Concepts of Proportionality in Investment Protection of Patents and Access to Health Resources

A thesis submitted in fulfilment of the requirements for the degree of

Doctor of Philosophy in Law

At

The University of Waikato

By

Dilara Aydin

2024

ABSTRACT

This thesis seeks to demonstrate why investment protection of patented health resources is disproportionate and how the disproportionate power can be mitigated. The argument asserts that the protection of patented health resources under international investment agreements ("IIAs") goes beyond the intended purpose of intellectual property ("IP") law and can hinder access to health resources. While IP rights are significant components of IIAs, their inclusion within the scope of investment allows investors to challenge measures against their IP rights through the investor-state dispute mechanism ("ISDS"). A measure can be subject to a review of arbitral tribunals even though such measure serves the public interest.

The intersection of IP and international investment law can raise challenges to distributive justice. The availability of ISDS can undermine the flexibilities provided by the Agreement on Trade Related Aspects of Intellectual Property Rights ("TRIPS Agreement") and prevent states from acting in their national interests. Considering this aspect, this thesis argues that investment protection of patented health resources is disproportionate, drawing on (i)midlevel proportionality and global justice. Global social cooperation and economic interdependence, driven by international trade and investment, justify applying global justice principles. Third World Approaches to International Law ("TWAIL") support arguments presented in this thesis by offering a critical perspective on the international law system.

The ISDS system imposes an additional legal layer for states. Such layer can hinder the rights to have a healthy life, rights to life and living a life with dignity, conflicting states' human rights obligations. Therefore, this thesis argues that investment protection disproportionately benefits the patent holders. Consequently, this thesis scrutinises how this disproportionate benefit can be mitigated. To this end, this thesis investigates case law in investment arbitration where arbitral tribunals have applied (ii)judicial proportionality to determine if judicial proportionality can mitigate the disproportionate protection of patented health resources as an investment. This thesis further reveals midlevel proportionality in newly concluded IIAs where the purpose is to restore disproportionate investment protection of patented health resources. This thesis presents the first comprehensive analysis on proportionality principle in the context of patent and international investment law.

ACKNOWLEDGMENTS

I have received support from many throughout my Ph.D. journey. First, I wish to start by expressing my appreciation to my supervisors, Dr. Alberto Alvarez-Jimenez and Prof. Alpana Roy, for their support and encouragement during this time. I am particularly grateful for Dr. Alvarez-Jimenez's meticulous feedback, consistent engagement in meetings and thesis discussions, and valuable reading suggestions. His guidance has been invaluable.

Furthermore, I am grateful to the University of Waikato for supporting my research by providing a scholarship. The tuition fee waiver and monthly stipend provided me with the necessary financial support, allowing me to focus on my studies.

The Ph.D. journey can be incredibly lonely and emotionally challenging. I am deeply thankful to my friends, colleagues and non-academics for their moral support and love. I could not complete my research without their immense support. In particular, I am thankful to Samuel Skinner, Sema Uras and George Michelles for kindly and generously volunteering their time and effort to proofread my thesis.

My special thanks to my parents and my sister for their continuous encouragement and inspiration to follow my dreams. I am grateful my family for listening to me during challenging times and for their emotional support. Their constant encouragement and their trust have been invaluable to me. I would like to dedicate my work to them - my dad Önay, my mom Semra, my dear sister Selin- and to Ayse Aydoğan who supported women's education throughout her life.

Finally, I would like to extend my special gratitude to Prof. Abbe E. L. Brown and the University of Aberdeen for hosting me as a visiting Ph.D. student. I am grateful for the opportunity to interact with colleagues and present my work during my time there. In particular, I am indebted to Prof. Brown for her inspiration during my LLM degree, which motivated me to pursue my Ph.D. She supported me since then and provided me with thoughtful, constructive, and detailed feedback and suggestions for this work during my time in Aberdeen. I am truly grateful for her invaluable support, without which this work would not have been possible.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

BIT	Bilateral Investment Treaty
CECA	Comprehensive Economic Cooperation Agreement
CETA	European Union-Canada Comprehensive Economic and Trade Agreement
CIFA	Cooperation and Facilitation Investment Agreement
CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
ECHR	European Convention on Human Rights
ECT	Energy Charter Treaty
ECtHR	European Court of Human Rights
EU	European Union
FCN	Friendship, Commerce, and Navigation
FCTC	Framework Convention on Tobacco Control
FET	Fair and Equitable Treatment
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade in Services of the World Trade Organisation
IBA	International Bar Association
ICC	International Chamber of Commerce
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICJ	International Court of Justice
ICSID	International Centre for Settlement of Investment Disputes
IIAs	International Investment Agreements
ILC	International Law Commission
INB	Intergovernmental Negotiating Body
IP	Intellectual Property
ISDS	Investor-State Dispute Settlement
J & J	Johnson & Johnson
MFN	Most-Favoured Nation Treatment
MoA	Margin of Appreciation
MPP	Medicine Patent Pool
MSD	Merck Sharp & Dohme
NAFTA	North American Free Trade Agreement
NHS	National Health Service

NIH	National Institutes of Health
NT	National Treatment
OECD	Organisation for Economic Co-operation and Development
PAHO	Pan American Health Organisation
PCT	Patent Cooperation Treaty
PM	Philip Morris
R&D	Research & Development
SCC	Stockholm Chamber of Commerce
SCJ	Supreme Court of Justice
TCA	Tribunal de lo Contencioso Administrativo
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TWAIL	Third World Approaches to International Law
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNCITRAL	United Nations Commission on International Trade Law
UNCTAD	United Nations Conference on Trade and Development
UPR	Universal Principle of Right
US	United States
USD	United States Dollar
USMCA	The United States-Mexico-Canada Agreement
VCLT	Vienna Convention on the Law of Treaties
VIAC	Vienna International Arbitral Centre
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organisation

CHAPTER 1- INTRODUCTION

1.1. Overview

The aim of this thesis is to demonstrate that the investment protection of patented health resources is disproportionate. The protection of patent rights, particularly for health resources, exceeds the original intent of their creation, and undermines accessing health resources.[1] When formulating International Investment Agreements ("IIAs"[2]), states should exclude protection of patented health resources from the scope of protection against expropriation and fair and equitable treatment ("FET") standards. The argument advanced in this thesis that investment protection of patented health resources is disproportionate is based on principles of midlevel proportionality and global justice. Additionally, Third World Approaches to International Law ("TWAIL") support these arguments by offering a critical perspective on the design and formulation of international law, highlighting the unequal representation between the Global South and the Global North. Today, this perspective addresses access issues faced by disadvantaged groups in the Global North. This thesis is crucial for states, academics, and arbitrators as it identifies and highlights the disproportionate nature of the current system and suggests options to mitigate these issues.

Social cooperation exists at the global level, and international economic interdependence, resulting from international trade and investment, justifies the application of global distributive justice principles.[3] This economic interaction, including free trade, contributes to international distributive inequalities when ongoing transfers to the least advantaged are absent.[4] This absence can be observed in access to health resources, as experienced in the late 1990s and early 2000s concerning HIV/AIDS. In line with this, as Pogge puts forward, advantaged groups shape institutional order, leading to severe human rights consequences.[5] The international intellectual property regulations, like the Agreement on Trade-Related Aspects of Intellectual Property Rights[6] (hereinafter "TRIPS Agreement"), exemplify these

[1]Health resources encompass medicine, vaccines, therapeutics, diagnostics, any products and processes related to human health that can be patented).
[2]In this thesis, international investment agreements encompass bilateral investment agreements ("BITs") and free trade agreements ("FTAs") that contain investment chapters.
[3]Charles R. Beitz *Political Theory and International Relations* (Princeton University Press, Princeton, 1999) at 144-145.
[4]At 145-146.
[5]Thomas Pogge *World Poverty and Human Rights: Cosmopolitan Responsiblities and Reforms* (Polity Press, Cambridge, 2008) at 174-201.
[6]Marrakesh Agreement Establishing the World Trade Organization 1867 UNTS 3 (opened for signature 15 April 1994, entered into force on 1 January 1995), annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights) [TRIPS Agreement].

forces. Today, IIAs further exacerbate these consequences. Intellectual property ("IP") rights have been included in investment treaties since the first bilateral investment treaty ("BIT") between Germany and Pakistan.[7] Today, IP rights are incorporated in most of the IIAs in one way or another. However, the intersection of these two legal areas poses challenges to global distributive justice because the availability of investor-state dispute settlement ("ISDS") for patent rights, potentially hinders the application of flexibilities of patent rights (compulsory licencing or flexibilities to grant IP rights like patentability) and prevents states from acting according to their national interests. Some high-profile cases have attracted considerable attention and increased these concerns.[8] The overlap between these two areas remains significant as IP holders, so called *investors*, continue to initiate ISDS claims against governments.[9] While no investor has succeeded[10] so far, concerns will continue as long as ISDS remains available for patent rights, particularly for patented health resources. Certainly, states may refrain from using TRIPS flexibilities to address their national interests due to the risk of costly investment claims and high compensation, which may be a deterrent for states to pursue further regulatory actions or may influence other states from taking similar measures.

At the international level, minimum standards of IP protection are provided under the TRIPS Agreement.[11] However, member states still have the autonomy to decide the extent of protection they offer to IP holders. In this respect, the TRIPS Agreement maintains the territoriality aspects of IP rights. The TRIPS Agreement further provides flexibilities to member states so that the social function of IP rights is preserved, and abuse of IP rights is prevented. One could question the effectiveness of the flexibilities of patents provided by the TRIPS Agreement to ensure affordable access to health resources. Ultimately, the agreement does offer some mechanism to establish a *balance* between the holder and the

[7]Treaty for the Promotion and Protection of Investments Germany and Pakistan 457 UNTS 24 (signed 25 November 1959, entered into force 28 April 1962) (hereinafter "Germany-Pakistan BIT 1959").
[8]*Eli Lilly and Company v The Government of Canada (Final Award)* ICSID UNCT/14/2, 16 March 2017 (hereinafter "*Eli Lilly v Canada Final Award*"); *Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (Award)* ICSID ARB/10/7, 8 July 2016 (hereinafter "*Philip Morris v Uruguay Award*"); *Philip Morris Asia Limited v The Commonwealth of Australia (Award)* UNCITRAL PCA 2012-12, 17 December 2015 (hereinafter "*Philip Morris v Australia Award*").
[9]*Bridgestone Licensing Services, Inc. and Bridgestone Americas, Inc. v Republic of Panama (Request for Arbitration)* ICSID ARB/16/34, 7 October 2016; *Theodore David Einarsson, Harold Paul Einarsson and Russell John Einarsson, Geophysical Service Incorporated v Government of Canada (Notice of Arbitration)* ICSID UNCT/20/6, 18 April 2019 (hereinafter "*Einarsson v Canada Notice of Arbitration*"); *beIN Corporation v. Kingdom of Saudi Arabia (Notice of Arbitration)* UNCITRAL, 01 October 2018.
[10]*Eli Lilly v Canada Final Award; Philip Morris v Uruguay Award, Philip Morris v Australia Award*; *Bridgestone Licensing Services, Inc. and Bridgestone Americas, Inc. v Republic of Panama (Award of the Tribunal)* ICSID ARB/16/34, 14 August 2020 (hereinafter "*Bridgestone v Panama Award of the Tribunal*").
[11]TRIPS Agreement.

public. In case of disputes between member states concerning the minimum standards set out by the TRIPS Agreement or the flexibilities, they can resort to the WTO dispute settlement mechanism[12], along with the national dispute mechanism available for IP holders.

This balance has been disrupted, as IP holders have power to challenge governmental actions directly before a private arbitral tribunal. The ISDS system adds another layer, potentially resulting in legal disputes even for countries that wish to act in the interest of the public. Potential expensive legal procedures or high compensation and regulatory chill are the main concerns of investment protection of patented health resources, as they undermine state actions aimed at addressing public health, even when such actions align with the TRIPS Agreement. As a result, investment protection has negative impact on equitable global access to health resources. Equal access does not mean that everyone will have access at the same time, but international law should not become a barrier preventing this progress.[13] Such barriers can impede the right to have a healthy life, the right to life and living a life with dignity, contradicting human rights obligations under the Universal Declaration of Human Rights ("UDHR") Article 3, UDHR Article 25; the International Covenant on Economic, Social and Cultural Rights ("ICESCR") Article 12; International Covenant on Civil and Political Rights ("ICCPR") Article 6.[14] Lack of health products has an adverse impact on an "individuals' capacity to live a human life of normal length".[15] The current patent system has significant consequences on "human lives and happiness and freedoms" as reminded by Sen in the context of the AIDS epidemic.[16] Medical care is part of the human right to health as recognised by the UDHR Article 25[17], the ICESCR Article 12[18], and various other human rights treaties.[19] As emphasized by the UN Committee on Economic, Social and Cultural

[12]Currently, the Appellate Body is not available, and this thesis is aware of the crises concerning the appointments of members. Please see: "Dispute Settlement: Appellate Body" World Trade Organization <https://www.wto.org/english/tratop_e/dispu_e/appellate_body_e.htm>; Peter Van den Bossche *The Demise of the WTO Appellate Body: Lessons for Governance of International Adjudication?* (World Trade Institute, Working Paper No. 02/2021).

[13]International Covenant on Economic, Social and Cultural Rights 993 UNTS 3 (16 December 1966) (hereinafter "ICESCR"), art 2 states that the rights protected under the Covenant, including the right to health, are deemed subject to progressive realization and that States have resource constraints and that it necessarily takes time to implement the treaty provisions.

[14]*Universal Declaration of Human Rights* GA Res217 (1948) (hereinafter "UDHR"), art 3; UDHR, art 25; ICESCR, art 12; International Covenant on Civil and Political Rights UNTS 999 (opened for signature 16 December 1966, entered into force 23 March 1976) (hereinafter "ICCPR"), art 6.

[15]Madhavi Sunder *From Goods to a Good Life: Intellectual Property and Global Justice* (Yale University Press, New Haven 2012) at 178.

[16]At 179.

[17]UDHR, art 25.

[18]ICESCR, art 12.

[19]International Convention on the Elimination of all Forms of Racial Discrimination 660 UNTS 195 (opened for signature 7 March 1966, entered into force 4 January 1969), art 5; Convention on the Rights of the Child 1577 UNTS 3 (opened for signature 20 November 1989, entered into force 2 September 1990), art 24.

Rights, the right to health is linked to and dependent upon the realisation of other rights such as access to food, housing, work, education, dignity and equality[20], which has significant role in human capacity to live human life. It is further associated with the right to participate in and benefit from scientific advancements. Everyone has the right to enjoy scientific progress without discrimination as it plays a crucial role in establishing accessible means for preventing, controlling, and treating[21] illnesses like Covid-19.

The availability of patents for health resources within the current international patent law system already poses an access problem, as it allows patent holders to set prices and monopolise the market, impacting access to the resources, particularly for those who are financially disadvantaged. Investment protection exacerbates this issue further by undermining TRIPS flexibilities (which could otherwise promote affordability), allowing IP patent holders/investors to initiate cases in a private arbitration system. This thesis argues that global distributive justice and cooperative theories can address the concerns of patent protection as an investment, potentially enhancing economic, political, and legal institutions.

The principle of proportionality can find its way to restore the balance in this context. Investment protection of patented health resources is considered disproportionate, as can be suggested by midlevel proportionality, an echo of public value or public space in an intellectual property policy. Midlevel proportionality is a reflection of distributional justice problems of IP rights.[22] It aims at removing disproportional reward in terms of the covered IP right, size or scope.[23] If there is an excessive or disproportional leverage, either market or scope, this leverage should be limited or annulled.[24] Given the reasons outlined above, investment protection disproportionately benefits the patent holder, regardless of how far states' regulatory power is protected under ISDS. Therefore, should be restricted. From now on, this principle of proportionality will be referred to as *midlevel proportionality* in this thesis. Consequently, private arbitrators should not have authority over cases of patented health resources; states should limit access to ISDS within their IIAs for protection against

[20]*Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)*, Un Doc E/C.12/2000/4 (11 August 2000) (hereinafter "*Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)*") at [3].
[21]*General Comment No.25 (2020) on Science and Economic, Social and Cultural Rights (article 15(1) (b), (2), (3), and (4) of the International Covenant on Economic, Social and Cultural Rights)* UN Doc E/C.12/GC/25 (30 April 2020) (hereinafter "*General Comment No.25 (2020) on Science and Economic, Social and Cultural Rights (article 15(1) (b), (2), (3), and (4) of the International Covenant on Economic, Social and Cultural Rights)*") at [67- 71].
[22]Robert P. Merges *Justifying Intellectual Property* (Harvard University Press, Cambridge, 2011) at 191.
[23]At 150.
[24]At 151.

expropriation and FET standards as they are absolute standards. It is argued in this thesis that even if investors have access to bringing claims for patents in relation to health resources, the arbitrators should provide maximum level of deference to states. This principle further operates in many ways in the legal framework, including IP and investment law. The arbitral tribunals have adopted this principle[25], borrowing from the European Court of Human Rights ("ECtHR") jurisprudence, where there is a need to balance interests. From now on, the principle of proportionality, which originated in Germany and extended to Europe, encompassing constitutional, administrative, and human rights law, will be referred to as *judicial proportionality*. In this regard, this thesis examines case law in investment arbitration where arbitral tribunals have applied judicial proportionality to determine if judicial proportionality can mitigate the disproportionate protection of patented health resources as an investment. Finally, this thesis reveals midlevel proportionality in newly concluded IIAs where the purpose is to restore disproportionate investment protection of patented health resources. It should be noted that the principle of proportionality (judicial proportionality and midlevel proportionality), however, has Western origins, which can influence its operation.

It is important to highlight that the principle of proportionality is not the only concept rooted in Western traditions. The frameworks of international IP law and international investment law primarily reflect the interests and perspectives of Global North countries, today impacting disadvantaged people in both the Global North and Global South. Hence, the relevance of TWAIL becomes tenable. The historical engagement of these concepts is facilitated by the critiques offered by TWAIL, which perhaps can shed light on why investment protection of patents is disproportionate and the concerns on global justice about such protection. Considering both TWAIL critiques and the goal of achieving global justice in ensuring the availability of health resources, this thesis examines the intersection of IP and investment, with a particular focus on the role of proportionality in this context.

1.2. Research Questions

Initiating ISDS against states is a significant legal mechanism for IP/investors to enforce their rights, almost serving as a safety valve for them. However, one should consider the expense and the extent of such safety. As highlighted above, the interaction between IP and

[25] *Tecnicas Medioambientales Tecmed, S.A. v The United Mexican States (Award)* ICSID ARB(AF)/00/2, 29 May 2003 (hereinafter "*Tecmed v Mexico Award"*); *LG&E Energy Corp, LG&E Capital Corp, and LG&E International, Inc. v. The Argentina Republic) (Decision on Liability)* ICSID ARB/02/1, 3 October 2006 (hereinafter "*LG&E v Argentina Decision on Liability*").

investment law is ongoing. Therefore, it is necessary to look into how to balance or scale back from the impact of investment protection of IP rights, which requires an analysis of proportionality.

In this respect, this thesis investigates three main questions:

1- Why and how has the investment protection of patented health resources become disproportionate through midlevel principles from the perspective of global distributive justice (cosmopolitanism)?
2- Can the application of judicial proportionality by arbitral tribunals assist in scaling back from this disproportionate protection in ISDS cases involving patented health resources to preserve global justice?
3- How do some newly concluded regional agreements mitigate the disproportionate investment protection of patented health resources?

These questions are addressed with the goal of achieving global justice in accessing health resources, drawing on critiques from TWAIL.

1.3. Significance of the Research and Contribution

As elaborated throughout this thesis, while there is existing literature on the relationship between IP and investment law, few of them are focused on the role of proportionality.[26] In fact, none of them has conducted a comprehensive analysis of proportionality using its midlevel facet in this context. Midlevel principles in the context of IP are not very developed, either. Yet, the midlevel facet of proportionality can promote the social function and territoriality principle in the context of IP and investment, thus promoting global justice principles aimed at accessing affordable health resources. Midlevel proportionality can help identify and remove the additional layers imposed by the ISDS system in patent law, thereby preserving states' rights to establish their own laws based on their needs. This thesis draws on theories of global justice as the underlying theory for promoting accessing health resources.[27]

[26]Tuomas Mylly "Human Rights and Intellectual Property in Investor to State Dispute Settlement" in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) at 411.
[27]Pogge, *World Poverty and Human Rights: Cosmopolitan Responsiblities and Reforms*, above n 5; Thomas W. M. Pogge *Realizing Rawls* (Cornell University Press, Ithaca, 1989); Peter Singer *Practical Ethics* (3rd ed, Cambridge University Press, Cambridge 2011); Martha C. Nussbaum *Frontiers of Justice: Disability, Nationality, Species Membership* (The Belknap Press, Cambridge, 2006); Amartya Sen *The Idea of Justice* (The Belknap Press, Cambridge, 2009); Beitz, *Political Theory and International Relations*, above n 3; Darrel Moellendorf *Cosmopolitan Justice* (Westview Press, Boulder, CO, 2002); Gillian Brock "Liberal Nationalism versus Cosmopolitanism: Locating the Disputes" (2002) 16(4) PAQ 307.

Moreover, while there are some studies to some extent using TWAIL in the areas of IP and international investment law separately, there has been even less exploration of their intersection from the TWAIL perspective.[28] In addition, the proportionality principle has not been explicitly considered through the lens of TWAIL. The lack of this analysis might be due to the extensive reach of the proportionality principle worldwide even though its application or interpretation can vary. However, applying it in the global sphere requires a cautious approach, and the TWAIL perspective reminds the roots of the principle.

This thesis contributes to the existing literature by highlighting the reasons for the disproportionate nature of investment protection. It underscores the disproportionate power held by IP holder/investors, particularly in situations involving affordable access to health resources. The research stresses the importance of designing investment protection for IP laws within IIAs in a manner that mitigates such disproportionate power, urging states to do so. This thesis is therefore significant for states, academics, and arbitrators as it highlights the disproportionate nature of such a system. In this context, this thesis examines proportionality in three places: the midlevel facet to demonstrate why investment protection is disproportionate, judicial proportionality derived from European legal system in the analysis of investment cases to assess its potential to mitigate disproportionality, and finally, midlevel facet in practice within newly concluded agreements. By doing so, this thesis answers three main questions identified in Chapter 1.2.

1- Why and how has the investment protection of patented health resources become disproportionate through midlevel principles from the perspective of global distributive justice (cosmopolitanism)?

The availability of ISDS for patented health resources creates excessive leverage and disproportionate power, deviating from the intended purpose of IP rights. Furthermore, the ISDS mechanism undermines the flexibilities provided by the TRIPS Agreement as it creates an additional legal barrier, which may have distributive justice implications when the issue at hand concerns patents. Even if an investor does not bring an investment claim, the availability of ISDS gives power to investors to use the mechanism to deter states from enacting measures. In this regard, this thesis argues that the investment protection of patented health resources is disproportionate and needs to be mitigated. The theoretical framework of

[28]Pratyush Nath Upreti "A TWAIL Critique of Intellectual Property and Related Disputes in Investor-State Dispute Settlement" (2022) 25(1) J World Intellect Prop 220.

midlevel proportionality is established in Chapters 2 and 3, and the disproportionate nature of investment protection for patented health resources is detailed in Chapter 4.

2- Can the application of judicial proportionality by arbitral tribunals assist in scaling back from this disproportionate protection in ISDS cases involving patented health resources to preserve global justice?

As demonstrated in Chapter 5, judicial proportionality in cases concerning patented health resources may fail to sufficiently respect the public's needs and may potentially burden states with additional evidentiary requirements as needed by the test. The application of judicial proportionality in investment cases involving patented health resources risks overlooking the significance of the measures in public welfare or broader societal objectives of patent law, and may risk the territoriality principle of IP law. Therefore, this thesis suggests that tribunals handling cases concerning patented health resources should employ the police powers doctrine in their expropriation and FET analyses.

3- How do some newly concluded regional agreements mitigate the disproportionate investment protection of patented health resources?

As detailed in Chapter 6, United States-Mexico-Canada Agreement ("USMCA")[29], the European Union-Canada Comprehensive Economic and Trade Agreement ("CETA")[30], and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership ("CPTPP")[31] trade agreements present a more nuanced approach to protecting patented health resources and providing investor-state dispute mechanisms for patent holders/foreign investors. These three trade deals largely address the concerns raised in this thesis concerning human rights to health. They have either eliminated or limited the ISDS mechanism for indirect expropriation and FET claims, aligning with promoting access to health resources as a fundamental aspect of having a healthy life and a life with dignity under UDHR Article 25 and the ICESCR Article 12[32] in line with global justice.

[29]United States-Mexico-Canada Agreement (signed 30 November 2018, entered into force 1 July 2020) (hereinafter "USMCA").
[30]European Union-Canada Comprehensive Economic and Trade Agreement (signed 30 October 2016, provisionally applied since 21 September 2017) (hereinafter "CETA").
[31]Comprehensive and Progressive Agreement for Trans-Pacific Partnership (signed 8 March 2018, entered into force 30 December 2018) (hereinafter "CPTPP").
[32]UDHR, art 25; ICESCR, art 12.

1.4. Methodology and Sources

This research follows a qualitative, doctrinal research method, focusing on legal research by analysing international and regional sources. It is significant to employ a theoretical approach to address the inherent injustice in the current expansionist structure of IP law. In this respect, this thesis adopts a framework of global distributive justice to determine the inequities of the system and to identify the objectives that must be achieved. This approach facilitates the identification of inadequateness in the existing system and offers insights into potential improvements. As elaborated in Chapter 2, this thesis benefits from different global justice theories as they endorse the idea that regardless of one's origin or residence, everyone should have access to health resources.

This thesis further benefits from TWAIL as a critical methodology. This approach highlights the historical issues and unequal economic and political powers of states in shaping IP and investment systems. They have contributed to today's challenges concerning access to health resources and states' ability to regulate aligning their own societal goals. TWAIL provides both historical and analytical perspectives. Furthermore, this thesis compares various IIAs and model agreements. While the purpose is not to conduct a fully comparative study, it seeks to illustrate the nuances between the different agreements and their implications and to underscore the differences between the Global South and the Global North. A comparative approach would allow cross-referencing and assist in developing the argument.

This study relies on primary and secondary sources, that can be categorised into two different areas of law: international intellectual property law, which primarily focuses on patents, and international investment law. Examining the development of these frameworks is essential to demonstrate the political and economic dimensions of this research. Primary sources for the IP context are the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property (hereinafter "Paris Convention")[33]. These agreements are significant within IP context because the TRIPS Agreement establishes minimum international standards of IP, while the Paris Convention represents the first major international step in international patent protection. Additionally, the Doha Declaration[34] on the TRIPS is particularly a significant source as it aims to promote access to medicine.

[33]Paris Convention for the Protection of Industrial Property 828 UNTS 305 (opened for signature 20 March 1883, entered into force 7 July 1884) (hereinafter "Paris Convention").
[34]*The Doha Declaration on the TRIPS Agreement and Public Health* WT/MIN (01)/DEC/2 20 November 2001, (WTO Ministerial Document) (hereinafter "Doha Declaration").

Moreover, bilateral investment agreements, free trade agreements, and investment agreements serve as additional primary sources of this research to demonstrate and analyse the protection of intellectual property rights and their relationship with access to medicines, vaccines, diagnostics, and therapeutics. Particular emphasis will be given to the recently concluded treaties: United States-Mexico-Canada Agreement, the European Union-Canada Comprehensive Economic and Trade Agreement, and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership for the purpose of proportionality analysis in the last chapter. Throughout this thesis, Model BITs, particularly Indian Model[35] or the United States Model[36] are referred to illustrate the varying and contrasting approaches in the formulation of IIAs.

The UDHR[37], the ICESCR[38], and the ICCPR's[39] documents are referred to support arguments in this thesis. Additionally, referencing the Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights, hereinafter "ECHR")[40] and the case law of the European Court of Human Rights is necessary as arbitral tribunals have relied on these sources in their legal reasoning for rendering awards.

Case law, particularly when IP is the subject matter of the dispute, is a significant source for identifying the pitfalls of the system and understanding how arbitral tribunals have interpreted the law thus far. References to these cases support the arguments in this thesis. Particularly, *Eli Lilly v Canada*[41] and *Philip Morris v Uruguay*[42] are key cases discussed in this thesis. *Eli Lilly v Canada* is a particularly significant source, as it addresses issues related to state sovereignty, flexibilities in patent law, and the question of whether judicial conduct can be challenged through investment claims apart from denial of justice. In addition, the *Philip Morris v Uruguay* case serves as another important source, as it involves discussions

[35]2015 Model Text for the Indian Bilateral Investment Agreement (hereinafter "Indian Model BIT 2015") <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3560/download> It is identified that the Indian Model BIT can be found with two dates as its adoption, 28 December 2015 and 14 January 2016 (the Ministry of Finance, Government of India) In this thesis, the date appeared in UNCTAD is used, therefore it will be referred as Indian Model BIT 2015, not Indian Model BIT 2016 since the Government of India website was inaccessible at the time of writing; Prabhash Ranjan and Pushkar Anand "The 2016 Model Indian Bilateral Investment Treaty: A Critical Deconstruction" (2017) 38(1) Nw. J. Int'l L. & Bus 1 at 7, n (36).
[36]2012 Model Text for the United States Bilateral Investment Agreement <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2870/download> (hereinafter "US Model BIT 2012").
[37]*Universal Declaration of Human Rights.*
[38]International Covenant on Economic, Social and Cultural Rights.
[39]International Covenant on Civil and Political Rights.
[40]Convention for the Protection of Human Rights and Fundamental Freedoms 213 UNTS 222 (opened for signature 4 November 1950, entered into force 4 November 1953) (hereinafter "ECHR").
[41]*Eli Lilly v Canada Final Award.*
[42]*Philip Morris v Uruguay Award.*

about public health and sparked debates regarding the applicability of the margin of appreciation ("MoA") doctrine. The research is limited to having few IP-investment cases available, which restricts practical examples and results in more theoretical discussion. Furthermore, the absence of precedent in ISDS means that arbitral tribunals are not bound by previous case law, a fact which reduces ability to make definitive assertions about ISDS practices in some circumstances.

In light of the abovementioned, the primary sources of this research encompass IIAs, international intellectual property agreements, international human rights agreements/documents, and case law. Furthermore, secondary sources such as books, journals, articles, websites, online conferences, and media outlets contribute to building the arguments. Particularly, issues related to access during the Covid-19 pandemic heavily rely on websites and media sources. Media outlets play a significant role in uncovering issues related to accessing health resources.

1.5. Thesis Structure and Limits

This thesis comprises seven chapters, including this introductory chapter and a conclusions chapter. Each chapter is briefly outlined below. Chapter 1, this introductory chapter, offers an overview of this thesis, introduces the research questions, presents the methodology and sources (primary-secondary), outlines this thesis structure and scope limitations, and defines key terms frequently used throughout this thesis. This chapter briefly outlines the concerns related to affordable access to health resources due to the inclusion of intellectual property rights in IIAs.

The second chapter of this thesis focuses on to the evolution of the proportionality principle within the legal framework, followed by an exploration of theories of global distributive justice. This chapter frames the roles attributed to proportionality: as a midlevel principle and as judicial proportionality as a methodological tool in arbitration cases. The detail of the principle is provided throughout this thesis. The significance of this chapter lies particularly in its inclusion of the TWAIL approach, which serves as the foundation for the critiques presented in this thesis. In this way, it is aimed to shed light on the historically unbalanced development of both international investment law and international intellectual property law in the following chapter.

The third chapter is divided into two main sections. The first part delves into the development and existing legal framework of international intellectual property law, while the second part concentrates on international investment law. Examining their development is crucial to understanding the influence of industrialist lobbyist on the formulation of international IP law and grasping the main purpose of such patent protection to technologies/inventions. Similarly, delving into the development of international investment law reveals a clear imbalance between global exporting and importing countries, which has reflected directly formation of IIAs. TWAIL critiques serve to strengthen the arguments presented in this section. IP analysis specifically focuses on patent law, its flexibilities, and its implications for accessing affordable medicines, vaccines, diagnostics, and therapeutics. This analysis is crucial for understanding why patents can act as barriers to access in the first place. Due to the extensive nature of intellectual property law, narrowing the scope only to patent law is necessary as it is not possible to delve into every type of IP law within this research. Following, this chapter explores the midlevel facets of the proportionality principle. It explores how the understanding reflects the Western roots and discusses the adjustment to the principle that provides a proper balance. The principle helps understanding why investment protection of IP, particularly availability of ISDS results in disproportionate power in favour of investors/IP holders. After exploring the development of international investment law, this chapter provides substantive rights provided by IIAs, and applicable law. Substantive rights are limited to claims against expropriation and FET, as they do not depend on any specific treatment of foreigners or nationals such as most-favoured nation treatment and national treatment. They are absolute and independent investment standards, requiring no special considerations for their implementation by the host state.[43] This chapter is significant for providing an understanding of both areas of law. It sets up the next chapter, which explores the interaction of IP and investment law in detail.

Chapter 4 focuses on the intersection of intellectual property and investment law. It explores the scope of IP protection as an investment and examines how states' measures concerning patent flexibilities, such as compulsory licencing, may lead to a violation of a treaty standards. This chapter aims to demonstrate disproportionate power held by IP owners due to the availability of ISDS, which eventually affects affordable health resources. The purpose is to emphasise how this situation restricts states from implementing regulatory measures

[43]Jonathan Bonnitcha, Lauge N. Skovgaard Poulsen and Michael Waibel *The Political Economy of the Investment Treaty Regime* (Oxford University Press, Oxford, 2017) at 104-105.

related to public health and gives investors/IP holders the power to bring claims even if those measures fall within the scope of states' sovereignty. While acknowledging different claims and varying success rates depending on whether measure is regulatory, administrative, or judicial, this thesis does not conduct an additional analysis. The core argument remains that investment protection, especially ISDS, adds a legal layer that discourages states from taking necessary measures. This chapter continues with the analysis of *Eli Lilly v Canada* and *Philip Morris v Uruguay*, which strengthens the argument regarding disproportionate power of investors. These cases address issues of state sovereignty and public health. Finally, this chapter provides some examples to illustrate the regulatory chill created by ISDS in the context of IP law. It is particularly significant since the examples show how the ISDS mechanism adds an additional layer to access to health resources.

Chapter 5 explores the role of judicial proportionality in investment disputes and attempts to determine whether its application should be maintained, having in mind the global justice views on access to health resources. This investigation involves an analysis of ISDS case law where proportionality principle was applied in expropriation and FET claims, in order to understand the practice of arbitral tribunals. Furthermore, this chapter investigates the relevance of the ECtHR jurisprudence, especially the MoA doctrine, which has become highly debated, particularly in the context of IP. This chapter answers the second question of this thesis: Can the application of judicial proportionality by arbitral tribunals assist in scaling back from this disproportionate protection in ISDS cases involving patented health resources to preserve global justice?

Chapter 6 explores the emerging trends of IIAs, particularly the mega-regional IIAs, which indicate a more nuanced approach to ISDS mechanism for IP chapters. This chapter aims to evaluate USMCA, CETA and CPTPP to assess how effectively they incorporate the social aspects of patent rights. This chapter primarily focuses on patent provisions in IP chapters, as well as expropriation and FET rules in the investment chapters. At times, comparisons with model BITs from particularly Global South countries are provided to highlight main concerns about ISDS. The proportionality analysis in this chapter aims to reveal the midlevel facet, involving an analysis of the conflict between accessing the societal function of IP, community interest, and investment protection of patents. The purpose is to evaluate relevant aspects of the IP-investment relations that involve scaling back from the disproportionate reward to the IP holder, which answers the third question of this thesis.

Chapter 7, as a concluding chapter, brings together findings and insights gathered from Chapter 2 to Chapter 6. It outlines the contribution of the research and offers recommendations and suggestions for future research.

1.6. Definitions of Key Terminologies

This section aims to define some key terms frequently referenced in this thesis. Territoriality principle, social function, Global South and Global North, global justice and proportionality are included here.

1.6.1. Territoriality Principle

The term *territoriality* is often referred to throughout this thesis, so it is necessary to define it. Territoriality is one of the fundamental principles of intellectual property law.[44] The purpose of the principle is to enable countries to design their national intellectual property laws according to their technological and economic capabilities.[45] This allows them to pursue their specific economic, social and cultural objectives, foster innovation and safeguard their social goals such as health.[46] The concept of territoriality has its roots in history of IP law, where privileges were confined within the sovereign territory.[47] While international law initially emerged as a response to this, IP law still preserves the territoriality nature.[48]

1.6.2. Social Function of IP

The terms *societal function* or *social/societal objectives* are sometimes used interchangeably. The social function of IP refers to the interest of the community. Property, including IP, should serve human values, benefiting not only the owners but also the community.[49] Intellectual property should contribute to social and economic equality, thereby enhancing social, economic, and political order and stability.[50] Thus, the social function of IP requires that IP rights should not undermine public interest. The social function of IP seeks to mitigate

[44]Hanns Ullrich "TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy" (1995) 4(1) Pac.Rim L.& Pol'y J 153 at 157.
[45]Emmanuel Oke "Territoriality in Intellectual Property Law: Examining Goals and Treating Intellectual Property Law: Examining the Tension between Securing Societal Goals and Treating Intellectual Property as an Investment Asset" (2018) 15(2) Scripted 313 at 315.
[46]At 315.
[47]At 316.
[48]At 316.
[49]Colin Crawford "The Social Function of Property and the Human Capacity to Flourish" (2011) 80(3) Fordham L. Review 1089, at 1090-1091.
[50]At 1134.

and restrain expansionist tendencies.[51] The social function highlights that IP rights should not operate solely to benefit a few at the expense of many others; instead, they should serve the interests of society, contributing to public acceptance and upholding the social contract between the owner and the public.[52]

1.6.3. Global South vs Global North

This thesis employs Global South and Global North division as a reflection of countries' socio-economic and political differences. The *Global North* refers mostly to economically developed countries such as the United States, the European countries, Japan, Australia and so on. They are often referred to as the *Western world*. In contrast, the *Global South* refers to economically developing and least- developed countries, such as Latin America countries, countries in Africa, China or India. They are often referred to as the *Third World*.[53] This division is not a reflection of countries' geographical location.

