveness of the Canadian environment and allow innovators—domestic and international—to gain a fair reward for their innovation and creativity. The Index will continue to monitor these developments in 2025.

Patent Rights and Limitations

7. Patent term restoration for pharmaceutical products:
As part of commitments made under the Canada-United States-Mexico Agreement (CUSMA), Canada agreed to introduce a patent term adjustment (PTA) mechanism. The purpose of this mechanism is to compensate patent applicants for any undue delay in prosecuting the patent application. In May 2024, the Canadian Intellectual Property Office (CIPO) published draft changes to existing patent regulations introducing this new PTA. Unfortunately, under the office's proposed system, PTA will be difficult, if not impossible, to obtain for most applicants. More broadly, any PTA granted is set to run concurrently with a separate and distinct form of term restoration, namely, supplementary protection for biopharmaceutical patents. Yet these are two completely different types of patent term restoration seeking to compensate rightsholders for different forms of regulatory delay. PTA is due to what is under the CUSMA termed "unreasonable" delays in patent prosecution. Certificates of supplementary protection (CSP) for biopharmaceutical patents are meant to restore time lost during sanitary registration and the marketing authorization process for new medicines and biopharmaceutical technologies. As such, one form of restoration has nothing to do with the other.

The Canadian government's interpretation and implementation of its commitments under the CUSMA is reminiscent of how the government chose to handle the introduction of the CSP mechanism under the Comprehensive Economic and Trade Agreement (CETA) with the EU. The relevant amendments made to the Patent Act (Sections 106–134) and implementing regulations published in the *Canada Gazette* provide an—on paper—maximum restoration period of two years. However, the effective availability of this term of restoration was severely restricted through several technical carve-outs.

To begin with, under Section 116(4), the Canadian government retained the right to reduce the term of protection at its discretion. Second, the implementing regulations contained a "Timely Submission Requirement" that set a timeline for the submission of CSP applications based on the regulatory status of a product in a set of "prescribed economies." Thus, the availability of a CSP was made contingent on early market entry. Finally, the law also contained an export claw-out, with Section 115(2) effectively exempting the infringement of CSP protection if the activity is for the purpose of export. As noted at the time in the Index, these limitations and restrictions all but nullify the underlying rationale of the mechanism in the first place. And now the same is happening in the case of PTA. Instead of strengthening Canada's national IP environment and stimulating more R&D and related economic activity, such actions hollow out the national IP environment and incentives for future innovation. The Index will continue to monitor these developments in 2025.

Copyrights and Limitations

14. Scope of limitations and exceptions to copyrights and related rights:
In 2024, the Canadian legislature continued to examine Bill C-27 ("An Act to enact the Consumer Privacy Protection Act, the Personal Information and Data Protection Tribunal Act and the Artificial Intelligence and Data Act and to make consequential and related amendments to other Acts"), with fresh proposed amendments published by the government late in 2023. This is the first legislative initiative in Canada that seeks to establish a framework for the national development and application of AI and machine learning technologies. These technologies are important areas of future economic activity as advances in computational power and new technological advancements allow for scientific breakthroughs and innovation to take place through the analysis of large volumes of data and information.

With respect to IP, neither the originally proposed draft Artificial Intelligence and Data Act nor the Ministry of Innovation, Science, and Industry's proposed amendments address copyright protections in the context of AI. 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 Canada and across the world. Additionally, the results of the government's public consultation "Copyright in the Age of Generative Artificial Intelligence" indicate many rightsholders view this as a critical area in need of reform.

Separately, there was no progress on the long-standing issue of educational exceptions in 2024. As has been noted repeatedly in the Index, the 2012 amendments to the Copyright Act considerably broadened Canada's framework for exceptions to copyright, including the expansion of education and personal use exceptions. Canadian Supreme Court decisions that same year also widened the scope of the judicial interpretation of existing exceptions to the extent that continued compatibility with the Berne three-step test was highly questionable. The past 12 years have seen several rounds of litigation culminating in a Supreme Court ruling in 2021, yet the issue remains unresolved. As the Index pointed out in 2012, at best, the changes to Canada's copyright regime would lead to a higher level of uncertainty for publishers and, at worst, a shrinking of their industry and business model. Today, it is clear that both have occurred. Industry figures suggest that the Canadian publishing industry has suffered greatly over the past decade with estimated uncompensated copying outside of fair dealing amounting for over CAD200 million.

The net effect of the reforms and 2012 Supreme Court rulings has been a contraction in the publishing sector, with the Canadian publishing industry and individual rightsholders reporting decreased publishing income. The bottom line is that after over a decade of litigation and uncertainty, Canadian rightsholders have failed to achieve effective redress for the clear violation of their copyright or to gain any further understanding of what constitutes fair dealing and what does not within the context of education. In 2022, the federal government appears to have finally recognized the dire impact of the 2012 amendments and subsequent Supreme Court rulings. In the 2022 budget, *A Plan to Grow Our Economy and Make Life More Affordable*, the government stated plainly that it would "work to ensure a sustainable educational publishing industry, including fair remuneration for creators and copyright holders, as well as a modern and innovative marketplace that can efficiently serve copyright users." Unfortunately, the past two years have seen no further action. 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:
In 2021, the Ministry of Health launched a *National Strategy for Drugs for Rare Diseases*. The strategy consists of four individual components, including the final one, "Investing in Innovation." However, the strategy does not include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.