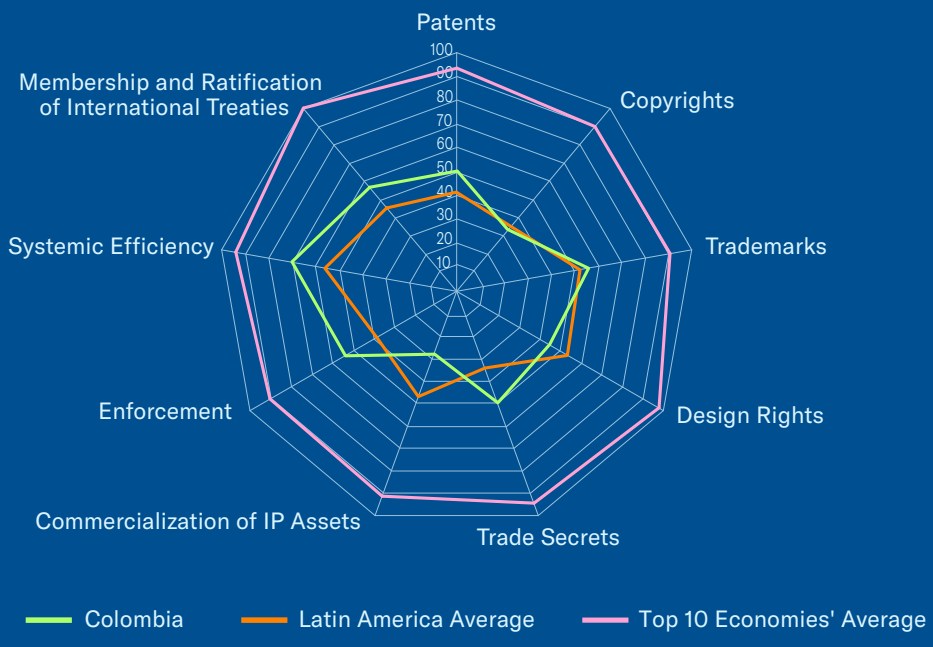
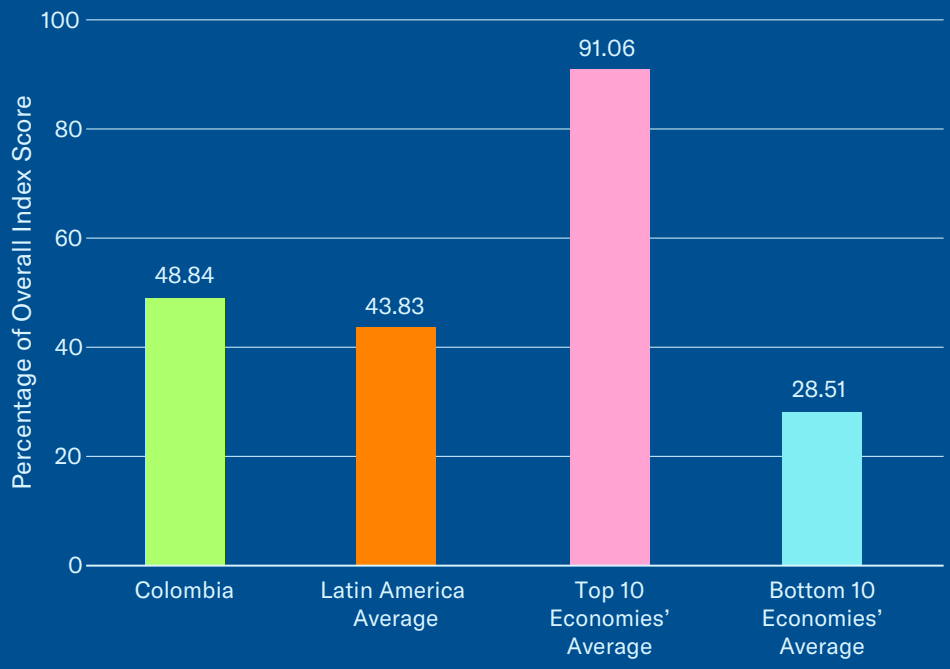
Colombia

Rank
31/55

Category Scores



Overall Score in Comparison



Key Areas of Strength

- Stronger copyright enforcement efforts through the National Directorate of Copyright (DNDA) injunctive-style relief action against online piracy
- Acceded to Convention on Cybercrime in 2020
- The 2019 Colombian Constitutional Court issued a ruling (Ruling C-345-19) recognizing 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—this includes 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