1.6.4. Global Justice

The theory of global justice is extensively explored in Chapter 2. However, it must be noted that the term *global justice* is sometimes interchangeably referred as *distributive justice*, *global distributive justice* or *cosmopolitanism*.

1.6.5. Proportionality

This thesis encompasses two different facets of proportionality principle. Hence, it is important to specify which aspect each chapter refers in order to prevent any confusion. As highlighted in Chapter 1.1., this thesis explores midlevel proportionality and judicial proportionality in the context of IP-investment. Chapter 2.4. is an introductory section that explores the development of the principle within the legal framework as a methodological tool, referred to as judicial proportionality in this thesis. Chapter 2.5. introduces midlevel principles to illustrate the origins of midlevel proportionality. Chapter 3.2.7. explores the midlevel proportionality in the context of IP. This section is significant as it establishes the foundation for demonstrating that investment protection of patented health resources is disproportionate. Throughout this thesis, midlevel proportionality is often invoked to address or highlight disproportionate situations or seek to remove a disproportionate situation.

[51]Christophe Geiger "The Social Function of Intellectual Property Rights, or How Ethics Can Influence the Shape and Use of IP Law" in Graeme B. Dinwoodie (ed) *Methods and Perspectives in Intellectual Property* (Edward Elgard Publishing, Cheltenham, 2013) 153 at 154; at 176.
[52]At 1623-165; at 176
[53]Antony Anghie "Rethinking International Law: A TWAIL Retrospective" (2023) EJIL 34(1) 7 at 12.

Therefore, it should be noted that when *disproportionate* is used in order to highlight excessive leverage, it refers to midlevel proportionality. Chapter 5 examines how judicial proportionality is applied by the arbitral tribunals in investment arbitration. Finally, the proportionality analysis in Chapter 6 aims to reveal midlevel facet of proportionality.

1.6.6. Health Resources

This thesis employs the term of *health resources* to encompass medicine, vaccines, therapeutics, diagnostics, any products and processes related to human health that can be patented. This choice is made to avoid repetitive lengthy explanations.

CHAPTER 2- THEORETICAL FRAMEWORK

2.1. Introduction

This thesis investigates midlevel proportionality to understand its function and why and how investment protection of IP rights, particularly patents, becomes disproportionate. It further examines judicial proportionality within the field of investment to determine whether it can address this disproportionate protection under investment arbitration. By doing so, the objective is to discover whether or how the principle operates in a way that advances global justice in relation to access to health resources in patent-investment interaction. Given the purpose is promoting progressive accessibility to health resources globally, this thesis is guided by cosmopolitan and cooperative theories of distributive justice.[54]

The issue of accessing health resources is considered a global distributive justice problem since income and wealth inequality between individuals and unfair distribution of health products are pervasive problems worldwide.[55] Access to patented health products is thus seen as an "individual claim".[56] Unfair distribution threatens access to health for those who are economically disadvantaged. The current international patent law system, as explored in Chapter 3, is already one reason of such a distribution problem. Investment protection exacerbates this problem even more by undermining the applicability of TRIPS flexibilities, allowing foreign investors to initiate cases in a private arbitration system and creating a regulatory chill that discourages states from acting in the public interest. For sure, to be initiated an investment case by a foreign investor, there should be an available investment agreement between the host state in question and the investors' home state. Still, existing agreements may pose the risk of accessing health resources. Therefore, the role of proportionality becomes crucial in mitigating this risk, and this thesis adopts cosmopolitan theories while examining this principle.

This thesis benefits from cosmopolitan ideas in enhancing the economic, political, and legal institutions, including patent protection under investment agreements. Given the significant influence of politics and international relations on the formulation of the agreements, it

[54]Michael Boylan "Medical Pharmaceuticals and Distributive Justice" (2008) 17(1) Camb. Q. Healthc. Ethics 30 at 31-32.
[55]World Health Organisation "Health Inequities and Their Causes" (22 February 2018) <https://www.who.int/news-room/facts-in-pictures/detail/health-inequities-and-their-causes> at 1.
[56]In global justice theories, individuals are the claimants or subjects of the theories. Thus, the rights/demands of the citizens are referred as individual claims. Please see Thomas Pogge "Global Ethics and Global Justice" in Jean-Marc Coicaud and Lynette E. Sieger *Conversations on Justice from National, International, and Global Perspectives: Dialogues with Leading Thinkers* (Cambridge University Press, New York, 2018) 167 at 167.

becomes imperative to adapt legal norms to effectively address today's challenges in the distribution of health resources. Cosmopolitan theories also advocate that everyone is entitled to receive care for their well-being, including access to health resources in accordance with UDHR Article 25.[57] The enforceable power of these human rights is also a topic of global justice, a fact which holds particular significance in the context of IP law. This underscores the importance of using the flexibilities of IP law and the Doha Declaration[58] actively, as detailed in Chapter 3. Promoting affordable access to health resources by relaxing the international patent system, particularly its investment protection, is significant for ensuring human well-being and enabling individuals to pursue a life they value. Global justice underscores that IP has also social and cultural impacts. Being able to have good health and having access to health resources should not be a matter of luck or an unchangeable factor beyond one's control like place of birth; instead, these should be available to everyone regardless of where one lives, as supported by global justice.

Consequently, it is important to posit the proportionality principle within the theory of global distributive justice and scrutinise the current system critically from a TWAIL perspective. The analysis of proportionality reveals that its application within the patent-investment context is heavily built on Western law; even in the context of international law, it retains a colonial foundation that could negatively affect the distribution of benefits and burdens among states. Therefore, midlevel proportionality analysis within the TWAIL criticism would reflect the disproportionality of investment protection of patent as it potentially undermines the universal access of affordable health resources. In tackling such a distribution problem, the global distributive justice theories are introduced as an initial step. Those theories highlight two justice questions: how to distribute resources and to whom. Next, TWAIL is explored by outlining its nature, objectives, and its relevance to the purpose of this thesis. This chapter, then, continues with the analysis of proportionality principle in law to trace its development which highlights that it lacks understanding and perspective of TWAIL. TWAIL complements global justice efforts to promote equal and affordable access to health resources for all by highlighting the unequal representation of states in the international arena and the predominant influence of Western concepts in international law, consequently creating disparities in access. This chapter then outlines Merges's midlevel principles. However, the details of midlevel proportionality are thoroughly examined in Chapter 3.2.7 since the

[57]UDHR, art 25.
[58]Doha Declaration.

analysis requires a preliminary discussion on the development of IP law to understand how Merges's proportionality is closely linked to its Western origins and how it can be amended in a way to promote affordable access to health resources, thereby highlighting the disproportionate nature of investment protection of patented health resources.

2.2. Proportionality and Distributive Justice

The roots of the proportionality principle in Western legal systems can be traced back to Aristotelian justice.[59] As Knoll suggests, justice for Aristotle is the most significant ethical virtue.[60] Aristotle applies proportionality to determine whether the distribution is just or unjust.[61] For Aristotle, proportion means "equality of ratios" of something.[62] Aristotle acknowledges that qualities of people vary, and in his just world, shares should be distributed in proportion to people's different qualities, their unequal worth, or merit.[63] In *Nicomachean Ethics*, Aristotle designates two distributive justice principles. The first principle requires that everyone receive proportionate to his worth.[64] The second principle states "if the persons be not equal, their shares will not be equal".[65] In Aristotelian thought, shares are distributed "according to merit"[66]; "… all men agree that what is just in distribution must be according to merit".[67] Aristotle's justice theory adopts a desert-based principle of distributive justice. Aristotle links this desert theory with merit, people desert things depending on merit. Proportionality plays a key role in the desertist theory.[68] To demonstrate these principles, Aristotle gives the shoemaker and the builder as an example. If a shoemaker wants the builder's work, the shoemaker must offer his own work in return proportionally.[69] There should be a proportion in this exchange as different professions have different/unequal worth. Though, since Aristotle, both the distributive justice theories and proportionality have evolved in time.

[59]Eric Engle "The General Principle of Proportionality and Aristotle" in Liesbeth Huppes-Cluysenaer and Nuno M. M. S. Coelho *Aristotle and The Philosophy of Law: Theory, Practice and Justice* (Springer Netherlands, Dordrecht, 2013) 265 at 265.
[60]Manuel Knoll "The Meaning of Distributive Justice for Aristotle's Theory of Constitutions" (2016) 1 Pege 57 at 58.
[61]Aristotle *The Nicomachean Ethics* (M.A. F. H. Peters (translator),10th ed, Kegan Paul, Trench Trübner & Co Ltd., London, 1906) at 147.
[62]At 145.
[63]At 145.
[64]At 145.
[65]At 145.
[66]At 145.
[67]At 145.
[68]At 136-179.
[69]At 154.

Before exploring proportionality, an analysis of modern distributive justice theories is conducted to demonstrate how the investment protection of patents poses a threat to the fair distribution of health resources. This underscores the necessity of cooperative and cosmopolitan distributive justice theories to address this issue. All the theories discussed below can contribute to addressing the issue of accessing health resources. The emphasis is on a global distributive justice theory and a cooperative approach as a solution for investment protection of patents, benefiting from the insights of each theory rather than solely focusing on one specific cosmopolitan theory.

2.2.1. Two Critical Questions: How to Distribute and to Whom?

Distributive justice deals with the distribution of benefits and burdens within society or across societies subject to changes in economic, political, and social structure.[70] The theories of distributive justice vary in terms of who the recipients are and how the goods and resources should be distributed. The theories discussed here answer mainly those two critical questions. Every approach has strengths and weaknesses, and each defender has criticized one another. It is still significant to discuss the main theories and their affiliated defenders to show why access to healthcare goods and resources within the context of IP-investment law requires cooperative and cosmopolitan distributive justice consideration and how the current system undermines such an approach.

The choice of distributive justice as the underlying theory in this thesis is motivated by its compelling ability to encapsulate justice principles rooted in liberal philosophical values. This suggests the potential incorporation of these principles into international intellectual property and investment law. Given that Western liberal countries are the most influential actors shaping this field, presenting a liberal idea can underline the ethical obligation of ensuring a fair distribution of resources, particularly concerning one of the most crucial needs for a human being: health. In addition, global distributive justice theories have an egalitarian dimension, and cosmopolitan views aim at achieving equal distribution globally regardless of state borders. The connection between distributive justice theories and justification of property rights, including intellectual property rights[71], further strengthens the reason for adopting global distributive justice theories.

[70]Julian Lamont and Christi Favor "Distributive Justice" in Edward N. Zalta (ed.) (Winter 2017 Edition) The Stanford Encycloaedia of Philosophy <https://plato.stanford.edu/archives/win2017/entries/justice-distributive/ > at 1.
[71]Peter Drahos *A Philosophy of Intellectual Property* (eBook, Anu eText, 2016); Merges, above n 22.

Before delving into the distribution principles, the first question should be clarified: Who are the recipients of distribution? The answer addresses the relationships involved in making judgments: domestic, international and global.[72] Domestic distributive justice deals with injustices within the state, nation, or a political community, for instance, domestic low wages policies for workers, whilst international and global distributive justice extends that scope.[73] The theories that extend this national scope are also known as cosmopolitanism.[74] Generally, a distinction is made between international and global justice by differentiating the identity of entities, in other words, the beneficiaries.[75] International justice deals with the justice between states or nations; on the other hand, global justice removes the state borders and considers individuals as agents, the beneficiaries.[76] If the recipient is a state, the question falls under the domain of international justice. If the issue addresses individual interest that everyone can claim, it signifies a discussion in global justice. Territorial claims and resource claims, and wars are examples of international justice.[77] Access to medicine or health products/resources is a right for every single human being in the world, regardless of nationality, religion, race, or residency[78]. Therefore, the protection of patents as an investment is a question of global distributive justice.

The second question of distributive justice answers how to distribute goods and resources. The principles of distribution vary according to the approach of how to distribute and to whom. Capability-based egalitarianism (Amartya Sen, Martha Nussbaum), contractarianism (John Rawls, Thomas Pogge, Charles Beitz, Darrel Moellendorf, Gillian Brock), utilitarian (Peter Singer), or rights-based approach (Thomas Pogge) are examples of such diversity.[79] In addition, Michael Boylan divides theories into two schemes as competitive (such as capitalism) and cooperative (like socialism or egalitarianism).[80] While wealth is distributed among the powerful under competitive schemes and cannot ensure that everyone can access

[72]Oisin Suttle *Distributive Justice and World Trade Law: A Political Theory of International Trade Regulation* (Cambridge University Press, Cambridge, 2018) at 33.
[73]At 33-34.
[74]Simon Caney *Justice Beyond Borders: A Global Political Theory* (Oxford University Press, Oxford, 2005) at 103-104.
[75]Gillian Brock and Nicole Hassoun "Global Justice" in Edward N. Zalta (ed) (Fall 2017 Edition) The Stanford Encyclopedia of Philosophy < https://plato.stanford.edu/entries/justice-global/#GlobInteJust > at 2.
[76]At 2.
[77]Pogge "Global Ethics and Global Justice", above n 56, at 172.
[78]UDHR, art 25; ICESCR, art 12; *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)*.
[79]Pogge, *World Poverty and Human Rights: Cosmopolitan Responsibilities and Reforms*, above n 5; Pogge, *Realizing Rawls*, above n 27; Singer, *Practical Ethics*, above n 27; Nussbaum, *Frontiers of Justice: Disability, Nationality, Species Membership*, above n 27; Sen, *The Idea of Justice*, above n 27; Beitz, *Political Theory and International Relations*, above n 3; Moellendorf, *Cosmopolitan Justice*, above n 27; Brock "Liberal Nationalism versus Cosmopolitanism: Locating the Disputes", above n 27.
[80]Michael Boylan "Global Distributive Justice" in Deen K. Chatterjee (ed) (2011) Encyclopedia of Global Justice <https://link.springer.com/content/pdf/bfm%3A978-1-4020-9160-5%2F1.pdf> at 404.

basic goods, cooperative schemes can reach much more people in terms of providing more basic goods.[81] When there is a public health issue, as the one addressed in this thesis, cooperative schemes should be favoured.[82] Both competitive and cooperative theories have benefits and weaknesses. Competitive theories are effective for creating wealth, rewarding valuable works, and thus, encouraging high productivity.[83] Though, while capitalism has a reward system, it does not necessarily reward excellence or hard work; instead, it rewards market demand.[84] Capitalism is the most efficient economic system capable of rapidly enhancing or generating wealth for individuals.[85] However, this wealth is left in the hands of a certain class of people who buy labour or have an investment in financial products.[86] As Lysandrou puts it, capitalism concentrates enormously on wealth ownership; thus, it expands inequality among individuals.[87] It is one of the reasons why capitalism fails to provide global common goods.[88] The term *common goods* is used in different contexts ranging from international law to economy[89]; and which goods are common varies.[90] In this thesis, the term *common good* is used as "the production of goods and services that are necessary to sustain a life of dignity for all peoples of the world"[91], which would eventually covers affordable health products including medicines and vaccines.

Yet, for Friedman, capitalism has promoted people's liberty and welfare.[92] He argues that there is a connection between economic freedom and democratic freedom.[93] Capitalism, in his mind, is needed for political freedom.[94] However, as he also acknowledges, economic freedom may not be sufficient for democracy, and undemocratic systems and capitalism can exist together, such as Fascist Italy or Fascist Spain.[95] In this vein, today's debate is over the characterisations of institutions like international financial institutions since there is an absence of an adequate level of democracy as expected by the emerging global society,

[81]At 404.
[82]Michael Boylan *Morality and Global Justice: Justifications and Applications* (Westview Press, New York, 2011) at 111.
[83]At 78-79.
[84]At 79.
[85]At 77.
[86]B. S. Chimni "Capitalism, Imperialism, and International Law in the Twenty-First Century" (2012) 14(1) Oregon Review of International Law 17 at 21.
[87]At 22.
[88]At 26.
[89]Nerina Boschiero "Covid-19 Vaccines as Global Common Goods: An Integrated Approach of Ethical, Economic Policy and Intellectual Property Management" (2021) Global Jurist 1 at 9-17.
[90]Chimni "Capitalism, Imperialism, and International Law in the Twenty-First Century", above n 86, at 39-40.
[91]At 40.
[92]Milton Friedman and with the assistance of Rose D. Friedman *Capitalism and Freedom* (40th ed, University of Chicago Press, Chicago, 2002) at 7-22.
[93]At 7-22.
[94]At 7-22.
[95]At 10.

particularly the so called *Third World* countries.[96] Consequently, capitalism is overly individualistic; its only essence is wealth and capital increase. It lacks social responsibility or responding basic needs.[97] Therefore, capitalism fails to address public health issues as part of the basic needs to be met by common goods and to provide accessible health resources as common goods. The cooperative schemes, as opposed to competitive ones, can offer a solution to access health resources. As indicated above, the subject this thesis relates to global distributive justice, and it should be addressed through cooperative and cosmopolitan theories.

2.2.2. The Principles of Distribution

People, especially those who live in economically disadvantaged positions, encounter challenges in accessing affordable medications, vaccines and disinfectants. Partly because, those resources are not covered by pharmaceutical companies' access strategic programs.[98] Research conducted by Access to Medicine Foundation has determined 199 medicines, diagnostics and control products as essentials for a healthcare system to function properly.[99] All these products are controlled by large pharmaceutical companies through patents or market domination.[100] However, research shows that only limited proportion of those products are covered by an access strategy in economically developing and developed countries.[101] The difficulty and inequality of access to healthcare resources are more apparent ever than before due to Covid-19 as it is a global pandemic.[102] The global inequality has become more visible in the distribution of the Covid-19 vaccine; unlike Global South countries, Global North countries have rapidly accessed to vaccines.[103] Though, for the first time, Global North (exceptions like Germany), notably the US, has supported a TRIPS waiver in relation to Covid-19 vaccines; yet as detailed in Chapter 3.2.6.1, the accepted waiver remains highly restricted.[104] Vaccines have been the key product against Covid-19.

[96]Chimni, "Capitalism, Imperialism, and International Law in the Twenty-First Century", above n 86, at 23-24.
[97]Boylan, *Morality and Global Justice: Justifications and Applications*, above n 82, at 76; Chimni "Capitalism, Imperialism, and International Law in the Twenty-First Century, above n 86, at 20.
[98]"Key Finding: Access Strategies: Less than Half of Key Products are Covered by Pharma Companies' Access Strategies in Poorer Countries" (2021) Access to Medicine Foundation <https://accesstomedicinefoundation.org/access-to-medicine-index/results/less-than-half-of-key-products-are-covered-by-pharma-companies-access-strategies-in-poorer-countries> at 1.
[99]At 1.
[100]At 1.
[101]At 2-5.
[102]At 4.
[103]Mark Peterson "Global Vaccine Divide- More Science Collobarotaion Needed" *University World News* (Global, 2 April 2021) <https://www.universityworldnews.com/post.php?story=20210402151906225>.
[104]Katherine Tai "Statement from Ambassador on the Covid-19 TRIPS Waiver" (press release, 05 May 2021) <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>; Ministerial Decision on the TRIPS Agreement, Adopted on 17 June 2022 WT/MIN(22) /WT/L/1141, 22 June

Yet, the need was broader, encompassing not only vaccines but also therapeutics and diagnostics like test kits to prevent the spreading of the virus and to treat patients.

It is demonstrated that whereas pharmaceutical patents increase the benefits of distribution for the Global North, unfortunately, this has not been the same case for the Global South.[105] This equilibrium changed at the time of Covid-19 for China, as a part of the Global South; yet again, predominantly Global South had been suffering from the lack of health resources, including vaccines.[106] There has already been inequality of access when it comes to the patented health resources due to the international patent system; investment protection of patents raises even more problematic questions of distributive justice. The investment protection of patents undermines applying TRIPS flexibilities (the legal mechanism that can address the needs of member states despite IP protection like compulsory licencing or flexibilities to grant IP rights like patentability); thus, the system makes it even more difficult for economically disadvantaged people to access patented health resources. As highlighted before, the current system creates disadvantages for some groups, both in the Global North and the Global South. However, Global South countries are particularly in a disadvantaged position since they heavily rely on Global North's investments or technologies[107], even though their reliance should not be at the expense of measures related to the public, including health.[108] It is acknowledged that sometimes a major challenge in the distribution of goods and resources, such as those needed to respond to Covid-19, is meeting -greater demand. Enhancing production safely to meet such demand can be very difficult.

This thesis supports that the cosmopolitan views can address this debate; therefore, more focus will be given to cosmopolitanism. It is not necessary to agree with every aspect of the theories. However, they all address that the current patent system (including its investment protection) is unfair as discussed in the following chapter, and goods and resources should be distributed to everyone regardless of their nationality or citizenship.[109] Thus, the focal point should be the fair distribution of goods and resources. All cosmopolitan theories discussed

---

2022 (Ministerial Conference 12 Session, Geneva) (hereinafter "Ministerial Decision on the TRIPS Agreement, Adopted on 17 June 2022").

[105]Margaret Chon "Intellectual Property and the Development Divide" (2006) 27(6) Cardozo Law Rev. 2821 at 2871.

[106]Leng Shumei "China Approves 7th Self-Developed Covid-19 Vaccine, can Cross-Neutralize Variants" *Global Times* (online ed, China) <https://www.globaltimes.cn/page/202106/1225877.shtml>; Editoral 1Covid-19: India Records New Case High as Brazil Registers Deadliest Month1 *EuroNews* (India, 30 April 2021) <https://www.euronews.com/2021/04/30/covid-19-india-records-new-case-high-as-brazil-registers-deadliest-month>.

[107]Johannes Kniess "Must We Protect Foreign Investors?" (2018) 5(2) MOPP 205 at 205.

[108]At 222.

[109]Simon Caney "International Distributive Justice" (2001) 49(5) Political Studies 974 at 976; at 988.

here have limitations and criticism. Yet, it should be recognised that they address the challenges pertaining to access issues to health resources. Therefore, this thesis adopts a comprehensive approach, drawing upon the valuable insights of each theory rather than solely concentrating on one particular cosmopolitan theory. The following sections introduce different theories of cosmopolitanism and how they address injustices in the distribution of goods and resources.

2.2.3. John Rawls' Distributive Justice

John Rawls's works are influential in the discussions on distributive justice and the works of contractarian cosmopolitans. Therefore, in order to understand the contractarian view, Rawls's theory of justice as fairness need to be introduced. Rawls's theory is classified as a contractarian theory since he hypothetically projects a social contract in which in the original position, people would agree on his two principles of justice.[110] Those two principles explain the proper method for distributing benefits and burdens.[111] Rawls's idea is based on the social cooperation, a principle of mutual benefit, a concept of reciprocity.[112] The more advantaged group acknowledges that without one-another, no one will have satisfactory life and their well-being depends on one-another.[113] Rawls's first principle requires providing equal basic liberties for everyone while his second principle permits social and economic inequalities provided that they benefit everyone, in particular, the least advantaged members[114] (difference principle).[115] The second principle also requires that positions of authority and responsibility must be open to all (fair equality of opportunity principle).[116]

2.2.4. Global Distributive Justice Theories (Cosmopolitanism)

John Rawls' theory of justice is transformed to the international level notably, by Beitz and Pogge. They advocate for applying Rawls' two principles of justice globally. The section begins with Beitz's contribution, followed by Pogge's, and then explores other theories of global justice. It is important to note that this thesis draws insights from these theories.

[110]John Rawls *A Theory of Justice* (revised ed, The Belknap Press, Cambridge, 1999) at 10.
[111]At 5.
[112]At 13; at 88.
[113]At 13.
[114]Please see the definition of least-advantaged members: "the income class with lower expectations" in John Rawls *Justice as Fairness: A Restatement* (2nd ed, Harvard University Press, United States of America, 2001) at 59.
[115]Rawls, above n 110, at 53; at 72.
[116]At 53; at 72.

According to Beitz, as a result of globalisation, states are not self-constrained anymore as they are in international, economic, political and cultural relations, which indicates a global scheme of social cooperation.[117] Beitz suggests that if social cooperation grounds distributive justice, and it exists for Beitz at the global level, international economic *interdependence* (as a result of international trade and investment) is also sufficient to claim the presence of the global distributive justice principles.[118] This economic interference, even free trade, has a role in international distributive inequalities when ongoing transfers to the least advantaged are absent.[119] Beitz appropriately highlights that the most vulnerable countries are those heavily dependent on the exports from a limited number of countries.[120] Beitz also suggest that global regulative structures have developed as result of that interdependence which have significant distributional consequences.[121] The TRIPS Agreement, which sets minimum standards of intellectual property rights for member states, is one of the significant examples of such structures that have substantial distributive consequences. Accessing medicines or vaccines is an example of these distributional consequences, as seen in the distribution of the Covid-19 vaccines. The details of these negative consequences are examined in Chapter 3.

Furthermore, Beitz argues that since individuals in the original position are unaware of which society they will belong to (veil of ignorance), they cannot choose to apply Rawls's principles solely to the society they belong.[122] Therefore, Rawls's principles should be applied globally.[123] While Beitz was criticized for the extent/degree of *interdependence* which would be enough to create the global difference principle[124], Beitz makes clear that as long as states are not economically autarkic, there will be interdependency, and thus, social cooperation.[125] This thesis aligns with Beitz's position regarding the expansion of distributive responsibilities on a global scale. The reason behind this stems from the distributive implications of the activities engaged by the WTO members within the WTO system, notably TRIPS Agreement. However, what is problematic for the purpose of this thesis is that Beitz's emphasis on the distribution of natural resources. According to Beitz, representatives of states in the original position would agree on the principles of justice concerning natural resources since natural

[117]Beitz, *Political Theory and International Relations*, above n 3, at 144.
[118]At 144-145.
[119]At 145-146.
[120]At 147.
[121]At 149.
[122]At 151.
[123]At 151.
[124]Simon Caney "Cosmopolitanism and Justice" in Thomas Christiano and John Christman (ed) *Contemporary Debates in Political Philosophy* (Wiley-Blackwell, Oxford, 2009) 387 at 391.
[125]Beitz, *Political Theory and International Relations*, above n 3, at 152.

resources are located unevenly and this does not give rise to excluding others benefitting from them.[126] Caney criticized Beitz's particular emphasis on natural resources for the purpose of distribution and considered that Beitz's theory of justice excludes economic resources which result from economic interaction and cooperation.[127] In *Political Theory and International Relations*, Beitz refers to natural resources as well as the benefits derived from them as the scope of distributive principles.[128] While benefits derived from natural resources are not necessarily as inclusive as the economic products discussed by Caney, the subjects of justice principles are not as narrow as Caney analysed either. Yet, it seems that according to Beitz's theory, it is disputable whether patented products would be included in these distributional principles. For the purpose of this thesis, the significance of his theory lies in viewing individuals, rather than states, as the objects/beneficiaries of the global difference principle.

Another contractarian that extends Rawlsian principles at an international level like Beitz is Thomas Pogge.[129] Pogge argues that instead of giving moral standing to nationality as Rawls does, individuals should be representative of a single globe.[130] Pogge identifies two concepts: institutional cosmopolitanism and interactive cosmopolitanism.[131] Institutional cosmopolitanism assigns the responsibility of fulfilment of human rights to institutional schemes; whereas interactional cosmopolitanism assigns it to individual or collective agents.[132] Pogge criticises Rawls as, according to Pogge, fairness of the institution[133] should be the focal point of distributive justice principles (institutional form), and members have obligations to others regardless of their institutions (interactive forms).[134] Pogge argues that global institutions have great contribution to global poverty, and affluent people share responsibility to compensate the poor.[135] Furthermore, global institutions have negative duty to prevent such institutions from ignoring basic human rights.[136]

[126]At 137-138.
[127]Simon Caney "Global Interdependence and Distributive Justice" (2005) 31(2) RIS 389 at 391.
[128]Beitz, *Political Theory and International Relations*, above n 3, at 138.
[129]Pogge, *Realizing Rawls*, above n 27, at 24.
[130]At 247; at 256.
[131]Thomas W. Pogge "Cosmopolitanism and Sovereignty" (1992) 103(1) Ethics 48 at 50.
[132]At 50.
[133]See the definition of institution: "…the basic structure of a society's basic mode of economic organisation; the procedures for making social choices through the conduct of, or interactions among, individiuals and groups, and limitations upon such choices; the more important practices regulating civil (noneconomic and nonpolitical) interactions, such as the family or the education system; and the procedures for interpreting and enforcing the rules of the scheme." in Pogge, *Realizing Rawls*, above n 27, at 22-23.
[134]Pogge, "Cosmopolitanism and Sovereignty", above n 131, at 50-51.
[135]Pogge, *World Poverty and Human Rights: Cosmopolitan Responsiblities and Reforms*, above n 5, at 176-264.
[136]At 176-264.

Pogge bases his global economic right[137] on the UDHR Article 25(1):[138]

> Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services ...

From this point of view, Pogge adopts a rights-based approach. In a similar vein, Pogge includes economic resources to this rights-based approach in some of his writings as Henry Shue does. However, Shue rejects ranking the Rawlsian two principles of justice described above.[139] Shue argues that giving priority to the first principle privileges political rights incorrectly since subsistence rights are essential for civil and political rights, and if we accept the latter, we will need the former.[140] For Shue, subsistence rights are basic rights, "minimum reasonable demand upon the rest of humanity", which is a tool for assessing distributive aspects of global institutions.[141] Regardless of the different aspect between Pogge and Shue, one of the most significant arguments advanced by Pogge for the purpose of this thesis is that advantaged groups shape institutional order.[142] This reality has severe human rights consequences and this institutional order have been imposed to worse off even though alternative systems exist to prevent severe poverty.[143] The international intellectual property regulations are an example of such forces.

It is believed that expanding Rawlsian distributive principles ("equality of opportunity and the regulation of global equality by the difference principle"[144]) globally facilitates global justice. In this way, disadvantaged groups would receive consideration at the global level.[145] However, it is uncertain whether the first principle (equal basic liberties of everyone) of Rawls is sufficient or adequate if his list of the primary goods ("political liberty and freedom of speech and assembly; liberty of conscience and freedom of thought;...;right to hold personal property"[146]) is applied at the global level. According to Nussbaum and Sen, Rawls's primary goods list does not take into account the different "basic capacities" of people;

[137]Thomas W Pogge "An Institutional Approach to Humanitarian Intervention" (1992) 6(1) North American Philosophical Publications 89 at 89.
[138]UDHR, art 25.
[139]Kok-Chor Tan *Justice Without Borders Cosmopolitanism, Nationalism, and Patriotism* (Cambridge University Press, New York, 2004) at 48.
[140]Caney, "International Distributive Justice", above n 109, at 979.
[141]Henry Shue *Basic Rights: Subsistence, Affluence, and U.S. Foreign Policy: 40th Anniversary Edition* (Princeton University Press, New Jersey, 2020) at 19.
[142]Pogge, *World Poverty and Human Rights: Cosmopolitan Responsiblities and Reforms*, above n 5, at 174-201.
[143]At 174-201.
[144]Tan, above n 139, at 60. The principles are explained in Chapter 2.2.3.
[145]At 61.
[146]Rawls, above n 110, at 53.

therefore, the list is limited; Sen defines its' narrowness and limitation as "fetishist".[147] Indeed, the most problematic issue of Beitz and Pogge's extension of Rawls' justice as fairness at a global level is that the index of Rawls's primary goods itself is already disputed.[148] Indeed, while the primary goods are required to achieve life plans, it does not necessarily mean that those goods are the metric of just distribution.[149]

Another cosmopolitan approach is duty-based, which is seen as a supplement to the rights-based approach, but some, like O'Neil, have evaluated the duty-based approach as superior.[150] According to O'Neill, the argument that disadvantaged groups has the right to assistance, for instance, does not provide access to that right if there is no assigned duty, and thus, the right to assistance becomes an "empty right".[151] O'Neill relies on Kantian deontological ethics and suggests that moral duty should be institutionalised to assign, specify and enforce rights.[152] For O'Neill, current states and international institutions fall short of securing rights for individuals whose states fail to secure for them, or for those without any state.[153] O'Neill has been criticised because the theory seems to fall short in explaining the inadequacy of the rights-based approach in terms of its enforceability.[154] Critics argue that the inability to assign and enforce duties within a right does not necessarily render that right is inadequate.[155] While the critics have a point, O'Neill highlights and reminds a very practical problem of human rights, which this thesis can benefit from in relation right to health. As this thesis argues, if global justice is assumed to be fully functioning meaning that everyone is entitled to have the right to health in accordance with ICESCR Article 12 or UDHR 25, it becomes crucial to identify to whom to assign these rights; otherwise, the rights lose their substance.[156] This practical dilemma may be a significant obstacle in addressing issues of justice pertaining access to health resources.

---

[147]Tan, above n 139, at 61.
[148]Sen, *The Idea of Justice*, above n 27, at 254; Robert C. Hockett and Mathias Risse *Primary Goods Revisited: The "Political Problem" and Its Rawlsian Solution* (Cornell Law Faculty Publications Legal Studies Research Paper Series No. 06-30, 2006); R. J. Arneson "Primary Goods Reconsidered" (1990) 24(3) Noûs (Bloomington, Indiana) 429; Further, according to Drahos, while abstract object -which covers intellectual property- can/should be covered by Rawlsian primary goods as a political liberty, people in the original position would not allow maximising proprietorial control over them neither at the domestic level nor global level. At the global level, people in the original position would not permit arrangements that intervene sovereignty of states to rule property rights, intervene its territoriality. For details, Drahos, *A Philosophy of Intellectual Property*, above n 71, at 199-229.
[149]G. A. Cohen *Rescuing Justice and Equality* (Harvard University Press, Cambridge 2008) at 294.
[150]Tan, above n 139, at 49-50.
[151]At 51.
[152]At 50-53.
[153]Onora O'Neill *Bounds of Justice* (Cambridge University Press, Cambridge, 2000) at 180-181.
[154]Tan, above n 139, at 52.
[155]At 52.
[156]Onora O'Neill "The Dark Side of Human Rights" (2002) 81(2) International Affairs 427; UDHR, art 12; ICESCR, art 5.

Both Sen and Nussbaum follow the egalitarian approach.[157] Capability egalitarians are against the list of primary goods because they find that it is limited. Therefore, can extend the scope by claiming that as long as inequalities between people exist, basic rights of disadvantaged groups will not be fulfilled.[158] Sen claims that both equal access to resources and equal access to welfare are problematic; therefore, equality should focus on capability, the things people have reason to value to do.[159] Nussbaum suggests that resources "are not good in their own right; they are good only insofar as they promote human functioning".[160] According to Sen, whether an opportunity is advantageous would depend on whether people have capability or reason to value (if someone has lower capability to do something, it means they have less opportunity; yet, people have freedom to choose what they value to do).[161] Since Sen's approach focuses on the capability of individuals rather than groups or societies, this approach is criticized as an individualist one.[162] Sen gives value to the freedom of achieving something rather than what is achieved.[163] It does not matter if the person actually uses it; what matters is that the person has the opportunity to enhance one's capacity.[164] In line with Aristoteles, for Sen, what people value is education, health, food, clothing to fulfil her/his potential as a human being rather than wealth.[165] In this respect, Sen particularly emphasises the importance of preventing and mitigating health problems including AIDS, polio, or others and refers to it as a center of justice.[166] For Sen, if we consider public health as a public good, then it would be disputable why economically disadvantaged people would be offered smaller shares of health products than the affluent.[167] The question of whether this capability approach can address patent injustice is already discussed by Julie Clague.[168] While this analysis focuses particularly on biotechnology, Clague clarifies that the capability approach acknowledges the necessity of relaxing the current patent system (as discussed in Chapter 3), particularly in the pharmaceutical sector, to reduce inequalities between the South and the North by empowering the South to ensure its maximum participation. On the other

[157]Sen, *The Idea of Justice*, above n 27; Nussbaum, above n 57.
[158]Tan, above n 139, at 53.
[159]Sen, *The Idea of Justice*, above n 27, at 231-232.
[160]Martha C. Nussbaum "Human Functioning and Social Justice: In Defense of Aristotelian Essentialism" (1992) 20(2) Political Theory 202 at 233.
[161]Sen, *The Idea of Justice*, above n 27, at 231-232.
[162]It is disputable whether his theory is an individualistic one. See more discussion Sen, *The Idea of Justice* above n 27, at 244.
[163]Sen, *The Idea of Justice*, above n 27, at 235-238.
[164]At 235-238.
[165]At 253.
[166]At 259.
[167]Amartya Kumar Sen *Development as Freedom* (Knopf, New York, 1999) at 42; at 128; at 144.
[168]Julie Clague ""Patent Injustice": Applying Sen's Capability Approach to Biotechnologies" in Mathias Nebel and Nicholas Sagovsky Severine Deneulin (ed) *Transforming Unjust Structures: The Capability Approach* (Springer Netherlands, Dordrecht, 2006) 177.

hand, one can still argue that patent protection is necessary for people to flourish, people like investors, for instance.

