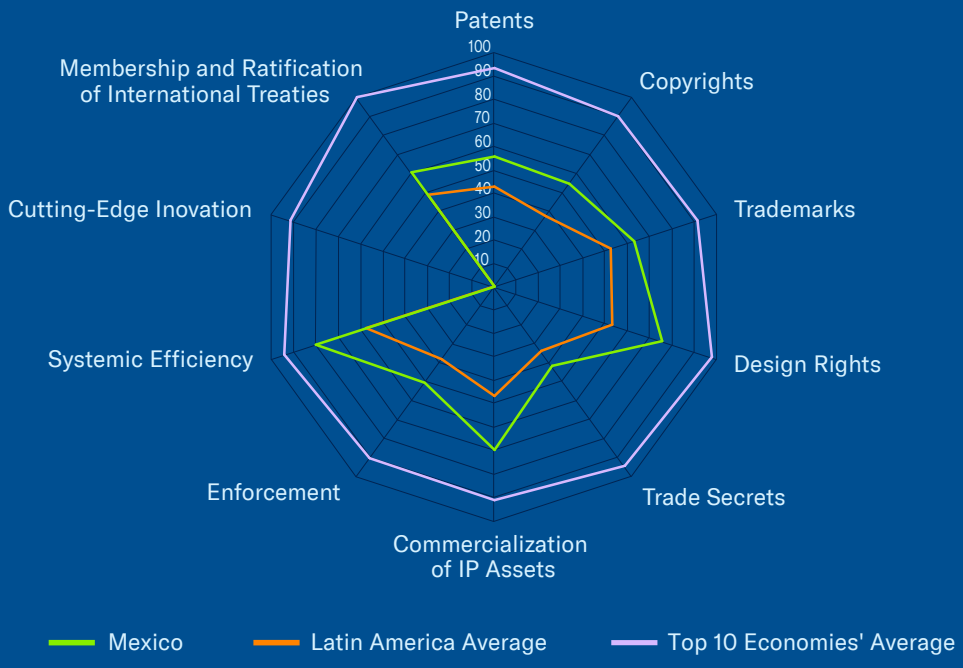
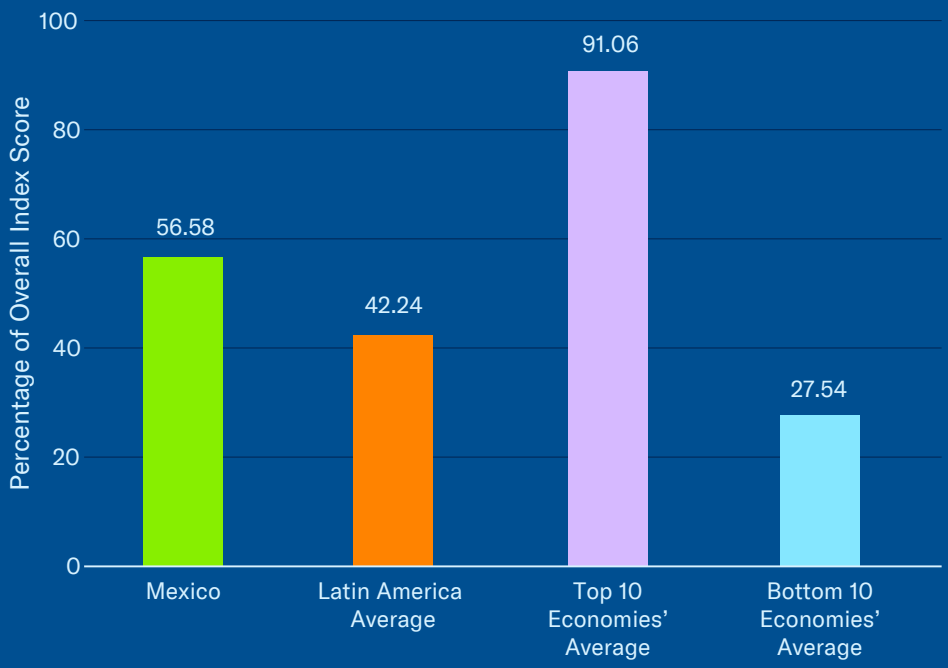
# Mexico

