

Policy Integration for Sustainable Development: An Analysis of Patent Regulation in Latin America

Alexandre San Martim Portes

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**Australian
National
University**

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Supervisory Panel

Prof Susan K. Sell (Primary Supervisor)

Prof Jean-Frédéric Morin (Primary Supervisor)

Dr Belinda Townsend (Chair)

Prof Sharon Friel (Associate Supervisor)

A/Prof Ashley Schram (Associate Supervisor)

Statement of Original Authorship

I, Alexandre San Martim Portes (28/04/2024), hereby declare that the thesis here presented is the outcome of the research project I have undertaken during my candidacy, that I am the sole author unless otherwise indicated, and that I have fully documented the source of ideas, references, quotations, or paraphrases attributable to other authors.

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Dedication

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Abstract

Policy integration is one of the main challenges in promoting sustainable development. Global governance mechanisms, such as the Sustainable Development Goals (SDGs), highlight the importance of integrating different policy domains to promote effective outcomes for sustainable development. Although the SDGs present an opportunity for a comprehensive transformational change, intrinsic trade-offs among the social, economic, and environmental dimensions of sustainable development can hinder the achievement of this global agenda. Tackling these trade-offs and reconciling conflicting goals is a central part of the domestic implementation of the SDGs.

Global governance mechanisms often overlook how trade regulation, such as patent protection, impacts the achievement of the SDGs. While granting monopoly rights to patent holders can incentivise local innovation, it can also affect how developing countries access technologies crucial for sustainable development, including public health, energy transition, and food security. Most countries in Latin America have committed to patent regulation in trade agreements that can restrict their policy space to promote sustainability goals.

Against this background, this thesis examines to what extent Latin American countries have integrated sustainability goals into recent patent regulation and the conditions for policy integration. This thesis draws on a theoretical framework that combines perspectives from international political economy, global governance, and policy studies to identify the conditions for policy integration. This framework views policy integration for sustainable development as a political process in which domestic and transnational actors promote competing interests and perspectives on patent regulation and sustainability issues, also emphasising the relevance of policy space for integrative policymaking.

This thesis uses a mixed-methods research design that combines a Qualitative Comparative Analysis (QCA) of 17 Latin American countries with four qualitative case studies of patent regulation in Brazil and Chile taking place between 2015-2022. This thesis argues that the extent of policy integration for sustainable development depends on the existing legal and political policy space and the active role and coordination of policymakers, civil society organisations, and the domestic industry. The results of this study indicate that policy

integration for sustainable development is context contingent, changing in scope and content depending on how policymaking institutions navigate private and public interests in patent policymaking. The results also show that Latin American countries constantly tailor patent regulation to achieve national development purposes and tackle significant challenges, such as the COVID-19 pandemic.

This research provides evidence of the lack of mainstreaming of the SDGs into national policies. The cases explored in this thesis indicate that health was the only sustainability issue in most policymaking discussions, suggesting that the SDGs are not a strong normative force to promote changes in patent regulation. Consequently, Latin American countries demonstrated more concerns with dealing with the COVID-19 pandemic and designing responses to the pandemic compared to changing patent regulation to mainstream sustainability goals.

This thesis contributes to the growing research agenda on policy integration for sustainable development, introducing a set of conditions that can be further tested in other policy areas, such as climate change. The findings also contribute to understanding how transnational actors influence domestic policymaking and the role of trade regulation in enabling or hindering sustainability goals. This thesis also provides evidence of the role of civil society and the domestic industry in shaping political agendas, contributing to the literature on coalitions, lobbying, and participatory policymaking.

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List of Abbreviations

ABIA	Brazilian Interdisciplinary AIDS Association
ABIFINA	Brazilian Association of Fine Chemicals, Biotechnology, and its Specialties
ACHIPI	Chilean Association of Intellectual Property
ASECH	Chilean Association of Entrepreneurs
BCN	Library of the Chilean National Congress
CIF	Pharmaceutical Innovation Chamber
CSO	Civil Society Organisation
ECLAC	UN Economic Commission for Latin America and the Caribbean
ECOSOC	UN Economic and Social Council
EFTA	European Free Trade Association
GATT	General Agreement on Tariffs and Trade
GTPI	Working Group on Intellectual Property
HLPF	High-Level Political Forum on Sustainable Development
INAPI	Chilean Institute for Industrial Property
INPI	Brazilian Institute for Industrial Property
Interfarma	Associação da Indústria Farmacêutica de Pesquisa
IPRs	Intellectual Property Rights
LES	Licensing Executives Society Chile
OECD	Organisation for Economic Cooperation and Development
PGR	Brazilian Attorney General
PhRMA	Pharmaceutical Research and Manufacturers of America
ProMed	Association of Local Medicines Producers
PTAs	Preferential Trade Agreements
QCA	Qualitative Comparative Analysis
SDGs	Sustainable Development Goals
SOFOFA	Federation of the Chilean Industry
STF	Brazilian Supreme Court
TCU	Brazilian Court of Auditors
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights

UN	United Nations
UPOV	International Union for the Protection of New Varieties of Plants
VNR	Voluntary National Review
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

Chapter 1

Introduction

In July 2022, United Nations (UN) member states met at the High-Level Political Forum on Sustainable Development (HLPF) under the auspices of the United Nations Economic and Social Council (UN ECOSOC). This meeting had the challenging task of bringing the sustainability agenda back to the centre of global governance, which had been focused primarily on the COVID-19 pandemic since its outbreak in 2020. This forum presented a new opportunity for countries to reflect on the progress of the 2030 Agenda for Sustainable Development since 2015 and the strategies to meet its ambitious goals by 2030.

Critically, the Ministerial Declaration agreed upon in the HLPF underscored the need to improve access to health technologies, such as vaccines, “through appropriate dissemination of technology and know-how in accordance with World Trade Organisation (WTO) rules” and using the flexibilities in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (UN ECOSOC, 2022, p. 6). The reference to intellectual property rights (IPRs) in this declaration is not surprising since many countries in the Global South and civil society organisations (CSOs) had advocated for a more balanced application of patent protection during the pandemic as a response to the slow progress in scaling up vaccine production (Thambisetty et al., 2022).

While the explicit mention of IPRs in a sustainable development policy document seems appropriate given the intersection of patent regulation and sustainability goals (Adbel-Latif & Roffe, 2021; Rognstad & Ørstavik, 2021; Ruse-Khan, 2011a), this was one of the few times that this struggle between the protection of and access to technology was addressed at a HLPF since the creation of the Sustainable Development Goals (SDGs) in 2015. Despite the omission of patent regulation in the wider global sustainable agenda, the intersection of patents and sustainability is a common challenge at the domestic level, where policymakers must reconcile the goals of these different policy fields.

This thesis investigates to what extent Latin American countries have integrated sustainable development goals into their patent protection regulation and the conditions that promote

positive integration for sustainable development. At the core of this issue is how power dynamics shape policymaking for sustainable development and how countries in the Global South must navigate domestic and international interests when integrating sustainability goals into patent regulation. This thesis also examines how the position of a country in the international trade system and its industrial capabilities define the policy space to achieve sustainable development.

This chapter proceeds as follows. Section 1.1 provides contextual background and Section 1.2 presents the research scope. Section 1.3 situates the research questions within gaps in the wider literature. Section 1.4 presents the thesis argument. Section 1.5 describes the key contributions of this thesis. Section 1.6 concludes with a thesis outline.

1.1 What is Policy Integration for Sustainable Development?

Policy integration for sustainable development is a political process through which policymakers integrate sustainability goals into a variety of policy domains. Policy integration, i.e., the act of reconciling goals from different policy fields, is especially critical for addressing sustainable development since it is a complex and cross-cutting issue that transcends individual policy domains (Bogers et al., 2023; Jochim & May, 2010; Stafford-Smith et al., 2017). Policy integration differs from other concepts often used in the academic literature, such as policy coherence, in that it does not focus on intersectoral coherence but on the reconciliation of goals within a policy domain. This is a challenging task, given the inherent trade-offs among the economic, environmental, and social dimensions of sustainable development (Breuer et al., 2019; Kroll et al., 2019). This thesis examines policy integration for sustainable development, underscoring which dimensions policymakers prioritise and why.

Policy integration is a political phenomenon that involves divergent interests and ideas that shape how political institutions respond to complex issues. This thesis views policy integration for sustainable development as a process in which interests, ideas, and institutions at international and national levels influence policymaking processes and shape responses to sustainability issues. Understanding how these variables combine and interact explains

differences in policy integration of patent protection and sustainable development across countries.

Patent regulation presents a compelling case to study policy integration since it is a type of international trade regulation that can impact several sustainability-related areas, such as health, biodiversity, and energy (Cullet, 2003; Raiser et al., 2017; Rosendal, 2016). The current international intellectual property (IP) regime is the result of decades of struggles between public and private interests (May & Sell, 2006; Sell, 2003). While granting monopoly rights to private inventors can incentivise innovation, rising levels of protection can also restrict population-wide access to knowledge and technology necessary to promote sustainable development (Brown, 2012; Drahos & Braithwaite, 2004; Kapczynski, 2008). These competing interests (i.e., strengthening IP protection versus access to public goods) are promoted through different ideas of what patent regulation should look like and its role in innovation and the public good. These ideas influence policymaking institutions, defining the levels of patent protection and whether patent law contains measures to limit monopolies. The focus of this thesis on patent regulation allows a deeper understanding of how international power dynamics both shape domestic policy and are domestically contested, influencing how countries tackle sustainability goals.

This thesis examines the extent to which Latin American countries have integrated sustainability goals into patent regulation since the establishment of the SDGs in 2015. Although this thesis analyses policy integration as a domestic phenomenon, both sustainable development and patent protection are forms of global norms and regulations present in global governance instruments. This section provides a brief context for these instruments, demonstrating their development over the past few decades and their influence on domestic policies. Section 1.1.1 outlines sustainable development as an international norm that emerged in the past three decades, culminating in the creation of the SDGs in 2015. Section 1.1.2 explains patent protection as a form of international regulation diffused to Latin American countries through trade agreements with provisions on patent protection that can spill over to several policy areas. Section 1.2.3 discusses the potential implications of patent protection for achieving sustainability goals.

1.1.1 Global Sustainability Governance and Policy Integration

Sustainable development is a global norm that has evolved through different global governance mechanisms since the Brundtland Report in 1987 (United Nations, 1987). The political processes that promoted sustainable development as a global norm are comprehensively documented in the literature, showing how this norm was created and strengthened to become widely accepted and transformed into the SDGs (Hadden & Seybert, 2016; Lafferty, 1996; Marong, 2003). Since the creation of these global sustainability mechanisms, countries have adopted instruments to implement the SDGs at the domestic level. For example, governments have designed national sustainable development strategies (Meadowcroft, 2007), produced voluntary national reviews (VNRs)¹ (Allen et al., 2018), and created specific policies to achieve sustainability goals (Quental et al., 2011). The domestic application of these global norms reveals that countries tackle inherent trade-offs among the SDGs and between the sustainability agenda and other policy and regulation domains (Bornemann & Weiland, 2021; Le Blanc, 2015; Nilsson & Weitz, 2019).

Integration is a central element of the global sustainability agenda. Since the 1987 Brundtland Report, sustainable development has been understood as a type of development that “meets the needs of the present without compromising the ability of future generations to meet their own needs” (United Nations, 1987, p. 7). This new form of development should support economic growth that is “forceful and at the same time socially and environmentally sustainable” (United Nations, 1987, p. 7). Since the 1987 Brundtland Report, the idea of international development that integrates economic, social, and environmental dimensions has become a global norm and evolved into more concrete forms of global governance, such as other UN declarations and the SDGs (Fukuda-Parr, 2016; Redclift, 2005).

In 2015, the UN members agreed upon the 17 SDGs as part of the UN 2030 Agenda for Sustainable Development (UN General Assembly, 2015). The SDGs address the integration of the three dimensions of sustainability, expanding the agenda from the previous Millennium Development Goals (MDGs) to include other areas previously neglected in international development, such as environmental objectives (Loewe, 2012). As shown in Table 1.1,

¹ Voluntary national reviews (VNRs) are non-mandatory documents produced by UN member states to report on their progress in achieving the SDGs.

environmental issues are explicitly present in SDGs 13, 14, and 15. Regarding social goals, SDG 1 on poverty was expanded to include all forms of poverty and global inequality was included in SDG 10. Economic goals are also present, with explicit references to promoting economic growth in SDG 8. Members of the UN committed to implementing instruments to achieve the 17 SDGs and their numerous targets by 2030. To do so, countries must address tensions among the SDGs and reconcile policy goals.

Table 1.1: The Sustainable Development Goals (SDGs)

SDGs (2015 – 2030)
SDG 1 – End poverty in all its forms everywhere.
SDG 2 – End hunger, achieve food security and improved nutrition, and promote sustainable agriculture.
SDG 3 – Ensure healthy lives and promote well-being for all at all ages.
SDG 4 – Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all.
SDG 5 – Achieve gender equality and empower all women and girls.
SDG 6 – Ensure availability and sustainable management of water and sanitation for all.
SDG 7 – Ensure access to affordable, reliable, sustainable and modern energy for all.
SDG 8 – Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all.
SDG 9 – Build resilient infrastructure, promote inclusive and sustainable industrialisation and foster innovation.
SDG 10 – Reduce inequality within and among countries.
SDG 11 – Make cities and human settlements inclusive, safe, resilient and sustainable.
SDG 12 – Ensure sustainable consumption and production patterns.
SDG 13 – Take urgent action to combat climate change and its impacts.
SDG 14 – Conserve and sustainably use the oceans, seas and marine resources for sustainable development.
SDG 15 – Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss.
SDG 16 – Promote peaceful and inclusive societies for sustainable development, provide access to justice for all and build effective, accountable and inclusive institutions at all levels.
SDG 17 – Strengthen the means of implementation and revitalise the Global Partnership for Sustainable Development.

Source: UN General Assembly A/RES/70/1 (2015).

One of the main elements of the 2030 Agenda is its integrative approach, both within the agenda and with other policy instruments. Integration within the Agenda expects that the 17 SDGs “are integrated and indivisible and balance the three dimensions of sustainable development: the economic, social and environmental” (UN General Assembly, 2015, para. 1). Many scholars have examined the intersection of the various SDGs and their targets, identifying potential synergies and tensions that must be addressed during domestic implementation (Bornemann & Weiland, 2021; Le Blanc, 2015; Nilsson & Weitz, 2019).

Integration with other policies refers to mainstreaming sustainable development into policymaking in all domains. This form of integration appears in several UN documents as crucial for sustainable development. For example, the 2019 SDG Summit resolution (UN General Assembly, 2019, p. 5) urged countries to mainstream the 2030 Agenda into “national planning instruments, policies, strategies, and financial frameworks”. Similarly, the Ministerial Declaration from the 2022 High-Level Political Forum on Sustainable Development (UN ECOSOC, 2022) reinforced the importance of integrating sustainable development into COVID-19 pandemic recovery plans. Finally, as this thesis also shows, VNRs and other sources provide examples of how countries can integrate the 2030 Agenda into national plans and strategies.

Both forms of integration (i.e., within the SDG 2030 Agenda and with other policy sectors) are relevant for this thesis, which investigates how sustainability is integrated into policymaking and which elements of the agenda are prioritised. In the case of patent regulation, integration means that devising regulatory instruments to achieve SDG 9 (Industrialisation and innovation) should not create barriers to other goals, such as SDG 3 (Health and well-being). Therefore, these goals should be considered together during the creation of new policies, incorporating sustainability issues into patent regulation while ensuring that all dimensions of the 2030 Agenda are integrated. Nevertheless, as this thesis demonstrates, patent regulation is a politically contentious area where public and private interests often clash, and power structures shape policy integration for sustainable development.

1.1.2 Trade Agreements and Patent Regulation: Conflicts Between Patent Protection and Access to Knowledge

This thesis focuses on patent regulation, a form of intellectual property rights (IPRs) that confers monopoly rights to inventors. Patent rights are usually conceded for 20 years, following the WTO TRIPS Agreement requirements, and give owners the exclusive right to make, use, or sell the patented invention. In the case of most countries in the Latin American region, domestic patent regulation results from the implementation of international trade agreements. Most regulatory aspects of patent protection, such as duration of protection and patentability requirements, are defined in the WTO TRIPS Agreement and expanded in numerous bilateral and regional trade agreements. This section provides a brief account of the history of the international patent protection regime, highlighting the conflicts between the protection of and access to knowledge inherent to this field.

The current international regime governing IPRs results from economic transformations in the global economy between the 1970s and 1980s, when international trade expanded to unprecedented levels, and knowledge-intensive goods became critical assets for multinational corporations (Primo Braga & Fink, 1996). As innovative products such as pharmaceuticals, software and hardware, and other technological goods became central to the new globalised economy, differences in IP protection systems gained attention as potential trade barriers and an economic threat for several high-income countries (Halabi, 2018; Primo Braga, 1989). Consequently, conversations on creating an international agreement on IPRs became a central part of international trade negotiations.

In the Tokyo Round of the General Agreement on Tariffs and Trade (GATT), which took place between 1973 and 1979, counterfeiting emerged as a critical issue, strengthening the agenda to include IP as part of the international trade regime (Matthews, 2002). This agenda was firmly pushed by the United States (US) and supported by other developed countries, most notably Japan and European nations (Draho, 2002). On the other hand, the Global South (primarily India and Brazil) disagreed with the inclusion of an IPRs agreement within GATT since the treaties administered by the World Intellectual Property Organisation (WIPO) already covered international IP standards (Deere Birkbeck, 2008). However, several developed countries regarded WIPO as toothless and inadequate for the effective protection of their IPRs (May & Sell, 2006).

The GATT negotiations from the 1970s to the 1990s reveal the two main narratives constructed on IPRs and international development. On the one hand, the US, the European Community, and Japan saw constant infringement of their IP, which resulted in financial losses for their investments in research and development (R&D). Hence, the argument was made that patent protection was necessary to prevent these losses and stimulate higher levels of investment in research and development (Matthews, 2002). On the other hand, countries in the Global South, such as Brazil and India, showed concerns about the impact of strict IP protection on technology transfer and access to technology in the Global South (Drahos, 2002).

Sell (2003) shows that corporate actors also firmly pushed for domestic policy changes in the US, with flow on effects in international negotiations. For example, one significant change in domestic trade policy in the US was the introduction of the 1984 Trade Act, amending Section 301 and allowing the US government to investigate other countries' implementation of IPRs and act unilaterally against the infringement of IPRs (Sell, 2011). The possibility of trade sanctions and retaliation from the US represented a real threat to developing countries, shifting the balance of power during the multilateral negotiations of an IP agreement, which officially started in the Uruguay Round and launched with the Ministerial Declaration of 20 September 1986. As shown in this thesis, this strong relationship between transnational firms and the US government is still relevant to explaining recent changes in patent regulation in Latin America.

Despite the opposing views on an international agreement on IPRs embedded into the multilateral trade regime, the negotiations of the GATT Uruguay Round were finalised in 1994 with the signature of the WTO TRIPS Agreement as Annex 1C of the Agreement Establishing the WTO. This outcome was strongly influenced by an asymmetry of knowledge, capacities, and economic power between the Global North and South. Developed countries (most notably the US) utilised a carrot and stick approach in conjunction with their access to resources and knowledge, which gave them an advantage in the negotiations (Drahos, 2002; Drahos & Braithwaite, 2004).² In contrast, developing countries lacked negotiating capacity

² Drahos (1995) shows that business lobby groups, such as the International Intellectual Property Alliance (IIPA) and the Intellectual Property Committee (IPC), provided technical and legal expertise to the US during the TRIPS negotiations.

and did not have adequate knowledge of the negotiated technical issues (Deere Birkbeck, 2008; Matthews, 2011).

The WTO TRIPS Agreement entered into force in 1995 and represented a significant gain for high-income, technology-intensive countries and a crucial change in the international IP regime. An entirely new set of rules and institutions had to be introduced for several WTO members. In the field of patents, for instance, the TRIPS Agreement provides a minimum of 20 years for patent protection in all fields of technology,³ meaning that countries that did not grant patents to pharmaceuticals had to amend their patent laws.

Although countries promoting international IP protection achieved most of their demands with the TRIPS Agreement, they had not attained all their expectations. In fact, as Susan Sell argues, developed countries got 95% of what they wanted. However, “that 5% has always mattered, and 95% was never enough” (Sell, 2011, p. 448). Developed countries, in particular the US, saw the WTO TRIPS Agreement as minimum IP standards, creating space for further increase in protection. Other countries, including those in the Global South, saw the agreement as a ceiling or a maximum level of protection. As multilateral negotiations in the WTO became increasingly more contested, developed countries, most notably the US and the EU, shifted their efforts to preferential trade agreements (PTAs) (Sell, 2011).

In these PTAs, IP regulation tends to be a vital part of the text, and the so-called “TRIPS-plus provisions” often increase patent protection (Ruse-Khan, 2011b). TRIPS-plus refers to provisions that go beyond the TRIPS Agreement standards, including those extending patent rights and introducing new IP modalities (e.g., traditional knowledge). Some examples of TRIPS-plus provisions related to patents are the extension of patent duration, data exclusivity, patent linkage, and limitations of the grounds for compulsory licenses (Gleeson et al., 2019; Morin, 2006). Since these TRIPS-plus provisions concede extended rights to patent owners, they can reduce competition, restrict the gaps and ambiguities left in the TRIPS Agreement, and hinder the development of sustainable development policies in the Global South (Kuanpoth, 2006; Ruse-Khan, 2011a; Yu, 2021).

³ TRIPS Agreement, Article 27, paragraph 1: “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (...)”.

Like other countries in the Global South, Latin American countries have dealt with the challenges associated with the rising levels of patent protection. Since the 2000s, most countries in the region have actively promoted PTAs with the Global North, including the US, the EU, Japan, and the European Free Trade Association (EFTA) (Quiliconi, 2014). Figure 1.1 shows Latin American countries' membership to PTAs with the US, the EU, or EFTA. These three trade partners often include TRIPS-plus provisions in their PTAs (Morin & Surbeck, 2020). Most notably, countries in Central America and on the Pacific coast (Chile, Colombia, Ecuador, Peru, and Mexico) have adopted TRIPS-plus PTAs with the three trade partners. In contrast, Brazil and other South American countries focused mainly on intra-regional agreements and did not ratify PTAs with the US, the EU, or EFTA.⁴

Figure 1.1: Latin American Countries' Membership to PTAs with the US, the EU, or EFTA.



Source: Author's elaboration based on Morin and Surbeck (2020).

⁴ Despite the resistance from South American countries, the European Union signed a trade agreement with the MERCOSUR countries (Brazil, Argentina, Paraguay, and Uruguay) in 2019. However, the agreement has not been ratified.

Importantly, Latin American countries do not only passively accept patent regulation from trade agreements. Policymakers and non-state actors often reshape patent regulation to reflect domestic goals or tackle policy challenges (Eimer et al., 2016; Shadlen, 2017). This thesis sees this iterative process of tailoring patent regulation to the domestic context as a window of opportunity for policy integration for sustainable development. In this process, sustainability areas affected by patent regulation can be integrated to reconcile conflicting goals. The overlap of patent regulation and sustainable development is explained in the next section.

1.1.3 The Intersection of Patent Regulation and Sustainable Development

Policy integration for sustainable development in the field of patent regulation can happen in various ways, depending on how the overlap of these two policy fields takes place and is understood by policymakers. Interestingly, the UN 2030 Agenda is virtually silent about patent regulation, providing little guidance on how policymakers should navigate the potential conflicts and synergies between patent regulation and sustainability goals. While the 2030 Agenda recognises the role of science, technology, and innovation as cross-cutting variables for achieving the SDGs, SDG 3 (Health and well-being) is the only goal explicitly mentioning IPRs. More precisely, Target 3.b promotes the research and development of vaccines and medicines, access to affordable essential medicines, and the use of TRIPS flexibilities. Target 3.b states:

“Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all” (SDG 3, Target 3.b).

Although the 2030 Agenda recognises the impacts of IPRs on access to medicines for achieving sustainable development, the focus of Target 3.b is on essential medicines. As argued by Fukuda-Parr and Treanor (2018), these medicines, if interpreted as those on the WHO list of essential medicines, include mainly drugs for which generics are widely available. Therefore, this target does not necessarily include branded drugs protected by patents, which generates

an intense financial burden on developing countries. Moreover, the authors argue that Target 3.b does not capture issues related to the research and development of new drugs, removing access to medicines from broader industrial and innovation policies (Fukuda-Parr & Treanor, 2018).

Haugen (2021) investigates the reason behind the omission of IPRs in the 2030 Agenda. One of his main arguments is that IP is a complex issue with conflicting perspectives, and this lack of consensus obstructs the inclusion of this topic in international negotiations. In addition, he indicates that the strength of different advocacy campaigns might have shaped how IPRs are included in the 2030 Agenda. Haugen (2021) argues that SDG 3 explicitly references the TRIPS flexibilities because civil society organisations (CSOs) have successfully linked unaffordable medicines to IPRs on previous occasions, such as the HIV/AIDS epidemic. Other social movements have arguably not been strong enough to include similar references in the context of other goals.

WIPO, the main international organisation in the field of IPRs, explored the intersection of the SDGs and IPRs in a 2021 report, highlighting the importance of innovation for sustainable development (WIPO, 2021). The report shows how IPRs can foster innovation, serving as a vector to achieve SDG 9 (Industrialisation and innovation) while mentioning several other goals that can benefit from innovation, such as SDG 3 (Health and well-being) and SDG 13 (Climate change). As described by Daren Tang, WIPO's Director-General, "intellectual property, as a key driver of innovation, fosters the kinds of inclusive economic, social, and cultural growth that are needed to allow us to overcome our greatest common challenges" (WIPO, 2021, p. 3). As Bannerman (2020) highlights, WIPO's approach demonstrates a restricted view on development, providing little guidance on how IPRs can directly affect other goals apart from SDG 9 or through innovation.

Despite the omission of patent regulation in the 2030 Agenda, the scholarly literature has produced evidence that patent protection can potentially affect the achievement of several SDGs (Adbel-Latif & Roffe, 2021; Bannerman, 2020; Yu, 2021). Considering the complexity of sustainable development, the potential effects of patent regulation are even more significant than simply economic development (Rognstad & Ørstavik, 2021). Three areas are prominent in the literature and relevant to this thesis: public health and access to medicines, energy

transition and climate change, and biodiversity protection (Abdel-Latif & Roffe, 2021; Brown, 2017; Correa, 2002; Jefferson, 2020).

One of the most prominent cases of the intersection of patent protection and sustainable development is in the field of public health. As discussed above, the WTO TRIPS Agreement and subsequent PTAs contain patent regulation that can reduce developing countries' policy space to formulate domestic legislation and policies for public goods (Ruse-Khan, 2009; Thrasher, 2021). More precisely, stringent patent rules can negatively affect access to medicines if they allow extended monopoly rights over drugs, causing a rise in prices and hampering competition (Tenni et al., 2022). TRIPS-plus provisions that increase patent protection, such as patent term extensions, can reduce policy space further.

After the signing of the WTO TRIPS Agreement in 1994, the increased levels of patent protection in international agreements faced contestation from the Global South. The contestation of this regime was particularly significant in the late 1990s and early 2000s, as countries began to experience the consequences of the TRIPS Agreement in practice (Deere Birkbeck, 2008; Shadlen, 2017). In the late 1990s and early 2000s, the HIV/AIDS epidemic highlighted the struggles some countries faced in accessing antiretroviral drugs due to patents granted to pharmaceutical companies. In this period, governments from the Global South and civil society organisations (CSOs) confronted the international IP regime to promote access to medicines and the use of TRIPS flexibilities (Hein & Moon, 2013; Matthews, 2011; Sell & Prakash, 2004).

As a result of the struggle between patent protection and access to medicines, the WTO members agreed upon the 2001 Declaration on the TRIPS Agreement and Public Health (also known as the Doha Declaration). The Declaration states in Article 4 that the TRIPS Agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all" (Doha Declaration, 2001, Article 4). The Declaration represented a significant step in recognising that the interpretation of the agreement depends on the needs of each country and that the agreement's flexibilities can be implemented legally. In addition, the Declaration also reinforces in paragraph 7 "the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2" (Doha Declaration, 2001, para.

7). Thus, in recognising the access to technology gap, the Doha Declaration reinforces that the TRIPS Agreement should not be a barrier to disseminating technologies and gives developing countries policy space to implement the agreement's flexibilities (Correa, 2002).

Access to medicines is directly connected to the 2030 Agenda in SDG 3 (Good health and well-being) and has recently gained even more attention in international politics during the COVID-19 pandemic. The COVID-19 pandemic, as this thesis shows, prompted governments around the world to respond to this health crisis. The struggles between technology producers and consumers were evident at the international and domestic governance levels, as transnational firms were unable to produce vaccines at a large scale and distribute doses to least-developed nations (Sekalala et al., 2021; Thambisetty et al., 2022). In this context, the availability of TRIPS flexibilities to tackle the health crisis is crucial (Baker, 2022). As this thesis shows, similar to the HIV/AIDS epidemic, this health emergency brought non-state actors together to negotiate legislative proposals in Latin American countries, aiming to tailor patent regulation for public health.

Another policy area that strong patent protection can affect is the energy transition, i.e., the shift from fossil fuels to renewable energy sources, such as wind, solar, and biofuels. Renewable energy is directly linked to SDG 7 (Affordable and clean energy) and has gained much attention in the context of sustainable development, especially considering the impact of energy production on climate change and the rising number of environmental disasters caused by current energy production practices. An important factor in access to renewable energy is access to modern technologies for renewable energy production. A 2018 WIPO report shows that green energy technology development is concentrated mainly in four countries (Japan, the US, Germany, and China), which account for over 60% of all patent families and international applications (Rivera León et al., 2018). In this context, technology transfer from these technology sources to other parts of the world, such as Latin America, is essential to achieve the SDGs.

The 2030 Agenda tackles the urgency of technology access in developing countries, reinforcing the need for global mechanisms promoting capacity building, technology development, and transfer (Sampath, 2019). However, like other international instruments, the 2030 Agenda encourages the diffusion of environmental technologies while being silent about patent protection (Ørstavik, 2021). SDG 7 is a clear example of this, where the goal recognises the

importance of technology promotion for energy transition but lacks explicit references to international technology transfer or intellectual property rights.

A third key area of intersection is the impact of patent protection for plant varieties and genetic resources on biodiversity conservation. The biotechnology industry's rapid growth and economic importance have increased investments in biological prospecting, i.e., the search for compounds in native organisms for commercial application in industrial areas, such as food, pharmaceuticals, and cosmetics. This issue is of great importance for biodiversity-rich countries, such as those in the Latin American region, since they need to find ways to balance the economic, environmental, and social impacts that bioprospecting can produce. Biodiversity conservation is an important part of SDG 2 (Zero hunger), SDG 14 (Life below water), and SDG 15 (Life on land).

Different from public health and the energy transition, the regulation of patents in a biodiversity context is more complex and fragmented, formed by different multilateral agreements. The patentability of plants has historically not been a universal practice, and international negotiations since the 1960s have attempted to find common ground on plant breeders' rights. In 1961, the Union for the Protection of New Varieties of Plants (UPOV) members adopted the first Convention for the Protection of New Varieties of Plants,⁵ which allowed IP to be obtained for plants of all botanical genera and species (UPOV, 1961, Article 4). The Convention was revised in 1972, 1978, and 1991, furthering the protection of new plant varieties with an increased scope of protection and period of exclusivity. As Jefferson (2020, p. 51) describes, UPOV 1991 created a more stringent IP protection system, allowing "more kinds of plant objects to be privatised, for longer periods of time, and subject to fewer limitations".⁶ Importantly, UPOV standards prioritise plant uniformity and stability, which may accelerate current trends of biodiversity loss (Kochupillai & Köninger, 2022) and affect local communities' access to seeds (Aistara, 2012).

These areas help operationalise sustainable development for the analysis in this thesis and are outlined in more detail in Chapter 4.

⁵ See Jefferson (2014) for a comprehensive account of UPOV's history.

⁶ UPOV 1991 faced resistance in several developing countries. The Latin American countries that have ratified UPOV 1991 are Costa Rica, the Dominican Republic, Panama, and Peru (UPOV, 2023).

1.2 Research Scope

Sustainable development has emerged as a global objective to tackle vital global governance issues, such as poverty, biodiversity loss, climate change, and health. Implementing such an ambitious agenda is not an easy task, requiring the coordination of public and private actors at different governance levels. As a complex policy problem, the implementation of the 2030 Agenda requires new approaches beyond traditional policymaking (Bressers, 2004), including integrating sustainability goals into a range of policy domains. However, countries have little guidance from global governance instruments on how to support integrative policymaking. In this context, it is crucial to understand how policy integration for sustainable development takes place and the conditions to achieve it.

The intersection of patent regulation and sustainable development is particularly significant for policy integration, considering that patent regulation is a cross-cutting issue affecting all technological fields. In the context of rising IP protection, patent regulation might restrict flexibilities and reduce the policy space necessary to implement the sustainable development agenda. Integrating these two issues depends on how patent regulation is implemented domestically and how tensions between patent protection and sustainable development are addressed.

Most importantly, as climate and health crises become increasingly common, conflicts between public and private actors regarding IP ownership tend to become more frequent. The protection and access to new technologies to solve sustainability issues will likely be at the centre of future global governance instruments. The COVID-19 pandemic provides a timely example of the tensions between patent regulation and sustainability goals. As argued above, inequities in the distribution of vaccines and COVID-19 treatments show how patent protection can create barriers to public health goals.

In the current context of global health and environmental crises, it is crucial to understand in which conditions countries can promote sustainability goals and how trade regulation can encourage or hinder domestic responses to these global issues. This thesis contributes to a better understanding of domestic policymaking for sustainable development, explaining how and when policy changes occur and paying particular attention to the interplay of international and domestic actors in this process.

The SDGs are part of a crucial agenda for global sustainability governance, prompting countries to integrate sustainability concerns into domestic policymaking. Concomitantly, countries must also implement patent regulation with rising levels of protection due to their membership in trade agreements. The overlap of patent regulation and several sustainability areas raises concerns about how countries promote policy integration for sustainable development. This research is particularly interested in processes after the implementation of international patent commitments. Once new regulatory instruments are implemented and distributional effects are in place, how do countries tailor these instruments and integrate sustainability goals?

While the literature documents the political struggles of creating and changing patent regulation domestically (Deere Birkbeck, 2008; Eimer et al., 2016; Matthews, 2011; Shadlen, 2017), little attention has been paid to the integration of sustainable development goals into patent regulation. Similarly, the literature on the 2030 Agenda has examined policy integration as a crucial aspect of sustainable development (Jochim & May, 2010; Stafford-Smith et al., 2017), but there is little empirical knowledge on the different ways that countries can promote policy integration for sustainable development and the conditions for integrated policymaking.

For example, as this thesis shows, some Latin American countries actively discussed sustainability issues at the TRIPS Council, while others did not engage with sustainability topics. Similarly, some countries successfully amended their patent laws to promote sustainability goals while others did not. There is little knowledge of the conditions that explain these variations across Latin American countries. This research aims to fill this gap, answering the following research questions:

Research Question 1: To what extent have Latin American countries integrated sustainable development objectives into patent regulation?

Research Question 2: What conditions promote policy integration for sustainable development in the field of patent regulation in Latin America?

Research Question 3: How do these conditions generate policy integration?

This research focuses on Latin America for two main reasons. First, as discussed above, countries in the region are parties to several PTAs that increased the level of patent protection. Differences in international patent commitments might explain whether and how countries promote policy integration for sustainable development. Second, Latin American countries are not technology-intensive economies, meaning that they have limited technology production and tend to import technologies crucial for sustainable development, such as health and clean energy. This position as technology importers indicates that Latin American countries are not necessarily the primary beneficiaries of the patent system. In this context, transnational firms are often the main users of the patent system and can influence how patent law is designed domestically. Consequently, tensions between transnational actors who use these patent protection systems and domestic actors who are users of technology are expected to shape policy integration in Latin America. As documented in the literature, power asymmetry and struggles between private and public interests are often at the centre of these tensions (Sell, 2003).

The focus on Latin America also allows for a regional analysis, highlighting differences and similarities across countries. This regional focus allows for a comparison across countries with similar historical backgrounds and political systems, enabling a comparative perspective of variables that influence policy integration for sustainable development in patent regulation. My knowledge of the Latin American context and fluency in Portuguese and Spanish were also critical during data collection and analysis.

Finally, Latin America provides an interesting insight into how the Global South addresses policy integration. Although Latin American countries are not representative of all Global South countries, this thesis shows how middle and high-income countries in the Global South with relatively strong trade relations with major high-income economies (in particular, the US and the EU) address tensions in the global sustainability agenda in the context of patent regulation.

This thesis uses a theoretical framework based on political economy, global governance, and policy studies to answer these research questions (outlined in Chapter 2). This framework builds on Kaufmann's (2017) grassroots global governance theory and suggests that global meta-concepts, such as sustainable development, can vary in their domestic implementation due to different views on the concept and competing interests from domestic and

transnational actors, such as policymakers, firms, and civil society. Based on Shadlen's (2017) work on IP protection in Latin America, the theoretical framework also emphasises that the domestic implementation of international patent regulation is an iterative process that creates opportunities to integrate sustainability goals into new regulatory developments.

This thesis adopts a case-based mixed-methods approach to examine policy integration for sustainable development in Latin America. This methodology comprises two parts. In the first part, a Qualitative Comparative Analysis (QCA) of 17 Latin American countries was conducted to unveil causal relations between policy integration for sustainable development and four conditions: international patent commitments, trade dependence, civil society access to policymaking, and domestic innovation. This method shows the different combinations of conditions that result in policy integration, allowing the selection of several conditions to test simultaneously to identify configurations that enable integrative policymaking (Berg-Schlosser et al., 2009; Ragin, 2008). The second part consists of qualitative case studies using interviews and policy documents to examine policy integration for sustainable development in Brazil and Chile. The selection of these countries was based on the QCA results (both countries presented the same configuration of conditions in the QCA) and similarities in recent changes in patent regulation. In both countries, two types of patent regulation were analysed: patent term extensions and compulsory licensing.

1.3 Existing Accounts of Policy Integration for Sustainable Development

Policy integration for sustainable development is a topic that has gained significant attention since the introduction of the 2030 Agenda in 2015. Several scholars have investigated the current process of implementation of the SDGs, focusing on the integration of goals (Le Blanc, 2015; Tosun & Leininger, 2017; Wong & van der Heijden, 2019). These works focus on various aspects of policy integration for sustainable development, including its theoretical significance and empirical application. This section briefly examines the literature on policy integration for sustainable development, identifying gaps that this thesis addresses.

A significant number of works examine policy integration for sustainable development at the global level. These works investigate whether international agreements and organisations integrate the SDGs. For example, Azizi et al. (2019) analyse policy integration in the context of

multilateral environmental agreements, arguing that there is timid progress towards integration in these agreements. Similarly, Bogers et al. (2022) and Montesano et al. (2024) show that international organisations – such as the International Labour Organisation (ILO), the Food and Agriculture Organisation (FAO), and the EU – have increasingly used the SDGs framework, but policy integration remains a challenge. Overall, this literature indicates that the lack of integration of the SDGs into other global governance instruments remains a crucial challenge for the achievement of the 2030 Agenda. This thesis investigates policy integration at the domestic level to understand how sustainability goals appear in domestic politics and provide insights into the future of the global sustainable development agenda.

The conflicts and trade-offs within the SDGs are also critical issues in the literature on policy integration for sustainable development. Scholars have argued that overcoming these conflicts is a significant challenge in the implementation of the 2030 Agenda and for policy integration at the domestic level (Stafford-Smith et al., 2017; Tosun & Leininger, 2017). Wong and van der Heijden (2019) argue that avoiding such conflicts in policymaking is a significant cause of the lack of transformational changes and policy integration. Therefore, it is essential to understand how policymaking happens and why specific topics are included in these processes. For example, Tosun and Leininger (2017) examine how countries address the interlinkages in the SDGs, finding that a primary explanation for policy integration is how policymaking processes occur rather than other factors, such as level of income or form of government. This thesis builds on this body of work, providing evidence of other explanations for policy integration.

The literature also investigates how conflicts and trade-offs are dealt with within public administration. Dunlop and Russel (2012) explain regulators' roles in the integration of sustainable development in UK public services, underscoring the lack of signals and guidance from the central government to promote sustainable development. The challenges of policy integration at the domestic level are also studied by scholars interested in policy integration in areas other than sustainable development. For example, Trein and Maggetti (2019) investigate administrative coordination, showing significant variation across policy fields and countries. These works reinforce the importance of understanding policymaking institutions as arenas where policy integration happens, a variable further explored in this thesis.

This thesis is situated in a growing body of literature interested in the politics of policy integration. For instance, Solorio et al. (2022) investigate participatory decision-making in policymaking processes. Their research examines the role of indigenous consultation in environmental policies in Mexico, arguing that the current perspectives on policy integration in the literature are Western-focused and fail to grasp the state-society interactions in Latin America. More broadly, Cejudo and Trein (2023a, 2023b) have recently advanced a research agenda on the political dynamics that shape policy integration (explained in more detail in Chapter 2). This thesis builds on this body of the literature, focusing on the politics of sustainable development and patent regulation.

Regarding policy integration for sustainable development in fields related to IPRs, Ashford and Hall (2011, p. 270) argue that “industrial policy, environmental law and policy, and trade initiatives must be ‘opened up’ by expanding the practice of multi-purpose policy design and that these policies must be integrated”. However, the authors do not explicitly mention IPRs or patent regulation. To my knowledge, the concept of policy integration for sustainable development has not been used in the context of patent regulation. There is some consideration of the intersection of IPRs, health, and sustainability as a policy coherence issue (Morin & Orsini, 2013; Ruckert et al., 2017). This thesis expands on these works to understand how policy integration is shaped by the interaction of domestic and transnational factors. There are also other works at the intersection of patent regulation and sustainable development (as discussed below), but these works do not engage with the concept of policy integration.

Few works analyse the intersection of patent regulation and sustainable development as a concept or global governance instrument. For example, Ruse-Khan (2011a) discusses the concept of sustainable development in international IP law, underscoring the importance of maintaining policy space in the Global South. Similarly, Yu (2021) examines the SDGs in the context of WTO TRIPS-plus regulation, arguing that IP negotiation should not compromise developing countries’ abilities to meet their present and future needs. This thesis builds on these relevant insights, providing an empirical analysis of the overlap of these two policy areas.

Finally, most of the empirical literature on sustainability goals in the field of patent regulation has tackled one issue at a time rather than investigating the integration of the entire 2030

Agenda. As described in the sections above, scholars have examined different aspects of sustainability and patents, such as health, biodiversity, food, and energy. However, the concept of policy integration has not been applied to this field. This research draws on this literature to identify relevant variables, such as the role of state and non-state actors in regulatory processes (outlined further in Chapter 2).

1.4 The Argument

The main argument I make in this thesis is that policy integration for sustainable development is context contingent. The context in which policymaking takes place refers to several variables that enable or hinder the integration of sustainability goals into another policy domain. These variables include the political institution where the policy is developed, the domestic and transnational actors negotiating the policy, the interests shaping the final policy outcome, and external factors that prompt policy responses.

In this work, I show that certain conditions appear as enablers of policy integration for sustainable development in patent regulation across Latin American countries and policy initiatives.

I argue in this thesis that policy integration for sustainable development is directly linked with the policy space available for countries to develop responses to policy problems. In the field of patent regulation, the policy space in a given country is defined by its international patent commitments and political pressure from transnational firms and trade partners interested in maintaining high levels of patent protection globally. The empirical evidence in this thesis shows that policy space defines policy options (i.e., which policies are feasible within this space) and the capacity of policymakers to respond to sustainability issues.

Policymakers and the political institutions where they act are essential to understand policy integration. Each political institution is an arena in which state and non-state actors fight to promote their views on the integration of patent regulation and sustainable development. The success of these actors depends on their capacity to mobilise other actors and counteract opposing views, which can take place through coalitions, public campaigns to influence policymakers, and lobbying and advocacy activities. In this thesis, I show that, although policymakers are willing to integrate sustainability goals into new regulatory developments,

their initiatives only became concrete regulations when supported by a cohesive coalition of domestic non-state actors that countervail transnational forces.

