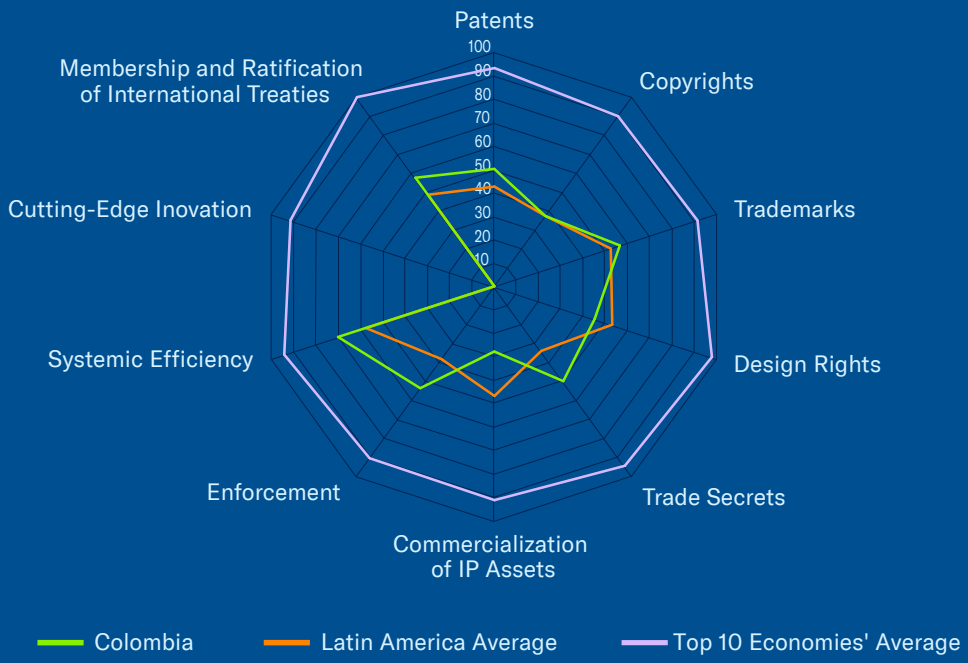
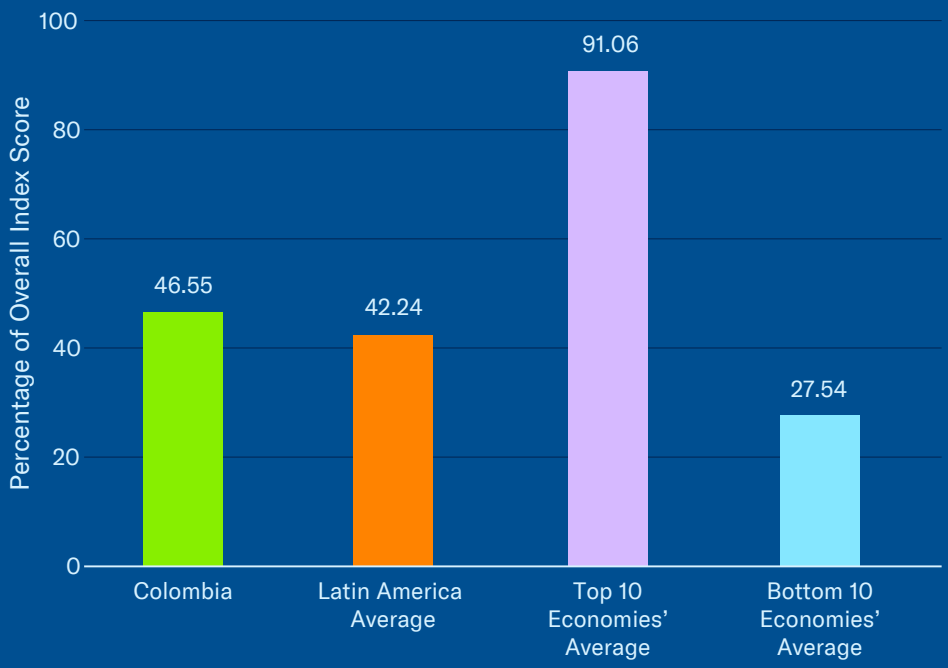
Colombia