Luck egalitarianism, which is another egalitarian theory, addresses interpersonal inequalities resulting from factors beyond one's control, such as being born in an impoverished state or born with some disadvantages, or having a disability.[169] As Cecile Fabre suggests, people who live in impoverished states should be compensated for their involuntary situation.[170] The main objections to luck egalitarians are that luck egalitarians do not consider relations of people and they do not refer to morally arbitrary inequalities which result in voluntary choices.[171] Egalitarians argue that it is not fair for a person to be in a worse position than others without having made his own choices or mistakes; similarly, it also unfair for a person to be in a worse position than others even though they both equally deserve the same.[172] Their argument is very relevant in terms of accessing affordable medicines or vaccines. It is not one's choice to be born/to live in a country, for instance, where there is a low rate of invention and high reliance on importation. That can also be a significant problem for people with low income regardless of whether they live in the Global South or North. The current patent system reveals the inequality between individuals depending on where they were born or live.

Along with the theories above, another cosmopolitan approach is utilitarianism which is affiliated with Peter Singer.[173] According to Singer, "if it is in our power to prevent something bad from happening, without thereby sacrificing anything of comparable moral importance, we morally ought to do it".[174] Singer suggests that people are obligated to help one another even if they are not part of the same society.[175] For Singer, affluent people are obligated to give away their wealth until we reach a form of marginal utility (strong version).[176] He proposes a modest version rather than a strong version: "which required us to prevent bad things from happening unless in doing do we would be sacrificing something of moral

[169]Kevin K. W. Ip *Egalitarianism and Global Justice: From a Relational Perspective* (Palgrave Macmillan US, New York, 2016) at 2.
[170]At 4.
[171]At 2.
[172]Larry S. Temkin "Illuminating Egalitarianism" in Thomas Christiano and John Christman (ed) *Contemporaty Debates in Political Philosophy* (Wiley-Blackwell, Malaysia, 2009) 154 at 157; G. A. Cohen "On the Currency of Egalitarian Justice" (1989) 99(4) Ethics 906.
[173]Peter Singer *Famine, Affluence, and Morality* (Oxford University Press, Oxford, 2016).
[174]At 5-6.
[175]At 103, at 47.
[176]At 27-29.

significance..."[177]. Even though Singer's strong version is morally correct, it may put too much burden on average citizens in affluent countries.[178] Yet, people should "give away enough" to reduce famine or end the extremity of consumption society where expenditures of individuals are frivolous.[179]

2.2.5. Debating Cosmopolitanism: Resisting Oppositions and Advocating Its Defence for Access to Health Resources

Cosmopolitanism has received considerable objections from various perspectives, such as defenders of nationalism like Miller and Tamir, defenders of society of states like Rawls, and proponents of realism like Hendrickson, Zolo, and Waltz.[180] Tamir and Miller argue that people have an obligation towards fellow nationals[181], whereas Barry suggests that this obligation extends to fellow citizens[182]. Miller finds the idea of redistributing resources to foreigners through a cosmopolitan perspective unacceptable as it would entail fellow nationals to distribute their resources to non-nationals.[183] Additionally, while Miller agrees with Shue on human rights to liberty, security and subsistence, he maintains that the obligation of safeguarding these rights lies solely with fellow-nationals.[184] As opposed to what cosmopolitanism requires, Miller contends that if states choose to redistribute their resources beyond their borders, it would be at the discretion of states themselves.[185] According to patriotic defenders, the critique of cosmopolitanism is not that cosmopolitans cannot preserve the moral significance of patriotism to the same extent as patriotic defenders do, but cosmopolitans' impartiality diminishes the value of patriotism.[186] It is further quite interesting that even though some cosmopolitans like Pogge and Beitz are influenced by Rawls, Rawls himself rejects such an approach. According to the 'society of states approach', states should respect states' sovereignty.[187] Particularly, for Rawls, states only consider their own national interest, power, wealth, and they lack moral motives.[188] For realism defenders Hendrickson, Zolo and Waltz, cosmopolitanism is against human nature.[189] Further, for

[177]At 28.
[178]Tan, above n 139, at 42.
[179]Singer, *Famine, Affluence, and Morality*, above n 173, at 29.
[180]Caney "International Distributive Justice", above n 109, at 980-988.
[181]David Miller *On Nationality* (Clarendon, Oxford, 1997) at 49; Yael Tamir *Liberal Nationalism* (Princeton University Press, Princeton, 1995) at 88-89.
[182]Brian Barry "Nationalism versus Liberalism? " (1996) 2(3) Journal of the ASEN 430 at 430-431.
[183]Caney, "International Distributive Justice", above n 109, at 981.
[184]Miller, above n 181, at 74.
[185]Tan, above n 139, at 100.
[186]At 148.
[187]Caney, *Justice Beyond Borders: A Global Political Theory*, above n 74, at 128-129.
[188]At 128-129.
[189]Caney, "International Distributive Justice", above n 109, at 987.

Waltz, the international system itself requires that states only seek their own wealth but not the wealth of others outside their borders.[190]

The opposition to cosmopolitanism primarily relies on nationalistic sentiments, either to fellow citizens, or to fellow nationals, they are sceptic regarding humans' nature, particularly the affluent's, willingness to share resources and goods with foreigners. In Rawlsian's point of view, distributive justice is limited to domestic scope, implying that tackling global poverty requires the humanitarian assistance rather than distributional principles.[191] This thesis rejects nationalistic oppositions, recognising the influence of globalisation, particularly evident in economic and technologic means. The movement of investments or intellectual property rights, for instance, exemplify the reality of globalisation, thereby highlighting the need for global justice. Today's world is interconnected, and global interactions among individuals are inevitable. Such interactions require a departure from discussions that are focused on nationality or any kind of reciprocity as states are interdependent in terms of economic, population -particularly workforce- and technology. Cross-border trade, foreign direct investment, immigration, transfer of information or knowledge, and cultural exchange, in short, global interactions, are causes of globalisation.[192] They are also the inevitable effects of globalisation at the moment. Yet, international institutions, international structure and designation of laws do not reflect that reality, as will be discussed further below. As Singer asserts, even though expansion of trade activities resulting from globalisation has had benefits to many people in poverty, it has also failed to aid the ten percent of the people who are most impoverished.[193] The current structure of international law has been in favour of advantaged or affluent groups instead of the disadvantaged and the economically suffering groups. As Buchanan rightly points out:[194]

> Among the elements of the global basic structure are the following: regional and international economic arrangements (including General on Tariffs and Trade, North American Free Trade Agreement, and various European Union treaties), international financial regimes (including the International Monetary Fund, the World Bank, and various treaties governing currency exchange mechanisms), an increasingly global system of private property rights, including intellectual

[190]At 987-988.
[191]John Rawls *The Law of Peoples with "The Idea of Public Reason Revisited"* (4 ed, Harvard University Press, United States of America, 2002) at 106-117.
[192]International Monetary Fund "Globalisation: A Brief Overview" (May 2008) <https://www.imf.org/external/np/exr/ib/2008/053008.htm>.
[193]Singer, *Famine, Affluence, and Morality*, above n 173, at 66.
[194]Allen Buchanan "Rawls's Law of Peoples: Rules for a Vanished Westphalian World" (2000) 110(4) Ethics 697 at 705-706.

> property rights that are growing importance as technology spreads across the globe, and a set of international and regional legal institutions and agencies that play an important role in determining the character of all of the preceding elements of the global basic structure.

The current international patent law framework under the TRIPS Agreement serves a significant example since the agreement was imposed by Global North actors through the lobbying activities of multinational corporations, as explored in Chapter 3. The adoption of the TRIPS Agreement and its global distributive justice implications are addressed in Chapter 3. Additionally, IIAs between states constitute another set of global structures that entail distributive consequences, as discussed in Chapter 3 and Chapter 4. Consequently, these arrangements require an analysis through global justice, particularly in the context of fair distribution of health resources. As mentioned before, all the cosmopolitan theories have their own criticism. However, they share a common and fundamental purpose: to achieve global justice.

All discussed theories can address the issue of accessing health resources, as explained below; therefore, this thesis benefits from each theory of cosmopolitanism. From Beitz and Pogge's arguments, this thesis benefits from the need to improve the economic, political, and legal institutions to achieve global justice, such as IP protection under investment agreements. Politics and international relations play a significant role in shaping agreements, which can require legal norms to be adjusted to tackle current problems faced in distributing health resources. However, Beitz's theory of justice seems to be limited to natural resources, which do not necessarily relate to pharmaceutical products. Therefore, Beitz's theory would enhance this thesis through its cosmopolitan aspect, advocating for the global application of distributive principles.[195] Beitz also has some works on the moral rights of copyrights and has appeared in some IP scholars' works[196]; however, it is irrelevant for the purpose of this research. The right-based approach relies on the UDHR Article 25, which requires that everyone, from their birth till death, deserves to receive necessary care for their living, and access to health resources is a significant part of this necessary care. The article in question applies to every human being equally; thus, if there is any kind of limitation to it, it should be nullified.

[195]Drahos, *A Philosophy of Intellectual Property*, above n 71, at 213.
[196]Brian Angelo Lee "Making Sense of "Moral Rights" in Intellectual Property" (2011) 84(1) TLR 71; Charles Beitz "The Moral Rights of Creators of Artistic and Literary Works" (2005) 13(3) JOPP 330; Ole-Andreas Rognstad *Property Aspects of Intellectual Property* (Cambridge University Press, Cambridge, 2018).

In the meantime, as advocates of the duty-based approach assert, human rights regulations, such as UN human rights treaties, should have enforceable power within the legal system. This argument becomes an issue in IP flexibilities in terms of their practicality and applicability like the Doha Declaration[197], which will be detailed in the next chapter. Someone who supports the duty-based approach would require an enforceable human rights mechanism under the international intellectual property rights regulation system. Whether the duty-based approach is superior to the rights-based approach, as O'Neill argues, or whether it is a supplement does not change the fact that, for this thesis, the human right to health and the human right to life as a result of access to health resources, should be more effective than their mere appearances. This is a necessity both in international intellectual property agreements and investment agreements.

In addition to the aforementioned theoretical perspectives, the capability approach offers an understanding of the need to re-evaluate/relax the international patent system concerning health resources since health is one of the fundamental dimensions that enables individuals to flourish and achieve a life that they value. The capability approach acknowledges and emphasises broader social and cultural impacts of IPRs, as opposed to the economic perspective on IP, which can overlook the concept of IPRs. One drawback of the capability approach is that it can require more stringent IP protection in the pursuit of human development objectives. However, in the context of this thesis, such an outcome is found inapplicable as the objective of this thesis is to ensure equitable access to health resources to enable individuals to lead fulfilling lives according to their own values. Some IP scholars have already adopted a capability approach to IP[198]; however, its application to the IP protection as an investment and its impact on human development has not been explored extensively. Thus, incorporating the capability approach into the discourse of IP- investment would enhance this analysis.

Luck egalitarians aim to reduce inequalities that arise as a result of people's luck, such as the place of birth. Luck-egalitarians would argue that scientifically developed countries have an obligation to help ensure distributional justice by allowing others to access their

[197]Doha Declaration.
[198]Margaret Chon "Intellectual Property "from below": Copyright and Capability for Education" (2007) 40(3) U.C. Davis Law Review 803 at 803; Sunder, above n 15; Tzen Wong and Graham Dutfield (ed) *Intellectual Property and Human Development: Current Trends and Future Scenarios* (Cambridge University Press, New York, 2011).

innovations.[199] For instance, difficulties in accessing health resources in Global South could be addressed by lowering prices to reduce inequalities. This luck-egalitarian argument can also find place within the IP-investment debate; however, this thesis limits itself to applying this theory only to the extent of reducing/removing luck as a factor in the case of accessing health resources.

Finally, this thesis finds utilitarianism the most problematic approach for the purpose of this thesis as Singer sees justice as humanitarian aid. Yet, as a utilitarian, Singer also aims to achieve marginal utility, as explained before. With regards to intellectual property rights, Singer claims that they "must be assessed by reference to the common good of humankind".[200] On one hand, Singer does not support the pre-TRIPS regime by arguing that the system did not incentivize inventors to develop drugs needed in the Global South.[201] On the other hand, Singer acknowledges the inability of certain people to afford needed health resources due to high monopoly prices as a result of the TRIPS Agreement.[202] This thesis is sceptical of the utilitarian concept of justice since this thesis does not agree that justice is a humanitarian aid or justice is a sort of math that can be calculated to reach marginal utility or overall human well-being. Still, Singer's view seems unrealistic given the challenging nature of abolishing patents in the pharmaceutical sector, as it is evident from the inability of states to reach an agreement on a temporary waiver on Covid-19 related patents during a global health crisis.[203]

Consequently, this thesis draws upon the insights of each theory rather than solely focusing on a specific cosmopolitan theory. In this aspect, it argues that the current structure of patent protection as an investment potentially undermines the principles of global justice, particularly with regards to the equitable distribution of patented health resources, as explored in Chapter 3 and Chapter 4. This issue represents significant concerns of global justice that should be addressed through the cosmopolitan and cooperative views. Despite aligning with the TRIPS Agreement or relevant investment agreement, interferences in the protection patents for health products or processes could still be contested as a violation of a

[199]Calvin Wai Loon Ho "Utilitarianism and Patents: Justification and Change" (2010) 2(3) Asian Bioethics Review 202; Amitaya Banerjee "Who has Responsiblity for Access to Essential Medical Drugs in the Developing World?" (2006) 4(2) Ethics and Economics 1.
[200]Doris Schroeder and Peter Singer "Access to Life-Saving Medicines and Intellectual Property Rights: An Ethical Assessment" (2011) 20(2) Cambridge Quarterly of Healthcare Ethics 1 at 6.
[201]At 8.
[202]At 8-9.
[203]World Trade Organization "TRIPS, the Intellectual Property System and Covid-19" (2023) <https://www.wto.org/english/tratop_e/trips_e/trips_and_covid19_e.htm>.

substantive right of a treaty if an applicable investment agreement is in place. Although success of foreign investors is not guaranteed[204], the investment arbitration process alone has a *chilling effect*, and it can pose a financial burden for Global South, as experienced in the *Philip Morris v Uruguay* case, where all the legal expenses were covered by Michael Bloomberg.[205]

In this respect, this thesis delves into the proportionality principle in the context of patent-investment. Both areas of law (IP and investment) and the proportionality principle have Western roots. To address the significance of these origins and their potential impact on global affordable access to health resources, this thesis benefits from TWAIL.

2.3. What is Third World Approaches to International Law (TWAIL)?

This thesis draws on the TWAIL approach, offering a critical perspective on the Westernized international legal framework. As the subsequent chapters of this thesis demonstrate, it is particularly relevant to international intellectual property rights and international investment law. TWAIL scholarship has made significant contributions to the fields of international law, international economic law, intellectual property, and international investment law.[206] The integration of critiques offered by TWAIL scholars is a significant element to strengthen the arguments articulated in this thesis and complement global distributive justice propositions.

The primary questions pertaining to TWAIL are its' definition, underlying purpose, and the factors that have contributed to its emergence. TWAIL is defined as a methodology since it offers "a body of methods used in the activity of international legal analysis"; a theory since

[204]For instance, the decision of *Philip Morris v Uruguay* lowers the chance of success of similar cases, hence disincentivise tobacco companies: Alberto Alverez-Jimenez "Tobacco Control Measures and International Investment Law after *Philip Morris v. Australia* and *Philip Morris v.* Uruguay" (2018) 29(2) ARIA 147 at 170.
[205]Myre Davies "Michael Bloomberg fights big tobacco in Uruguay" *BBC* (Rio de Janeiro, 7 April 2015).
[206]B. S. Chimni "The Past, Present and Future of International Law: A Critical Third World Approach" (2007) 8(2) MJIL 499; Antony Anghie "Time Present and Time Past: Globalization, International Financial Institutions, and the Third World" (2000) 32 N.Y.U. J. Int'L. & Pol. 243; Antony Anghie *The Third World and International Order: Law, Politics, and Globalization* (Martinus Nijhoff, Leiden 2003); B. S. Chimni "The International Law of Jurisdiction: A TWAIL Perspective" (2022) 35(1) LJIL 29; B.S. Chimni "Critical Theory and International Economic Law: A Third World to International Law (TWAIL) Perspective" in John Lineralli (ed) *Research Handbook on Global Justice and International Economic Law* (Edward Elgar, Cheltenham, 2013) 251; Anghie, "Rethinking International Law: A TWAIL Retrospective", above n 31; R. A. Mahshelkar "Intellectual Property Rights and the Third World" (2001) Current Science 81(8) 955; Marsha S. Cadogan "A TWAIL-Constructivist Critique of the IP and Development Divide in the Age of Innovation – Has the Protection of Place Based Goods Changed the Narrative for the Caribbean?" in Susy Frankel (ed) *The Object and Purpose of Intellectual Property* (Edward Elgar, Cheltenham, 2019) 57; Antonius R. Hippolyte "James Thuo Gathii Aspiring for a Constructive TWAIL Approach towards the International Investment Regime" in Stephan W. Schill, Christian J. Tams and Rainer Hofmann *International Investment Law and Development: Bridging the Gap* (Edward Elgar, Cheltenham, 2015) 180; Enakshi Jha "TWAIL and Investment Law: The Perpetual Struggle" (2016) 5(2) NLIU L. Rev 217.

it is a "system of ideas explaining something"; and a scholarly approach/school of thought.[207] For Mutua and Anghie; TWAIL is characterised as a "political and intellectual movement".[208] For them, TWAIL is "anti-hierarchical, counterhegemonic, suspicious of universal creeds and truths, coalitionary movement".[209] TWAIL is regarded as a critique of the global dominance of Western countries, and it is a manifestation of this opposition within the field of international law. [210]

TWAIL emerged as an intellectual movement at Harvard Law School in the mid-1990s; however, its origins can be traced back to the Bandung Conference, which was held in the aftermath of the World War II decolonisation movements.[211] The "Third World" represents a group of countries that share a historical experience of colonialism, while they have distinct geographical, oppositional, and political realities from Western countries.[212] It should be reminded that in this thesis, the term *Global South* is used interchangeably with the concept of *Third World*.

The impact of colonialism in international law is not just superficial; it has played a central role in shaping the system which still influences today's relationship between states.[213] The decolonisation process did not result in fundamental changes in the formulation of international law; it only replaced the former structure with neo-colonialism where the Third World has been unable to go beyond its subordinate role in the international legal system.[214] Similarly, according to TWAIL scholars, although international law assures principles of sovereign equality and self-determination, it carries the influence of imperialism and the dominance of colonisation.[215] As demonstrated in the subsequent analysis, this belief is evident in the evolution of the concept of proportionality within law, within the framework of

[207]Obiora Chinedu Okafor "Critical Third World Approaches to International Law (TWAIL): Theory, Methodology, or Both?" (2008) 10(4) ICLR 371 at 376-377.
[208]Makau Mutua and Antony Anghie "What Is TWAIL?" (2000) 94 JSTOR 31 at 36.
[209]At 36-38.
[210]At 36.
[211]At 31; James T. Gathii "TWAIL: A Brief History of Its Origins, Its Decentralized Network, and a Tentative Bibliography" (2011) 3(1) Trade L. & Dev. 26 at 28.
[212]Mutua and Anghie, above n 208, at 35.
[213]Antony Anghie "The Evolution of International Law: Colonial and Postcolonial Realities" (2006) 27(5) Third World Quarterly 739 at 748-749.
[214]At 749.
[215]Antony Anghie *Imperialism, Sovereignty and the Making of International Law* (Cambridge University Press, Cambridge, 2005) at 196-199.

international IP and international investment law. These areas of law are representation of the legitimacy crises in international law, a subject that TWAIL engages with.[216]

Additionally, today's international rules prioritise homogeneity rules and ignore the unequal development of states.[217] The pursuit of harmonisation of intellectual property at the global level, serves as an example this phenomenon. The TRIPS Agreement, or the principle of proportionality, illustrates this tendency. The relevance of the Third-World approach to this thesis and the necessity of third-world categorisation is plausible, given the growing political and economic differences between the Global North and the Global South.[218] This division appears even more in legal frameworks that contribute to this division, especially in the context of access to health resources. Yet, it should be noted that the Global North may, at times, be required to embrace policies that align with the TWAIL critiques. In this thesis, the purpose is not to highlight the economic and development distinctions between the Global South and the Global North but rather to emphasise the individual claim of accessing affordable health resources.

2.3.1. Why TWAIL?

Based on the aforementioned explanations, it is fair to assert that the primary goal of TWAIL is to achieve actual neutral international law standards where Third World is equally and actively involved in the formulations in the same way as Global North does.

One of the core objectives of TWAIL is to "understand, deconstruct, and unpack" the function of international law and its institutions that establish and preserve the subordination of Global South to Global North.[219] This purpose will become clear in Chapter 3.1., where the historical evolution of international intellectual property rights is explained. Other goals of TWAIL are to suggest alternative legal paradigms for international law and institutions and address the underdevelopment issues of the Global South through scholarly thought, policy, and political engagement.[220] Thus, TWAIL challenges the international law structure and its framework as it reflects Global North ideologies and economic interests at the expense of people in Global

[216]Mutua and Anghie calls international law illegitimate; please see: above n 208, at 31. Their ideas supported by various scholars who critically examine the misperception of the "neutrality, fairness, and justness of international law".
[217]B.S. Chimni "Third World Approaches to International Law: A Manifesto" 2006 8(1) International Community Law Review 3 at 5.
[218]At 5.
[219]Mutua and Anghie, above n 208, at 31.
[220]At 31.

South.[221] TWAIL is also committed to developing and integrating democratic norms that govern relations among Global South-North countries, with the aim to provide a new understanding of international law in a way that serves an egalitarian global economic order.[222] In sum, TWAIL engages in three themes: i)a critical analysis of international legal frameworks that prioritise the interests of capital at the expense of fundamental considerations for the Global South as a result of those countries' historical roots, ii)commitment to history to reveal realities and social functions embedded within the international legal system, iii)the reformation and reconceptualization of international law to challenge the entrenched traditions of colonialism.[223]

International law, (intellectual property in this context), does not have robust norms that prioritise justice principles and, consequently, global justice.[224] Hence, the experiences, insights, and critiques offered by TWAIL could potentially advocate for nuanced formulations of international law that advances global distributive justice (cosmopolitanism). As detailed in the subsequent chapters, the formulations of intellectual property law and the existing regime of investment arbitration constitute *legal colonialism*, where Global North countries continue to colonise the Global South through the mechanism of international law, trade relations, and supposed development promises such as technology transfer or investment. Yet, these international mechanisms give rise to serious legitimacy problems. In addition, the principle of proportionality seems to have become a tool to legitimise neo-colonial practices.

As mentioned before, the TWAIL scholarship has been employed to criticize almost every aspect of international law, including intellectual property and investment law;[225] and its contribution to international law is undeniable. The TWAIL scholarship is particularly significant in the context of intellectual property rights because those rights are significant instruments in today's technological environment in which the Global North can exercise its dominance over the Global South. This phenomenon is one of the issues addressed by the TWAIL critiques.

[221]Kwadwo Appiagyei-Atua "Ethical Dimensions of Third-World Approaches to International Law (TWAIL): A Critical Review" (2015) 8(3-4) AJLS 209 at 213.
[222]At 215.
[223]James Thuo Gathii "The Agenda of Third World Approaches to International Law (TWAIL)" in Jeffrey L. Dunoff and Marka A. Pollack (ed) *International Legal Theory: Foundations and Frontiers* (eBook ed, Cambridge University Press, 2022) 153 at 158-161.
[224]S.R. Ratner *Ethics and International Law: Integrating the Global Justice Project(s)* (Public Law and Legal Theory Research Paper Series Paper No. 315, 2013) at 26.
[225]Upreti, "A TWAIL Critique of Intellectual Property and Related Disputes in Investor-State Dispute Settlement", above n 28, at 230.

The TWAIL critique of international intellectual property law primarily centers on the characterisation of IP as a colonial transplant, the process of commodification of knowledge, now an investment asset, the hegemonic power exercised by the Global North,[226] and eventually, its crucial role in the connection between global capitalism and international law. The critiques of TWAIL offer valuable insights into the disadvantages experienced by the Global South in the context of global economic order as the structure of international intellectual property rights contributes to the growing North-South divide.

The critique of TWAIL can challenge the ideologies and practices that shaped the structure of international economic law, which eventually resulted in intellectual property rights' being included as a trade commodity in the free trade and liberalisation movement. As explained in Chapter 3, international intellectual property law was imposed on the Global South as a precondition to join WTO, an international trade organisation. This bargaining power of the Global North is one of the concerns of TWAIL, as it results in unfavourable outcomes for the Global South while serving the economic interests of the Global North and its private industries. The primary purpose of the TWAIL critique in this thesis is not to prevent liberal policies entirely; instead, it aims to draw attention to liberal policies' implications on people with the help of cosmopolitanism.[227] The inclusion of TWAIL in this thesis is not intended to deepen the differences between the Global South and the Global North. By including TWAIL, this thesis aims to address the problems faced by economically disadvantaged groups in accessing health resources both in the Global North and the Global South, as emphasised by Anghie.[228]

In light of TWAIL, as detailed in Chapter 3, the exercise of intellectual property rights poses significant challenges regarding the right to health and the right to property, and the judicial proportionality principle can become a mechanism to justify prioritising property. Through the TWAIL critiques and cosmopolitanism, the structure and the practice of international IP and investment law can shift from a state-centric perspective to an individual-focused perspective. Thus, the interests of people rather than private entities can be prioritised to promote access to health resources.

[226]At 222-223.
[227]Joseph E. Stiglitz *Globalisation and Its Discontents Revisited: Anti-Globalization in the Era of Trump* (W.W. Norton & Company, New York, 2018).
[228]Anghie, "Rethinking International Law: A TWAIL Retrospective", above n 53, at 103.

With cosmopolitanism in mind, this thesis delves into the proportionality principle. Proportionality analysis starts with its development in law and continues with Merges's midlevel principle. Then, it analyses judicial proportionality under ISDS system. Finally, this thesis looks at the midlevel proportionality in the latest trends within investment agreements. Chapter 2.5. only frames Merges's proportionality as a midlevel principle while the other analyses of proportionality are expounded upon in Chapter 5 and Chapter 6, respectively. The next section outlines the spread of proportionality in law, followed by a discussion on Merges's midlevel principles.

2.4. Proportionality in Law

As mentioned before, the root of the proportionality principle is found Aristotelian thought as geometrical justice. It is developed from equity and distributive justice ratios of Roman law tradition.[229] Since then, proportionality has evolved and found its place in domestic law, particularly in German legal tradition.[230] It has spread from Germany to Europe, and finally to common law systems.[231] It has become a methodological tool in various areas of law ranging from constitutional and administrative to human rights law.[232] Judicial proportionality has become sort of a unitive principle of common and civil law systems.[233] It is even referred to as the "foundational element of global constitutionalism"[234] as it is applied very extensively. Yet, debates exist regarding the cultural distinction between American balancing and European (German) proportionality concerning how they are framed.[235] It is certain that judicial proportionality has been created by Western world. Nevertheless, the focus of this thesis is on the operation of this Western principle within the context of patent-investment, and whether and how it disentangles from its roots. The principle has also been integrated into international law, international investment law, WTO law and human rights law.[236] Chapter 5 extensively delves into the operation of judicial proportionality within the

[229]Thomas Cottier and others "The Principle of Proportionality in International Law: Foundations and Variations " (2017) 18 BRILL NIJHOFF 628 at 628.
[230]At 629.
[231]Iddo Porat "Some Critical Thoughts on Proportionality" in Giorgio Bongiovanni, Giovanni Sartor and Chiara Valentini (ed) *Reasonableness and Law* (Springer Netherlands, Dordrecht, 2009) 243 at 243.
[232]Engle, "The General Principle of Proportionality and Aristotle", above n 59, at 266, at 271.
[233]At 266.
[234]Alec Stone Sweet and Jud Mathews "Proportionality Balancing and Global Constitutionalism" (2008) 47(1) Colum. J. Transnat'l L 72 at 160.
[235]Porat, above n 231, at 243-244; Moshe Cohen-Eliya and Iddo Porat *Proportionality and Constitutional Culture* (Cambridge University Press, New York, 2013).
[236]*Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States of America) (Merits)* [1986] ICJ Rep 14; *Oil Platforms (Islamic Republic of Iran v. United States of America) (Judgment)* [2003] ICJ Rep 161; *Brazil-Aircraft* WT/DS46/ARB, 28 August 2000 (Decision by the Arbitrators); *EC-Bananas III* WT/DS27/ARB, 9 April 1999 (Decision by the Arbitrators) (hereinafter "*EC-Bananas III*"); *Tecmed v Mexico Award*; *LG&E v Argentina Decision on Liability*; *Otto-Preminger-Institut v Austria* (1994) Series A no 295/A; *İ .A. v Turkey* ECHR 42571/98, 13 September 2005.

context of international investment law, which constitutes one of the focal points of this thesis.

A three-tier test developed by German legal tradition in public law has introduced a methodology of balancing or weighing.[237] Certain arguments have been made that the proportionality principle, as a methodology of balancing, prevents courts from addressing fundamental questions about what is right or wrong, instead focusing on whether interference in rights is appropriate or intensive, in pursuit of objectivity.[238] If that is the case, in the context of patent-investment, the application of judicial proportionality in an ISDS case could potentially neglect the specific needs of a country while implementing a patent flexibility. This could lead to a disregard for local circumstances and challenges, which are significant factors in determining patent policies in the domestic law. Relying on judicial proportionality, arbitral tribunals have frequently invoked the principle of proportionality when contrasting public welfare against and investors' interest.[239] Chapter 5 delves into whether judicial proportionality can be the dynamic within international investment arbitration and examines whether this Western principle can effectively safeguard the needs of disadvantaged groups in both Global South and Global North, if a measure is taken by the state to that extent. The analysis in Chapter 5 aims to examine whether judicial proportionality can function to promote affordable access to health resources and remove disproportionate barriers of investment protection, aligning with the requirements of global justice.

A three-tier test -suitability, necessity, *stricto* sensu- is developed by German tradition that supposedly provides an objective process.[240] While the three-tier test cannot be a mechanical test, it aims to weigh/balance different interests to determine whether a measure is excessive.[241] While this alleged objectivity can build and protect trust in the legal system, legal decisions and decision-makers, the application should not enhance one's welfare at the expense of public interest when it comes to accessing affordable health resources. The

[237]Cottier and others, above n 229, at 628.
[238]Stavros Tsakyrakis "Proportionality: An Assault on Human Rights?" (2009) 7(3) International Journal of Constitutional Law 468 at 469, at 487. *The writer claims that the principle "pretends to be objective, neutral, and totally extraneous to any moral reasoning". For details, please see at 469-475.
[239]*Tecmed v Mexico Award*; *LG&E v Argentina Decision on Liability.*
[240]For details of three-tier test, please see Michael A. Newton and Larry May *Proportionality in International law* (Oxford University Press, New York, 2014) at 36-37; Thomas Cottier and others *The Principle of Proportionality in International Law* (NCCR Trade Regulation Working Paper No 1212/38, December 2012) at 5. "Three-tier test questions first, whether the measure suitable for/serves a legitimate public purpose/government aim; second, whether there could have been a less intrusive measure to the infringed rights to achieve the purpose of the measure; third, whether a measure is excessive and gives relative weight to each principle."
[241]Cottier and others, above n 229, at 629.

application of proportionality can further come with a cost: It may reduce the capacity of legal doctrines to effectively address specific domestic needs, a key aspect for intellectual property, given its territoriality nature and societal objectives.

Proportionality has also found a place in the doctrine of intellectual property rights as a midlevel principle, serving as a limitation of the rights. Positioned as one of the midlevel principles, proportionality maintains its connection to distributive justice roots, as explored in Chapter 3.2.7. Midlevel proportionality is included in this thesis because the concept aims at removing any disproportionate leverage associated with it. Midlevel proportionality is another facet of the proportionality principle within the context of intellectual property, closely linked to its protection as an investment. Midlevel principles are found in this chapter because this chapter establishes the framework of this thesis. However, the detailed analysis of the role of midlevel proportionality, as a means to achieve cosmopolitan ideals of distributive justice is undertaken in Chapter 3.2.7. Finally, in Chapter 6, this thesis reveals midlevel proportionality through the lens of TWAIL and highlights recent trends in IIAs which aim to address the disproportionate investment protection of patented health resources.

2.5. The Concept of Midlevel Principles

Before delving into the midlevel principles, it should be clarified that this thesis primarily draws on Robert Merges's book, *Justifying Intellectual Property*[242] and partially Merges's concept of proportionality. This is because Merges is the only scholar who has extensively studied proportionality as a midlevel principle in the field of IP law. This thesis acknowledges that Merges' theory is not the sole and definitive approach. The purpose here is not to formulate a new midlevel theory for IP law. Rather, this thesis focuses on examining how proportionality is interpreted in IP context, suggesting adjustments to Merges's concept of proportionality and determining how investment protection becomes disproportionate. The critiques and suggestions regarding Merges's midlevel proportionality in this thesis stem from TWAIL perspectives and highlights the potential of midlevel principle as a tool for advancing global justice ideas.

In legal theory, midlevel principles play a role in bridging different doctrines, rules and practices in a specific area of law.[243] Midlevel principles connect different doctrines and

[242]Merges, above n 22.
[243]José Juan Moreso and Chiara Valentini "In the Region of Middle Axioms: Judicial Dialogue as Wide Reflective Equilibrium and Mid-level Principles" (2021) 40(5) Law and Philosophy 545 at 574.

practices.[244] They serve as intermediaries between moral values and legal rules.[245] In IP theory, the foundations of IP address whether IP should be granted while midlevel principles answer the question of how IP should be protected.[246] Thus, midlevel principles deal with the operation of IP law. Merges's idea of midlevel principles is developed by Jules Coleman's *The Practice of Principle*.[247] In tort law, corrective justice (Coleman's midlevel principle) ties legal doctrines (negligence- strict liability) to practices (accident insurance).[248] Coleman states that:[249]

> I prefer to begin not to the top, but in the middle, by asking what principles, if any, are embodied in the legal practices we are presently engaged in…We do not begin with any presupposition about the moral status of the principles we will find. Rather, we simply seek to identify the normatively significant elements of the practices and explain them as embodiments of principle.

For Coleman, corrective justice is a midlevel principle because it both is found in and makes sense of the practice of tort law.[250]

Merges identifies four midlevel principles as having roles in the operation of IP law: non-removal, dignity, efficiency and proportionality.[251] Non-removal refers to the things that belong to the public domain, such as the things that cannot be copyrighted, patented, or limited in terms of duration of IP rights.[252] Efficiency is a principle aimed at ensuring that the body of law operates smoothly and at minimal expense, such as fair use defence of copyright.[253] Dignity, on the other hand, concerns the importance of respecting and acknowledging creators' work, such as their right to use, sell, licence, or exclude others.[254] Moral rights of an author are a classic example of dignity.[255] These principles can operate independently, collectively or they can sometimes overlap.[256]

---

[244]Merges, above n 22, at 139.
[245]Justine Pila "Pluralism, Principles and Proportionality in Intellectual Property" (2014) 34(1) Oxford Journal of Legal Studies 181 at 187-188.
[246]Robert P. Merges "The Relationship Between Foundations and Principles in IP law" (2012) 49(4) The San Diego Law Review 957 at 961.
[247]Merges, above n 22, at 7; Jules L Coleman *The Practice of Principles: In Defence of a Pragmatist Approach to Legal Theory* (Oxford University Press, New York, 2001).
[248]Coleman, above n 247, at 54-55.
[249]At 5-6.
[250]At 54-56.
[251]Merges, above n 22, at 9.
[252]At 141-143.
[253]At 151-155.
[254]At 156.
[255]At 156.
[256]At 139-158.

This thesis solely focuses on midlevel proportionality and its operation and a thorough examination is provided in Chapter 3. However, the difference between midlevel proportionality and judicial proportionality should be clarified once more. Judicial proportionality is a methodological tool; whereas midlevel proportionality is a substantive principle.[257] Yet, it should be noted that some considered judicial proportionality to be a midlevel principle, albeit a procedural one.[258] For the purpose of this thesis, midlevel proportionality serves as a substantive principle that determines how something should be legally protected. This becomes clear in Chapter 6, which examines newly concluded IIAs where investment protection of patented health resources is substantially restricted.

2.6. Conclusion

This chapter established the theoretical framework of this thesis. In this respect, this chapter began by examining the concept of global justice, emphasising access to health products as an individual claim. This chapter then handled the fact that global and cooperative theories of justice need to be adopted to make health resources accessible. Thus, this chapter discussed various theories of global justice and advocated for global access to health resources. By adopting a global justice theory, this thesis admitted the world is interconnected, as illustrated in the next chapter where international IP law and the development of international investment are explored. Moreover, this chapter rejected nationalistic oppositions by acknowledging the impact of global regulatory frameworks on current issues such as the difficulties economically disadvantaged communities face in accessing health resources. This chapter then explored TWAIL, discussing its nature, objectives, and relevance to this thesis. TWAIL is seen as complementary to global justice efforts, particularly in advocating for equitable and affordable access to health resources. TWAIL assists this thesis by illustrating disparities in state representation and bargaining power in the international arena and during negotiations of IIAs, emphasising the influence of Western concepts in international law that contribute to inequalities in access to health resources. Yet, it should be noted that TWAIL's perspective on nuanced formulations (which can promote accessing affordable health resources) benefits the disadvantaged groups in the Global North.