This research also shows that Latin American countries constantly tailor patent regulation, adjusting it to achieve national development purposes and tackle significant challenges, such as the COVID-19 pandemic. Tailoring processes are particularly crucial for policy integration because they are opportunities to revise existing regulations and integrate sustainability goals into them. I also argue in this thesis that the type of regulation or policy has important implications for policy integration. Tailoring patent regulation that threatens monopoly rights, such as compulsory licensing, faced strong opposition from both domestic and transnational actors in Brazil and Chile. In contrast, tailoring the length of these monopoly rights faced less resistance from domestic actors, enabling policy change.

International trade agreements, such as the TRIPS Agreement and TRIPS-plus PTAs, often disregard the domestic context in which they are implemented. The findings in this thesis argue for more flexibilities in these agreements to allow countries to adjust international regulation to their context. Although some flexibilities already exist, the decision to use them is often political, defined by the domestic context. Consequently, global IP governance must consider these contextual conditions in the design of international regulation.

Finally, although policy integration is a crucial element within the global sustainability agenda, the evidence presented in this thesis supports the argument that sustainable development was not a strong driver for policy change in the field of patent regulation. This research provides evidence of the lack of mainstreaming of the SDGs into national policies and the cherry-picking of goals. The case studies in this thesis indicate that health was the only sustainability issue in most policymaking discussions, suggesting that the SDGs are not a relevant normative force to promote changes in patent regulation. Consequently, Latin American countries presented more concerns with dealing with the COVID-19 pandemic and creating a regulatory framework to enable pandemic responses compared to changing patent regulation to mainstream sustainability goals.

1.5 Empirical and Theoretical Contributions

In this thesis, I make both empirical and theoretical contributions to the literature on policy integration, sustainable development, and patent regulation. The current literature on policy integration has traditionally focused on public administration, discussing coordination across government bodies. While recent works have made significant efforts to shift their focus from public administration approaches to include a political analysis of policy integration (Cejudo & Trein, 2023a, 2023b; Tosun & Lang, 2017), there is a gap in understanding the conditions for policy integration and the political-economic dynamics shaping this phenomenon. This thesis provides empirical evidence of policy integration for sustainable development, contributing to theoretical developments in this field, in particular in relation to the role of non-state actors in shaping policy outcomes. This evidence also contributes to other works that tackle IPRs and sustainability as coherence issues (Ruckert et al., 2017).

This thesis builds on previous works on the politics of patent regulation and access to knowledge (Brown, 2012; Sell, 2003, 2010), providing new evidence of private power and civil society activism in the context of sustainable development and the COVID-19 pandemic. This thesis also provides evidence of the role of the transnational and domestic industry in sustainable development, underscoring how industrial interests shape sustainability policies. These findings contribute to the literature on the political influence of corporations in the context of sustainable development (Bendell & Kearins, 2005; Slob & Weyzig, 2010), providing insight into the relevance of these actors in promoting or hampering sustainability goals.

The analysis in this thesis contributes to the emerging research on the lack of adoption of the global sustainability agenda. As described by authors such as Hadden and Seybert (2016) and Biermann et al. (2022), the UN sustainable development agenda has not achieved a widespread consistency of action or conformity of behaviour, showing little empirical results of policy change. This thesis contributes to this literature, showing that the UN sustainable development narrative did not promote significant policy changes for action on sustainable development in Brazil and Chile. This thesis also finds evidence of cherry-picking in policy integration for sustainable development, contributing to the growing literature on the selective adoption of the SDGs (Ferrón Vélchez et al., 2022; Forestier & Kim, 2020).

This thesis shows that tailoring international regulation can provide opportunities for new goals to be incorporated domestically. Building on Shadlen's (2017) work, I demonstrate that tailoring patent regulation depends on the type of regulation and how it affects IP ownership by transnational and domestic firms. Different patent regulations have different distributional effects and, therefore, different political and economic dynamics during policymaking. The empirical analysis presented here also shows how and when patent policy can change, contributing to the literature on coalitions between CSOs and the domestic industry (Sell & Prakash, 2004; Thaiprayoon, 2015; Townsend et al., 2021).

Finally, the case-based mixed-methods approach used in this thesis enables an investigation of causal relations in policymaking. This thesis provides a helpful framework for other researchers who want to use a mixed-methods approach to research policy integration in various domains and contexts. Future research interested in the conditions for integration of other complex policy areas can apply the combination of QCA and case studies to investigate the different political and economic dynamics inherent to those domains.

1.6 Thesis Outline

This thesis comprises seven chapters. Chapter 2 describes the theoretical framework and variables utilised in this thesis. This chapter explains how theories on the domestic adoption of international norms can be used to analyse policy integration for sustainable development at the domestic level. Further, it details how countries implement and adjust patent regulation depending on their domestic contexts.

Chapter 3 presents the research methodology, comprising a case-based mixed-methods research design for an in-depth analysis of policy integration. It justifies the case selections, namely Latin America as the main focus, Brazil and Chile as countries for in-depth analysis, and patent term extensions and compulsory licensing as case studies. Chapter 3 also details the data collection and analysis.

Chapter 4 is dedicated to the Qualitative Comparative Analysis (QCA) of 17 Latin American countries, which identifies the different combinations of conditions that lead to policy integration of patent regulation and sustainable development in Latin America. This chapter details the QCA methodology, paying particular attention to the strategy adopted for

calibrating the conditions. A detailed analysis of the QCA's outcome is presented, indicating two pathways for policy integration in Latin America. This chapter also explains how these results informed the case selection and analysis in the subsequent chapters.

Chapter 5 presents the results from the analysis of policy integration for sustainable development in patent regulation in Brazil. It does so through a nuanced analysis of two policy developments, namely a Supreme Court decision that ended patent term extensions and a law proposal changing rules related to compulsory licensing. This chapter explains how different actors were mobilised during these processes, underscoring the importance of the COVID-19 pandemic for policy integration in Brazil. The cases of policy integration in Brazil also emphasise the role of coalitions between domestic firms and CSOs to promote health objectives.

Chapter 6 reports the results of the case study analysis of policy integration for sustainable development in patent regulation in Chile. This chapter focuses on two cases of policy integration: an amendment to the IP law reducing patent term extensions and a combination of law proposals and health declarations aimed at promoting compulsory licensing. This chapter examines the conditions for policy integration in the context of TRIPS-plus PTAs, highlighting how transnational pressure reduced the scope of policy integration in compulsory licensing regulation. This chapter also argues that policy integration for sustainable development depends on policymakers' ability to promote sustainability goals and navigate domestic and transnational interests.

Chapter 7 discusses the results of the QCA and case studies. This comparative analysis demonstrates that, while policy integration is context contingent, it is possible to identify the main conditions that promote integrated policymaking. This chapter finds that the scope of policy integration depends on the existing legal and political policy space, the political salience of sustainability issues, and the ability of policymakers to navigate domestic and transnational interests. This chapter also outlines the implications of this research for the study of policy integration, sustainable development, and patent regulation and suggests avenues for future research.

Chapter 2

Theoretical Framework: The Political Economy of Policy Integration for Sustainable Development

In the Introduction, I demonstrated that policy integration is a central concept for sustainable development. While countries have committed to sustainability goals, they also have to comply with patent regulation that can positively or negatively affect several areas of sustainable development, including health, climate change, and biodiversity conservation. In this context, countries must navigate the potential conflicts between patent regulation goals on the one hand, and sustainable development goals on the other, when promoting policy integration. Despite the relevance of these conflicts for the advancement of the global sustainability agenda and the implementation of IP-related trade agreements, there is a gap in understanding how countries integrate these two policy domains.

This chapter presents the theoretical framework guiding this thesis. This framework is developed from key theoretical perspectives in international political economy, global governance, and policy and development studies to address the central research question and gap in the literature: To what extent have Latin American countries integrated sustainable development objectives into their patent regulation?

This chapter proceeds as follows. Section 2.1 outlines the core concept of policy integration and demonstrates its relevance for sustainable development. It distinguishes this concept as a political phenomenon distinct from other policy concepts in the literature. This section introduces issue salience as a key variable for understanding how Latin American countries have integrated sustainable development goals with patent regulation. Section 2.2 outlines key theories for investigating the domestic implementation of global norms and regulations. Kauffman's (2017) grassroots global governance theory is used to examine the role of domestic and transnational non-state actors in shaping policy integration for sustainable development in Latin American countries. Furthermore, the thesis framework draws on the work of Deere Birkbeck (2008) and Shadlen (2017) to understand the tailoring of global patent regulation in developing countries. Section 2.3 outlines key variables informing the theoretical

framework from the literature: policy space, state and non-state actors, and coalitions. Lastly, Section 2.4 combines these theories into the theoretical framework utilised in this thesis.

2.1 Policy Integration

Policy integration is a central concept for this thesis, which seeks to understand to what extent Latin American countries have integrated sustainable development goals into their patent protection regulation and to identify the conditions that promote positive integration for sustainable development. With the emergence of complex global issues, such as sustainability, policy integration has become a key concept in international and domestic politics (Bornemann & Weiland, 2021; Le Blanc, 2015; Stafford-Smith, 2017; Tosun & Leininger, 2017). This section outlines the different definitions of policy integration used in the literature and the recent theoretical developments in this field that are utilised to develop the theoretical research framework.

Policy integration as a concept emerged in the 1980s in relation to marine policy (Underdal, 1980) but has been widely used in international politics since the 1990s in other fields, such as international labour governance (Tosun & Lang, 2017). Since then, other policy fields have used the concept of policy integration to tackle other transdisciplinary issues. The field of environmental policy is a significant area that has promoted the mainstreaming of environmental goals into other sectoral policies (Persson, 2004). Environmental Policy Integration (EPI) emerged in the context of growing concern with integrating different environmental, economic, and social issues in the early 2000s, becoming a guiding principle for domestic and international policies (Biermann et al., 2009; Jordan & Lenschow, 2010). Similarly, climate change is another complex issue where the concept of policy integration has been promoted to link multiple policy domains (Adelle & Russel, 2013; Rietig, 2013).

Sustainable development, as described in Chapter 1, aims to integrate numerous policy domains. Since the 1987 Brundtland Report (United Nations, 1987), the idea of international development that integrates economic, social, and environmental dimensions has gained more relevance and evolved into more concrete forms of global governance, such as the SDGs and other UN declarations (Fukuda-Parr, 2016; Redclift, 2005). With an integrative approach, the SDGs are an ambitious global governance instrument that aims to promote policy changes

in 17 different but interconnected areas. Bornemann and Weiland (2021, p. 96) argue that policy integration in the context of the SDGs supports a “comprehensive, reciprocal, and complex form of goal integration”, which differs from integration in other fields, such as the environment.

Despite the widespread use of the term policy integration in global sustainability governance, there is little consensus in the literature and policy on what this concept means and how to promote it effectively. The first issue is the plethora of concepts used in the literature that are similar to policy integration. One of the most popular concepts is policy coherence, which is particularly common in the field of sustainable development, and authors often use it interchangeably with policy integration (Glass & Newig, 2019; Stafford-Smith et al., 2017). Policy coherence suggests that different sectors should meet similar goals or not contradict and hamper each other’s objectives (OECD, 2016). This concept is undoubtedly relevant in the context of the SDGs, especially because governments must ensure that policies in various policy domains do not conflict with each other (UN General Assembly, 2015).

While policy coherence helps understand the implementation of different parts of the 2030 Agenda, policy integration is a more nuanced concept to understand how this agenda is mainstreamed into national policies. The departure from policy coherence to integration is essential to this research as it enables an explicit focus on how domestic policymaking addresses potential tensions between sustainability issues and various policy domains, such as patent regulation. This understanding is in line with the literature that defines integration as a political process and not only an outcome, differentiating it from concepts such as policy coherence and coordination (Cejudo & Michel, 2017; Tosun & Lang, 2017).

Other government-focused concepts, such as whole-of-government and horizontal policymaking, are also commonly used to refer to integrative approaches in policymaking (Aoki et al., 2023; Carey et al., 2015). These different concepts from the literature usually have the same starting point: the recognition that policymaking traditionally has a siloed approach and does not consider cross-cutting issues nor promote the integration of different policy domains. Although these terms express similar ideas of integrated policymaking, they primarily focus on horizontal coordination between public administrations (Trein & Maggetti, 2019; Train et al., 2020a), which is a common phenomenon in the area of patent regulation. For example, it is common for countries to create inter-ministerial committees to discuss

patent regulation, often involving the ministries responsible for industry, innovation, health, and other fields (Comité de Desarrollo y Propiedad Intelectual, 2013; Inter-Ministerial Group on Intellectual Property, 2023). Although the existence of such committees is in line with the literature on policy coordination in public administration, this literature does not investigate the political and economic causes of integration. The analysis in this thesis contributes to this literature by providing an analysis of non-state actors' role in policy integration, expanding integration beyond administrative and public actors.

Policy integration is a concept that goes beyond the idea of coherence or administrative coordination. This thesis follows Cejudo and Trein's (2023a, p. 9) definition of policy integration as "a political process that entails the coordination of actors and agencies across policy subsystems [and] the combination of instruments from different policy sectors, [...] as a response to a complex policy problem that not one policy sector, policy instrument, or agency can solve".

This definition is best suited for this research for three reasons. First, it views policy integration as a political process. Since policy integration requires the cooperation of actors from different policy domains (Tosun & Lang, 2017), political conflicts inherent to these domains can be exacerbated in this process. As Cejudo and Trein (2023a, p. 10) describe, policy integration is not a single moment when those tensions are entirely solved but "a process that requires deliberate political efforts". As described in Chapter 1, political conflicts are particularly relevant in the context of patent regulation, and these struggles inherent to this policy field can enable or hinder efforts to promote policy integration for sustainable development.

Second, this definition includes a combination of different policy instruments. Analysing policy integration across different sectors requires a comprehensive understanding of the various policy instruments commonly employed in each policy domain and how they can be used for integration. This thesis shows how policy integration for sustainable development occurs in Latin America through a diversity of policy and regulation instruments, such as VNRs, compulsory licensing legislation, and public health declarations.

Lastly, this definition of policy integration underscores its relevance for cross-cutting policy programs that include transversal policy goals, i.e., goals that are not restricted to one single policy field (Cejudo & Michel, 2017; Jordan & Lenschow, 2010). Studying patent regulation can provide valuable insights into the political dynamics of policy integration since patent

regulation is often a means to achieve other policy goals. For example, patent protection can be designed to promote domestic innovation, protect foreign innovation, or promote public goods. Which goals are prioritised depends on how policymakers navigate divergent interests from domestic and transnational actors and which issues are politically salient.

This thesis draws on the theory of issue salience in policymaking. Salience refers to the relative importance political actors attribute to a specific issue, shaping political agendas and prompting the development of policies in areas of interest (Beyers et al., 2017; Epstein & Segal, 2000; Wlezien, 2005). Issue salience is a significant motivator for policy change and has been identified as a driver for environmental policies (Spendzharova & Versluis, 2013) and trade policy (Nguyen, 2019). Sustainable development is undeniably a relevant concept for global governance, but the political salience of sustainable development domestically is still unclear. Moreover, only recently have scholars examined how issue salience contributes to policy integration (Kefeli et al., 2023). Issue salience is relevant for policy integration for sustainable development because it can explain the cherry-picking or the lack of comprehensive integration of the SDGs and patent regulation. In the context of rising global issues, such as pandemics and climate change, the analysis of policy integration can reveal if sustainable development remains a priority once other global challenges emerge.

In sum, policy integration for sustainable development is viewed in this thesis as a political process in which state and non-state actors come together to influence a policy outcome in a complex, cross-cutting area. In this process, policymakers navigate competing interests and ideas on the policy issue to define a political agenda that defines the scope of policy integration.

2.2 Understanding the Domestic Integration of Global Norms and Regulation

The previous section demonstrated that policy integration for sustainable development is a political process shaped by different actors, policymaking institutions, and interests. This definition assumes that national governments in Latin America will design policies for sustainable development, and there are possible political struggles in the integration of patent protection and sustainability goals. This section outlines key theories of the domestic implementation of global norms and regulations that are crucial to understanding the

domestic process of norm creation (Section 2.2.1) and tailoring (Section 2.2.2) in Latin American countries when global sustainable development norms reach the domestic level.

2.2.1 Sustainable Development as a Global Meta-Concept

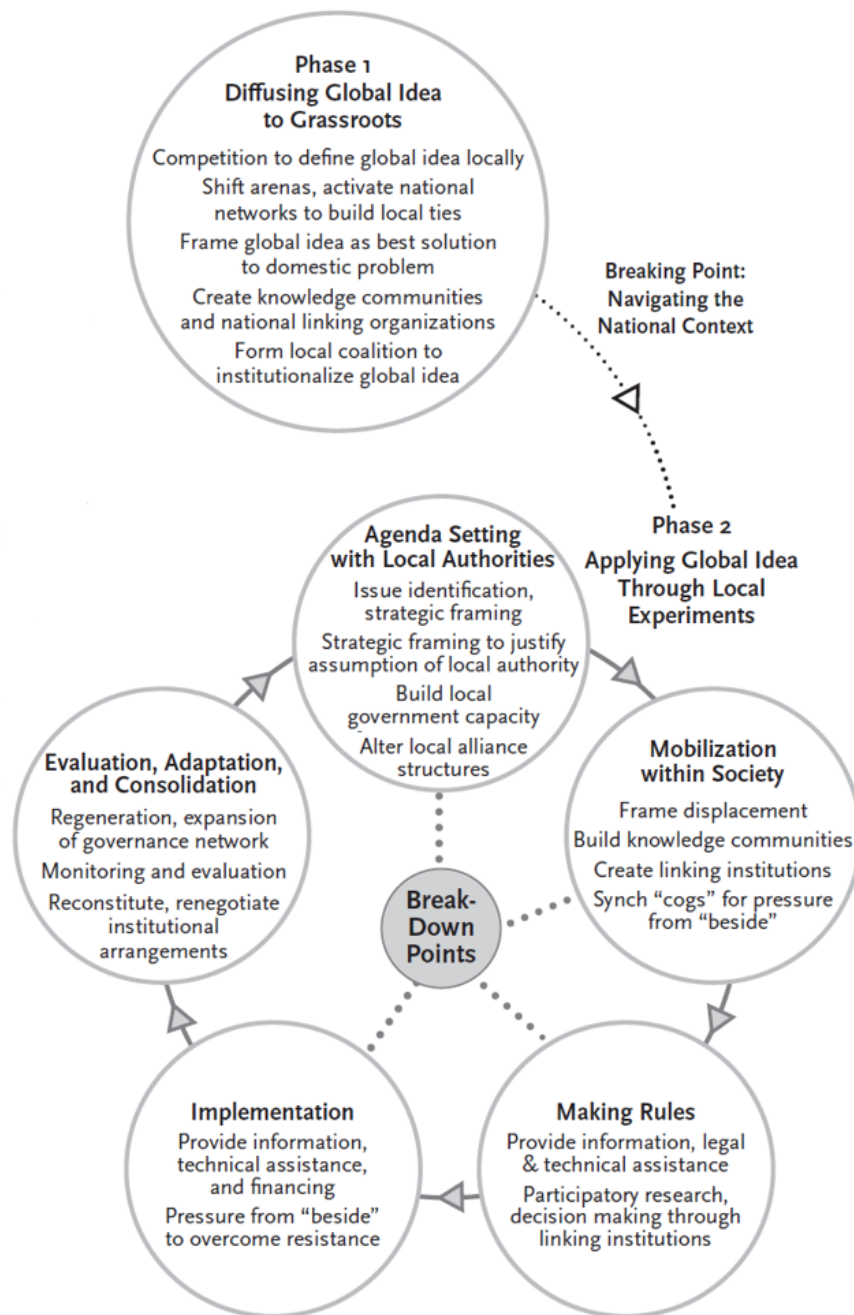
International relations scholars have long recognised the relevance of norms in international politics. Part of the literature in this field has been dedicated to understanding the life cycle of international norms, from their emergence to their diffusion across international organisations or jurisdictions (Finnemore & Sikkink, 1998). Other scholars have attended to the complex process of domestic implementation of international norms, which involves divergent ideas, actors, and power dynamics (Acharya, 2004; Eimer et al., 2016; van Kersbergen & Verbeek, 2016). This literature highlights that the global norm life cycle continues after the norm reaches the domestic setting, and the outcomes of domestic implementation can vary depending on the context in which norms are applied.

In addition to expanding the norm cycle, recent literature has also paid attention to the role of the Global South in norm dynamics. Countries in areas such as Latin America were often seen as norm takers, passively adopting norms from the Global North. More recent works have shown the contrary, portraying non-Western regions as places with normative agency, actively shaping global rules (Fukuda-Parr & Muchhala, 2020; Eimer et al., 2016; Helleiner, 2014). For example, the analysis of Eimer et al. (2016) shows that the implementation of international norms related to IPRs in Brazil and India led to a creative reinterpretation of rules from international agreements. Understanding the role of the Global South as norm entrepreneurs suggests that these countries may promote policy integration for sustainable development in various ways depending on how international norms and regulations are internalised.

Kauffman's (2017) grassroots global governance theory provides an excellent framework that addresses the domestic adoption of global norms. Drawing on the case of watershed management in Ecuador, Kauffman (2017) shows the active role of actors in the Global South in shaping norms domestically and internationally. Kauffmann (2017) argues that the domestic level is not just the object of global governance but a space that transforms and creates norms. Even though this thesis is not focused on grassroots movements at the local level, Kauffman's

(2017) framework is useful in explaining how domestic actors adapt global ideas to fit national contexts. Figure 2.1 presents an adapted version of Kauffman’s (2017) theory, focusing on the application of global ideas at the domestic level. As the figure shows, non-state actors play a crucial role in shaping global norms through various strategies, including agenda-setting, mobilisation, providing information to policymakers, and monitoring results.

Figure 2.1: Kauffman’s (2017) Grassroots Global Governance Process (adapted)



Source: Adapted from Kauffman (2017, p. 23).

A central element in Kauffman's (2017) theory is the global ideas and debates that influence domestic discussions. Competing views on norms and differences in how countries implement them exist because global ideas tend to be "meta-concepts" that are often broad and ambiguous. Sustainable development is one of these cases where meta-concepts can lead to variance in implementation. As shown in the literature, the definition of sustainable development is a contested process that reveals different views on sustainability (Connelly, 2007). While the UN SDGs provide more concrete measurements of the norm, they are still a broad concept that can present significant variances in domestic implementation.

This thesis builds on Kauffman's (2017) theory to understand the agency of domestic and transnational non-state actors in shaping policy integration for sustainable development. The domestic adoption of meta-concepts is particularly interesting in the case of the SDGs since it is an agenda that can be implemented in many forms since there are 17 different goals to be implemented. Although the 17 goals help countries operationalise and implement the 2030 Agenda, they also allow countries to cherry-pick specific goals that are easier to implement or politically convenient (Ferrón Vélchez et al., 2022; Forestier & Kim, 2020). This thesis empirically investigates how this meta-concept is integrated into policymaking and whether some parts of the 2030 Agenda have more relevance than others, highlighting the active role of domestic actors in this process.

Critically, Kauffman (2017) argues that the national context acts as a filter that shapes transnational networks' capacities to influence policymaking. Transnational actors must navigate countless formal and informal norms and political institutions that can enable or constrain their capacities to engage with local actors and expand their networks. If transnational actors are not capable of overcoming these filters, they will not be successful in promoting domestic change. This framework is also helpful in explaining policy integration. Transnational firms must overcome contestation and opposition when promoting their views on patent protection and sustainable development. As such, the framework used in this thesis considers both domestic and international variables since the interplay of actors and instruments on both levels helps explain policy integration for sustainable development.

2.2.2 The Implementation and Tailoring of International Patent Commitments

The previous subsection described sustainable development as a meta-concept, underscoring that countries may implement the SDGs in various ways depending on domestic implementation processes. In contrast, patent protection is a more concrete form of international regulation defined by formal provisions in international trade agreements. Although trade agreements imply certain expectations regarding how countries implement patent regulation, they often have flexibilities that leave room for interpretation (Correa, 2022; Ruse-Khan, 2011b). Ultimately, the implementation of trade agreements depends on the interpretation of their provisions. This subsection focuses on tailoring as a theoretical concept that helps explain policy integration. Tailoring refers to the process of adjusting international patent commitments to fit the national context. This subsection shows that the implementation of domestic patent regulation is an iterative and path-dependent process in which countries decide whether to implement flexibilities and constantly revise previous regulatory choices.

This thesis is mainly concerned with new regulatory developments in the field of patent protection that become opportunities for policy integration for sustainable development. Such regulatory developments are often part of long-term processes of implementation and tailoring of international patent commitments. Since the introduction of the TRIPS Agreement in 1995, developing countries have chosen different paths in the implementation of patent regulation that have influenced domestic legislation and future regulatory developments. For example, this thesis shows that Brazil adopted provisions on patent term extensions during the implementation of the TRIPS Agreement in the 1990s, which shaped recent changes to patent regulation (see Chapter 5).

The theoretical framework utilised in this thesis draws on Deere Birkbeck's (2008) seminal book on the implementation of the TRIPS Agreement, which highlights patterns across countries and develops a theory on how developing countries implement international trade regulation. Deere Birkbeck (2008) analyses variation in TRIPS implementation across developing countries, arguing that the implementation of IPRs is a complex political game in which the main actors are developed and developing countries. These actors are supported by a range of stakeholders, including firms, CSOs, international organisations, academics, trade officials, and national IP offices. The author also indicates that countries can present

variance in their implementation of the TRIPS Agreement depending on how they approach its flexibilities, a crucial variable for policy integration.

The variation in implementation of the TRIPS Agreement identified by Deere Birkbeck (2008) provides the background to explain recent changes in patent regulation in Latin America. Most importantly, the domestic implementation of international patent regulation is not a static process, and countries constantly revise and adjust patent regulation to tackle new challenges or solve issues created by previous choices in the implementation of trade agreements. This iterative process is well explored in Shadlen's (2017) work, which describes the implementation of patent protection for pharmaceuticals in Latin America in two stages. The first stage took place with the entry into force of the TRIPS Agreement, as countries were obliged to introduce patents for pharmaceutical products. During this stage, policymaking conflicts revolved around establishing novel pharmaceutical patent systems to implement the international agreement.

In the second stage, new conflicts emerged because of the pharmaceutical patent system in place. As a result, new policymaking conflicts revolved around resolving these issues in the process of 'tailoring' or adjusting national patent systems to make them more compatible with national conditions. This process of tailoring patent regulation is crucial for policy integration since it creates opportunities to revise existing regulations and mainstream sustainability goals. As the SDGs emerged as new global goals in international and domestic politics, countries may use sustainability goals to promote changes to patent protection, integrating patent regulation with sustainable development objectives.

Tailoring patent regulation depends on the distributional effects of the regulation in place. Shadlen (2017) argues that the longer the time between the first implementation of patent rights and the tailoring process, the stronger the patent system's legacies. For example, if an existing regulation is beneficial for certain groups, such as transnational pharmaceutical firms, it can be challenging for state and non-state actors to promote subsequent tailoring that reduces those benefits. This is the case for patent term extensions, one of the cases examined in this thesis in Brazil and Chile (see Chapters 5 and 6). Patent term extensions are beneficial for innovative, transnational firms that can extend the duration of their patents due to administrative delays in approval. Governments can find it challenging to tailor or amend

these regulations once in place due to contestation from powerful domestic and transnational actors.

In sum, drawing on the theories of tailoring (Shadlen, 2017) and variation in TRIPS implementation (Deere Birbeck, 2008) enables a focus on the implementation of domestic patent regulation as an iterative and path-dependent process. An iterative process allows countries to reassess the outcomes of current regulations and provides opportunities for policy integration for sustainable development. Most importantly, patent regulation is path-dependent, and regulatory choices during the implementation of the TRIPS Agreement or TRIPS-plus PTAs produce outcomes that can benefit specific groups to the detriment of others. The struggles of tailoring patent regulation in the context of rising concerns with sustainable development might provide the right opportunity for policy integration. In this context, coalitions among state and non-state actors play a crucial role in promoting tailoring, a variable explained in the next section.

2.3 Conditions for Policy Integration

The previous sections outlined concepts and theories to examine the integration of patent protection for sustainable development as a political process and identified key variables at the international and domestic levels to investigate integration. This section combines theories related to the (international) political economy of patent regulation, global governance, and policy integration, to identify the main conditions (variables) in the theoretical framework that will be interrogated through the empirical analysis. Section 2.3.1 discusses policy space as an essential variable to enable policy integration. Section 2.3.2 introduces the main variables related to state and non-state actors and their role in policymaking. Finally, Section 2.3.3 outlines coalitions as a variable for policy integration for sustainable development.

2.3.1 Policy Space

Policy integration is a process that involves tackling cross-cutting issues and breaking down policy siloes. I argue that creating integrative policies depends on the policy space available for policymakers. The concept of policy space is often used in the literature on the

implementation of the TRIPS Agreement (Ruse-Khan, 2009; Thrasher, 2021) but has not been applied to the context of policy integration for sustainable development or the implementation of the SDGs. This thesis assumes that policy integration can be significantly hindered in cases where countries do not have policy space to create or adjust patent regulations.

Policy space is understood in the context of this research as the legal and political “boundaries within which decision-makers can create policies” (Jackson, 2021, p. 1). These boundaries result from trade relations and the expansion of international trade law that can restrict a country’s ability to pursue policies that support its social and economic development (Mayer, 2009; Shadlen, 2005). One of the main fields where developing countries have made concessions in their policy space is patent protection. The TRIPS Agreement entered into force in 1995 and represented a crucial change in the international IP regime, introducing a new set of rules to be implemented by all WTO members (Deere Birkbeck, 2008; Helfer, 2004, 2009). In the field of patents, for instance, the TRIPS Agreement provides a minimum of 20 years for patent protection in all fields of technology,⁷ meaning that countries that did not grant patents to pharmaceuticals had to amend their IP laws (with some countries offered a period in which to do so based on their developing or least developed country status).

Policy space in the field of patent regulation is closely related to TRIPS flexibilities, i.e., the “possible variations in the manner in which the TRIPS Agreement’s provisions are interpreted and implemented” (Correa, 2022, p. 4). These flexibilities allow countries to implement the agreement and design policies that are adequate to their domestic needs, giving them room to manoeuvre to address public interest issues or deliver public goods (Ruse-Khan, 2009; Thrasher, 2021). These flexibilities, however, have become more restricted as new regional and bilateral PTAs have increased the level of patent protection with the so-called “TRIPS-plus provisions”. Some examples of TRIPS-plus provisions related to patents are the extension of patent duration, data exclusivity, patent linkage, and limitations of the grounds for compulsory licenses (Gleeson et al., 2019; Morin, 2006). Since these TRIPS-plus provisions concede extended rights to patent owners, they can reduce competition, restrict the gaps and

⁷ TRIPS Agreement, Article 27, paragraph 1: “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. (...)”.

ambiguities left in the TRIPS Agreement, and hinder the development of sustainable development policies in the Global South (Kuanpoth, 2006; Ruse-Khan, 2011a; Yu, 2021). Table 2.1 provides examples of TRIPS-plus provisions in PTAs signed by Latin American countries and their policy space effects.

Table 2.1: Examples of TRIPS-Plus Provisions and Their Policy Space Effects.

TRIPS-plus provision	Definition	Example	Policy space effects
Patent term extension	Provisions that extend the duration of patent protection beyond 20 years.	US-Chile PTA, Article 17.10.2: “With respect to pharmaceutical products that are subject to a patent, each Party shall: (a) make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process.”	Patent term extensions extend monopoly terms, hindering competition. Extended patent terms can also result in high costs for pharmaceutical production, reducing access to a wider population.
Patentability scope	Provisions that ensure the patentability of particular inventions, including plants and animals.	US-Colombia PTA, Article 16.9.2: “Any Party that provides patent protection for plants or animals on or after the date of entry into force of this Agreement shall maintain such protection.”	Patentability scope reduces countries’ capacity to define patentability criteria domestically. These provisions can expand monopoly rights to fields closely related to sustainability, such as biodiversity.
Revocation restrictions	Restricts revocation rights for patents to cases of fraud and misrepresentation, limiting TRIPS flexibilities.	US-Central America PTA, Article 15.9.4: “Each Party shall provide that a patent may be revoked or cancelled only on grounds that would have justified a refusal to grant 15-16 the patent. However, a Party may also provide that fraud, misrepresentation, or inequitable conduct may be the basis for revoking, cancelling, or holding a patent unenforceable.”	This provision restricts a country’s ability to revoke patents on other grounds, such as in public interest cases.

TRIPS-plus provision	Definition	Example	Policy space effects
Data exclusivity	Data exclusivity provisions protect clinical data submitted by a pharmaceutical company from being used by other firms for market authorisation. This type of provision often imposes data exclusivity for five years.	US-Chile PTA, Article 17.10.1: “If a Party requires the submission of undisclosed information concerning the safety and efficacy of a pharmaceutical or agricultural chemical product which utilizes a new chemical entity, which product has not been previously approved, to grant a marketing approval or sanitary permit for such product, the Party shall not permit third parties not having the consent of the person providing the information to market a product based on this new chemical entity, on the basis of the approval granted to the party submitting such information. A Party shall maintain this prohibition for a period of at least five years from the date of approval for a pharmaceutical product and ten years from the date of approval for an agricultural chemical product. Each Party shall protect such information against disclosure except where necessary to protect the public.”	This type of provision prevents competitors (generic pharmaceutical producers) from using the same clinical data as the first patent applicant, thereby hampering the entry of generic drugs into the market. Consequently, such provisions can affect access to medicines.

Source: Author’s elaboration based on Morin and Surbeck (2020).

Another important distinction within policy space is the formal and legal (de jure) autonomy that states have to create policy and the de facto policy autonomy (Mayer, 2009). In this thesis, policy space is understood as both the legal boundaries within which patent regulation can be designed and the government’s ability to contest these boundaries. The first element refers to the international legal commitments in the field of IPRs, as described above. The legal policy space is particularly relevant to understanding differences in policy integration across regulatory areas. This thesis assumes that restricted legal space due to trade agreements can

limit the scope of integration achieved in the policy design. Therefore, the more stringent the international patent commitments, the less room to manoeuvre domestic actors have in promoting sustainable development issues.

The political dimension of policy space refers to the political feasibility of promoting changes to domestic patent policy regulation. This political feasibility is strongly affected by the influence of trade partners (in particular, the US) on domestic policymaking. Ideas are central to understanding how trade partners and domestic state and non-state actors connect. As described by Sell and Prakash (2004), IP politics are inherently ideational. Different and often opposing views on patent regulation are key to understanding policy integration for sustainable development. Policymakers with an ideological stance similar to the US government and transnational firms are more likely to promote stronger patent protection. In contrast, policymakers with an ideological stance similar to CSOs are likely to promote TRIPS flexibilities and safeguards.

Scholars have shown that, during the negotiations and implementation of the TRIPS Agreement, the US government and transnational companies played a crucial role in deploying economic and political pressure on developing countries (Deere Birkbeck, 2018; Palmedo, 2020). In addition, Shadlen (2008, 2017) shows that developing countries engage in PTAs with developed countries with TRIPS-plus provisions (patent regulations which can limit integration for sustainable development goals) based on their trade dependence with those developed countries. In addition, the export sector in developing countries can push for the adoption of stringent patent regulations to strengthen trade relations with developed countries (Shadlen, 2008, 2017).

In this sense, integrating patent protection and sustainable development might create conflicts between the two trade partners and become a political issue for these countries. Policy space can be strongly limited by these political pressures, which take various forms through government and non-state actions. The influence of these transnational actors can explain hesitancy in promoting policy integration for sustainable development when this integration means imposing limits on the rights of patent owners.

Transnational firms can also directly pressure developing countries to implement strong patent regulations. This pressure often takes place through the work of industry organisations as part of transnational networks, such as organisations that work to advocate for the rights

of transnational pharmaceutical firms. Industry organisations played an important role during the negotiation of the TRIPS Agreement (Sell & Prakash, 2004) and the domestic implementation of patent regulation (Deere Birkbeck, 2008; Shadlen, 2017). In such cases, industry organisations can pressure domestic governments to maintain certain levels of patent regulation, usually opposing attempts to curtail patent protection.

Considering both legal and political dimensions of policy space, international patent commitments and international pressure from trade partners are expected to reduce the policy space where developing countries can design policies that integrate patent protection and sustainable development issues. These variables are, therefore, included in the theoretical framework (see Section 2.4). The operationalisation of these variables is discussed in the next chapter.

2.3.2 State and Non-State Actors

The previous subsection showed that international regulation and transnational actors can shape policy integration for sustainable development in Latin America. This subsection explains the domestic side of policy integration and the actors involved in this process. State and non-state actors are crucial to understanding policy integration for sustainable development since they use the available policy space to promote regulatory changes and influence policymaking outcomes. This subsection describes these actors and their role in integrative policymaking, identifying them as crucial variables for the theoretical framework.

Policymaking takes place in governmental institutions, such as IP offices, the legislature, and ministries. These institutions are arenas where different actors can promote their ideas on policy integration for sustainable development. State actors play a central role in these arenas since they are responsible for proposing the tailoring of patent regulation, incentivising the participation of non-state actors, or removing sustainability issues from patent-related discussions. In this context, political elites and congress representatives can be instrumental in promoting policy integration (Cejudo & Trein, 2023b).

This thesis assumes that policy integration for sustainable development can change significantly depending on the arena where it takes place. Notably, the relationships between state and non-state actors can allow certain ideas on policy integration to be promoted while

rejecting others. These relationships are particularly relevant in the field of patent regulation, where there are normative struggles between the protection of and access to technology and knowledge.

This struggle of normative views is a prominent variable in Deere Birkbeck's (2008) work, where the TRIPS implementation is described as a fight for ideas. On both sides of the implementation spectrum, actors make strategic use of ideas and knowledge to shape governmental views on the need for IP reforms or to promote the use of TRIPS flexibilities. For example, during the implementation of the TRIPS Agreement, IP advocates, such as multinational firms, built the normative idea that their property must be protected as it was necessary for the public good. These arguments were crucial in mobilising actors in developing countries where TRIPS compliance left little room for manoeuvre. On the other hand, resistance from developing countries and CSOs was based on the normative argument that more patent protection could undermine access to knowledge and public goods. Although Deere Birkbeck (2008) explains the role of ideas in the context of the TRIPS Agreement, this thesis shows similar dynamics in current regulatory developments in Brazil and Chile with TRIPS-plus provisions and TRIPS flexibilities.

The negotiations and implementation of international patent commitments (i.e., the TRIPS Agreement and other trade agreements) are contentious political processes. The domestic negotiations of access to and protection of knowledge and technology often create political cleavages between domestic and transnational groups. Among these actors, CSOs have been particularly vocal in raising awareness of patent protection's impacts on public goods (Matthews, 2011). The literature on the international political economy of patent protection has paid particular attention to the role of these groups in advocating for TRIPS flexibilities that can explain policy integration for sustainable development.

A prominent example of civil society activism to promote the use of policy space in developing countries took place right after the signing of the TRIPS Agreement. In the late 1990s and early 2000s, the HIV/AIDS epidemic highlighted the struggles some countries faced in accessing antiretroviral drugs due to patents granted to pharmaceutical companies (Hein & Moon, 2013; Matthews, 2011; Sell & Prakash, 2004). In this period, governments from the Global South and

CSOs confronted the international patent protection regime to promote access to medicines and the use of TRIPS flexibilities.⁸

In the field of sustainable development, authors have also highlighted the role of CSOs in shaping the global sustainability agenda. Sénit et al. (2017) underscore that the negotiations of the SDGs involved an extensive process of consultation with civil society organisations across various countries. However, they find variance in how CSOs participate depending on how consultations are designed and the inclusiveness they promote. Participatory spaces are, therefore, crucial elements to understanding the power CSOs have to shape policy outcomes (Gaventa, 2006). This thesis shows that participation varies significantly domestically depending on the arena where policymaking takes place, affecting policy integration for sustainable development.

Like CSOs, industry groups can also influence policy integration for sustainable development. These groups can represent a myriad of interests, such as generic pharmaceutical producers, innovative industries, and the export sector. For example, the domestic industry can object to the tailoring of patent regulations since it can damage the country's relationship with trade partners. On the other hand, other domestic groups might incentivise tailoring to ease access to patented technologies.

Countries with more robust innovation systems might be more interested in implementing more stringent patent regulations to protect their industry, reducing policy space. On the other hand, countries with less innovative industries might be more interested in using the existing flexibilities of the patent system to incentivise the domestic industry. These dynamics have been documented by Shadlen (2017) in the pharmaceutical industry but can be applied to other areas as well.

These domestic industry groups can directly affect policy integration for sustainable development. These groups can justify their position in relation to the use of flexibilities and the adequate level of patent protection based on the provision of public goods for sustainability. The academic debate on the effectiveness of the patent system in promoting sustainable development is at the centre of these groups' arguments for more or less patent

⁸ See Hein & Moon (2013), Matthews (2011), Sell and Prakash (2004), and Thrasher (2021) for a more comprehensive account of the role of civil society organisations and coalitions in response to the HIV/AIDS epidemic.

protection. For example, innovative firms often justify strong patent protection as a requirement for innovation in key sustainability areas. As such, policy integration for sustainable development means implementing high levels of patent protection. In contrast, other firms may argue that sustainability is only achieved with TRIPS flexibilities that allow competition and access to technology, arguing for limits to patent protection. This is the case with the generic pharmaceutical industry, which is often harmed by TRIPS-plus protection that extends pharmaceutical monopolies.

The contentious politics of patent protection have historically shown that this is an ongoing struggle where interests diverge, and both sides argue for different outcomes. This thesis shows that policy integration for sustainable development depends on policymakers' capacity to use the opportunity of tailoring patent regulation to promote sustainability goals. This capacity is directly related to the influence of these different non-state actors, shaping policy integration.

2.3.3 Coalitions

A final element to understanding the influence of domestic and transnational actors in policymaking is how they build coalitions. Coalitions bring actors with similar interests together, creating stronger narratives to shape policy outcomes. Coalitions can be formed by different types of actors, including interest groups, political parties, and state actors (Fischer & Maggetti, 2016). For example, different industries or sectors might build coalitions at the domestic level to promote their perspective on policy integration and strengthen their lobbying capacity with the government. Similarly, transnational actors can build coalitions with domestic actors to ensure that their interests have a voice in the domestic arena (Saguié, 2007; Yanacopulos, 2005).

Shadlen's (2017) work is again helpful for this research in that it shows how the presence of coalitions at the domestic level informs the degree of compliance with international patent regulation in Latin America. Shadlen (2017) argues that when transnational actors pressuring for strong patent protection mobilise local actors and do not face contestation from opposing groups, it is more likely that the country will over-comply with international standards. This type of coalition is the case, for instance, of the export sector, which can be mobilised to

advocate for over-compliance with patent regulation if they believe this compliance will result in better relations with major trade partners, such as the US.

On the other hand, when coalitions for over-compliance cannot expand their influence due to strong opposition from domestic groups, the result will be minimalist compliance. Shadlen (2017) shows that, in Argentina, over-compliance with patent rules was not possible because the domestic pharmaceutical sector, which is mostly a producer of generic drugs, was strong enough to contest transnational actors. Since transnational actors could not expand their coalitions due to domestic resistance, they could not influence the Argentinian patent system. Thus, the mobilisation of domestic actors is key to the success or failure of campaigns led by transnational actors.

2.4 Theoretical Framework

Drawing on the theoretical perspectives presented above, Table 2.2 presents the theoretical framework utilised in this research. The first component of the framework focuses on explaining how Latin American countries have integrated sustainable development and patent protection. This component draws on theories on the domestic implementation of global norms to understand how the global agenda is translated domestically. As explained above, global meta-concepts, such as sustainable development, vary significantly in their domestic implementation. As such, it is crucial to consider how these concepts are used in domestic policy. The case of the SDGs is particularly interesting, since countries often choose specific parts of the 2030 Agenda to implement rather than the entire agenda. Issue salience is a concept that helps understand what policymakers identify as priorities for national interests.

The concept of tailoring (Shadlen, 2017) is also central to the first component of the framework. Tailoring patent regulation is a common process in developing countries, and this thesis investigates policy integration for sustainable development in the context of recent tailoring initiatives in Latin America. This theoretical framework views tailoring initiatives as opportunities for Latin American countries to integrate sustainability issues into patent regulation.

Table 2.2: Theoretical Framework.