Rank
33/55

Category Scores



Overall Score in Comparison



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Key Areas of Strength

- 2024 judgment ordered the disabling of access to several copyright-infringing websites, including SkyLatinaTV, and included a dynamic element
- Stronger copyright enforcement efforts through DNDA injunctive-style relief action against online piracy
- Acceded to the Convention on Cybercrime in 2020
- Colombian Constitutional Court issued a ruling (Ruling C-345-19) that recognizes the constitutionality of statutory damages for copyright infringement, introduced by 2018 amendments to the Copyright Law
- Targeted incentives in place for the creation and use of IP assets for SMEs, including reduced filing fees and technical assistance
- Efforts to coordinate interagency IP enforcement and to raise public and stakeholder engagement in IP policymaking and education

Key Areas of Weakness

- 2024 compulsory license issued for the HIV/AIDS treatment dolutegravir
- No special IP incentives for orphan medicinal product development
- 2023 Ministry of Health Resolution 881 continues policy history of use of compulsory license and public interest declarations to leverage price reductions for biopharmaceuticals
- Substantial barriers are in place for licensing activities, including direct government intervention and review of technology transfer and licensing agreements
- Key life sciences IP rights are missing, including patent term restoration and mechanisms for early patent dispute resolution
- Uncertainty about the availability of RDP for biopharmaceuticals
- Inadequate and delayed prosecution of and penalties for IP infringement

Indicator	Score
Category 1: Patents Rights and Limitations	**4.50**
1. Term of protection	1.00
2. Patentability requirements	0.50
3. Patentability of CIIs	0.50
4. Plant variety protection	1.00
5. Pharmaceutical-related enforcement	0.25
6. Legislative criteria and use of compulsory licensing	0.00
7. Pharmaceutical patent term restoration	0.00
8. Membership of a Patent Prosecution Highway	1.00
9. Patent opposition	0.25
Category 2: Copyrights and Limitations	**2.59**
10. Term of protection	0.84
11. Exclusive rights	0.25
12. Expeditious legal remedies disabling access to infringing content online	0.50
13. Cooperative action against online piracy	0.00
14. Limitations and exceptions	0.25
15. TPM and DRM	0.25
16. Government use of licensed software	0.50
Category 3: Trademarks Rights and Limitations	**2.25**
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	0.25
Category 4: Design Rights and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights, industrial design rights	0.50
Category 5: Trade Secrets and the Protection of Confidential Information	**1.50**
23. Protection of trade secrets (civil remedies)	0.50
24. Protection of trade secrets (criminal sanctions)	0.50
25. Regulatory data protection term	0.50
Category 6: Commercialization of IP Assets	**1.67**
26. Barriers to market access	0.25
27. Barriers to technology transfer	0.25
28. Registration and disclosure requirements of licensing deals	0.00
29. Direct government intervention in setting licensing terms	0.00
30. IP as an economic asset	0.50
31. Tax incentives for the creation of IP assets	0.67
Category 7: Enforcement	**3.76**
32. Physical counterfeiting rates	0.49
33. Software piracy rates	0.52
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	0.50
Category 8: Systemic Efficiency	**3.50**
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	0.50
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	**4.00**
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	0.50
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	1.00
52. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
53. Post-TRIPS FTA	1.00

Percentage of Overall Score: 46.55% • Total Score: 24.67

Spotlight on the National IP Environment

Past Editions versus Current Score

Colombia's overall Index score has increased from 24.42 out of 50 indicators in the twelfth edition to 24.67 out of 53 indicators. This reflects a score increase for indicator 12.

Patent Rights and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: In April 2024, the Colombian Government through the Department of Industry and Commerce, SIC (*Superintendencia de Industria y Comercio*), granted to the Ministry of Health a compulsory license for the HIV/AIDS treatment dolutegravir. As noted last year, the issuing of the license is based on a Ministry of Health Resolution and public interest request from June 2023. As detailed over the course of the Index, Colombia has moved in a decidedly negative direction on the issue of compulsory licenses. Up until the mid-2010s, the imposition and discussion of compulsory licensing for biopharmaceuticals had not been a recurring issue in Colombia. But over the past 10 years, the government has used compulsory licenses as a health policy tool to contain pharmaceutical expenditure. To begin with, Article 70 of the 2014–2018 National Development Plan widened the basis for the issuing of compulsory licenses in a manner that goes beyond the TRIPS Agreement, Article 31, the 2001 Doha Ministerial Declaration, and the subsequent General Council decision concerning Paragraph 6. The provision allows Colombian authorities to define public health emergencies broadly and to actively seek compulsory licenses, allowing for grounds outside extreme circumstances, including industrial or commercial objectives, to play a role in the issuing of compulsory licenses.

