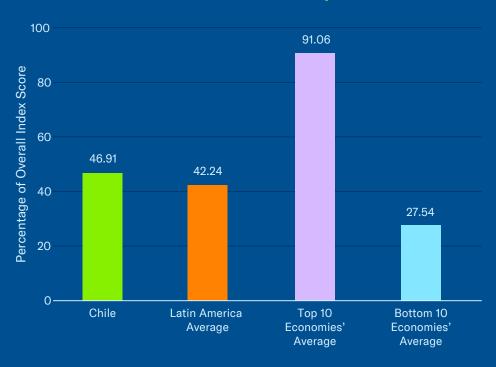




## **Category Scores**



## **Overall Score in Comparison**



# Chile

## Key Areas of Strength

- Joined the Madrid Protocol in 2022
- IP law amendments (Law 19,309) extend term of protection for design rights and improve the enforcement environment
- Member of GPPH
- Stronger efforts to increase transparency and public reporting of customs' enforcement activities
- Commitment to improve the IP environment through international trade agreements
- Efforts to streamline IP registration
- Promotion of IP commercialization

## **Key Areas of Weakness**

- No special IP incentives for orphan medicinal product development
- Uncertainty on accessibility of term restoration with IP law amendments (Law 19,309)
- Threat of compulsory licensing based on cost considerations for COVID-19 and HCV drugs persists
- Patchy patent protection for biopharmaceuticals, including obstacles to patentability and lack of effective patent enforcement
- High levels of counterfeiting and piracy for an OECD economy—55% estimated software piracy
- Lack of a sufficient framework to tackle online piracy, although some success in disabling access to infringing websites

Indicator		Score
Category 1: Pater	nts Rights and Limitations	3.94
1. Term of protect	ction	1.00
2. Patentability r	requirements	0.25
3. Patentability	of CIIs	0.00
4. Plant variety p	protection	0.74
5. Pharmaceutic	al-related enforcement	0.00
6. Legislative or of compulsor		0.00
7. Pharmaceutic	al patent term restoration	0.70
8. Membership	of a Patent Prosecution Highway	1.00
9. Patent opposi	ition	0.25
Category 2: Copy	rights and Limitations	2.13
10. Term of protect	ction	0.63
11. Exclusive righ	ts	0.25
	egal remedies disabling inging content online	0.50
13. Cooperative a	ction against online piracy	0.00
14. Limitations ar	nd exceptions	0.25
15. TPM and DRN	<i>I</i>	0.00
16. Government u	use of licensed software	0.50
Category 3: Trade	emarks Rights and Limitations	2.25
17. Term of protect	ction	1.00
18. Protection of	well-known marks	0.50
19. Exclusive righ	ts, trademarks	0.50
20. Frameworks a		0.05
of counterfeit	goods	0.25
Category 4: Desig	gn Rights and Limitations	1.10
21. Industrial des	ign term of protection	0.60
22. Exclusive righ	ts, industrial design rights	0.50
Category 5: Trade	e Secrets and the Protection of rmation	1.00
23 Protection of	trade secrets (civil remedies)	0,25
	trade secrets (criminal sanctions)	0.25
	ita protection term	0.50
	mercialization of IP Assets	3.92
26. Barriers to ma		0.25
	chnology transfer	0.75
28. Registration a requirements	of licensing deals	0.75

	Indicator	Score
	29. Direct government intervention in setting licensing terms	0.75
	30. IP as an economic asset	0.75
	31. Tax incentives for the creation of IP assets	0.67
	Category 7: Enforcement	3.52
	32. Physical counterfeiting rates	0.57
	33. Software piracy rates	0.45
	34. Civil and precedural remedies	0.50
	35. Pre-established damages	0.50
	36. Criminal standards	0.50
	37. Effective border measures	0.25
	38. Transparency and public reporting by customs	0.75
	Category 8: Systemic Efficiency	3.00
	39. Coordination of IP rights enforcement	0.75
	40. Consultation with stakeholders during IP policy formation	0.50
	41. Educational campaigns and awareness raising	0.75
	42. Targeted incentives for the creation and use of IP assets for SMEs	0.50
	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: 46.91% • Total Score: 24.86

# Spotlight on the National IP Environment

#### **Past Editions versus Current Score**

Chile's overall score remains unchanged at 24.86 out of 53 indicators.

### **Patent Rights and Limitations**

6. Legislative criteria and use of compulsory licensing of patented products and technologies: Chile has over the course of the Index shifted its policies on the use of compulsory licenses and has embraced the use of these licenses as a potential cost containment policy. In 2017, the Chilean Chamber of Deputies passed a bill that directed the Ministries of Economy and Health to issue compulsory licenses for medicines based on broad grounds that go beyond international standards, including price considerations, and to import less expensive generic versions of medicines. The government was reportedly considering compulsory licenses for the prostate cancer drug Xtandi and hepatitis C drug Sovaldi. In 2018, these efforts for the issuing of an involuntary license based on cost were endorsed by the outgoing government. In 2018, the Chamber of Deputies approved a resolution that requested the use of compulsory licenses for drugs formulated with sofosbuvir. Subsequently, in response to a request presented by some patient groups and parliamentarians, the Minister of Health issued Resolution 399, which discusses the public health justification for a compulsory license. A third resolution by the Chamber of Deputies with the same request was approved later that same year and, in response to that request, the Minister of Health issued Resolution 1165 rejecting the patentee's challenge to Resolution 399/2018.