Research question	Theoretical constructs	Variables
1) To what extent have Latin American countries integrated sustainable development objectives into patent regulation?	Domestic implementation of global meta-concepts (Kaufmann, 2017)	Policy integration of patent protection and sustainable development (Dependent Variable)
	Tailoring of patent regulation (Shadlen, 2017)	
	Salience in policy integration (Kefeli et al., 2023)	Issue salience (Independent Variable)
2) What conditions promote policy integration for sustainable development in the field of patent regulation in Latin America?	Policy space (Jackson, 2021)	Legal policy space (international commitments) (Independent Variable)
		Political policy space (political and economic pressure) (Independent Variable)
	Political arenas for policy integration (Cejudo & Trein 2023b)	State actors (Independent Variable)
3) How do these conditions generate policy integration?	Non-state actors and patent protection (Deere Birkbeck, 2008; Kauffman, 2017; Matthews, 2011; Shadlen, 2017)	Non-state actors (Independent Variable)

The second component of this framework is focused on identifying the conditions for policy integration for sustainable development and explaining how they operate. The concepts and variables in this component are based on the theoretical perspectives from the literature on the (international) political economy of intellectual property rights. The first variable as a condition for integration is policy space. Policy space refers to the legal and political space that countries have to design policies. In the case of this thesis, this space indicates how much room to manoeuvre Latin American countries have in tailoring initiatives. The second set of variables refers to the domestic side of policy integration and includes legal policy space (international commitments), political policy space (political and economic pressure), and the role and influence of state and non-state actors, including CSOs and industry groups.

Chapter 3

Researching Policy Integration for Sustainable Development: A Mixed-Methods Approach

Chapter 2 presented the theoretical framework guiding this thesis and outlined the crucial variables for investigating policy integration for sustainable development in Latin American patent regulation. This thesis analyses these variables collectively rather than the individual effect of each condition on policy integration. Therefore, studying these variables requires a research design that takes into consideration different configurations of conditions. This chapter introduces the mixed-methods approach used in this thesis to interrogate the impact of different configurations of these conditions on policy integration for sustainable development in patent regulation in Latin America.

This chapter proceeds as follows. Section 3.1 provides a brief reminder of the study aim, situating the research questions in the methodological approach. Section 3.2 details the research design adopted to answer the research questions, and Section 3.3 describes the case selection. Section 3.4 explains data collection and analysis for each part of this thesis. Finally, Section 3.5 discusses research limitations.

3.1 Situating the Research Questions in the Methodological Approach

This thesis aims to improve understanding of the conditions that enable policy integration for sustainable development using patent regulation in Latin America as a case study. In the previous chapter, I demonstrated that international and domestic variables shape policy integration for sustainable development, which may look different depending on the combinations of political and economic conditions in Latin American countries. As such, this thesis answers the following research questions:

Research Question 1: To what extent have Latin American countries integrated sustainable development objectives into their patent regulation?

Research Question 2: What conditions promote policy integration for sustainable development in the field of patent regulation in Latin America?

Research Question 3: How do these conditions generate policy integration?

These research questions aim to unveil Latin American countries' particular political and economic structures and dynamics that shape how patent regulation and sustainable development are integrated during policymaking. This research follows a pragmatic constructivist underpinning (Haas & Haas, 2002), which locates ideas about politics and the world within the social conditions from which they emerge and are constructed, and views institutions as venues where these ideas develop. As this thesis shows, policy integration of patent protection and sustainable development varies depending on the context of each Latin American country and the different political arenas where it takes place.

This thesis answers these research questions using a mixed-methods methodology that combines a Qualitative Comparative Analysis (QCA) with in-depth case studies. This approach is suitable for studying causal relations between political and economic variables that influence policymaking processes related to policy integration (Fischer & Maggetti, 2016; Rihoux et al., 2011).

3.2 Research Design: Case-Based Mixed-Methods

This thesis applies a combination of case-based methods, which “help us both to elucidate causation and to specify the range of applicability of our account of causal mechanisms” (Byrne, 2009, p. 2). A QCA was conducted to analyse configurations of conditions for policy integration in 17 Latin American countries (Section 3.2.1). From this analysis, two countries were selected (Brazil and Chile) to investigate two types of patent regulation (patent term extensions and compulsory licensing) as a multiple-case study (Section 3.2.2). Combining QCA with case studies provides a comprehensive ‘bird’s eye view’ of the key variables shaping policy integration for sustainable development in patent regulation in Latin America, with nuanced and in-depth analysis of specific instances on the ground. The temporal scope of this research is from 2015 to 2022, which reflects the most current period of the implementation of the 2030 Agenda since its creation in 2015.

3.2.1 Qualitative Comparative Analysis

QCA is a mixed-methods approach widely used in social sciences that combines qualitative and quantitative techniques (Berg-Schlosser et al., 2009; Rihoux et al., 2013). One of the main advantages of QCA is that it allows the analysis of causal complexity, i.e., when the “outcome may follow from several different combinations of causal conditions” or causal pathways (Ragin, 2008, p. 23). In this sense, QCA allows observing configurations of conditions rather than the net effect of each variable on outcomes (Berg-Schlosser et al., 2009; Ragin, 2008). This aspect is particularly relevant for this thesis since it aims to understand the role of different variables (or conditions) that, when combined, enable or hinder policy integration. In addition, unlike correlational methods that often use large-N, the QCA approach allows researchers to observe causal relations in smaller samples. Therefore, another advantage of this method is that it is suited to studies with small or intermediate-N focused on a specific sample (Ragin, 2008).

QCA is a set-theoretic method in which cases are conceptualised as elements belonging to certain conditions and outcomes. QCA was designed initially to analyse configurations of crisp-set memberships. In crisp-set QCA (csQCA), cases are assigned one of two membership scores in each set analysed: 1 (membership in the set) or 0 (non-membership in the set). Fuzzy-set QCA (fsQCA) extends crisp sets, allowing membership scores in the interval between [0] and [1]. Since partial membership is possible in fsQCA, it allows for a more precise analysis of each condition and configuration (Ragin, 2008; Schneider & Wagemann, 2012). This thesis applies fsQCA since it allows for more fine-grained scaling of membership scores.

The application of QCA in this thesis follows four steps. The first step is the definition of the theoretical framework guiding the analysis (detailed in Chapter 2). Based on this framework, the second step is the selection of the cases, conditions, and outcomes. A total of 17 Latin American countries were selected (Section 3.3) and the relevant conditions and outcomes were operationalised (Section 3.4). In the third step, membership scores for each case and conditions were set. This process, known as calibration, is based on substantive qualitative knowledge of the cases. Finally, in the fourth step, the fs/QCA software (Ragin & Davey, 2022) was used to analyse the dataset created with cases, conditions, and outcomes. Chapter 4 (QCA) describes these different steps in detail and presents the results of the analysis.

QCA is an excellent method to analyse the combination of conditions that lead to policy integration of patent protection and sustainable development. QCA is an exciting method for policy studies, providing evidence of causal connections between variables and the outcome. This kind of evidence can help guide future policymaking processes, indicating the multiple possible pathways to achieve sustainability goals in patent regulation. This method allows a comparative analysis of several Latin American countries, highlighting patterns in the region and suggesting combinations of conditions that are further examined using in-depth case studies. Case studies complement the findings of the QCA with a more detailed account of how the different conditions operate in practice and the forms in which they interact with each other. This thesis analyses four case studies, outlined in the next subsection and detailed in Chapters 5 (Brazil) and 6 (Chile).

3.2.2 Qualitative Case Studies

As defined by Gerring (2004, p. 342), a case study is “an intensive study of a single unit for the purpose of understanding a larger class of (similar) units”. Delving into case studies allows familiarity with each case’s context, social structures, and particularities that would otherwise not be fully understood. Case study designs are particularly appropriate for research that aims to answer “how” and “why” questions and to consider contextual conditions as relevant to the phenomenon studied (Baxter & Jack, 2008; Yin, 2015). Therefore, a case study design is appropriate for this research since it unveils causal mechanisms while considering each country’s uniqueness in its policymaking processes and social dynamics.

The research design adopted in this thesis is a multiple-case study with four cases. These four cases can be divided into two types of patent regulation: patent term extensions and compulsory licensing. Each type of regulation is analysed for Brazil and Chile. The rich, in-depth analysis of the case studies facilitates a cross-case analysis, provided in Chapter 7 (Discussion). The same analytical framework guides each case study, allowing the combination of evidence from the four cases, underscoring their differences and similarities, and allowing a synthesis of the findings across cases and methods.

Case studies are a research design commonly applied in the analysis of the implementation of patent protection in developing countries. Most notably, Matthews (2011) and Shadlen (2017)

explore the implementation of patent regulation using a multiple-case study research design. These studies successfully examine the socioeconomic factors that influence patent law and policymaking in several related areas, including innovation and access to medicines. Case studies are often used to study the implementation of the SDGs and policy integration, giving a nuanced perspective on domestic approaches to sustainability (Diep et al., 2020; Koch & Krellenberg, 2018; Masuda et al., 2021).

This thesis utilises a mixed-methods approach, combining a QCA and case studies for a more comprehensive understanding of policy integration (Schneider & Rohlfing, 2013, 2014). Although other scholars have used QCA to study policy integration (Trein et al., 2020b, 2023), these studies are focused on issues other than patent regulation and sustainable development (Baulenas & Sotirov, 2020; Train et al., 2020a). In addition, other authors have applied QCA to examine sustainability issues (e.g., Bazzan et al., 2022; Marks et al., 2018) but do not focus on patent regulation or policy integration. Therefore, this thesis provides a novel contribution to studying policy integration for sustainable development in the field of patent regulation.

3.3 Case Selection: Patent Regulation in Latin America

This thesis examines policy integration for sustainable development, focusing on patent regulation in Latin America. The QCA provides a regional analysis, and the case studies are focused on Brazil and Chile and two specific types of patent regulation (patent term extensions and compulsory licensing). This section explains the rationale behind these case selections. Section 3.3.1 explains the choice of Latin America as the focus of this thesis. Section 3.3.2 discusses the selection of Brazil and Chile for the case studies. Finally, Section 3.3.3 details patent term extensions and compulsory licensing as relevant patent regulations.

3.3.1 Latin America

Latin America is a compelling region to study the intersection of patent regulation and sustainable development. I chose to focus this research on Latin America for two main reasons. First, Latin America provides a unique example of a region with a diversity of trade agreements and, consequently, international patent regulation commitments. Latin American countries, similar to all country members of the WTO, must comply with the WTO TRIPS

Agreement and provide a minimum period of patent protection of 20 years to all innovations, regardless of the technology field. However, several countries in the region are also parties to bilateral or regional PTAs with substantive TRIPS-plus and TRIPS-extra content. As shown in Table 3.1, most countries in the region have engaged in such PTAs, except for the Common Market of the South (MERCOSUR) countries (Argentina, Brazil, Paraguay, and Uruguay),⁹ Venezuela, and Cuba. Selected PTAs in Table 3.1 are limited to the US, EU, and the European Free Trade Association (EFTA) since these trade partners are often the ones introducing patent and patent-related TRIPS-plus provisions that increase the levels of patent protection (Morin & Surbeck, 2020).

Table 3.1 also shows countries' membership to the International Union for the Protection of New Varieties of Plants (UPOV). As explained in Chapter 1, UPOV conventions have significant implications for patent rights related to plant breeders' rights. Critically, UPOV standards prioritise plant uniformity and stability, which may accelerate current trends of biodiversity loss (Kochupillai & Königer, 2022), affecting SDGs 14 and 15. Table 3.1 indicates that countries in the region have committed to different UPOV conventions and requirements that might affect policy integration for sustainable development.

Chapter 2 (Theoretical framework) showed that this thesis understands policy integration as directly connected with policy space. Legal policy space can be significantly reduced when countries commit to TRIPS-plus provisions in trade agreements. Therefore, it is essential to take into consideration the diversity of patent and patent-related commitments (e.g., UPOV, data exclusivity) that can affect how countries promote the integration of patent regulation and sustainable development.

⁹ These countries are signatories of an economic agreement with the European Union with TRIPS-plus content, but this agreement has not been ratified.

Table 3.1: International Patent Commitments in Latin America.

Country	Code	Relevant PTAs	UPOV Convention
Argentina	ARG	NA	UPOV 1978
Bolivia	BOL	NA	UPOV 1978
Brazil	BRA	NA	UPOV 1978
Chile	CHL	US, EU, EFTA	UPOV 1978
Colombia	COL	US, EU, EFTA	UPOV 1978
Costa Rica	CRI	US, EU, EFTA	UPOV 1991
Ecuador	ECU	European Union	UPOV 1978
El Salvador	SLV	US, EU, EFTA	NA
Guatemala	GTM	US, EU, EFTA	NA
Honduras	HND	US, EU, EFTA	NA
Mexico	MEX	US, EU, EFTA	UPOV 1978
Nicaragua	NIC	US, EU	UPOV 1978
Panama	PAN	US, EFTA	UPOV 1991
Paraguay	PRY	NA	UPOV 1978
Peru	PER	US, EU, EFTA	UPOV 1991
Uruguay	URY	NA	UPOV 1978
Venezuela	VEN	NA	NA

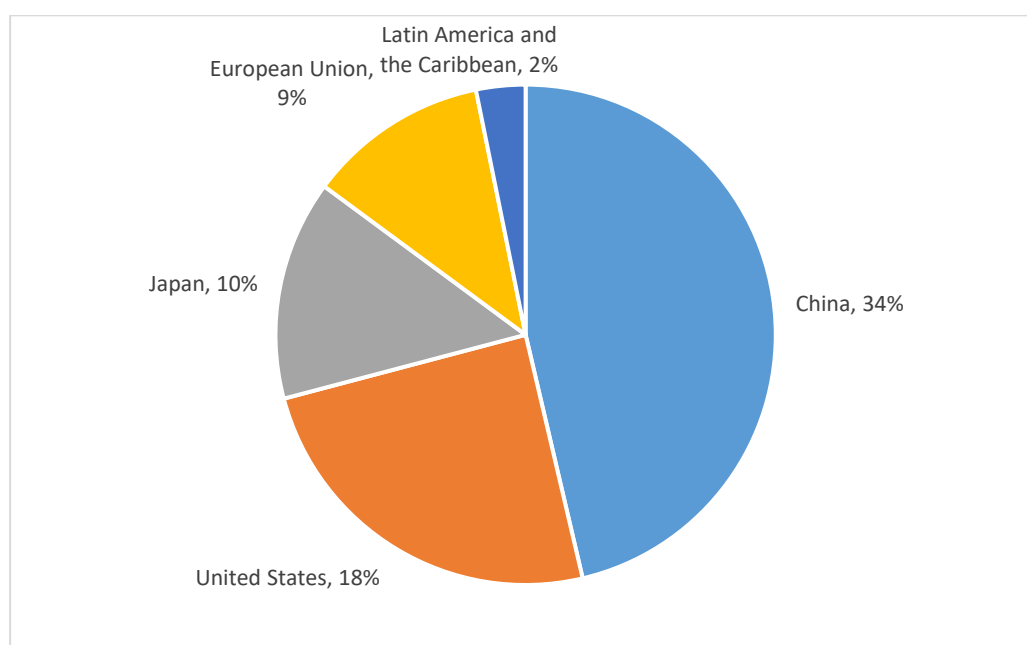
Source: Morin and Surbeck (2020), UPOV (2023).

The second reason for the selection of Latin America is the region's place in global innovation. As argued in the previous chapters, policy integration of patent protection for sustainable development involves political and economic processes related to the production of and access to knowledge and technology related to sustainability. Figure 3.1 shows the participation of Latin American countries in the total number of patents granted in the world for selected technologies (biotechnology, environmental technologies, and pharmaceuticals). These countries accounted for 2% of patents granted between 2015 and 2022.

This minor role in global innovation situates the countries in the Latin American and Caribbean region as technology importers rather than intensive technology producers or exporters vis-à-vis their main trade partners. This technology-importing position can be an important driver

for the contestation of international patent regulation and the promotion of policy changes domestically (Reichman, 2009; Serrano, 2016). The domestic contestation of international regulation is where sustainable development goals can be advanced or integrated. Because of this combination of international regulatory commitments with domestic contestation, the Latin American region is suitable for the study of policy integration for sustainable development. This diversity of commitments represents different degrees of legal policy space that can influence domestic actors' ability to promote policy integration.

Figure 3.1: Total Patents Granted Between 2015-2022 in Selected Countries and Technologies.



Source: WIPO IP Statistics (WIPO, 2022).

The QCA enables an analysis of all Latin American countries except island countries (i.e., Cuba and the Dominican Republic). The scope of this selection is 17 countries (listed in Table 3.1). The decision to focus on these countries was based on their cultural proximity to facilitate the comparative analysis. Caribbean countries, such as Guyana and Suriname, presented different historical and institutional characteristics and were excluded from the analysis. In addition, the 17 countries presented publicly available information required to conduct this research, such as their VNRs (i.e., voluntary reports on SDGs implementation) and data on patent grants.

3.3.2 Brazil and Chile

The second part of this thesis analyses the extent of policy integration for sustainable development through the qualitative analysis of two types of patent regulation in Brazil and Chile. I chose these two countries based on the QCA results following recommendations in the literature for case selection for in-depth analysis after conducting a QCA (Schneider & Rohlfing, 2013). There are different strategies to select case studies from QCA results depending on the research goals. Schneider and Rohlfing (2013) suggest that selecting typical cases, or cases that presented the outcome, increases the confidence that there is a link between the solution and the outcome. This comparative analysis of typical cases is particularly robust in building or testing hypotheses on causal mechanisms. While other approaches to case selection can also enrich the analysis, such as comparing typical and deviant cases, the goal of this thesis is to understand how different conditions (variables) interact and enable policy integration for sustainable development in patent regulation in Latin America. Therefore, the comparative analysis of typical cases is best suited to answer the research questions of this thesis.

As will be discussed in Chapter 4, the QCA results indicate two paths of possible combinations of conditions (variables) which can lead to policy integration for sustainable development, and either could be included in the in-depth analysis. However, I chose to explore Path 1 in the case studies as it has a more robust explanatory capacity (higher consistency and coverage in the dataset). Additionally, choosing two countries in the same solution path allowed me to focus on the causal processes of that path, highlighting the different ways that the conditions identified in the QCA promote the outcome.

Brazil and Chile were both identified from the QCA results as enabling policy integration for sustainable development through Path 1, which indicated that the absence of US trade dependence and the presence of civil society access to policymaking enabled policy integration for sustainable development. These countries were selected because both promoted recent changes in patent regulation, focusing on the same types of regulation (i.e., patent term extensions and compulsory licensing).

Brazil is a compelling country to study the integration of patent protection for sustainable development. Since the implementation of the TRIPS Agreement, conflicts between domestic and transnational actors have shaped the country's patent regulation and responses to health

crises (see Chaves et al., 2007; Meiners, 2008). Chile, in contrast, was one of the first Latin American countries to engage in PTAs with substantial patent commitments, adopting TRIPS-plus provisions that can affect the achievement of sustainability goals since the early 2000s (Roffe, 2004).

Finally, choosing countries with the same QCA result helps understand the different ways that the outcome (policy integration for sustainable development) takes place. The operationalisation of policy integration in the QCA and the case studies was undertaken in different ways, allowing a more nuanced understanding of policy integration as a context-contingent, heterogeneous phenomenon. In the QCA, policy integration is operationalised as a binary variable, focused on the presence of patent regulation in VNRs and the presence of sustainability goals in TRIPS Council interventions (see Chapter 4). In the case studies, policy integration is operationalised as the presence of sustainability goals in patent regulation (see Chapters 5 and 6).

The case selection for this thesis provides an innovative approach to case studies after QCA. While most authors underscore the use of case studies to confirm QCA results, compare contrasting cases, or analyse outliers (Schneider & Rohlfing, 2013), the approach taken in this thesis shows that selecting countries with the same result can yield a more nuanced, in-depth understanding of the processes linking conditions and variance in the outcome.

3.3.3 Patent Term Extensions and Compulsory Licensing

This subsection explains the patent regulations investigated in the qualitative, in-depth case studies in both Brazil and Chile. Patent regulation is an umbrella term for various types of regulation related to patent rights, including the duration of patent terms and patentability requirements. It also includes patent-related regulation that affects patent owners, such as data exclusivity. Each type of regulation has different implications for patent rights holders and users that can affect policy integration for sustainable development.

The approach taken in this thesis to analyse policy integration was to identify relevant regulatory developments in the selected countries (Brazil and Chile) during the timeframe of this study (2015-2022). Based on initial interviews with experts in these countries (see Section 3.4), I identified two types of patent regulation that were negotiated, reformed, or proposed

in both countries in this period that could affect the SDGs, namely patent term extensions and compulsory licensing. These were cases of domestic tailoring of patent regulation in ways that enabled integration with the SDGs (primarily through access to medicines) in both countries.

Patent term extensions are a form of TRIPS-plus regulation, i.e., a regulation that protects the standards of the TRIPS Agreement. This type of protection is a common requirement in bilateral trade agreements with high-income trade partners, most notably the US and EFTA (Morin & Surbeck, 2020). The primary justification for patent term extensions is delays in patent prosecution. Since backlogs in patent examination are a common issue globally, many countries compensate inventors who have their patents negatively affected by administrative delays, extending the total term of patent protection. Countries use various legal mechanisms to grant such extensions, such as the US term adjustments as foreseen in Section 154 of the Patent Act (35 USC § 154) and the European Supplementary Protection Certificate (Regulation EC N.469/2009).

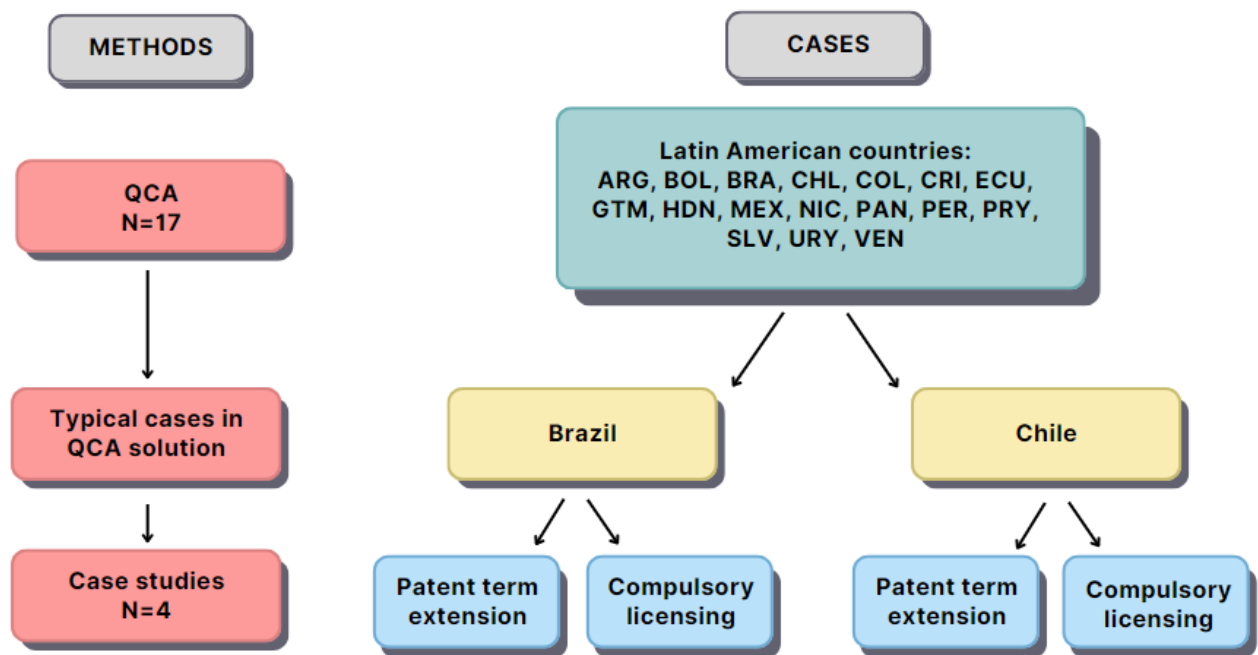
Patent term extensions are an excellent type of regulation to understand policy integration for sustainable development. As a TRIPS-plus regulation that affects sustainable development, it is an example that can enable novel insights into how countries implement and tailor commitments from PTAs, underscoring the role of domestic policy space for policy integration. In both Brazil and Chile, policymakers promoted initiatives to reduce the duration of such extension for reasons linking its effects to sustainability goals. However, the scope and outcome of these initiatives depended on a combination of economic and political factors within each country, as the results in Chapters 5 and 6 show.

Compulsory licensing presents a different type of regulation as it is a WTO TRIPS flexibility. According to the TRIPS Agreement, countries are allowed to grant compulsory licenses to respond to public health emergencies. The WTO Doha Declaration reinforces this right and states in Article 4 that the TRIPS Agreement “can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all” (Doha Declaration, 2001, Article 4). Even though compulsory licenses are recognised in the Doha Declaration as a legal mechanism that countries can apply to fulfil public health objectives, developing countries still seem reluctant to implement them. The limited global application of compulsory licenses happens for numerous reasons, including limited domestic capacity and possible international retaliation

(Beall & Khun, 2012). As this thesis shows, both countries presented reluctance to promote new legal tools for compulsory licensing. Nevertheless, they still achieved policy integration using existing tools or limiting the scope of application of new legislative initiatives, as shown in Chapters 5 and 6.

Figure 3.2 summarises the research design and case selection.

Figure 3.2: Research Design and Case Studies.



3.4 Data Collection and Analysis

The research conducted in this thesis involved collecting data from a variety of sources. For each step of this research (QCA and case studies), I collected and analysed different data that required knowledge of the region and the two countries selected for the case studies. For the QCA, a combination of qualitative and quantitative data was retrieved from public sources and coded (calibrated). The case studies used a combination of legislative proceedings, policy documents, news articles, and interviews. This section details the data used in this research and the methods employed during the analysis.

3.4.1 Qualitative Comparative Analysis

The QCA tests combinations of conditions that lead to an outcome. The outcome of the QCA in this thesis is the integration of patent regulation and sustainable development. As explained in detail in Chapter 4, policy integration was operationalised in the QCA as the mention of sustainability goals in interventions at the TRIPS Council and the mention of patent regulation in Voluntary National Reviews (VNRs). The conditions tested are international patent commitments, trade dependence, domestic innovation capacity, and civil society access to policymaking. The choice of these conditions was based on the analytical framework presented in Chapter 2. The data collected for the QCA is secondary data and publicly available. After collecting and analysing the relevant data, I created a dataset with the QCA conditions and outcomes (see Appendix A, Table A1).

For the outcome (policy integration), I retrieved VNRs from the UN Economic Commission for Latin America and the Caribbean (ECLAC) portal for the SDGs (UN ECLAC, 2023), collecting 40 VNRs published by the 17 Latin American countries between 2015 and 2022. I analysed each VNR individually, searching terms related to patent regulation and coding each instance according to the section or SDG they related to (e.g., SDG 3 – Health and well-being, SDG 9 – Industrialisation and innovation). I coded [1] for countries mentioning patent regulation in SDGs and [0] for those not mentioned. Instances where patent regulation appeared in a broader context, without referring to any particular goal, were also coded as [1].

For the TRIPS Council interventions, I searched for sustainability issues from the WTO database of TRIPS documents and meetings (e-TRIPS Gateway) (WTO, 2023). I searched for the terms “health”, “energy”, “biodiversity”, “sustainability”, and “sustainable development” in all meetings taking place from 2015 until 2022. I retrieved 26 interventions and coded them individually according to the issue related to sustainability mentioned in the intervention.

The data sources for international patent commitments are the TRIPS-plus dataset (Morin & Surbeck, 2020), the official list of UPOV members (UPOV, 2023), and the OECD webpage (OECD, 2023). I coded the memberships of each country to TRIPS-plus trade agreements with the US, UPOV 91 Convention, and OECD membership. This coding allowed me to take into consideration different patent and patent-related regulatory commitments.

Trade dependence, similar to TRIPS-plus PTA membership, was narrowed down to the US for feasibility and relevance of the US as an actor. This variable is particularly relevant to assess Latin American countries' trade dependence on a significant trade partner that can retaliate against loose compliance with international patent regulation or the use of flexibilities. The data source for trade dependence is the World Integrated Trade Solution Database (WITS) (World Bank, 2023).

Domestic innovation capacity was operationalised using Global Innovation Index (GII) reports for the period 2015-2022 (WIPO, 2023) and WIPO's patent applications (PATENTSCOPE Database) (WIPO, 2022). I coded the eight GI reports, searching for mentions of Latin American countries, and entered the value in the database. From WIPO's database, I collected the absolute number of patent applications by residents in the period 2015-2022 and entered them into the database.

Lastly, civil society access to policymaking was measured using Varieties of Democracy (V-Dem) scores for the variable "CSO consultation" (Coppedge et al., 2023) and each country's classification in the CIVICUS Civic Space Monitor 2022 (CIVICUS Monitor, 2022).

The dataset resulting from data collection was calibrated for QCA using the calibration process detailed in Chapter 4.

3.4.2 Interviews

Interviews with experts and actors working in the fields of patent regulation and sustainable development are an effective method to collect information on the policymaking processes. The interview process for this thesis consisted of the identification and recruitment of relevant actors, the elaboration of semi-structured interviews, and the analysis of the data.

I conducted interviews with experts in three countries. The participants selected were involved in the process of policymaking related to intellectual property rights and sustainable development goals in various forms, such as policy design, institutional management and coordination, and social activism. The participants include government officials, international organisation practitioners, activists, academics, and lobbyists.

The recruitment process involved contacting relevant institutions, such as national patent offices, as well as an online search for relevant non-state actors. Snowball sampling, i.e., a process in which interviewees recommended other potential participants, also helped identify relevant participants. The purposive and snowball sampling adopted in this thesis allowed the identification of primary state and non-state actors in policymaking.

The process of recruitment and interviewing took place in two stages. The first stage was a preliminary round of interviews with relevant actors and experts in three countries (Brazil, Chile, and Costa Rica).¹⁰ This first round of interviews aimed to provide knowledge on recent developments related to patent regulation and the three areas included in the QCA (health, energy, and biodiversity). The interviews also aimed to understand the implementation of the SDGs in each country. I conducted a total of 12 interviews in this first round. The content of the interviews helped delimit the scope of this thesis. Given the results of the QCA and the similarities in recent regulatory developments in Brazil and Chile, the scope of this research was restricted to these two countries.

The second stage was a more comprehensive round of interviews to understand the different actors involved in the case studies. In this round of interviews, I interviewed 21 participants, including academics, policymakers, industry representatives, and activists. The number of people working in each area varied depending on availability and size of the country. Table 3.2 shows the number of interviews conducted in each country.

I interviewed all participants virtually, using videoconferencing software. The interviews were recorded and transcribed for analysis. All participants were de-identified. The analysis of the interviews involved identifying themes related to the analytical framework in the participants' answers. Table 3.3 shows some examples of questions targeted directly to the variables of the analytical framework introduced in the previous chapter.

¹⁰ Costa Rica was initially chosen for the case study analysis as it is a key country in international negotiations related to biodiversity and IPRs (Aistara, 2012).

Table 3.2: Total Interviews Conducted.

	Brazil	Chile	Costa Rica
Government	4	6	3
CSOs	8	2	1
Industry	1	2	0
Others (academics, practitioners)	1	2	3
Total	14	12	7

Table 3.3: Examples of Interview Questions Based on the Variables.

Variables	Questions
Policy integration	• What was the motivation for the policy/regulatory changes? • How were sustainability issues introduced in the discussions? • How does your organisation understand the intersection of patent regulation and sustainable development? • Does the approved legislation/policy promote sustainability goals?
Policy space	• What constraints were faced during the negotiations? • How was the engagement of the transnational sector? • Did transnational firms and trade partners object to the proposal?
Domestic non-state actors	• What organisations were involved in drafting the legislation/policy? • Was there mobilisation from CSOs? How did this mobilisation take place? • Did the domestic industry engage with the proposal? What sectors were involved? How did this engagement take place? • Did the export section object to the proposal? • Did your organisation participate in formal or informal coalitions with other non-state actors? Why?
State actors	• Who proposed the legislation/policy? Why? • How did the institution allow the participation of non-state actors?

3.4.3 Case Studies

The analysis of the case studies necessitated an in-depth knowledge of each case. This required the careful analysis of legal proceedings, supported by interviews and news articles. Each of the four cases required collecting data related to many legislative processes. The findings of the case studies are divided into two chapters, one for each country, covering patent term extensions and compulsory licensing (Brazil in Chapter 5 and Chile in Chapter 6).

This research uses different data sources for data triangulation. Drawing from multiple data sources is crucial to validate the findings and develop a more comprehensive understanding of the context and subject studied (Carter et al., 2014; Natow, 2020).

The primary data sources for Chapter 5 (Brazil) are official documents related to the policymaking process. In the case of patent term extensions, I retrieved and analysed documents submitted to the Supreme Court by actors participating in the unconstitutionality claim (ADI N. 5,529) and official documents produced by the Supreme Court Ministers or other governmental entities. These documents are publicly available online on the Brazilian Supreme Court's website (Supremo Tribunal Federal, 2023). In total, I retrieved 440 documents. From these documents, I selected 203 documents, which reflected actors' positions and official statements. Finally, I removed documents that appeared more than once or were submitted by actors not officially approved as *amicus curie*. The final number of records analysed was 192. Of these documents, 58 were submitted by the *amici curie* to present their views on the issue, and 102 were additional documents submitted as evidence to support their arguments. The remaining 33 documents included governmental documents submitted by the Brazilian Attorney-General, the Supreme Court, and other relevant government entities.

In the case of compulsory licensing, I retrieved and analysed the official proceedings from the Brazilian Congress and Senate related to law proposals N. 12 and Law N. 14,200. The source of these documents is the official website of the Brazilian Congress (Congresso Brasileiro, 2023). These proceedings included the different versions of the law proposal as well as official reports from the different commissions in both legislative houses responsible for evaluating the legislative draft. I also included in the analysis the position of Congress and Senate representatives and the presidential veto. Documents from non-state actors, including CSOs and transnational firms, were also included. In addition to these documents, I used information from interviews with civil society organisations, policymakers, industry organisations, and academics. I triangulated this data with news articles, grey literature, and the official websites of the actors involved.

Chapter 6 (Chile) draws on similar data sources. The primary data sources are the proceedings from the Chilean Congress and Senate. These documents are publicly available online at the Library of the Chilean National Congress (Biblioteca del Congreso Nacional de Chile [BCN],

2023). These documents cover the entire legislative process for Law N. 21,355, i.e., discussion in Congress and the Senate and the economic and financial commissions in each house from 2018 to 2021. Other legal documents (hepatitis C and COVID-19 resolutions) were also retrieved from the Library of the Chilean National Congress. News articles and interviews with Chilean government officials, policymakers, industry, and civil society complement this data.

Finally, I also conducted an analysis of all USTR 301 Special Reports from 2015-2022. I collected all reports from the USTR Website and analysed each report to identify reactions from the US regarding changes in domestic patent regulation in Brazil and Chile. In total, eight documents were analysed, and the data was used in both Chapters 5 and 6.

The qualitative analysis of interviews, policy documents, and grey literature was based on a thematic analysis to identify and interpret patterns of meaning (Braun & Clarke, 2022). This approach is suited to understanding how certain groups of actors conceptualise a particular phenomenon (Joffe, 2012). The identification of patterns in qualitative data allowed an analysis of the conditions for policy integration for sustainable development based on policymakers' and non-state actors' understandings of this phenomenon.

This research takes an abductive approach, i.e., there is an iterative process between theory and empirical work. While data collection started with certain theoretical assumptions about the phenomenon studied, the empirical observation revealed which parts of the existing framework needed to be adjusted. According to Timmermans and Tavory (2012, p. 170), abduction allows researchers to produce "new hypotheses and theories based on surprising research evidence". For example, in the interviews and documents, I searched for evidence for political policy space. To do so, I identified documents or quotes from relevant actors showing the possibility of retaliation from firms and trade partners influencing the policy outcome.

3.5 Limitations

Finally, it is essential to acknowledge the limitations of this research design. First, the operationalisation used in the QCA reflects a particular understanding of how the theoretical variables can be observed in real life. Therefore, policy integration, as well as the conditions, can be operationalised in various ways. Using other data sources and calibration measures can

result in different results from those presented in this thesis. The operationalisation used in this thesis reflects the best data available to measure the variables selected for the QCA. Another limitation of the QCA approach is the limited number of cases in this thesis. However, while adding more cases to the QCA could increase empirical diversity, the results show strong explanatory capacity, as explained in Chapter 4.

I also faced some limitations in conducting the in-depth case studies. Although most documents used in this thesis were publicly available and retrieved from online sources, some supplementary material, such as meetings between IP policymakers and firms, are not available. However, most of this type of information could be retrieved through interviews or other sources. Another limitation is related to participant recruitment. The number of potential participants in the field of patent protection in Latin America is relatively small. Snowball sampling helped identify more participants, but several potential participants never responded to my emails or refused to be interviewed. In these cases, I relied on publicly available documents to identify those actors' relevance and actions during policymaking.

Chapter 4

Pathways for Policy Integration for Sustainable Development in Latin America

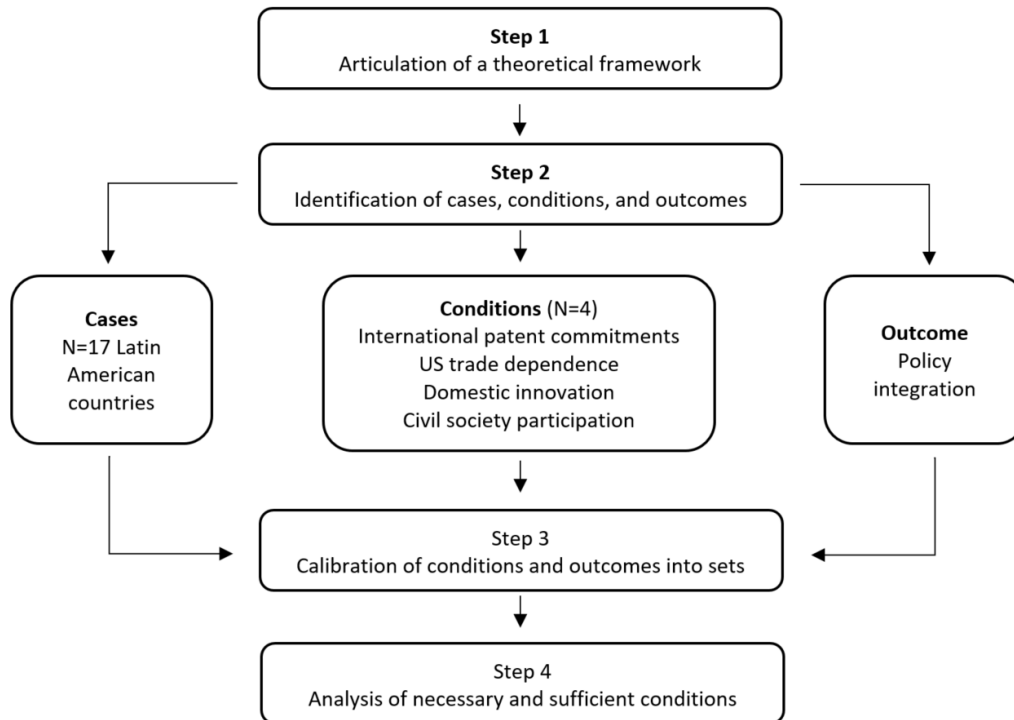
This thesis argues that policy integration for sustainable development is context-contingent and dependent on a combination of domestic and international factors that influence policymaking processes. In other words, policy integration is not the result of one single variable but a combination of conditions, and the different configurations and interactions among conditions shape policy outcomes. Chapter 3 introduced the research design applied in this thesis, explaining its case-based mixed-methods approach to examine policy integration for sustainable development in Latin America. This chapter details the first step of this empirical research, which is a Qualitative Comparative Analysis (QCA) of 17 Latin American countries.

In this chapter, I find that policy integration for sustainable development in Latin America results from a combination of policy space and agency of domestic actors in promoting sustainability goals in the context of patent regulation. While policy space appears in Latin American countries as both legal and political space, the latter presents stronger relevance in explaining policy integration. In addition, the results indicate that participatory policymaking that includes civil society also enables policy integration. This chapter also suggests that domestic innovation is not a relevant condition for policy integration for sustainable development.

The QCA was conducted in four steps, as shown in Figure 4.1. The first step consisted of defining a theoretical framework and the conditions to be analysed. Chapter 2 provides a detailed explanation of the theoretical framework and identifies the main variables. From these variables, four conditions were selected: international patent commitments, US trade dependence, domestic innovation capacity, and civil society access to policymaking. Section 4.1 explains step two, i.e., the operationalisation of the outcome and conditions. Step three is the calibration of the policy integration and the four conditions, detailed in Section 4.2. Section 4.3 describes the dataset used in this chapter, and Section 4.4 presents the results of

the QCA (step four). Section 4.5 discusses the results of the QCA, and Section 4.6 outlines how the results inform the case studies.

Figure 4.1: QCA Analysis Process.



Source: Author's elaboration of the QCA step process, adapted from Ngqangashe et al. (2022).

4.1 Operationalisation of the Outcome and Conditions

The key variables for investigating policy integration for sustainable development, as identified in the theoretical framework in Chapter 2, are issue salience, legal policy space (international commitments), political policy space (political and economic pressure), and state and non-state actors. This chapter focuses on four independent variables: legal policy space (international commitments), political policy space (political and economic pressure), non-state actors (innovative industry), and non-state actors (CSOs). These variables were chosen based on the availability of data that could be operationalised for a QCA. Table 4.1 presents a summary of variables, conditions, and data used in the QCA. This section explains the operationalisation of the outcome, namely policy integration (Section 4.1.1) and conditions (Section 4.1.2).

Table 4.1: Data Used in the QCA.

Variables	QCA condition/outcome	Data
Policy integration	Outcome: Integration of patent protection and sustainable development	• Voluntary National Reports • TRIPS Council interventions
Policy space (legal)	Condition 1: International patent commitments	• Membership to TRIPS-plus PTAs • Membership to UPOV 91 • Membership to OECD
Policy space (political)	Condition 2: US trade dependence	• Trade intensity with the US
Non-state actors (innovative industry)	Condition 3: Domestic innovation capacity	• WIPO's Global Innovation Index • Number of patents granted to residents
Non-state actors (civil society)	Condition 4: Civil society access to policymaking	• CIVICUS classification • V-Dem score for civil society access to policymaking

4.1.1 Outcome: Policy Integration for Sustainable Development

The focal outcome for this QCA is policy integration for sustainable development in the field of patent regulation. For this part of this research, integration is operationalised as the simultaneous mention of patent regulation and sustainable development in policy outputs. The main goal of this operationalisation is to identify whether policymakers consider sustainability issues in policies related to patent regulation and vice-versa. This analysis is looking for evidence that these two policy fields are tackled simultaneously by policymakers rather than assuming what integration looks like. For example, this chapter does not analyse in detail if integration expands or restricts patent rights (Chapters 5 and 6 provide this in-depth analysis).

Considering the complexity of sustainable development, the impacts of patent regulation on sustainable development can be seen across many policy domains (Adbel-Latif & Roffe, 2021; Bannerman, 2020; Rognstad & Ørstavik, 2021). As described in Chapter 1, three areas are prominent in the literature and are explored in this analysis: public health and access to medicines (Correa, 2002; Sell, 2003; Thambisetty et al., 2022), energy transition and climate

change (Brown, 2017; Sampath, 2019; Zhuang, 2017), and biodiversity protection (Jefferson, 2020; Karapinar & Timmerman, 2008; Matthews, 2011). Therefore, throughout the data analysis, I searched for integration in these three fields (explained in more detail in Section 4.2).

I used two sources of data for policy integration: Voluntary National Reviews (VNRs) and interventions at the TRIPS Council produced during 2015-2022. In the first source, integration was documented when countries mentioned patent regulation or related intellectual property issues (e.g., flexibilities, data protection, and access and benefit sharing of genetic resources) in their VNRs. Since VNRs are produced to detail the implementation of the SDGs, the presence of patent regulation in those documents represents national efforts to integrate patent regulation into strategies for sustainable development. A total of 40 VNRs were collected for 17 countries, and of these, 19 indicated at least one policy integration outcome.