Examining the roots of the proportionality principle in law was necessary to uncover Western origins of the judicial proportionality analysis in Chapter 5 and to understand Merges'

[257]Pila, above n 245, at 191-192.
[258]Moreso and Valentini, above n 243, at 575.

midlevel proportionality. This chapter then introduced midlevel principles with a focus on Merges's midlevel principles. It is also highlighted that midlevel principles play a role in the operation of IP law and how IP rights should be protected. A thorough investigation of midlevel proportionality is left to Chapter 3, as the analysis requires a preliminary discussion on the development of international IP law. The discussion in Chapter 3 will aim to clarify how and why Merges's midlevel proportionality can be adjusted to enhance access to health resources, ultimately offering the disproportionate nature of investment protection of patented health resources. This chapter further distinguished judicial proportionality as a methodological tool, as takes part in Chapter 5, and midlevel proportionality as a substantive principle. The next chapter continues with the development of international IP law, specifically focusing on patent law and its flexibilities, as well as international investment law. This basis in Chapter 3 is necessary before establishing why investment protection for patented health resources is disproportionate.

CHAPTER 3- INTELLECTUAL PROPERTY RIGHTS AND INVESTOR- STATE DISPUTE SETTLEMENT

3.1. Introduction

The previous chapter established the theoretical framework of this thesis to help determine why and how investment protection of IP rights, particularly patents, becomes disproportionate. Thus, the previous chapter established the foundation for this thesis by leveraging global distributive justice ideas (cosmopolitanism) to address the unequal distribution of health resources. The previous chapter relied on cosmopolitanism to focus on globalisation and set the stage for this chapter's exploration of global governance in intellectual property law. As explored in the previous chapter, although each theory of global distributive justice has its own criticism, they all share a fundamental purpose: achieve global justice. This thesis, therefore, aims to establish that access to affordable health resources is a matter of global justice. This aim is also supported by the UN Secretary-General's High-Level Panel on Access to Medicines Report, which states: [259]

> …access to medicines, vaccines, diagnostics and related health technologies as a serious, multidimensional global problem, with challenges that affect all people and all countries. Adopting a broad approach is necessary at this juncture in history, …the costs of health technologies are rising globally and are being felt by individuals and by public and private insurance schemes in both wealthy and resource- constrained countries alike. These rising costs have the potential to push more people into poverty.

This thesis additionally draws on TWAIL critiques of international IP law and investment law, a fact which offers insights beneficial to both Global North and Global South. In the current conjecture, while Global South faces particular challenges, as detailed in the following chapters, TWAIL critiques are also relevant for Global North. This will be become clear in Chapter 6, where recently concluded regional investment agreements are discussed.

Section 3.2. starts by scrutinising the justification of intellectual property law, encompassing theories like labour, personality, and utilitarianism. Then, it delves into the framework of international IP law and its evolution. Given this thesis's focus on ensuring access to health resources in relation to patent law and its risks associated with its investment protection, particular emphasis is given to the international patent law framework and the flexibilities

[259] *Report of the United Nations Secretary- General's High-Level Panel on Access to Medicines: Promotion innovation and Access to Health Technologies* (14 September 2016) at 12.

provided by the TRIPS Agreement. As discussed in the following section, some views suggest that patents do not impede access to medicines/vaccines; instead, they promote innovation. However, in response to those arguments, Chapter 3.2.6. discusses issues related to Covid-19 related health technologies to demonstrate how patents can be a barrier to access. This examination aims to illustrate that despite the flexibilities offered by the international patent law system, these flexibilities may not be very effective to safeguard affordable access. This was a concern during a pandemic, when access to such technologies became a matter of life and death. The exploration of the development of international IP law and the flexibilities provided by the TRIPS Agreement will emphasise the complexities of patent protection in every technology and the implications for accessing affordable health resources, as exemplified through Covid-19 health technologies.

Following the examples of Covid-19 health technologies and their relation to patents, Chapter 3.2.7 addresses midlevel principles and focuses on midlevel proportionality. This provides the foundation for understanding why investment protection of patented health resources is disproportionate. The analysis of Merges's midlevel proportionality reveals that Merges' core concept of *deserve* alone does not effectively serve as a tool for distributive justice in determining disproportionate concept. This chapter will propose that *deserve* can function to an extent it harms others. In addition, midlevel proportionality can properly mitigate excessive leverage, disproportionate situations, where IP, mainly patent, undermines the social function of IP rights.

This thesis particularly deals with patent protection as an investment under the IIAs. Therefore, to understand the notion of international investment protection and what IIAs offer to foreign investors, it is first necessary to explore the concept of international investment law. With this purpose, Section 3.3. delves into the development of international investment law, applicable law in investment arbitration, and the substantive protections provided under IIAs. As national treatment and most-favoured nations depend on the different treatment of national and foreign investors, the emphasis is only given to protection against expropriation and fair and equitable treatment in the final part of this section, in Chapter 3.3.3. This analysis will demonstrate how IIAs, specifically ISDS, can operate in a manner that supports multinational corporations in increasing their profits, regardless of the impact on the public interest, health, or the environment in the host state.

3.2. Intellectual Property Law and Its Justifications

It is significant to understand the justifications behind intellectual property law as they contribute to the global expansion of intellectual property and provide a foundation for its development in this field. Intellectual property law involves protection and enforcement of the creations, inventions, distinguished signs of goods and services, or other works.[260] It provides exclusive rights to a wide range of things that we are surrounded by, from books, movies, computer programmes, songs and performances to pharmaceutical products like medicines, vaccines, therapeutics, genetically modified plants, designs and protection of trade secrets.[261] Intellectual property rights protect the "creation of the mind"[262], and intellectual property generally refers to intangible properties.[263] The word *intellectual* itself is a description of those products that are the creation of the mind, and *property* represents the form of arrangement that provides exclusive rights to the creators or owners.[264] It might be arguable whether everything in this field is a creation of the human mind or a property right similar to any tangible right, as opposed to monopoly or the right to exclude to incentivise.[265] Yet, intellectual property is a common term particularly since the establishment of the World Intellectual Property Organisation in 1967.[266] Although property rights for intangibles are different from property for tangible assets, giving *property* status to legal rights for intangibles raises challenging questions on how to draw boundaries when determining intangible property.[267]

It would not be wrong to assert that the wording of intellectual property is more of a conceptual matter, and linguistic issues may remain ineffective in solving normative problems.[268] Nonetheless, this wording is strictly linked to justifications of intellectual property rights, serving as a significant indicator of the politicisation of intellectual property law. The development of intellectual property law in the global scope and the current international intellectual property law discussions are evidence of the politicisation of IP law. This politicisation raises significant distributive justice problems, as this thesis presents. The

[260]Abbe E. L. Brown and others *Contemporary Intellectual Property: Law and Policy* (5th ed, Oxford University Press, Oxford, 2019) at 3.
[261]Lionel Bently and others *Intellectual Property Law* (5th ed, Oxford University Press, Oxford, 2018) at 1.
[262]World Intellectual Property Organisation "What is Intellectual Property?" <https://www.wipo.int/about-ip/en/>.
[263]David I. Bainbridge *Intellectual Property* (9th ed, Pearson Education Limited, Harlow, 2012) at 25.
[264]Bently and others, above n 261, at 1.
[265]At 1.; Rochelle Dreyfuss and Susy Frankel "From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property" (2015) 36(4) MIJL 557 at 558.
[266]Bently and others, above n 261, at 2, n 3.
[267]At 3.
[268]Kenneth Einar Himma "The Justification of Intellectual Property: Contemporary Philosophical Disputes" (2008) 59(14) Journal of the American Society for Information Science and Technology 1143 at 1146.

political dimension of intellectual property law has revealed the Global North-Global South division, wherein countries express their different perspectives on the protection of IP or respond differently to various contemporary issues like gene or pharmaceutical patents. Yet, those policies have similar implications for those live in economically or socially disadvantaged circumstances in both the Global North and Global South. As mentioned previously, these distinctions are related to varying interpretations of intellectual property law justification. The first sub-section in this chapter outlines the development of international intellectual property law and its' frameworks. Before delving into this discussion, theories on the justification of intellectual property law are provided below.

3.2.1. Justifying Intellectual Property Rights

Several justifications of intellectual property rights have been developed over time. These justifications underlie Western intellectual property law theories. Intellectual property rights give right to the owner an exclusive use which raises questions about the justification for this exclusivity.[269] There is no doubt that the burden of justification lies on those who seek to limit the maximal use (use by others) of intangible assets.[270] As socialist or communist states reject that property exists[271], and as third world states have had to adopt Western states' intellectual property law, it has been Western states' burden to develop justifications to intellectual property. Three classical theories have been generated: labour theory (Lockean theory), utilitarian theory (Bentham) and personality theory (Kant, Hegel).

Labour theory is generally associated with John Locke and influenced by the natural law theory.[272] His writings indicate intellectual outcome as a property. "Every Man has a property in his own Person".[273] Everyone has a right to claim property of their labour is the main idea in the labour theory.[274] Though, as an opposition, it is claimed that intellectual property rights are simply a privilege to receive profits from the market which is not bound to self-ownership, labour, or a natural right.[275] Utilitarian theory, also known as incentive-based theory, is the typical model of Anglo-American intellectual property law.[276] The rationale

[269]Edwin C. Hettinger "Justifying Intellectual Property" (1989) 18(1) Philosophy & Public Affairs 31 at 35.
[270]At 35.
[271]Himma, above n 268, at 1144.
[272]Drahos, *A Philosophy of Intellectual Property*, above n 71, at 49.
[273]At 50.
[274]At 49.
[275]Hettinger, above n 269, at 40; Andreas Von Gunten *Intellectual Property is Common Property: Arguments for the Abolition of Private Intellectual Property Rights* (Buch & Netz, Zurich, 2015) at 11.
[276]Michael Spence *Intellectual Property* (Oxford University Press, Oxford, 2007) at 64; Adam D. Moore *Intellectual Property and Information Control: Philosophic Foundations and Contemporary Issues* (Routledge/ Transaction Publishing,

behind this theory is that creativity and scientific progress can be promoted and nurtured if creators or authors are awarded by being granted intellectual property rights.[277] The purpose of granting IP rights is to allow the owners to restrict the current availability for their creation for some time until the creation becomes available in the future, which is a paradoxical approach.[278] Similarly, patent protection prevents the dissemination of a new product before the inventor is compensated for their investment, which seems like patent systems slow down the dissemination of patented products and can hamper scientific progress.[279]

Lastly, intellectual property rights are justified by the personality theory associated with Kant and Hegel.[280] The existence of moral rights in the copyright system in Continental Europe is rooted in the personality theory.[281] However, this justification has received criticism, such as Kant's arguments that books cannot be treated the same way as all other types of creations are treated and that creative work is not solely an individual's output but it is effort and result of a collective process.[282] Since copyright is not the focus here, this discussion will not be explored further. However, it is significant to note that all justifications of intellectual property have received criticism. While justifications of IP cannot justify every norm in this area of law separately, they collectively work together to serve different purposes.[283]

Despite criticisms exemplified above, justification theories of IP represent how Western countries rationalise the creation of such a system to *protect* intellectual output. Regardless of whether the justification theories are accepted or not, the IP law system exists and the current system can create significant global distributive justice problems like accessing affordable health products. TWAIL readings and their critiques would also contribute to shaping this perspective. This thesis focuses only on the patent system concerning health technologies. Before discussing the patent system and problems in relation to justice, the next section begins with the intellectual property law framework and its evolution over time. The historical progression of both copyright and patent law is explored simultaneously to provide a comprehensive framework for the development of intellectual property law.

New York, 2004) at 47; Tom G. Palmer "Are Patents and Copyrights Morally Justified- The Philosophy of Property Rights and Ideal Objects" (1990) 13(3) Harv. J. L.& Pub. Pol. 817 at 849.
[277]Spence, above n 276, at 63-66.
[278]At 48.
[279]Hettinger, above n 269, at 48.
[280]Drahos, *A Philosophy of Intellectual Property*, above n 71, at 49-52.
[281]At 95.
[282]Gunten, above n 275, at 16-17.
[283]Spence, above n 276, at 43.

3.2.2. International Intellectual Property Law Framework and Its Development

There is a widely known story about how international intellectual property law is developed in time. It is very hard to claim that the Global South was involved in any way during the designation of international intellectual property law systems. The multilateralization of intellectual property law is divided into three different periods as identified by Ruth Okediji: the era of imperialism/colonialism (1500's-1945), the era of formalism (1945-1990's) and the era of consolidation (1994- current).[284] When these three periods are examined closely, it becomes apparent that the development of intellectual property law is very parallel with the historical events. It is very significant to know the historical progress of the world to understand why intellectual property law is actually a Western world creation and why Global South countries have little or maybe no voice at the international level. Hence, as the development of intellectual property law is analysed here, historical facts will be incorporated to provide context and understanding. To be able to comprehend why IP, mainly patent protection, poses a theoretical challenge within the framework of investment law, it is crucial to grasp the nature of intellectual property rights. That effort requires exploring historical development of IP.

As far as it is known, the earliest contact of European people to non-European people was through maritime exploration and trade before the 15th century; but in time, instead of gold or spices, slaves had become subject of this trade and played significant role in global economy.[285] In time, local behaviour, customs and attitudes took over European traditions in trade; and eventually, new rules, authorities and institutions were established to deal with locals and Europeans in non- European countries.[286] These colonial rules were consistently strengthened throughout the 19th century, including IP rules even though intellectual property law was not fully developed to encourage innovation before the 17th century, even in Europe.[287] However, the development of international law, including intellectual property law, was influenced heavily by the colonial project of Western countries.[288] The colonial spread of IP law becomes apparent when examining its development since IP rights were

[284]Ruth L. Okediji "The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System" (2003) 7 SGJ IInt Comp Law 315 at 320-341.
[285]At 320-321; Norrie Macqueen *Colonialism* (Routledge, London, 2007) at 1-17.
[286]Okediji, "The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System", above n 284, at 320-321.
[287]At 324-325.
[288]Chimni, "Capitalism, Imperialism, and International Law in the Twenty-First Century, above n 86, at 27.

created to access colonial markets and establish uniformity across the regions that were under colonial rule, especially in their commercial dealings.[289]

The first notions of IP can be detected in the 15th century in Venetian Republic as a customary law practice to encourage inventors/authors.[290] By the 16th century, the Venetian Republic established a formal institutional framework for IP, which later spread to other European regions, including France and the Holy Roman Empire.[291] Eventually, with the emergence of competition in trade and the rise of London, the development of IP law shifted to England.[292] Formal intellectual property rights may not have existed before the 17th century, but significant steps during the 16th and 17th centuries, particularly in England, were taken for formal intellectual property protection even though these protections were considered intellectual privileges rather than intellectual property rights.[293] In the case of copyright, governments required official licensing -the exclusive right to publish and prevent others- to publish books in Europe during the 15th and 16th centuries to prevent the spread of ideas against governments and religions.[294] For instance, in England, information privileges were given to Stationers' Company because the Queen wanted to control printed information to protect the Crown's interests.[295] Similarly, Stationers had an interest in this arrangement as they aimed to preserve their monopoly and expand their impact beyond their region to Scotland.[296] This system was replaced by the *Act of Anne* following the union of England and Scotland as there was no monopoly like stationers in Scotland and Ireland.[297]

The *Act of Anne* was the first legal framework that considered copyrights as property rights since the right to print books was given solely to authors, reflecting Locke's labour theory.[298] When the *Act of Anne* came into force in 1709, the monopoly control given to Stationers over existing books was reduced to 21 years, and public interest was recognised.[299] Most importantly, the *Act of Anne* allowed authors to print their books if they had not been printed

[289]Okediji, "The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System", above n 284, at 316-321.
[290]Peter K. Yu "Currents and Crosscurrents in the International Intellectual Property Regime " (2004) 38(1) Loy. L.A.L. Rev. 323 at 330.
[291]At 332.
[292]At 332.
[293]Drahos, *A Philosophy of Intellectual Property*, above n 71, at 16-40.
[294]Brown and others, above n 260, at 32.
[295]Drahos, *A Philosophy of Intellectual Property*, above n 71, at 30.
[296]Drahos, *A Philosophy of Intellectual Property*, above n 71, at 30.
[297]Brown and others, above n 260, at 32.
[298]At 33.
[299]Bainbridge, above n 263, at 34-35.

and published before.[300] Over time, the justification of copyright and the *Act of Anne* were challenged in courts; however, the primary approach in England remained focused on protecting the freedom of trade while acknowledging the labour of authors by rewarding.[301] While this part does not directly focus on patents or the main subject of this thesis, it is included to explain the early development of IP rights. It is necessary to show how these rights have evolved in time.

In the case of patents, England holds a significant role in shaping the international patent system.[302] This is closely linked to the early advancements in industrialisation that also played a role in the Industrial Revolution.[303] Before the industrial revolution, the patent was a state/monarch favour in Europe.[304] Patent letters/open letters were given to people as proof of this reward.[305] The first example of such a letter was granted in 1311 to a Flemish weaver who wished to conduct trade activities in England.[306] In 1449, as far as it is known, John of Utyman received such a letter for the invention for the first time.[307] Yet, it was accepted prerogative-based monopolies significantly interfered negative liberties by restricting individuals from engaging certain trade activities entirely.[308] Once common law courts were given the authority to deal with prerogative-based monopolies, they determined that, with some exceptions, monopolies were contrary to common law.[309] *Statute of Monopolies* (1623) clarified this conclusion by stating that monopolies inhibit trade; thus, monopolies were contrary to law, except in cases involving new manufacture.[310] The Statute made clear that patents were only privileges not natural rights as Lockean would argue.[311] Even back then, it was accepted that monopolies have a detrimental effect on trade activities, despite they had not been regarded as property yet.

In the 18th century, nationals and resident foreigners were allowed to get intellectual property protections if they fulfilled necessary conditions; however, IP protections were not available overseas unless authors/inventors travelled and sought protection in foreign lands as foreign

[300] At 34-35.
[301] Drahos, *A Philosophy of Intellectual Property*, above n 71, at 30-39.
[302] Bainbridge, above n 263, at 392.
[303] At 392.
[304] Brown and others, above n 260, at 365.
[305] At 365.
[306] Bainbridge, above n 263, at 392.
[307] Brown and others, above n 260, at 365.
[308] Drahos, *A Philosophy of Intellectual Property*, above n 71, at 43.
[309] At 41-44.
[310] At 44.
[311] At 44.

residents.[312] The industrial revolution played a significant role in the international protection of intellectual property. The rise of science and technology in transportation, communication, and the manufacturing of goods led to an increase in cross-border trade of goods, including intellectual goods. Yet, during the 19th century, foreign intellectual property owners could receive protection for their intangible properties only if bilateral agreements containing reciprocal provisions were available.[313] Authors and inventors sought uniform protection because they were unable to determine the level of protection they could receive in a particular country.[314] They eventually reached a level of protection, reciprocity, and national treatment through the Berne Convention for the Protection of Literary and Artistic Works (1886)[315] and the Paris Convention for the Protection of Industrial Property (1883)[316]. Whereas the Berne Convention protects "every production in literary, scientific and artistic domain, whatever the mode or form of its expression"[317], the Paris Convention protects "industrial property, including patents, trademarks, industrial designs, utility models, service marks, trade names, geographical indications, and the repression of unfair competition"[318]. These agreements are now administered by the World Intellectual Property Organization (WIPO), an agency of the United Nations, and they are still in effect, after having several revisions. However, territoriality principle remained fully intact, allowing states to formulate their own national laws, with the sole condition of having to provide the same level of protection to foreigners from signatory states.[319]

The second multilateralism, which took place during the decolonisation era after World War II, witnessed the recognition of the sovereignty of new states (former colonies) and legalisation of their participation in the international community, even in the international intellectual property area.[320] However, many of the former colonies had never truly experienced sovereignty over the creation of intellectual property laws, as evidenced by their lack of involvement in the Berne Convention and Paris Convention.[321] They were already

[312]Yu, "Currents and Crosscurrents in the International Intellectual Property Regime", above n 290, at 333.
[313]At 333-352.
[314]At 335-354.
[315]Berne Convention for the Protection of Literary and Artistic Works 828 UNTS 211 (opened for signature 9 September 1886, entered into force 4 December 1887) (hereinafter "Berne Convention").
[316]Paris Convention.
[317]Berne Convention (as amended on 28 September 1979), art 2 (1).
[318]Paris Convention (as amended on 28 September 1979), art 1(2).
[319]Berne Convention (as amended on 28 September 1979), art 5; Paris Convention (as amended on 28 September 1979), art 2.
[320]Okediji, "The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System", above n 284, at 325-326.
[321]Peter Drahos "Developing Countries and International Intellectual Property Standard-Setting" (2002) 5(5) The Journal of World Intellectual Property 765 at 766-767.

under the influence of their colonial powers' intellectual property law; hence, what those two conventions had achieved was establishing a connection between European countries through extending the scope of rights geographically.[322] When new states had a chance to review their patent law like India, Brazil, Argentina, Mexico and the Andean Pact, they all offered weaker patent rights in the pharmaceutical sector, and their generic companies became a threat to Western domination of the international pharmaceutical industry.[323] The Paris Convention provides patent protection in all fields; however, some countries were able to exclude some fields from patentability, such as pharmaceutical products, plant varieties and others, as mentioned above.[324] In fact, 49 members, out of 98, excluded pharmaceutical products, 45 members, out of 98, excluded animal varieties, and this list can easily be extended.[325] Further, the Berne Convention does not respond to new information technology and cooperation between countries.[326] Mainly countries were able to implement the conventions as they wished. There was no enforcement mechanism under these conventions if any member failed to fulfil obligations. In addition, Southeast Asia countries increased manufacturing, which allowed them to compete with Global North countries; and the Global North had started to lose its advantages in industries like textiles.[327] So, the Global North failed to receive what it wished from these two conventions.

As previously noted, since the Second World War, intellectual property rights have become even more significant for the Global North, particularly the United States. This is largely due to the fact that many Global North products (such as information, medicine, or entertainment) are intellectual property origin. While the Global South was trying to lower the protections under the Paris Convention, industries in Global North (like the United States, the European Union and Japan) put pressure on governments to provide an international agreement to strengthen intellectual property protection and link IP to trade.[328] Thus, the Global North shifted its focus from WIPO to the General Agreement on Tariffs and Trade (GATT). Especially, the pharmaceutical industry exerted considerable pressure to include an

[322]At 766; Okediji, "The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System", above n 284, at 323-324.
[323]Drahos, "Developing Countries and International Intellectual Property Standard-Setting", above n 321, at 767-768.
[324]*Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods-Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for The Protection of Intellectual Property* MTN.GNG/NG11/W/24, 5 May 1988 (Note prepared by the International Bureau of WIPO).
[325]Drahos, "Developing Countries and International Intellectual Property Standard-Setting", above n 321, at 768.
[326]Paul Goldstein and Bernt P. Hugenholtz *International Copyright: Principles, Law and Practice* (2nd ed, Oxford University Press, Oxford, 2010) at 10.
[327]Okediji, "The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System", above n 284, at 336.
[328]Yu, "Currents and Crosscurrents in the International Intellectual Property Regime", above n 290, at 343-355.

intellectual property agreement as part of the Uruguay Round because stakeholders in the pharmaceutical industry wanted to limit the production of generic medicines and prevent competition.[329] However, the major shift would be to link the intellectual property to trade and to adjust "to the new division of labour evident in the global economy"[330] rather than solely preventing pirating at a global scale. Consequently, negotiations began to create a new IP agreement to "upgrade, update and reshape"[331] the existing standards, ensuring maximum benefit of intellectual property rights on a global scale. This initiative marked the beginning of the era of third multilateralism. This was a result of industrialist lobbyist coalitions, the text of TRIPS represents a compromised one, as explained below.[332]

In the 1980's, intellectual property rights were included in the multilateral trade negotiations by the virtue of the United States' pushes, despite oppositions and rejections by countries in the Global South like India, Brazil, Argentina, Cuba, and Nigeria, among others.[333] The bilateral agreements between the United States and the Global South as well as the introduction of the Special 301 Watch List in early 1989 by the United States were pivotal in breaking the resistance and bringing the Global South to the planned intellectual trade agreement.[334] The way how the negotiations of this brand-new trade-related agreement unfolded is also very well-known. Negotiators representing the Global South countries did not much prior experience, adequate understanding of intellectual property and its potential implications of these rights.[335] Two texts were presented: one of them was proposed by Global South and the other one was a combined proposal between Global North.[336] Through pressure by the Global North, particularly by the United States, Japan, and the European Union, their proposed text, entered into force in 1995 with minor changes, and it was named the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).[337]

---

[329]Joseph E. Stiglitz "Economic Foundations of Intellectual Property Rights" (2008) 57(6) Duke Law Journal 1693 at 1701.
[330]Ruth Okediji "Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection" (2003-2004) 1 UOITJ 125 at 135.
[331]Okediji, "The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System", above n 284, at 336.
[332]Upreti, "A TWAIL Critique of Intellectual Property and Related Disputes in Investor-State Dispute Tettlement", above n 28, at 223.
[333]Drahos, "Developing Countries and International Intellectual Property Standard-Setting", above n 321, at 773-775.
[334]At 773-775.
[335]Daniel Gervais "International Property, Trade & (and) Development: The State of Play" (2005) 74(2) Fordham Law Review 505 at 509.
[336]Daniel Gervais "International Intellectual Property and Development: A Roadmap to Balance?" (2005) 2(4) Journal of Generic Medicines 327 at 328.
[337]TRIPS Agreement; Gervais, "International Property, Trade & (and) Development: the State of Play", above n 335, at 509; Peter Drahos "Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines" (2007) 28(1) Liverpool Law Review 11 at 11-13.

The TRIPS Agreement provided by the World Trade Organization as a part of the Uruguay Round of Multilateral Trade Negotiations was a huge and significant step for the international intellectual property rights law. The TRIPS Agreement includes minimum standards of the substantive law in all kinds of IP[338]; it puts minimum obligations to remedies in articles 44, 45, 46, and 53; it provides administrative and judicial processes in articles 42, 43, and 47; it offers special requirement related to border controls in article 51; and maybe most importantly, it ensures that states comply with the agreement through WTO's dispute settlement mechanism. It can be questioned why Global South states accepted the TRIPS terms and became members of WTO. There are several reasons for that. But mainly, they wanted to be a part of global trade, particularly in textiles and agriculture; they did not have adequate knowledge and experience in IP to work together effectively and, they aimed to stop the threats about trade sanctions by the United States.[339]

The purpose of the TRIPS Agreement, which effectively reflects Western ideas, is provided in its preamble: "Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights…".[340] As evident from the preamble of the TRIPS Agreement, the international IP legal framework is perceived as a means to lower distortions and obstacles to international trade.

IP owners would be reluctant to commercialise their work in another country if they are unable to monopolise it and reap the returns. In line with the objective of enhancing international trade through an international IP system, it is suggested that IP fosters economic development.[341] Some suggest that the economic development of a country, particularly in the Global South, is closely linked to the presence and enforcement of IP laws; likewise, a country lacking in any IP protection or having weak IP protection would be likely to experience lower levels of economic development as IP is necessary to create and use new technologies.[342] These claims could be accepted if the formulation of the international IP

[338]TRIPS Agreement, art (1) states that "…Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement…".
[339]Rami M. Olwan *Intellectual Property and Development: Theory and Practice* (Springer, Heidelberg, 2013) at 74.
[340]TRIPS Agreement Preamble Para 1.
[341]Peter M. Beattie "The (Intellectual Property Law &) Economics of Innocent Fraud: The IP & Development Debate" (2007) 38 (1) IIC 6 at 10.
[342]Robert M. Sherwood *Intellectual Property and Economic Development* (Routledge, New York 1990) at 6; Jean Raymond Homere "Intellectual Property Rights Can Help Stimulate the Economic Development of Least Developed Countries" (2004) 27 (2) Columbia Journal of Law and Arts 277 at 286-288; Michael P. Ryan "Knowledge-Economy Elites, the International Law of Intellectual Property and Trade and Economic Development" (2002) 10 Cardozo J. Int'l & Comp. L. 271 at 301.

regime adequately represented the interests and perspectives of the Global South as much as the Global North. As previously mentioned, negotiations predominantly included representation from the Global North, and many countries in the Global South accepted the laws outlined in the TRIPS Agreement without fully being able to assess their implications within their own jurisdictions.[343] Additionally, Global South countries often find themselves in the position of being net importers of IP, lacking the developed infrastructure and economies that can benefit from these IP rights unlike Global North.[344] Finally, they struggle to leverage and commercialise their products at the international level due to resource capacity issues, such as external debts, stagnant or slow-growing economic conditions, high levels of unemployment, and lack of interest in innovation.[345] Therefore, this thesis questions the idea that international IP law would foster the development of the Global South. As elaborated in Chapter 3.2.6., it argues that international IP law can undermine public health by preventing the production of generic products, even in times of dire need, which can result in unequal distribution of health resources. The reason behind this becomes clearer as the international patent law formulated in TRIPS Agreement is explored in the next section.

While the justification of the IP protection seemed like IP rights were related with the incentive rationale, this rationale has turned to the trade-related commodification through the TRIPS Agreement as Professor Frankel puts rightly.[346] It remains unclear whether this system continues to offer incentives or if it instead reduces intellectual work by focusing primarily on profit generation through monopolies rather than fostering societal advancement via intellectual outcome. Now, IP rights are recognised as investments in IIAs, further undermining incentive rationales of IP rights by reducing their value solely to monetary terms.[347] Moreover, they fail to represent the interests of the Global South to the same extent as they do those of the Global North economies, thereby promoting preferential development.

IIAs are evident of continuation of the third multilateralism of intellectual property rights since they aim to enhance the strength of IP protection. The following section investigates patent law framework and its exceptions in the Paris Convention and the TRIPS Agreements

[343]Ikechi Mgbeoji "The Comprador Complex: Africa's IPRs Elites, Neo-Colonialism and the Enduring Control of African IPR Agenda by External Interests" (2014) 26 IPJ 313.
[344]Cadogan, above n 206, at 65.
[345]At 65.
[346]Susy Frankel "Interpreting the Overlap of International Investment and Intellectual Property Law" (2016) 19(1) JIEL 121 at 122-123.
[347]At 122-123.

to demonstrate how and why it can raise global distributive justice issues by adversely impacting access to medicines, vaccines, diagnostics and therapeutics.

3.2.3. International Patent Law Framework

The Paris Convention (along with its amendments) and particularly the TRIPS Agreement, constitute the primary foundations of international patent framework. The TRIPS Agreement incorporates the Paris Agreement by mandating member states to comply with certain provisions of the Paris Convention,[348] while also including many others that are not covered by the Paris Agreement. Being applicable to WTO members, which consist of 164 states as of July 2016, the TRIPS Agreement holds significance in shaping global patent standards.[349] The TRIPS Agreement has a very large coverage, mandating member states to align their domestic patent laws with the minimum standards outlined in the agreement.[350] The objective here is to analyse the international patent law framework and key provisions within the TRIPS Agreement concerning access to health resources to illustrate obligations and flexibilities afforded to member states to the WTO.

The Paris Convention protects industrial property, including patents, utility models, industrial designs, trademarks, service marks, trade names and geographical indications. Unlike the TRIPS Agreement, Paris Convention does not introduce any substantive law of patent beyond requiring patent protection.[351] However, Paris Convention was significant as it was the first major step to ensure that inventions were protected in member countries[352]. It brought some significant elements like the principles of national treatment, mention of the inventor in the patent, independence of national patents, or the right of priority for subsequent filings in other member countries within 12 months.[353] But, since the TRIPS Agreement has a significant role in determining the minimum requirement of substantive law of patent in member countries, from now on, the analysis will continue by taking the TRIPS Agreement as basis.

[348]TRIPS Agreement, art 1, art 2 and art 3.
[349]World Trade Organization "Members and Observers" (26 July 2016) <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm>.
[350]TRIPS Agreement, art 1(1).
[351]Paris Convention, art 4.
[352]World Intellectual Property Organisation "Paris Convention for the Protection of Industrial Property" <https://www.wipo.int/treaties/en/ip/paris/#:~:text=This%20international%20agreement%20was%20the,were%20protected%20in%20other%20countries.>.
[353]Paris Convention, art 2; art 4ter; art 4bis; art 4 [A-C].

3.2.4. TRIPS Agreement

As highlighted earlier, the TRIPS Agreement stipulates minimum standards of substantive patent law while providing flexibilities to those requirements.[354] Starting from the exploration of substantive law, this part proceeds to the flexibilities within the patent law framework, taking into account the unequal representation of states during the negotiations. Apart from the flexibilities inherent in patent law, such as use without authorisation, TRIPS Agreement provides only two flexibilities within its general provisions and basic principles, along with the recognition of the autonomy of states in implementing the agreement within their domestic legislation as outlined in Article 1.

Article 7 and Article 8 can be considered a reflection of the Global South countries' view. Both articles aim to protect public welfare, public health, and public interest and prevent abusive behaviour. Article 7 specifically requires that intellectual property rights should be protected and enforced "…in a manner conducive to social and economic welfare, and to balance of rights and obligation."[355]. Moreover, Article 8 explicitly obligates members to provide measures "…to prevent the abuse of IPRs by right holders or the resort to practices which unreasonably restrain trade…"[356] Although these articles may seem to have limited apparent significance in law-making, their existence remains crucial and should not be disregarded in either law-making or decision-making processes. It is important to recognize that the WTO dispute settlement mechanism has recently appreciated the importance of these two principles even more.[357] In the case of *Australia- Plain Packaging*, the WTO Dispute Settlement Body extensively employed Articles 7 and 8, recognising their significance and interpreting their function in accordance with the Doha Declaration. In this respect, the Panel stated that: [358]

> …we note that paragraph 5 of the Doha Declaration is formulated in general terms, inviting the interpreter of the TRIPS Agreement to read "each provision of the TRIPS Agreement" in the light of the object and purpose of the Agreement, as expressed in particular in its objectives and

[354]TRIPS Agreement, art 6: Exhaustion of IP rights; art 27: Flexibilities as to Substantive Protection; art 30; art 31; art 31bis; art 66: Transition flexibility for Least-Developed Countries.
[355]TRIPS Agreement, art 7.
[356]TRIPS Agreement, art 8.
[357]*Australia- Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging* WT/DS435/R, WT/DS441/R, WT/DS458/R, and WT/DS467/R 28 June 2018 (Panel Report) (hereinafter "*Australia-Tobacco Plain Packaging*"); *European Communities- Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* WT/DS174/R 15 March 2005 (Panel Report) (hereinafter "*EC- Trademarks and Geographical Indications*"); *Canada- Patent Protection of Pharmaceutical Products* WT/DS114/R 17 March 2000 (Panel Report) (hereinafter "*Canada- Patent Protection of Pharmaceutical Products*").
[358]*Australia-Tobacco Plain Packaging*, at [7.2408-7.2409].

> principles. As described above, Articles 7 and 8 have central relevance in establishing the objectives and principles that, according to the Doha Declaration, express the object and purpose of the TRIPS Agreement relevant to its interpretation.
>
> This paragraph of the Doha Declaration may, in our view, be considered to constitute a "subsequent agreement" of WTO Members…

Substantive patent laws are outlined in section five of the TRIPS Agreement. Article 28 explicitly states that third parties are prohibited from making, using, offering for sale, or importing the patented product or process without the consent of the patent holder.[359] Thus, inventors who have patent protection have the right to prevent third parties from certain acts. In return, the right holder should disclose the invention, as Article 29 requires.[360] This suggests that the public gains access to information in relation to the invention, which can be used at the end of the patent protection term. This is the form of the social contract between the public and the patent holder. However, as explained below, this is not always the case in the pharmaceutical sector. Furthermore, the TRIPS Agreement obligates member states to provide 20 years of protection from the filing date.[361] Thus, member states were no longer able to offer shorter periods of patent protection. As the agreement entered into force, countries had to revise their patent law in their domestic law, like India did. For instance, India included product patents and increased the duration of the patent protection from 14 years to 20.[362]

With the TRIPS Agreement, member states started to provide patent protection for both products and processes in all sectors, including pharmaceuticals, according to Article 27(1)[363], as long as they fulfil patentable requirements: new, inventive steps and capable of industrial application. Again, as it was in the case of the extension of patent duration, India had to introduce an amendment in 2004 to include product patents to comply with the TRIPS Agreement.[364] Article 27(2) and Article 27(3) provide member countries with the flexibility to exclude certain inventions from patentability, for instance, protection of *ordre public* and morality.[365] The use of *may* in both provisions indicates that member states do not have to

[359]TRIPS Agreement, art 28.
[360]TRIPS Agreement, art 29.
[361]TRIPS Agreement, art 33.
[362]G. Krishna Tulasi and B. Subba Rao "A Detailed Study of Patent System for Protection of Inventions" (2008) 70(5) Indian Journal of Pharmaceutical Sciences 547 at 551-552.
[363]TRIPS Agreement, art 27.
[364]Tulasi and Rao, above n 362, at 553.
[365]TRIPS Agreement, art 27(2); art 27(3).

implement such exceptions from patentability, but they have the choice to do so. The article provides grounds for denying the grant of a patent. Article 27(2) states that: [366]

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

The protection of *ordre public* and morality is such a vague concept that it varies significantly from one member state to another. However, states should be given wide sovereignty to determine the concept based on their local public values.[367] The TRIPS Agreement might be *lex specialis* in issues concerning patents; however, the interpretation of Article 27(2) is likely to benefit from the interpretation of GATT Article XX(a), GATT Article XX(b), GATT Article XX(g) and GATS XIV(a), GATS XIV(b) and GATS XIV(g) as TRIPS Agreement is an integral part of the WTO system.[368] In line with GATT Article XX(a), members have flexibility to define public morals in accordance with their own value systems.[369] Similarly, aligning the interpretation of necessity requirements with GATT XX(b) would suggest that there should be no other reasonable measure available that is less consistent with TRIPS.[370] While exclusion from patentability may be intended to prevent commercial exploitation, it cannot solely be based on the grounds that such exploitation is prohibited by law.[371] The protection of human, animal, plant, or health is also included within the same article as exception to patentability, although the wording suggests that they are not distinct grounds for denying patentability. Nevertheless, the article should be interpreted that if there are any concerns regarding the protection of human, animal, or plant life or health, this alone should be enough to be considered as an exception, without the need for demonstrating concerns

[366]TRIPS Agreement, art 27(2).
[367]Carlos M. Correa *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2nd ed, Oxford University Press, Oxford, 2020) at 279.
[368]Marrakesh Agreement Establishing the World Trade Organization 1867 UNTS 3 (opened for signature 15 April 1994, entered into force on 1 January 1995), art 2.2.; *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* WT/DS50/R 5 September 1997 (Report of the Panel) at [7.19]; Caroline Henckels "The Ostensible 'Flexibilities' in TRIPS: Can Essential Pharmaceuticals Be Excluded From Patentability in Public Health Crises?" (2006) 32(2) Monash Law Review 335 at 339.
[369]*European Communities- Measures Prohibiting the Importation and Marketing of Seal Products* WT/DS400/AB/R, WT/DS401/AB/R 22 May 2014 (Reports of the Appellate Body) at [5.199]; *Brazil- Certain Measures Concerning Taxation and Charges* WT/DS472/R, WT/DS497/R 30 August 2017 (Reports of the Panel) at [7.558].
[370]*Korea- Measures Affecting Imports of Fresh, Chilled and Frozen Beef* WT/DS161/AB/R, WT/DS169/AB/R 11 December 2000 (Report of the Appellate Body) at [164]; WTO Analytical Index GATT 1994 Article XX (DS Report).
[371]Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, above n 367, at 283; Antony Taubman, Hannu Wager and Jayashree Watal *A Handbook on the WTO TRIPS Agreement* (2nd ed, Cambridge University Press, Cambridge, 2020) at 102.

related to *ordre public* or morality.[372] Yet, there are opposite views on this matter, arguing that exceptions related to human, animal, plant life or health must also address the protection of *ordre public*.[373] Another exception is provided in the third paragraph of Article 27. According to Article 27(3): Members may also exclude from patentability:[374]

> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes…

Again, member states have the option to exclude diagnostic, therapeutic and surgical methods or others, as outlined paragraph 3(b), should they choose to do so. However, when paragraph 3(a) is interpreted, it is hardly possible to exclude products like equipment, substances or apparatus from patentability, those necessary to execute treatments or diagnose, such as diagnostic kits.[375] Not long ago, a dispute arose over Covid-19 diagnostic kits between two companies in the United States. In the early stages of the coronavirus pandemic, Labrador Diagnostic LLC, owned by Fortress Investment Group, brought a patent infringement lawsuit against Biofire Diagnostics LLC and its French partner Biomerieux S.A. in the United States about the development of Covid-19 test kits.[376] The lawsuit, although eventually dropped due to media backlash, exemplified a clear example of the profit-first approach and highlighted that the patentability of diagnostic kits can harm production and thus, accessibility. Diagnostic kits can play a crucial role, particularly during a pandemic by detecting the individuals who carry the virus and thus, preventing the spread.