In a separate development, in 2019, President Sebastian Pinera urged Congress to approve the Drugs Act II (Lev de Farmacos II) as one of the measures of the National Drug Policy that seeks to improve the availability of drugs and to reduce outof-pocket costs through, among other policies, the expansion of compulsory licenses. During the bill's long iteration through Congress, new provisions have been added that greatly extend the reach of nonvoluntary licenses, incorporating discretionary elements such as "shortage" or "economic inaccessibility" of products as a legitimate ground for issuing a license. The draft bill also includes provisions that effectively reduce a rightsholder's use of its trademarks in the course of trade. At the time of research, the legislation was still pending.

In 2020, in response to the COVID-19 global pandemic, the Chamber of Deputies passed a unanimous resolution endorsing the use of compulsory licenses for any and all products, diagnostics, medical devices, and other medical paraphernalia related to the COVID-19 global pandemic. This was followed up with a legislative proposal and set of amendments published by a group of senators. This proposal, Bulletin 13,572-11, would introduce an expedited and abbreviated process for the hearing and granting of compulsory licensing applications; the pre-fixing of applicable royalties to a maximum of 5% of the sales price of the licensed product; and a broad elimination of liability for manufacturers, individuals, and legal entities that violate existing IP rights (including patent rights and trade secrets) for the production or distribution of any "medicines, vaccines, and other technologies subject to patent rights, utility models, undisclosed information, intended to meet public health needs or other public interest within the national territory, in a context of health alert, epidemic or pandemic decreed by the health authority, and that without knowledge of the existence of affected industrial property rights or acting in good faith, violate the provisions of Law No. 19.039."

As stated repeatedly in the Index, compulsory licensing is not a cost containment tool; cost is not a relevant justification or basis for compulsory licensing 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. As Chile and the global community move forward in 2025 and beyond, the COVID-19 pandemic will continue to have a profound impact on the global economy and on how we interact and live as a global society. Individual economies will experience the pandemic's continued health and economic impact differently, with varying levels of severity experienced depending on the individual health and socioeconomic circumstances of that economy. But almost two years after WHO declared the COVID-19 global health emergency to be over, the critical takeaway is clear: the global community today is in a far better position to manage the socioeconomic impact of any future pandemic than it was in 2019. This is in large measure due to the extraordinary efforts of IP-intensive industries and, in particular, the research-based biopharmaceutical industry. The innovative, scientific, and technological progress that has allowed the global community to function during the COVID-19 pandemic did not emerge overnight. Instead, these technologies and products are the fruit of a pre-existing innovation ecosystem that relies on IP rights to enable the allocation of resources, formation of partnerships, and transfer of technology on commercial terms.

Without strong and clear IP rights, it is unlikely that any of the vaccines, treatments, or other medical and nonmedical products and technologies—or the underlying science—that have been essential to help societies function and successfully fight the COVID-19 pandemic would exist. Undermining these incentives and rights through the use and threats of compulsory licensing is counterproductive and is more likely to leave the world, including Chile, more vulnerable to the next global health challenge.

### **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); 12. Expeditious legal remedies disabling access to infringing content online; 13. Availability of frameworks that promote cooperative action against online piracy; and 15. Technological protection measures (TPM) and digital rights management (DRM) legislation: As noted over the course of the Index, rightsholders face significant challenges in protecting their copyrighted content in Chile. As a contracting party to both the WIPO Internet Treaties and the 2003 United States-Chile Free Trade Agreement (FTA), Chile is obliged to provide a minimum standard of copyright protection for rightsholders that is currently not available. Both the U.S.-FTA and WIPO Internet Treaties contain several important standards and measures related to copyright enforcement in the internet and digital realm, including a defined notice-andtakedown mechanism for communication service providers; extensive TPM and DRM protection provisions; definitions of obligations pertaining to related rights; protection against satellite piracy; and general civil and criminal enforcement procedures for all IP rights, including copyrights. But over 20 years after ratification of the FTA and accession to the WIPO Internet Treaties. major gaps still exist in Chile's legal framework, and enforcement remains inadequate.