For example, the Chilean 2017 report states that the national government will facilitate the implementation of TRIPS flexibilities to improve access to medicines, showing an effort to integrate patent protection and public health (Chilean National Government, 2017). Another example of integration is the creation of regimes to provide access to and benefit from the sharing of genetic resources, linking patent regulation to biodiversity conservation, as described in the Uruguayan 2017 report (Uruguayan National Government, 2017). References to patent protection and innovation in VNRs were also considered in the analysis but measured differently during the calibration of the dataset (see Section 4.2). In some instances identified in this thesis, policy integration occurred in reference to access to medicines or technology (such as the Chilean example above), while in others, it aimed to more generally incentivise innovation in sectors related to sustainable development. For example, Peru's 2020 report indicates that the Institute for Competition and Intellectual Property Protection (INDECOPI) had carried out activities to ensure transparency in the registration of patents related to COVID-19 and incentive domestic innovation in this sector (Peruvian National Government, 2020).

Integration in the second source was noted when countries raised sustainable development issues at the WTO TRIPS Council. The WTO TRIPS Council is the most relevant multilateral forum for WTO members to discuss international patent regulation. Hence, promoting sustainability views in this forum strongly indicates integrated policymaking. This analysis

involved collecting interventions made by Latin American countries that linked patent regulation to health, energy, biodiversity, and sustainable development as an indicator of integration. While the collection of these interventions was not focused on specific forms of policy integration (such as that focused on TRIPS flexibilities), all the data retrieved was related to access to medicines or technology transfer. For example, in 2015, Ecuador defended a mechanism for technology transfer that integrated patent rights and environmentally sound technologies. In 2017, Bolivia supported compulsory licenses to overcome public health issues (WTO, 2023). A total of 24 interventions between 2015 and 2022 were collected.

4.1.2 Conditions

Condition 1 (C1): International patent commitments. While all countries have to comply with the WTO TRIPS Agreement, most countries in Latin America have committed to intellectual property standards that go beyond the multilateral level and require higher standards. As discussed in Chapter 2, countries that must comply with strong patent protection might exhibit reduced (legal) policy space that can limit their capacity to address public interest issues or deliver public goods (Ruse-Khan, 2009; Thrasher, 2021). Commitments beyond the WTO TRIPS Agreement in the context of this research refer to the country's membership to PTAs with TRIPS-plus provisions and to UPOV 91. Membership to the Organisation for Economic Cooperation and Development (OECD) is also considered for this condition since it signals an interest in complying with international trade regulations, including patent protection.

Condition 2 (C2): US trade dependence. The relevance of the US as a trade partner is another crucial variable for domestic policymaking in the field of patent protection. Chapter 2 argues that political policy space refers to limitations in applying flexibilities or changing patent regulation due to the pressure from transnational firms and trade partners. Therefore, this condition measures how compliant with international patent regulation the country might be based on trade pressure (see, for instance, Deere Birkbeck, 2008). This condition is operationalised as the relevance of the US as a trade partner, using the trade intensity index (TII). This index indicates if the trade value between two countries is greater or smaller than expected based on their trade with the rest of the world (World Bank, 2022). Countries with high TII indicate strong export ties to the US and are more vulnerable to trade pressure.

Three reasons justify the focus on the US in this condition. First, the US is a key actor in the diffusion of TRIPS-plus regulation in trade agreements. For instance, all trade agreements between the US and Latin American countries contain provisions that increase the level of patent protection (Morin & Surbeck, 2020). Here, it is important to note that there is an overlap between this condition and the previous one (international patent commitments), as Latin American countries with closer trade relations with the US are expected to be part of trade agreements with this country. Nevertheless, this overlap does not create any issues for this analysis since QCA is designed to unveil configurations of conditions.

Second, the US has historically used unilateral measures to ensure the implementation of patent protection in other countries. Notably, the US uses the USTR 301 Special Report to name and shame countries and justify trade retaliation (Sell, 2010). Lastly, there is a close relationship between the US government and transnational firms that have advocated for stronger patent protection globally (Sell, 2003).

Condition 3 (C3): Domestic innovation capacity. This condition refers to a country's capacity to generate innovation. Although Chapter 3 describes Latin American countries as mostly technology importers, the presence of incipient innovative activities can be a factor for policy integration. WIPO's Global Innovation Index (GII) is used to assess Latin American countries' innovation potential, which considers numerous variables related to the institutional, human, and infrastructure capacity to generate innovation. The GII is substantiated by WIPO's data on domestic patent applications in three areas: pharmaceuticals, environmentally sound technologies, and biotechnology. These two data sources identify countries with outstanding regional innovation capacity, as described in Section 4.2.

Condition 4 (C4): Domestic civil society access to policymaking. As discussed above, CSOs have played a crucial role in linking patent protection to other policy fields, influencing policymaking in patent-related areas, such as access to medicines and biodiversity. Therefore, countries with civil society organisations participating in domestic policymaking are expected to promote the integration of patent regulation for sustainable development. Even though some countries might have strong CSOs, their access to policymaking varies significantly. Therefore, this condition focuses on CSOs' access to policymaking and governments' openness to the influence of these organisations, measured using the Varieties of Democracy (V-Dem) scores for the variable "CSO consultation" (Coppedge et al., 2023) and each country's

classification in the CIVICUS Civic Space Monitor 2022 (CIVICUS Monitor 2022) (see calibration below for more details).

4.2 Calibration

In QCA, the calibration of sets consists of attributing membership scores for all conditions and outcomes. This QCA was calibrated using a four-value approach (0 = fully out, 0.33 = more out than in, 0.67 = more in than out, and 1 = fully in) and was conducted in two steps. First, two main qualitative anchors were defined, classifying cases into full membership [1] and non-membership [0]. The remaining values – first classified as ambiguous – were further analysed to define their membership as either [0.33] or [0.67]. The four-value approach adopted in this analysis allows for more flexibility in attributing membership scores without losing strict qualitative anchoring.

Outcome: Countries with strong policy integration present full membership [1] to the outcome. Strong policy integration means that integration takes place in both sources (VNRs and TRIPS Council) and in at least two of the three policy areas (health, energy, and biodiversity). A score of zero [0] was given to countries with no integration. Cases presenting integration in both sources but in only one policy area, or two policy areas in only one source received a score of 0.67. Countries showing integration in only one policy area and in only one source received a score of 0.33. The data used for this calibration was retrieved from the UN Economic Commission for Latin America and the Caribbean (ECLAC) portal for the SDGs (ECLAC, 2022) and the WTO database of TRIPS documents and meetings (e-TRIPS Gateway) (WTO, 2022).

International patent commitments (C1): Full members [1] of this set are countries with high patent commitments. These countries are signatories to TRIPS-plus PTAs with the US and are members of UPOV 91. Non-members [0] are countries with low regulatory commitments, i.e., only needing to comply with the TRIPS Agreement. A score of 0.67 was given to countries that are party to US TRIPS-plus PTAs but not members of UPOV 91. Countries with a score of 0.33 are not party to these international agreements but have applied to become members of the OECD. The sources for this data are the TRIPS-plus dataset (Morin & Surbeck, 2020), the official list of UPOV members (UPOV, 2023), and the OECD webpage (OECD, 2023).

US trade dependence (C2): The calibration of this condition is based on the trade intensity index¹¹ between the US and each Latin American country in the period 2015-2021. Full membership [1] was attributed to countries with an index higher than 3, showing significant trade dependence. Countries were assigned as non-members [0] if this share was less than 1. If the trade intensity index was between 1 and 1.9, countries received a score of [0.33]. A score of [0.67] was attributed to countries presenting an index between 2 and 2.9.¹² The data source is the World Integrated Trade Solution Database (WITS) (World Bank, 2022).

Domestic innovation capacity (C3): Local innovation is operationalised using the number of times that each country is referred to as an outstanding innovative country in the Global Innovation Index (GII) reports (2015-2022). In addition, the number of domestic patent applications (in the fields of pharmaceuticals, biotechnology, and environmentally sound technologies, 2015-2020) substantiated the calibration.

Full members [1] of this set are countries with robust innovation capacity. These countries are mentioned in all eight GII reports and have a remarkably high number of patent grants. Given the significant discrepancy in patent grants among Latin American countries, only cases with more than 600 grants were considered exceptionally high. Non-members [0] are countries with weak innovation capacity. These countries were not mentioned in GII reports and had zero or very limited patent applications (less than 100). Ambiguous cases are divided into countries mentioned in all GII reports but with less than 600 patent grants [0.67] and countries mentioned in at least one report [0.33]. The sources for this data are WIPO's patent applications database (WIPO, 2022) and GII (WIPO, 2021).

Domestic civil society mobilisation and access to policymaking (C4): Membership to this condition was based on two criteria: Varieties of Democracy (V-Dem) scores for the variable "CSO consultation" (Coppedge et al., 2023) and each country's classification in the CIVICUS Civic Space Monitor 2022 (CIVICUS Monitor, 2022). V-Dem CSO consultation ordinal scale is used to operationalise the relevance of CSOs in policymaking. According to V-Dem's

¹¹ TII is calculated as: $Tij = (x_{ij}/X_{it})/(x_{wj}/X_{wt})$, Where x_{ij} and x_{wj} are country i 's exports and world exports to country j . X_{it} and X_{wt} are country i 's total exports and total world exports, respectively (World Bank, 2022).

¹² In cases where the TII provided a borderline value (e.g., Ecuador), I triangulated this data with other trade data on export trends to the US to confirm set membership in comparison to the other cases. All trade data was retrieved from the World Bank (2022).

Codebook, countries receive a score of 2 if CSOs are important stakeholders, a score of 1 if CSOs are consulted to some degree, and 0 if they are not consulted. The average value of the scores for the period 2015-2022 was analysed in combination with the CIVICUS civil space monitor.

The CIVICUS Monitor categorises countries into five categories. Countries categorised as “open” enable and protect peoples’ ability to enjoy the civic space. In countries with a “narrowed” civic space, individuals and civil society organisations can exercise their rights (such as freedom of association, peaceful assembly, and expression), but violations of these rights also occur. Civic space is “obstructed” if it is contested by those in power holders who impose legal and practical constraints on the complete enjoyment of fundamental rights. “Repressed” countries have significantly constrained civic space, and individuals and civil society organisations face numerous threats, such as imprisonment, injury, and death. Finally, “closed” countries present complete legal and practical closure of civic space.¹³

Full membership [1] was given to countries classified by CIVICUS as “open” or “narrowed” with a V-Dem score of 2. Countries were classified as non-members [0] if they were “closed” or “repressed” with a V-Dem score equal to or lower than 1. Countries with a score of 0.67 are categorised as “narrowed” with a V-Dem score equal to or higher than 1 or “obstructed” with a score higher than 1. Countries with a score of 0.33 are categorised as “obstructed” with a score equal to or less than 1 or “repressed” with a score higher than 1. Table 4.2 summarises the conditions, outcome, and calibration criteria. Appendix A, Table A2 details the scores for the outcome and all conditions for the 17 countries.

¹³ The description of these categories was adapted from the CIVICUS Monitor website (2022), where a complete description of the categories and methodology can be found.

Table 4.2: Summary of Conditions/Outcome and Calibration Criteria.

Conditions/Outcome		Calibration criteria	ID
Outcome:	Policy for integration sustainable development in patent regulation	[1] Integration in both sources (VNRs and TRIPS Council) and at least two of the three policy areas. [0.67] Cases that present integration in both sources but in only one policy area, or two policy areas but in only one source. [0.33] Countries that present integration in only one policy area and in only one source. [0] Countries that did not present any integration.	INTEGR
C1:	International patent commitments	[1] Countries signatory to TRIPS-plus PTAs with the US and members of UPOV 91. [0.67] Countries party to US TRIPS-plus PTAs and members of OECD but not members of UPOV 91. [0.33] Countries that applied to be a member of the OECD. [0] Only TRIPS Agreement.	PATENT
C2:	US trade dependence	[1] Trade intensity index is above 3. [0.67] Trade intensity index between 2-2.9. [0.33] Trade intensity index between 1-1.9. [0] Trade intensity index below 1.	USTRADE
C3:	Domestic innovation capacity	[1] Countries mentioned in all eight GII reports and more than 600 patent grants. [0.67] Countries mentioned in all GII reports but with less than 600 patent grants. [0.33] Countries mentioned in at least one report. [0] Countries not mentioned in GII reports and with zero or very limited number of patent applications (less than 100).	INNOV
C4:	Civil society	[1] Countries classified by CIVICUS as “Open” or “Narrowed” and V-Dem score of 2. [0.67] Countries classified by CIVICUS as “Narrowed” with a V-Dem score below 2 or “Obstructed” with a score higher than 1. [0.33] Countries classified by CIVICUS as “Obstructed” with a V-Dem score equal to or less than 1 or “Repressed” with a score above 1. [0] Countries classified by CIVICUS as “Closed” or “Repressed” with a V-Dem score lower than 1.	CSO

4.3 Data Description

Based on the operationalisation and calibration described above, this section presents a description of the dataset used in this chapter. Figure 4.2 shows the distribution of scores for each condition and the outcome in the QCA results. All cases presented some degree of integration in the period analysed since no country was coded as [0] for policy integration. However, seven countries presented a low score in integration (0.33) since they only promoted policy integration in one policy area or data source. Ten countries presented more consistent integration (scoring 0.67 or 1), showing more consistency in their integration efforts.

The distribution of scores for international patent commitments shows that ten countries in the sample need to comply with standards beyond the TRIPS Agreement. In contrast, seven countries are not signatories to PTAs with the US or members of UPOV 91. Similarly, US trade dependence varies significantly in the region. Three countries present high trade dependence (Costa Rica, Mexico, and Nicaragua), while five are not dependent on the US export market (Argentina, Bolivia, Paraguay, Uruguay, and Venezuela). Figure 4.3 shows that the majority of the countries analysed (10) do not present trade dependence in relation to the US. This data indicates that most countries in Latin America should not be affected by trade pressure. However, the US is a crucial trade partner for several countries, which may hinder integration.

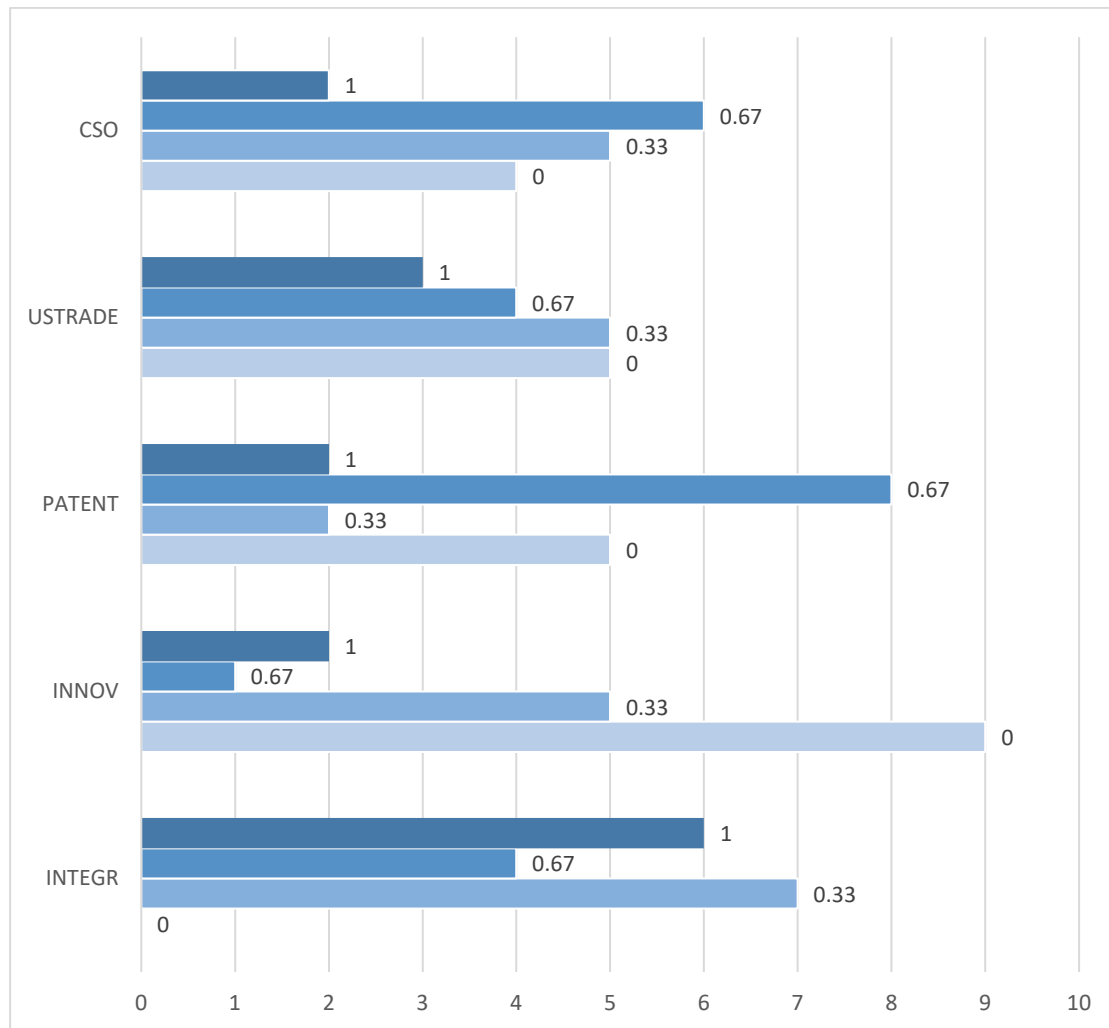
As discussed before, Latin America is not a region with strong innovation capacity in comparison to high-income countries, such as the US and countries in the European Union. Thus, it is not surprising that most countries were coded as [0] in the calibration for domestic innovation. Nevertheless, a few cases received a high score given their comparatively more robust innovation industries.

Finally, Latin American countries were split almost evenly in civil society access to policymaking. A small number of countries scored [1], indicating that CSOs might struggle to participate in policymaking in the region.

Figure 4.3 shows the distribution of policy integration by sustainability area. As Figure 4.3 shows, most of the policy integration identified in the data was related to health. This result was expected, given that almost all countries in the region linked patent protection to public health during the COVID-19 pandemic, which was a key crisis during the research period.

However, the large number of cases with a score of [0.33] indicates that policy integration did not go beyond the health crisis for almost half of the sample. On the other hand, six countries presented strong policy integration, demonstrating a consistent interest in bringing together patent regulation and sustainability.

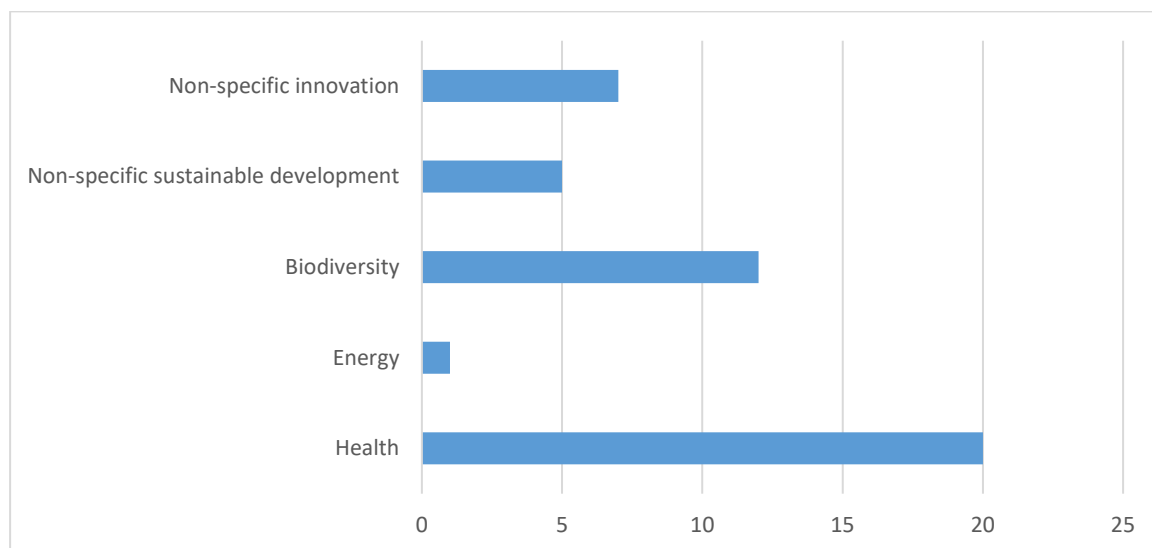
Figure 4.2: Distribution of QCA Calibration by Condition.



Source: Author's elaboration.

Figure 4.3 also shows that energy was the least often tackled topic in policy integration for sustainable development, and several policy documents presented references to patents and innovation without presenting a clear connection between innovation and sustainable development goals.

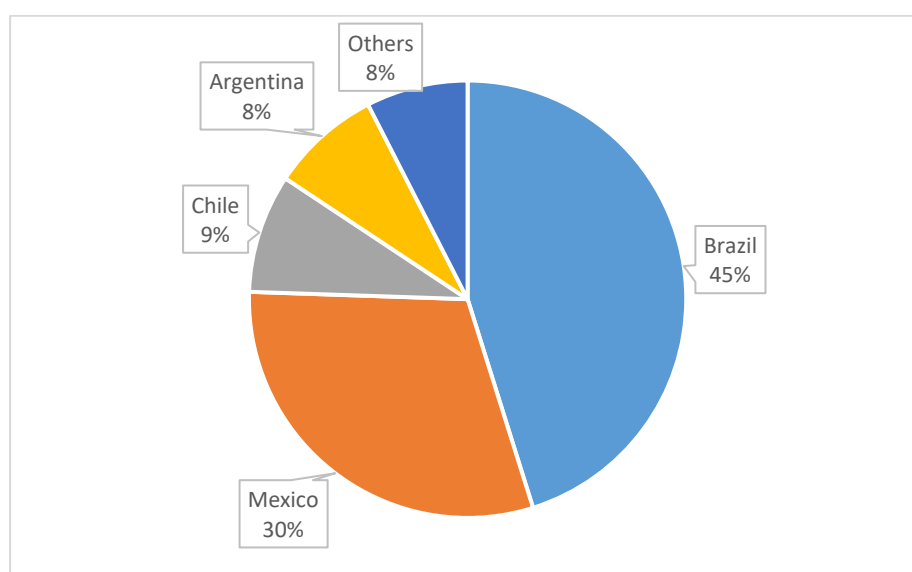
Figure 4.3: Distribution of Policy Integration by Sustainability Area (Number of Policy Documents).



Source: Author's elaboration.

Figure 4.4 presents the distribution of patent grants for residents divided by country. Brazil and Mexico are particularly outstanding in this category, with a much higher number of domestic patent applications than the rest of the region. These countries were also consistently mentioned in all GII reports.

Figure 4.4: Share of Total Patent Grants for Residents in Latin America and Selected Technologies, 2015-2022.



Source: Author's elaboration based on data from WIPO (2022).

Figure 4.5 maps the calibration of policy space, combining international patent commitments with trade dependence. Countries shaded a darker colour on the map exhibit a more restricted policy space (i.e., the sum of scores closer to [2]).

Figure 4.5: Policy Space Restriction Based on International Patent Commitments and Trade Dependence.



Source: Author's elaboration.

Finally, civil society's access to policymaking also varies significantly among cases. Two countries show strong participation of CSOs in policymaking (Costa Rica and Uruguay). Both countries have very high V-Dem scores, indicating that CSOs are often consulted in policymaking. In contrast, four countries (Honduras, Mexico, Nicaragua, and Venezuela) are not open to civil society consultation. Figure 4.6 shows the calibration for this condition. Countries with a score closer to [1] are more open to civil society participation in policymaking.

Figure 4.6: Civil Society’s Access to Policymaking in Latin America.

Source: Author’s elaboration.

4.4 Results

The analysis of the dataset created with the outcomes and conditions is based on *consistency* and *coverage*. Consistency indicates the degree to which the cases sharing a given condition (or combination of conditions) display the outcome. Thus, consistency shows how closely the condition is a subset of the outcome. Coverage, on the other hand, is “the degree to which a cause or causal combination ‘accounts for’ instances of an outcome” (Ragin, 2008, p. 44). Coverage is particularly useful in gauging empirical relevance (Ragin, 2008). It is also important to note that QCA allows the analysis of the presence and absence of the outcome and conditions. However, causality is not assumed to be symmetrical, i.e., the presence and the absence of the outcome may require different explanations (Berg-Schlosser et al., 2009).

The results of the QCA are presented below and divided into two sections: necessity (Section 4.4.1) and sufficiency (Section 4.4.2).

4.4.1 Necessity

The first part of the QCA is the analysis of *necessity*, which assesses whether any conditions are always present when the outcome is also present. In this analysis, the fs/QCA software examines all conditions individually to assess their consistency and coverage. Based on the existing recommendations in the literature, the minimum acceptable level of consistency for the test of necessity was set at 0.9 and coverage of at least 0.51 (Ngqangashe et al., 2022; Paykani et al., 2018).

Table 4.3 shows the consistency and coverage results for each condition. No individual conditions presented a consistency score higher than 0.9 and, therefore, are not individually necessary for integration or lack of integration.

Table 4.3: Analysis of Necessary Conditions.

Conditions tested	Integration		No Integration	
	Consistency	Coverage	Consistency	Coverage
C1: International patent commitments				
Yes	0.484	0.663	0.834	0.625
No	0.726	0.889	0.551	0.368
C2: US trade dependence				
Yes	0.392	0.562	0.779	0.610
No	0.727	0.857	0.441	0.284
C3: Domestic innovation capacity				
Yes	0.302	0.768	0.276	0.384
No	0.758	0.657	0.834	0.395
C4: Civil society				
Yes	0.637	0.912	0.441	0.345
No	0.543	0.640	0.888	0.572

4.4.2 Sufficiency

The next step of the QCA is the analysis for sufficiency. A cause is sufficient but not necessary if it can produce the outcome, “but it is not the only cause with this capability” (Ragin, 2014, p. 99). For the analysis of sufficiency, the “truth table” was constructed (for a detailed explanation of the truth table and the minimisation process, see Duşa (2018)). Since this QCA tests four conditions, the truth table has 16 rows (2^4) reflecting all possible combinations of causal conditions. Only eight combinations of conditions, displayed in Table 4.4, were found empirically in the dataset.

The analysis for sufficiency of conditions considers only the combinations that consistently resulted in the outcome. Based on the literature, the consistency threshold was set at 0.80 (Ngqangashe et al., 2022). The combinations of conditions highlighted in green and orange presented a consistency higher than the threshold. The three last combinations presented a Proportional Reduction in Inconsistency (PRI) score lower than 0.7 and, therefore, were not included in the analysis for sufficiency. Note that the solutions in orange are consistent with the outcome but occurred only once. The analysis includes these solutions since this chapter uses a small sample (17 cases).

Table 4.4: Truth Table and Consistencies for Integration and no Integration.

PATENT	USTRADE	INNOV	CSO	Consistency for				Cases
				INTEGR	PRI	~INTEGR	PRI	
0	0	0	1	1	1	0.305	0	ARG, BOL, URY
1	0	0	1	1	1	0.441	0	PAN, PER
0	0	1	1	1	1	0.284	0	BRA
1	0	1	1	1	1	0.331	0	CHL
0	0	0	0	0.865	0.873	0.466	0.113	ECU, PRY, VEN
1	1	0	1	0.872	0.66	0.751	0.34	CRI
1	1	1	0	0.830	0.493	0.668	0.34	MEX
1	1	0	0	0.687	0.423	0.770	0.576	COL, SLV, GTM, HND, NIC

The fs/QCA software provides three solutions: complex, parsimonious, and intermediate (see Appendix A, Table A3). The intermediate solution, “which tends to be the preferred solution due to its high interpretability” (Paykani et al., 2018, p. 6), suggests that the two configurations are consistent with the outcome integration. These results are displayed in Table 4.5 and Figure 4.7. The intermediate solution has a consistency of 0.893 and a coverage of 0.759. This result suggests that at least 89% of the cases with the solution’s configurations also presented the outcome. The coverage indicates that those combinations were present in 75% of cases with the outcome. The most empirically robust solution is $\sim$ USTRADE*CSO (low trade dependence AND civil society access to policymaking) with a coverage of 0.607.

The parsimonious solution displayed in Appendix A, Table A3 suggests that low trade dependence ($\sim$ USTRADE) presented a consistency of 0.896 and coverage of 0.789. This result indicates that not having the US as a major export partner is sufficient to explain the integration of patent protection and sustainable development.

The truth table analysis of sufficient conditions for no integration ($\sim$ INTEGR) resulted in low consistency (<0.8) for all conditions and configurations. This outcome suggests that the conditions included in this QCA are not sufficient to explain the lack of integration. Due to the asymmetric nature of QCA, it is impossible to infer the results for no integration.

It is noteworthy that this solution presents a high coverage, explaining the outcome for almost all countries in the sample. Nicaragua was the only country that presented integration, but it was not explained in the QCA solution.

Table 4.5: Results of the QCA (Intermediate Solution).

	Outcome: INTEGR	
	Path 1	Path 2
PATENT	-	⊗
INNOV	-	⊗
USTRADE	⊗	⊗
CSO	●	-
Consistency	1	0.857
Raw coverage	0.607	0.214
Unique coverage	0.214	0.152
Cases	ARG, BOL, BRA, CHL, PAN, PER, URY	ARG, BOL, ECU, PRY, URY, VEN
Solution consistency	0.893	
Solution coverage	0.759	

Legend: ● Presence of condition; ⊗ Absence of condition; - Condition not included in the solution.

Figure 4.7: Results of the QCA (Intermediate Solution).



Source: Author's elaboration.

4.5 Discussion of Results

This chapter applies QCA to identify the different configurations of conditions that lead to the integration of patent regulation for sustainable development in Latin America. Drawing on a theoretical framework encompassing both international and domestic variables, this research examines the role of economic and political conditions in the design of integrated policymaking. Based on the framework, four conditions were selected: international patent commitments, dependence on the US as an export market, domestic innovation, and civil society access to policymaking. At the international level, it was expected that strong patent commitments (such as TRIPS-plus provisions in PTAs) and US trade dependence would curb domestic initiatives to integrate patent protection and sustainable development. At the domestic level, it was expected that the lack of domestic innovation activities and strong access of CSOs to policymaking would support policy integration.

The results of this analysis suggest that two configurations are sufficient to explain strong policy integration (Table 4.5). The first path indicates that the combination of low trade dependence and strong civil society access to policymaking leads to policy integration. As discussed in the literature (see Deere Birkbeck, 2008), threats of trade sanctions from the US were a significant motivator for developing countries to implement international intellectual property standards. In this sense, countries might refrain from integrating patent rules with sustainability areas if this integration can result in potential political conflicts with their trade partners. Hence, the result of this QCA indicates that Latin American countries are more willing to tackle patent regulation in the context of sustainability when the risk of trade retaliation is low.

Similarly, the literature indicates that CSOs are essential in raising awareness of the conflicts between patent protection and public goods (Matthews, 2011). In addition, CSOs are essential actors in pushing the sustainable development agenda and promoting social and environmental standards (see Sénit et al., 2017). Therefore, the policy space created by low trade dependence combined with openness to civil society participation in policymaking allows the integration of sustainability concerns into VNRs and their declarations at the TRIPS Council.

The second path indicates that low trade dependence can also act in combination with low international patent commitments and weak domestic innovation. Low patent commitments are expected to positively contribute to the policy space required for integrating patent protection and delivering public goods (Ruse-Khan, 2009). However, this QCA suggests that low trade dependence and low patent commitments require low domestic innovation to produce policy integration. Therefore, the second path suggests that countries dependent on foreign innovation are more willing to promote policy integration. A possible explanation for this result is that countries with weaker innovation systems can raise questions about the impacts of patent regulation on sustainable development without worrying about retaliation from innovative local industries.

As mentioned in the previous section, the first path has higher coverage than the second path. This result does not mean that the second path is irrelevant to this analysis. On the contrary, it shows that the outcome can result from alternate paths, even if the empirical significance of that path is low. In other words, even though less frequent, the lack of civil society access to policymaking can be compensated by the combination of low patent commitments and weak domestic innovation.

Based on the results of the QCA, it is possible to argue that trade agreements can impact policy integration for sustainable development when they restrict policy space. The QCA results support the argument that the ratcheting up of patent protection through international trade agreements can hinder the advancement of mainstreaming sustainable development into patent regulations. At the same time, these results also suggest that domestic interests can dominate international ones. For this to happen, the combination of policy space and domestic interests or access to policymaking must be present. Reconciling policy goals in the field of patent regulation can be challenging when international pressure restricts domestic action. These results underscore the crucial role of domestic actors in providing resistance to these pressures.

Finally, as discussed in Section 4.2, international patent commitments and trade dependence are likely to present overlaps in membership since countries with strong trade relations with the US also tend to be members of US-PTAs. Nevertheless, the results in this chapter show that these two conditions, although related, do not need to be presented simultaneously. This

result suggests that the absence of international patent commitments or the absence of trade dependence can act individually despite the connection between the two.

4.6 From QCA to In-Depth Case Studies

The results presented in this chapter provide exciting insights into the (international) political economy of policy integration that will be further examined with in-depth case studies. The following two chapters examine how the QCA solution operates on the ground. This thesis focuses on the first path, i.e., the absence of trade dependence and the presence of civil society organisations in policymaking. This choice is justified by the more significant consistency and coverage values of this path.

As described in this chapter, most countries in Latin America presented some form of policy integration for sustainable development, especially in the context of the COVID-19 pandemic. Even though the “yes” or “no” coding used in the QCA helps identify where policy integration takes place, this analysis does not provide a clear distinction of the different forms in which integration can occur. The subsequent chapters show a more nuanced analysis of policy integration in Brazil and Chile, emphasising these differences.

In addition, the QCA suggests the combination of conditions that led to policy integration. However, it does not explain how the different conditions interact to produce the outcome. The following chapters investigate how these conditions shape specific policies in Brazil and Chile, unveiling causal mechanisms and alternative explanations for integrated policymaking.

Chapter 5

Navigating Public and Private Interests During the Pandemic: Policy Integration for Sustainable Development in Brazil

The previous chapter presented the QCA results and argued that policy integration for sustainable development results from different combinations of conditions. One of these combinations suggests that policy integration takes place when *civil society participation in policymaking* is present and *trade dependence* is absent. This chapter presents the results from two qualitative case studies in Brazil that occurred during 2015-2022 and demonstrate different degrees of policy integration for sustainable development: patent term extensions and compulsory licensing. The chapter demonstrates that while both of the QCA conditions (civil society and absence of trade dependence) were important to policy integration in these two cases, other important variables were at play that were not captured in the higher order QCA.

The first case is a Brazilian Supreme Court decision to end patent term extensions in Brazil, which was announced in 2021. The second case is a new amendment to the Brazilian Industrial Property Law focused on compulsory licensing, also introduced in 2021. This amendment originated during the COVID-19 pandemic to expand the application of compulsory licenses to technology transfer (i.e., introducing measures to mandate the transfer of know-how from patent owners). Both cases are emblematic examples of policy developments that were nominally directed to change the existing patent law and motivated by sustainable development objectives. However, as this chapter shows, the scope of integration differed between these cases. While the decision to end patent term extensions achieved the proposed integration goals, the amended compulsory licensing change presented a narrower scope of success.

As explained in Chapter 3 (Methodology), this chapter provides an analysis of legal proceedings, official documents, and 14 interviews with actors involved in policymaking and

experts to examine the conditions for policy integration for sustainable development in these patent regulations. The findings outlined below demonstrate that successful policy integration can occur in different ways, presenting significant variations depending on the combination of conditions present during policymaking. This chapter also suggests that, in addition to the QCA conditions (civil society and absence of trade dependence), domestic pharmaceutical firms were key in shaping policy integration for sustainable development. In particular, the combination of normative goals (health) with economic objectives (industrial capacity) provided strong motivation for policy change in Brazil. This chapter also illustrates how international pressure can vary depending on the policy change proposed, shaping the scope of policy outcomes.

This chapter proceeds as follows. Section 5.1 briefly describes the Brazilian Industrial Property Law and the country's prior attempts to shape patent regulation to promote public health goals (which are aligned with sustainable development goals). This section also outlines the two case studies analysed in this chapter: the Supreme Court decision ADI N. 5,529 (patent term extension decision, year 2021) and Law N. 14,200 (compulsory licensing legislation, year 2021). Section 5.2 examines to what extent integration happened in each of the cases, identifies what aspects of sustainability emerged during the policymaking process, and interrogates the role of the QCA conditions in producing these outcomes. Section 5.3 examines three key variables from the qualitative case analysis that further help explain policy integration: policymaking institutions and individuals, the domestic pharmaceutical industry, and the COVID-19 pandemic. Finally, Section 5.4 concludes the chapter.

5.1 Brazilian Patent Regulation: Patent Term Extension and Compulsory Licensing

This thesis investigates the role of different international and domestic variables in shaping policy integration for sustainable development. In Chapter 1, I showed that current patent regulation in Latin America is the result of the implementation of international trade agreements and adjustments by domestic forces to fit the national context. Similar to other Latin American countries, Brazilian patent regulation has undergone constant transformations since the implementation of the WTO TRIPS Agreement. This section provides a background

on the Brazilian Industrial Property Law and introduces the two case studies of this chapter: patent term extensions and compulsory licensing.

Brazil's views on international patent protection have gone through numerous processes of resistance, adoption, and tailoring (Chaves et al., 2007; Mello e Souza, 2011; Shadlen, 2017). Brazil strongly opposed the introduction of IPRs in the WTO negotiations, being a leading resistance to the global expansion of patent protection in the 1980s. However, after the negotiations of the TRIPS Agreement, Brazil rapidly changed its position from opposing the newly created patent regime "to grudgingly accepting new global norms in the early 1990s [and] to over-complying by the middle of the decade" (Shadlen, 2017, p. 116). The process of tailoring patent rights after over-compliance began in the 2000s and emerged in response to different policy challenges.

Brazil started implementing the WTO TRIPS Agreement immediately after it entered into force in 1995 and did not use some of the flexibilities available for developing countries (Chaves et al., 2007). Most significantly, at the time of the signing of the WTO TRIPS Agreement, Brazil did not provide patents for pharmaceuticals¹⁴ and had to adjust its regulations to comply with the international agreement. The TRIPS Agreement established a transitional period of 10 years (until 2005) for developing countries to introduce patents for pharmaceutical products and processes. Countries that decided to make use of this transitional period had to implement a "mailbox" system, in which countries accepted patent applications after 1995 but would wait until 2005 to start patent prosecution.¹⁵

Brazil did not use the transitional period established in the WTO TRIPS Agreement, promulgating a new industrial property law (Law N. 9,279) on 14 May 1996. In this new legislation, Brazil adopted a mailbox system for applications submitted from 1 January 1995 to 14 May 1997 and a pipeline system for pre-1995 applications. In the pipeline system, the Brazilian Patent Office (Instituto Nacional de Propriedade Industrial [INPI]) accepted patent applications in technological fields that had not been recognised in Brazil until then (including

¹⁴ Brazil stopped granting patents for pharmaceutical products in 1945 and for pharmaceutical processes in 1969 (Oliveira et al., 2004).

¹⁵ See Starling Erse (2018) for a comprehensive analysis of the mailbox system in Brazil.

pharmaceuticals)¹⁶ if the patent had already been filed in another country (Nunes Barbosa, 2012).

This over-compliance with the WTO TRIPS Agreement resulted in tensions between patent protection and the provisions of public goods, especially in the context of the HIV/AIDS crisis (Chaves et al., 2007; Hasenclever et al., 2010; Marques, 2000). In the 2000s, the Brazilian government promoted several changes to its patent law in the process of tailoring the previous implementation of international commitments (Shadlen, 2017). Tailoring, as explained in Chapter 2, refers to the process of adjusting patent regulations to fit the national context. In this process, the pipeline system was removed, and a prior consent rule was introduced, by which all pharmaceutical applications approved by INPI had to be sent to the National Health Regulatory Agency (ANVISA) for review.¹⁷ This process also included new rules on compulsory licensing that will be explained in the following sections.

This brief account of the Brazilian Industrial Property Law underscores how patent regulation has experienced constant change. While these changes are constrained by international factors (legal and political pressure), there have been significant developments motivated by domestic interests, including civil society activism and industrial development policies. Sections 5.1.1 and 5.1.2 explore recent developments in patent regulation in Brazil regarding patent term extensions (ADI N. 5,229) and compulsory licensing (Law N. 14,200), respectively. These two cases expand on this history of conflicting public and private interests in patent regulation and provide examples of policy integration for sustainable development.

5.1.1 ADI N. 5,529 and the End of Patent Term Extensions in Brazil

Patent term extensions are a case of over-compliance in the Brazilian patent law that underwent a tailoring process in the period analysed in this thesis. These extensions were introduced into the Brazilian legislation to compensate inventors for administrative delays. Paranhos et al. (2020) describe that the patent office INPI expected to receive many patent applications for pharmaceuticals as soon as the new Industrial Property Law (Law N. 9,279) entered into force. Since the examination of applications for pharmaceuticals was a new task

¹⁶ Art. 229 of the Brazilian Industrial Property Law.

¹⁷ Prior consent was eliminated in 2021.

for the Brazilian patent office, potential delays in processing these applications could occur. To ensure that these delays would not significantly impact the total protection of the granted patent, Law N. 9,279, which was introduced in 1997, included the Sole Paragraph of Art. 40, which granted patent term extensions to applications negatively affected by administrative delays. This provision is considered TRIPS-plus and a case of over-compliance with the TRIPS Agreement (Shadlen, 2017). This provision reads:

“Art 40: The patent for invention shall be valid for a period of 20 (twenty) years, and the patent for utility model shall be valid for a period of 15 (fifteen) years counted from the deposit date.”

“Sole Paragraph: The validity period shall not be less than 10 (ten) years for the patent for invention and 7 (seven) years for the patent for utility model, counted from the grant date, except in cases where INPI (National Institute of Industrial Property) is prevented from examining the merits of the application due to proven judicial proceedings or force majeure.”

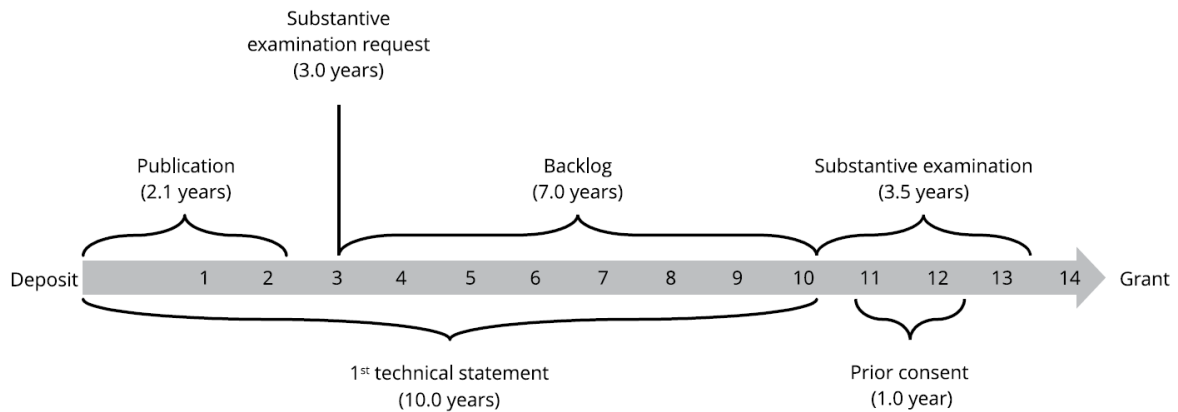
Art. 40 determines that patents must be protected for 20 years, counting from the deposit date, complying with Art. 33 of the TRIPS Agreement.¹⁸ Sole Paragraph, in contrast, ensures that ten years of protection must be counted from the grant date. This difference means that the total time of patent protection depends on the duration of the entire administrative and technical examination. For example, if a patent application for an invention takes 12 years to be processed, it would still have ten years of protection counted from the grant date, totalling 22 years of effective protection. Since there is no limit to how long these delays can take, this provision arguably established an undetermined duration of patent protection in the country (Cabral, 2022).

Even though this provision was designed to be applied in exceptional cases, patent term extensions became almost a rule for pharmaceutical patents. This widespread grant of extensions resulted from Brazil having a significant backlog in patent applications and one of the slowest examination processes in the world (Mercadante & Paranhos, 2022). This delay in patent prosecution is even longer in the case of pharmaceutical patents. Figure 5.1 shows a typical timeline of pharmaceutical patent prosecution in Brazil. Since patent applications take

¹⁸ TRIPS Agreement, Art. 33: “The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date”.

an average of 13.5 years to be granted, most applications for pharmaceutical patents have received the automatic extension provided by the Sole Paragraph of Art. 40.