Along with the exceptions to patentability, the TRIPS Agreement provides exceptions to rights conferred in Article 30.[377] Although Article 30 brings exceptions to rights granted to the holder such as preventing third parties from making, using, offering for sale, or importing the patented products/process without her/his consent. The article lays down three conditions: First, exception to patent rights should be "limited"; second, exception to patent rights should

---

[372]Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, above n 367, at 288-289.
[373]Taubman, Wager and Watal *A Handbook on the WTO TRIPS Agreement*, above n 371, at 102.
[374]TRIPS Agreement, art 27(3).
[375]Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, above n 367, at 308.
[376]Nicole Wetsman "A SoftBank-owned company used Theranos patents to sue over COVID-19 tests" (19March 2020) The Verge <https://www.theverge.com/2020/3/18/21185006/softbank-theranos-coronavirus-covid-lawsuit-patent-testing>; A company that bought Theranos' patents is using them to sue a health startup working on coronavirus tests, after Theranos suit, Fortress makes patents available on royalty-free basis for COVID-19 tests; A Softbank-owned company used Theranos patents to sue over COVID-19 tests.
[377]TRIPS Agreement, art 30.

not "unreasonably conflict with a normal exploitation of the patent", and third, exception to patent rights should not "unreasonably prejudice the legitimate interests of the patent owner".[378] The article does not offer an exhaustive list; rather, exceptions are left to the member states to determine as long as they fulfil the three requirements cumulatively. The language of the article automatically suggests a case-by-case assessment. Examples of such exceptions can be research purposes or experimental use, like Bolar exception (use of patented pharmaceutical products to obtain regulatory approval for putting on the market just after patent expiration of product).[379]

Another exception to the right holders' exclusive rights is provided in Article 31[380] of TRIPS Agreement with the title of other use without authorisation of the right holder, in other words, compulsory licence. Compulsory licence is a type of licencing agreement that is forced to the right holder, allowing a state or a third party authorised by the government to use the patented product/process in exchange for compensation.[381] Article 31 allows states to introduce a compulsory licence in their domestic law; however, member states do not have to include such a system. If member states wish to designate one, then they have to comply with the requirements provided in the TRIPS Agreement. The compulsory licence system is significant in the distribution of patented health products/process as it allows producing cheaper/more affordable products. The only aim is to explain the system of the compulsory licence under the TRIPS Agreement. The importance of system becomes clear where challenges of patents is explored in relation to Covid-19 health resources in Chapter 3.2.6.

Under Article 31 of the TRIPS Agreement, there is no restriction on the type of patent that can be subject to compulsory licence or the categorisation of the member states that can permit compulsory licence. Regardless of their economic level, any member state can allow compulsory licence in relation to any kind of patent.[382] Either a government or a third party can seek the compulsory licence according to the TRIPS Agreement; it does not impose any restriction. The TRIPS Agreement suggests that the authorisation of compulsory licence should be considered on its individual merits, which means the grounds of such licence are not limited.[383] Failure to work (in line with the Paris Agreement Article 5(A)) and public

[378]TRIPS Agreement, art 30.
[379]Taubman, Hannu Wager and Watal, above n 371, at 118.
[380]TRIPS Agreement, art 31.
[381]Cynthia Ho *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press, Cary, 2011) at 127.
[382]TRIPS Agreement, art 31.
[383]TRIPS Agreement, art 31(a).

interests like government use, blocking patents, or anti-competitive practice are some examples of grounds for compulsory licensing.[384] However, the scope and duration of the compulsory licence are restricted to the purpose of the use.[385] In addition, as Ho highlights, the member states have freedom to declare the authorisation purpose.[386] The issuance purpose of the compulsory licence is very significant in the context of investment protection of patents, as detailed in Chapters 4 and 5.

Article 31 regulates the use of the compulsory licence for the supply in the domestic market only.[387] The conditions for issuance of a compulsory licence for the purpose of export will be addressed in Chapter 3.2.5. The compulsory licence should be non-exclusive and non-assignable.[388] TRIPS Agreement requires conditions before issuing a compulsory licence. First, there should be an effort to obtain voluntary licence by the proposed user on "reasonable commercial terms and conditions".[389] This effort should continue "within a reasonable period of time".[390] However, it is not clear how long the proposed user should try to obtain a voluntary licence or what reasonable commercial terms and conditions mean. It is presumed that the determination would be made on a case-by-case basis. The nature of the technology would be relevant in the determination of reasonableness.[391] Those preconditions can be waived in case of a "national emergency or other circumstances of extreme urgency or case of public non-commercial use".[392] For sure, the patent right holders have rights under the TRIPS Agreement. The patent holder should receive "adequate remuneration" considering the "economic value of the authorisation".[393] The adequacy of remuneration is yet another vague and unclear rule of the Agreement, as in the case of the reasonableness of the commercial terms and the duration to obtain the voluntary licence.[394] The vagueness of these terms is acknowledged by scholars and that the TRIPS Agreement leaves the definition of these issues

[384]Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 130-133.
[385]TRIPS Agreement, art 31(c).
[386]Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 136.
[387]TRIPS Agreement, art 31(f).
[388]TRIPS Agreement, art 31(d); art 31 (e).
[389]TRIPS Agreement, art 31(b).
[390]TRIPS Agreement, art 31(b).
[391]Daniel Gervais *The TRIPS Agreement- Drafting History and Analysis* (2nd ed, Sweet & Maxwell, UK, 2003) at 250-251.
[392]TRIPS Agreement, art 31(b).
[393]TRIPS Agreement, art 31(h).
[394]This thesis acknowledges that legal rules of international law are sometimes arranged (including IIAs) in a way that leaves room for interpretation and application by tribunals, as parties may not always provide clear guidance. Please see Kenneth W. Abbott and Duncan Snidal "Hard and Soft Law in International Governance" (2000) 54(3) International Organisation 421 at 423.

to member states, ultimately to the WTO dispute settlement system.[395] It should be noted that a formulation has been proposed for the calculation of adequate remuneration.[396] There are models for determining adequate remuneration for compulsory licence[397]; however, these suggestions are often based on the value of the generic product rather than the economic value of authorisation, as required by the TRIPS Agreement Article 31(h). For some, the economic value of the authorisation does not necessarily mean the economic value of patent right itself.[398] Others interpret it as "the authorisation to be granted by the patentee for using such patent".[399] Thus, potentially, it might not align with the TRIPS requirements. Establishing precise definitions in these ambiguous areas would facilitate the issuance of compulsory licenses with fewer complications or challenges.

Moreover, patent rights holders have the right to challenge compulsory licence decisions through judiciary or other independent higher authorities, both in relation to the authorisation and to the remuneration of the licence.[400] Certainly, the nations of the right holders have the option to initiate a dispute within the WTO dispute system against another member state if the domestic law is deemed to contravene TRIPS Agreement rules.[401] However, more critically, patent right holders can themselves potentially initiate cases under ISDS, through IIAs, in other words TRIPS-plus. The potential risks associated with these rights are explored in Chapter 4. Additionally, while compulsory licence, as outlined in Article 31, offers flexibility to use a patent without the authorisation of the right holder, as the title of the article describes, it primarily addresses domestic supply. However, it falls short in addressing the need of states who do not have sufficient manufacturing facilities. So far, this chapter has

[395]Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 133- 139; Correa, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, above n 367, at 305- 306; Olasupo Owoeye *Intellectual Property and Access to Medicines in Africa: A Regional Framework for Access* (Routledge, Milton, 2019) at 20-24.

[396]Details of Adequate Remuneration please see: James Love "Remuneration Guidelines for Non- Voluntary Use of a Patent"(WHO/TCM/2005.1,2005)WHO/UNDP<https://iris.who.int/bitstream/handle/10665/69199/WHO_TCM_2005.1_eng.pdf>; Yousuf A. Vawda "Compulsory Licenses and Government Use: Challenges and Opportunities" in Carlos M. Correa and Reto M. Hilty (ed) *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (eBook, Springer, 2022) 73 at 96.

[397]Love, "Remuneration Guidelines for Non- Voluntary Use of a Patent", above n 396: Adequate Remuneration is recommended a standard 4 percent royalty, with variation up or down by 2 percent depending on therapeutic value and government contribution to the costs of R&D for the product by the UN Development Program's 2001 Human Development Report. Japan and Canada have also their own model. Finally, the Tiered Royalty Method is another suggested method, which remuneration is based on (1) a proxy for the therapeutic benefit of the products, and (2) a measure of affordability.

[398]Tsai-Yu Lin "Compulsory Licences for Access to Medicines, Expropriation and Investor- State Arbitration Under Bilateral Investment Agreements- Are There Issues Beyond the TRIPS Agreement?" (2009) 40 Int'L Rev. Intell. Prop. & Competition Law 152 at 163.

[399]Selin Sinem Erciyes "Determination of Royalty in Case of Compulsory Licence" (03 March 2022) Gun + Partners <https://gun.av.tr/insights/articles/determination-of-royalty-in-case-of-compulsory-license>.

[400]TRIPS Agreement, art 31(i); (j).

[401]*Brazil-Measures Affecting Patent Protection* WT/DS199/4, G/L/454, IP/D/23/Add.1 19 July 2001 (Notification of Mutually Agreed Solution) (hereinafter "*Brazil-Measures Affecting Patent Protection*"). Parties decided the discuss the issue in a special session.

established an overview of international patent law. The next section aims to show that patent law can create a barrier when it comes to accessing medicines, vaccines, diagnostics, and therapeutics, and thus public health. The next section further includes the Declaration on the TRIPS Agreement and Public Health that resulted in an amendment in the agreement with the incorporation of Article 31bis and the rationale behind of this amendment.

3.2.5. Patent Law and Access to Medicines, Vaccines, Diagnostics, and Therapeutics

One might question why patent protection would hinder access to medicine, vaccines, diagnostics, and therapeutics, thereby affecting public health. An argument in favour of patent protection suggests that why investors would undertake such work without the promise of economic benefit in return for their effort and investment. This is the incentive-based approach to intellectual property, perhaps the most advocated theory by IP proponents.[402] It is suggested that the patent system is created to serve as a reward for inventors, promoting technological advancement and facilitating the distribution of knowledge.[403] However, once IP became a trade issue through the approval of the TRIPS Agreement, intellectual property protection evolved beyond serving as merely an incentive to invent; it became a means for generating profit.[404] Contrary to claims made by pharmaceutical companies and IP proponents, the World Health Organisation reports that only 1% of expenditure in R&D is allocated to addressing significant health problems.[405] Consequently, the patent incentive-based approach has led inventors to invest in sectors where profitability is higher, such as hair growth or beauty. Furthermore, today's international patent law framework has significant implications, particularly concerning access to medicines or vaccines, as will be illustrated below. Therefore, this thesis questions the incentive-based approach that can favour strong patent protection, and it focuses instead on unequal distribution of health resources and the societal impacts of such patent protection on the public. In fact, as explored in Chapter 4, investment protection of patent extends beyond the incentive-based approach.

The minimum standards introduced by the TRIPS Agreement have raised serious concerns regarding access to health products and processes since it required substantial changes in

[402]United States Constitution, art I, § 8, cl 8; Mark A. Lemley "Property, Intellectual Property, and Free Riding" (2005) 83 Texas L. Rev. 1031; Dan L. Burk and Mark A. Lemley "Policy Levers in Patent Law" (2003) 89(7) Va. L. Rev. 1575; Mark A. Lemley "Taking the Regulatory Nature of IP Seriously" (2014) 92 TE X. L. RE V. 68

[403]Carlos M. Correa "Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing" in Carlos M. Correa (ed) *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (South Centre, Geneva, 2013) 1 at 1.

[404]Dreyfuss and Frankel, "From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property", above n 265, at 562-563.

[405]World Health Organisation "Global Observatory on Health R&D" (2021) <https://www.who.int/research-observatory/why_what_how/en/>.

member states' domestic IP law. While the TRIPS Agreement requires member states to provide minimum standards of protection, these standards were usually higher than previous standards in some member countries.[406] As highlighted above, India, for instance, had to extend the duration of patent protection from 14 years to 20 years.[407] New Zealand and Australia also had to extend the patent term.[408] Additionally, the application for compulsory licence had been revised and subjected to limitations in some countries to comply with the TRIPS agreement.[409] Before the TRIPS Agreement, over 40 countries, such as Brazil or Argentina, did not provide product patent protection for medicines.[410] These examples of domestic law changes in some countries illustrate that the TRIPS Agreement increased the level of patent protection. Additionally, the TRIPS Agreement mandates the establishment of effective enforcement mechanisms to safeguard IP standards in member states.[411] Consequently, generic versions of the patented invention can be marketed after the expiration of the patent duration, leading to delays in the marketing of these products and processes.[412] Generic products typically offer lower prices, fostering competition among competitors and driving down prices, thereby making health products/processes more affordable and accessible. However, the monopolistic approach mandated by the TRIPS Agreement, has harmed the system. Under the TRIPS Agreement, patent right holder/holders have exclusive rights, allowing them to control production by permitting or refusing manufacturers or suppliers, thereby limiting production. This limitation on production impedes accessibility and affordability.

There were specific factors that prompted countries to safeguard their ability to employ compulsory licence.[413] The lawsuit brought by almost 40 Western drug companies together with the South African Pharmaceuticals Manufacturers Association against South Africa's amendments in their Medicine Act to provide low-cost HIV/AIDS antiretroviral drugs was

[406]Karin Timmermans "Ensuring Access to Medicines in 2005 and Beyond" in Pedro Roffe, Geoff Tansey and David Vivas-Eugui (ed) *Negotiating Health: Intellectual Property and Access to Medicines* (Routledge, London, 2006) 41 at 41.
[407]Tulasi and Rao, above n 362, at 553.
[408]New Zealand Intellectual Property Office "History of IP in New Zealand" (2024) <https://www.iponz.govt.nz/about-iponz/history-of-ip-in-new-zealand/>; John Revesz *Trade- Related Aspects of Intellectual Property Rights* (Australia Productivity Commission, May 1999) at 10.
[409]Revesz, above n 408, at 10; Mark Steel *The GATT Legislation in Particular relating to Patents, Trade Marks, Border Enforcement and Geographical Indications* (New Zealand Ministry of Commerce) at 4.
[410]Haochen Sun "The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health" (2004) 15(1) EJIL 123 at 124 n 2.
[411]TRIPS Agreement, Part III.
[412]Timmermans, above n 406, at 41.
[413]Ellen 't Hoen and others "Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All" (2011) 14(1) Journal of the International AIDS Society 15 at 17; Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 333-334.

one of factors.[414] The claims were against the Amendment Act, particularly Section 15C which allows Minister of Health to prescribe conditions for compulsory licence and parallel imports to protect public health.[415] This issue was addressed in the US Special 301 Watch List as: "South Africa's Medicines Act appears to grant the Health Minister ill-defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights.".[416] As a result of public pressure, the case was dropped.[417] However, this serves as an illustration of how international law can operate to prioritise financial gains of some industries of some countries over a country's particular needs. Another factor, one of the main engines for getting into an act, was the political pressure against Brazil to amend their patent law in 1996 before the transition period of the Agreement; yet Brazil faced a WTO dispute brought by the United States due to its local working requirement in its compulsory licence rule.[418] Along with these examples, the unavailability of exporting low-cost drugs under TRIPS Agreement finally resulted in the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) in November 2001.[419] While the Doha Declaration did not bring substantial changes to the TRIPS Agreement, it can be interpreted as an acknowledgment of health-related challenges. As evident from the given examples, some countries faced legal and political pressures from Western countries, notably the United States, without this acknowledgment. Through the Doha Declaration, Global South countries secured a degree of affirmation regarding the use of compulsory licences, but the scope was limited due to the efforts of Global North. Nevertheless, the Doha Declaration should not be viewed as the end of such pressures. Subsequent chapters illustrate how investment protection under the IIAs has been used as another form of pressure, even when public pressure is at stake.

[414]At 333-334.
[415]Republic of South Africa Government Gazette Medicines and Related Substance Act 1997 (South Africa) Section 15C (a): "notwithstanding anything to the contrary contained in the Patents Act. 1978 (Act No. 57 of 1978) determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine. or with his or her consent" and (b)"the conditions on which any medicine, which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic. but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported."
[416]Office of the United States Trade Representative "1999 Special Report 301" (30 April 1999) at 22.
[417]Médecins Sans Frontières "1998: Big Pharma versus Nelson Mandela" (20 February 1998) <https://www.msfaccess.org/1998-big-pharma-versus-nelson-mandela>.
[418]*Brazil-Measures Affecting Patent Protection.*
[419]Pedro Roffe, Christoph Spennemann, and Johanno von Brawn "From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health" in Pedro Roffe, Geoff Tansey and Vivas-Eugui (ed) *Negotiating Health: Intellectual Property and Access to Medicines* (Routledge, London, 2006) 9 at 16-18; Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 197.

The Doha Declaration explicitly states that the TRIPS Agreement does not and should not restrain members from undertaking necessary measures to safeguard public health; the interpretation and implementation of the Agreement should support the protection of public health[420], in line with Articles 7 and 8 of the Agreement. In fact, Paragraph 5(a) of the Declaration remind of the significance of Articles 7 and 8 by expressly stating that "…each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed..." [421]. In addition, the Declaration makes clear that every member has the right to grant compulsory licences and is free to designate the grounds for such licence[422]; every member has the right to define the meaning of national emergency or other extreme urgency[423]; every member also has the freedom to designate their own laws in relation to parallel imports and exhaustion of IP rights.[424]

The Declaration failed to address concerns about accessing medicines and vaccines in countries lacking adequate facility to produce affordable pharmaceutical products for their domestic markets. This presents significant problems because even if a compulsory licence is intended to be issued, production would not occur if infrastructure capable of producing the generic version in the member state did not exist. Consequently, some member states would remain reliant on the original product that is priced freely by the patent holder if they could not receive generic product from other member states which would hinder equal access to affordable health resources. The Declaration clearly disregarded the varying levels of development and production capacities among member countries as well as discouraging local R&D and production.[425] At the Doha WTO Ministerial, member states gave the Council for TRIPS to "find an expeditious solution…before the end of 2002".[426] However, even during the urgent need for access to HIV/AIDS treatment drugs, member states could not reach an agreement promptly. When more than 3 million people were being infected with HIV every year[427], delaying such a critical decision was unacceptable. Unfortunately, eight months later than the deadline, they could adopt a solution, but an interim one only. The length of the discussion was attributable to the discussions about the scope of the exemption,

[420]Doha Declaration, Paragraph 4.
[421]Doha Declaration, Paragraph 5 (a).
[422]Doha Declaration, Paragraph 5 (b).
[423]Doha Declaration, Paragraph 5 (c).
[424]Doha Declaration, Paragraph 5 (d).
[425]Amaka Vanni *Patent Games in the Global South Pharmaceutical Patent Law Making in Brazil, India and Nigeria* (Hart, Great Britain, 2019) at 135-136.
[426]Doha Declaration, Paragraph 6.
[427]Max Roser and Hannah Ritchie "HIV/AIDS is one of the world's most fatal infectious disease" (November 2014, revised November 2019) Our World in Data < https://ourworldindata.org/hiv-aids>.

beneficiary countries, and exporting countries.[428] While certain countries pushed for expanding the 31(f) waiver to include other epidemics, the United States insisted on a more restricted approach and limiting the exemptions to HIV/AIDS, tuberculosis, and malaria.[429] The United States and the European Council sought to limit the number of beneficiaries, which would exclude high-income Global South countries; those countries argued that all members of WTO should determine their manufacturing capacities.[430] In the determination of exporting countries, the United States had a different opinion than the others, including Europe.[431]

Eventually, this interim waiver to Article 31, known as Article 31bis, was adopted through a decision dated August 30, 2003.[432] Subsequently, in 2005, the decision was proposed as an amendment to the TRIPS Agreement, requiring ratification by two-thirds of the members.[433] However, the deadline for the formal acceptance of the amendment was extended five times and this requirement was eventually fulfilled in January 2017, nearly 12 years later.[434] The adoption process of the Article 31bis amendment, which spanned nearly 15 years, illustrates systemic challenges that threaten access of securing significant flexibilities. While significant, the sufficiency of such flexibility remains debatable.

Through Article 31bis, a barrier to exporting pharmaceutical products to countries that were unable to produce domestically was lifted. However, Article 31bis involves complex procedures, formalities, and rules. Firstly, members intending to import or export pharmaceutical products must modify or amend their national law to apply such waiver. Since this waiver is only related to Article 31(f), the remaining requirements of classical compulsory licence still apply, including prior negotiation for a voluntary licence.[435] Procedural requirements must be met by both the importing and exporting countries, in addition to a generic company willing to produce products according to the waiver. The importing country, typically one of the technologically least-developed countries and other

[428]Duncan Matthews "WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?" (2004) 7(1) JIEL 73 at 85-88.
[429]At 86.
[430]At 87.
[431]At 88.
[432]Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003.
[433]Amendment of the TRIPS Agreement, Decision of the General Council of 6 December 2005, WT/L/641, 8 December 2005.
[434]Muhammad Z. Abbas and Shamreeza Riaz "WTO "Paragraph 6" System for Affordable Access to Medicines: Relief or Regulatory Ritualism?" (2018) 21(1-2) The Journal of World Intellectual Property 32 at 36.
[435]Abbas and Riaz, above n 434, at 38; Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 208.

member states lacking manufacturing capacity for a specific product, must notify the TRIPS Council of this situation. Conversely, the exporting country is responsible for ensuring compliance with relevant regulations and protocols.

Importing countries are required to notify the TRIPS Council about the name of the product, and the estimated amount, and they must indicate their lack of manufacturing capacity (except the least-developed countries).[436] In addition, exporting countries must have national laws that permit such compulsory licences and they should notify the TRIPS Council by providing comprehensive details of the licence, including the name and address of the licensee, the name and quantity of the product, destination countries for the supply, and the duration of the licence.[437] In addition, the generic companies need to post these necessary information regarding the licence on their websites.[438] The product must be distinguishable with the shape, colour, size, packaging, or perhaps by a different trademark name.[439] Additionally, both importing and exporting countries must issue compulsory licencing.[440] Further requirements may be required by domestic law, such as restrictions on products, limitations on importing countries, duration restrictions, single-country limitations, or regulatory approval for domestic use.[441]

Since the adoption of Article 31bis with the Decision in August 2003, the system has been used only once by Rwanda for the treatment of HIV/AIDS.[442] The world was facing a Covid-19 pandemic, and again it took nearly two years from the first TRIPS waiver submission to reach a decision.[443] The duration raises concerns about timely action, as elaborated in the following section. Despite the unequal distribution of vaccines and oral drugs for treatment during the pandemic and despite the presence of manufacturers ready to produce vaccines, the compulsory licence under Article 31bis was not used, as further discussed below.

[436]Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 313; Abbas and Riaz, above n 434, at 38.
[437]Abbas and Riaz, above n 434, at 39; Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 208- 209.
[438]Abbas and Riaz, above n 434, at 39; Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 208- 209.
[439]Amendment of the TRIPS Agreement, Decision of the General Council of 6 December 2005, WT/L/641, 8 December 2005, Annex to the TRIPS Agreement, para 2(ii)
[440]Abbas and Riaz, above n 434, at 38-39.
[441]Ho, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights*, above n 381, at 210- 214.
[442]Nicholas G. Vincent "Trip-ing Up: The Failure of Trips Article 31Bis " (2020) 24(1) Gonzaga Journal of International Law 1 at 19.
[443]Ministerial Decision on the TRIPS Agreement, Adopted on 17 June 2022.

So far, in this section, the international IP law framework, with a specific focus on patent law and the flexibilities of patent law have been examined. The objective was to highlight the challenges of the flexibilities and exceptions outlined in the TRIPS Agreement. The following section delves into the issue of access to Covid-19 related health resources. The aim here is to demonstrate that these concerns are not merely theoretical but have real-world implications.

3.2.6. Example Issues Related to Medicines, Vaccines, Diagnostics and Therapeutics in the Time of Covid-19

This section addresses the issue that has been highly topical for the past almost four years: access to medicines, vaccines, diagnostics and therapeutics to fight against Covid-19 outbreak. The purpose here is to determine the potential negative impact of patent law on public health and access, even during a time of global urgency. This section serves to highlight the unequal distribution of health resources resulting from patent protection, in reality. These critiques highlight the fact that every single person can be adversely impacted by the patent law framework, regardless of their place of residence since patent protection limits production to a level insufficient to meet global needs.

As Nussbaum discusses well, patent protection on medicines, vaccines, and on overall health resources has an adverse impact on "individuals' capacity to live a human life of normal length".[444] The current patent system has significant consequences on "human lives and happiness and freedoms" as reminded by Sen in the context of the AIDS epidemic.[445] Medical care is part of the human right to health as recognised by the UDHR Article 25, the ICESCR Article 12, and various other human rights treaties.[446] As emphasised by the UN Committee on Economic, Social and Cultural Rights, the right to health is linked to and dependent upon the realisation of other rights such as access to food, housing, work, education, dignity and equality[447], which has significant role in human capacity to live human life. Accessing health resources is further associated with the right to participate in and benefit from scientific advancements, and everyone has the right to enjoy scientific progress without discrimination since access plays a crucial role in establishing accessible means for

[444]Sunder, above n 15, at 178.
[445]At 179.
[446]UDHR, art 25; ICESCR, art 12; International Convention on the Elimination of all Forms of Racial Discrimination, art 5; The Convention on the Rights of the Child, art 24.
[447]*Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)* at 2.

preventing, controlling and treating[448] illnesses like Covid-19. Yet, as detailed below, in the case of the Covid-19 pandemic, the current system has put an unequal burden on the people in the Global South once again. At the same time, Global North has ended the pandemic by easing restrictions due to trust in the vaccination rate. The economic impacts of Covid-19 have hit the Global South more, which has affected the development rate in poverty, healthcare, and education,[449] along with high number of hospitalisations and deaths.

The first case was identified on 31 December 2019 in Wuhan, China.[450] Due to an upsurge in the number of cases around the world, not just in China, the World Health Organisation (WHO) declared the Covid-19 outbreak as a pandemic on 11 March 2020.[451] The WHO had declared an end to the pandemic[452], but there had been many challenges of equal distribution of vaccines. Since the Covid-19 pandemic was the most recent global health crisis, the focus is given to the products/processes in relation to Covid-19 to demonstrate unfair distributional problems of the patent law system. However, it should be kept in mind that the issue of access to medicines or vaccine is not limited to Covid-19 pandemic. In response to Covid-19, there have been global efforts, collaborations, instances of non-cooperation and pharmaceutical litigations related to patents. The following sections illustrates these issues respectively.

3.2.6.1. Response from Countries to Covid-19 and Pandemic Prevention: TRIPS Waiver and Intergovernmental Negotiating Body

In October 2020, India and South Africa suggested to waive Sections 1,4,5, and 7 of Part II and enforcement of these sections under Part III of the TRIPS Agreement (includes patent section) until vaccines would be widely administrated and global immunity would be achieved for most of the population.[453] Their proposal revised in May 2021 with support from many Global South countries, such as Bolivia, Venezuela, Egypt and Indonesia and co-

[448]*General Comment No.25 (2020) on Science and Economic, Social and Cultural Rights (article 15(1) (b), (2), (3), and (4) of the International Covenant on Economic, Social and Cultural Rights)* at [67- 71].
[449]Rosa Balfour, Lizza Bomassi and Marta Martinelli *Coronavirus and the Widening Global North-South Gap* (Carnegie Europe, April 2022) at 1.
[450]GOV.UK "Covid-19: Epidemology, Virology, and Clinical Features" (17 May 2022) <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-background-information/wuhan-novel-coronavirus-epidemiology-virology-and-clinical-features>.
[451]World Health Organisation "Listing of WHO's response to Covid-19" (29 January 2021) <https://www.who.int/news/item/29-06-2020-covidtimeline>.
[452]UN "WHO Chiefs Declares end to COVID-19 as a Global Health Emergency" (5 May 2023) <https://news.un.org/en/story/2023/05/1136367>.
[453]Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 IP/C/W/669, 2 October 2020 (Council for Trade-Related Aspects of Intellectual Property Rights). They proposed certain provisions to be waived: Sections 1,4,5, and 7 of Part II, enforcement of these sections under Part III.

sponsorship of 63 WTO countries.[454] The proposal covered all types of intellectual property rights applicable not only to vaccines but also to treatments and diagnostics.[455] The WTO Ministerial Decision on the TRIPS Agreement in relation to COVID-19, adopted on 17 June 2022[456], was very limited compared to what was aimed by the Global South. It is argued that all collaborations, whether voluntary licences or knowledge sharing like mRNA-hub, were undertaken to prevent the TRIPS waiver or as a result of growing pressure created by the TRIPS waiver.[457] The 17 June 2022 dated decision, in fact, was not a waiver as requested by the Global South. The decision served as a clarification of the flexibilities already existing in the TRIPS Agreement and extension of Article 31(f).[458] The decision was limited to Covid-19 vaccines, even though therapeutics and diagnostics played a crucial role in combating the pandemic. However, member states were not able to agree on expanding the scope.[459] It is important to recognise that the 17 June 2022 dated decision provides reassurance to states for the issuance of compulsory licence since it clarifies the use of compulsory licences under the TRIPS Agreement. Whether a TRIPS waiver was necessary for access to medicine is not the primary focus of this thesis. However, this part underscores that international IP law has major role in promoting access to necessary health resources.

Another global response by countries to the pandemic was under the WHO. Member states of the WHO have committed to negotiate an international instrument (treaty, convention, accord, or similar instruments) under WHO to develop pandemic prevention, readiness and response.[460] Meetings as part of the Intergovernmental Negotiating Body (INB) have been held to establish a mechanism to address problems revolving around the access to tools to prevent pandemics and health care services for all.[461] Since the first draft text, intellectual property is addressed, recognising that IP should not be a barrier for states taking initiatives

[454]Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Revised Decision Text IP/C/W/669/Rev.1, 25 May 2021 (Council for Trade-Related Aspects of Intellectual Property Rights); Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/684 30 September 2021 (Council for Trade-Related Aspects of Intellectual Property Rights)
[455]Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, 25 May 2021, above n 454.
[456]Ministerial Decision on the TRIPS Agreement, Adopted on 17 June 2022.
[457]Siva Thambisetty and others "Addressing Vaccine Inequity During The Covid-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond" 2022 57(1) Cambridge Law Journal 1 at 24-25.
[458]Ministerial Decision on the TRIPS Agreement, Adopted on 17 June 2022 at 3b.
[459]World Trade Organisation "TRIPS and Public Health"
<https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm>.
[460]World Health Organisation "Pandemic prevention, preparedness and response accord" (23 June 2023) <https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord>.
[461]"Pandemic prevention, preparedness and response accord", above n 460.

to safeguard public health, particularly considering its impacts on pricing.[462] Draft Article 11 provides that member states should cooperate on issues such as IP and encourage entities to non-exclusive licences to ensure equitable geographical distribution of pandemic-related products.[463] According to Draft Article 11, member states should enhance and develop mechanism for the transfer knowledge, IP and data.[464] Accordingly, member states should also ensure that flexibilities under the TRIPS Agreement are in use and secure equitable and affordable access to health technologies to mitigate social disparities.[465] Additionally, during pandemics, member states should consider supporting time-bound waivers of IP.[466] Draft Article 12 establishes the WHO Pathogen Access and Benefit-Sharing mechanism to facilitate the quick and timely development of pandemic-related products.[467] While emphasises on IP highlights the understanding of its impact on equal access to affordable products, the draft text currently lacks sufficient mechanisms to compel states to act in accordance with, instead at the stage of suggestions. However, it is unlikely that the text will go beyond this, given that some states have already expressed that there will not be an agreement if the IPRs are restricted largely.[468] This is another example of how intellectual property, particularly patents, plays a significant role and serves as a bargaining power for some states, even in matters of health.

Covid-19 has highlighted the impact of patent law on public health and access during a time of global emergency. While many initiatives have aimed to accelerate the distribution of resources to fight against Covid-19, the examples discussed here to show that access to health resources has often relied on patent owners' preferences and highlight the unequal distribution of health resources. This thesis acknowledges that there have been additional barriers with regards to the distribution of Covid-19 vaccines, such as logistics.[469]

[462]World Health Organization Proposal for Negotiating Text of the WHO Pandemic Agreement, Seventh Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response A/INB/9/3 13 March 2024 at Preamble Paragraph 10.
[463]Art 11 (1)(c)
[464]Art 11(2).
[465]Art 11(4).
[466]Art 11(3)(b).
[467]Art 12.
[468]Stefan Anderson "No Pandemic Accord Without Intellectual Property Protection, says German Health Minister" Health Policy Watch (16 October 2023) <https://healthpolicy-watch.news/no-pandemic-accord-without-intellectual-property-protection-says-german-health minister/#:~:text=%E2%80%9CFor%20countries%20like%20Germany%20and,property%20rights,%E2%80%9D%20said%20Lauterbach>.
[469]Mathumalar Loganathan Fahrni "Management of Covid-19 Vaccines Cold Chain Logistics: A Scoping Review" (2022) 15(1) Journal of Pharmaceutical Policy and Practice.