Rank
23/55

## Category Scores




## Overall Score in Comparison



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## Key Areas of Strength

- 2021 publication of IMPI study on economic impact of IP-intensive industries in Mexico: analysis carried out with EUIPO and modeled on EPO and USPTO studies
- 2020 amendments to Industrial Property Law implements some provisions of USMCA
- 2020 amendments to the Federal Law on Copyright implements many provisions of USMCA
- Term of protection for industrial design rights extended to 25 years
- Efforts to ease ability to commercialize IP assets and develop public-private partnerships, particularly for public research organizations and universities
- Dedicated endeavor to streamline IP review process and criminal justice system and to harmonize to international standards
- Efforts to increase awareness of importance of IP rights

## Key Areas of Weakness

- No special IP incentives for orphan medicinal product development
- Partial and ambiguous protection for life sciences IP
- Gaps exist in enforcement against online piracy
- Significant gaps exist in application of remedies, such as severe delays and difficulty securing adequate damages
- Inadequate border measures for trade-related infringement of IP rights
- USMCA patent obligations are not fully met, most notably requirements for an effective pharmaceutical-related patent enforcement and resolution mechanism

| Indicator | Score |
|---|---|
| **Category 1: Patents Rights and Limitations** | **4.99** |
| 1. Term of protection | 1.00 |
| 2. Patentability requirements | 0.50 |
| 3. Patentability of CIIs | 0.00 |
| 4. Plant variety protection | 0.74 |
| 5. Pharmaceutical-related enforcement | 0.25 |
| 6. Legislative criteria and use of compulsory licensing | 1.00 |
| 7. Pharmaceutical patent term restoration | 0.00 |
| 8. Membership of a Patent Prosecution Highway | 1.00 |
| 9. Patent opposition | 0.50 |
| **Category 2: Copyrights and Limitations** | **3.79** |
| 10. Term of protection | 0.79 |
| 11. Exclusive rights | 0.50 |
| 12. Expeditious legal remedies disabling access to infringing content online | 0.25 |
| 13. Cooperative action against online piracy | 0.50 |
| 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** | **2.50** |
| 17. Term of protection | 1.00 |
| 18. Protection of well-known marks | 0.50 |
| 19. Exclusive rights, trademarks | 0.50 |
| 20. Frameworks against online sale of counterfeit goods | 0.50 |
| **Category 4: Design Rights and Limitations** | **1.50** |
| 21. Industrial design term of protection | 1.00 |
| 22. Exclusive rights, industrial design rights | 0.50 |
| **Category 5: Trade Secrets and the Protection of Confidential Information** | **1.25** |
| 23. Protection of trade secrets (civil remedies) | 0.50 |
| 24. Protection of trade secrets (criminal sanctions) | 0.50 |
| 25. Regulatory data protection term | 0.25 |
| **Category 6: Commercialization of IP Assets** | **4.17** |
| 26. Barriers to market access | 0.50 |
| 27. Barriers to technology transfer | 0.50 |
| 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 | 0.50 |
| 31. Tax incentives for the creation of IP assets | 0.67 |
| **Category 7: Enforcement** | **3.54** |
| 32. Physical counterfeiting rates | 0.53 |
| 33. Software piracy rates | 0.51 |
| 34. Civil and precedural remedies | 0.50 |
| 35. Pre-established damages | 1.00 |
| 36. Criminal standards | 0.75 |
| 37. Effective border measures | 0.00 |
| 38. Transparency and public reporting by customs | 0.25 |
| **Category 8: Systemic Efficiency** | **4.00** |
| 39. Coordination of IP rights enforcement | 0.50 |
| 40. Consultation with stakeholders during IP policy formation | 0.75 |
| 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** | **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** | **4.25** |
| 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 | 0.75 |
| 49. Patent Law Treaty and Patent Cooperation Treaty | 0.50 |
| 50. Membership of the International Convention for the Protection of New Varieties of Plants, act of 1991 | 0.00 |
| 51. Membership of the Convention on Cybercrime, 2001 | 0.00 |
| 52. The Hague Agreement Concerning the International Registration of Industrial Designs | 1.00 |
| 53. Post-TRIPS FTA | 1.00 |