Figure 5.1: Brazilian Pharmaceutical Patent Prosecution Timeline.



Source: Mercadante and Paranhos (2022, p. 7).

Although the backlog in patent examinations was a well-known issue for Brazilian authorities and applicants, the patent legislation remained unchanged for over 20 years. In 2013, the Brazilian Association of Fine Chemicals, Biotechnology and its Specialties (ABIFINA), an organisation representing the domestic industry, filed an unconstitutionality claim (ADI N. 5,061) with the Brazilian Supreme Court (Supremo Tribunal Federal [STF]). The claim argued that Art. 40, Sole Paragraph, violated several fundamental constitutional principles: the temporariness of patent protection (Art. 5, XXIX), the principle of isonomy (Art. 5, *caput*), consumer protection (Art. 5, XXXII, and Art. 170, V), freedom of competition (Art. 170, IV), legal security (Art. 5, *caput*), the objective responsibility of the state (Art. 37, § 6), the principle of efficiency in administrative action (Art. 37, *caput*) and the principle of reasonable duration of the process (Art. 5, LXXVIII).

Even though the Court ultimately dismissed this case since ABIFINA did not have the legitimacy to initiate an unconstitutionality claim,¹⁹ Rodrigo Janot, then Attorney-General of the Republic (Procurador Geral da República [PGR]), argued that the claim was based on pertinent arguments and that Sole Paragraph of Art. 40 was indeed unconstitutional. In 2016, Janot filed another unconstitutionality claim (ADI N. 5,529) against Art. 40, Sole Paragraph, using the same arguments used in ABIFINA's request. Since the Attorney-General is one of the individuals who can file an unconstitutionality claim, the Supreme Court approved the request.

The main argument for the unconstitutionality claim was that the Sole Paragraph of Art. 40 generated an undetermined time of patent protection in Brazil. Since the duration of a patent examination can vary significantly, the country's total patent protection duration became unclear. This lack of a determined term duration goes against Art. 5, XXIX²⁰ of the Brazilian Constitution, which states that industrial property protection should be a temporary privilege that must consider the country's social interest and technological and economic development. As argued by PGR:

"The lack of definition of the term of the monopoly of exploitation of industrial property causes serious damage to social rights and the rights and the economic order [...]. The consumer becomes hostage to prices and products defined by the monopoly holder [...]. Free competition and consumer protection, pillars of the economic order, are sacrificed disproportionately in favour of the private interest of monopoly holders" (PGR, 2016, Doc. 1, p. 13).²¹

¹⁹ Based on Art. 103 of the Brazilian Federal Constitution, only the following individuals or organisations may file a direct action of unconstitutionality: I - the President of the Republic; II - the Bureau of the Federal Senate; III - the Bureau of the House of Representatives; IV - the Bureau of the Legislative Assembly or the Legislative Chamber of the Federal District; V - the Governor of the State or of the Federal District; VI - the Attorney-General of the Republic; VII - the Federal Council of the Brazilian Bar Association; VIII - political parties represented in the National Congress; IX - trade union confederation or class entity of national scope.

²⁰ Art. 5 [...] XXIX states "the law shall ensure the authors of industrial inventions a temporary privilege for their use, as well as protection for industrial creations, the ownership of trademarks, company names and other distinctive signs, taking into account the social interest and the technological and economic development of the country; [...]".

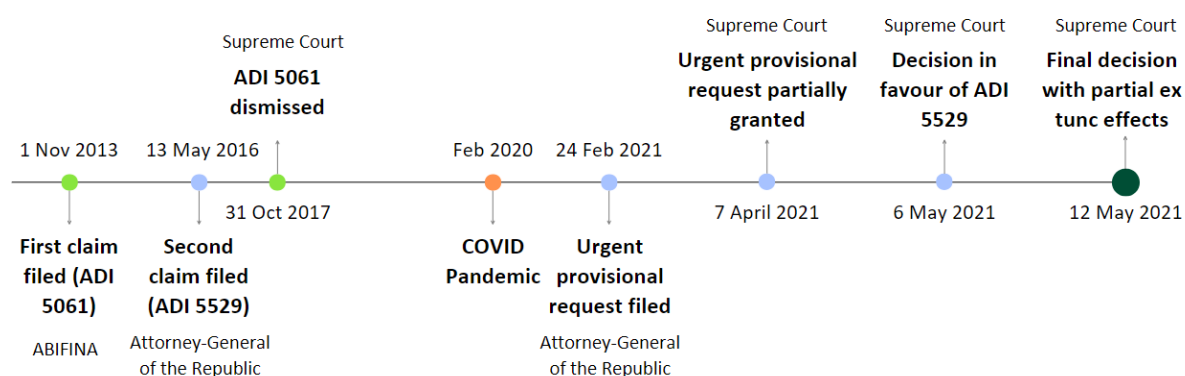
²¹ The complete list of documents submitted to the Supreme Court related to ADI N. 5,529 is available in Appendix B1.

Another crucial part of the argument was that the Sole Paragraph of Art. 40 was only triggered when the patent examination took longer than ten years for inventions and seven years for utility models. In this sense, extensions were only granted because of INPI's inefficiency in processing examinations. The Attorney-General (PGR, 2016, Doc. 1) stated in the initial petition that patent term extensions transferred the burden of administrative inefficiency to society, which had to wait an undetermined period to explore industrial inventions commercially.

Following the start of the process in 2016, it slowly progressed in the Supreme Court. It was only after the COVID-19 pandemic that the process developed more quickly. On 24 February 2021, the Attorney-General of the Republic, Antônio Augusto Brandão de Aras, filed a request for urgent provisional protection (“tutela provisória de urgência”), requesting the immediate suspension of Art. 40, Sole Paragraph. Aras justified the urgency of the request based on the health crisis created by the pandemic, arguing that the provision had a “direct impact on the fundamental right of health” and hindered the production of “generic pharmaceuticals against the new coronavirus and its current and future variants” (PGR, 2021, Doc. 440, p. 5). Supreme Court Minister Dias Toffoli, the process rapporteur, partially granted the request, suspending the effects of the provision only for patents related to pharmaceutical products and processes and other health materials and equipment.

In May 2021, the Brazilian Supreme Court ultimately supported the claim. The final decision, approved by nine of the eleven ministers, revoked the Sole Paragraph of Art. 40, ending patent term extension for new patent applications. It also decided that the new rule would apply retroactively (*ex tunc*) only for patents related to pharmaceutical products and processes and health equipment and technologies (Pinto Ido, 2021).

A timeline with the main events is shown in Figure 5.2. The process started with ABINIFA's unconstitutionality claim in 2013, which was officially dismissed in 2017. ADI N. 5,529 began in 2016 when PGR filed a second unconstitutionality claim. The role of the Attorney-General of the Republic (PGR) was also vital after the beginning of the pandemic when he filed an urgent provisional request to suspend the Sole Paragraph of Art. 40.

Figure 5.2: Timeline of ADI N. 5,521.

Source: Author's elaboration based on submissions to the Supreme Court.

ADI N. 5,529 created a significant change in the Brazilian patent legislation with implications for many sustainable development objectives. As discussed in Section 5.2, the decision pays particular attention to the impacts of patent term extensions on public health. It recognises that pharmaceuticals are the primary inventions affected by the Sole Paragraph of Art. 40, extending their patent protection duration and impacting the country's public health objectives.

5.1.2 Expanding the Scope of Compulsory Licensing in Law N. 14,200

In the period analysed in this thesis (2015-2022), changes to patent regulation were not limited to patent term extensions. In the context of the COVID-19 pandemic, several drafts of laws related to compulsory licensing were proposed in the Brazilian Congress and Senate. Compulsory licensing is present in the Brazilian Industrial Property Law in Articles 68 to 74. In its original version from 1996, Art. 71 describes that a compulsory, temporary, and non-exclusive licence could be granted for the exploitation of a patent in cases of national emergency or public interest.²² The compulsory license must be granted without prejudice to the rights of the respective holder. It is conditional to a Federal Government declaration of a health emergency, provided that the patent holder or its licensee does not address this emergency.

²² Art. 71 was further regulated by Decree N. 3,201 (1999) and Decree N. 4,830 (2003).

Compulsory licensing is not a novel instrument in Brazilian patent regulation, and the application of this TRIPS flexibility was crucial in Brazil's response to the HIV/AIDS crisis in the early 2000s. Given the need for urgent responses to this health crisis, Brazilian policymakers promoted the tailoring of the patent law, allowing the compulsory licensing of medicines and leading to the reduction of prices during negotiations with transnational pharmaceutical firms (Shadlen, 2017).

In two instances, Brazil threatened to issue compulsory licenses for antiretroviral drugs (2001 and 2005). The only instance Brazil granted a compulsory license was in 2007 when the national government issued Decree N. 6,108, allowing the production of Efavirenz (EFV) without the consent of the patent owner (Medicines Law & Policy, 2023). Since then, Brazil has not issued other compulsory licenses, despite pressure from CSOs (see, for instance, Bermudez (2018) on protests for the licensing of Sofosbuvir).

During the period of focus for this research, with the rise of COVID-19 cases as a public health emergency, compulsory licensing gained the attention of different state and non-state actors as a potential instrument to address access to medicines and vaccines during the pandemic in Brazil. Between 2020 and 2021, 13 law proposals focused on changing, streamlining, and clarifying rules for compulsory licensing were introduced in the legislative houses. For instance, law proposals N. 1,184 and N. 1,320 filed in 2020 suggested clarifications in the conditions for granting compulsory licenses and their duration in the context of public health emergencies. These proposals were concerned with potential drugs and vaccines being introduced in the market within monopoly rights that could hinder the Brazilian population's access to these COVID treatments.

On 6 June 2021, Senator Paulo Paim filed another law proposal (PL N. 12) amending the Industrial Property Law, proposing changes to the regulation of compulsory licenses (Art. 71). This proposal incorporated all other proposals in progress since 2020 in order to focus the legislative process on only one comprehensive proposal. The main goal of PL N. 12 was to streamline the application and grant of compulsory licensing in the context of public emergencies and national interest. For example, the amendment established timeframes for the executive and INPI to act on identifying relevant patents and expediting the granting process.

As explained in the legislative commissions responsible for evaluating the proposal:

“The main aim of the proposals in question is to exclude the possible restriction that patents may represent against expanded access to vaccines and other technologies useful in dealing with situations such as public calamities, national emergencies, and defence of the public interest, as is currently the case in the fight against the SARS-Cov-2 virus” (Brazilian National Congress, 2021a, p. 8).²³

PL N. 12 also aimed to introduce a set of new provisions to Art. 71 that expanded the scope of compulsory licensing. These provisions were focused on the transfer of technology from patent owners to licensees. Critically, Paragraph 8 of the proposal determined that patent owners had to share know-how:

“§ Paragraph 8 - The owner of the patent or patent application, which is the subject of a compulsory licence, must provide the necessary and sufficient information for the effective reproduction of the object protected by the patent or patent application and the other technical aspects applicable to the case in question, as well as the results of tests and other data necessary for the granting of its registration by the competent authorities.”

Another form of sharing essential knowledge was also proposed in Paragraph 9, which understood sharing biological materials as necessary for compulsory licensing:

“§ Paragraph 9 - If there is biological material that is essential to the practical realisation of the object protected by the patent or patent application, the owner must provide this material to the licensee.”

This proposal was very ambitious and innovative, aiming to create novel legal instruments for technology transfer, enabling compulsory licensing in the context of vaccines. Importantly, there is no international precedent of compulsory licensing legislation that includes know-how. In this sense, this legislation attempted to create new norms that expanded on the existing flexibilities of the TRIPS Agreement.

The proposal was received positively in both legislative houses. On 6 July 2021, the National Congress voted on the proposal and approved it with 425 votes in favour, 15 against, and four abstentions (Brazilian National Congress, 2021b). A month later, the proposal was approved in the Senate with 61 votes in favour and 13 against (Brazilian National Senate, 2021). After the Congress and Senate approved the law proposal, it required approval from the executive to finalise the legislative process.

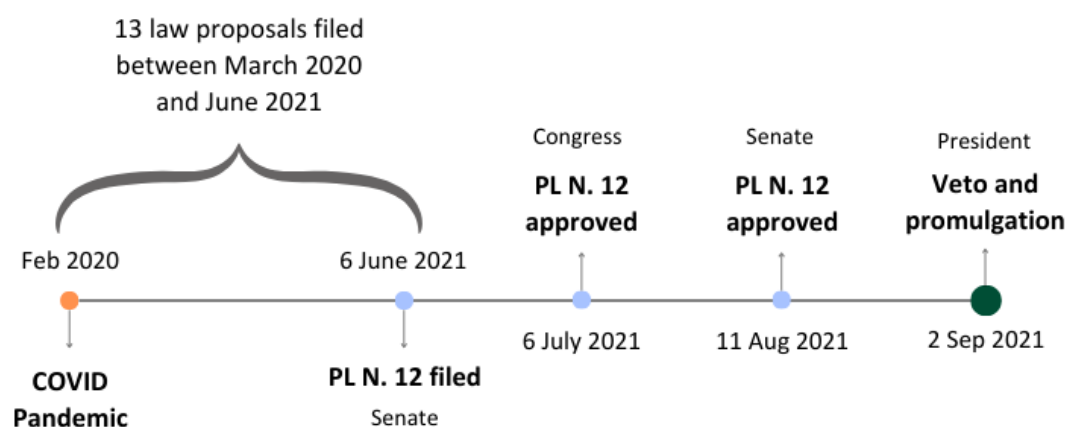
²³ The complete list of documents related to Law N. 14,200 is available in Appendix B1.

On 2 September 2021, Jair Bolsonaro, then President of Brazil, published his decision to approve the amendment but partially vetoed some provisions. The vetoed provisions were the ones described above related to the compulsory licensing of know-how and biological materials. The justification for the veto was the following:

“Despite the merit of the legislator’s intention, the legislative proposal runs counter to the public interest since it could bring chaos to the national patent system and could give rise to conflicts with the pharmaceutical and chemical industries. It should also be noted that know-how is the exclusive property of the company, which will have the prerogative to license it or not” (Presidency of the Republic, 2021a, para. 5).

The presidential veto also argued that every patent application must contain sufficient information in its descriptive report for a technician in the field to be able to reproduce it. In addition, the licensee must decide whether to produce information additional to that already disclosed in the patent. This situation could take a significant amount of time, to the point where the triggering event for the compulsory licence would be extinguished by the time it was actually produced.

Despite opposition from civil society organisations (CSOs) and some legislators, the veto was maintained. The proposal officially became Law N. 14,200 on 2 September 2021. The timeline below (Figure 5.3) shows the main events related to Law N. 14,200.

Figure 5.3: Timeline of Law N. 14,200.

Source: Author's elaboration.

The case of compulsory licensing in Brazil indicates legislators' interest in using this instrument to reduce the effects of the pandemic. The limitations of this instrument in regard to vaccines and biological medicines prompted legislators to submit a proposal that created new rules on the transfer of technology. Nevertheless, the inclusion of mandatory sharing of know-how and biological material was not approved by the president based on the possible economic and political implications that this provision would bring to the country. This veto indicates the limitations of tailoring, which will be explored in the following sections.

5.2 Explaining Policy Integration for Sustainable Development: QCA Outcome and Conditions

The recent legislative changes presented above represent examples of policy integration for sustainable development that occurred during the tailoring of patent protection in the period from 2015 to 2022. Before analysing the relevant conditions that led to policy integration, it is crucial to examine how each of these cases integrated patent protection and sustainable development. Section 5.2.1 examines how policy integration happened and what aspects of

sustainability appeared during policymaking. Sections 5.2.2 and 5.2.3 interrogate the role of the QCA conditions in producing the outcome.

5.2.1 Policy Integration for Sustainable Development

It is noteworthy that the term “sustainable development” did not appear in the proceedings for ADI N. 5,529 or Law N. 14,200. Actors involved in the policymaking process also indicated that the concepts of “sustainability” or “sustainable development” were not used to mobilise other actors or promote policy changes (Interviews BR03, BR04, BR07). Nevertheless, it was evident throughout the policymaking processes that both legislative changes were motivated by public health objectives (aligning with these goals in the sustainable development agenda). Although policymakers were not intentionally promoting sustainable development, the public health goals promoted in these legislations positively impact the achievement of the SDGs.

In the case of the Supreme Court decision (patent term extension), there was a clear motivation from the government, CSOs, and the national pharmaceutical industry to end patent term extensions and expedite the entry of generic medicines into the Brazilian market. Since the beginning of the case, the primary justification for ending extensions was the costs that prolonged patent protection incurred to the government, affecting the population’s access to medicines. Most actors participating as *amicus curiae* (i.e., parties that provide information to the Court) were organisations working in the health sector, such as civil society representatives or pharmaceutical firms. Consequently, the debate in the Court focused primarily on the impacts of Art. 40, Sole Paragraph, on public health.

While public health was the dominating topic in the discussions, the initial claim in 2016 indicated that patent term extensions could also affect the right to food. More specifically, the Attorney-General argued that patent term extensions “sacrificed free competition, consumers, and social rights such as the right to health and food” (PGR 2016, Doc. 1, p. 26). Organisations representing the biotechnology industry also framed the issue of patent term extensions in terms of the right to food, arguing that extensions benefited biotechnological developments crucial for food security in Brazil (e.g., ANDEF 2017, Doc. 56). However, this argument did not resonate with the Supreme Court since it was not present in the final

decision. On the contrary, the final decision was targeted at public health objectives. In the final decision, the Supreme Court Ministers stated that:

“The longer the exclusivity period enjoyed by the holder of the pharmaceutical patent, the greater the burden on public authorities and society, considering the need for large-scale acquisition of medicines to implement public health policies. This context becomes even more serious and urgent in the face of the international health emergency resulting from the COVID-19 pandemic” (STF 2021, Doc. 440, p. 6).

Similarly, the amendment to Art. 71 on compulsory licensing was also primarily motivated by public health objectives. Addressing the COVID-19 pandemic was the primary goal of Law N. 14,200 since its inception in 2020. The public health framing was also evident in the news brief released by the Brazilian government when the law was approved:

“The measure aims to allow the government to order the compulsory licensing of patents in exceptional cases in order to deal with public health emergencies. This measure could be used, for example, to break patents on vaccines and medicines in the event of a pandemic” (Presidency of the Brazilian Republic, 2021b, para. 2).

In both cases, the terms “sustainable development” or “sustainability” did not appear in the discussions in the legislative process. However, the case of Law N. 14,200 (compulsory licensing) differs from the Supreme Court decision (patent term extension) since other sustainability issues (such as the right to food) were not discussed during the policymaking process in the former. This restrained scope can be explained by the existing public health crisis (COVID-19 pandemic) and the more restricted practical application of compulsory licenses.

Considering public health as part of sustainable development, it is possible to argue that both cases of patent term extensions and compulsory licensing integrated patent protection for sustainable development. However, these cases also presented different scopes of integration. This chapter views the case of patent term extensions as an example of successful policy integration for sustainable development since the Supreme Court decision achieved the proposed integration goals set by the Brazilian Attorney General in its initial request and even expanded the outcome, including a retroactive application of the decision. In contrast, the outcome of the compulsory licensing legislation presented a narrow scope of policy integration since crucial parts of the initial proposal were removed in the final veto. These different scopes of integration are discussed in more detail in Chapter 7.

The QCA results outlined in Chapter 4 suggest that Brazil presents one of the combinations of conditions that generate policy integration. This combination is the presence of *civil society participation in policymaking* and the absence of *trade dependence*. The following subsections present the findings of the qualitative case analysis for both the patent term extension case and compulsory licensing case for these two conditions.

5.2.2 Civil Society Access to Policymaking

The first variable identified in the QCA path 1 for policy integration is civil society access to policymaking. The QCA data suggests that Brazil has a strong presence of CSOs in policymaking (Chapter 4). In the field of patent regulation, CSOs have historically been active in advocating for public health goals in the context of the WTO TRIPS Agreement. During the HIV/AIDS crisis, for example, these organisations engaged in coalitions with the domestic industry to promote flexibilities to promote access to medicines (Chaves et al., 2007; Nunn et al., 2009; Villardi, 2018). Consequently, these organisations have developed technical knowledge and skills as well as built networks of influence that help explain their current engagement with policymaking (Interviews BR01, BR07, BR11). I found that CSOs had a crucial role in the development of both ADI N. 5,529 (patent term extension revocation, explored in Section 5.2.2.1) and Law N. 14,200 (compulsory licensing amendment, explored in Section 5.2.2.2). Section 5.2.2.3 summarises the key findings of the two qualitative case studies regarding the extent of civil society participation in policymaking.

5.2.2.1 Patent Term Extensions

The case of patent term extensions was a decision taken by the Supreme Court. In this type of Court hearing, governmental institutions and non-state actors often participate as *amicus curiae*. A total of 16 organisations participated in ADI N. 5,529 as *amicus curiae*, including CSOs and industry associations (see Table 5.1 for key actors and alignment). Based on the actors participating in the process, the analysis suggests two main coalitions and their interests based on analysis of their submissions to the Court. The first coalition sought to end patent term extensions (i.e., in favour of the unconstitutionality claim). Generic manufacturers and civil

society organisations championed this position. The second group was interested in maintaining patent term extension (i.e., against the claim). Transnational and domestic biotechnology firms, transnational pharmaceutical firms, and other innovative industries supported this position.

Table 5.1: Actors (*Amici Curiae*) and Position on Revoking Patent Term Extensions

In favour of the unconstitutionality claim	Against the unconstitutionality claim
Brazilian Interdisciplinary AIDS Association (ABIA)	Association of Biotechnology Companies in Agriculture and Agribusiness (AGROBIO)
Brazilian Association of Fine Chemicals, Biotechnology and its Specialties (ABIFINA)	National Plant Defence Association (ANDEF)
FarmaBrasil Group	Interfarma
Brazilian Association of Generic and Biosimilar Medicines Industries (PróGenéricos)	Brazilian Industrial Property Agents Association (ABAPI)
Brazilian Intellectual Property Institute (IBPI)	Brazilian Intellectual Property Association (ABPI)
	Inter-American Association of Intellectual Property (ASIPI)
	National Association of Research and Development of Innovative Companies (ANPEI)
	Brazilian Electrical and Electronics Industry Association (ABINEE)
	Brazilian Association of Lawtechs and Legaltechs (AB2L)
	CropLife Brazil

Source: Author's elaboration based on submissions to the Supreme Court.

The leading civil society actor in this process was the Brazilian Interdisciplinary AIDS Association (Associação Brasileira Interdisciplinar de AIDS [ABIA]), an organisation working on access to medicines, mainly in the context of the HIV/AIDS epidemic (ABIA, 2016, Doc. 9). ABIA's participation as *amicus curiae* also represented the Working Group on Intellectual Property (Grupo de Trabalho sobre Propriedade Intelectual [GTPI]) (ABIA, 2020). GTPI is a coalition of Brazilian CSOs working at the intersection of patent protection and public health.

GTPI currently has 18 member organisations²⁴ and is coordinated by ABIA. The organisation's primary goals are to strengthen "measures to protect the right to health and against the adoption of measures to expand intellectual property protection" by "encouraging changes in Brazilian and international normative frameworks and the actions of policymakers" (ABIA, 2023, para. 1).

ABIA, similar to the organisations part of GTPI, is critical of the impacts of patented drugs on public health. Ending Art. 40, Sole Paragraph, is directly connected to these organisations' interests in providing affordable medicines in the public health system (ABIA, 2020, Doc. 150). In their request to join ADI N. 5,529, ABIA/GTPI argued that patent term extensions adversely affected the public health system. They argued that maintaining monopolies for extended periods meant the Health Ministry had to commit larger shares of its budget to acquire medicines, increasing the costs for the population and threatening people's health (ABIA, 2016, Doc. 9).

Based on academic work and reports, ABIA/GTPI provided information to the Court that was crucial for the end of patent term extensions. As described by a member of ABIA, the organisation's participation in the Supreme Court decisions occurred "through opinion articles, interviews, [...] direct meetings with the ministers' offices, [and] direct submissions to the process, [including] several new studies" (Interview BR014). For example, ABIA (2020, Doc. 154) included in its submissions a report produced by academics of the University of São Paulo (USP) comparing Brazilian regulation to that of other countries. This report showed that the Brazilian regulation was unique in the world since it was automatic and indiscriminate (USP, 2020, Doc. 155). This type of information, together with their relentless activism on other fronts, such as media outlets, played a central role in ADI N. 5,529 (Interviews BR07, BR14).

Lastly, the Brazilian Intellectual Property Institute (Instituto Brasileiro de Propriedade Intelectual [IBPI]) is another CSO participating in this process and that presented views favourable to the unconstitutionality claim. This organisation was formed by lawyers and academics working in IP law and is based at the University of São Paulo (USP). IBPI was an essential actor in this coalition since academics provided studies that built the arguments used in the Court. These novel studies analysed the legal and socioeconomic implications of patent

²⁴ GTPI members include ABIA, Doctors Without Borders Brazil, the Brazilian Institute for Consumer's Rights, and other health-focused CSOs (ABIA, 2023).

term extensions for the first time, supporting the argument that the Court should revoke Art. 40, Sole Paragraph.

Finally, the public purchase of generic drugs is a primary source for more affordable medicines. Therefore, the interest of CSOs in lowering the costs of medicines for patients is directly connected to the generic production of pharmaceuticals, aligning CSOs' interests with the domestic pharmaceutical industry. This role of the coalition between CSOs and domestic industry is analysed in Section 5.3.

5.2.2.2 Compulsory Licensing

CSOs advocating for an amendment to the compulsory licensing legislation (Law N. 14,200) presented strategies similar to those in the first case. However, civil society participation in policymaking differed from the previous case in the forms of participation and number of organisations. In the former patent term extension case of ADI N. 5,529, CSOs had the opportunity to engage directly with the Supreme Court, submitting documents with evidence to support their arguments. In the legislative process of Law N. 14,200 (compulsory licensing case), this advocacy took place using various instruments, such as direct communication with congress representatives, raising awareness in social media, and public information initiatives (Abong, 2021).

The context of the COVID-19 pandemic stimulated the work of various CSOs in the field of public health, and PL N. 12 on compulsory licensing was a particularly relevant part of the movement "Vaccines for All", led by Oxfam Brazil. In this movement, several CSOs, including Oxfam and GTPI, framed compulsory licensing as crucial to ensure access to vaccines to fight the pandemic in Brazil (Oxfam Brasil, 2022). It is also noteworthy that there was a much larger engagement of CSOs with this public health movement and the compulsory licensing law proposal than with the Supreme Court case. My analysis of the Supreme Court documents reveals that several organisations involved in the "Vaccines for All" movement, including Oxfam Brasil, did not engage with the Supreme Court decision.

Two reasons explain why compulsory licensing gained more attention from CSOs than patent term extensions in this period. First, the case of ADI N. 5,529 (patent term extensions) took place in a very technical venue, and the knowledge of ABIA/GTPI in combination with

academics was crucial to ensure their participation in the process. As described by a member of GTPI, this organisation has a “niche knowledge of intellectual property issues” that other organisations do not have (Interview BR07). While other organisations could have participated as *amicus curiae*, the Supreme Court would have assessed the technical knowledge of these organisations in relation to patent protection before allowing their participation. Arguably, it is expected that only CSOs with technical knowledge are able to discuss specific aspects of patent regulation, such as whether patent term extensions are TRIPS-compliant or TRIPS-plus.

Second, the law proposal on compulsory licensing had a clear motivation to facilitate access to COVID-19 vaccines. Access to vaccines was a public debate, bringing together several sectors of the population and gaining attention from several CSOs working in this space during the health crisis. As such, the proposal on compulsory licensing was strongly motivated by a larger frame on public health and access to vaccines in the context of the pandemic, which can explain the interest of a more significant number of CSOs in this law proposal than the Supreme Court decision.

For example, there was a significant mobilisation of civil society through the “Life asks permission”²⁵ campaign by the “Vaccines for All” movement, which had organisations send “hundreds of emails” to Brazilian legislators and “thousands of posts” on social media demanding the approval of PL N. 12. In addition, different forms of public-facing mobilisation took place, including light projections at the National Museum in Brasilia and in the National Congress with the phrases “life asks for permission” and “approve PL N. 12/21” (Oxfam Brasil, 2022, para.2). Section 5.3 discusses issue salience further.

5.2.2.3 Civil Society Participation Summary

The analysis of ADI N. 5,529 (patent term extension case) shows that the participation of the key organisation ABIA/GTPI as *amicus curiae* allowed it to directly participate in the discussions, providing an opportunity to shape the Supreme Court decision and the creation of an informal coalition with the domestic industry and academics. This coalition’s submission to the Supreme Court framed patent term extensions as deleterious for the national industry and public health and provided evidence that supported their arguments. As a result, several

²⁵ In Portuguese “A vida pede licença” in reference to compulsory licenses.

arguments used by the coalition were also used by the Supreme Court Ministers in their final decision (STF, 2021, Doc. 440). In the case of PL N.12 (compulsory licensing), coalitions were mainly restricted to CSOs with resources to mobilise resources and promote compulsory licensing of vaccines and public-facing advocacy. The presence of CSOs in policymaking underscores the crucial role of these organisations in promoting sustainable development objectives. However, the difference in policy outcomes for the cases analysed indicates that CSOs alone do not explain policy integration.

5.2.3 Trade Dependence and International Pressure

In addition to civil society participation in policymaking, the QCA results outlined in Chapter 4 suggest that the absence of trade dependence was also crucial for policy integration in Brazil. This section outlines the findings of the qualitative case studies of patent term extensions (Section 5.2.3.1) and compulsory licensing (Section 5.2.3.2) in Brazil and provides evidence that trade dependence manifested in different forms in these cases, including political and economic pressure from trade partners and transnational firms. This section also argues that the effective influence of these foreign actors varied depending on the regulatory changes proposed in the two cases. Section 5.2.3.3 summarises the key findings of the two qualitative case studies regarding the influence of trade dependence on policy integration.

5.2.3.1 Patent Term Extensions

Economic threats and international political pressure were evident in the context of the case of patent term extensions. Submissions to the Supreme Court by organisations representing transnational pharmaceutical and biotechnology firms, such as Interfarma and Croplife, respectively, clearly indicated possible negative consequences for the country in the case the Court revoked patent term extensions. For example, some actors argued that this decision would negatively impact the Brazilian economy, resulting in less foreign direct investment and industrial activity (AB2L, 2021, Doc. 171; ANDEF, 2021, Doc. 177). In addition, another form of economic threat was related to the availability of pharmaceutical goods in Brazil. It was argued by Interfarma (Interfarma, 2021, Doc. 115) that the end of patent term extensions could result in firms not introducing certain drugs into the Brazilian market and hampering the

development of new medicines targeted at the needs of the Brazilian population. For instance, Interfarma indicated that:

“The consequences for the country if Art 40, Sole Paragraph, is found unconstitutional are: (i) a lower incentive for international laboratories to prioritise Brazil in the launching of diverse drugs medicines, causing delays in the offer of new products for the treatment or even cure of diseases; and (ii) a lower incentive to develop products to treat diseases with high incidence in Brazil, such as infectious diseases typical of developing countries” (Interfarma, 2021, Doc. 115, p. 7).

Importantly, a member of Interfarma argued that the problem with the Brazilian patent system was not the extensions, but the backlog in patent prosecution, which is a “massive problem” and part of a “dysfunctional system” (Interview BR04).

In addition to the potential economic consequences for the Brazilian economy, other forms of international political pressure were also seen in the submissions to the Supreme Court. An example of international political pressure can be seen in submissions of domestic innovative firms (AB2L, 2021, Doc. 347) that included a letter from José Graça Aranha, WIPO regional director. In this letter, Aranha reinforced that other WIPO members have regulatory instruments to compensate inventors for administrative delays. Therefore, the Brazilian legislation was not exceptional and should not be found unconstitutional.

Another example of economic and political pressure was presented by Interfarma (2021, Doc. 388). During the modulation of ADI 5529, the possibility of applying the unconstitutionality decision *ex tunc* only to pharmaceuticals was being discussed by the Supreme Court ministers. Interfarma submitted a letter signed by six ambassadors (Belgium, Denmark, France, Japan, UK, and Sweden) arguing that “the sectorial discrimination proposed in the Rapporteur’s vote could also harm the country’s relations at the international level, besides hindering the entry of foreign investments” (Doc. 388, 2021, p. 5).

These examples show how transnational firms mobilised governments to threaten the Brazilian government and deter the end of patent term extensions. It is important to note that different sectors of domestic firms tended to echo the arguments of transnational firms in regard to patent term extensions, in particular, those linked to technological fields other than pharmaceuticals (AB2L, 2021, Doc. 171; ANDEF, 2021, Doc. 177). Nevertheless, these threats did not resonate with the Supreme Court. The Ministers did not mention these threats during

voting, and the final decision was not favourable for the transnational firms (STF, 2021, Doc. 1).

5.2.3.2 Compulsory Licensing

The case of the compulsory licensing amendment presented differences to the Supreme Court case. As described above, the proposal submitted for approval envisioned the transfer of know-how and biological materials from patent holders, but the presidential veto explicitly removed these provisions to avoid conflicts with pharmaceutical firms (Presidency of the Republic, 2021a). This justification indicates the limitations of the absence of trade dependence found in the QCA results. Although Brazil is not dependent on trade with the US or the EU in the sense used in the QCA, and the absence of trade agreements provides enough policy space for the country to pursue ambitious policies, this case suggests that the fear of political and economic retaliation is still relevant for policymaking.

Transnational pharmaceutical firms were crucial for this outcome. For example, Interfarma had meetings with governmental institutions to voice their concern about the provisions that would make technology transfer mandatory (Estado de São Paulo, 2021; Interfarma, 2021a). Interfarma emphasised that “these procedures are not comparable in any other country, and they go against the terms established by the TRIPS agreement and promote a scenario of enormous legal uncertainty for the innovation environment” (Interfarma, 2021b, para. 3). In a news article paid for by these organisations, the author stresses the “legal uncertainty” that the transnational pharmaceutical industry had faced with both initiatives related to patent protection (Granjeia, 2022).

Finally, despite the engagement of some foreign governments with the Supreme Court case (patent term extensions), high-income countries did not present an official position in relation to either case. For instance, the US often presents its views on developments related to IP regulation and policies in other countries in the USTR Special 301 report. The reports for 2020, 2021, and 2022 did not present any relevant comment in relation to patent protection legislation in Brazil.

5.2.3.3 Trade Dependence and International Pressure Summary

In conclusion, the absence of trade dependence had different implications for policy integration. First, the economic threats of revoking patent term extensions clearly did not influence the Supreme Court's decision. Although the coalition against ADI N. 5,529 argued that revoking Art. 40, Sole Paragraph could reduce foreign direct investment and discourage the development and commercialisation of new drugs in Brazil, there was no evidence that these arguments affected the Ministers' decisions (including those who voted against the unconstitutionality claim). At the same time, the case of compulsory licensing shows that creating new rules on compulsory licensing was stopped by the fear of retaliation from transnational firms. Therefore, removing a TRIPS-plus rule from the Brazilian legislation was feasible, while creating new rules for compulsory licensing was not. Policy integration for sustainable development still occurred in both cases, but the scope of compulsory licensing was restricted by international pressure from transnational firms. Finally, the international repercussions of both cases were minimal.

This section shows in detail how the two conditions identified in the QCA operate in practice to promote policy integration for sustainable development through the qualitative findings of the cases of patent term extension and compulsory licensing. This section shows that the QCA results only partially explain the extent to which policy integration for sustainable development happened in Brazil. The following section identifies three other variables from the qualitative analysis that are important to understanding these two cases of integration.

5.3 Expanding the QCA Results: Identifying Other Variables

The previous sections demonstrated that trade dependence (or international pressure) and civil society participation in policymaking shaped policy integration for sustainable development in both cases in Brazil. This analysis provided a more nuanced analysis of the QCA variables, which were expanded with qualitative interviews and document analysis. From the theoretical framework and empirical qualitative analysis, I identified three other key variables for policy integration for sustainable development: policymaking institutions and individuals (Section 5.3.1), the domestic pharmaceutical industry (Section 5.3.2), and the COVID-19 pandemic (Section 5.3.3).

5.3.1 Policymaking Institutions and Individuals

I found that in both cases in Brazil, governmental institutions and individuals within these institutions played a crucial role in promoting policy integration for sustainable development. As shown in the previous section, the outcome of ADI N. 5,529 (patent term extension) was the result of different variables, including civil society activism and the existence of sufficient policy space to revoke patent term extensions. Nevertheless, the Supreme Court Ministers and the Attorney-General had central roles in connecting the issue of extended patent protection to public health issues, advocating for the revocation of the Sole Paragraph of Art. 40. The Attorney-General was fundamental in this policymaking process since he started the process in 2016 and requested urgent provisional protection after the start of the COVID-19 pandemic, speeding up the decision-making process.

Furthermore, the Supreme Court Ministers decided on the retroactive (*ex tunc*) application of the decision to pharmaceutical products and processes. This decision expanded the scope of application of the decision, indicating that the Supreme Court's concern with the implications of patent term extensions for public health was not limited to the COVID-19 pandemic. Critically, the retroactive decision reflects the Supreme Court Ministers' individual views on the subject, indicating that individual perspectives played a more central role in this case than compulsory licensing.

While ADI N. 5,529 was restricted to the Supreme Court, the case of Law N. 14,200 on compulsory licensing was a law proposal that went through the entire legislative process. This process, which entails approval in the Congress and Senate in addition to presidential veto, involves different stages and opportunities for lobbying from non-state actors. I found that non-state actors in favour of or against PL N. 12 actively engaged with policymakers during the entire legislative process. For example, civil society activism through the "Vaccines for All" movement was crucial to ensure that the proposal was accepted (Abong, 2021).

As a result, there was strong consensus in both the Congress and Senate on the importance of the law proposal in the context of the COVID-19 pandemic. This result indicates the importance of civil society, highlighting the importance of opportunities for input in policymaking institutions. A civil society activist argued in an interview that Brazilian CSOs often attempt multiple times to promote changes in patent law for public health. Successful

initiatives take place in a “favourable timing” that benefits from “windows of opportunities” to promote these changes:

“There are times when there is a conjunction of those who are proposing alternatives and a turn in the ‘political mood’. In short, there are times when an opportunity [for policy change] arises” (Interview BR11).

However, as discussed above, the president vetoed the most controversial parts of the proposal on technology transfer for this case. The lobbying by transnational firms that supported this decision did not appear strong enough to change the vote of Congress and Senate representatives. Nevertheless, it was capable of shaping the executive veto. As stated by Interfarma:

“From the time the law proposal was presented until it was approved, Interfarma acted strongly with the Civil House, the Ministries of Economy, Foreign Affairs and Health, as well as representatives of the National Congress, embassies, other civil society organisations and PhRMA, arguing that these provisions [on technology transfer] should be vetoed because they were incompatible with the TRIPS Agreement” (Interfarma, 2021b, para. 2).

Other non-state actors also argued that the vetoed provisions would have no practical implications and arguably adverse effects on the economy. For instance, the Brazilian Intellectual Property Association (Associação Brasileira da Propriedade Intelectual [ABPI])²⁶ argued that any attempts to overturn the presidential veto would generate legal uncertainty and a sharp drop in patent applications in the country.²⁷ They also argued that it would discourage future investments and strategic commercial partnerships between international pharmaceutical laboratories and public research institutes (Migalhas, 2022). In this case, a powerful individual (the President of the Republic) was able to narrow the scope of integration.

It is also crucial to consider that the participation and influence of non-state actors in Supreme Court decisions in Brazil is more transparent than in the legislature. The submissions to the Supreme Court were direct forms of intervention and were publicly available online. In the

²⁶ ABPI’s institutional partners include firms working in the pharmaceutical and biotechnology sectors (e.g., Bayer) and representative organisations also participating in this decision (Interfarma and CropLife) (ABPI, 2023).

²⁷ Despite some initial discussions to overturn the presidential veto, the National Congress was in favour of the president’s decision (Brazilian National Congress, 2021b).

legislature, lobbying activities do not necessarily occur transparently, and information on these activities depends on disclosures in publicly available documents or interviews. Thus, there is a limitation in this research when comparing these two policymaking processes. Nevertheless, the results indicate the importance of open institutions for policy integration for sustainable development. The role of institutions and individuals is neglected in the QCA but was vital for both cases.

5.3.2 Domestic Pharmaceutical Industry

The QCA and qualitative analysis demonstrated the importance of CSOs in enabling policy integration for sustainable development in both cases in Brazil. The analysis of policy integration in Brazil reveals that coalitions with the domestic pharmaceutical industry were a vital strategy adopted by CSOs to promote health goals in patent regulation. This section outlines the findings regarding a related key variable, namely the formation of coalitions between CSOs and the domestic pharmaceutical industry, which enabled integration in the case of patent term extension revocation in Brazil. This section argues that the domestic pharmaceutical industry was a crucial actor in this coalition since this sector has the material and economic power to promote policy change. In contrast, the lack of apparent engagement between the domestic pharmaceutical industry and CSOs in the case of compulsory licensing can help explain the limited outcome reached by this legislation.

In the case of patent term extension, during the Supreme Court hearings, it was evident that the interest of CSOs in lowering the costs of medicines for patients was aligned with the generic production of pharmaceuticals. Domestic pharmaceutical firms, which primarily produce generic drugs, had their economic activities directly affected by the extension of patent protection since extended patent terms delay their entrance into the market. Three industry organisations participated as *amicus curiae* in the Supreme Court: the Brazilian Association of Fine Chemicals, Biotechnology and its Specialties (Associação Brasileira das Indústrias de Química Fina, Biotecnologia e suas Especialidades [ABIFINA]), FarmaBrasil Group, and the Brazilian Association of Generic and Biosimilar Medicines Industries (PróGenéricos). These three groups represent the leading pharmaceutical laboratories in the country. For instance, ABIFINA has 15 members, including some of the leading generic

pharmaceutical manufacturers (e.g., Aché, EMS, and Eurofarma, among others) (ABRADILAN, 2022). Some of these members are also associated with FarmaBrasil and PróGenéricos.

The importance of generic drugs in the arguments raised by this coalition is evident in their submissions to the Court. For instance, ABIFINA (2017, Doc. 63, p. 15) argued that delaying access to new technologies created a “barrier to the entry of generic drugs (which are known to be more financially accessible) inevitably leads to the exclusion of parts of the population”. Similarly, ABIA (2016, Doc. 9, p. 12), a key CSO, argued that the extension of patent protection was “frontally opposed to the guarantee of the right to health, since it impedes the effect of price reduction caused by free competition between reference companies and generic producers, besides also impeding direct production by public laboratories”. Therefore, there was an evident alignment between the interests of CSOs and domestic generic pharmaceutical manufacturers in the form of an informal coalition. As described by a member of ABIA, the collaboration between civil society, academics, and “the national pharmaceutical sector played a vital role” in the Supreme Court decision (Interview BR07).

This coalition of CSOs and domestic firms is also present in documents, news articles, and activities promoted by these organisations (ABIA, 2020; ABIFINA, 2016). For example, in a news brief, ABIFINA perceived the engagement of CSO ABIA in the patent term extension decision as an “ally”. The organisation declared that ABIA’s participation as *amicus curiae* would be “a fundamental contribution to the success of [ABIFINA’s] actions” (ABIFINA, 2016, par. 6). Such coalitions were described in an interview with a member of ABIA as important to achieving the CSOs’ goals, but limited to cases where “the economic interests of the national domestic industry are related to national interests”, such as public health (Interview BR14).

Since the start of the hearings, the coalition of CSOs and domestic pharmaceutical firms argued that patent term extensions clashed with the social interest because they negatively affected the national public health system and patients (ABIA 2016, Doc. 9; ABIFINA 2017, Doc. 63). In the context of an unconstitutionality claim, public health is a reasonable argument because the right to health is considered a fundamental right in the Brazilian Constitution (Art 6). However, the main argument of this coalition was the financial impact of patent term extensions on public expenses. For example, ABIA (2016, Doc. 9; 2020, Doc. 150) argued that the economic loss of patent term extension based on the medicines often purchased by the Brazilian government was significant and harmful to the public health system.