3.2.6.2. Collaborations and Non-cooperation

Several vaccines have been developed to fight against Covid-19, such as Oxford/AstraZeneca, Pfizer/Biontech, Janssen by J&J, Moderna, Sputnik, Sinovac and others, and research shows that vaccines reduce risks of death, spread of the virus and the severity of symptoms.[470] Different countries and regions have approved different vaccines. It is acknowledged that there had also been a vaccine hesitancy and refusal of vaccination in public which might have impacted the rate of the vaccination.[471] Some argue that the varying vaccination rates among nations are not primarily linked to patent protection but rather to other factors and that focusing on the global patent system like a patent waiver would prevent taking necessary steps to tackle fundamental issues like vaccine hesitancy.[472] However, vaccine hesitancy has not only been experienced in Global South countries, but also in Global North countries. In fact, while the Global North was wasting vaccines, the Global South did not even have a vaccine dose for every single person. Thus, for this thesis, what is significant from a global distributive justice point of view is the availability of the vaccine to everyone wishing to receive the doses. In terms of Covid-19, the most crucial aspect has been to accelerate the production and rapid dissemination of products. Ensuring equal availability of vaccines to all individuals is essential for the fair and equal distribution of patented health resources. Ultimately, everyone, regardless of their place of residency, ethnicity, religion, or financial situation, should have the right to access health resources, at least affordable ones.[473]

Along with vaccines, several oral drugs are approved for the treatment of Covid-19 like; Kaletra (lopinavir/ritonavir), Veklury (remdesivir), Lagevria (molnupiravir), and Paxlovid (nirmatrelvir, ritonavir). Since the early days of Covid-19, several patent issues have arisen, in fact, there has also been a lawsuit which took place between two diagnostic companies with regards to patents under Covid-19 tests. This part provides and discusses some of those issues that have been drawing attention in the Covid-19 pandemic. Along with the drugs for treatment and disputes between the two diagnostic companies, the emphasis particularly is

[470]NHS "Coronavirus (COVID-19) vaccine" <https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/>.
[471]Asavari Raut and Others "Acceptance, Hesitancy and Refusal towards Covid-19 Vaccination" (2023) 21 Clin Epidemiol Glob Health.
[472]Nature "Covid vaccine IP waiver agreed" (online ed, 13 April 2022) at 443; Maria Chaplia "TRIPS: Developing countries will not benefit from IP waived vaccines" (15 June 2022) The Parliament <https://www.theparliamentmagazine.eu/news/article/trips-developing-countries-will-not-benefit-from-ip-waived-vaccines>; Julio S. Solis Arce and Others "Covid-19 Vaccine Acceptance and Hesitancy in Low- and Middle- Income Countries" (2021) 27(8) Nature Medicine 1385 at 1385-1392.
[473]ICESCR, art 12.

given to the vaccines that are considered most effective: Oxford/AstraZeneca, Pfizer/Biontech, J&J, and Moderna.[474] While conclusion of some voluntary licences can be considered as positive examples, they remain inadequate and clearly serve commercial interests rather than public health, which may not come as a surprise. Once again, current debates in relation to Covid-19 prove that the TRIPS Agreement raises significant global distributive justice problems as it can undermine equal access to necessary health products. There has been considerable inequality in the distribution of the health products to combat Covid-19, especially in vaccine distribution, as discussed below. The debates on access to vaccines, inequality in vaccination rates among nations, and the nationalistic approach of Global North countries in hoarding vaccines provide an unfortunate reality of the distributional justice problem of current global patent arrangements.[475]

3.2.6.3. Collaborations and Non-cooperation about Treatments of Covid-19

At the very first stage of the pandemic, some doctors started using an HIV drug named Kaletra- a combination of lopinavir and ritonavir antivirals- for the treatment of coronavirus.[476] AbbVie owns the Kaletra's patent, and according to MedsPAl, in some territories, the patent has protection until at least 2026.[477] In March 2020, as AbbVie was not able to provide enough supply of lopinavir/ritonavir, the Israeli government issued a compulsory licence to receive the drug from India, when some patent applications of AbbVie for Kaletra were rejected (due to lack of novelty and inventive step).[478] In response to the Israeli government's action, AbbVie announced that they would not enforce patent rights globally for HIV and coronavirus.[479] As the patent system is designed to provide patent holders to prevent third parties from making, using, offering for sale, selling or importing[480], it ultimately rested in AbbVie's hand whether or not to exercise these rights. This example illustrates some significant aspects of the current international patent system. First, it shows

[474]"What to Know About the Different Covid-19 Vaccines" *Medical News Today* (29 March 2022) <https://www.medicalnewstoday.com/articles/which-covid-vaccine-is-best#summary>.
[475]Helen Lock "Vaccine Nationalism: Everything You Need to Know" (12 February 2021) Global Citizen <https://www.globalcitizen.org/en/content/what-is-vaccine-nationalism/>.
[476]Donato Paolo Mancini "AbbVİe Drops Patent Rights for Kaletra Antiviral Treatment" *Financial Times* (UK 23 March 2020) <https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b>.
[477]Mancini, above n 476.
[478]Medicines Sans Frontières "Compulsory Licences, the TRIPS Waiver, and Access to COVID-19 Medical Technologies, MSF Briefing Document" (May 2021) <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies> at 5; Pearl Cohen Zedek Latzer Baratz "IP Rights for COVID-19 Vaccines: Worldwide Stakes of Israeli Compulsory Licences" (19 July 2021) Lexology <https://www.lexology.com/commentary/intellectual-property/israel/pearl-cohen-zedek-latzer-baratz/ip-rights-for-covid-19-vaccines-worldwide-stakes-of-israeli-compulsory-licences>.
[479]OCHA "MSF Responds to FDA Approval of COVID-19 Treatment Nirmatrelvir/Ritonavir" (22 December 2021) ReliefWeb <https://reliefweb.int/report/world/msf-responds-fda-approval-covid-19-treatment-nirmatrelvirritonavir> at 2.
[480]TRIPS Agreement, art 28.

that strong patent protection may impact access since domestic companies would not be able to produce even when the supply of the product is limited. Further, it confirms that even a high-income country like Israel can be affected by the patent law framework due to a lack of adequate supply. Further, it is unfortunate that AbbVie did not take such an action before when the need was particularly in Global South countries during the HIV epidemic.[481]

Similar to Kaletra, Gilead Sciences' antiviral remdesivir with the brand name Veklury, originally developed for the Ebola virus, was proved to be effective at the first stage of the COVID-19 pandemic.[482] Per vial of remdesivir costs $390 and treatment costs per person $2,340.[483] In May 2020, Gilead entered into royalty-free voluntary licencing agreements with several generic companies in India, Pakistan and Egypt to increase the supply, particularly in low and middle-income countries, supposedly in 127 countries.[484] Yet, five generic companies were inadequate to meet the need for vials. Hungary issued a compulsory licence for treatment of Covid-19.[485] Gilead Sciences announced on 26 April 2021, that they would donate 450,000 vials of remdesivir to India, right after they filed a lawsuit against the Russia government on the decision of compulsory licence.[486] Interestingly, some of the generic products were sent to India as humanitarian aid by Russia.[487] This example illustrates how patents can operate by preventing others from using without authorisation and showcases the power held by patent holders in determining licensing terms and the number of companies involved.

The facts of the lawsuit starts with a request for issuance of a compulsory licence on remdesivir by civil society. However, Gilead Sciences rejected granting a voluntary licence,

[481]Medicines Sans Frontières "South Africa should override patent on key HIV medicine after widespread stock out problem" (27 October 2015) <https://www.msf.org/south-africa-should-override-patent-key-hiv-medicine-after-widespread-stock-out-problem>.
[482]Richard T. Eastman and others "Remdesivir: A Review of Its Discovery and Development Leading to Emergency Use Authorization for Treatment of COVID-19" (2020) 6(5) ACS central science 672 at 672.
[483]Victoria Rees "Gilead Prices Remdesivir at $2,340 per Patient for Developed Countries" *European Pharmaceutical Review* (online ed, 30 June 2020).
[484]Stephanie Pilkington "Insight: Remdesivir and the Role of Patents in Tackling Covid-19" *Bloomberglaw* (online ed, 17 July 2020); Reuters "Gilead Says Signed Non-Exclusive Voluntary Licencing Agreements with 5 Generic Pharmaceutical Manufacturers based in India, Pakistan to Further Expand Supply of Remdesivir" (14 May 2020) <https://www.reuters.com/article/idUSFWN2CU0RP/>.
[485]Thiru "Hungarian Compulsory License for Remdesivir Raises a Stir with BIO, PhRMA and the US Chamber of Commerce" (8 March 2021) KEI < https://www.keionline.org/35558>.
[486]Reuters "Russia Extends Production of Covid-19 Drug Remdesivir without Patent for a Year" (30 December 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/russia-extends-production-covid-19-drug-remdesivir-without-patent-year-2021-12-30/>; "Covid-19 Related Information" (2022) Supreme Court of the Russian Federation <https://vsrf.ru/lk/practice/cases/11085980>.
[487]"Russia Extends Production of Covid-19 Drug Remdesivir without Patent for a Year, above n 486.

which is the first step of a compulsory licence, to the Russian company, Pharmasyntrz.[488] As a result, in December 2020, the Russian Federation, with a decree dated 31 December 2020, No.3718-r, allowed Pharmasyntrz to use patented inventions without the consent of Gilead, provided that compensation be paid within three months.[489] On 30 December 2021, the Russian government extended producing a generic version of the remdesivir for another year.[490] The Supreme Court of Russia Federation denied the Gilead's claims on 27 May 2021.[491] The decision was made due to the "interests of security", which seems appropriate especially comparing the prices between remdesivir and the generic product, four times lower than Gilead's product, as well as considering the exclusion of Russia from receiving the generic products produced by other generic companies.[492] It is important to remind that states have the authority to issue a licence without the authorisation of the patent holder, flexibility provided by the TRIPS Agreement[493] and companies have an obligation to respect the use of TRIPS flexibilities[494].

Few key issues deserve particular attention. First of all, Gilead's behaviour shows one more time that the patent system gives a one-way power to one patent holder company that it can choose to whom to licence products voluntarily, even in the case of an emergency like a pandemic. Secondly, even though several voluntary licences are given to multiple generic companies, still the supply of needed products can be inadequate. Further, there seems to be misinformation about how many generic companies in which countries received voluntary licences from Gilead. Some media outlets mention five generic companies, some of them seven similar to Gilead's media release, according to MSF; the number is nine.[495] The variation in numbers of generic companies could be attributed to the expansion of the licencing in time. However, it appears to be a notable lack of transparency concerning

[488]"Russian Government Advised- 'Issue Compulsory Licence to Make Generic Covid-19 Drug Available'"(6 November 2020) Make Medicine Affordable <https://makemedicinesaffordable.org/russian-government-advised-issue-compulsory-license-to-make-generic-covid-19-drug-available/>.
[489]Government of the Russian Federation Order No.3718-r (31 December 2020) <http://actual.pravo.gov.ru/text.html#pnum=0001202101050003>.
[490]Government of the Russian Federation Order No.3718-r, above n 489.
[491]Production Card Case No. AKPI21-303 (04 January 2021) <https://vsrf.ru/lk/practice/cases/11085980>.
[492]"Russia Allows Domestic Pharmaceutical to Continue Producing U.S. Company's Covid-19 Drug" (31 December 2021) <https://www.rferl.org/a/russia-remdesivir-generic-patent/31634198.html>.
[493]TRIPS Agreement, art 31.
[494]Paul Hunt *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health - Annex: Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* UN Doc A/63/263 (11 August 2008) (hereinafter "*Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*") Guideline 26.
[495]"Remdesivir: Five Indian and Pakistani Firms to Make Drug to 'Fight Coronavirus'" *BBC News* (India 14 May 2020); Gilead Sciences "Gilead Sciences Announces Steps to Expand Availabilit of Remdesivir in India" (press release, 26 April 2021).; Hannah Balfour "Gilead to Support Indian Covid-19 Crisis with Donation of Remdesivir" *European Pharmaceutical Review* (online ed, 27 April 2021).

Gilead's voluntary licences program as the final status of its program, including the texts of the agreements, is unavailable. While companies are not obligated to be transparent as they operate as commercial entities aiming to generate profit, considering the significant role of pharmaceutical companies in ensuring a healthy life and preventing fatalities in critical circumstances, the lack of transparency prevents one from knowing in which countries medicines/vaccines are available and whether pricing affects accessibility. Thus, transparency plays a critical role in addressing distributional justice problems. The information concerning operations and projects provided by pharmaceutical companies is a part of responsible management of IP.[496] Gilead's licencing program, along with details about quantities and pricing strategies, can provide valuable insights for organisations aiming to enhance and facilitate access to medicine program.[497] In addition, if Gilead intends to expand production to meet global demand through generic companies, one may question why Gilead would refuse Russian companies to manufacture generics; why Gilead would sue the government for compulsory licence decision, or why they would not give up patent at least for the duration of the Covid-19 pandemic, as proposed by the Global South in the text of the TRIPS waiver. What Gilead calls to "control generic manufacturing" is "safeguarding against disruption of generic remdesivir"[498].

Clearly, one more time, a pharmaceutical company prioritises profits over people even though the voluntary licence scheme can be assessed as progressive. In fact, Gilead made it very clear their profit-first approach by initiating a lawsuit when the government used the flexibilities under their domestic law, which was in line with the TRIPS Agreement Article 31.[499] However, states have the obligation to provide equal access to health resources within their borders, and since everyone has the right to access the highest standard of physical and mental health, private entities should not undermine this fundamental aspect.[500] While states

[496]Marijn Vernoef "Which Information Matters Most? Transparency by Pharma that Builds Access to Medicine Plus Trust and Engagement" (2 October 2020) <Access to Medicine Foundation https://accesstomedicinefoundation.org/news/which-information-matters-most-transparency-by-pharma-that-builds-access-to-medicine-plus-trust-and-engagement#:~:text=Greater%20transparency%20brings%20direct%20benefits,can%20lead%20to%20new%20solutions.>.
[497]Vernoef, above n 496; *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*, Guideline 6.
[498]"Gilead Sciences Announces Steps to Expand Availability of Remdesivir in India" Gilead Sciences (press release, 26 April 2021).
[499]Civil Code of the Russian Federation Part 4 2006 (Russia), art 1360, art 1363; TRIPS Agreement, art 31.
[500]*General Comment No.25 (2020) on Science and Economic, Social and Cultural Rights (article 15(1) (b), (2), (3), and (4) of the International Covenant on Economic, Social and Cultural Rights)* at [83-84]: "States have extraterritorial obligations with regard to the full realization of the right to participate in and to enjoy the benefits of scientific progress and its applications. States parties also have an extraterritorial obligation to regulate and monitor the conduct of multinational companies over which they can exercise control, in order for the companies to exercise due diligence to respect the right to participate in and to enjoy the benefits of scientific progress and its applications, also when acting abroad."; *General Comment No.24 (2017) on State Obligations under the International Covenant on Economic, Social and Cultural Rights in*

may be the parties to the ICESCR, the responsibility for compliance rests with all members of the society, including businesses such as pharmaceuticals, as determined by the UN Office of the High Commissioner.[501] Business have also responsibilities to "respect the internationally recognised human rights of those affected by their by their activities", they should "avoid infringing on the human rights of others", they should avoid causing or contributing to adverse human rights impacts and address such impacts".[502] The Organisation for Economic Co-operation and Development ("OECD") Guidelines clarify that while states are obligated to protect human rights, like health, businesses also have responsibilities regardless of states' ability or willingness to meet these obligations and that they should not contribute to human rights violations.[503] More specifically, there are guidelines on human rights responsibilities for pharmaceutical companies in relation to access to medicines.[504] These guidelines state that pharmaceutical companies should integrate human rights considerations, pay particular attention to the needs of disadvantaged individuals, and respect the use of TRIPS flexibilities.[505]

The remdesivir example clearly demonstrates the inadequacy of TRIPS flexibilities compared to the strength given to the rights to patent holder (prevent others using it), thereby undermining fundamental human rights, despite the responsibilities of companies. In fact, patents should be exercised in a way that promotes the advancement of science and ensures access to its benefits[506], contrary to how companies practise in real life. While Gilead's claims concerning the order was not adopted in the conditions of extreme necessity as required by law were denied[507], it still bears a threat where flexibilities are used. It should also be noted that these issues were before the Ukraine invasion by Russia and before most countries applied sanctions. Furthermore, while the United States, where Gilead is based, and

---

the Context of Business Activities UN Doc E/C.12/GC/24 (10 August 2017) (hereinafter "*General Comment No.24 (2017) on State Obligations under the International Covenant on Economic, Social and Cultural Rights in the Context of Business Activities*").

[501]*Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)*, at [42].

[502]*OECD Guidelines for Multinational Enterprises on Responsible Business Conduct* (2023) (hereinafter "*OECD Guidelines*") at 14; at 25.

[503]*OECD Guidelines* at [41-48].

[504]Paul Hunt *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* UN Doc A/63/263 (11 August 2008).

[505]*Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*, at Guideline 1, Guideline 5, Guideline 26, Guideline 28.

[506]*General Comment No.25 (2020) on Science and Economic, Social and Cultural Rights (article 15(1) (b), (2), (3), and (4) of the International Covenant on Economic, Social and Cultural Rights)* at [60].

[507]"Russian Constitution, art 2, art 17, art 18, art 55; Federal Constitutional Law of 6 November 2020, art 5, art 16, art 24; Civil Code of the Russian Federation, art 1229, art 1360; Decree of the President of the Russian Federation of 23 May 1996 No. 763; Federal Law of 21 November 2011 No. 323-ФЗ "On the Basics of Health Protection of Citizens in the Russian Federation", art. 2; "Remdesivir": Decision of the Supreme Court of the Russian Federation 27 May 2021 – Case No. АКПИ21-303" (2021) 52(9) IIC Int Rev Ind Prop Copyr Law.

Russia has an investment treaty in force, the company sued the Russian compulsory licence decision in national court rather than bringing it as a claim under ISDS. Whether Gilead's patent would constitute an investment and whether Gilead has a right to bring an investment claim under ISDS are issues beyond this thesis. However, it is important to note that while an investment tribunal typically only orders compensation, a favourable outcome in domestic courts may safeguard the patent holder's rights, enabling them to maintain their monopoly, control and profitability in the respective market.

There have been other progressive steps taken by pharmaceutical companies concerning the treatment of Covid-19. Though, it is suggested that those were steps taken as a result of the pressure from the potential TRIPS waiver.[508] A royalty-free, voluntary licence was given to the UN-backed, non-profit foundation, Medicine Patent Pool ("MPP"), with an effective date of 26 October 2021 by MSD for molnupiravir, an oral drug for the treatment of Covid-19.[509] It was the first time a pharmaceutical company gave a licence to an international organisation to licence its product by publishing the agreement fully. While this was a very significant move in the pharmaceutical industry, a closer examination of the agreement underscores that there would be a long way to go to meet the needs of the global population quickly.

Through the licence agreement, MSD allowed MPP to grant non-exclusive sublicence to manufacturers to supply Covid-19 medicine in 105 low- and middle-income countries listed in Exhibit B.[510] So far 27 generic manufacturers from eleven different countries including Kenya, Pakistan, China, India have signed to manufacture molnupiravir to supply listed countries.[511] However, several countries which also have significant numbers of Covid-19 cases were excluded from receiving lower price generic products like Brazil, Thailand, Argentina, Russia, Turkey, Mexico, Peru and Colombia.[512] In fact, MSD left out half of the world's population from receiving generic cheaper products.[513] So those countries which are

[508]Thambisetty and others, above n 457, at 24-25.
[509]Merck Sharp & Dohme Corp. and Medicines Patent Pool Foundation License Agreement (signed and entered into force 26 October 2021) <https://medicinespatentpool.org/uploads/2021/10/2021-10-26-MPP-MSD-Head-license-Executed-agreement-1.pdf>.
[510]License Agreement between Merck Sharp & Dohme Corp and Medicines Patent Pool Foundation, Art 2.3; Art 2.4; at [29-31] < https://medicinespatentpool.org/licence-post/molnupiravir-mol> (hereinafter "MSD & MPP License Agreement").
[511]Medicines Patent Pool "27 Generic Manufacturers Sign Agreements with MPP to Produce Low-Cost Versions of COVIP-19 Antiviral Medication Molnupiravir for Supply in 105 Low-and- Middle- Income Countries" (20 January 2022) <https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir>.
[512]Othoman Mellouk "The Covid Treatment Pill is here- and Big Pharma will Ultimately Decide Who Gets it" *Guardian* (online ed, 20 February 2022).
[513]Medicines Sans Frontières "License between Merck and Medicines Patent Pool for global production of promising new Covid-19 drug Molnupiravir disappoints in its access limitations" (27 October 2021) <https://msfaccess.org/license-between-merck-and-medicines-patent-pool-global-production-promising-new-covid-19-drug>.

exempted from the MPP-MSD deal had to pay MSD's price $712/per course, instead of generic products price at $19,99/per course.[514] This serves as an example of the power held by patent holders and its unequal distribution effects on the society. Patent holders have the authority to set prices, even if the prices are significantly higher than the actual production cost, as exemplified by MSD's pricing practices. Moreover, they have the discretion to determine how much each country pays by disregarding certain countries through their decisions on licence agreements, as demonstrated by MSD's practice. Once more, this emphasises a profit-first approach undermines equal access to health, which is a practice contrary to international human right mechanisms.[515] While their efforts in granting licences to provide a supply to many countries can be appreciated, particularly when compared to other companies, it is important to be aware of the limitations explained here.

Furthermore, the agreement, in clauses 6.2(g) and 10.3(g), prevents any subsidiaries, affiliates, or sublicensees as well as MPP to "challenge the validity, enforceability or scope of any claim within the patent in a court or other governmental agency of competent jurisdiction, including in a re-examination or opposition proceeding".[516] MSD might be giving a voluntary licence to MPP to sublicence the oral drug, but the trade-off is that it prevents companies from challenging the patent. The no-challenge may be a common practice in pharmaceutical licencing agreements; however, they can be anti-competitive (competition would lower the cost) when they protect the invalid patent.[517] This is marked as the first example where MPP accepted such a condition to receive the voluntary licence, thereby giving up the use of a mechanism that could lower the prices.[518] It seems that MSD's progress still puts commercial interests first. Failure to reduce prices of the needed health products would hinder widespread availability, consequently affecting equal distribution, particularly during an emergency like Covid-19 pandemic. Before entering into a voluntary licence agreement with the MPP, MSD had had previously signed non-exclusive voluntary licence agreements with five Indian generic companies, all of which had WHO prequalified

[514]Make Medicines Affordable "MPP-Merck Molnupiravir License Reveals the Limits of Voluntary Measures During a Pandemic" (29 October 2021) <https://makemedicinesaffordable.org/mpp-merck-molnupiravir-license-reveals-the-limits-of-voluntary-measures-during-a-pandemic/>.
[515]ICESCR, art 12; UDHR, art 25; *General Comment No.25 (2020) on Science and Economic, Social and Cultural Rights (article 15(1) (b), (2), (3), and (4) of the International Covenant on Economic, Social and Cultural Rights)*; *General Comment No.24 (2017) on State Obligations under the International Covenant on Economic, Social and Cultural Rights in the Context of Business Activities*; *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)*.
[516]MSD & MPP License Agreement, art 6.2(g); art 10.3(g).
[517]Pedro Caro de Sousa, *Licensing of IP Rights and Competition Law* (OECD, DAF/COMP (2019)3, April 2019) at 23.
[518]Peter Beyer "Report of the Medicines Patent Pool Expert Advisory Group on the Proposed Licence Agreement with Merck Sharp& Dohme (MSD) on Molnupiravir" Medicines Patent Pool (25 October 2021) at 2.

manufacturing facilities.[519] The agreement between MPP and MSD can be considered as an expansion of those voluntary agreements to boost manufacturing. Yet, all these moves, considering the extent of the virus, can remain insufficient.

Following the MSD's move, Pfizer also signed a voluntary licence agreement with MPP on 16 November 2021 to sublicence the oral drug Paxlovid (nirmatrelvir + ritonavir) to the qualified manufacturers.[520] Similar to MSD's agreement, Pfizer's agreement was royalty-free until WHO declared an end to the Covid-19 health emergency.[521] The price of Paxlovid (combination of nirmatrelvir and ritonavir) for a five-day course, as required, costs around $530 per patient.[522] Through the sublicence agreements, it is expected that prices will be lowered. At the time of the writing of this thesis, 36 generic manufacturers in 13 different countries including Ukraine, Pakistan, China, Bangladesh, Brazil, Vietnam have signed the agreement to supply nirmatrelvir with ritonavir to the listed 95 countries.[523] Pfizer excluded 17 countries from the listed countries, which is more than MSD did.[524] The countries listed as eligible to receive generic production in Pfizer's agreement constitute 53% of the world's population. Yet again, it is only half of the world population, which could be considered disappointing taking into consideration the number of infected people globally. Not long after Pfizer's deal with MPP, on 22 April 2022, WHO recommended Paxlovid best therapeutic solution for patients who have mild and moderate symptoms and are at a high risk of hospitalisation.[525] The WHO requested Pfizer to enlarge the geographical scope of MPP's licence agreement, ensure a transparent deal and pricing policies, and allow more generic companies to manufacture for faster dissemination.[526] The transparency request from WHO

[519]"Merck Signs Deals with Five Indian Firms to Boots supply of oral Covid-19 Drug" *Pharmaceutical Technology* (online ed, 28 Aril 2021).
[520]Licence Agreement between PF Prism Holdings B.V and Medicines Patent Pool Foundation (signed and entered into force 15 November 2021) <https://medicinespatentpool.org/licence-post/pf-07321332>.
[521]Licence Agreement between PF Prism Holdings B.V and Medicines Patent Pool Foundation, Art.7.3. <https://medicinespatentpool.org/licence-post/pf-07321332>.
[522]Carl Zimmer and Rebecca Robbins "Pfizer's Covid Pill Works Well, Company Confirms in Final Analysis" *The New York Times* (online ed, 14 December 2021).
[523]"Update: Ukrainian company Darnitsa signs sublicence agreement with MPP bringing to 36 the number of generic manufacturers to produce generic versions of Pfizer's oral Covid-19 treatment" *Medicines Patent Pool* (online ed, 22 March 2022)<https://medicinespatentpool.org/news-publications-post/update-ukrainian-company-darnitsa-signs-sublicence-agreement-with-mpp-bringing-to-36-the-number-of-generic-manufacturers-to-produce-generic-versions-of-pfizers-oral-covid-19-treatment>.
[524]Kerry Cullinan "Pfizer and Medicines Patent Pool Reach 'Ground-breaking' Voluntary Licensing Deal for New COVID-19 Treatment Pill" (16 November 2021) Health Policy Watch <https://healthpolicy-watch.news/pfizer-and-medicines-patent-pool/>.
[525]World Health Organization "WHO recommends highly successful COVID-19 Therapy and Calls for wide Geographical Distribution and Transparency from Originator" (22 April 2022) <https://www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator>.
[526]"WHO recommends highly successful COVID-19 Therapy and Calls for wide Geographical Distribution and Transparency from Originator", above n 525.

holds significance in obtaining actual and accurate data regarding the availability of pills and their distribution, including information on pricing. This allows gathering information about how expensive the products are, what the prices' impacts on access, and which countries and locations have limited access to generic products.

As mentioned above, in Chapter 3.2.4., at the very beginning of the pandemic, Labrador Diagnostics, owned by Fortress Investment Group, filed a lawsuit against Biofire and its parent company Biomerieux, which were working on Covid-19 tests due to infringement of two Theranos patents (was bought in 2017). After Biomerieux's headquarter announced the lawsuit brought by the Fortress subsidiary, Labrador announced that they were not aware that the defendants were working on Covid-19 and that they were going to issue royalty-free licences to be used in tests related to Covid-19.[527] This is another example of how patents can impede further technological development.

Subsequent to the discussion on therapeutics and medicines for the treatment to Covid-19, the following part of this section looks into concerns about Covid-19 vaccine to showcase unequal distribution. Unfortunately, very few positive initiatives have been taken by pharmaceutical companies to enhance production. Concerns about access to vaccines appear to be even more dramatic when one considers the efforts of patent holders to boost production. Unequal vaccine distribution and "vaccine nationalism" have been seen since December 2020, when the first vaccine was delivered.[528] Intellectual property rights and pharmaceutical' controls over products have been playing a critical role in this inequality despite the high number of cases and death.

3.2.6.4. Covid-19 Vaccines

Throughout the Covid-19 pandemic, high-income countries, most of the time the Global North, stocked up on vaccines beforehand by paying whatever price had been decided by pharmaceutical companies even though manufacturing was limited.[529] Patent protection gives power to pharmaceutical companies to limit production and freedom to decide vaccine prices. Countries blocked each other's supply at a time there was a scarcity of products: January

[527]Richard Llyod "After Theranos suit, Fortress makes Patent available on Royalty-Free Basis for COVID-19 Tests" (17 March 2020) IAM <https://www.iam-media.com/article/after-theranos-suit-fortress-makes-patents-available-royalty-free-basis-covid-19-tests>.; Anna Holmes "A company that bought Theranos' Patents is using them to sue a health Start-up Working on coronavirus tests" (18 March 2020) Insider <https://www.businessinsider.com/theranos-patents-fortress-labrador-diagnostics-lawsuit-biofire-coronavirus-tests-2020-3?r=US&IR=T>.
[528]Siva Thambisetty and others, above n 457, at 2.
[529]Mehr Muhammad Adeel Riaz and others "Global Impact of Vaccine Nationalism during COVID-19 Pandemic" (2021) 49(1) Tropical Medicine and Health 101at 101.

2021, the EU threatened AstraZeneca to block the export of vaccines to non-European countries[530]; in April 2021, the European Union blocked the 250,000 vaccines that were supposed to be sent to Australia[531]. So, at the very beginning of the vaccination process, Western countries had a battle to get share from the limited product supply, they followed a "me first" approach rather than need approach. Eventually, the Global North secured more than half of the global supply before the end of 2020, which means that the first products were secured for only 14% of the population in the world.[532]

Vaccination data shows that inequality has existed among nations and that most vaccinated states have been in the Global North, except for a very few Global South countries. Even four years after the administration of the first vaccine, only 70% of the world population has received at least one dose of the vaccine.[533] While most people in the Global South have not even received their first doses, the countries which purchased much more vaccines than they needed have been throwing vaccines away as they expire.[534] Such an example was seen when the United Kingdom threw away 600,000 of doses AstraZeneca, the United States discarded 82,1 million doses and Canada wasted more than half of their AstraZeneca doses.[535] One might question the reasons behind this situation. While it is not difficult to assume that production capacity is insufficient, the global patent system further limits the process. Patent holders have the power to control production and prices, and there are challenges in using flexibilities under the TRIPS Agreement, as explained in Chapter 3.2.3., and further identified in the following chapters handling investment protection of patents.

On the one hand, some parts of the world have not even received their first doses; on the other hand, high-income countries have been able to stock vaccines and then they have been throwing excessive stocks away. While this has been the situation in the case of Covid-19 patents, pharmaceutical companies (by sharing knowledge, providing royalty-free voluntary

[530]Daniel Boffey "EU threatens to block Covid Vaccine Exports amid AstraZeneca Shortfall" *Guardian* (online ed, Brussels, 25 January 2021).
[531]Daniel Hurst, Paul Karp and Christopher Knaus "Scott Morrison calls on European Union to supply outstanding AstraZeneca Covid vaccine doses" *Guardian* (online ed, 7 Wednesday 2021).
[532]Deborah Gleeson and Brigitte Tenni "While Australians line up for COVID-19 boosters, low vaccination rates in poor countries continue to cost lives" *Conversation* (online ed, 18 July 2022).
[533]Our World in Data "Coronavirus (COVID-19) Vaccinations" <https://ourworldindata.org/covid-vaccinations>.
[534]David Goldman Alabama Just Tossed 65,000 Vaccines. Turns Out It's Not Easy To Donate Unused Doses" *NPR* (online ed, 10 August 2021) <https://www.npr.org/sections/goatsandsoda/2021/08/10/1025463260/alabama-just-tossed-65-000-vaccines-turns-out-its-not-easy-to-donate-unused-dose?t=1659105449311>.
[535]Samuel Lovett "An absolute scandal': UK threw away 600,000 vaccine doses after they passed expiry date" *Independent* (online ed, 15 November 2021); Joshua Eaton "The U.S. has wasted over 82 million Covid vaccine doses" *NBC News* (online ed, 6 June 2022); Saba Aziz "With Millions of Covid-19 Doses Wasted, Has Canada Kept its Donation Promises?" *Global News* (online ed, 9 December 2022).

licences) and high-income countries (under the WTO as discussed above), Global North, have made limited effort to enhance production and ensure equal distribution. Countries ignored extraterritorial human rights obligations to others, as rooted in human rights documents. The UDHR Article 1 states that "…should act towards one another in a spirit of brotherhood.".[536] More directly, ICESCR Article 2 states that "Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation…"[537] and Article 12 requires that "...the steps to be taken by the States parties to the present Covenant to achieve the full realization of this right shall…".[538] The importance of international assistance and cooperation is further highlighted by the UN Special Rapporteur to ensure timely response to pandemics globally.[539] In addition to that, pharmaceutical companies prioritised selling products at a high price without considering the needs of countries.[540] This practice undoubtedly undermines principles of global justice and equality in accessing health resources, which contradicts the human right to life, to health, to enjoy a life with dignity[541], responsible business practice[542], and the theory that investors are encouraged to innovate and make their inventions available to society. In fact, it jeopardises the social function of patent.

Whereas AstraZenaca has sold its products at a production cost to the European Union, as European Union invested in, low-income Global South countries have paid higher price for the same vaccine since the beginning.[543] Likewise, Pfizer and Moderna have increased their prices since their vaccines have proven effective.[544] However, this increase means that it is even more difficult for some countries to purchase the product. As previously noted, businesses, more specifically pharmaceutical companies, also have obligations concerning human rights. They must avoid contributing to any human rights violations; if such violations

[536]UDHR art 1,
[537]ICESCR art 2 (1)
[538]ICESCR art 12(2)
[539]*Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)* at [45]; *Committee on Science and Economic, Social and Cultural Rights Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights* UN Doc E/C.12/2020/1 (17 April 2020) at [23].
[540]Siva Thambisetty and others, above n 457, at 7; Rebecca Robbins "Analysis: Moderna, Racing for Profits, Keeps COVID Vaccine Out of Reach of Poor" *Next Billion* (online ed, 13 October 2021).
[541]ICCPR, art 6; *Report of the Covenant on Civil and Political Rights Human Rights Committee for 2019 General comment No. 36 on Article 6: Right to Life* UN Doc CCPR/C/GC/36 (3 September 2019) at [26].
[542]*OECD Guidelines*; *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines*.
[543]Carmen Paun and Ashleigh Furlong "Poorer countries hit with higher price tag for Oxford/AstraZeneca vaccine" *Politico* (online ed, 22 February 2021).
[544]Donato Paolo Mancini, Hannah Kuchler and Mehreen Khan "Pfizer and Moderna raise EU vaccine prices" *Financial Times* (online ed, 1 August 2021).

occur, they are obligated to address them.[545] Pharmaceutical companies have further responsibilities regarding their pricing mechanism. They need to ensure that their products are affordable to as many people as possible and that individuals with socio-economic disadvantages can access necessary resources[546], in contrast to the practices of AstraZeneca, Pfizer, or Moderna. As highlighted by the UN Special Rapporteur, "lower prices do not necessarily mean lower profit".[547] As WHO head, Tedros Adhanom Ghebreyesus, said: "we see a two-track pandemic"[548]. All these examples highlight the significant power conferred by the patent system which empowers the patent owner to commercialise the product as they wish without taking into account its implications on society.

The collaboration between pharmaceutical companies and countries have been very limited. The Biden administration brought two rivals, Merck and J&J, together to boost one shot J&J vaccine, for the United States only.[549] It was announced that the Biden administration would provide $268.8 million to Merck to upgrade their manufacturing facilities to satisfy the safety standards of the productions.[550] A similar arrangement was made with Sanofi to supply vaccine to Europe.[551] J&J also made a "fill and finish" (finish stage of the manufacturing process) deal with Aspen in South Africa; however, the vaccines filled and finished in South Africa were shipped to Europe even though people in Africa had been vaccinated significantly less than Europe.[552] As it is put very appropriately, it is a "neo-colonial approach"[553] of Europe. In addition to their neo-colonial approach, they also jeopardised the

[545]*OECD Guidelines* Chapter IV; *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* Guideline 1, Guideline 2, Guideline 5.
[546]*Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* Guideline 33 and Guideline 34.
[547]*Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* at 23.
[548]"WHO's Tedros says COVID-19 Vaccine Inequity Creates 'Two-Track' Pandemic" (8 June 2021) Reuters.
[549]Christopher Rowland and Laurie McGinley "Merck will help make Johnson & Johnson Coronavirus Vaccine as Rivals team up to help Biden accelerate shots" *The Washington Post* (3 March 2021).
[550]"Why We're Excited to Partner on Johnson & Johnson's COVID-19 Vaccine" (10 March 2021) <https://www.merck.com/stories/why-were-excited-to-partner-on-johnson-and-johnsons-covid-19-vaccine/>; Kevin Dunleavy "Merck plant in Durham, N.C. gets $105M to upgrade for J&J Vaccine Production" (11 March 2021) Fierce Pharma <https://www.fiercepharma.com/manufacturing/merck-plant-durham-n-c-set-to-produce-bulk-substance-for-j-j-vaccine#:~:text=Manufacturing,Merck%20plant%20in%20Durham%2C%20N.C.%20gets%20%24105M,upgrade%20for%20J%26J%20vaccine%20production&text=On%20Wednesday%20afternoon%20President%20Joe,million%20shots%20from%20the%20drugmaker>.
[551]David Meyer "Its COVID-19 Vaccine Bogged down in trials, Sanofi to Manufacture BioNTech/Pfizer Doses" *Fortune* (11 September 2021); "Sanofi to Provide Manufacturing Support to Johnson& Johnson for their COVID-19 Vaccine to Help Address Global Supply Demands" (press release, 22 February 2021) <https://www.sanofi.com/en/media-room/press-releases/2021/2021-02-22-10-40-00-2179318>; Eric Sagonowsky "After Pfizer deal, Sanofi offers a hand to Johnson& Johnson for COVID-19 vaccine production" (22 February 2021) <https://www.fiercepharma.com/pharma/after-pfizer-deal-sanofi-offers-a-hand-to-johnson-johnson-for-covid-19-vaccine-production>.
[552]Gordon Brown "The World is Making Billions of Covid Vaccine Doses, so Why is Africa Not Getting Them?" *Guardian* (16 August 2021)
[553]Brown, above n 552.

global supply by pausing the production of the vaccine in Leiden in late 2021, at a time when many Global South countries were in need of the vaccine.[554]

Other pharmaceutical companies have also made some arrangements with countries in the Global South. Pfizer/BioNTech made a "fill and finish" deal with Biovac in South Africa to manufacture around 100 million doses a year for Africa.[555] It was aimed to start manufacturing towards the second half of 2022.[556] BioNTech and Sanofi also reached an agreement that would Sanofi to access BioNTech's infrastructure and expertise to help BioNTech to manufacture over 125 million doses for Europe while Sanofi would continue developing a vaccine together with GSK.[557] Another fill and finish contract was also signed by Pfizer/BioNTech with Novartis to produce 50 million doses in 2021 and more than 24 million doses in 2022.[558] Once more, these are outcomes of the patent system, which allows holders to determine how to commercialise/licence their products and conditions. It is significant to remind that these are voluntary arrangements rather than the use of TRIPS flexibilities by states, like compulsory licence.