In 2016, the Ministry of Health and the Colombian government actively considered issuing a compulsory license for the oncology drug Glivec on the grounds of high prices. Subsequently, the Government issued a "Declaration of Public Interest" via Resolution 2475 and committed to unilaterally reducing the price of Glivec by about 45%. The National Commission of Prices of Medicines and Medical Devices issued Circular No. 3 of 2016, which defines the general pricing methodology applicable to all drugs under a public interest declaration. In contrast to the then existing price-setting methodology—whereby the average price was calculated from a group of 17 economies—public interest medicines were to be subject to the lowest price available, including prices of follow-on products. As detailed in the Index at the time, this practice all but nullified any existing IP protection and was highly questionable in light of Colombia's obligations under TRIPS and the U.S.-Colombia Trade Promotion Agreement.

Shortly after the issuance of Circular No. 3, the National Pricing Commission issued Circular No. 4, which set the price of Glivec at about 44% of its former price. Subsequently, in 2017, the government issued Decree No. 670, which regulates the use of the public interest measure. The decree requires that any public interest declaration be issued by an interinstitutional technical committee composed of representatives from the Ministry of Commerce, Industry, and Tourism; the National Planning Department; and the Ministry of Health. After these developments, a new application for a public interest declaration was made and accepted for review for medicines related to the treatment of hepatitis C by the Ministry of Health in late 2017 through Resolution 5246. Unlike previous applications, this application did not identify a specific patent or set of patents to which the declaration should pertain, instead simply identifying the whole class of products.

In 2020, the government issued Decree 476 in response to the COVID-19 pandemic. Although the decree did not explicitly amend existing legislation related to compulsory licensing, Article 1, Subsection 1.7 of the decree granted the Minister of Health broad and full authority to make a Declaration of Public Interest related to any and all "medicines, medical devices, vaccines and other health technologies that are used for the diagnosis, prevention and treatment of COVID19." Although not legally a compulsory license, the decree had the same practical impact of eliminating rightsholders' ability to freely use a granted exclusivity right.

The same logic is present in a legislative proposal introduced in the Colombian Senate, Bill 372 on Pharmaceutical Safety. The proposed legislation seeks to address the manifold biopharmaceutical challenges posed by the COVID-19 pandemic. Although the draft bill intended to address the complex issue of securing biopharmaceuticals and medical supplies during an international health emergency, it also included an exceptionally broad basis for the overriding of IP rights through both automatic compulsory licenses for health technology goods deemed "essential" and the suspension of any and all IP rights through executive fiat. These negative developments were followed by the issuing of the compulsory license for the HIV/AIDS treatment dolutegravir in 2024. Much of the logic in the SIC's resolution and the underlying request from the Ministry of Health is based on the perceived high cost of dolutegravir. But as stated repeatedly in the Index, compulsory licensing and the overriding of property rights are not a cost containment tool; cost is not a relevant justification or basis for compulsory licensing or equivalent declarations under the TRIPS agreement. TRIPS Article 31, the amendments introduced in the 2001 Doha Ministerial Declaration, and the subsequent General Council decision allowing the export of medicines produced under a compulsory license (outlined in Paragraph 6) form the legal grounds for compulsory licensing for medicines.

The chairman's statement accompanying the General Council decision (concerning Paragraph 6 of the Doha Declaration) underscores that these provisions are not in any way intended for industrial or commercial objectives, and, if used, it is expected that they would be aimed solely at protecting public health. In addition, Article 31 and the Doha Declaration suggest that compulsory licensing represents a "measure of last resort" to be used only after all other options for negotiating pricing and supply have been exhausted.