The pharmaceutical industry presented similar views. ABIFINA (2017, Doc. 63) and FarmaBrasil (2020, Doc. 92) underscored the vital role of generics in providing medicines to the Brazilian population. Based on a report prepared by Ferres Economia (2018, Doc. 99), the organisation claimed that generic drugs could reduce the price of medicines by 35% to 80%. Similarly, PróGenéricos (2020, Doc. 105) suggested that generic pharmaceutical companies are crucial for public health and the economy since they are “responsible for job generation, being certain that companies that produce generic drugs also contribute directly to the generation of wealth for the country, through taxes collected and the generation of foreign exchange through the export of generic drugs”. Therefore, the domestic pharmaceutical industry argued that generic manufacturers are critical economic actors and provide cheaper products that are more affordable to the population and the Brazilian government.

It is essential to underscore that the position favourable to ending patent term extensions was limited to the generic pharmaceutical sector, not other domestic industries. The National Association of Research and Development of Innovative Companies (Associação Nacional de Pesquisa e Desenvolvimento das Empresas Inovadoras [ANPEI]), the Brazilian Electrical and Electronics Industry Association (Associação Brasileira da Indústria Elétrica e Eletrônica [ABINEE]), and the Brazilian Association of Lawtechs and Legaltechs (Associação Brasileira de Lawtechs e Legaltechs [AB2L]) also participated in ADI N. 5,529 as *amicus curiae*, arguing that ending patent term extensions would affect the entire economy, in particular innovative firms. These organisations worked closely with transnational firms to advocate for the maintenance of patent term extensions.

The domestic pharmaceutical industry was also present in the discussions related to the compulsory licensing legislation (case two). However, the evidence suggests that their participation was less active than in the previous case. For instance, ABIFINA presented a favourable position to one of the first compulsory licensing proposals in 2020 but did not have an official position on PL N. 12 (ABIFINA, 2020). FarmaBrasil released a note on the first proposals, not necessarily in favour of early versions of the law:

“The use of compulsory licences must be supported by the existing legal apparatus and by technical and economic studies to support a government request. In the social and economic situation in which the country finds itself, the possible approval of a bill that

would allow the intellectual property system to be weakened, in addition to representing a step backwards, would cause serious legal instability” (FarmaBrasil, 2020).

I found that the domestic pharmaceutical industry was not as favourable and engaged with the legislative proposals on compulsory licensing as it was in the case of patent term extensions. The organisations that were active in the Supreme Court (patent term extension) either did not engage with PL N. 12 (compulsory licensing) or presented ambivalent positions. One of the reasons for this difference is that compulsory licensing has a much more limited application than patent term extensions. Domestic pharmaceutical firms have a greater incentive to promote the end of patent term extensions since it affects a wide range of medicines that they can produce. Chapter 7 discusses the role of these firms and differences across cases in more detail.

Overall, the active involvement of the domestic pharmaceutical industry in support and coalition with CSOs was found to be an essential variable for integration for sustainable development. In the case of patent term revocation, the industry saw CSOs as an ally and was active in supporting regulations that aligned with sustainable development goals. In contrast, the domestic pharmaceutical industry was less active in the compulsory licensing case, which achieved a narrower scope of integration.

5.3.3 Issue Salience: Policymaking During the COVID-19 Pandemic

The third variable that I identified as important in influencing the policy outcome for integration in both cases in Brazil was the COVID-19 pandemic. The pandemic is a contextual variable that created the impetus for policy change in both cases analysed in this chapter. I argue that the pandemic provided the grounds for policy integration as a salient issue but had a limited effect on the creation of new rules on compulsory licensing. In addition, the crisis response limited policy integration to public health, which is a narrower approach to sustainable development.

In the case of patent term extensions, CSOs and the domestic pharmaceutical industry promoted the view that maintaining patent term extensions would harm governmental actions to fight the COVID-19 pandemic. For example, FarmaBrasil argued that the unconstitutionality claim “may have short-term consequences for at least six molecules that

will potentially have medical applications in the fight against COVID-19” (FarmaBrasil, 2020, Doc. 92, p. 4). The organisation also illustrated the impacts of patent term extensions on pandemic responses using the example of Favipavir (Avigan), a drug at that time studied as a potential treatment for COVID-19. This medicine’s patent was filed in Brazil in 1999, and due to administrative delays, it received a four-year extension. Therefore, while this medicine had been in the public domain in various countries since 2019, it would still be protected in Brazil until 2023 (FarmaBrasil, 2021, Doc. 185).

In contrast, the topic of public health and COVID-19 did not present a cohesive response from the transnational industry and domestic innovative industries. The national biotechnology industry did not engage with a public health framing until the urgent provisional protection (“tutela provisória de urgência”) decision in February 2021. After that, these organisations promoted a framing that attempted to drive the discussion away from pharmaceuticals. For example, they argued that revoking Art. 40, Sole Paragraph would not impact access to COVID-19 medicines (AB2L, 2021, Doc. 171; AGROBIO, 2021, Doc. 173). In addition, they underscored that this debate should not be restricted to the public health and pharmaceuticals domain since patents from the most diverse economic areas, in particular the agribusiness sector, could be affected by the decision.

Another framing employed here was that if the problem was the access to medicines, there were other routes that the Brazilian government could use. For instance, ADEF (2021, Doc. 177) argued that the Brazilian legislation and IP policies provide other mechanisms to regulate abusive monopoly prices, namely compulsory licenses and price control. Interfarma (2020, Doc. 115) and ABPI (2016, Doc. 38) also reinforced that price regulation mechanisms exist, meaning that patent owners are limited as to what they may charge for their medicines.

The compulsory licensing legislation was primarily motivated by the COVID-19 pandemic. As described above, Law N. 14,200 was the result of several different proposals aiming to address compulsory licensing in the context of a health emergency. The legislative commission responsible for evaluating the law proposal underscored the relevance of compulsory licensing in the context of the pandemic.

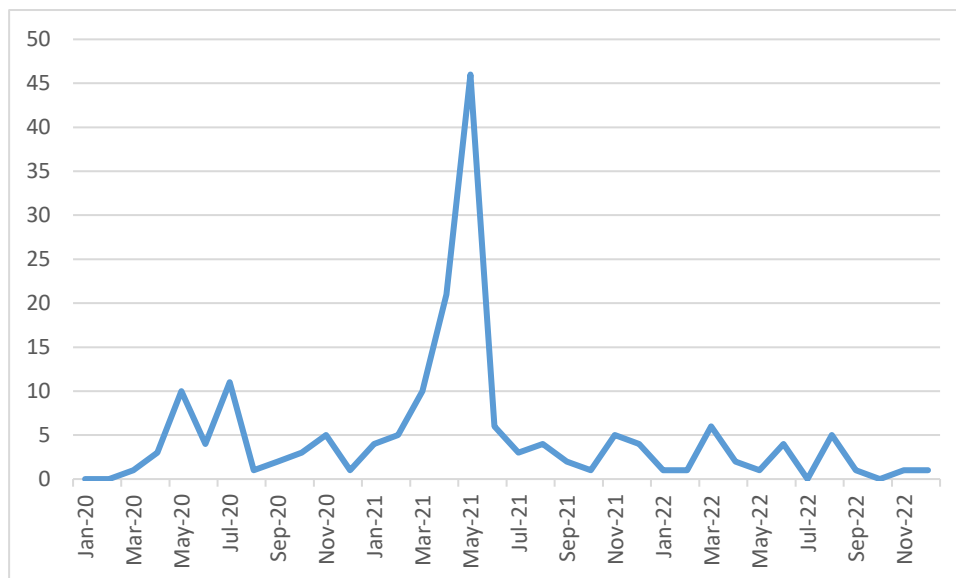
“It should be noted that the issue of compulsory licensing of patents has recently been the subject of much discussion around the world, mainly because of the process of immunisation against COVID-19, a disease responsible for a pandemic that has caused

many negative impacts on society. The disease has already caused around 4 million deaths, a figure that could be much higher given the expected under-reporting” (Brazilian National Congress, 2021a, p. 7).

Brazil was severely affected by the pandemic, with over 500,000 deaths between 2020 and 2021 (Brazilian Ministry of Health, 2023). As such, IPRs in the context of the pandemic became a salient issue in Brazilian politics. Figure 5.4 below shows a significant increase in news articles mentioning “COVID-19” and “intellectual property” in selected Brazilian media outlets. The peak of articles on the intersection of IP and the pandemic took place around the same time that both cases in this chapter were negotiated.

With the possibility of a vaccine emerging as a response to COVID-19, legislators explored different policy options to tackle the pandemic. Similar to the Supreme Court case, the pandemic was not only a primary motivator to start the compulsory licensing proposal but also prompted a quicker response from the legislature.

Figure 5.4: News Articles Mentioning “COVID-19” and “Intellectual Property” in Selected Brazilian Media Outlets.



Source: Author’s elaboration based on data from Factiva.

It is important to note another difference between the two cases. The case with patent term extensions was not initially motivated by the pandemic; instead, the primary motivation for

ending extensions was the ongoing costs for the government and reduced availability of medicines for the population. The pandemic added a level of urgency to the discussion, allowing the case to be discussed and decided quickly. Additionally, the health issues debated in the Supreme Court were much broader than those related to COVID-19, which helped mobilise the national pharmaceutical industry.

Overall, COVID-19 was an important contextual factor that was salient in public and political discourse in both cases, and links to the variable of issue salience identified in the theoretical framework (Chapter 2). This variable was not included in the QCA but emerged as a strong condition through the qualitative analysis in the two cases.

5.4 Conclusion

This chapter explores two cases of policy integration for sustainable development in Brazil. In the first case, a Supreme Court decision revoked patent term extensions to applications affected by administrative delays. The chapter finds that the tailoring of this patent regulation was explicitly motivated by public health objectives. Even though other sustainable development issues, such as food security, were also mentioned in the submissions to the Supreme Court, only health concerns were present in the final decision.

Similarly, the second case shows that the tailoring of compulsory licensing regulation attempted to create new norms on technology transfer to enable public health goals. Nevertheless, these new rules were vetoed by the presidential veto, limiting policy integration. Even though the new legislation integrates health goals into patent regulation, the original intention of policymakers was to expand this legislation to vaccines, which was not possible due to the influence of transnational actors.

This chapter demonstrates the importance of CSOs, confirming the QCA results. These results also show that international pressure occurs in different forms through transnational firms' lobbying and trade partners' pressure. The capacity of policymakers to promote policy integration for sustainable development was significantly shaped by the domestic capacity to counterbalance foreign interests.

This chapter identifies three further essential conditions that were important for integration. First, institutions and individuals were key. In particular, access to participatory policymaking

was a crucial element for policy integration for sustainable development. In the case of the Supreme Court, this enabled non-state actors to coordinate actions, influencing the revocation of patent term extensions. Related to this was the second variable, the role of the domestic pharmaceutical industry. In the first case, the domestic industry acted in coalition with CSOs. In contrast, the case of compulsory licensing shows that only CSOs actively participated in the legislative process, indicating that this regulation did not suit the domestic pharmaceutical sector's interests. The absence of a strong coalition between CSOs and the domestic industry may have hindered the scope of integration.

Finally, this chapter finds that the COVID-19 pandemic motivated policymakers to respond to this urgent health crisis. The pandemic was particularly relevant to justify the end of patent term extensions and a key motivator for the compulsory licensing proposal. Despite its political salience, the pandemic was not sufficient to avoid the presidential veto of provisions related to know-how in the compulsory licensing law proposal.

Chapter 6

Tailoring Within Limited Policy Space: Policy Integration for Sustainable Development in Chile

The previous two chapters presented the first two parts of the empirical analysis of this thesis. In the first part, I conducted a QCA to identify regional patterns and causal explanations for policy integration for sustainable development in patent regulation in Latin America (Chapter 4). The second part consisted of the first two in-depth cases of policy integration, focusing on patent term extensions and compulsory licensing in Brazil (Chapter 5). The QCA results indicate that both Brazil and Chile present the same combination of conditions that led to policy integration (presence of civil society participation in policymaking and absence of trade dependence). The qualitative case analysis adds further nuance to this combination of conditions and three additional key variables to explain differences in integration: institutions and individuals, the domestic pharmaceutical industry, and the COVID-19 context.

This chapter presents the results of the qualitative analysis of two cases of recent regulatory changes and initiatives of policy integration for sustainable development in Chile. Chile is a compelling case to examine policy integration for sustainable development in patent regulation since it was one of the first Latin American countries to engage in PTAs with substantial patent commitments, adopting TRIPS-plus provisions that can affect the achievement of sustainability goals since the early 2000s. Chile enacted its current Industrial Property Law (Law N. 19,039) in 1991, which has undergone several changes to reflect the country's TRIPS-plus commitments.

This chapter first examines a recent amendment to this law enacted in 2021 that narrowed the duration of supplementary protection (i.e., imposed limits to patent term extensions) (Law N. 21,355) and was a positive example of policy integration for sustainable development (case one). In case two, five regulatory proposals took place in the timeframe analysed (2015-2023): two successful regulations promoting compulsory licenses introduced in 2018 and 2020 (related to hepatitis C and COVID-19, respectively) and three law proposals to facilitate compulsory licensing that failed (Law N. 21,355) or where the negotiations have come to a

halt (Fármacos II and pandemic-related compulsory licensing). The results presented in this chapter are based on the analysis of legal proceedings, official documents, and 12 interviews with actors involved in policymaking and experts.

From 2015 to 2022, Chile presented both successful and failed attempts to promote the tailoring of patent regulations for sustainable development. In aiming to balance patent protection and access to medicines, Law N. 21,355 of 2021 (case one: patent term extension) presents a case of successful integration, providing incremental changes to its patent regulation to facilitate innovation without restricting access to medicines. However, Chilean legislators and policymakers simultaneously avoided controversial topics, such as compulsory licensing (case two). Attempts to promote compulsory licensing were only partially successful because they were restricted to specific regulations and had limited practical application. Overall, policy integration was only partially successful, with a narrowing of patent term duration in case one and limited declarations for health in case two (with most attempts at tailoring compulsory licensing failing to secure support).

As this chapter shows, patent term extensions presented a positive case of policy integration for sustainable development since policymakers achieved their intended public health goals, even if restricted by Chile's international patent commitments. In contrast, the analysis of initiatives related to compulsory licensing finds mixed or narrow outcomes, with some positive cases (public health declarations) and some failed or stalled negotiations (law proposals). This chapter argues that the policymakers played a crucial role in establishing the boundaries for tailoring patent regulation, defining which types of regulation could be changed (patent term extensions) and which could not (compulsory licensing). This agenda-setting was strongly driven by transnational actors due to their influence on policymaking.

This chapter proceeds as follows. Section 6.1 outlines Chilean Industrial Property Law and examines recent tailoring initiatives related to patent term extensions and compulsory licensing. Section 6.2 examines to what extent integration happened in each of the cases, identifies what aspects of sustainability emerged during the policymaking process, and interrogates the role of the QCA conditions in producing these outcomes. Section 6.3 examines the role of three critical variables that further help explain successful and failed attempts at policy integration: policymaking institutions and individuals, the domestic

pharmaceutical industry, and the COVID-19 pandemic. Finally, Section 6.4 concludes the chapter.

6.1 Chilean Patent Regulation: Patent Term Extensions and Compulsory Licensing

As argued before in this thesis, patent regulation in Latin America is the result of both international and domestic variables that have influenced the implementation of patent-related provisions from trade agreements. This section explores the current Chilean Industrial Property Law of 1991, the role of trade agreements in shaping this legislation, and the main tailoring initiatives introduced by the recent amendment (Law N. 21,355 of 2021). This section also explores recent legislative and regulatory initiatives on compulsory licensing.

Chile's current patent regulation was first established in Law N. 19,039 of 1991 (Industrial Property Law). Although this legislation was enacted before the TRIPS Agreement, it already introduced some TRIPS standards, such as the patentability of pharmaceuticals, which were not allowed in previous legislation. Some legislators indicated their concerns with the public health impacts of these new standards, but the final version of the law introduced a provision that allowed patents for medicines²⁸ (Biblioteca del Congreso Nacional de Chile [BCN], 2018a). On the other hand, Escobar (2010) argued that the early adoption of pharmaceutical patents provided Chile with experience in dealing with this type of patent, allowing the country to have an easier transition when implementing the TRIPS Agreement.

Law N. 19,039 is the current industrial property law in force, and it has undergone many changes and adjustments in the past 30 years. As this chapter finds, international forces led some of these transformations while domestic interests drove others. The TRIPS Agreement is the first of these international forces. Even though the Industrial Property Law already complied with some TRIPS norms, it still required several amendments to the patent law. For example, the TRIPS Agreement requires countries to provide 20 years of patent protection,

²⁸ Transitional Provision: Art 1 - "Notwithstanding the provisions of the second paragraph of Article 39 of this Act, a patent may only be applied for in respect of invention patents in respect of medicines of all kinds, medicinal pharmaceutical preparations and their chemical preparations and chemical reactions, provided that a patent application has been filed in their country of origin after the entry into force of this Law."

but Chile only granted 15 years (BCN, 2018b). Even though Chile should have implemented the TRIPS Agreement by 1 January 2000, it only proposed a new patent regulation in 1999. This proposal became Law N. 19,996 in 2005, introducing changes to adjust the Chilean regulation to the TRIPS Agreement.

Chile's trade liberalisation process is crucial to understand the country's current patent regulation. Even though Chile actively promoted unilateral trade liberalisation in the 1980s, bilateral liberalisation in the 1990s and 2000s was the main driving force behind the implementation of TRIPS-plus forms of patent regulation (Garuz & Garcia, 2007). After ratifying the TRIPS Agreement, Chile quickly expanded its trade relations through PTAs with several trade partners, including the US, Japan, and the EU. These agreements often have chapters on intellectual property rights with TRIPS-plus or TRIPS-extra provisions, i.e., provisions providing a level of protection beyond what is required in the TRIPS Agreement or introducing new forms of protection not included in the multilateral agreement. By 2022, Chile had ratified 16 PTAs that contain TRIPS-Plus and TRIPS-extra provisions (Morin & Surbeck, 2020). Five of these PTAs contain relevant patent or patent-related provisions (including provisions on data exclusivity and the requirement to accede to UPOV 91) and are displayed in Table 6.1.

Table 6.1: Chile's Preferential Trade Agreements Containing Relevant Patent or Patent-Related Provisions.

PTA	Signature	Entry into force	# Relevant provisions	Relevant provisions
Chile – European Free Trade Association (EFTA)	2003	2004	3	Patent term extension, data exclusivity, and UPOV 91
Chile – US	2003	2004	7	Several patent provisions, data exclusivity, and UPOV 91
Chile – Japan	2007	2007	1	UPOV 91
Chile – Australia	2008	2009	3	Patent novelty disclosure grace period, patent revocation restrictions, and UPOV 91
Chile – Turkey	2009	2011	1	UPOV 91

Source: Author's elaboration based on Morin and Surbeck (2020).

The implementation of these PTAs has required Chile to adjust its patent law to comply with TRIPS-plus provisions. Law N. 20,160, which entered into force in 2007, introduced significant changes to patent law to comply with the US and EFTA PTAs, introducing provisions on patent term extension in Chile (Section 6.1.1). The example of these PTAs shows that external forces have significantly driven Chilean patent regulation. Nevertheless, as argued in this chapter, domestic forces have also played an important role in shaping patent regulation in the form of compulsory licensing in Chile (Section 6.1.2).

6.1.1 Narrowing the Duration of Patent Term Extensions in Law N. 21,355 (2021)

Patent term extensions were first introduced into the Chilean Industrial Property Law during the implementation of the PTA with the US. This trade agreement, which came into force in 2004, included a TRIPS-plus provision that guarantees the possibility of extending patent protection due to administrative delays. Article 17.9, paragraph 6, of the US PTA states:

“Each Party shall provide for the adjustment of the term of a patent at the request of the patent owner to compensate for unreasonable delays that occur in granting the patent. For the purposes of this paragraph, an unreasonable delay shall be understood to include a delay in the issuance of the patent of more than five years from the date of filing of the application in the Party or three years after a request for examination of the application has been made, whichever is later, provided that periods of time attributable to actions of the patent applicant need not be included in the determination of such delays.”

As described above, Law N. 20,160, which entered into force in 2007, is the legislation implementing international commitments from the US and EFTA PTAs, including patent term extensions. Articles 53 Bis 1 to 5 regulate this protection, establishing the grounds for extending the patent term beyond 20 years (see Appendix B2). According to this legislation, an extension is granted if there are unjustified administrative delays in the patent examination or the sanitary registration of a patented pharmaceutical product. In addition, the patent examination must have taken more than five years counted from the filing date of the application or more than three years counted from the expert examination requirement.

The latter ground for extension (“three years counted from the expert examination requirement”) created controversies among Chilean experts and users of the patent system at the time of its introduction because the Chilean legislation did not have a formal “request for examination” phase (BNC, 2021). This term is present in Chilean law because it is the

language used in the US PTA (BNC, 2021). In addition, another crucial issue identified by the Chilean government at the time was that supplementary patent protection was not subject to any time limit. This lack of a time limit for extensions could give rise to the excessive duration of a patent.

Given these issues, a comprehensive reform of the Chilean Industrial Property Law has been underway since 2013 (Boletín N. 8,907-03). Due to the lack of progress in this reform process, the Chilean Ministry of Economy and Ministry of Finance filed a new amendment to the Industrial Property Law with Congress in 2018. In this new amendment, the recommended changes to the Industrial Property Law were targeted to specific objectives to expedite the negotiation and approval of this proposal. This new proposal aimed to adjust the administrative process for patent applications and change some of the functioning of the National Industrial Property Institute (INAPI).

Critically, this amendment, approved and promulgated in 2021 as Law N. 21,355, promoted a few modifications strongly motivated by domestic interests, tailoring patent term extensions to the national context. This amendment changed supplementary protection in two ways. First, it established a maximum of five years for the extension of supplementary protection, following other legislation around the world, such as the US (BNC, 2021). In addition, it reduces the period within which the applicant can request a term extension from six months to sixty days after the patent is granted.

As discussed in this chapter, these changes to patent term extensions were strongly motivated by sustainability objectives (in this case, public health). Since supplementary protection directly affects the duration of patent monopolies and access to medicines, it is not surprising that public health has been a prominent topic since the introduction of supplementary protection in Chile.²⁹ This chapter finds that, during the negotiations of Law N. 21,355, there was a consensus among government and non-state actors that these amendments to supplementary protection were necessary for Chile's economic and social development.

²⁹ For instance, during the negotiations of Law N. 20,160 of 2007, members of the Senate argued that introducing patent term extensions to the Chilean patent regulation sought to “achieve coherence and harmony between Chile's international commitments national interests, particularly in terms of public health, avoiding the unjustified extension of patents” (BCN, 2018c, p. 38).

This chapter views this legislation as a successful case of policy integration for sustainable development in patent regulation. Although Chile's international commitments legally constrain the scope of the proposal, policymakers achieved the goal that they initially set: to narrow the duration of patent term extensions to achieve health goals (i.e., access to medicines).

Figure 6.1 shows a timeline of the main events related to supplementary protection in Chile.

Figure 6.1: Timeline of Supplementary Protection in Chile.



Source: Author's elaboration.

6.1.2 Health Declarations and Legal Proposals on Compulsory Licensing

Along with patent term extensions, compulsory licensing is another topic recently at the centre of patent regulation in Chile. As discussed in Chapter 1, compulsory licensing is a topic that often presents little consensus among actors in the IP system. As such, negotiations of regulation related to compulsory licensing are often contentious, hindering significant advancements in this area. This section examines five recent initiatives in this area that took place between 2015-2022: two resolutions on public health and compulsory licenses, the negotiations of Law N. 21,355, and two law proposals on access to medicines and compulsory licenses that have come to a halt. This section shows that, despite the number of initiatives

on compulsory licensing, most proposals have failed to change the existing legislation and practices, impacting policy integration for sustainable development.

Decree N. 236 of 2005 regulating the Chilean Industrial Property Law (Law N. 19,039 and subsequent amendment Law N. 19,996) defines compulsory licenses in Art. 2 as an “authorisation granted by the competent authority to a third party to use an invention without or against the will of its owner, due to the occurrence of any of the grounds established in Article 51 of the Law”. The grounds for compulsory licensing in Art. 51 are the following: (i) when the owner of the patent has engaged in conduct or practices that have been declared contrary to free competition; (ii) when for reasons of public health, national security, non-commercial public use, or national emergency or other reasons of extreme urgency, declared by the competent authority; or (iii) where the non-voluntary licence is to exploit a subsequent patent that could not be exploited without infringing a patent.

During the period analysed in this thesis, compulsory licensing has become a prominent issue in Chilean patent regulation as new legislative and regulatory proposals sought to streamline this instrument and promote the compulsory licensing of certain pharmaceuticals. The first relevant proposal is “Fármacos II” (Boletín N. 9,914-11), a 2015 law proposal to regulate generic bioequivalent medicines and an antitrust instrument to control the vertical integration of laboratories and pharmacies. This proposal aims to increase medicine’s affordability through regulatory reforms related to drug price, safety, and market concentration. Since 2018, compulsory licenses have also been discussed as an essential part of access to medicines (Chilean National Congress, 2019). As part of this law draft, an amendment to Art. 51 of the Industrial Property Law was proposed by members of Congress. This proposed amendment states that:

“It shall always be understood that there are reasons of public health with respect to the request for non-voluntary licenses of pharmaceutical products, special foods, or medical devices that are included in the plans and programs of the Ministry of Health due to their economic inaccessibility or shortage” (Chilean National Congress, 2019).

The main controversy in this proposal is the expansion of the compulsory licensing grounds to economic inaccessibility. As discussed in the sections below, this expansion of compulsory licensing grounds became a critical issue for transnational pharmaceutical firms and the US, which have vehemently opposed this legislation since 2019. Domestically, this proposal also generated intensive discussion in Congress and the Senate, hindering the approval of this

legislation. At the time of this thesis, the progress of the legislation negotiations had come to a halt.

In addition to *Fármacos II*, a second critical relevant proposal focuses on health emergencies and compulsory licensing (Boletín N. 13,572-11). This proposal was filed by a group of members of the national congress (including Congress representative Giorgio Jackson) on 9 June 2020 and aims to regulate non-voluntary licenses for patents and utility models of medicines, vaccines, and medical technologies necessary for disease prevention, diagnosis, and treatment. It also proposes establishing a special procedure for this purpose in the context of health alerts, epidemics, or pandemics.

The proposal tackles different issues related to compulsory licensing, with the primary goal of streamlining the process of issuing such licences, making it more efficient. One of the main contentious parts of this proposal is ensuring compulsory licensing for government use.³⁰ The Chilean Supreme Court assessed this proposal, publishing a document on 23 July 2020 with minor suggestions to adjust the proposal, and no further developments have taken place since 2020 (Chilean National Senate, 2023).

Lastly, there have been attempts to include compulsory licensing regulation in the negotiations of the recent amendment to the Industrial Property Law examined in case one (Law N. 21,355 of 2021). Although Law N. 21,355 did not promote changes to compulsory licensing, Congress and Senate representatives attempted to include this issue in the discussions. Congress representative Giorgio Jackson and Senator Latorre attempted to expand TRIPS flexibilities during the negotiations throughout 2018-2021, with a particular interest in expanding the rules for compulsory licenses. Jackson and Latorre proposed an amendment that would expand the grounds for compulsory licensing to include the lack or insufficient exploitation of the patented invention (BCN, 2021). As explained in the sections below, this proposal was rejected during the legislative process.

³⁰ Article 5. Government use - "If, in the cases regulated by this law, the applicant for the compulsory licence is a Public Service or other public law entity, said entity or its contractors may import, manufacture and distribute the object of the licence application or other form of exploitation thereof, as from the date on which the administrative act is issued by which said entity provides for said import, manufacture or other exploitation to be the object of the licence."

The three compulsory licensing-related law proposals analysed in this chapter (Fármacos II, health emergencies compulsory licensing, and Law N. 21,355) show that Chilean policymakers have not been successful in tailoring compulsory licensing legislation. Nevertheless, some advancements were possible through health declarations that enabled producers to apply for compulsory licenses. Two resolutions are relevant in this context: one related to Sofosbuvir, a drug to treat hepatitis C, and one related to COVID-19 treatments.

Since 2017, CSOs and congress representatives (including Congress representative Giorgio Jackson) have collaborated to promote compulsory licensing for different pharmaceuticals. This group of actors requested the Ministry of Health to consider implementing a compulsory license for two drugs – Enzalutamide, used for cancer treatment, and Sofosbuvir, used to treat hepatitis C – on the basis of public health (Chilean Ministry of Health, 2018). This process led to Resolution N. 1,014 in the National Congress with a formal request to the Ministry of Health to address access to medicines for hepatitis C. On 9 March 2018, the Ministry of Health published Resolution N. 1,135, recognising the severity of the hepatitis C problem in Chile and deeming it a serious public health issue (Chilean Ministry of Health, 2018). This decree and resolution provided the grounds for the industry to apply for compulsory licensing for Sofosbuvir.

After the beginning of the COVID-19 pandemic, another request was made by Congress representative Giorgio Jackson and other members of Congress to facilitate access and availability to medications and technologies to prevent and treat COVID-19. Resolution N. 896 was approved on 17 March 2020 with 127 votes out of 135 members of Congress. The resolution requested the Minister of Health to declare the existence of public health reasons for the granting of non-voluntary licenses regarding patent applications and patents related to “vaccines, drugs, diagnostics, devices, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis, and treatment of persons infected with the coronavirus SARS-CoV-2” (Resolution N. 896, para. 5).

The response of the Health Minister to Resolution N. 896 was published as Resolution N. 3,244 of 2020 and indicated that compulsory licensing matters were discussed in the context of Fármacos II (more on the overlap of these proposals in Section 6.3):

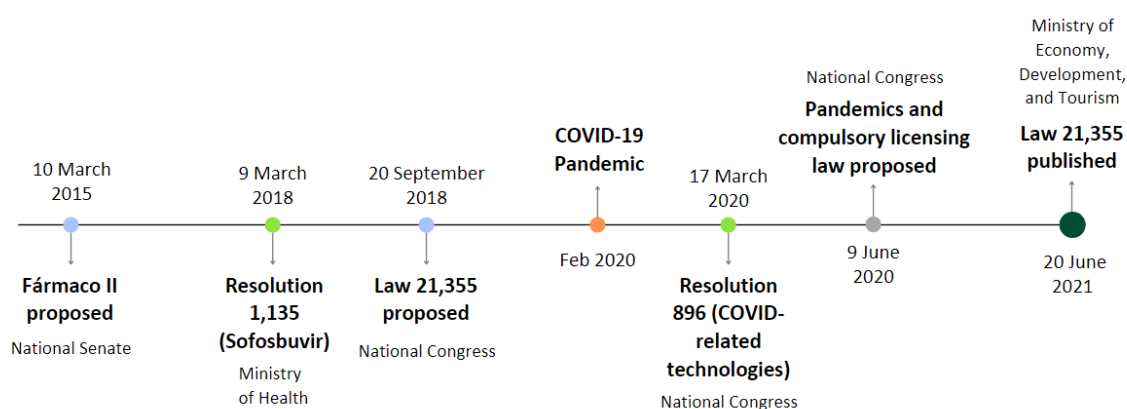
“In this regard, I would like to inform you that what has been consulted is a matter of law and has already been discussed in the bill that amends the Health Code to regulate

generic bioequivalent medicines and avoid the vertical integration of laboratories and pharmacies, Boletín N. 9,914-11 [Farmacos II]" (Chilean Ministry of Health, 2020).

This chapter argues that, although policymakers achieved policy integration with these declarations, their practical application is unclear due to the lack of engagement of the domestic pharmaceutical industry (in the case of hepatitis C) and lack of response from institutions (in the case of COVID-19).

Table 6.2 presents a summary of the policies and law proposals included in this chapter and the outcome achieved. Figure 6.2 shows a timeline of the main events related to compulsory licensing in Chile.

Figure 6.2: Timeline of Compulsory Licensing Regulation in Chile.



Source: Author's elaboration.

The section has demonstrated that Chilean patent regulation was constantly contested throughout the research period. Even though international commitments are a primary driver of regulatory changes in Chile, the tailoring of these commitments to fit the national context also plays an important role. The results of the empirical analysis and interviews are outlined in the following sections.

Table 6.2: Summary of Policy Documents and Policy Integration Outcome.

Provision / Law	Goal	Outcome related to policy integration for sustainable development
Law N. 21,335 (2021)	Narrowing the duration of patent term extension	Provisions to limit patent term extensions approved
	Expanding the grounds for compulsory licensing	Provisions to promote compulsory licensing rejected
Resolutions N. 1,014 and N. 1,135 (2018)	Health resolution providing the grounds for compulsory licensing of Sofosbuvir	Approved in the legislature and supported by the Ministry of Health
Resolutions N. 896 and N.3244 (2020)	Health resolution providing the grounds for compulsory licensing of COVID-related technologies	Approved in the legislature but unclear support from the Ministry of Health
Fármacos II (in progress)	Expanding the grounds for compulsory licensing	Stalled negotiations
Pandemics and compulsory licensing proposal (in progress)	Clarifying compulsory licensing rules and government use	No progress since 2020

6.2 Explaining Policy Integration for Sustainable Development: QCA Outcome and Conditions

The recent legislative changes presented above represent examples of policy integration for sustainable development with different levels of success and failure. Although both patent term extensions and compulsory licensing presented some degree of integration with sustainability goals, some attempts to tailor patent regulation were not successful. Before analysing the relevant conditions that led to policy integration, it is crucial to examine how each of these cases integrated patent regulation and sustainable development. Section 6.2.1 examines to what extent policy integration occurred in each case and what aspects of sustainability appeared during policymaking. Sections 6.2.2 and 6.2.3 interrogate the role of the identified QCA conditions in producing the outcome.

6.2.1 Policy Integration for Sustainable Development

The analysis of the five legislative and regulatory processes in this chapter reveals that the term “sustainable development” was not used to motivate, justify, or define the scope of policy changes in Chile. Although the term “sustainable development” did not appear in the official proceedings throughout any of the analysed legislative and regulatory processes, public health was a theme relevant to the justification of the proposed legislation and regulations across the two cases. For example, in the case of the amendment that imposed limits to patent term extensions (case one) (Law N. 21,355 of 2021), the initial presentation of the proposal in Congress stated:

“Our current law has resulted from several reforms incorporating new rights and better protection standards. However, practice and comparative experiences show the need for limitations and exceptions to industrial property rights that make it possible to balance the interests of protection and promotion of innovation with others equally relevant to the country’s development, such as, for example, access to medicines” (BCN, 2021, p. 7).

Public health appeared as an essential driver for the entire amendment and the establishment of exceptions, and it was especially important for curtailing patent term extensions:

“Regarding patents for inventions, clarifications are made about the period for designating an expert for an application for [patent term extensions], and a limit is placed on this to avoid excessive delays in the entry into the market of products competing with the patented product. This is very important in sectors such as pharmaceuticals so as not to delay access to generic products artificially” (BCN, 2021, p. 4).

The case of patent term extensions indicates that policymakers in Chile actively promoted the tailoring of patent regulation towards sustainability objectives (in this case, health).

In contrast to case one, my analysis of the various initiatives concerning compulsory licensing in Chile (case two) demonstrates that policy integration for sustainable development was only possible in some cases and with limited scope. As stated above, I included five proposals in the analysis in this period. I found that two specific declarations on compulsory licensing for hepatitis C and COVID-19 in 2018 and 2020, respectively, were excellent examples of policy integration for sustainable development as they promoted TRIPS flexibilities for public health.

For example, the public health declaration on hepatitis C (Resolution N. 1,135 of 2018) shows that the Chilean Health Minister acknowledged that “access to hepatitis C treatment is a public

health problem” and agreed with the request by the National Congress and CSOs that this problem “justifies the granting of non-voluntary licenses” (Chilean Ministry of Health, 2018, p.4).

Similarly, Resolution N. 896 on COVID-related technologies requested the Health Minister to:

“Declare the existence of public health reasons for the granting of non-voluntary licenses contemplated in Article 51º Nº 2 of Law Nº 19.039 on Industrial Property, with respect to all patent applications and granted patents affecting vaccines, medicines, diagnostics, devices, supplies and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of persons infected by the SARS-CoV-2 coronavirus, for public health reasons” (Resolution N. 896, Art. 2).

Although these instruments show how policy integration can occur in text, the practical implementation and feasibility of compulsory licensing in Chile remain unclear. Notably, the requests above from Congress depend on corroboration from the Ministry of Health (which only happened for the hepatitis C declaration) and interest from domestic firms in applying for a compulsory license (which did not occur in either case). As explained in Section 6.3, the domestic pharmaceutical industry is relatively small in Chile, restraining the country’s capacity to produce its own medicines.

In contrast, policy integration for sustainable development was unsuccessful in the case of Law N. 21,355 (case two) since the attempts to include compulsory licensing provisions into the proposal were rejected during policymaking. In addition, policymakers also attempted to include health goals in the proposals on pandemic-related compulsory licensing and Fármacos II, but the stalled negotiations indicate a resistance to policy integration regarding compulsory licensing.

I found that in both cases in Chile, negotiations were primarily focused on public health despite having the potential to affect a range of areas of sustainability issues. Document analysis revealed no discussion about energy or biodiversity for either case and a few references to food security issues in the first case. This result was confirmed in interviews with policymakers in the field of energy and climate (Interviews CH01, CH02, and CH10), who saw little discussion of the impacts of patent regulation in their fields.

As a staff member of the Chilean Ministry of Energy argued, discussions related to intellectual property rights “are very niche, very much for a very small group of people”. In contrast, “the

debate is much broader regarding technological development or the implementation of new technologies” (Interview CH01). Therefore, there is a political and societal interest in debating policies for new technologies, but patent regulation, like other IPRs, is still very niche and limited to a few actors.

As argued in the previous chapter, this thesis considers public health and access to medicines as crucial elements of sustainable development. In both the cases of curtailing patent term extension and compulsory licensing, while sustainable development was not explicitly cited, public health was a common rationale for tailoring regulations. Overall, policy integration was only partially successful, with the narrowing of patent term duration in case one, limited declarations for health in case two, and other attempts at tailoring compulsory licensing in case two failing to secure support.

6.2.2 Civil Society Access to Policymaking

The first variable identified in the QCA analysis as important for policy integration of patent regulation for sustainable development in Chile is civil society access to policymaking (see Chapter 4). The QCA shows that Chile has the highest V-Dem score for civil society access to policymaking in the region, indicating the relevance of CSOs in Chilean politics. However, although the literature argues that Chile underwent a revival of its CSOs and political mobilisation in the 1980s, scholars also point out that civil society has become less organised and mobilised since the 1990s (Millaleo, 2014; Oppenheim, 2007; Oxhorn, 2011). The analysis of the legislative initiatives in this chapter confirms these findings. This chapter finds that the inclusion of different non-state actors, including civil society, is evident from the early stages of drafting new legislation and regulations across the two case studies. However, as discussed below, there are clear limitations to the number of organisations involved and their capacity to shape policy outcomes.

The primary data for this chapter are the official documents and proceedings from the Chilean Congress and Senate and qualitative interviews. It is crucial to consider that many legal and regulatory proposals analysed in this chapter resulted from ongoing consultations between government and non-state actors that are not comprehensively recorded and publicly available. However, there is evidence from other data sources confirming the participation of

civil society in these processes. For example, the Director of the National Intellectual Property Institute (INAPI) explained that the recent amendment to the Industrial Property Law (Law N. 21,355) (case one) was a “cross-cutting project agreed with the various actors in the industrial property universe” (BNC, 2021, p. 151). This information was also confirmed in interviews (Interviews CH4 and CH14).

In addition, Infolobby, the Chilean website for tracking lobby activities with public institutions, has 48 entries related to INAPI’s engagement with private actors since 2015 (Consejo para la Transparencia, 2023). However, most of these meetings involved corporations, with little engagement with CSOs. In an interview, a member of INAPI suggested that the number of civil society organisations in Chile working closely on IP issues is limited and poorly organised. This member of INAPI argued that “there are organisations that are groups of people but not very organised, [and] that generate little knowledge. So, normally, they are rather politicised [...] and they don’t technically say very substantive things. So no, in Chile, we don’t have such an organised civil society yet” (Interview CH05).

The findings indicate that CSOs had a limited role in patent term extensions (Section 6.2.2.1) and compulsory licensing (Section 6.2.2.2). Section 6.2.2.3 summarises the key findings of the two qualitative case studies regarding the extent of civil society participation in policymaking.

6.2.2.1 Patent Term Extensions

Among the non-state actors participating in the negotiations of Law N. 21,355 (case one), Innovarte was the only CSO working directly with patent regulation. Innovarte was created in 2008 with the support of the Ford Foundation to promote a “balanced system of intellectual property rules that protect access to knowledge, innovation, and health” (Innovarte, 2023, para. 1). Innovarte was the only non-state actor to present arguments in favour of expanding TRIPS flexibilities, underscoring their importance to achieve health goals in the context of patent term extensions.

Luis Villarroel, Director of Innovarte, stated during the negotiations of Law N. 21,355 that IP protection should take into account “aspects that are desirable for the community, such as access to health, food and the innovation itself since these exclusive rights generate a patent protection that does not allow it to be used in other innovations” (BCN, 2021, p. 57). Using

the example of the public health declaration on hepatitis C, Villarroel indicated that access to medicines is a crucial issue for Chile, and this new amendment to the IP law should also tackle the affordability of treatments (BCN, 2021).

The fact that only one CSO participated in this legislative process indicates that patent term extensions are not a salient issue among the public or other organisations working on health policy. The analysis of this case suggests that there was an evident involvement of many non-state actors in the negotiations of this law proposal (such as the Chilean Association of Intellectual Property [ACHIP], Licensing Executives Society Chile [LES], and Chilean Association of Entrepreneurs [ASECH]) (BCN, 2021). Nevertheless, only one CSO actively works in this space and had limited participation in the negotiations. This section finds that Innovarte advocated for health goals in the case of patent term extensions, but its role was not as central as suggested in the QCA.

6.2.2.2 Compulsory Licensing

In contrast to the first case, Innovarte had a more central role in promoting health declarations for compulsory licensing (case two). Innovarte appears as a leading actor in both resolutions (hepatitis C and COVID-19), working closely with Congress representatives to promote compulsory licensing (Chilean Ministry of Health, 2018). This relationship is explored in more detail in Section 6.3. Importantly, Innovarte also worked with organisations representing cancer patients (Agrupación de Pacientes Oncológicos and Fundación Nuevo Renacer) when advocating for the hepatitis C public health declaration on compulsory licensing.

Innovarte also argued in favour of compulsory licensing regulation in the negotiations of Law N. 21,355. Villarroel argued there was “a need to improve compulsory licensing, where government use is allowed without any other procedure than notifying the patent holder and then paying the patent holder”. Villarroel also explained that “Chile does not have this compulsory licensing procedure [i.e., government use], requiring a court case even when it is the state that requires it” (BCN, 2021, p. 58). However, as described above, the final version of Law N. 21,355 does not include compulsory licensing.

Finally, Innovarte has actively advocated for compulsory licensing regulation in the Fármacos II and pandemic-related compulsory licensing proposals. This advocacy is present in

publications (see, for instance, Innovarte, 2022a), meetings with policymakers, such as the Public Health Subsecretary (Innovarte, 2022b), and webinars (see, for instance, Innovarte, 2022c).

Interestingly, organisations working with patients and public health, such as those mentioned above representing cancer patients, had a limited role in patent policy during the period analysed. Different from other countries, such as Brazil, where health activism is strongly linked with access to medicines, this is not the case in Chile. The *Fármacos II* proposal (case two), for example, tackled issues related to drug prices (through antitrust measures), showing that medicine affordability is an important issue for Chilean policymakers.

A main reason for the lack of engagement of these organisations is that access to medicines might not be a crucial topic in CSOs' agendas. Apart from those representing cancer patients mentioned above, other health-related organisations might not see patent regulation as a barrier to their goals. For example, a member of a CSO working with people living with HIV and HIV prevention argued that “at the national level, [...] access to [antiretroviral] medicines is not a problem today, as access is already covered and works well” (Interview CH10). Therefore, there is a fragmentation of where and how civil society engagement occurs, and the role of patent protection is not relevant to most organisations (BCN 2021; Interview CH10).