Along with the agreements mentioned above, BioNTech has signed a joint venture agreement with Fosun Pharma in China to manufacture and sell an mRNA vaccine named Comirnaty/BNT162b2 in China.[559] According to the deal, Fosun Pharma commercialises the product in China; whereas, BioNTech keeps full rights to the development and commercialisation of the product globally.[560] Furthermore, Fosun Pharma agreed to pay $135 million up-front to BioNTech for any potential future investment and milestone payment,

[554]Zachary Snowdon Smith "Johnson& Johnson Reportedly Pauses Covid Vaccine Production Despite Sharp Need in Developing Countries" *Forbes* (9 February 2022); Fraiser Kansteiner "J&J pauses COVID-19 vaccine production at Dutch plant in temporary pivot to RSV shot: NYT" (8 February 2022) Fierce Pharma <https://www.fiercepharma.com/manufacturing/j-j-temporarily-freezes-covid-19-vaccine-production-at-key-leiden-plant-report>.

[555]Reuters "South African Firm to Help make Pfizer/BioNTech COVID Vaccine" (22 July 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/pfizerbiontech-strike-south-africa-covid-19-manufacturing-deal-with-biovac-2021-07-21/>.

[556]Above n 555; Reuters "South Africa's Biovac to Start Making Pfizer- Biontech COVID-19 vaccine in early 2022" (7 December 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/south-africas-biovac-start-making-pfizer-biontech-covid-19-vaccine-early-2022-2021-12-06/>.

[557]Sanofi "Sanofi to Provide Support to BioNTech in Manufacturing their COVID-19 Vaccine to help Address Public Health needs" (press release, 27 January 2021); Sanofi "Sanofi- GSK Next Generation COVID-19 Booster Delivers Strong Immune Response against Variants of Concern, including Omicron" (press release, 13 June 2022); Sagonowsky, above n 551.

[558]Novartis "Novartis Signs New Initial Agreement with BioNTech to Support Fill and Finish of the mRNA Pfizer-BioNTech COVID-19 Vaccine" (21 October 2021) <https://www.novartis.com/news/media-releases/novartis-signs-new-initial-agreement-biontech-support-fill-and-finish-mrna-pfizer-biontech-covid-19-vaccine>.

[559]Angus Liu "BioNTech, Fosun Pharma eye 1B doses of COVID-19 Vaccine Capacity with new China JV" (10 May 2021) Fierce Pharma <https://www.fiercepharma.com/manufacturing/biontech-fosun-pharma-eye-1b-doses-covid-19-vaccine-capacity-new-china-jv>.

[560]BioNTech "BioNTech and Fosun Pharma form COVID-19 Vaccine Strategic Alliance in China" (press release, 16 March 2020).

while future profits from vaccine sales in China will be shared.[561] The agreement appears to be a mere business deal aimed at expanding the product geographically, rather than prioritising the emergency and availability of the product. Certainly, holding a patent is the primary source behind such agreements.

AstraZeneca was one of the first Covid-19 vaccines to use a viral vector similar to J&J vaccine. As a result of blood clots from the vaccine that cause death in very rare circumstances, some countries moved away from the vaccine, either donating or throwing away like Canada.[562] Still, it has been considered one of the most effective vaccines.[563] AstraZeneca has signed a voluntary agreement with Serum Institute of India to boost supply in India as well as other large number of Global South countries.[564] The licence covers countries such as India, Bangladesh, or Nepal while excluding countries like the United Kinngdom or Europe where AstraZeneca itself provides vaccines.[565] Similarly, in September 2020, AstraZeneca reached a technological order agreement with Fiocruz in Brazil, followed by a technology transfer agreement in June 2021 to provide more affordable vaccines for Brazil.[566] Production started in July 2021 and the first doses were ready in February 2022.[567] This can be considered as a positive step considering the geographical expansion of the vaccine. Yet, it should be reminded once more that the decision ultimately lies within the power of patent holders.

Moderna is another mRNA vaccine that has 94.1% efficacy.[568] As far as it is known, Moderna has not signed any voluntary licencing agreement while providing vaccines to the COVAX initiative.[569] In fact, the United States government urged the company to act to supply more

[561]"BioNTech and Fosun Pharma form COVID-19 Vaccine Strategic Alliance in China", above n 560.
[562]"More than half of Canada's AstraZenaca vaccine doses expired, will be thrown out" *CTV News* (online ed, Canada, 6 July 2022).
[563]World Health Organisation "The Oxford/AstraZeneca COVID-19 Vaccine: What you Need to Know" (13 June 2022) <https://www.who.int/news-room/feature-stories/detail/the-oxford-astrazeneca-covid-19-vaccine-what-you-need-to-know>.
[564]AstraZeneca "Serum Institute of India Obtains Emergency Use Authorisation in India for AstraZeneca's COVID-19 vaccine" (press release, 6 January 2021).
[565]Fraiser Kansteiner "U.K. inspects AstraZeneca vaccine partner's India manufacturing, setting stage for supply boost" (16 February 2021) Fierce Pharma <https://www.fiercepharma.com/manufacturing/serum-institute-india-up-for-british-audit-as-astrazeneca-looks-to-boost-covid-19>.
[566]"Fiocruz Releases first 100% Brazilian COVID-19 Vaccine" Fiocruz (press release, 22 February 2022); MSF "MSF welcome Fiocruz's step Towards Transparency of AstraZenaca Deal" MSF (press release, 3 November 2020).
[567]"Fiocruz Releases first 100% Brazilian COVID-19 Vaccine", above n 566.
[568]World Health Organisation "The Moderna COVID-19 Vaccine: What you need to Know" (18 August 2022) <https://www.who.int/news-room/feature-stories/detail/the-moderna-covid-19-mrna-1273-vaccine-what-you-need-to-know>.
[569]Gavi "Gavi and Moderna Reach Agreement for Additional Supply to COVAX" (10 December 2021) <https://www.gavi.org/news/media-room/gavi-and-moderna-reach-agreement-additional-supply-covax>.

doses to the world through the COVAX initiative.[570] Moderna reached a deal to send 110 million doses to the Africa Union.[571] In the first quarter of 2022, the company announced that it was not going to initiate any patent dispute over its Covid-19 vaccine in 92 low- and middle-income countries which were selected by the COVAX mechanism (except South Africa).[572] Moderna further announced that it was going to build a $500 million mRNA vaccine hub in Kenya to enhance its products for low- and middle-income countries[573]. The hub aims to supply up to 500 million doses yearly.[574] While these are positive developments and align with responsible business, they remain limited, considering the existence of over 15.000 patents related to mRNA vaccines worldwide.[575]

Some collaborations through voluntary licensing and donations have been made by pharmaceutical companies or Western countries, as exemplified earlier. Unfortunately, these examples demonstrate that companies have a very strong power to control licences through patent protection, a power that they have chosen to exercise even during a pandemic. However, given the world population and vaccination rates, these initiatives have been limited. This situation raises questions about whether the power or reward that is provided through the patent system are justifiable[576], particularly as insufficiency was experienced during an exceptional event; the validity of system becomes even more questionable in other emergencies or domestic health problems. Even though the first vaccine was administrated in December 2020, only 67% of the population was fully vaccinated as of 26 November 2023 and 7,031,216 people died from coronavirus by 11 February 2024.[577] An average of 2.500 people died daily.[578] Moreover, according to Oxfam, the number of deaths in low-income countries is four times more than the number of deaths in high-income countries, mainly those in the Global North.[579] It is apparent that these collaborations did not progress as

[570]Peter Sullivan "Biden official warns Moderna to 'step up' on vaccine doses for the world" *The Hill* (online ed, 13 October 2021).
[571]Kevin Dunleavy "Moderna, amid mounting pressure to address vaccine inequality, says it's working on new COVAX deal" (16 November 2021) <https://www.fiercepharma.com/pharma/under-pressure-moderna-talks-to-pledge-covid-19-vaccines-to-poor-countries-report>.
[572]Ashleigh Furlong "Moderna to Share Vaccine tech, Commits to Never Enforce COVID-19 Jab Patents" *Politico* (online ed, 8 March 2022).
[573]Furlong, above n 572.
[574]Furlong, above n 572.
[575]Amy Maxmen "The WHO's Push for Global mRNA Vaccine Access: Will the WHO hub Realise its Vision Before the Next Global Health Crisis?" (26 February 2024) Think Global Health <https://www.thinkglobalhealth.org/article/whos-push-global-mrna-vaccine-access>.
[576]Sigrid Sterckx "Patents and Access to Drugs in Developing Countries: An Ethical Analysis" in Michael J.Selgelid Thomas Pogge (ed) *Health Rights* (Routledge, London, 2016) 297 at 303.
[577]"WHO Covid-19 Dashboard" <https://data.who.int/dashboards/covid19/deaths?n=c>.
[578]"WHO Covid-19 Dashboard", above n 577.
[579]OXFAM International "COVID-19 Death toll Four times Higher in Lower- Income Countries than Rich One" (press release, 3 March 2022).

quickly as they could have if the patent law system had provided more flexibility, lower patent protection, or if there had been less political pressure on countries. However, it should be noted once more that this thesis acknowledges other barriers related to Covid-19 vaccines distribution as well, like logistics.

In addition to collaborations, there were instances of lack of cooperation concerning Covid-19 vaccines. Voluntary licence requests from several generic companies, both from the Global South and the North, have been refused by big pharmaceutical companies.[580] Biolyse, a Canadian company, Incepta from Bangladesh, Teva in Israel, and Bavarian Nordic in Denmark were unable to persuade the Covid-19 vaccine developers to collaborate.[581] It is unfortunate that these companies, which were ready to support global vaccine production for those in need, were not able to contribute. Following J&J's refusal voluntary license, Bolivia notified the WTO of its intention to purchase a generic version of the J&J vaccine from Biolsye in February 2021 and Biolyse announced its interest in exporting vaccines to the government of Bolivia as well as other countries in need in March 2021.[582] There had been no sign from the Canadian government regarding the issuance of a compulsory license, a Global North country, which did not support the TRIPS waiver (the TRIPS waiver is designed to accelerate access to vaccines in response to the Covid-19 pandemic for a certain duration) due to the existing flexibilities such as a compulsory license (a system already in place under the TRIPS Agreement to give authority to a third party to make, use, or sell the invention, in exchange for remuneration).[583] This exemplifies the complexities of compulsory license system and highlights how it can remain unused even in times of urgent need. Canada's lack of response to this request contradicts with its claim that the TRIPS flexibilities were functioning as intended.[584] One can speculate if one of the elements of the Canadian government's stance was driven by a fear of facing an investment claim, particularly given its previous experience with the *Eli Lilly v Canada* case.

So far, this thesis has addressed how pharmaceutical practices have affected the access to health resources related to diagnosis, treatment, and prevention during the Covid-19

[580]Ashleigh Furlong "Big vaccine makers reject offers to help produce more jabs" *Politico* (online ed, 14 May 2021).
[581]Furlong, above n 580.
[582]Muhammed Zaheer Abbas "Canada's Political Choices Restrain Vaccine Equity: the Bolivia- Biolyse Case" (South Centre, 136, September 2021) at 9.
[583]At 6.
[584]At 6.

pandemic. The following section delves into the litigations between pharmaceutical companies about patents in an effort to preserve their monopoly and control.

3.2.6.5. Pharma Litigations

Along with those collaborations between states or companies, several disputes have also arisen between companies in the days of Covid-19. Pharmaceutical companies have been seeking their shares of the substantial profits from the sale of the vaccines by litigating their competitors for patent infringement, with the goal of securing royalties. Pfizer/BioNTech and CureVac, for instance, have been engaged in legal battles in the United States and Germany.[585] Similarly Pfizer/BioNTech has also been involved in patent disputes with Moderna in various countries, including the United States, Germany, Netherlands, the United Kingdom and Ireland.[586] Furthermore Moderna has involved in patent disputes with Arbutus and Genevant[587], Alnylam has initiated lawsuit against both Moderna and Pfizer/BioNTech.[588] It is not possible to delve into the details of each lawsuit here and neither is that the task of this thesis. The purpose here is to highlight the patent fights between rivals to show that a patent serves more than its incentive function. Instead, patents are used to generate substantial profits, even during a pandemic time, when lives are at stake and extensive vaccination is urgently needed. Rather than prioritizing sharing knowledge and technology, pharmaceutical companies focus on maximising their own benefits and profits.

---

[585]CureVac "CureVac Files Patent Infringement Lawsuit in Germany Against BioNTech" (press release, 5 July 2022); Kevin Dunleavy "CureVac's Patent Infringements Case against BioNTech has $500 M of 'Potential Upside': Analyst" (12 July 2022) Fierce Pharma <https://www.fiercepharma.com/pharma/curevacs-patent-infringement-case-against-biontech-has-500-million-potential-upside-analyst>; "BioNTech, Pfizer Sue Curevac in U.S. Over COVID-19 Vaccine Patent Claims" *U.S. News* (online ed, 26 July 2022); Phil Taylor "BioNTech Wins Round in CureVac mRNA Patent Dispute" (20 December 2023) Pharmaphorum <https://pharmaphorum.com/news/biontech-wins-round-curevac-mrna-patent-dispute#:~:text=Shares%20in%20CureVac%20have%20plummeted,COVID%2D19%20vaccines%20was%20invalid.>; Marisa Woutersen "BioNTech Wins Latest Round in Covid-19 Patent Clash" (21 December 2023) LSIPR <https://www.lifesciencesipreview.com/big-pharma/biontech-wins-latest-round-in-covid-19-patent-clash-5328>.

[586]Zoey Becker "Clash of the titans: Moderna Sues Pfizer, BioNTech for mRNA Patent Infringement" (26 August 2022) Fierce Pharma <https://www.fiercepharma.com/pharma/clash-titans-moderna-sues-pfizer-and-biontech-patent-infringement>; Fraser Kansteiner "Moderna Mounts 2 New Patent Lawsuits Against mRNA Rivals Pfizer, BioNTech: Report" (11 July 2023) Fierce Pharma <https://www.fiercepharma.com/pharma/covid-vaccine-patent-war-heats-moderna-mounts-additional-infringement-lawsuits-against>; Zoey Becker "Moderna Loses a Covid Vaccine Patent in Europe Amid Heated Clash with BioNTech, Pfizer" (21 November 2021) < https://www.fiercepharma.com/pharma/covid-19-patent-war-rages-biontech-win-moderna-european-patent-ruled-invalid>; Blake Brittain "Pfizer, BioNTech Countersue Moderna over Covid-19 Vaccine Patents" (2 December 2022) < https://www.reuters.com/legal/pfizer-biontech-countersue-moderna-over-covid-19-vaccine-patents-2022-12-05/>.

[587]Fraiser Kansteiner "Moderna Mounts Defense in Covid-19 Vaccine Patent Feud with Arbutus, Gevenant" (10 May 2022) Fierce Pharma <https://www.fiercepharma.com/pharma/moderna-mounts-defense-covid-19-vaccine-patent-feud-arbutus-genevant>; Zoey Becker "Moderna Nabs a Win in Arbutus Patent Case as Appeals Court Upholds Prior Invalidation" (12 April 2023) <https://www.fiercepharma.com/pharma/moderna-prevails-again-over-arbutus-appeals-court-upholds-2018-decision-strike-arbutus>.

[588]Zoey Becker "Alnylam Sticks with Aggressive Litigation Strategy against Pfizer and Moderna, filing yet another Patent Lawsuit" (30 May 2023) <https://www.fiercepharma.com/pharma/alnylam-hopes-third-times-charm-another-covid-19-vaccine-suit-against-pfizer-moderna>; Zoey Becker "Alnylam to Appeal Covid-19 Vaccine Patent Ruling in Moderna Case" (28 August 2023) <https://www.fiercepharma.com/pharma/alnylam-appeal-covid-19-vaccine-patent-ruling-moderna-case>.

One of the opposing views to the incentive-based approach is that inventors themselves do not receive the royalties, but they generally licence them to big companies. Thus, they are not always the ones who are compensated for their work in sales. An example of this was Moderna's applications which excluded some scientists from being co-inventors of their work and offered then only co-ownership with negotiable conditions.[589] Moderna's Covid-19 vaccine was developed through public/private collaborations by scientists at Moderna as well as the United States National Institutes of Health (NIH).[590] However, according to NIH, when Moderna filed several patent applications with the United States Patent and Trademark Office, three scientists from NIH who were co-inventors were left out.[591] Pursuant to Public Citizen analysis, only one out of four applications refer to only one of the scientists from NIH.[592] The co-inventor status of NIH scientists would mean that government would be able to licence the patent in question, and the government would be able to receive shares from the loyalties and be able to recoup the investment they made from taxes of citizens.[593] The battle of patent co-ownership or co-investors between Moderna and NIH shows that the United States has fallen under its own Western inventiveness imposition since its own governmental research agency itself seems to be left behind by a major United States based pharmaceutical company. What was experienced by the NIH scientists is one of the arguments voiced against the Western incentive-based or natural rights approach. Often, inventors licence their inventions to their employer or the big pharmaceutical companies, so they may not even receive the loyalty in return for their labour or their work as an incentive.

While the leading Covid-19 vaccine manufacturers have been dealing with patent disputes, they have been reluctant to give voluntary licences and share their technology and knowledge for the sake of equal distribution of vaccines. And yet, most of the time, vaccines were funded by the government, citizens' taxes, or most of the time, funding risks are undertaken by universities or governments as was the case of several Covid-19 vaccines,

[589]Heidi Ledford "What the Moderna- NIH COVID Vaccine Patent Fight Means for Research" (30 November 2021) Nature <https://www.nature.com/articles/d41586-021-03535-x>.
[590]Ledford, above n 589; William Honaker "NIH's fight for Ownership of Moderna's COVID-19 Patent Highlights Hazards of Business Collaborations (31 March 2022) IP Watch Dog <https://www.ipwatchdog.com/2022/03/31/nihs-fight-ownership-modernas-covid-19-patent-highlights-hazards-business-collaborations/id=148040/#>.; Kevin Dunleavy "Moderna, U.S. clash in patent dispute over origins of COVID-19 vaccine: report" (10 November 2021) Fierce Pharma <https://www.fiercepharma.com/pharma/moderna-u-s-clash-patent-dispute-over-development-covid-19-vaccine-report>.
[591]Honaker, above n 590.
[592]Dunleavy, above n 590.
[593]Dunleavy, above n 590; Ledford, above n 589.

Oxford/AstraZeneca, Moderna and BioNTech.[594] In fact, it is reported by kENUP that in 2020, more than €93bn was spent on Covid-19 vaccines as well as therapeutics by public sectors, and more than 95% of these amounts were allocated to vaccines[595], which shows that companies are reluctant to share their technologies and are instead focused on maximising their profits. Another research conducted by the Knowledge Network on Innovation and Access to Medicine shows that most of the research and development of vaccines source was obtained through the governments.[596] More than 97% of the funding for the research and development of the Oxford/AstraZeneca vaccine was provided by taxpayers or charities like the United Kingdom government, British and American scientific institutes, the European Commission and different charities such as Wellcome Trust.[597] Similarly, the United States government funded almost all research and development, with $10 billion, of the Moderna vaccine, which was developed together with NIH scientists.[598] Likewise, BioNTech obtained more than $445 million from the German government for its vaccine development.[599] Given the examples of how pharmaceutical companies funded their research in cases of urgent need like Covid-19 vaccines and how they still prioritised profit despite receiving funding from other sources, it becomes plausible that relying solely on an incentive-based approach without considering human rights obligations of pharmaceutical companies is not the right approach for the arrangement of the global patent system. The patent system, functioning as a reward mechanism, is connected to sales volume[600], as notably experienced in the Covid-19 pandemic, when pharmecutiacal companies rapidly developed vaccines in response to global demand. As Pogge highlights, this widens the gap between high-income and low-income

[594]Micheal Safi "Oxford/AstraZeneca Covid Vaccine Research 'was 97% Publicly Funded'" *Guardian* (online ed, 15 April 2021).
[595]Businesswire "Governments Spent at Least €93bn on COVID-19 Vaccines and Therapeutics During the Last 11 Months" (11 January 2021) <https://www.businesswire.com/news/home/20210110005098/en/Governments-Spent-at-Least-€93bn-on-COVID-19-Vaccines-and-Therapeutics-During-the-Last-11-Months>.
[596]Knowledge Portal on Innovation and Access to Medicines "Covid-19 Vaccine R&D Investments" (8 July 2021) <https://www.knowledgeportalia.org/covid19-r-d-funding>.
[597]Safi "Oxford/AstraZeneca Covid Vaccine Research 'was 97% Publicly Funded'", above n 594.
[598]Bob Herman "Biden admin warns Moderna to "Step-Up" Global Vaccine Supply" (14 October 2021) AXIOS <https://www.axios.com/2021/10/13/covid-vaccine-moderna-biden-global-supply-covax>.
[599]*A Double Dose of Inequality* (Amnesty International, POL 40/4621/2021, 22 September 2021) at 53. The tax paid by BioNTech from its global COVID-19 vaccine sales has been highlighted. Please See: Joe Miller "German City Reaps Tax Windfall from BionTech's Covid Vaccine Success" (26 December 2021) Financial Times <https://www.ft.com/content/5a705ebc-ce1f-4525-8406-d2875a32c473> Hence one can claim that BioNTech ultimately contributed to German taxpayers in return. However, this claim lacks a strong foundation. Firstly, the tax primarily benefits Germany, even though profits are generated by charging high prices in other countries, raising concerns about global justice. Additionally, BioNTech's partnership with Pfizer, a United States-based company, complicates the matter. While Pfizer earns substantial profits from the vaccine, it pays considerably lower taxes, falling well below the United States corporate tax rate. Please See: Emergency "Pharmaceutical Companies Reaping Immoral Profits from Covid Vaccines yet Paying Low Tax Rates" (15 September 2021) <https://en.emergency.it/press-releases/pharmaceutical-companies-reaping-immoral-profits-from-covid-vaccines-yet-paying-low-tax-rates/>.
[600]Thomas Pogge and Krishen Mehta "A New Deal After COVID-19" (2022) 19(3) Globalizations 497 at 500.

countries, preventing some from accessing patented products[601] despite the fact that everyone has right to benefit from scientific progress.[602] As experienced during Covid-19, this gap has further implications: poverty, healthcare and education, affecting integral components[603] of human right to health. Therefore, in the health sector, companies like pharmaceuticals cannot follow, as Friedman puts, "The social responsibility of business is to increase its profits"[604], focusing solely on sales and profit. As highlighted earlier, people in Global South have been more severely impacted than in Global North.

So far, it has been demonstrated that patent protection can easily become a barrier to access. As this thesis suggests, investment protection of patented health resources can exacerbate this even more. In this aspect, this thesis claims that investment protection of patented health resources becomes disproportionate. To demonstrate this, this thesis draws on midlevel principles in IP law. Chapter 2.5. already introduced the concept of midlevel principles, but a detailed discussion of midlevel proportionality required an initial exploration of IP theory and its development. With this background, the next section delves into midlevel proportionality in intellectual property theory, which serves as a basis for determining why investment protection becomes disproportionate and creates excessive leverage in favour of IP holders.

3.2.7. Merges's Proportionality as a Midlevel Principle in IP Law

This section explores midlevel proportionality. As indicated in Chapter 2.5., this thesis primarily relies on Merges's *Justifying Intellectual Property* with some adjustment of the midlevel proportionality. This thesis critiques Merges's midlevel proportionality from a TWAIL perspective and emphasises its potential as a tool for advancing global justice ideas in relation to investment protection of patented health resources. This section first presents Merges's concept of midlevel proportionality and then highlights the differences of Merges's approach with global justice in mind. The proportionality principle within midlevel context further sets up for Chapter 4, which demonstrates the disproportionate layers provided by the ISDS mechanism. The emphasis here is given to patent law since this thesis centers around accessing affordable health resources within the framework of patent law.

[601]Thomas Pogge "Are we Violating the Human Rights of the World's Poor?" (2011) 14(2) 1 at 26.
[602]ICESCR Article 15.
[603]*Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)* at [2].
[604]Milton Friedman "A Friedman Doctrine- The Social Responsibility of Business is to Increase its Profits" *The New York Times* (United States, 13 September 1970).

Merges's midlevel proportionality is a reflection of the distributional justice problems of IP rights.[605] Merges claims that midlevel proportionality connects different rules in IP law like the scope of the rights, their limitations, and remedies in case of a violation.[606] He highlights that individual control over individual assets often conflicts with reallocating resources from one person to another[607] such as ensuring affordable patented health resources. Midlevel proportionality aims to remove disproportional reward with regards to the covered IP right, size, or scope.[608] Upon this discussion, the following question arises: How can one determine if a reward is excessive or disproportionate?

For Merges, the core principle in answering this question is "deserve: individual contribution" while any basis for society's claims of redistribution comes from social contribution ("a component that can best be thought of as owing its origins to social forces and factors- his periphery").[609] For Merges, the share of social contribution (hence social claims) is smaller than individual contribution since creative work comes from unique talents.[610] Merges's concept of the "deserve core" and "individual contribution" appear to draw inspiration from Aristotelian philosophy. Aristotelian justice suggests that "benefits should be distributed in proportion to one's desert, and political rights should be assigned to those who make a full contribution to the political community, like property".[611] The injustice based on the desert, according to Aristotle, result in "disproportionate excess"[612], these influences are evident in Merges's thoughts. Merges's Westernised application of proportionality as a midlevel principle seems influenced by Aristotelian philosophy.

If there is an excessive or disproportional leverage -power beyond what is rightfully deserved-, either market or scope, this leverage should be limited or annulled.[613] Disproportionate reward or leverage is defined by Merges, in case of patent, when the holder has "power or control over a much larger market than is actually deserved in light of the work

[605]At 191.
[606]At 160.
[607]At 135.
[608]At 150.
[609]At 121.
[610]At 122.
[611]Fred Miller "Aristotle's Political Theory" in Edward N. Zalta and Uri Nodelman (ed) (1 July 2022) The Stanford Encyclopedia of Philosophy <https://plato.stanford.edu/archives/fall2022/entries/aristotle-politics/>. Meaning of desert: Please See Fred Feldman and Brad Skow "Desert" in Edward N. Zalta (ed) (Winter 2020) The Stanford Encyclopedia of Philosophy< https://plato.stanford.edu/cgi-bin/encyclopedia/archinfo.cgi?entry=desert>: "A typical desert claim is a claim to the effect that someone – the "deserver" – deserves something – the "desert" – in virtue of his or her possession of some feature – the "desert base.""
[612]Wayne P. Pomerleau "Western Theories of Justice" Internet Encyclopedia of Philosophy <https://iep.utm.edu/justwest/#SH1b>.
[613]Merges, above n 22, at 151.

covered by IP right".[614] Proportionality aims to reduce or remove excessive or disproportionate leverage where intellectual property rights provide power beyond what is deserved or when specific and unfair circumstances require.[615]

According to Merges, proportionality can also reveal itself in legal standards like patentability.[616] Merges argues that inventive step/non-obviousness requirement can be fulfilled only if nontrivial advancement beyond prior art is demonstrated.[617] This ensures that the contribution is proportional with the rights given to the patent holder. Merges gives different examples in the practice of intellectual property law and deduces that IP protection should not provide disproportionate leverage or reward in disparate situations; if such circumstances happen, then IP rights should be limited.[618] Merges precisely suggests that market exchange through entitlements, patent for instance, does not necessarily mean that this market outcome is fair, and distributive justice practice allows making adjustments.[619]

So far, this section has explored the main aspects of Merges's concept of midlevel proportionality. The following section continues with discussions where this thesis aligns and differs from Merges's views.

3.2.7.1. Differences with Merges's Midlevel Proportionality

The differences between Merges and this thesis lie in the concept of deserve as merely the purpose of redistribution. For this thesis, the purpose of redistribution does not merely stem from social contribution, nor is the only basis for patent right directly related to individual contribution. The purpose of redistribution, as explained in Chapter 2 and throughout this research, as advocated by global justice principles, is to reduce the number of disadvantaged individuals in the world. Accessing health resources is a significant element in achieving this goal.

For Merges, a property right, such as a patent, can be granted when technological contribution is proportional to the legal rights conferred[620], like preventing others from making, using, offering for sale, selling, or importing. Merges overlooks one of the

[614] At 151.
[615] At 151; at 161; at 190.
[616] At 161.
[617] At 161.
[618] At 162.
[619] At 185-186.
[620] At 161.

fundamental purposes of granting patents, which is to recover the financial investment made in the invention and focuses solely on the individual contribution of the investor and the concept of reward. It is not only technological advancement (contribution) that matters but also the source of financing for the invention, the labour invested, and the benefits or harms to global society. Further, this thesis disagrees with his suggestions that the share of social claims is smaller than what patent holders deserve and contribute. Some examples would clarify why this thesis disagrees with points.

In this respect, recent examples have been observed during the Covid-19 pandemic. As outlined earlier in Chapter 3.2.6., many R&D funds for Covid-19 products were funded by governments, meaning by taxpayers. Despite this, companies have been reluctant to licence products, continuing to reap profits. A noteworthy example is Moderna. Moderna received US$5 billion from their third-quarter sales in 2021, while their R&D was funded by the United States government and that it holds many patents in Delaware, a tax haven in the United States where income from patents is untaxed, allowing Moderna with opportunity to avoid taxes.[621] That is only one example that highlights the disproportionate nature of the system, regardless of the usefulness or benefits of the technology. It demonstrates how the system promotes rent-seeking, as Merges himself describes it as a wealth transfer, typically from the taxpaying public to private companies.[622] Further, intellectual property, in this case, patent protection, is meant to incentivise the inventors. Even if funding belongs to a private company, the true beneficiaries, scientists, today may detached from their work. This was exemplified above in the Moderna Covid-19 vaccine where NIH scientists were discarded.[623] Within Merges's deserving core, this cannot be seen as proportional as the true innovators are not always the ones benefitting from the system. Hence, beneficiaries may not necessarily be proportional to individual contribution. Merges's midlevel proportionality also raises the question of how to define individual contribution: Is individual contribution based on funding or actual work?

Furthermore, Merges's emphasis on deserving core or individual contribution can be justified to an extent by the harm it can cause to others, such as either preventing the dissemination of

[621]Medicines Sans Frontières "Moderna posts billions in profit from Covid-19 vaccine but won't share technology" (4 November 2021) <https://www.doctorswithoutborders.org/latest/moderna-posts-billions-profit-covid-19-vaccine-wont-share-technology>; Jillian Deutsch "Moderna Accused of Parking Vaccine Profits in Tax Heavens: Report" (13 July 2021) Politico < https://www.politico.eu/article/moderna-vaccine-profits-tax-havens/>.
[622]Merges, above n 22, at 170.
[623]Geiger, "The Social Function of Intellectual Property Rights, or How Ethics Can Influence the Shape and Use of IP Law", above n 51, at 154.

the product by patent holders' refusing voluntary licences or by governments' hindering the issuance of compulsory licences. Merges's proportionality appears to ignore the existence of the social function of IP rights. In instances where patent owners reveal reluctance or engage in limited voluntary arrangements during times of need can lead to an unfair distribution of resources, undermining the social function of the IP system and resulting in disproportionate leverage in the market, which Merges ignores.

Merges discusses surplus[624] value, questioning whether patent owners/sellers deserve all market returns as they are allowed to set the price freely. For instance, the former chief financial officer of Pfizer stated concerning BioNTech/Pfizer Covid-19 vaccine that the price would likely be increased after the pandemic claiming that typically the vaccine at non-pandemic times would be $150-$175 per dose, not $19.50.[625] One of the challenges associated with patents, as already discussed in Chapter 3.2., is the ability of the patent holder to set prices, compelling the buyers to purchase at the dictated rates due to the monopoly control over the market. Thus, the amount that can be reaped from the market and the benefit from scientific progress may not always be fair. Taking into account this example and possibly other health products that are significant for life or to increase life quality[626], the surplus value, which exceeds the normal price considerably, cannot be justified by patent owners/beneficiaries. These concerns do not automatically result in the revocation or cancellation of a patent under the current global intellectual property system. However, they would be a part of a series of questions on patent flexibility, like compulsory licence, which can be brought as a reason for an investment claim, as detailed in Chapter 4. It must be reminded that in this thesis, fairness or disproportionate reward, is not merely viewed through the lens of Merges' desert rationale. Rather, it is derived from the fact that the monopoly created by patents provides a level of power (investment protection) that can hinder access to affordable health resources for others, which is inherently linked to the human right to have a healthy life. While Merges's proportionality principle could have been considered as an aim to benefit all, his analysis fails to do so. Proportionality as a midlevel principle could, in fact,

[624]Merges, above n 22, at 186: Surplus value is defined as goods sold on the market have some sort of natural or normal value and that, at times, due to various market dynamics a seller can charge more than this amount.
[625]Eric Sagonowsky "Pfizer eyes higher prices for COVID-19 vaccine after the pandemic wanes: exec, analyst" (23 February 2021) Fierce Pharma <https://www.fiercepharma.com/pharma/pfizer-eyes-higher-covid-19-vaccine-prices-after-pandemic-exec-analyst>.
[626]ICCPR, art 6; ICESCR, art 12; UDHR, art 25; *General Comment No.25 (2020) on Science and Economic, Social and Cultural Rights (article 15(1) (b), (2), (3), and (4) of the International Covenant on Economic, Social and Cultural Rights)*; *General Comment No.24 (2017) on State Obligations under the International Covenant on Economic, Social and Cultural Rights in the Context of Business Activities*; *Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000).*

serve as a tool for justice in the intellectual property- health debate as long as they apply it in a way to uphold the purpose of patent rights rather than benefiting a few people in the global society. As explored in this chapter, patents should benefit not only the patent holders, but also the public since the public should be able to enjoy the patented resources. However, the access and enjoyment are not distributed equally among all parties globally, and investment protection adds a further layer to it, as explored in Chapter 4. This layer, in the view of this thesis, is considered to be disproportionate leverage, as detailed in Chapter 4.

Some suggest that Article 7 and Article 8 of the TRIPS Agreement can be seen as expressions of the proportionality principle serving as a protection against excessive leverage of IP rights holders/patent holders, as influenced by Merges' midlevel proportionality merely with a deserve core.[627] However, interpreting Article 7 and Article 8 as manifestation of midlevel proportionality based solely on Merges's deserving concept without taking into account the impact on public would limit their effectiveness in serving social function. It would impede creating a proper balance between the patent holder and the public, especially in ISDS cases involving the patented product/process pertaining to public health and, thus, to the right to have a healthy life. Yet, if midlevel proportionality operates when patent protection undermines the social function of IP rights, truly excessive leverage can be scaled back.

In this respect, investment protection of patents clearly exceeds a just return from the patent protection one can normally expect. Given that the investment protection of patents adds an additional layer to the use of patent system flexibilities and contributes to the regulatory chill, as will be detailed in Chapter 4.5., granting such non-monetary leverage (eventually provides economic benefit) cannot be justified, regardless of technological advancements (contributions to the community). This requires an adjustment of such power. Patent protection is supposed to compensate R&D costs and the risks taken by investors; however, ISDS is so much more than one claim as it can create regulatory chill and undermine TRIPS flexibilities. In this respect, it is argued that the distribution of intellectual property rights can only be just if no one receives extensive return beyond incentives for future and fair compensation to reimburses developing the product.[628] In this respect, investment protection of patents offers an extensive leverage to patent holders, diverging from the original intent of patent protection. The detailed reasons behind this becomes apparent in Chapter 4.

[627]Max Wallot "The Proportionality Principle in the TRIPS Agreement" in Hanns Ullrich and others *TRIPS plus 20: From Trade Rules to Market Principles* (eBook, Springer Nature, 2016) 213 at 234.
[628]Mathias Risse *On Global Justice* (Princeton University Press, United States of America, 2012) at 244.

So far, the purpose of this chapter has been to offer a comprehensive overview and understanding of the legal framework in intellectual property law, focusing on patent law. This was crucial before establishing the relationship with international investment law. The initial part of this chapter explored the concept and legal framework of intellectual property, highlighting its role in hindering accessing health resources and outlined the arguments against the deserve based proportionality as a midlevel principle within the IP legal framework. Subsequent sections of this chapter will focus on the concept of investor-state dispute settlement, the evolution of investment law and its substantive rights, particularly emphasising fair and equitable treatment and expropriation, to set up Chapter 4. This chapter finally concludes with an analysis of the sources and applicable laws in international investment law. Following that, Chapter 4 determines the reasons why investment protection of patented health resources is deemed disproportional, and Chapter 6 shows how that disproportion is aimed to be mitigated in the newly concluded regional IIAs in Chapter 6 via the embodiment of proportionality principle. It should be noted that the core of proportionality as midlevel principle here is the social function of IP rights rather than merely what patent holders may deserve based on its technological advancements (as Merges argues). Yet, with some modification to Merges' midlevel proportionality, investment protection would be disproportional since it provides so much more than the original intention of the patent law framework, as elaborated further in Chapter 4.