Colombia is not a least developed country (as defined by the UN) or a low-income economy as defined by the World Bank's lending categories. In fact, the World Bank classifies Colombia as an upper-middle-income economy. The latest available figures on national output from the World Bank show that Colombia had a GDP per capita at purchasing power parity of $21,548 in 2023. This was higher than that of Brazil ($20,584) and just under the average for the region ($21,823) and other upper-middle-income economies ($23,158). In contrast, least developed countries had an average per capita GDP of $4,215, and low-income economies had an even lower average of $2,398.

Developing new medicines is a long-term, high-risk, resource-intensive process. The fixed costs in terms of laboratory, research facilities, and researchers are high. Tufts University research from 2016 suggests that it costs $2.6 billion, on average, to develop a new drug. International experience and the basic economics of the biopharmaceutical industry show how critical IP rights are to incentivize and support this R&D of new medical technologies and products. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. IP rights provide a limited-term market exclusivity that gives firms sufficient time to recoup R&D investments made ahead of competition from additional market entrants who bore none of the costs of early-stage investment, R&D, and product commercialization.

Many drugs and therapies, including for HIV/AIDS, may not have been discovered without the legal rights provided to innovators through IP laws. Undermining these incentives through compulsory licensing as a cost containment tool hollows out Colombia's national IP environment and any incentives for future biopharmaceutical innovation. More broadly, the overriding of biopharmaceutical IP rights based on cost and price negotiations sets a wholly negative precedent that may be applied to other industries and sectors.

Copyrights and Limitations

12. Expeditious legal remedies disabling access to infringing content online:
In 2024, potential breakthrough developments occurred in Colombia with respect to the enforcement of copyright. In May 2024, a precedent-setting judgment ordered the disabling of access to several copyright infringing websites—including SkyLatinaTV—and included a dynamic element. The granting of this order is potentially of real significance in Colombia because the judgment not only affirmed the right to injunctive relief online but also included the dynamic element and ability to quickly update the order without having to restart legal proceedings. This judgment was followed up by a September 2024 order disabling access to the IPTV websites Latinos IPTV and Redcol IPTV. These 2024 orders come on the heels of a 2021 case whereby the National Directorate of Copyright (DNDA) ordered the disabling of online access to copyright-infringing material in two separate cases: the first case concerned the unauthorized publication of a scientific journal article, and the second case concerned the unauthorized broadcasting and dissemination of copyrighted audiovisual content through a local company IPTV Colombia Premium. Despite these positive developments, as has been detailed in past editions of the Index, overall, the copyright framework in Colombia remains rudimentary.

Colombian copyright law has historically not included reference to or recognized the unique challenges that digital and online piracy pose. The U.S.-Colombia FTA provides for a notice-and-takedown regime similar to the framework under the U.S. Digital Millennium Copyright Act. Despite this long-standing treaty obligation, no law introducing such a framework has to date been passed. As a result, the piracy of audiovisual content represents a major challenge to rightsholders in Colombia. The Latin American industry association ALIANZA (AlianzaContra la Piratería de Televisión Paga en América Latina) released the findings from a study of estimated rates of signal piracy and theft in Latin America in 2019. The study found that the total pirated or unreported market in Colombia was between 26% and 45% of the total number of potential end users. It is hoped that injunctive-style relief and the disabling of access to websites offering access to copyright-infringing material, in particular the dynamic element, will now be available to rightsholders more broadly and will provide a clear and expeditious path for creators to effectively enforce their rights in Colombia. As a result of these positive developments in 2024, the score for this indicator has increased by 0.25.

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:
The 2010 Law 1392 introduced a national legal framework and definition of rare diseases, including the right to comprehensive health care.

Subsequent implementing regulations have established and defined a national list of approved rare diseases (Resolutions 3681, 2048, and 123). Article 11 of Law 1392 includes reference for the need to encourage and incentivize research into "early diagnoses and possible medications, preventive treatments, psychological and psychiatric aspects associated with these diseases, not only from the point of view of the patients but also from that of their families." Similarly, Decree 481 of 2004 (which defines "vital" medicines to the Colombian health system) seeks to incentivize research and development. In 2024, the Ministry of Health published a national plan for rare diseases and orphan drugs (*Plan Nacional de Gestión para las Enfermedades Huérfanas/Raras*). Detailing the health needs of the rare disease community, this document also refers to and seeks to promote research on rare disease and orphan drugs in Colombia. However, none of these legislative or regulatory initiatives include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.