6.2.2.3 Civil Society Participation Summary

The results in this section suggest that civil society's access to policymaking alone is not a sufficient condition to explain policy integration for sustainable development. This section shows that, although very limited, CSOs participated in regulation and policymaking in different institutions in Chile (i.e., INAPI and the legislature). Innovarte, the only organisation actively present in patent discussions, framed TRIPS flexibilities as crucial for public health goals in both cases. However, initiatives to tailor compulsory licensing legislation and regulation for sustainability and health were not successful, suggesting that the advocacy of CSOs was limited and restricted by other variables (see Section 6.3).

6.2.3 Trade Dependence and International Pressure

In addition to civil society participation in policymaking, the QCA results suggest that the absence of trade dependence is also crucial for policy integration of patent regulation for sustainable development in Chile (Chapter 4). This section draws on the qualitative interviews and document analysis and demonstrates that international pressure was primarily absent in the case of patent term extensions, enabling policy integration for sustainable development (Section 6.2.3.1). In juxtaposition, this chapter shows that international pressure shaped the outcomes in the case of compulsory licensing (Section 6.2.3.2). These results suggest that international pressure varied significantly depending on the type of patent regulation being negotiated and its impacts on patent owners. Section 6.2.3.3 summarises the key findings of the two qualitative case studies regarding the influence of trade dependence on policy integration.

6.2.3.1 Patent Term Extensions

As described in Chapter 3, Chile is a signatory to a trade agreement with the US. Therefore, it is expected that the US closely follows the implementation of patent protection in the country, as it does with other trade partners. The USTR Special 301 Report, the primary mechanism used by the US to track the implementation of IPRs in other countries, provides insights into how the US reacted to Chile's recent changes to patent regulation. Chile was on the report's Watch List (WL) when the PTA entered into force in 2004 but was moved to the Priority Watch List (PWL) from 2007 onwards (USTR, 2004-2007). Chile remained on the PWL during the period analysed in this thesis (2015-2022) due to issues in the implementation of the US-PTA (USTR, 2015-2022).

Among the different issues identified in the implementation of the US-PTA in Chile, the US repeatedly urged Chile to implement its "system for addressing patent issues [...] in connection with applications to market pharmaceutical products" (USTR, 2015, p. 57). In addition, the US also urged "adequate protection against unfair commercial use [...] of undisclosed tests or other data generated to obtain marketing approval for pharmaceutical products" (USTR, 2018, p. 62).

Law N. 21,355 (case one) appears in the 2022 USTR report, where the US acknowledged the new legal development without criticism. I did not find any evidence that trade partners or transnational firms reacted to the changes in Law N. 21,355 regarding patent term extensions. Considering that the legislation approved only promoted small changes to patent regulation, the impact of these changes on patent owners was minimal.

6.2.3.2 Compulsory Licensing

Different from patent term extensions, there is evidence that the US and transnational firms disapproved of the attempts to change compulsory licensing regulation in Chile. Compulsory licensing appears in the 2019 USTR report when the US raised concerns about the possibility of a compulsory license request to be filed in Chile for Sofosbuvir after the government released the regulation declaring hepatitis C a public health issue (case two). The report states that:

“The United States urges Chile to ensure transparency and due process in any actions related to compulsory licenses. To maintain the integrity and predictability of IP systems, Chile should use compulsory licenses only in extremely limited circumstances and after making every effort to obtain authorisation from the patent owner on reasonable commercial terms and conditions” (USTR, 2019, p. 65).

Similarly, in 2021 and 2022, the US was concerned with pharmaceutical patents in the context of Fármacos II (case two). The US argued that pharmaceutical stakeholders raised “concerns over the vagueness of certain provisions of the [‘Fármacos II’] bill under consideration by the National Congress” (USTR, 2021, p. 39). The USTR explicitly refers to the attempts to expand the scope of the grounds for compulsory licensing. Similarly, the 2022 US Investment Climate Statements on Chile also mentions Fármacos II, identifying a “lack of coverage being offered in price regulations as an outstanding issue of concern” (US Department of State, 2022, para. 58).

In addition to US pressure on patent regulation, Chile also faced pressure from transnational private corporations during the negotiations of patent regulation, especially from the Pharmaceutical Innovation Chamber (Camara de Inovacion Farmaceutica [CIF]). CIF is an organisation representing innovative foreign pharmaceutical industries in Chile, and its

members include major pharmaceutical firms such as Bayer, Pfizer, Janssen, and GSK (CIF, 2023).

CIF participated in the development of *Fármacos II*, indicating that the proposed changes to compulsory licensing presented a “departure from OECD countries’ regulations”. The organisation criticised the proposal, arguing that expanding compulsory licensing grounds to economic inaccessibility “is complex and interpretable” and could promote “breaches of bilateral and multilateral international treaties signed by Chile”. The proposed changes could also reduce the development of new medicines and “have undesirable effects on accessibility and timeliness of new treatments” (Boletín N. 9.914-11, pp. 20-23).

According to a news article from Ciper, CIF also had a vital role in the transnational mobilisation to respond to the health declaration on hepatitis C. CIF members met urgently after the Health Ministry approved the resolution on compulsory licensing for hepatitis C. In one of the meetings (22 March 2018), the organisation suggested writing statements against the Resolution to PhRMA and several foreign governments, including USTR (Sepúlveda, 2018).

Sepúlveda (2018) provides a detailed account of how CIF mobilised international actors against the resolution. Representatives of the sector in European and North American countries were mobilised through numerous meetings with officials from the Ministries of Health and Economy, visits to EU and US embassies, and an attempt to create a lobbying coalition with domestic industry groups. In response to the resolution on Sofosbuvir, Gilead submitted a letter to the Chilean Minister of Health requesting the annulment of the resolution (Gilead, 2018). In an interview with Ciper Chile (2018), Jean Jacques Duhard from CIF explained that the organisation acted against the Sofosbuvir resolution since this could be a precedent for other patented drugs, violating fundamental rules that Chile has committed to internationally.

CIF has also been openly against the compulsory licensing proposals. In an article published on CIF’s website, the organisation declared that they have worked closely with governments to ensure that treatments are available and affordable. CIF showed concerns about the *Fármacos II* project (case two), “where the grounds for granting non-voluntary patent licences are extended to subjective and undefined concepts, such as economic inaccessibility and shortage of supply” (CIF, 2021, para. 2).

6.2.3.3 Trade Dependence and International Pressure Summary

In conclusion, this section shows that international pressure occurred in various forms through governmental and non-governmental actors. This pressure by state and private actors is interconnected since transnational firms used their influence to mobilise governmental actors with the goal of stopping tailoring initiatives related to compulsory licensing. Similar to the cases in the previous chapter, these results show that the QCA conditions manifest in different ways depending on the type of patent regulation being negotiated. In the case of patent term extensions, this section finds that there was no pressure from international actors since policy integration for sustainable development involved minimal changes to patent term extensions. In contrast, policy integration for sustainable development in compulsory licensing prompted reactions from trade partners and transnational firms, stopping most legislative proposals. Therefore, this section argues that international pressure is a relevant variable to explain the failure of some proposals, which was not captured in the QCA results.

6.3 Expanding the QCA Results: Identifying Other Variables

The qualitative analysis in the previous section shows that the QCA results reported in Chapter 4 only partially explain policy integration for sustainable development in Chile, indicating that other variables must be considered to understand the policy outcomes in the case studies in this chapter. This section examines three variables identified in the theoretical framework and the empirical analysis in this chapter: policymaking institutions and individuals (Section 6.3.1), the domestic pharmaceutical industry (Section 6.3.2), and the COVID-19 pandemic (Section 6.3.3).

6.3.1 Policymaking Institutions and Individuals

The cases examined in this chapter show that policymaking can have different outcomes depending on where the policymaking takes place and the different institutions involved in this process. Differences in the type of policy or regulation (i.e., resolution or law) and the actors involved in policymaking also help explain why some attempts at policy integration

were successful while others failed in Chile. This section argues that policymaking institutions have a central role in enabling or hindering policy integration.

The case of patent term extensions (Law N. 21,355) suggests that the legislature worked closely with other government institutions to develop a law proposal that could overcome previous deadlocks in tailoring patent regulation. As described above, this law has a narrower scope since the negotiations of a previous law proposal from 2013 failed to progress in the legislature (BCN, 2021). To create a more feasible proposal, the National Congress and Senate worked with other policymaking institutions, including INAPI, the Ministry of Health, and the Ministry of Economy. This law was the result of this interaction across government institutions in the various stages of the negotiations, with evidence that they had met even before filing the proposal in the legislature (INAPI, 2022).

The first case highlights that these policymaking institutions had a crucial role in agenda-setting, shaping the extent to which sustainability goals are integrated into patent regulation. The definition of what could be discussed in this law proposal to allow a faster negotiation process allowed for changes in patent term extensions for public health reasons but removed any controversial topics, i.e., compulsory licensing. It is evident from the proceedings of Law N. 21,355 that INAPI was mainly focused on promoting changes to the patent law that enjoyed consensus among stakeholders in the IP community, e.g., inventors, government, and law firms. As described by a member of the Senate (Senator Galilea):

“This is a ‘short law’ that proposes urgent and transversally agreed adjustments to our industrial property system, which have been promoted by the Executive through the Ministry of Economy in view of their coherence with the aims of the productivity agenda and which have also been promoted by the other actors of the national industrial property system, who have actively participated in the legislative discussion by supporting this project with a critical but constructive view” (BCN, 2021, p. 181).

When Congress representatives Jackson and Latorre proposed changes to the proposal, adding new rules on compulsory licensing to the amendment, it was rejected in both houses. For example, INAPI’s director argued that:

“The proposed amendment falls completely outside [the scope of this proposal], as it deals with a matter on which there is no transversal consensus on the part of the actors of the industrial property system and points to a much more fundamental issue, which requires a broad discussion and within the framework of a different law proposal” (BCN, 2021, p. 204).

This focus on consensus was essential to define which provisions were maintained in the proposal (i.e., supplementary protection) and which were left out during negotiations (i.e., compulsory licensing). INAPI also argued that there was a sense of urgency in approving a new amendment to the Industrial Property Law. Since the original proposal to reform the Industrial Property Law faced setbacks in the legislature, contentious issues, such as compulsory licensing, had to be left out of this proposal. As a result, there was little space for expanding the scope of TRIPS flexibilities (BCN, 2021).

Even though the outcome of Law N. 21,355 did not include compulsory licensing, the health declarations on Sofosbuvir and COVID-19 show that policymakers successfully promoted policy integration for sustainable development using other regulatory instruments. The analysis of the two health declarations reveals that members of Congress were able to gain support in the legislature to approve regulations that viewed hepatitis C and COVID-19 as public health issues, allowing firms to apply for a compulsory license for treatments related to these diseases. However, resolutions are administrative acts and do not have the same legal relevance as legislation (Cordero Quinzacara, 2009). Their negotiation and approval are more expedited and restricted to legislative representatives without going through different commissions and consultations with other institutions. The positive outcome of health declarations suggests that such instruments can be easier to achieve, but other conditions, such as domestic industrial capacity, also limit their applicability (see Section 6.3.2).

Another noteworthy element from the negotiations was that policymakers constantly redirected any issues related to compulsory licensing to the *Fármacos II* proposal. For example, attempts to include compulsory licensing provisions in Law N. 21,355 were dismissed because this topic had already been included in *Fármacos II* negotiations (BCN, 2021). Similarly, as indicated above, the Ministry of Health referred to *Fármacos II* in response to the COVID-19 public health declaration (see Resolution N. 3,244, Ministry of Health, 2020).

The analysis of the five initiatives related to compulsory licensing in Chile reveals that most attempts at tailoring compulsory licensing regulation faced resistance from policymaking institutions. Supporters of expanding the grounds for compulsory licensing promoted their goals in different opportunities, including public health declarations and law proposals, in a forum shopping process. This analysis suggests that forum shopping was only partially

successful since all attempts to change or create new legislation on compulsory licensing failed (Law N. 21,355) or have come to a halt (Fármacos II and pandemic-related compulsory licensing).

Finally, the relationships between governmental institutions and non-state actors are crucial to understanding policy integration. It is evident from the proposals analysed in this chapter that Innovarte, the only active CSO in this area, worked closely with Congress representatives in legislation and regulatory initiatives, particularly Congress representative Giogio Jackson. As discussed above, the request to the Ministry of Health to declare hepatitis C a public health grounds for compulsory licensing was filed by Innovarte, together with other CSOs working with cancer patients and several Congress representatives, including Jackson. Similarly, Jackson worked with Innovarte on the COVID resolution (Interview CH15). Nevertheless, these findings suggest that this cooperation between CSOs and policymakers was only partially successful.

This section presents evidence that policymakers in Chilean institutions have a central role in promoting or hindering policy integration for sustainable development. It is evident that some tailoring initiatives, such as the creation of limits to supplementary protection, were not controversial, and all institutions enabled this outcome. In contrast, tailoring initiatives related to compulsory licensing often encountered barriers during negotiations. This section also indicates that the participation of non-state actors in these institutions is also relevant, which is explored in the next section.

6.3.2 Domestic Pharmaceutical Industry

This section investigates the role of domestic industry groups in the two cases of policy integration for sustainable development, underscoring how they framed the integration of patent protection and sustainability and their interests in promoting TRIPS flexibilities. This section argues that the Chilean domestic pharmaceutical industry was not a central actor in patent regulation negotiations and can help explain the various degrees of policy integration for sustainable development in the cases studied.

The official proceedings from the negotiations of Law N. 21,355, which adjusted the duration of patent term extensions, show that four non-state actors representing industry groups

participated in the development of this legislation: the Chilean Intellectual Property Association (Asociación Chilena de la Propiedad Intelectual [ACHIPI]), the Federation of the Chilean Industry (Federación Gremial de la Industria de Chile [SOFOFA]), the Association of Entrepreneurs of Chile (Asociación Emprendedores de Chile [ASECH]), and the Association of Local Medicines Producers (Asociación de Productores Locales de Medicamentos [ProlMed]). These industry groups represent several sectors of the Chilean industry. ProlMed, the only organisation related to pharmaceuticals, is a trade association that brings together the five leading manufacturers and exporters of medicines in Chile – Andromaco, Bagó, Laboratorio Chile, Recalcine, and Saval. Although not an industry group but also representing the private sector, ACHIPI is an organisation that brings together intellectual property professionals and is the only organisation in Chile that specialises in this subject (ACHIPI, 2023).

Industry representatives presented similar views on the changes to patent term extensions proposed in Law N. 21,355. They often underscored their interest in maintaining a patent protection level that reflected Chile's international commitments while fomenting domestic innovation and international investment. The primary interest of these organisations throughout the negotiations was to modernise the patent system to incentivise domestic innovation. For example, at the Congress' Economic Commission, SOFOFA's Director of Public Policy supported measures to promote "innovation, improve productivity, accelerate the modernisation of the state, and incorporate the concept of the economy of the future" (BNC, 2021, p. 43).

The domestic pharmaceutical industry presented positive views towards the proposed changes to patent term extension (case one). Jose Luis Cardenas (ProlMed) argued that the National Economic Prosecutor's Office raised an alert in 2016, reporting that patent applicants had abused patent protection extensions, potentially affecting free competition. Therefore, ProlMed agreed that the total time of patent protection extensions should be restricted to five years, highlighting that the relationship between protection and access should be balanced, allowing the incentive for research without preventing access to medicines (BCN, 2021).

Critically, apart from ProlMed, there were no other significant reactions to the proposed changes to patent protection extensions. In addition, since these organisations do not

represent significant patent owners (such as the transnational pharmaceutical industry), there was no apparent retaliation from these groups for the changes proposed in this legislation. As a result, the proposed tailoring to patent protection extensions was approved by the legislature without facing resistance.

The case of compulsory licensing presents a different context for industry engagement. In the legislative proposals, there is no evidence of support from the domestic industry to expand or streamline compulsory licensing regulations. More generally, there is no evidence in this analysis that the pharmaceutical industry groups directly engaged with any of the proposals described in this chapter. One of the main reasons for this lack of engagement is that the Chilean pharmaceutical industry is relatively small.

As argued by ACHIPI, “Chile has no capacity to produce a national medicine. In our industry, innovation is developed towards mining, salmon, forestry, [...] but not medicines. Therefore, there are no Chilean labs that are knocking on the government’s door saying, ‘I can make this and make it cheaper’” (Interview CH12). This evidence suggests that Chile does not have pharmaceutical laboratories interested in pushing a regulatory agenda that promotes TRIPS flexibilities. In addition, the goal of Chilean policies on access to medicines has been more focused on importing generics from overseas rather than strengthening the domestic industry. The minor role of the domestic industry is also confirmed in data from the Chilean government, which indicates that the pharmaceutical sector in Chile has been characterised mainly by the import of products rather than local production (InvestChile, 2022).

Similarly, the lack of engagement of the pharmaceutical industry has important implications for the public health declarations on hepatitis C and COVID-19. Even though these declarations successfully gained support in the legislature to promote compulsory licenses in cases of public health, they faced limitations in their practical application. To date, there has been no request from pharmaceutical firms to make use of these regulations. As a result, these declarations do not have concrete effects.

This section argues that there is no evidence of domestic pressure from pharmaceutical industry groups for policy integration. Critically, the lack of local pharmaceutical producers advocating for public health and the use of TRIPS flexibilities to produce generic versions of patented drugs is a significant variable that explains the lack of success of policy integration in relation to compulsory licensing. The main goal of the domestic industry, regardless of the

sector, was to comply with international standards. In this context, compulsory licensing, although legal in the TRIPS Agreement, might become a political issue for the country and its firms.

6.3.3 Issue Salience: Policymaking During the COVID-19 Pandemic

A third relevant variable identified in this thesis is the COVID-19 pandemic. As argued in the previous chapter, the pandemic is a contextual variable that created a sense of urgency in policymaking related to health. This chapter argues that the pandemic provided an important impetus for change in compulsory licensing regulation but did not affect policy negotiations related to patent term extensions. Therefore, the analysis in this chapter shows the pandemic's limited capacity to promote effective integration for sustainable development.

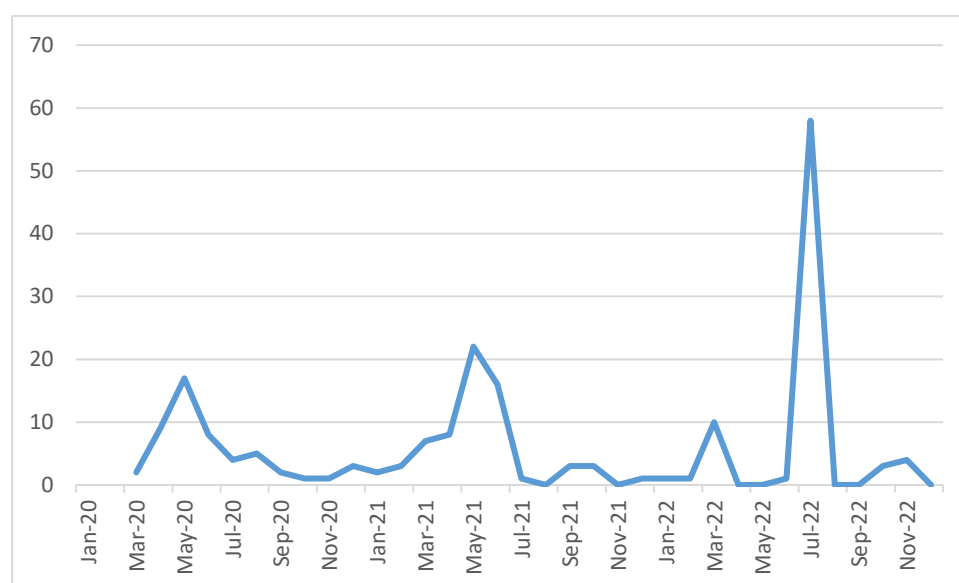
I found no evidence that the pandemic influenced the negotiations of Law N. 21,355 (case one). At the time of negotiations, there were no references to the COVID-19 pandemic and its relevance for either supplementary protection or compulsory licensing. After the pandemic started, a declaration of the Minister of Economy, Development, and Tourism (Lucas Palacios) argued that the modernisation of Chile's patent regulation was crucial for its post-pandemic recovery. His declaration was focused on the rising number of patent grants in Chile and how the law proposal would benefit the country's innovation system. As such, the proposed changes to patent regulation were an improvement to the existing system, establishing more efficient procedures for registration and contributing to better management and use of industrial property (BCN, 2021, p. 262).

The compulsory licensing case, in contrast, was partially motivated by the pandemic. The legislative proposal on pandemic-related compulsory licensing started at the beginning of the pandemic and had the primary goal of addressing possible inequities in access to technologies to fight the COVID-19 outbreak. Similarly, the COVID-19 health declaration is an excellent example of a quick response to a health crisis, enabling the compulsory licensing of COVID-19 treatments. However, as discussed above, this declaration was not used by the national pharmaceutical industry. In addition, the *Fármacos II* proposal was not motivated by the pandemic, and the current stalled negotiations indicate that the health crisis did not present as compelling grounds for the approval of new compulsory licensing regulation.

The analysis in this chapter also indicates that the COVID-19 pandemic was not the only relevant health issue that prompted responses from policymakers. The 2016 health declaration on Sofosbuvir shows that other health concerns can be equally successful in promoting policy integration for sustainable development. The joint efforts of policymakers and civil society pushed the government to declare hepatitis C a health concern and create the possibility of issuing a compulsory license.

The cases of supplementary protection and compulsory licensing in Chile reveal that the COVID-19 pandemic was only partially responsible for the tailoring initiatives studied in this chapter. This result suggests that the intersection of patent protection and sustainable development (or public health) was not salient enough to mobilise different sectors of civil society and push for the approval of COVID-related proposals. Figure 6.3 shows the number of news articles mentioning “COVID-19” and “intellectual property” in selected Chilean media outlets. The peak of articles on the intersection of IP and the pandemic took place in 2022, with the emergence of omicron cases in Chile (Instituto de Salud Pública, 2022). There is no evidence of a correlation between the different peaks of salience in Figure 6.3 and the cases in this chapter.

Figure 6.3: News Articles Mentioning “COVID-19” and “Intellectual Property” in Selected Chilean Media Outlets.



Source: Author’s elaboration based on data from Factiva.

6.4 Conclusion

This chapter explores two cases of policy integration for sustainable development in Chile. In the first case, an amendment (Law N. 21,355 of 2021) to the Chilean Industrial Property Law imposed limits on the duration of patent term extensions. The chapter finds that the tailoring of this patent regulation was explicitly motivated by public health objectives. Policymakers did not link this patent regulation to other sustainable development issues, such as renewable energy, indicating a prevalence of health concerns in this field.

The second case shows that the tailoring of compulsory licensing regulation took place in five different initiatives: two health declarations (on hepatitis C in 2018 and on COVID-19 in 2021) and three attempts to include compulsory licensing in existing law proposals or the creation of new legislation on compulsory licensing to enable public health goals. Only the health declarations are examples of successful policy integration for sustainable development since the legal negotiations failed or failed to secure support from policymakers. However, as explained above, the practical application of these declarations is limited.

This chapter analyses two conditions in the QCA result, namely civil society participation in policymaking and trade dependence, as conditions for policy integration for sustainable development in Chile. The qualitative data reported in this chapter indicates that civil society participation in recent patent regulation in Chile was relevant but limited in its capacity to set a political agenda. Only one CSO (Innovarte) was present during legislative debates or working directly with policymakers in the policies analysed in this chapter. Overall, the results in this chapter confirm that CSO participation is a relevant variable for policy integration but not sufficient to explain variation across cases.

In addition, international pressure was found to be crucial in shaping Chile's policy space. The US (using the USTR Special 301 Report) and transnational firms (using their influence) have halted initiatives related to compulsory licensing. These efforts were mostly effective, except for the public health declaration on hepatitis C. Other attempts to streamline compulsory licensing were unsuccessful, and international pressure seems to be affecting current proposals tackling compulsory licensing. These results suggest that the QCA failed to capture the importance of political pressure in Chile and its effects on policy integration for sustainable development.

The results in this chapter reinforce the central argument of this thesis that policy integration for sustainable development is context contingent. Chilean industrial capabilities were particularly relevant to explaining the lack of engagement from the domestic pharmaceutical industry and the narrow scope of policy integration in the case of compulsory licensing. Finally, this chapter finds that policymakers are key in defining a political agenda that can support or hinder policy integration for sustainable development.

Chapter 7

Discussion and Conclusion: Patent Regulation and the Political Economy of Policy Integration for Sustainable Development in Latin America

Sustainable development is a complex global problem, requiring policy responses that are not restricted to one single policy domain. Patent protection is a policy area that can affect the achievement of several SDGs, such as zero hunger (SDG 2), health and well-being (SDG 3), energy (SDG 7), climate action (SDG 13), and biodiversity (SDG 15). Although the literature on the intersection of patent regulation and sustainable development identifies areas of overlap (Adbel-Latif & Roffe, 2021; Rognstad & Ørstavik, 2021; Ruse-Khan, 2011a), it lacks an empirical analysis of this intersection and the conditions for enabling and constraining integration. In addition, the emerging literature on policy integration for sustainable development does not provide a comprehensive analysis of the political and economic dynamics that shape integration processes (Cejudo & Trein, 2023b; Tosun & Lang, 2017).

To address this gap, this thesis presents an empirical analysis of policy integration for sustainable development in Latin American patent regulation. This analysis is divided into two parts. The first part is a QCA of 17 Latin American countries that identifies causal patterns in the region. The QCA examines four conditions: international patent commitments, trade dependence, domestic innovation, and civil society access in policymaking. One of the paths resulting from this analysis indicates that policy integration for sustainable development takes place when countries have the presence of civil society access to policymaking and the absence of trade dependence.

Two countries that presented this configuration of conditions were selected for an in-depth qualitative analysis: Brazil and Chile. For both countries, two recent tailoring initiatives were examined: patent term extensions and compulsory licensing. Tailoring initiatives refer to adjustments of patent regulation to reflect the national context (Shadlen, 2016). Based on a mixed-methods approach, this thesis identifies five key conditions that influence policy

integration for sustainable development in patent regulation in Brazil and Chile. Each case presents a different combination of these conditions, affecting how policy integration takes place. Table 7.1 summarises the four cases and five variables identified and examined in this thesis.

Both cases of patent term extensions in Brazil and Chile show policymakers' interest in restricting the duration of patent protection, with the tailoring of these TRIPS-plus commitments in both cases motivated by health goals (i.e., access to medicines). In Brazil, a coalition between civil society and the domestic pharmaceutical industry actively supported the end of patent term extensions through its participation in the Supreme Court decision-making process. In contrast, Chilean civil society and domestic pharmaceutical industry presented limited participation in policymaking and relevance for the outcome, which was mainly driven by a consensus among policymakers.

In contrast to patent term extensions, compulsory licensing presented a more challenging task to policymakers in both countries. The tailoring of compulsory licensing regulation to create new norms for the streamlining and facilitation of such licenses was a highly controversial issue in both countries. In Brazil, legislation with regulatory innovations to mandate technology transfer gained support in the legislature but failed to be approved by the president. In Chile, law proposals failed to advance, but public health declarations of narrower application were passed.

The empirical analysis reveals that policy integration for sustainable development in patent regulation takes place mostly in the context of health. The cases examined in this thesis show that policymakers framed integration efforts around public health issues, primarily focusing on access to medicines. Although the QCA (Chapter 4) included other sustainability areas, i.e., energy and biodiversity, they did not appear as central for the policy developments analysed in the case studies. Based on these results, this thesis argues that policy integration for sustainable development is context contingent. The reconciliation of international expectations and domestic sustainability goals depends on the policy space available and the political-economic dynamics that shape the tailoring of patent regulations. Each of the four cases examined in this thesis shows a different constellation of conditions, suggesting that policy integration for sustainable development can be achieved in many ways, but the scope of integration can be limited or expanded depending on these conditions.

Chapter 7 – Discussion and conclusion

This chapter discusses the results of this thesis in a comparative approach. Section 7.1 discusses the scope of policy integration in each case. Section 7.2 provides an analysis of the political economy of policy integration to examine the similarities and differences between the cases. Section 7.3 reflects on the implications of these findings for the implementation of the SDGs, global sustainable development governance, and trade policy, situating the findings in the wider literature. Section 7.4 discusses the limitations of this thesis and suggests future research directions. Finally, Section 7.5 concludes the chapter.

Table 7.1: Summary of Cases and Variables.

		Chapter 5 – Brazil		Chapter 6 – Chile	
		Patent term extension	Compulsory licensing	Patent term extension	Compulsory licensing
Cases		Supreme Court decision ADI N. 5,529.	Law N. 14,200.	Law N. 21,355.	Sofosbuvir; COVID-19; Law 21,355; Fármacos II; Pandemic-related.
Outcome		Ended patent term extensions on public health grounds.	Amended IP Law to provide for compulsory licensing in the event of national or international emergencies.	Adjusted rules and the duration of extensions on public health grounds. (Minor adjustments)	Two resolutions provided health grounds for compulsory licensing; law proposals failed.
Policy integration		Successful policy integration motivated by health goals.	Policy integration limited by executive veto.	Successful policy integration motivated by health goals.	Policy integration limited to health resolutions (Sofosbuvir and COVID-19).
QCA variables	CSOs	CSOs provided information to policymakers and built coalitions with the domestic industry.	CSOs helped organise the original proposal.	1 CSO participated in negotiations and meetings with INAPI, but its influence was limited.	1 CSO was important for the resolutions and supported the law proposals.
	International pressure	Pressure from transnational firms and some governments but nothing from the US.	Transnational firms lobbied for the presidential veto.	Not relevant (no evidence).	Transnational firms and governments, including the US (USTR 301).
Other variables	Institutions	The Supreme Court and Attorney General promoted policy integration.	The proposal was accepted by the legislature but partially vetoed by the executive.	The proposal was accepted and easily negotiated by all institutions involved.	Law proposals faced resistance in the legislature.
	Domestic industry	Provided information and lobbied for the decision.	No evidence of engagement with the proposal or negotiations.	Limited engagement of the domestic industry. Small pharmaceutical industry.	Limited engagement of the domestic industry. Small pharmaceutical industry.
	COVID-19	Critical motivation for policy change.	Critical motivation for policy change.	Not relevant (no evidence).	Partially important (for the COVID-19 resolution and recent proposals).

7.1 Understanding Policy Integration for Sustainable Development

The first research question of this thesis aims to assess to what extent Latin American countries have integrated sustainable development goals into their patent protection regulation in the period from 2015 to 2023. Through the QCA and the four qualitative case studies, I find that policy integration for sustainable development in patent regulation is a common practice in the region. For example, the results in the QCA (Chapter 4) indicate that all countries in Latin America present some degree of policy integration for sustainable development, mainly due to the COVID-19 pandemic. However, a closer look reveals that the degree of policy integration varies significantly depending on the country, type of patent regulation, and other context-specific characteristics.

This section discusses two central findings related to how policy integration for sustainable development takes place in patent regulation in Latin America. Section 7.1.1 explains the variance in integration, and Section 7.1.2 details which parts of the global sustainable development agenda are integrated domestically in Latin American countries.

7.1.1 Scope of Policy Integration for Sustainable Development

Although the QCA and case studies suggest that all cases analysed in this thesis present some degree of policy integration, integration looks different in each case and for each type of patent regulation. The analysis in this thesis provides evidence that each type of patent regulation involves different political and economic dynamics that can enable or hinder the scope of integration. In Chapters 5 and 6, I show that these specific dynamics are also particular to each country and its social and economic structures. It is also crucial to consider what policymakers understand as the best result possible to achieve in each case, depending on the existing legal and political policy space. The four case studies can be divided into two main categories based on the scope of policy integration, as displayed in Table 7.2.

Broad policy integration means that the policy outcome reflects policymakers' understanding of integration and that policymakers did not face constraints in promoting integration. For instance, the case of patent term extensions in Brazil shows that policymakers (Supreme Court ministers in this case) understood this provision as a barrier to access to medicines and that the best response to achieve public health was to remove this barrier completely. In Chile, the

best response from policymakers was to limit the duration of such extensions. Certainly, policies in Chile are restricted by TRIPS-plus trade agreements (more on that below), but the policy outcome still reflects policymakers' intentions.

Narrow policy integration means that the policy outcome does not fully reflect initial conceptualisations of integration and that policymakers face constraints in promoting policy integration. The cases of compulsory licenses fall under this category. In Brazil, the legislative body understood the transfer of know-how as crucial to promoting public health goals. However, due to international pressure, the proposal was significantly changed in its final stages. Similarly, in Chile, policymakers aimed to create new compulsory licensing regulation through law proposals but failed to progress these proposals in the policymaking process. Two public health declarations were positive developments in policy integration but were limited in their practical application.

This typology of policy scope focuses on policymakers' perspectives because it highlights what ideas prevail in policymaking and is useful in the analysis of non-state actors' influence on policy decisions. Since policy integration might be understood differently depending on the actors involved, the emphasis on policymakers allows for an analysis of the proposed scope of integration more objectively.

Table 7.2: Scope of Policy Integration for Sustainable Development in the Case Studies.

	Broad policy integration	Narrow policy integration
	<i>Patent term extension</i>	<i>Compulsory licensing</i>
Brazil	Ending patent term extensions.	Reinforcing existing rules and clarifying some technical aspects. New norms on technology transfer not approved.
Chile	Narrowing the duration of extensions.	Recognising two specific public health issues (hepatitis C and COVID-19) to justify compulsory licenses. Legislative proposals not approved.

These results are crucial to the understanding of policy integration for sustainable development as a political phenomenon. Although the literature on policy integration has increasingly paid attention to the politics of integration (Cejudo & Trein, 2023b; Tosun & Lang, 2017), it does not capture the nuances of this process. This research contributes to this

literature, showing that policy integration occurs in different forms depending on the different combinations of conditions present or absent during policymaking. It is crucial to consider the interests and motivations of public and private actors that are directly and indirectly involved in policy design to understand when integration happens and how.

In the analysis of the case studies, the findings reveal variation in policy integration for sustainable development across different types of patent regulation. In both countries, there is a significant difference in the engagement of state and non-state actors in tailoring initiatives related to patent term extensions and compulsory licensing. This variance across regulations can be explained by the differences in the goals of these regulations and how tailoring affects patent owners.

Tailoring patent term extensions in Brazil and Chile differ in terms of goals and impact on patent owners. In Brazil, the Supreme Court decision effectively ended extensions. Even though this decision maintains the TRIPS standard of 20 years of patent protection, in practice, it reduced the effective protection that most pharmaceutical patents enjoyed in Brazil. In Chapter 5, I demonstrate that transnational pharmaceutical firms strongly opposed this decision since it represented a reduction in the duration of their monopoly over their inventions. Nevertheless, they failed to influence the outcome. In contrast, tailoring in Chile aimed to promote minor adjustments to patent term extensions. The impact of these changes on patent owners was much less dramatic than the ones achieved in Brazil, which helps explain the lack of interest from transnational firms in the Chilean case. Critically, Chile is still maintaining its TRIPS-plus commitments.

Different from patent term extensions, tailoring compulsory licensing regulation involved a process of creating new rules to streamline administrative steps to grant and use such licenses. New rules, such as expanding the grounds for compulsory licenses and mandating technology transfer, directly affect monopoly rights. Consequently, there was strong opposition from transnational firms and domestic actors in both Brazil and Chile. In both countries, policymakers attempted to create new rules and conditions for compulsory licenses but failed to achieve a significant outcome. Although both countries present some degree of integration, the outcome was arguably insignificant in terms of novelty or practical application.

Patent term extensions are a form of TRIPS-plus regulation, and policy integration in this regulation depends on a country's international patent commitments. Although policy integration was possible in both countries, the comparative analysis shows that Brazil had more legal policy space than Chile, which allowed the end of patent term extensions on public health grounds.

Even though the QCA path examined in this thesis does not include the level of international patent commitments (legal policy space) as a relevant variable, it is important to consider that this variable helps explain differences between tailoring extensions in Brazil and Chile. Revoking a TRIPS-plus regulation was possible in Brazil because it had not committed to such rules internationally. Chile, in contrast, is signatory to a PTA with the US and the European Free Trade Association (EFTA) that requires the implementation of patent term extensions (called supplementary protection in Chile). This reduced legal policy space means that Chile could adjust extensions but not eliminate them. As an international regulatory commitment, the elimination of patent term extensions was not politically feasible and not proposed in the negotiations.

7.1.2 Aspects of the SDGs Integrated

In addition to the scope of integration, this thesis provides novel insights into the application of sustainable development as a frame to promote policy integration. The starting point of this thesis was to understand how sustainable development was integrated into domestic policymaking decisions in patent protection. Based on the results of the QCA and the case studies, I argue that, although promoting sustainability goals, policy developments in Brazil and Chile did not incorporate concepts related to the 2030 Agenda, such as “sustainable development”.

First, the QCA results show a noticeable difference across sustainable development issues. As discussed in Chapter 4, most Latin American countries present integration in the field of public health due to the COVID-19 pandemic, which started in 2019. Energy transition, climate change, and biodiversity are much less significant issues for these countries. These differences and the relative importance of health issues are crucial to understanding the failures of sustainability as a normative concept to promote health goals in patent regulation.

The difference between policy integration at international and domestic levels is striking. The QCA provides an analysis of data on policy integration at the international level. In this analysis, the source of data for policy integration is (i) voluntary national reports (VNRs) that detail the domestic implementation of the SDGs and submitted in the context of the UN High-Level Political Forum on Sustainable Development and (ii) interventions at the TRIPS Council. These two sources of data reveal that concepts related to sustainable development were employed to promote policy integration. In the case of VNRs, it is evident that countries use terminologies related to sustainability as they detail the implementation of the SDGs. In the case of the TRIPS Council, concepts related to sustainable development appeared in some cases, showing that there is an effort to use the sustainability framework internationally.

In contrast, the analysis of the four case studies reveals that the same logic was not applied domestically. The case studies reveal that concepts such as “sustainable development”, “sustainability”, or “SDGs” did not appear in the discussions to change patent protection. As highlighted before, the cases analysed in this thesis show that policy integration was restricted to public health. Other aspects of the SDGs, such as food security, appeared in specific discussions but were not the primary motivators for the policy outcomes observed in this thesis. Promoting innovation also appeared in these discussions, but the main goal of policy changes was to tackle public health issues. The case of patent term extensions in Chile was the only case where innovation goals were relatively more central in the negotiations. Still, innovation was not the primary driver to reduce the duration of patent term extensions.

Recent literature suggests that the 2030 Agenda has provided a narrative change in international and domestic politics (Biermann et al., 2022). Despite these results, I argue that sustainable development as a normative concept has not been integrated into patent regulation in Brazil and Chile. There is no evidence from my empirical analysis that state or non-state actors used concepts related to sustainable development to promote changes in patent regulation. In interviews, policymakers working on IPRs indicated that the SDGs had not changed their work in any substantive way (Interviews BR03, CH04, CR04). Given the lack of mainstreaming the SDGs into IP policymaking, it is not surprising that state and non-state actors do not use sustainable development as a normative frame to promote policy changes.

The domestic application of the SDGs in the context of patent regulation is also affected by the lack of guidance in the 2030 Agenda on how to address potential tensions between patent protection and sustainability. As discussed in Chapter 1, the 2030 Agenda does not have a clear position on the role of patent regulation in sustainability. While SDG 9 (Industry and innovation) focuses on promoting innovation, it does not mention patent regulation or other forms of IPRs. SDG 3 (Health and well-being) is the only goal that mentions IPRs but refers to flexibilities only in the case of essential medicines.³¹

The absence of patent regulation in the SDGs makes this framework particularly weak in domestic policymaking. As such, non-state actors, such as CSOs, showed a clear preference to focus on public health, particularly during the COVID-19 pandemic, promoting sustainability goals but not intentionally promoting the SDGs or the 2030 Agenda.

The focus of policy integration for sustainable development on public health is not surprising. Public health has been a central topic in the contentious politics of patent regulation and the provisions of public goods (Haunss, 2013; Sell & Prakash, 2004). In contrast, other policy fields have less evident tensions with rising patent protection. For example, despite the existence of theoretical works on the potential implications of patent regulation for energy transition, there is little empirical evidence of this conflict happening in practice. In addition, given the history of restricted access to medicines during the HIV/AIDS crisis and the empirical evidence in public health, it is expected that this area is prominent and relevant for the integration of patent protection and sustainable development. The focus on public health indicates that attempting to integrate a broader and possibly vaguer concept is difficult in practice. It also suggests that “access to medicines” remains a significant informal norm in domestic and global politics (Hein & Moon, 2013).

The initial stages of this research included 12 preliminary interviews with several actors working in the fields of energy transition and climate change across different countries in Latin America (see Chapter 3). These interviews indicated that domestic actors working in these fields do not engage with patent protection as often as actors in the public health space do. Some interviewees argued that they were familiar with patent regulation and had been in contact with it regarding technology transfer agreements. However, there is little discussion

³¹ The Open Working Group that negotiated the SDGs requested to include several points on IPRs that were removed in the final versions of the 2030 Agenda (Open Working Group 2013, 2014a, 2014b).

on the implications (positive or negative) of patent regulation on the adoption of green technologies.

It is undeniable that health is a vital part of sustainable development, being an integral element of the SDGs and present in official documents related to the 2030 Agenda. Nevertheless, the lack of engagement with the concept of sustainable development not only suggests that there is a weak normative value in sustainability but also that countries are more concerned with tackling tangible, urgent problems. Sustainability is arguably too vague, while the COVID-19 pandemic was very salient and required immediate action from policymakers. Therefore, political salience is crucial to understanding policy outcomes and the impetus for policy change. In addition, other concepts used in international politics, such as One Health and Health in All Policies, have increasingly been used to mainstream health-related goals in other policy areas (Dye, 2022; World Health Organisation, 2022).

The first research question aims to understand how policy integration happens in Latin America, looking at both international and domestic levels. The results present important findings related to the empirical application of policy integration. Policy integration appears in different forms, and the scope of policy integration varies significantly. This scope depends on policy content, goals, and objectives that policymakers want to achieve. Furthermore, the concept of sustainable development is used in integration internationally but not domestically.

7.2 Conditions for Policy Integration

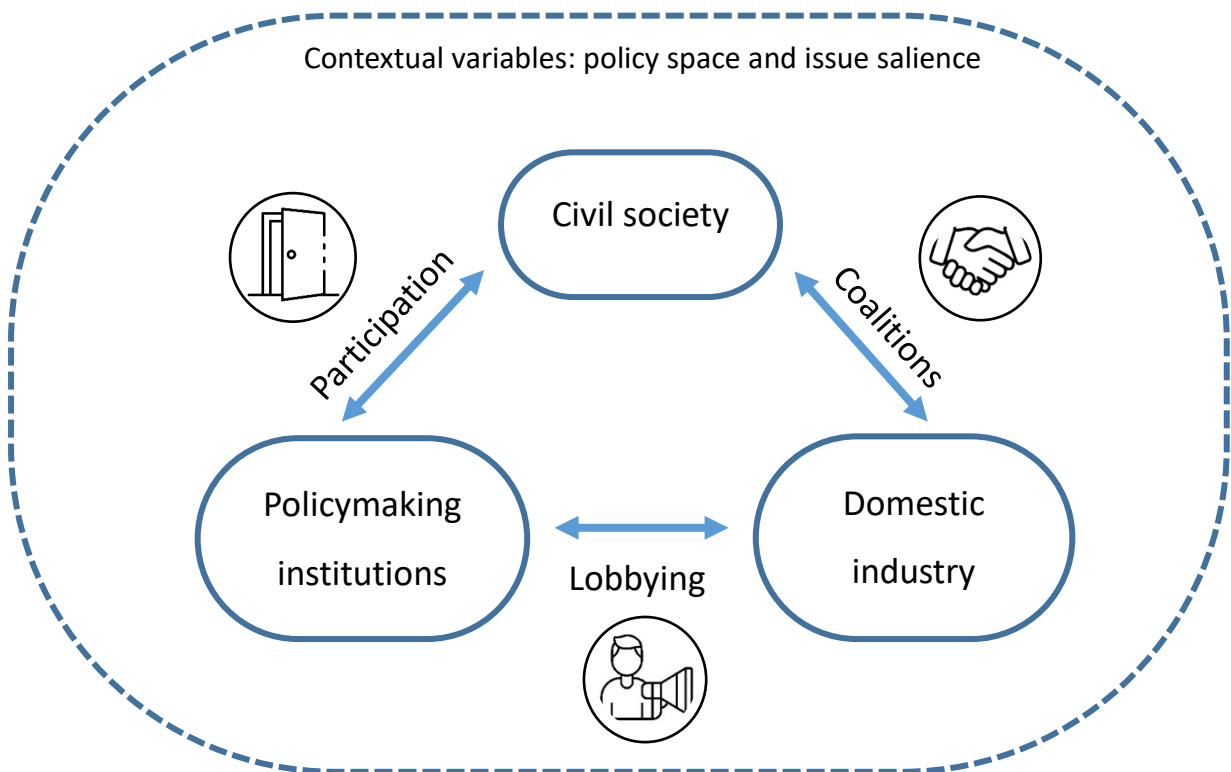
The second part of this thesis focuses on a causal analysis of policy integration. More precisely, the second set of research questions guiding this thesis aim to understand the conditions that led to policy integration and how these conditions operate in practice. To answer these questions, I draw on the results of the QCA and case studies to identify conditions and causal relations. I argue in this section that a combination of (political and legal) policy space and the active role of state and non-state domestic actors explains policy integration for sustainable development in Latin America.