**Percentage of Overall Score: 56.58% • Total Score: 29.99**

# Spotlight on the National IP Environment

## Past Editions versus Current Score

Mexico's overall score remains unchanged at 29.99 out of 53 indicators.

## Patent Rights, Related Rights, and Limitations

*5. Pharmaceutical-related patent enforcement and resolution mechanism:*
Although a 2003 Presidential Decree introduced a basic system for early adjudication of disputes related to biopharmaceutical patent infringement and the marketing of a follow-on product, as noted over the course of the past 10 editions of the Index, this has never represented an effective or transparent pathway because the patent holder receives no notification of potential infringement and is not formally involved in the adjudication process. Furthermore, the regulatory enforcement pathway has been limited to substance and formulation patents only; use patents have not been included. In practice, resolution of patent disputes is delayed and often ineffective, whether through administrative or judicial routes. Some reform proposals have been introduced over the course of the Index, but they have failed to sufficiently address the shortcomings of the existing system with some instead compounding the existing deficiencies.

In 2019, the Mexican Senate proposed modifications to the Health Law. Under the proposed system, only one patent could be listed per each new chemical entity, and patents for biologics would not be considered. If adopted, this reform would be a highly negative move by the Mexican authorities that would further devalue the existing linkage regime and rightsholders' ability to enforce their patents. Mexico, through the USMCA, is bound to introduce a more comprehensive and practical system of biopharmaceutical patent enforcement.

Article 20.50 of the USMCA provides a clear requirement that the contracting parties provide "a system to provide notice to a patent holder or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use…[and] adequate time and sufficient opportunity for such a patent holder to seek, prior to the marketing of an allegedly infringing product, available remedies."

As noted in previous editions of the Index, Mexico's revised Industrial Property Law (which implements the USMCA) does not contain any legal provisions related to the existing linkage regime. Transitional paragraph (5) of the law states that the IMPI shall "participate" with the Mexican Federal Commission for the Protection against Sanitary Risk (COFEPRIS) "in the establishment of the corresponding technical collaboration mechanism for inventions in the field of allopathic drugs." At the time of research, no new implementing regulations had been issued by either agency.

In 2023, IMPI began publishing a dedicated list of patents related to biopharmaceutical inventions. In this document, the agency stated that the publication of this list fulfills its legal requirements under the Industrial Property Law, established case law, and the requirements set out in the Health Regulations. This list is to be updated and republished every six months. In a separate development, COFEPRIS began publishing lists of follow-on applications allowing relevant patent holders the opportunity to oppose any applications. As mentioned last year, although these are positive developments, this does not constitute a "linkage mechanism" whereby a drug regulatory authority conditions the approval of a follow-on biopharmaceutical product on there being no relevant period of market exclusivity in place for the underlying reference product.