- History of use of compulsory license regime to leverage price reduction for biopharmaceuticals, including 2020 emergency COVID-19 laws, which provide an exceptionally broad basis for use of public interest declarations without sunset clauses or similar limitations
- Substantial barriers in place for licensing activities, including direct government intervention and review of technology transfer and licensing agreements
- Key life sciences IP rights missing, including patent term restoration and mechanisms for early patent dispute resolution
- Uncertainty over availability of RDP for biopharmaceuticals
- Inadequate or delayed prosecution of and penalties for IP infringement

Indicator	Score
Category 1: Patents, Related 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, Related Rights, and Limitations	**2.34**
10. Term of protection	0.84
11. Exclusive rights	0.25
12. Injunctive-type relief	0.25
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, Related Rights, and Limitations	**2.25**
17. Term of protection	1.00
18. Protection of well-known marks	0.50
19. Exclusive rights and trademarks	0.50
20. Frameworks against online sale of counterfeit goods	0.25
Category 4: Design Rights, Related Rights, and Limitations	**0.90**
21. Industrial design term of protection	0.40
22. Exclusive rights and 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

Indicator	Score
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. Preestablished 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: Membership and Ratification of International Treaties	**4.00**
44. WIPO Internet Treaties	1.00
45. Singapore Treaty on the Law of Trademarks and Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks	0.50
46. Patent Law Treaty and Patent Cooperation Treaty	0.50
47. Membership of the International Convention for the Protection of New Varieties of Plants, ct of 1991	0.00
48. Membership of the Convention on Cybercrime, 2001	1.00
49. The Hague Agreement Concerning the International Registration of Industrial Designs	0.00
50. Post-TRIPS FTA	1.00

Total: 24.42

Spotlight on the National IP Environment

Past Editions versus Current Score

Colombia's overall score remains unchanged at 48.84% (24.42 out of 50).

Area of Note

In late 2021, the government of Colombia approved a new *National Intellectual Property Policy*. The document, CONPES 4062, was drafted and released by the National Planning Department *(Departamento Nacional de Planeación)* and outlines Colombia's strategic direction and policy goals with respect to the protection of IP for the foreseeable future. The policy seeks to foster an environment that enables the creation and commercialization of IP assets; encourage the greater use of the national IP system to protect these assets; improve the administration and systemic efficiency of the national IP system; and increase harmonization with international standards. Overall, it is an ambitious document touching upon IP policies across the board. The policy and accompanying itemized Annex A contain 63 individual action items, including potential changes to the legal and regulatory environment. Key areas covered by the action items are potential legislative changes to existing copyright law (relating to TPM exceptions); the introduction of preestablished damages for copyright infringement through the issuing of new implementing regulations; greater efforts at cross-government coordination of IP enforcement; stronger awareness-raising efforts, particularly related to the licensing and commercialization of IP assets; and the potential joining of several international treaties, including the WIPO-administered Singapore Treaty on the Law of Trademarks and Patent Law Treaty, both of which are benchmarked in the Index.

The Colombian government should be congratulated for taking such a holistic approach to reforming the entire innovation and IP policy ecosystem through this long-term structural reform effort. As the economic data and analysis in the Index's accompanying Statistical Annex and the experiences of other economies strongly suggest, IP rights are the fundamental building blocks for innovation and advanced economic development to take place. For all economies—emerging and developed alike—what drives innovation, technological advances, and ultimately economic development and growth is the creation of new forms of intangible assets and IP. Focusing on international best practices and the extent to which Colombia's national IP system can adopt and adhere to such practices is of particular importance.

Full participation in the global IP system, PPH initiatives, and increased cooperation between IP offices can improve and harmonize the administration and functioning of the international IP system to help inventors and rightsholders domestically and internationally. Colombia has made noticeable strides on this front in the past few years. A PPH has been in place with the USPTO since 2012, and several other PPH agreements have been concluded since then, including with the Korean Intellectual Property Office, the Spanish Patent and Trademark Office, and with other Forum for the Progress and Integration of South America (PROSUR) economies. Colombia joined the Global Patent Prosecution Highway in 2017 and became a contracting party to the Convention on Cybercrime in 2020. Still, of the nine international treaties benchmarked in the Index, Colombia is not a contracting party to four: the Singapore Treaty on the Law on Trademarks; the Patent Law Treaty; the International Convention for the Protection of New Varieties of Plants, Act of 1991 (Colombia is a contracting party to International Convention for the Protection of New Varieties of Plants [UPOV] 1978); and the Hague Agreement Concerning the International Registration of Industrial Designs.