The QCA tests four conditions identified in the literature as relevant for the integration of patent protection policymaking and sustainability (trade dependence, international patent

commitments, domestic innovation, and civil society participation in policymaking). Chapter 4 explains that two different paths resulted from the QCA, but this thesis focuses on the path that combines trade dependence and civil society participation in policymaking. While the QCA indicates that this combination of conditions can promote policy integration, the case studies provide a more nuanced understanding of the role of these conditions, showing how they operate in practice and complementing them with three other variables (policymaking institutions, the domestic pharmaceutical industry, and the COVID-19 pandemic).

The conditions identified in this thesis are represented in Figure 7.1 and can be divided into contextual conditions, actors, and linking actions. The contextual conditions (international pressure and the COVID-19 pandemic) provide the setting for policy integration. The other three conditions relate to actors involved in policymaking: CSOs, the domestic industry, and policymaking institutions. Finally, linking actions are the most prevalent activities connecting actors during policymaking (represented via the arrows – participation in policymaking, coalition-building, and lobbying). This section details the contextual conditions (Section 7.2.1), actors (Section 7.2.2), and linking actions (Section 7.2.3).

Figure 7.1: What Conditions Led to Policy Integration for Sustainable Development in Latin America?



7.2.1 Contextual Conditions: Policy Space and the COVID-19 Pandemic

Contextual conditions explain the setting in which policy integration for sustainable development takes place. The results highlight two relevant contextual conditions in both countries: policy space and the COVID-19 pandemic. These two conditions explain the political boundaries of policymaking and the grounds for policy change.

Policy space is conceptualised in this thesis as both the legal and political space available for policymaking (Jackson, 2021). In the QCA, I test these two forms of policy space separately using international patent commitments and US trade dependence as measurements. Through this analysis, I found that policy integration in Brazil and Chile resulted from the absence of trade dependence. In the case studies, I expand these results, showing that political policy space must be viewed more broadly as an expanded understanding that encompasses trade dependence but also other forms of political and economic pressure.

The case studies show that, in the absence of effective international pressure, policymakers in Brazil and Chile used the existing policy space and enabled domestic actors to shape patent regulation for sustainable development. The effectiveness of international pressure resulted from the way that different political institutions responded to international pressures, changing the scope of policy integration. In the case of Brazil, the Supreme Court did not take into consideration the threats by the transnational pharmaceutical industry. In contrast, the president vetoed provisions in the compulsory licensing proposal to avoid retaliation from this industry.

Similarly, there is no evidence of international pressure in the case of patent term extensions in Chile, enabling a broad policy integration for sustainable development. However, the case of compulsory licensing presented mixed results. The example of the public health declaration on hepatitis C indicates that international pressure did not resonate with policymakers. In contrast, the law proposals (in particular *Fármacos II*) faced resistance from transnational firms and trade partners, hindering their approval.

As discussed in the previous section, the presence and effectiveness of international pressure were also connected to the type of patent regulation being tailored. Changes in patent term extensions did not gain attention from international actors in Chile and did not stop the Supreme Court decision in Brazil. In contrast, all legislative efforts related to compulsory

licensing faced strong opposition from international actors, who directly or indirectly halted these initiatives in both countries. Therefore, in both countries, there is evidence of effective international pressure that reduced the political policy space to promote integration for sustainable development.

The second contextual condition is the COVID-19 pandemic. The pandemic, which started in 2020, provided the grounds for urgent governmental action to tackle the health crisis. Crisis response required countries to quickly devise new regulatory instruments or adjust existing legislation to address the rising death toll and pressure on national health systems. Although the pandemic required both Brazil and Chile to create and adjust policies, the relevance of the health crisis for policy change was more prominent in Brazil.

In Brazil, both cases were primarily motivated by the COVID-19 pandemic. Although the Supreme Court case started before 2020, the pandemic accelerated the process and strongly influenced the outcome. In Chile, the pandemic only prompted a public health declaration. Other compulsory licensing regulations proposed in response to the pandemic were not successful. Interestingly, the pandemic did not influence the policymaking process on patent term extensions in Chile. Therefore, the pandemic was not a necessary condition for policy integration in all cases but part of sufficient combinations of conditions, playing an important role in mobilising state and non-state to promote policy change. In addition, the case of Sofosbuvir in Chile indicates that framing patents as a barrier to other health goals was equally effective. Health emergencies, such as the COVID-19 pandemic in Brazil or hepatitis C in Chile, provide a window of opportunity for tailoring patent regulation and promoting sustainability goals.

7.2.2 Actors

Complementing the two contextual conditions (policy space and the COVID-19 pandemic) described above, three other variables were identified and analysed in the case studies. In addition to civil society organisations (identified in the QCA, the analysis of the case studies shows that two other actors are responsible for policy integration: the domestic pharmaceutical industry and policymaking institutions and individuals within them.

7.2.2.1 Civil Society Organisations

Civil society access to policymaking is a condition identified in the QCA, suggesting that including these organisations in the decision-making process enables policy integration for sustainable development. The condition analysed in the QCA focuses on the structural characteristics of the countries, e.g., whether policymaking includes non-state actors and whether the government allows CSOs to carry out their advocacy activities. The case studies reveal a more nuanced picture of how access to policymaking happens in practice and the different strategies used by CSOs to advocate for public health goals.

The four case studies show that strategic framing is the primary strategy employed by CSOs to achieve their advocacy goals. These activities were focused on framing the abuse of monopolies as a threat to access to medicines and, more generally, public health. In particular, framing patent protection as a cost for the provision of public health services played a central role in the policy decisions. For example, in the case of patent term extensions in Brazil, CSOs used evidence from academic work to show the impacts of such extensions on the public budget. Similarly, the public health declaration on Sofosbuvir in Chile was also motivated by the high costs of the medicine produced by Gilead.

Public information is another critical strategy used by CSOs. These organisations used a combination of opinion pieces, webinars, and public protests to promote health objectives. These activities to inform the general public were particularly relevant in Brazil, where CSOs promoted large campaigns to raise awareness of the compulsory licensing legislation being negotiated during the pandemic. These activities were also relevant to inform legal analysts and intellectual property lawyers about the discussions taking place in the Supreme Court.

There are differences between Brazil and Chile. First, the size of the civil society ecosystem is much larger in Brazil than in Chile. As discussed in Chapter 5 (Brazil), Brazilian CSOs have experience working in the intersection of public health and patent protection, which was crucial in informing their mobilisation during the pandemic. In contrast, only one Chilean organisation showed similar capacity and expertise. In addition, Brazilian CSOs showed strong cooperation with academics to use scientific evidence in their claims, especially regarding the costs of medicines and accumulated costs for the government. The size of the Brazilian population and public health system also helps explain the government's interest in bringing pharmaceutical costs down.

This thesis provides evidence that CSOs were important actors in promoting policy integration for sustainable development in both countries. Their framing activities, together with public information and advocacy, were particularly relevant regarding patent term extensions in Brazil and Chile. However, the role of CSOs alone is not sufficient to explain policy integration. On the contrary, the cases of compulsory licenses in Brazil and Chile show that CSOs are not always successful in their advocacy activities. Therefore, it is essential to understand how other actors affect policy integration.

7.2.2.2 Domestic Pharmaceutical Industry

The domestic pharmaceutical industry is another important actor in policymaking identified in this thesis, and the analysis of the case studies reveals how the domestic industry influenced policy integration. The domestic industry is not a unitary actor, presenting differences among the varying sectors and their characteristics. This section explains how the different sectors of the domestic industry participated in policymaking activities and how their competing interests shaped policy outcomes in Brazil and Chile.

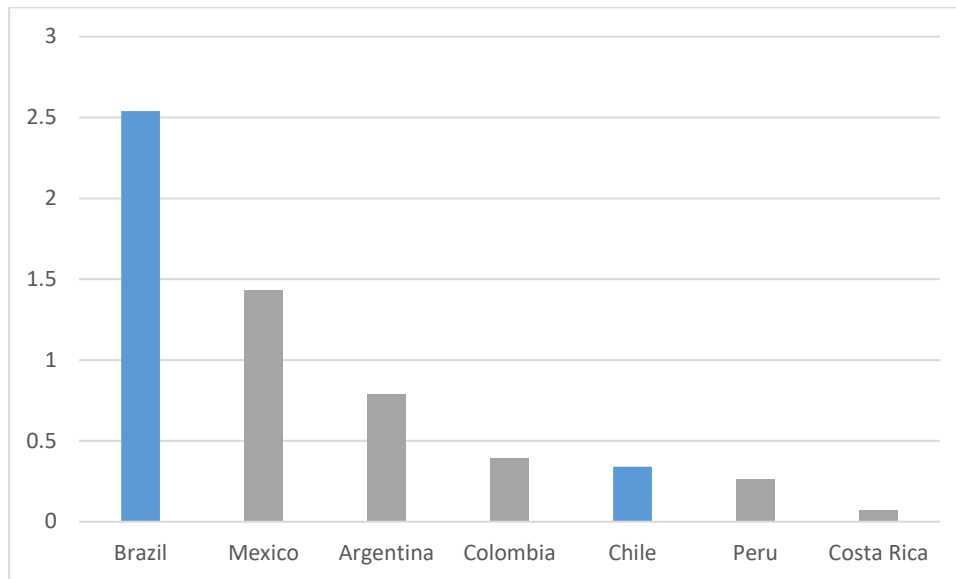
Divisions within the domestic industry are particularly evident in the case of patent term extensions in Brazil. The domestic pharmaceutical industry, which is a large producer of generic drugs, reinforced the framing that excessive patent protection had adverse effects on public health in Brazil. ABIFINA, one of the leading organisations representing this industry, was responsible for filing the first claim against the patent term extensions with the Supreme Court and was an active actor throughout the process.

In contrast, other sectors of the Brazilian industry opposed the unconstitutionality claim. These sectors were mainly linked to other industrial sectors, such as the electronic industry and start-ups. As discussed in Chapter 5 (Brazil), these sectors of the domestic industry were interested in maintaining patent term extensions to ensure international investments and trade relations with high-income countries. As such, the interests of these firms were closely related to the interests of the transnational firms. It is also noteworthy that some domestic industry sectors were even represented by the same law firm (Licks Attorneys) as transnational industry groups (i.e., Interfarma and CropLife) in the Supreme Court case.

The case of compulsory licensing shows a different reaction from domestic firms in Brazil. While in the case of patent term extension, domestic pharmaceutical firms were central actors, in this case, there is no evidence of their participation in the negotiations. The economic interests of these firms help understand this difference in reaction to patent regulation. The provision of patent term extensions affects all patented drugs in the country. Therefore, ending extensions allows generic producers to expand their product portfolio significantly. On the other hand, compulsory licensing legislation targets specific health emergencies and products. The impact of such legislation is more restricted and, therefore, would not have the same benefits for the domestic industry.

In Chile, domestic firms also participated in the policymaking process. Nevertheless, unlike Brazil, the domestic pharmaceutical industry did not have the same protagonist role. It is evident from the analysis of the cases in Chile that this industry was present in policymaking discussions but did not lead the policymaking process. Similarly, these organisations were not involved in promoting compulsory licensing legislation. An explanation for the lack of engagement from the national industry in Chile is that the domestic pharmaceutical industry is significantly smaller in Chile than in Brazil. As Figure 7.2 shows, the Brazilian pharmaceutical industry has a higher value added in the pharmaceutical sector (2.5%) than all other countries in the region. Chile has a minor role in the global pharmaceutical industry, with less than 0.5% of the global pharmaceutical industry value added.

Figure 7.2: Gross Pharmaceutical Industry Value Added by Latin American Country, 2017 (percentage).



Source: Author's elaboration based on Ostwald et al. (2020)

It is noteworthy that the QCA includes a condition that attempts to reflect the domestic industry, namely “domestic innovation”. The absence of this condition was part of the intermediate solution from the QCA in the second path. While this path was not further explored in the case studies (and Brazil and Chile did not present this path), the analysis of the case studies shows that the absence of domestic innovation also played a role in policy integration, since the generic pharmaceutical industry was pushing for policy integration.

In conclusion, the thesis argues that the economic interests of the domestic pharmaceutical industry were crucial to promote policy integration. This industry sector was a primary beneficiary of the end of patent term extensions in Brazil and a crucial actor in policymaking that led to policy integration in Brazil. In addition, the lack of engagement of this sector in Chile and Brazil in compulsory licensing helps explain the reduced scope of policy integration. While the absence of this industry in policymaking did not stop integration from happening, it limited the integration of health goals to patent regulation.

7.2.2.3 Policymaking Institutions and Individuals

Lastly, a third condition that helps understand policy integration for sustainable development in patent regulation in Latin America is the role of policymaking institutions and individuals within them. Policymaking institutions refer to the arenas where policies are negotiated and created, such as patent offices, the Congress, the Senate, and the Supreme Court (Timmermans, 2001). This section argues that the different policymaking processes and rules and openness to lobbying and other forms of engagement from non-state actors can significantly change policy integration.

Decisions on patent regulation in the four cases took place mainly at the legislative level, with the exception of the patent term extensions in Brazil, which took place in the judiciary (Supreme Court). However, other organisations have also been involved in the process, either directly or indirectly.

The two cases in Brazil provide interesting insights into the organisational differences that shaped policy integration. The Supreme Court allows relevant state and non-state organisations to participate in the hearings as *amicus curie*, giving these actors an opportunity to express their views on the subject and provide information to the ministers. Another essential characteristic of Supreme Court decisions is that they are final, i.e., they do not require approval from other institutions. Finally, the position of individuals is also more relevant in the Supreme Court since ministers have the power to voice their views, and it allows other individuals, such as the attorney general, to define the scope of policy integration.

Policymaking in the legislature presents a different configuration of actors and interests. In Brazil, there was evident excitement by Congress and Senate representatives regarding the compulsory licensing law. It was an essential agenda for politicians to act on during the pandemic. Nevertheless, the proposal was targeted by strong lobby activities from transnational firms and ended up being changed significantly after the Presidential veto. Since policymaking in the legislature requires a process with various steps and institutions, this process provides non-state actors with multiple opportunities to promote their interests and change policies. In addition, although Supreme Court decisions can be appealed, they cannot be vetoed by the president (STF, 2018).

In Chile, institutions were also crucial in designing policies and engaging with non-state actors. The Chilean IP office (INAPI) had a central role in policy design in the case of patent term extensions since it helped set the agenda for policy integration. In the negotiations of the patent term extension regulation, it was evident that INAPI and the legislature were focusing the discussions around topics of consensus among actors in the IP system. Focusing on less controversial issues allowed policymaking organisations to avoid deadlocks in the negotiations and promote incremental changes to patent regulation. As a result, debates on compulsory licensing were restricted to other legislative negotiations that faced resistance from domestic and international actors, such as the *Fármacos II* proposal. As this thesis shows, the legislative process of these proposals (in particular Law N. 21,355 and *Fármacos II*) involves a long negotiation process that includes many governmental and non-governmental actors.

Congress representatives also helped define the scope of policy integration in Chile. The relentless activity of Congress members (such as Congress representative Giorgio Jackson) to promote public health goals in patent regulation enabled the publication of health declarations in the case of Sofosbuvir and COVID-related medicines. However, the case of these declarations shows the limitations of policymaking institutions, since these declarations have limited application and more enforceable legislations were not approved.

In conclusion, the characteristics and rules in policymaking institutions help explain policy integration for sustainable development. As arenas for policy design, these institutions shape the scope of integration and the issues integrated. In addition, individuals within these organisations can promote their views on policy integration, but their ability to shape policy outcomes depends on how the institutions interact with other variables.

7.2.3 Connecting Activities in Policymaking

The analysis of the contextual conditions and actors involved in policymaking indicates that they are not sufficient to explain the outcome on their own. The scope of policy integration depends on the interaction among these different conditions. This section discusses how the different conditions are connected during policymaking and how these interactions change the scope of policy integration. Three linking activities are identified: coalitions, lobbying, and participation in policymaking.

Coalitions of different non-state actors are an important factor that expand the scope of policy integration. These coalitions were vital to strengthen framing strategies and promote a more significant advocacy movement to promote policy change. These coalitions also provided opportunities to share knowledge and expertise, expanding the reach of public campaigns and reducing costs for members of the coalition. The case of patent term extensions in Brazil is emblematic of how coalitions can promote policy integration. This case shows how a normative framing (pushed firmly by CSOs in promoting access to medicines and public health goals) in combination with economic interests (pushed by the industry to reduce costs for government and incentivise domestic industry) achieved a broad scope of policy integration.

The absence of this coalition in other cases does not mean that policy integration failed. However, the evidence suggests that whenever this coalition and alignment of interests was absent in policymaking, policy integration was restricted. For example, as discussed above, Chile did not present strong participation from its domestic pharmaceutical industry in the policymaking process. As a result, civil society, which is already very limited in size in Chile, did not achieve a broader scope of policy integration in the case of compulsory licenses.

Lobbying from domestic and international firms is another essential factor in explaining the scope of policy integration. Lobbying is understood in the context of this thesis as the various activities undertaken by business actors to persuade government decision-makers and influence their decisions (de Figueiredo & Richter, 2014). The analysis of the case studies shows that lobbying activities were present in both countries, but the scope of integration resulted from how these activities interacted with the other variables. It is important to note that lobbying was also a strategy used by CSOs. Nevertheless, the evidence in this thesis shows that these organisations benefited more from their direct participation in policy processes, as explained below.

Lobbying from domestic firms helps explain the broad scope of policy integration. For example, the case of patent term extensions in Brazil shows the influence of the domestic industry on the policy outcome, and the role that economic interests played in the final scope of policy integration was evident. Lobbying also narrowed the scope of policy integration or prevented it in some cases. As explained above, lobbying from transnational firms prevented law proposals from being negotiated or provisions from being approved.

The type of regulation is also important to explain resistance to lobbying activities. New rules on compulsory licensing triggered reactions from trade partners, while patent term extensions did not receive much attention from the international community. In addition, the Chilean case of public health declarations shows that this type of regulation, although less enforceable, was more likely to bypass transnational lobbying.

Finally, the third linking activity is participatory policymaking, allowing CSOs to influence policy outcomes. Non-state actors with fewer economic resources than firms can also participate in policy negotiations if institutions provide the space for them to voice their views and shape policy integration. Although this variable was already measured in the QCA, the analysis of the case studies reveals how this condition operates in practice. While firms also participated in policymaking processes, CSOs strongly benefited from these participatory spaces as a way to publicly present their normative views on patent regulation.

Participatory policymaking allowed the intervention of CSOs in different parts of the policymaking process in all cases studied in this thesis. Both instances of patent term extensions present significant participation from CSOs. The open and transparent participation at the Brazilian Supreme Court was unique among the cases. In contrast, the Chilean case presented an example of participatory policymaking that takes place at different levels, starting with consultation in INAPI to help design the new legislation and then progressing through other commissions in the legislature that also had non-state actors present.

The negotiations of new compulsory licensing legislation present a more restricted influence of CSOs. Participation was more limited in both countries, not because CSOs were prevented from participation but because the policymaking process did not take into consideration their views (Brazil) or because the proposals did not progress (Chile).

In summary, this thesis aims to understand what conditions led to policy integration in the cases of patent term extensions and compulsory licensing in Brazil and Chile. The results of this thesis provide evidence that not one single condition was responsible for the policy integration of patent protection and sustainable development. All conditions identified in the QCA and case studies, either contextual conditions or actors, operate in combination. The cases analysed in this thesis show that they might combine in different ways, and the results of the scope of policy integration depend on these combinations.

7.3 Implications for Theory, Methods, and Practice

The empirical research in this thesis provides novel insights into the (international) political economy of policy integration for sustainable development. It contributes to several branches of the literature on global governance, policy integration, and trade regulation. This section discusses the implications of the results to theory, methods, and practice.

The results presented in this thesis provide novel theoretical perspectives on policy integration for sustainable development. Only recently has the literature on policy integration paid attention to the political and economic dynamics that shape integrated policymaking (Cejudo & Trein, 2023b). This thesis contributes significantly to this literature, showing the different conditions that shape policy integration in Latin America. In addition, the different scopes of policy integration presented in this chapter are a useful typology for other studies aiming to analyse the extent to which sustainability issues are integrated into public policy and regulation.

The empirical analysis presented in this thesis also shows how and when policy can change, suggesting that civil society engagement in policymaking helps integrate political agendas and promote sustainability goals. This corroborates the existing empirical work on civil society's strategies in trade policy, which show that CSOs act in coalitions (Sell & Prakash, 2004; Thaiprayoon, 2015; Townsend et al., 2021) and promote strategic framing (Dür & Mateo, 2014; Nunn et al., 2009; Townsend et al., 2018), benefiting from the leadership of policymakers and favourable media attention (Townsend et al., 2023). The results in this thesis also underscore that access to policymaking does not necessarily mean that CSOs can influence policy outcomes. The evidence from compulsory licensing in Brazil and Chile shows how other conditions restrict civil society's capacity to promote policy integration effectively.

This thesis also provides important contributions to the theories that informed this study. Kauffman's (2017) grassroots global governance theory indicates that global norms are shaped domestically by local actors, transforming "meta-concepts" to match their interests and the local context. This thesis contributes to Kauffman's (2017) work, providing evidence of the role of international political and economic dynamics in shaping meta-concepts domestically. This thesis shows how Kauffmann's (2017) work and the literature on the politics

of IPRs (such as Deere Birkbeck, 2008) can be combined to understand transnational forces driven by economic interests in the domestic and local implementation of global norms.

The findings in this thesis also contribute new theoretical insights to Shadlen's (2016) work on the tailoring of patent regulation. Shadlen's (2016) work is primarily focused on coalitions, which are also an essential part of this thesis, as described in Section 7.2. However, the case studies suggest that tailoring also depends on the type of regulation being changed. As argued in this chapter, differences between patent term extensions and compulsory licensing shape policy integration for sustainable development. More precisely, changing different types of patent regulation has different implications for transnational patent owners and the domestic industry, altering the configuration of coalitions and power dynamics during policymaking.

This contribution to the concept of tailoring helps understand the capacity of the Global South to shape international norms and regulations. This thesis shows that countries that import and implement norms from global governance instruments, such as trade agreements, have different opportunities to change them to fit the domestic context. These findings contribute to the body of literature on the Global South's ability to actively shape global rules (Eimer et al., 2016; Fukuda-Parr & Muchhala, 2020; Helleiner, 2014). At the same time, this thesis underscores the limitations in tailoring processes, indicating that agency from the Global South is limited by structural factors, such as its position in the global economy.

These findings also contribute to the broader literature on the international political economy of global norms. In particular, this thesis builds on Sell's (2003, 2010, 2011) work to understand how ideas are used strategically to promote IP regulation, finding that competing narratives on access to medicines and protection of IP remain at the centre of patent policymaking. The results in this thesis contribute to the literature on monopolies and access to knowledge (Brown, 2012, 2019; Rikap, 2021), providing evidence of private power and strategic framing during the COVID-19 pandemic and complementing existing works with a novel perspective on the intersection of the international IP regime and sustainable development (Bannerman, 2020; Rognstad & Ørstavik, 2021; Yu, 2021).

This thesis highlights the relevance of international political economy variables for sustainable development, adding new empirical and theoretical insights to the literature on this intersection (Cadman et al., 2015; Carvalho, 2001; Thérien & Pouliot, 2020). While the literature has demonstrated the environmental impact of trade and the implementation of

production standards (Clapp & Helleiner, 2012; Langford et al., 2022; Spilker et al., 2017), this thesis provides evidence that transnational forces can impact the achievement of the 2030 Agenda domestically. This thesis also contributes to the literature on the political influence of corporations in the context of sustainable development (Bendell & Kearins, 2005; Slob & Weyzig, 2010), showing how lobbying and economic pressure are crucial strategies often used to hinder sustainability policies.

This thesis also shows that legal and political policy space is a central variable for policy integration for sustainable development. These findings confirm that trade regulation can impose limits on domestic policymaking, negatively affecting a country's capacity to attain its development goals (Thrasher, 2021). This analysis also provides empirical evidence of how constrained policy space can be observed on the ground, such as in the case of the presidential veto of the compulsory licensing legislation in Brazil, expanding on previous theoretical works (Correa, 2022; Ruse-Khan, 2009). These findings also have implications for other policy areas, in particular industrial policy. The current rise of (green) industrial policies suggests that policy space can define how countries are able to design industrial development strategies within legal and political constraints (Maskus, 2019; Mazzucato, 2021; Rodrik, 2014).

The results of this thesis contribute to the recent literature on the 2030 Agenda, which has found little impact of the SDGs on policy change (Biermann et al., 2022; Bogers et al., 2022). The analysis presented in this thesis corroborates the argument that sustainable development can be a helpful narrative at the international level. However, the relevance of this framing is drastically reduced once we zoom in on domestic policymaking processes. This research finds virtually no influence of sustainable development narratives on domestic discussions related to patent protection, showing that non-state actors prefer to use frames related to access to medicines to promote policy changes.

Finally, this thesis also contributes to broader discussions on the political economy of law and its implications for human well-being and sustainable development (Birchall, 2022; Gostin et al., 2019; Kapczynski, 2023; Pristor, 2019). The results in this thesis suggest that domestic legislative processes are strongly influenced by power dynamics that reinforce health inequities and reduce the capacity to tackle sustainable development issues. This thesis provides empirical evidence of these power dynamics and the importance of legislative processes that take sustainability into account.

Regarding the methods used in this research, this thesis presents a valuable strategy for combining QCA with case studies. Although other scholars have combined these two methods before (Álamos-Concha et al., 2022; Schneider & Rohlfing, 2013), the approach taken in this thesis provides an alternative to case selection based on typical cases. This approach allowed for an in-depth analysis of the conditions found in the QCA, highlighting its setbacks and providing alternative explanations for the outcome.

Lastly, this thesis has significant implications for policymaking in the fields of sustainable development and trade regulation. The results argue for more effective instruments to promote integrated policymaking in the various areas related to sustainable development. A siloed approach to policymaking persists and has hampered coordinated responses to sustainability issues. Critically, the 2030 Agenda is a long-term plan of 15 years that was created prior to the pandemic. The increase in climate-related disasters and the pandemic require fast and urgent policymaking that may be disconnected from long-term sustainability plans. Therefore, the global sustainable development agenda must address the limitation of the current SDGs and promote instruments to help countries break down policy siloes and address sustainability issues in an integrated manner in the context of multiple global crises.

As noted in the literature cited in this thesis, policymaking for sustainable development remains siloed. Interestingly, in the field of IPRs, different ministries must often collaborate, such as the Ministries of Economy, Trade, Biodiversity, and Health. However, moving from an administrative integration to policy integration that shapes how IP rules are designed requires addressing tensions between patent protection and sustainable development. As this thesis shows, addressing these tensions is a political and contentious endeavour, and overcoming the government's reluctance to deal with these tensions is key.

The findings also present important implications for trade policy. Trade negotiators and policymakers should take into consideration the relevance of policy space for sustainable development. Trade agreements should preserve enough space to allow countries to respond to sustainability-related emergencies, including health and environmental ones. Importantly, flexibilities must be preserved in international, regional, and bilateral agreements. Patent offices worldwide currently have virtually no sustainability goals embedded in their activities, hampering integrated policymaking for sustainable development. Therefore, non-state actors

should be included in the design of wider industrial and sustainability policies, allowing their perspectives on IPRs to be included in national development plans and patent policymaking.

7.4 Limitations and Future Research Directions

This thesis presents limitations in its scope that can be further analysed in future research. This thesis focuses on tailoring processes that took place in Brazil and Chile during the period analysed (2015-2022). Consequently, other policies that took place during this period, such as biodiversity laws that concern patent rights, were not included in the analysis. The approach taken in this thesis was to focus on attempts to change patent law that occurred in both countries (Brazil and Chile) to enable a comparative analysis. Future research can explore policies not included in this thesis and test the research findings in a broader range of regulatory issues.

The scope of this research was primarily limited to health (SDG 3). This focus was not an intentional selection but a result of the analysis of the empirical data that I collected. Consequently, this thesis focuses on aspects relevant to health, such as the CSOs that work in this space and the domestic pharmaceutical industry. More research can be undertaken to understand other sustainability aspects of policy changes in patent regulation. For example, further research can focus on why other domestic industry sectors did not engage in patent policymaking. Similarly, the lack of empirical work on the intersection of patent regulation and access to renewable energy is particularly remarkable and an interesting field for future research.

This thesis examines political and economic dynamics inherent to the pharmaceutical sector in Latin America. As this thesis highlights, each country has a specific social and economic context that defines political salience and priorities. Future research can test the results of this research in other contexts. For example, India and China are examples of countries in the Global South with relevant pharmaceutical industries to test the political and economic variables that shape industrial policies, patent regulation, and sustainable development.

This research is particularly interested in causal relations between political and economic variables and policy integration for sustainable development. It is important to consider that causality is complex, and the results in this thesis present one perspective on the causes of

policy integration. More work can be done using other methods to investigate other possible explanations for integration. For example, future research can examine the role of communities of practice within and across governments to understand if the experience of one country or policy field can lead others to promote policy integration.

The QCA presented in this thesis provides an excellent overview of patent integration in the region. However, some critical variables identified in the case studies are not straightforward to operationalise in the QCA. For example, trade dependence was operationalised using the Trade Intensity Index, which indicates the proximity between two countries based on trade volume. However, this index fails to capture the political side of trade, which might not correlate with trade volume. In addition, other variables, such as lobby activities, could only be identified in the detailed analysis of qualitative data and were not included in the QCA.

Finally, the COVID-19 pandemic presented a significant challenge during this study. As mentioned in Chapter 3, the start of the pandemic in 2020 created barriers to international travelling and fieldwork, which significantly impacted data collection. The health crisis also put stress on governments and many CSOs, which restricted my access to key informants. Although most of these limitations were overcome using other data sources, the lack of responses from potential participants impacted the development of this research. Future research can investigate whether the patterns found in this thesis influence policymaking in a post-pandemic world.

7.5 Conclusion

This thesis aimed to understand to what extent Latin American countries have integrated sustainable development goals into their patent protection regulation and to identify the conditions that promote positive integration for sustainable development. Drawing on a mixed-methods empirical analysis of 17 Latin American countries and four in-depth case studies, this thesis identified five key conditions for policy integration: policy space, issue salience, policymaking institutions and individuals, CSO participation in policymaking, and domestic pharmaceutical industry lobbying.

Policy space and issue salience are contextual conditions that define, respectively, policymakers' (legal and political) capacity to create or change patent regulation and the

relevance of sustainability goals for policymaking. Policy space in a given country is defined by its international patent commitments and political pressure from transnational firms and trade partners interested in maintaining high levels of patent protection globally. These commitments and pressure define policy options (i.e., which policies are feasible within this space) and the capacity of policymakers to respond to politically salient sustainability issues.

Within this context, policymaking institutions and individuals must navigate domestic and transnational interests and reconcile policy goals. Each political institution is an arena in which state and non-state actors promote their views on the integration of patent regulation and sustainable development. Policymakers address competing interests, setting the policy agenda based on their own understanding of the intersection of patent regulation and sustainability and the influence of domestic and transnational actors. Critically, the active role of CSOs in policymaking allows these groups to advocate for sustainability goals in patent regulation (such as access to medicines). This advocacy is particularly strengthened when the interests of CSOs match those of the domestic pharmaceutical industry.

The empirical analysis in this thesis finds that each policymaking process is unique and presents a different combination of these five conditions. In the presence of the five conditions listed above, countries are able to promote broad policy integration, such as in the cases of patent term extension. The absence of one or more conditions does not necessarily mean that policy integration is not possible. However, the scope of integration is reduced. The cases with a narrow scope of integration (such as the compulsory licensing cases in Brazil and Chile) have limited practical application, ultimately minimising the changes to promote its policy goals (in these cases, access to medicines).

This research also shows that Latin American countries constantly tailor patent regulation, adjusting it to achieve national development purposes and tackle significant challenges, such as the COVID-19 pandemic. Tailoring processes are particularly crucial for policy integration because they are opportunities to revise existing regulations and integrate sustainability goals into them. This thesis shows that countries in the Global South can shape international norms and regulation to fit their national context. Nevertheless, their capacity to do so depends on the policy space available and a synergy of interests across CSOs, industry, and government.

Finally, although policy integration is a crucial element within the global sustainability agenda, the evidence presented in this thesis argues that sustainable development is not a strong

driver for policy change in the field of patent regulation. The lack of mainstreaming of the SDGs into national policies and the cherry-picking of goals is a significant challenge for the global sustainability agenda and the achievement of the SDGs. In the context of multiple global crises, global governance must tackle the constraints that countries face when promoting sustainability and provide instruments for effective policy integration for sustainable development.

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Appendices

Appendix A: QCA Additional Materials

Table A1: QCA Dataset

Country	Integration (Outcome)									International patent commitment (C1)				US Trade dependence (C2)		Domestic innovation capacity (C3)			Civil society (C4)		
	Voluntary National Reports					TRIPS Council Minutes				OECD	US PTA	UPOV 91	PATENT	TII	USTRADE	Domestic patent applications	Mentions 2015-2022 GII	INNOV	V-dem CSO consultation	CIVICUS	CSO
Argentina	0	1	0	1	1	1	0	0	1	0.5	0	0	0.33	0.5	0	182	1	0.33	1.00	4	0.67
Bolivia	0	0	0	1	0	1	0	1	1	0	0	0	0	0.5	0	0	0	0	1.29	3	0.67
Brazil	0	0	0	0	1	1	0	1	0.67	0.5	0	0	0.33	1.0	0.33	1008	8	1	1.14	3	0.67
Chile	0	1	0	1	1	1	0	0	1	1	1	0	0.67	1.1	0.33	196	8	0.67	2.00	3	0.67
Colombia	1	0	0	0	0	1	0	0	0.33	1	1	0	0.67	2.1	0.67	77	4	0.33	1.14	2	0.33
Costa Rica	0	0	0	0	0	1	0	0	0.33	1	1	1	1	3.1	1	10	6	0.33	2.00	4	1
Ecuador	1	0	0	1	1	1	1	1	1	0	0	0	0	2.0	0.33	6	0	0	1.00	3	0.33
El Salvador	0	0	0	0	0	1	0	0	0.33	0	1	0	0.67	2.4	0.67	4	0	0	0.57	3	0.33
Guatemala	0	0	0	1	0	0	0	0	0.33	0	1	0	0.67	2.4	0.67	2	0	0	1.00	3	0.33
Honduras	0	0	0	0	0	1	0	0	0.33	0	1	0	0.67	3.0	0.67	1	0	0	1.00	2	0
Mexico	1	0	0	0	0	1	0	0	0.33	1	1	0	0.67	5.8	1	678	8	1	0.57	2	0
Nicaragua	1	0	0	1	0	1	0	0	0.67	0	1	0	0.67	4.2	1	3	0	0	0.00	1	0
Panama	1	0	0	1	0	1	0	0	0.67	0	1	1	1	1.2	0.33	22	0	0	1.00	4	0.67
Paraguay	0	0	0	1	0	1	0	0	0.67	0	0	0	0	0.2	0	0	0	0	1.00	3	0.33
Peru	1	1	0	0	1	1	0	0	1	0.5	1	0	0.67	1.1	0.33	15	2	0.33	1.43	3	0.67
Uruguay	1	1	0	1	0	1	0	0	1	0	0	0	0	0.4	0	26	3	0.33	1.71	5	1
Venezuela	0	0	0	0	0	1	0	0	0.33	0	0	0	0	0.5	0	2	0	0	0.00	2	0

Coding for the CIVICUS monitor: 1 = “Closed”, 2 = “Repressed”, 3 = “Obstrucuted”, 4 = “Narrowed”, 5 = “Open”.

Table A2: Cases divided into scores for each condition and outcome

	INTEGR	PATENT	INNOV	USTRADE	CSO
0	NA	BOL, ECU, PRY, URY, VEN	BOL, ECU, SLV, GTM, HND, NIC, PAN, PRY, VEN	ARG, BOL, PRY, URY, VEN	HND, MEX, NIC, VEN
0.33	COL, CRI, SLV, HND, GTM, MEX, VEN	ARG, BRA	ARG, COL, CRI, PER, URY	BRA, CHL, ECU, PAN, PER	COL, ECU, SLV, GTM, PRY
0.67	BRA, NIC, PAN, PRY	CHL, COL, SLV, GTM, HND, MEX, NIC, PER	CHL	COL, SLV, GTM, HN	ARG, BOL, BRA, CHL, PAN, PER
1	ARG, BOL, CHL, ECU, PER, URY	CRI, PAN	BRA, MEX	CRI, MEX, NIC	CRI, URY

Table A3: All solutions for the outcome “integration”

Complex Solution						
Configuration	Raw coverage	Unique coverage	Consistency	Cases with membership	>0.5	
~USTRADE*CSO	0.607	0.214	1	ARG, BOL, BRA, CHL, PAN, PER, URY		
~PATENT*~INNOV*~USTRADE	0.545	0.152	0.857	ARG, BOL, ECU, PRY, URY, VEN		
Solution coverage: 0.759						
Solution consistency: 0.893						
Parsimonious Solution						
Configuration	Raw coverage	Unique coverage	Consistency	Cases with membership	>0.5	
~USTRADE	0.789	0.789	0.896	ARG, BOL, BRA, CHL, ECU, PAN, PER, PRY, VEN, URY		
Solution coverage: 0.789						
Solution consistency: 0.896						
Intermediate Solution						
Configuration	Raw coverage	Unique coverage	Consistency	Cases with membership	>0.5	
~USTRADE*CSO	0.607	0.214	1	ARG, BOL, BRA, CHL, PAN, PER, URY		
~PATENT*~INNOV*~USTRADE	0.545	0.152	0.857	ARG, BOL, ECU, PRY, URY, VEN		
Solution coverage: 0.759						
Solution consistency: 0.893						

Appendix B: List of Documents used in the Case Studies

Appendix B1: Chapter 5 (Brazil)

Patent term extensions (ADI N. 5,529)

During the Supreme Court trial of ADI N. 5,529 regarding patent term extensions in Brazil, 440 documents were submitted. These documents were produced by CSOs, industry representatives, lawyers, governmental agencies, and the Supreme Court. From the 440 documents retrieved, the list below contains the ones cited in the Chapter 5.

Doc 1. Attorney General's Office (PGR). Initial petition. 13 May 2016.

Doc 9. ABIA. Amicus curiae request. 19 August 2016.

Doc 38. ABPI. Amicus curiae request. 11 November 2016.

Doc. 56. ANDEF. Amicus curiae request. 16 March 2017.

Doc. 63. ABIFINA. Amicus curiae request. 27 March 2017.

Doc. 92. FarmaBrasil Group. Amicus curie request. 14 May 2020.

Doc. 99. Ferres Economics. Report on patents and economic well-being. 25 July 2018.

Doc. 105. Pro Genéricos. Amicus curie request. 22 May 2020.

Doc. 115. Interfarma. Submission. 16 June 2020.

Doc. 150. ABIA. Submission. 17 October 2020.

Doc. 154. ABIA. Submission. 16 December 2020.

Doc. 155. University of São Paulo. Report. 4 December 2020.

Doc. 171. AB2L. Submission. 24 February 2021.

Doc. 173. AGROBIO. Submission, 25 February 2021.

Doc. 177. ANDEF. Submission, 25 February 2021.

Doc. 185. FarmaBrasil. Submission. 26 February 2021.

Doc. 347. AB2L. Submission. 13 April 2021.

Doc. 388. Interfarma. Submission. 10 May 2021.

Doc 440. STF. Final decision. 12 May 2021.

Appendices

Compulsory licensing (Law N. 14,200)

The list below contains the documents produced by the Brazilian government during the legislative process of PL N. 12 regarding compulsory licenses.

The main sources for law proposals and legislation approval processes are:

Brazilian National Congress. (2023). *Legislative activity*.

<https://www2.camara.leg.br/atividade-legislativa/>

Brazilian National Senate. *Legislative activity*. (2023).

<https://www25.senado.leg.br/web/atividade/>

Brazilian National Presidency. (2023). *Legislation search*.

<https://legislacao.presidencia.gov.br/>

Legislation and law proposals cited

Law proposal N. 1,184. Brazilian National Congress. 3 March 2020.

Law proposal N. 1,320. Brazilian National Congress. 31 March 2020.

Law proposal N. 12. Brazilian National Congress. 6 June 2021.

Law N. 14,200. Brazilian National Presidency. 2 September 2021.

Appendix B2: Chapter 6 (Chile)

Legislation and law proposals cited

Law N. 19,039. Ministry of economy, development, and reconstruction. 1991. Establishes rules applicable to industrial privileges and protection of industrial property rights.

Law N. 20,160. Ministry of economy, development, and reconstruction. 2007. Modifies law N. 19,039, on industrial property.

Boletín N. 8,907-03. 2013. Replaces laws Nº 19.039, on industrial property and Nº 20.254, which creates the National Institute of Industrial Property.

Law N. 21,355. Ministry of economy, development, and reconstruction. 2021. Amending law N. 19.039, on industrial property and law no. 20.254, establishing the national institute of industrial property

Decree N. 236 of 2005. Ministry of economy, development, and reconstruction. Regulates Law N. 19.039/1991.

Boletín N. 9914-11 (Ley Fármacos II).

Resolution N. 896. 17 March 2020.

Chilean Industrial Property Law (Art. 53 Bis 1-5)

Added parts **in bold**.

Paragraph II. Supplementary Protection

Article 53 Bis 1. Within ~~six months~~ **sixty days** of the grant of a patent, the owner shall be entitled to request a term of Supplementary Protection, provided that there has been an unwarranted administrative delay in the grant of the patent and the term of the grant has exceeded five years from the filing date of the application or three years from the request for examination, whichever is later.

The request for examination shall be made with the acceptance of the position referred to in Article 7(1).

The supplementary protection shall be extended only for the period shown to be an unjustified administrative delay, **and no additional term of protection may be granted for more than five years.**

Article 53 Bis 2. Within ~~six months~~ **sixty days** of the grant of a sanitary registration of a pharmaceutical product protected by a patent, the owner shall be entitled to request a term of Supplementary Protection for that part of the patent that contains the pharmaceutical product, provided that there has been an unjustified delay in the grant of the said registration. This supplementary protection may be requested by holders whose authorisation or sanitary registration has been granted one year after the application's filing date.

The supplementary protection shall be extended only for the period accredited as an unjustified delay by the administrative body in charge of resolving said registration.

Article 53 Bis 3. Unjustified delays do not include delays affecting patent applications or applications for sanitary registration attributable to:

- a) Opposition or any court-ordered appeal or action;
- b) Waiting for reports or proceedings from national or international bodies or agencies required for the patent registration process; and
- c) Actions or omissions on the part of the applicant.

Article 53 Bis 4. The application for Supplementary Protection shall be filed with the Industrial Property Court, which shall rule on the existence of unwarranted delays and the extension thereof in a single instance following the procedure laid down for appeals. The declared decision shall have the sole effect of extending the term of protection and shall not give rise to liability of any kind. Prior to the hearing of the case, the Court shall order the respective body to be notified so that it may issue its opinion within a period of sixty days.

Article 53 Bis 5. The termination of supplementary protection shall be noted in the margin of the respective register upon payment of a fee of 1 UTM for each year or fraction of a year of additional protection. Payment may only be made within the thirty days following the decision requiring it, without which the protection provided in this paragraph shall not be available.