To begin with, Chile's notice-and-takedown procedure does not meet the requirements of its FTA with the United States. Under current Chilean law, internet service providers (ISPs) are required to remove infringing content only on having "effective knowledge" (meaning that notice must be by a court, not by a rightsholder). Consequently, rightsholders' ability to practically benefit from and use the takedown system is extremely limited. In addition, although Law No. 20,435 introduced a voluntary system under which ISPs are to forward notices from rightsholders to suspected infringers, this has over the course of the Index shown to be ineffective. Regarding injunctive-style relief, there is a possibility of achieving an injunction through a court order, but no defined or practical enforcement route—whether administrative or judicial—is available to rightsholders. The availability of injunctive-style relief is hampered by the same lack of clear and practical rules and procedures affecting other forms of copyright enforcement in Chile. With respect to TPM and DRM, despite ratification of the WIPO Internet Treaties and the U.S.-Chile FTA, copyright law still only protects against the circumvention of, or interference with, ISPs. Circumvention by other parties is not illegal, nor is the manufacture, distribution, and sale of circumvention devices. Proposals have been put forward in the National Congress to amend existing statutes and introduce more robust measures including in 2021—but, overall, no meaningful action has taken place regarding the existing DRM and TPM legal framework over the course of the Index. This remains a key weakness in Chile's copyright environment. As noted in the Index, this does not mean that no positive developments have occurred over the past 20 years. On the contrary, the past few years have also seen the enactment of several new laws seeking to improve Chile's criminal enforcement environment, including with respect to IP rights.

Although positive, a new signal piracy law enacted in 2018 did not address the issue of circumvention devices. Similarly, the Ley Corta de INAPI reform package—in force since 2022—as well as the enactment of Laws 21,426, 21,577, and 21,595 (aimed at combating organized crime and illicit trade, including counterfeit goods) have helped strengthen Chile's IP enforcement environment. Although these efforts are welcomed and may over time help improve the copyright enforcement environment specifically, piracy data suggests that Chile continues to suffer from high rates of copyright infringement. The regional industry association ALIANZA (Contra La Piratería Audiovisual) periodically releases statistics on copyright piracy rates for the Latin American region. As of Q4 2023, an estimated 41.4% of Chilean households were consumers of online piracy. Unfortunately, this is not a one-off. Rates of piracy consumption have remained elevated in Chile over the past five years. For example, a 2020 study by the British research consultancy and web monitoring firm Muso found that Chile is a large market for online piracy in Latin America with over 1 billion recorded web visits to online sources of piracy, a per capita rate of 95 visits per person. Although Brazil was the largest total market for online piracy in Latin America—at over 7 billion web visits during the same period—on a per capita basis, Chile's rate was almost double: 95 visits per person in Chile versus 58 visits per person in Brazil. The Index will continue to monitor Chile's efforts at reforming its copyright environment in 2025.

# Commercialization of IP Assets and Market Access

27. Barriers to technology transfer: In April 2024, the government presented the National Congress with a legislative proposal for a new national technology transfer framework. The draft bill (16686-19) would introduce several important changes to Chile's R&D ecosystem and the technology transfer and commercialization process, IP rights included. Technology transfer is a critical mechanism for commercializing and transferring research from public and governmental bodies to private entities for the purpose of developing usable and commercially available technologies. Technology transfer activities based on academic-industry and public-private sector collaborations provide a significant and distinct contribution to the economic strength and wellbeing of economies in which such activities take place. The process enables public research institutions to obtain access to commercial research funds, state-of-the-art equipment, and leading-edge technologies, while allowing industry to benefit from the extensive knowledge and ingenuity of academic researchers. In the United States, the Patent and Trademark Law Amendments Act of 1980—commonly referred to as the Bayh-Dole Act—and the Stevenson-Wydler Technology Innovation Act have been instrumental in incentivizing technology transfer. These laws give institutions that receive federal support (such as American universities, small businesses, and nonprofits) control and the rights to any resulting intellectual property of their inventions or research. Studies have found a significant correlation in increased patenting activities at American universities after the legislation. The importance of the Bayh-Dole framework to building the modern U.S. innovation and R&D ecosystem cannot be overstated: its positive impact extends to the broader U.S. economy, exports and the development of U.S. international technological leadership.

Many Index economies have over the past two decades introduced similar technology transfer frameworks and have reaped the accompanying socioeconomic rewards. In Chile, the draft legislation seeks to promote the commercialization of publicly funded research through the greater use of IP rights to create and commercialize new IP assets. On a positive note, the draft law would make it easier for academic and public sector researchers to participate in the commercialization process, including in the development and management of spin-off companies. Less clear are other provisions of the bill. For instance, under draft Article 6, the bill would establish a new "National Repository of Scientific and Technological Knowledge and Information." This repository would require researchers with government funding to deposit their final research and any "data associated" with the repository within 60 days of completion. Under Article 7, the law would support what is termed "open science" through promoting "open access to scientific publications, data and codes linked to said activity." It remains unclear how the repository and the goals of furthering open access to scientific research and data will, first, operate in practice and, second, be compatible with the overarching goals of commercialization through the greater use of IP rights and the licensing of IP assets. The Index will 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:

The 2015 Law 20,850 (*Ley Ricarto Soto*) introduced a national definition and framework for covering high-cost medicines, including for many rare diseases. The law does not include any reference to or definition of any special IP-based market exclusivity incentives for orphan medicinal product development.