More broadly, as has been noted over the past ten editions of the Index, current Colombian IP laws and regulations could be reformed and better aligned with international best practices. Patentability standards continue to be restrictive and outside of international norms, especially for biopharmaceuticals and CIIs; the protection of copyright remains underdeveloped to face the challenges of the internet era; and estimated levels of physical and online counterfeit goods remain high. Rightsholders also face basic challenges with respect to technology transfer, licensing the use of IP assets, and the commercialization of IP assets. As such, the U.S. Chamber of Commerce stands ready to work with the Colombian government as it moves forward in implementing the *National Intellectual Property Policy* in 2023 and beyond.

Patent Rights, Related Rights, and Limitations

6. Legislative criteria and use of compulsory licensing of patented products and technologies: Up until the mid-2010s, the imposition and discussion of compulsory licensing for biopharmaceuticals had not been a recurring issue in Colombia. Article 70 of the 2014-18 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 out compulsory licenses. Article 70 also allows compulsory licenses on grounds outside extreme circumstances, including industrial or commercial objectives.

In 2016, the Ministry of Health and the Colombian government actively considered issuing a compulsory license on the oncology drug Glivec on the grounds of high prices. Subsequently, the Colombian government issued a "Declaration of Public Interest" via Resolution 2475 and committed to unilaterally reducing the price of Glivec by about 45%. On November 22, 2016, the National Commission of Prices of Medicines and Medical Devices *(Comisión Nacional de Precios de Medicamentos y Dispositivos Médicos)* 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 traditional price-setting methodology—whereby the average price is calculated from a group of 17 economies—public interest medicines are subjected to the lowest price available, including prices of follow-on products. In effect, this practice all but nullifies any existing IP protection and is 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 in December 2016, the National Pricing Commission issued Circular No. 4 in 2016, which set the price of Glivec at about 44% of its former price. Subsequently, in April 2017, the Colombian government issued Decree No. 670, which regulates the use of the public interest measure. The decree requires any declaration of public interest to 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 December 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; it instead identified the entire class of hepatitis C products. Local legal analysis suggests that Colombian authorities have taken no further action. Still, at the time of research, the situation remained unresolved. As such, it imposes yet another layer of uncertainty on rightsholders' ability to make use of their granted exclusive rights fairly and effectively in Colombia.

Furthermore, in March 2020, Decree 476 was issued by the Colombian government 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 grants 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 COVID-19." As mentioned, although not legally a compulsory license, such declarations essentially nullify any existing IP protection and carry the same practical impact of eliminating rightsholders' ability to freely use a granted exclusivity.

The same logic is present in a legislative proposal introduced in 2020 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 seeks to address the complex issue of securing biopharmaceuticals and medical supplies in the midst of an international health emergency, it includes 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. At the time of research, the bill was still pending, having undergone a semi face-to-face Public Hearing in March 2021. 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" and is to be used only after all other options for negotiating pricing and supply have been exhausted. This is currently not the case in Colombia. The Index will continue to monitor these developments in 2023.

Trade Secrets and the Protection of Confidential Information

25. Regulatory data protection (RDP) term: As has been noted in previous editions of the Index, a degree of uncertainty exists regarding the provision of RDP for submitted biopharmaceutical test data in Colombia. Decree 2085 of 2002 provides for a five-year period of RDP for both biopharmaceuticals and agrochemicals. Although less than international best practices and the benchmark 10-year period used in the Index, this is in line with Colombia's commitments under the U.S.-Colombia FTA. However, reports suggest that this protection is not fully available for all biopharmaceuticals. For example, Decree 1782, signed in 2014, which modifies the registration process for biological medicines, does not discuss RDP for biologics. As a result, with regard to RDP, the legislation introduces ambiguity as to whether five years of protection will be afforded to biologics under the new regime. Similarly, industry reports from the past few years suggest that the Colombian drug regulatory agency INVIMA has changed its administrative standards and that RDP is not being consistently granted to eligible products. The negative effect is the same for Colombian and foreign innovators. If rightsholders continue to face administrative barriers in accessing their statutory defined and granted term of RDP, the score on this indicator will be reduced to 0.