The linking of the approval of follow-on biopharmaceutical products to the exclusivity status of a reference product is an effective way of achieving a balance between the protection of pharmaceutical exclusivity (usually but not always through patent protection) and stimulating early market entry of follow-on generic products. Linkage ensures that any disputes are resolved before the marketing of a follow-on product. This grants innovators a fair opportunity to secure return on their long-term, high-risk R&D investment by ensuring they can effectively use their legally granted exclusivity. It also limits potential damages for generic manufacturers because no potentially infringing product is ever launched or approved for the market. Patients also benefit from the increased certainty, as they avoid the risk of having to change treatments depending on the outcome of a patent lawsuit. In summary, a well-balanced linkage system recognizes the crucial role of patent protection in promoting innovation and the role of generic entry in providing patients access to lower cost biopharmaceuticals. Having in place a functioning linkage regime that provides rightsholders with a meaningful and real ability to stop follow-on products from being launched when a granted term of exclusivity is in place would be a substantial improvement to the biopharmaceutical IP environment in Mexico. The USMCA's language on the requirements for an effective pharmaceutical-related patent enforcement and resolution mechanism is clear. Full implementation and application of these requirements in Mexican law and practice will result in a score increase for this indicator. 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); 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation:*
In 2024, a potentially impactful development occurred with respect to copyright enforcement in Mexico. In May, the Supreme Court upheld the validity of a series of critical amendments introducing a notice-and-takedown system in the 2020 amendments to the Federal Law on Copyright, part of Mexico's commitments under the USMCA. As has been noted over the course of the Index, Mexico has historically had one of the more challenging copyright environments in the OECD, lacking in both substantive IP rights and enforcement against online and hard goods piracy. The Federal Law on Copyright sets out standard exclusive rights of reproduction, public transmission, use, distribution, and sale but has not included provisions or mechanisms that are more specific to addressing internet or online infringement. Proposed copyright reforms have up until now not been successful. The USMCA contains several provisions that would strengthen standards of copyright protection in Mexico, including with regards to digital rights management and technological protection measures, cable and satellite piracy, and the introduction of a notice-and-takedown regime.

In 2020, amendments to the Federal Law on Copyright were published and incorporated many of the most important copyright provisions of the USMCA. Overall, the amendments strengthen the level of protection for copyrighted works in Mexico, extending this protection to the internet and the digital environment.

Specific changes include (1) a new notification system whereby ISPs are obliged to act expeditiously and remove suspected content upon receiving a notification (Articles 114 and 232); (2) robust DRM and TPM provisions outlawing the use, manufacture, sale, importation distribution, or otherwise offering to the public circumvention devices and technologies (Article 232); and (3) making illegal the use, manufacture, import, or other form of distribution of satellite signal decoders (Article 145). These are positive developments and resulted in score increases for indicators 11, 13, and 15 in the ninth edition of the Index.

However, as noted at the time, some parts of the amendments are unclear. For example, with respect to potential ISP liability for infringing content, Article 114(8) is clear that ISPs will not be responsible for any damage caused by potential copyright infringement as long as they act expeditiously and in good faith to remove infringing content and take measures to prevent the same infringing content from reappearing. However, in the same article, Subsection V, the law states that the "inability of an Internet Service Provider to meet the requirements set forth in this article by itself does not generate liability for damages for violations of copyright and related rights protected by this Law." For any notification system to be effective in addressing online infringement, it must be clear what the responsibilities and legal expectations are for each affected party. As has been noted in the Index, the Mexican authorities have not implemented regulations or further guidance. Given the positive 2024 ruling by the Mexican Supreme Court, this should now clear the way for any remaining regulatory processes to be executed and for the notice-and-takedown mechanism to finally become operational. It has now been over five years since the conclusion of the USMCA, and Mexico has still not put in place the relevant legal framework as agreed. 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:*

Interest in rare diseases has grown in Mexico in addressing rare diseases. In 2017, a federal commission was instituted to monitor and analyze rare diseases in Mexico. In 2023, the National Health Council announced that it was formally recognizing the World Health Organization's classification of rare diseases, some 5,500 conditions. The Council further instructed all relevant federal and local agencies to prioritize the diagnosis and access to care for patients with rare diseases, including the listing and availability of orphan drugs. With respect to incentives for R&D and the development of new treatments and technologies, Mexico does not currently have in place any special IP-based market exclusivity incentives for orphan medicinal product development.