3.3. Investor- State Dispute Settlement

The central focus of this thesis is the inclusion of patent protection within the scope of investment under the IIAs. In order to grasp the concept fully and analyse the proportionality principle and its role in accessing affordable health resources, it is imperative to provide a comprehensive overview of the context of international investment law. It is essential to look into the evolution of international investment law to gain a thorough understanding of the concept and its underlying purpose. Following this, the section continues with the applicable law. The application of the accurate law is essential as it determines the outcome of a case or can raise validity problems of the award rendered. This analysis would also establish the legal basis for determining the extent to which the international IP legal framework and/or international human rights laws may be applicable. Subsequently, the section proceeds to explore two commonly invoked substantive protections by the investors: expropriation and FET. It is significant to understand these two concepts before looking at the case law and

analysing judicial proportionality. By scrutinising the application of the judicial proportionality principle, it is aimed to shed light on whether it can safeguard states' efforts in promoting affordable health resources and, thereby, contribute to global justice.

3.3.1. Development of International Investment Law

Social and economic interactions between states created a need for global legal orders to manage and handle with inter-state relations, and investment law has emerged as a response to this demand.[629] As a result, following the end of Second World War and the end of Cold War, there was a shift from national law to international law in the area of investments.[630] To be able to understand the current legal system, it is necessary to examine the development of investment law and the basis for the substantive protections offered to investors under international investment agreements. Thus, this part sets out a brief background of international investment law.

International investment law developed in time from diplomatic protection and treatment of aliens, treaties on friendship, commerce, and navigation (FCN) to BITs and FTAs.[631] Guidelines and codes of practice from the World Bank, OECD, or International Bar Association ("IBA") have contributed to this progress.[632] During the 18th and 19th centuries, foreign investment flowed into the colonial states by imperial power[633] and foreign properties were protected through domestic law under the jurisdiction of the imperial state.[634] In the colonial states, these investments were not alien for imperial powers, but they were for indigenous community. The protection of investments belonging to imperial power was going to be a concern once colonised countries gained their independence.

In 1868, Argentinian legal scholar and diplomat Carlos Calvo presented a principle of international law for the first time: the equality between foreigners and nationals, the

[629]Stephan Schill *The Multilateralization of International Investment Law* (Cambridge University Press, Cambridge, 2009) at 1-2.
[630]At 3.
[631]Andreas Kulick "Narrating Narratives of International Investment Law: History and Epistemic Forces" in Stephan W. Schill, Christian J. Tams, and Rainer Hofmann (ed) *International Investment Law and History* (Edward Elgar, United Kingdom, 2018) 41 at 54.
[632]Joost Pauwelyn "Rational Design or Accidental Evolution? The Emergence of International Investment Law" in Zachary Douglas, Joost Pauwelyn and Jorge E. Viñuales *The Foundations of International Investment Law: Bringing Theory into Practice* (Oxford University Press, Oxford, 2014) 11 at 15.
[633]M. Sornarajah *The International Law on Foreign Investment* (2nd ed, Cambridge University Press, Cambridge, 2004) at 19-20.
[634]Rudolf Dolzer, Ursula Kriebaum and Christoph Schreuer *Principles of International Investment Law* (3rd ed, Oxford University Press, New York, 2012) at 67-71.

sovereignty of Latin American states and their national jurisdiction.[635] This doctrine was met with different perspectives among countries, while the Global South, predominantly Asian and African countries, supported this doctrine; European states and North American countries rejected it.[636] The absence of internationally recognised protection of foreign property, which solely relied on domestic law, was not aligned with the interests of foreign investors. The fact that Soviet Russia expropriated national enterprises and foreign properties following the Russian Revolution in 1917 and that the Mexican government attacked the United States interests in Mexican agrarian and oil business in Mexico in 1938 proved the need for a minimum standard of protection of/for foreign assets.[637] In the aftermath of the Second World War, foreign investments started to be safeguarded through norms of international customary law as the new capital-importing countries interacted with capital-exporting countries.[638] Despite the efforts to weaken these norms, the protection of foreign investment gained momentum in the 1990s since capital-importing countries sought to attract foreign direct investments and forge new economic partnerships.[639] While these nations posed a nationalist stance with regard to the protection of foreign investment, they pursued a different approach in their domestic policies as compared to their international stance as they actively signed BITs to attract investors.[640]

Early examples of BITs did not explicitly include an investment-state dispute settlement system for resolving disputes; instead, they allowed disputes to be submitted either to the International Court of Justice[641] or to ad hoc state-to-state arbitration.[642] The shift towards incorporating investor-state dispute settlement mechanism occurred with the BIT signed between Chad and Italy in 1969.[643] The trends towards promoting an investment-friendly environment and safeguarding the interests of nationals by states prompted the establishment of multilateral and regional agreements incorporating the investor-state dispute settlement

[635]Wenhua Shan "From 'North-South Divide' to 'Private-Public Debate': Revival of the Calvo Doctrine and the Changing Landscape in International Investment Law" 2007 27(3) Northwestern Journal of International Law & Business 631 at 632.
[636]At 632-635.
[637]Dolzer, Kriebaum and Schreuer, above n 634, at 4.
[638]At 67-86.
[639]At 67-86.
[640] Sornarajah, above n 633, at 23-24.
[641]*Barcelona Traction, Light and Power Company Limited (Belgium v Spain)* [1970] ICJ Rep 3. This case is very significant for the development of international investment law. For details please see: Saïda El Boudouhi "Barcelona Traction Re-Imagined: The ICJ as a World Court for Foreign Investment Cases?" in Ingo Venzke and Kevin Jon Heller (ed) *Contingency in International Law: On the Possibility of Different Legal Histories* (Oxford University Press, New York, 2021) 406.
[642]Dolzer, Kriebaum and Schreuer, above n 634, at 10.
[643]At 67-86.

mechanism, such as the Energy Charter Treaty ("ECT") (entered into force 1998)[644] and the North American Free Trade Agreement (1994) ("NAFTA")[645]. The aim of establishing an investment-friendly environment by guaranteeing legal stability by the capital-importing countries was of the factors for the negotiation and implementation of numerous IIAs containing investment provisions. Another factor was the desire of capital-exporting countries to protect their national investors on foreign soils. At the time of the writing of this thesis, there are 2222 BITs in force among 22835 totals and 388 treaties with investment provisions[646] in force among 462 totals.[647]

Initially, international investment law was designed to protect foreign investors from capital-exporting countries (mainly the Global North) in capital-importing countries (mainly Global South). Therefore, it is not surprising to find a biased approach against capital-importing countries in the IIAs.[648] Similar to international IP law, the international investment law regime was also imposed by the powerful Global North states to protect their investors abroad[649], with rules originating from Europe as accepted by the European Commission.[650] Originally, the Global South aimed to attract foreign investors, but such an aim made them vulnerable to accepting policies dictated by the Global North. As a result, IIAs often do not align with the development objectives of Global South.[651] The incorporation of IP rights into IIAs reflects this unequal bargaining power of the Global North, contradicting the development and public policy objectives of the Global South, as detailed in Chapter 4. While both Global North and Global South states have the same opportunities and rights under the IIAs in theory, countries in Global South have rarely exercised their rights under IIAs since their investors have had limited resources to invest in Global North economies.[652] This difference highlights the inequality of the international investment law.

---

[644]The Energy Charter Treaty (adopted 1 December 1994, opened for signature 17 December 1994, entered into force 16 April 1998) (hereinafter "ECT").
[645]The North American Free Trade Agreement (signed 1992, entered into force 1 January 1994) (hereinafter "NAFTA")
[646]Please see the terminological explanation; UNCTAD Investment Policy Hub "International Investment Agreement Navigator" <https://investmentpolicy.unctad.org/international-investment-agreements/model-agreements>
[647]"International Investment Agreement Navigator", above n 646.
[648]Olunmiloda Olabode "A TWAIL Approach to Reforming the International Investment Regime" in Mariela de Amstalden and others (ed) *International Economic Law: New Approaches and Issues"* (eBook, Springer, 2023) 93 at 94.
[649]Kate Miles "Imperialism, Eurocentrism and International Investment Law: Whereto from Here for Asia?" Submission for the Second Biennial General Conference of the Asian Society of International Law at 2.
[650]European Commission *Concept Paper: Investment in TTIP and beyond–the path for Reform Enhancing the Right to Regulate and Moving from Current Ad-Hoc Arbitration Towards an Investment Court* (May 2015) at 1.
[651]United Nations Economic Commission for Africa *Investment Policies and Bilateral Investment Treaties in Africa: Implications for Regional Integration* (February 2016) at 14; IISD "9th Annual Forum of Developing Country Investment Negotiators" < https://www.iisd.org/events/9th-annual-forum-developing-country-investment-negotiators>.
[652]Anghie, "Rethinking International Law: A TWAIL Retrospective", above n 53, at 15.

Today, despite the numerous treaties remaining in force, and ongoing negotiations for new ones, the investor-state dispute settlement system remains a subject of concern for various stakeholders, including the public, international organisations, intergovernmental organisations and countries themselves, both in the Global South and in the Global North. The emergence of Chinese investors abroad has changed the long-established liberal order, leading to the Global North becoming a recipient of foreign investments from China.[653]

Consequently, the Global North has expressed concerns about China's rise since the international investment regime has started to be used by China.[654] It is not possible to discuss the reasons of China's rise here, and it is not the purpose of this thesis either. The main objective here is to highlight that the Global North has become vulnerable to the international investment regime, even to the Global South countries. This may eventually lead to finding common ground between the Global North and the Global South, at least regarding fundamental human rights, such as health. The legitimacy concerns of investment arbitration are widely acknowledged today.[655]

The European Union had faced substantial pressure from various stakeholders, including the public and environmentalists to abolish the investor-state mechanism under the ECT because even the countries in the Global North are often faced with threats from investors whenever countries take steps to deal with climate change.[656] In response to these critics, parties to the ECT aimed to reform and modernise the treaty to align their sustainable development goals and obligations; yet, in the end the European Union decided to withdrew from the treaty.[657] The ECT represents just one example of how the environment for international investment protection is changing. Within the North American region, a new trade agreement, USMCA which replaces NAFTA, notably exempts the inclusion of the ISDS mechanism for

[653]Congyan Cai "New Great Powers and International Law in the 21st Century" (2013) 24(3) *EJIL* 755; Congyan Cai *The Rise of China and International Law: Taking Chinese Exceptionalism Seriously* (eBook, OUP, 2019); Graham Allison *Destined for War: Can America and China Escape Thucydides's Trap?* (Brunswick, Scribe, 2017); Anghie, "Rethinking International Law: A TWAIL Retrospective", above n 53, at 49.

[654]Anghie, "Rethinking International Law: A TWAIL Retrospective", above n 53, at 66; at 109.

[655]UNCTAD *IIA Issues Note: Reform of Investor-State Dispute Settlement: In Search of a Roadmap* (June 2013); Susan D. Franck "The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing Public International Law Through Inconsistent Decisions" (2005) 73(4) Fordham LR 1521; Charles N. Brower and Stephan W. Schill "Is Arbitration a Threat or a Boon to the Legitimacy of International Investment Law?" (2009) 9(2) Chi J Intl L 473; Malcolm Langford and others "Regime Responsiveness in International Economic Disputes" in Szilárd Gáspár-Szilágyi and others (ed) *Adjudicating Trade and Investment Disputes: Convergence or Divergence?* (Cambridge University Press, United Kingdom, 2020) 244.

[656]Dave Keating "EU Governments Under Pressure to Quit Energy Charter Treaty" (10 December 2019) Forbes <https://www.forbes.com/sites/davekeating/2019/12/10/eu-governments-under-pressure-to-quit-energy-chartertreaty/#323ad9bf63ed>.

[657]"Finalisation of the negotiations on the Modernisation of the Energy Charter Treaty" (24 June 2022) ECT <https://www.energychartertreaty.org/modernisation-of-the-treaty/>; "Energy Charter Treaty: Council gives final green light to EU's withdrawal" Council of the EU (30 May 2024).

Canada.[658] Conversely, the agreement signed between Canada and the European Union (CETA) offers a quasi-judicial system instead of investment arbitration. A comprehensive examination of the USMCA and CETA is provided in Chapter 6.

Despite these reformative measures, there are still many agreements; especially, BITs are in force. Most of the decisions rendered in 2021 were based on old generation IIAs signed between 1980 and 2010.[659] Thus, while the adverse impacts of ISDS have been acknowledged, many countries, especially those in the Global South, may still encounter the threat of ISDS. Therefore, the risks associated with treating patents as investment, as detailed in Chapter 4, remain valid. The next part of this section delves into the applicable law of ISDS, which is significant to determine the role of domestic law and international legal framework. This chapter then proceeds to explore expropriation and FET as substantive rights afforded to investors under IIA.

3.3.2. Applicable Law

The application of the law is significant, as the choice of law ultimately determines the outcome of a case, or it can raise validity problems regarding the decision rendered. Applying and ranking the appropriate applicable law is further very crucial for the analysis undertaken in this thesis, as applicable law would also answer various questions in investment arbitration disputes pertinent to intellectual property. For instance, the validity of a patent, whether a patent qualifies an investment, whether the state's interference aligns with the relevant law, or if such interference constitutes a breach of IIAs are some of the critical questions that could significantly influence the outcome of a case. Therefore, addressing these questions through appropriate applicable law bears paramount significance.

Despite the extensive number of case law, the matter of applicable law is still controversial, reflecting ongoing debates and unresolved complexities within the field.[660] While the principle of party autonomy is fundamental for the determination of the applicable law, three main sources of law have a pivotal role: investment treaties, general international law and

[658]Debevoise& Plimption "From NAFTA to USMCA: Main Changes to the Investor- Dispute Settlement System" (7 May 2020) <https://www.debevoise.com/insights/publications/2020/05/from-nafta-to-usmca-main-changes-to-the-investor>.
[659]UNCTAD *IIAs Issue Note: Review Of 2021 Investor–State Arbitration Decisions: Insights for IIA Reform* (July 2023).
[660]Stefan Riegler, Dalibor Valincic and Borna Dejanovic "Applicable Law in Investment Treaty Arbitration" (14 January 2022) GAR Global Arbitration Review <https://globalarbitrationreview.com/guide/the-guide-investment-treaty-protection-and-enforcement/first-edition/article/applicable-law-in-investment-treaty-arbitration> at 1.

domestic law.[661] The principle of party autonomy has been set by different institutions: ICSID Convention Article 42(1)[662], UNCITRAL Arbitration Rules Article 35(1)[663], International Chamber of Commerce ("ICC") Arbitration Rule Article 21(1)[664], Stockholm Chamber of Commerce ("SCC") Arbitration Rule Article 27(1)[665] or Vienna International Arbitral Centre ("VIAC") Rules of Investment Arbitration Article 27(1)[666]. These rules prioritise party autonomy, serving as the foundation for determining the rules of applicable law. Party autonomy constitutes a defining characteristic of the arbitration system, similar to commercial arbitration, and it becomes the duty of the arbitral tribunal to resolve this matter in the absence of choice of law.[667] Arbitral tribunals have to "decide on the basis of law"; yet, parties can decide otherwise according to the principle of party autonomy.[668] This rule is also included in UNCITRAL Arbitration Rules Article 35(2)[669] as well as the ICSID Convention Article 42(3)[670], ICC Arbitration Rule Article 21(3)[671], SCC Arbitration Rule Article 27 (3)[672] and VIAC Rules of Investment Arbitration Article 27(3)[673].

IIAs can provide guidance regarding the choice of law, but most of the time, they only refer to the provisions outlined within the treaty itself.[674] Nevertheless, even in the absence of such explicit reference, the treaty remains the primary source of the disputes, given that treaties serve as the basis of the arbitration proceedings.[675] Controversy has arisen concerning the existence of party autonomy/consent in choice of law when a treaty provides it, since IIAs are signed by states, not by investors.[676] However, it is now accepted that consent is given by states upon signing a treaty and by investors through the submission of an arbitration

[661]At 1; Andrea K. Bjorklund and Lukas Vanhonnaeker "Applicable Law in International Investment Arbitration" C. L. Lim *The Cambridge Companion to International Arbitration* (Cambridge University Press, 2021) at 225-227.
[662]Convention on the Settlement of Investment Disputes between States and Nationals of other States 575 UNTS 159 (opened for signature 18 March 1965, entered into force 14 October 1966) (hereinafter "ICSID Convention"), art 42(1).
[663]*Arbitration Rules on United Nations Commission on International Trade Law* UN Doc A/31/98 (15 December 1976) (hereinafter "UNCITRAL Arbitration Rules, art 35(1).
[664]Rules of Arbitration of the International Chamber of Commerce (entered into force 1 January 2021) (hereinafter "ICC Arbitration Rules"), art 21(1).
[665]Arbitration Rules of the Arbitration Institute of the Stockholm Chamber of Commerce (entered into force 1 January 2023) (hereinafter "SCC Arbitration Rule"), art 27(1).
[666]Vienna Investment Arbitration and Mediation Rules (entered in force 1 July 2021) (hereinafter "VIAC Rules of Investment Arbitration"), art 27(1).
[667]Yas Banifatemi "The Law Applicable in Investment Treaty Arbitration" in Katia Yannaca-Small (ed) *Arbitration under International Investment Agreements: A Guide to the Key Issues* (Oxford University Press, Cary, 2010) 191 at 191-192.
[668]Ole Spiermann "Applicable Law" in Peter Muchlinski, Federico Ortino and Christoph Schereuer (eds) *The Oxford Handbook of International Investment Law* (Oxford University Press, Oxford, 2008) 89 at 92.
[669]UNCITRAL Arbitration Rules, art 35(2).
[670]ICSID Convention, art 42(3).
[671]ICC Arbitration Rule, art 21(3).
[672]SCC Arbitration Rule, art 27 (3).
[673]VIAC Rules of Investment Arbitration art 27(3).
[674]Bjorklund and Vanhonnaeker, above n 661, at 227.
[675]Riegler, Valincic and Dejanovic, above n 660, at 3.
[676]Banifatemi, above n 667, at 195; Hege Elisabeth Kjos *Applicable Law in Investor-State Arbitration the Interplay Between National and International law* (Oxford University Press, Oxford, 2013) at 20-22.

request.[677] In some circumstances, like concession agreements, the applicable law is most likely to be specified.[678] Some treaties can also refer to international laws, domestic laws, or a law that is agreed on by the parties involved.[679] If a treaty lacks reference to any law, if the parties involved fail to provide an applicable law, or if an incidental issue falls outside the specified or chosen applicable law, then arbitral tribunals have a responsibility as well as discretion to determine the applicable law.[680] In some cases, arbitration rules assist the tribunal in determining the applicable law. Again, the ICSID Convention as well as the ICSID Convention Additional Facility Rules, the UNCITRAL Arbitration, the ICC Arbitration Rules, the SCC Arbitration Rules, and the VIAC Rules provide guidance to the arbitral tribunal. The design of these provisions influences the applicable law. While the ICSID Convention restricts the arbitral tribunal to host states' law, including its rules on the conflict of laws and to international law, others implement greater flexibility in this regard.[681]

In this respect, the arbitral tribunal may face four different scenarios: (i)parties agree on the application of domestic law; (ii) parties agree on the application of international law; (iii) the agreement provides application of both domestic and international law, or (iv) no choice of law.[682] Although there might be various potential scenarios in the determination of applicable law, both international law and domestic law would be likely to play a role.[683] Thus, even if domestic or international law is primarily applicable in a dispute, it does not necessarily preclude the relevance of the other.[684]

For instance, according to the ICSID Convention Article 42(1) the law of state party and its rules of conflict of law as well as international law can be applicable. Similarly, ICSID Convention Additional Facility Rules Article 54(1) states that "the law determined by the conflict of laws rules which it considers applicable and such rules of international law as the Tribunal considers applicable".[685] Since ICSID is the most preferred forum for resolving investment disputes, the cases and decisions under ICSID offer valuable insights into trends

[677]At 22.
[678]Bjorklund and Vanhonnaeker, above n 661, at 228.
[679]At 234.
[680]At 228.
[681]ICSID Convention, art 42(1); UNCITRAL Arbitration Rules, art 35(1); ICC Arbitration Rule art 21(1); SCC Arbitration Rule art 27(1); VIAC Rules of Investment Arbitration, art 27(1).
[682]Kjos, above n 676, at 158.
[683]Kjos, above n 676, at 157, Bjorklund and Vanhonnaeker, above n 661, at 242
[684]Kjos, above n 676, at 157-158.
[685]International Centre for Settlement of Investment Disputes Additional Facility Arbitration Rules (amended 1 July 2022) (hereinafter "ICSID Convention Additional Facility Arbitration Rules"), art 54(1).

and issues in ISDS, including applicable law. Therefore, a brief analysis concerning applicable law is offered through the lens of the ICSID Convention.

The wording of Article 42(1) has created uncertainty about whether the domestic law of a host state or international law should be applied primarily, notwithstanding the provision being read as a two-step process.[686] In the initial awards of the ICSID, the domestic law of the host state was prioritised and international law took a supplementary role (vertical approach).[687] Arbitral tribunals applied the rule as it is written "…shall apply the law of the Contracting State party to the dispute (including its rules on the conflict of laws) and such rules of international law as may be applicable.".[688] The *Amco* v *Rebuplic of Indonesia*[689] or *Klöckner* v *Cameroon*[690] are examples of such cases. This approach limits the application of international law despite the internationality of investment arbitration. Conversely, an alternative interpretation suggests that the wording of the provision gives great discretion to the tribunals regarding the selection of applicable law, and whether domestic or international, tribunals may adopt whichever they deem appropriate.[691]

3.3.2.1. Application of Domestic Law

As highlighted earlier, national law may need to be applied as decided by the parties to the IIA in question or a contract between the foreign investor and the host state. For instance, Article 10(4) of the China- Netherlands BIT states that:[692]

> The ad hoc tribunal shall decide a dispute in accordance with such rules of law as may be agreed by the parties. In absence of such agreement the tribunal shall apply the law of the Contracting Party to the dispute (including its rules on the conflict of laws), the provisions of this Agreement and such rules of international law as may be applicable.

In some cases, national law plays a role in underpinning international claims themselves such as the conclusion or termination of a contract.[693] Additionally, to be able to benefit from an IIA, the investor claimant must be a foreign investor, a determination made in accordance

[686]Bjorklund and Vanhonnaeker, above n 661, at 233.
[687]At 238.
[688]ICSID Convention, art 42(1)
[689]*Amco Asia Corporation and others v. Republic of Indonesia (Award in Resubmitted Proceeding)* ICSID ARB/81/1, 10 May 1988 at [27- 29], at [37- 40].
[690]*Klöckner Industrie- Anlagen GmbH er al. v United Republic of Cameroon and Societe Camerounaise des Engrais (Decision of the Ad-Hoc Committee Unofficial English Translation)* ICSID ARB/81/2, 3 May 1985 at [63].
[691]Bjorklund and Vanhonnaeker, above n 661, at 239.
[692]Agreement on Reciprocal Encouragement and Protection of Investments Between the People's Republic of China and the Kingdom of the Netherlands (signed 26 November 2001, entered into force 01 September 2004), art 10(4).
[693]Spiermann, above n 668, at 110-111.

with the domestic law of host state.[694] Further, certain issues are determined by the domestic law and can impact the jurisdiction of arbitral tribunal, such as whether an entity qualifies as an investment.[695] BITs often require that an investment must comply with the laws of the state to be considered valid and legal. In the case of *Bayindir v Pakistan*, the tribunal assessed whether Bayindir's had an investment in Pakistan in line with Pakistani laws as required by the treaty.[696]

Similarly, Article 42(1) of the ICSID Convention stipulates that in the absence of an agreement between parties on the choice of law, domestic law applies along with some rules of international law:[697]

> The Tribunal shall decide a dispute in accordance with such rules of law as may be agreed by the parties. In the absence of such agreement, the Tribunal shall apply the law of the Contracting State party to the dispute (including its rules on the conflict of laws) and such rules of international law as may be applicable.

3.3.2.2. Application of International Law

In some cases, parties to the disputes might choose international law either alone or in combination with national choice of law.[698] Some treaties can refer to principles of international law, like Article 26(6) of the Energy Charter Treaty[699]. The sources of international law are generally considered as indicated in the Statute of the International Court of Justice Article 38(1).[700] Additionally, some treaties may precisely refer to customary law concerning their FET provision or general principles of law along with the domestic law of the host state for the dispute settlement provision like China-Colombia BIT[701]. Or as

[694]Arnaud de Nanteuil *International Investment Law* (Edward Elgar Publishing, Northampton, 2020) at 66.
[695]Christoph Schreuer "Jurisdiction and Applicable Law in Investment Treaty Arbitration" (2014) 1(1) MJDR 1 at 4.
[696]*Bayindir Insaat Turizm Ticaret ve Sanayi A.S. v Islamic Republic of Pakistan (Decision on Jurisdiction)* ICSID ARB/03/29, 14 November 2005 at [105-110].
[697]ICSID Convention, art 42(1): There are discussions on whether international law should be applied as a complementary role or applied discretionary. Please see, Bjorklund and Vanhonnaeker, above n 661, at 238; Benedetta Cappiello "Applicable Law in Investment Arbitration" in Julian Chaisse, Leila Choukroune and Sufian Jusoh (ed) *Handbook of International Investment Law and Policy* (Springer, online ed, 2021) 1123 at 1133: "The Annulment Committee in *Klöckner v Republic of Cameroon* established that international law could only play supplementary or a corrective law regarding national law."
[698]Kjos, above n 676, at 213.
[699]ECT, art 26(6)
[700]Statute of the International Court of Justice 33 UNTS 993 (18 April 1946) (hereinafter "Statute of the ICJ"), art 38(1).
[701]Bilateral Agreement for the Promotion and Protection of Investments Between the Government of the Republic of Colombia and the Government of the People's Republic of China (hereinafter "China-Colombia BIT") (signed 22 November 2008, entered into force 02 July 2013), art 2; art 9(11).

Chile-Hong Kong, China SAR BIT[702], some IIAs may refer to applicable rules of international as the governing law.

In *Tecmed v Mexico*, the tribunal highlighted the applicable law in the BIT, which required the dispute to be resolved by applying both BIT provisions and international law.[703] The tribunal interpreted the international law by referring to Article 38 of the ICJ Statute and included references to the European Court of Human Rights, Inter-American Court of Human Rights, Iran-United States Claims Tribunal.[704] The applicability concerns regarding ECtHR are referred in Chapter 5.3. since it has become a highly controversial topic. Some have interpreted Article 42(1) of the ICSID Convention as allowing for the concurrent application of international law and domestic law, such as the annulment of the award in *Wena* v *Egypt.*[705] The annulment committee stated that both international and national law could be applied concurrently and independently due to their distinct conceptual framework.[706]

As mentioned at the beginning of this chapter, applying the appropriate law is fundamental in determining the ranking among relevant laws. Failure to adhere to appropriate law could potentially result in excessive power of arbitrators, potentially leading to decisions being annulled.[707] For the purpose of this thesis, the most significant aspect of determining the applicable law involves assessing the validity and scope of IP. National laws are particularly relevant in cases involving IP since they not only determine if the right is valid, but they also define the scope of the right.[708] Relying on the territorial principle in IP law, Ruse-Khan rightly suggested that IP rights in investment law must be derived from domestic laws regardless of the existence of explicit reference to domestic law.[709] In support for this conclusion, as this thesis agrees with, Upreti refers to the Guidelines on Intellectual Property and Private International Law of the International Law Association (ILA) Provision 11, which

[702]Investment Agreement between the Government of the Hong Kong Special Administrative Region of the People's Republic of China and the Government of the Republic of Chile (signed 18 November 2016, entered into force 14 July 2019), art 29(1): "… when a claim is submitted to arbitration under art 21.1(a) or 21.1(b) (Submission of a Claim to Arbitration), the tribunal shall decide the issues in the investment dispute in accordance with this Agreement and applicable rules of international law".
[703]*Tecmed v Mexico Award*, at [93].
[704]*Tecmed v Mexico Award*, at [116-117].
[705]Spiermann, above n 668, at 91; *Wena Hotels Limited v Arab Republic of Egypt (Decision on Annulment)* ICSID ARB/98/4, 5 February 2002.
[706]At [40-41].
[707]Bjorklund and Vanhonnaeker, above n 661, at 242.
[708]Pratyush Nath Upreti *Intellectual Property Objectives in International Investment Agreements* (Edward Elgar, London, 2022) at 125.
[709]Henning Grosse Ruse-Khan *The Protection of Intellectual Property in International Law* (Oxford University Press, United Kingdom, 2016) at 157.

states: "…registration, validity, abandonment, or revocation of a registered intellectual property right the court of the State of registration shall have exclusive jurisdiction" as an instrument of international in the absence of explicit reference to domestic law.[710]

FET and expropriation constitute perhaps the most prevalent arbitration claims initiated by foreign investors. They are considered further as two important standards so far for the context of IP-ISDS disputes.[711] Therefore, emphasis is given to these two standards. The subsequent section delves into the concept of these rights, followed by examples from case law. The discussion aims to provide an understanding of the complexities of the rights and raises some questions in relation to intellectual property rights, as further examined in Chapter 4.

3.3.3. Substantive Rights

This chapter continues with an analysis of substantive protections within investment treaties. While variations exist among treaties, it is observed that they predominantly cover six core protections for foreign investors: most-favoured nation treatment (MFN), national treatment (NT), fair and equitable treatment (FET), protection against expropriation, an umbrella clause and a free transfer of funds.[712] These protections can be categorised into two groups: non-contingent (absolute) such as FET and expropriation (direct- indirect), and contingent such as MFN and NT.[713] Contingent standards are contingent upon the treatment granted to other persons or entities, whereas non-contingent (absolute) standards serve to protect foreign investors regardless of the treatment accorded to others.[714] Given the limits of this thesis, it is not possible to cover all of these standards. Since protection against expropriation and FET are absolute standards, only these two standards are examined in this thesis. The analysis starts with an exploration of the FET standard, followed by a scrutiny of protection against expropriation.

[710]Upreti, above n 708, at 133; *Guidelines on Intellectual Property and Private International Law* Res 6/200 (13 December 2020) Provision 11.
[711]Pratyush Nath Upreti "Intellectual Property Rights in Investor-State Dispute Settlement: Connecting the Dots Through the Philip Morris, Eli Lilly and Bridgestone Awards" (2020) 31(4) ARIA 338 at 405.
[712]Bonnitcha, Poulsen and Waibel, above n 43, at 93-94.
[713]At 93-94; Campbell McLachlan, Laurence Shore and Matthew Weiniger *International Investment Arbitration: Substantive Principles* (2nd ed, Oxford University Press, Oxford, 2017) at [7.26].
[714]At [7.26].

3.3.3.1. Fair and Equitable Treatment

Fair and equitable treatment is one of the most applied substantive standards an IIA contains. In principle, FET encounters less challenges than expropriation, and provides a more supple way of remedy when claims do not meet the threshold for expropriation.[715] While FET clause is widely invoked, there are some concerns are attached to its existence. FET is quite a flexible and elastic standard that can easily be expanded through case law, and different formulations contribute to this expansion.[716]

Even though FET clause is one of the most applied substantive standards, some treaties do not include the clause at all (like Germany-Pakistan BIT[717]; Japan-Egypt BIT[718]); some may include it in their preamble; some others may designate the provision in the body of the treaty.[719] Where there is no FET clause in a treaty, an investor would not be able to receive the exact same level of protection from other standards or instruments that the customary international law would offer.[720] As mentioned, one way is to include FET in a preamble. While it does not give protection directly to investors or to the legally obliged states, it is a sign at the political level of intent of such fair and equal treatment.[721] Yet, some commentators interpret this type of reference as "reinforcing its role in the body of the treaty".[722] A reference to FET in the preamble cannot itself establish substantive protection, yet it can play a role in interpreting the treaty in accordance with the VCLT Article 31(1)[723] combined with the MFN clause. Using FET in the preamble combining with the MFN clause was strategized before to revoke the FET clause and the tribunal determined that more favourable substantive standards found in Pakistan's other BITs would be applicable.[724]

Even though FET clauses are included in IIAs most of the time, particularly since the 20th century, their formulation has evolved, and different variations still exist.[725] Tudor divides the

[715]Katia Yannaca-Small "Fair and Equitable Treatment Standard: Recent Developments" in August Reinisch (ed) *Standards of Investment Protection* (Oxford University Press, New York, 2008) 111 at 129-130.
[716]At 111-112.
[717]Germany-Pakistan BIT 1959.
[718]Agreement between Japan and the Arab Republic of Egypt Concerning the Encouragement and Reciprocal Protection of Investment (signed 28 January 1977, entered into force 14 January 1978).
[719]Ioana Tudor *The Fair and Equitable Treatment Standard in the International Law of Foreign Investment* (Oxford University Press, Oxford, 2008) at 22-23; Roland Kläger *Fair and Equitable Treatment' in International Investment Law* (eBook ed, Cambridge University Press, 2011) at 55-62.
[720]Kläger, above n 719, at 55.
[721]At 55-56.
[722]Tudor, above n 719, at 21.
[723]*Bayindir Insaat Turizm Ticaret Ve Sanayi AS v. Islamic Republic of Pakistan (Decision on Jurisdiction)* ICSID ARB/03/29, 14 November 2005 at [155].
[724]At [42-44], at [153-160].
[725]Kläger, above n 719, at 57.

design of FET clauses into five categories.[726] The first category is simply a statement of the FET clause without further description, such as "Each Party shall ensure fair and equitable treatment in its own territory of investments".[727] The second category links the FET clause to international law, which is commonly seen in treaties concluded by the United States, Canada and France.[728] The significance of referring to international law in formulating the FET clause is further discussed below in this part of this thesis. Some treaties may set examples of states' behaviour (non-exhaustive list) that can possibly breach the treaty along with a reference to international law such as the 1998 France-Guatemala BIT.[729] The fourth category of Tudor's division of the FET formulation encompasses treaties that link the FET clause to broad wordings like arbitrariness, discriminatory treatment, or unreasonableness, and this type of FET clauses are framed in a manner that captures a wide range of state conducts.[730]

The final type of FET formulation is characterised together with the "full protection and security" by the Tudor[731]; however, it should be acknowledged that "full protection and security" itself is also a separate treaty standard. An example of this type of FET formulation is found Cambodia-Cuba BIT Article II (2) and CETA Article 8.10 (1).[732] Further, NAFTA Article 1105(1) includes full protection and security along with reference to international law as formulised: "…shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.".[733]

Although NAFTA has been replaced with USMCA, this formulation remains important for the scope of this thesis since it was the agreement involved in *Eli Lilly* v *Canada* case, as addressed in Chapter 4. As opposed to NAFTA, CPTPP (a free trade agreement between Canada, Mexico, Australia, Brunei, Chile, Japan, Malaysia, New Zealand, Peru, Singapore, and Vietnam) Article 9.6 refers to customary international law together with FET and full protection and security by stating that "Each Party shall accord to covered investments treatment in accordance with applicable customary international law principles, including fair

[726]Tudor, above n 719, at [24-33].
[727]Australia-Thailand Free Trade Agreement (signed 5 July 2004, entered into force 1 January 2005).
[728]Catherine Yannaca-Small, *Fair and Equitable Treatment Standard in International Investment Law* (OECD, Working Papers on International Investment Number 2004/3, September 2004) at 2, n 2.
[729]Tudor, above n 719, at 26.
[730]At 27-28.
[731]At 28-29.
[732]Agreement between the Government of the Kingdom of Cambodia and the Government of the Republic of Cuba Concerning the Promotion and Protection of Investments (signed 26 September 2001), art II (2); CETA, Chapter 8, Section D, art 8.10 (1)
[733]NAFTA, art 1105(1).

and equitable treatment and full protection and security.".[734] CPTPP refers to its Annex-A (customary international law) for the interpretation of the FET clause, which is an issue covered in Chapter 6.[735]

Most of the treaties combine the FET clause with most-favoured-nation and national treatment or the duty the refrain from arbitrary and discriminatory treatment.[736] For instance, Article 2(2) of the 2001 Lebanon-Hungary BIT combines FET with both the obligations of MFN, NT and the duty of avoiding arbitrary and discriminatory behaviour by stating:[737]

> …shall at all times be accorded fair and equitable treatment and shall enjoy full protection and security in the territory of the other contracting party…shall refrain from impairing by unreasonable or discriminatory measures the management, maintenance, use, enjoyment, extension, sale or liquidation of such investments.

As highlighted earlier, some treaties incorporate references to international law or customary international law within the formulation of the FET clause. Such references to international law can be articulated in different ways like *in accordance with* or *in no case, shall provide less protection than the rules of international law*.[738] Sometimes the FET clause can be formed under the minimum standard of treatment title like NAFTA Article 1105, which raises controversy about the role international law plays in the formulation of FET clauses. However; according to some commentators, reference to international law should be considered as the international minimum standard, which is construed as a part of customary international law.[739] Additionally, whether FET constitutes a customary law or whether it is formulated as an *international minimum standard* is very controversial; the FET clause is enshrined in most of the IIAs.[740] Yet, where there is a reference to customary international law, it is generally accepted that FET is limited to the rules of the customary international law of minimum standards of treatment.[741]

---

[734]CPTPP, art 9.6.
[735]CPTPP, art 9.6, n 15.
[736]Kläger, above n 719, at 58.
[737]Agreement between the Republic of Lebanon and the Republic of Hungary for the Promotion and Reciprocal Protection of Investments (signed 22 June 2001, entered into force 23 July 2002), art 2(2).
[738]Kläger, above n 719, at 60.
[739]At 60-61.
[740]For further discussion please see Tudor, above n 719, 53-104; Mārtiņš Paparinskis *The International Minimum Standard and Fair and Equitable Treatment* (Oxford University Press, Oxford, 2013) at 154-167; Todd J Grierson-Weiler and Ian A. Laird "Standards of Treatment" in Peter Muchlinski, Federico Ortino and Christoph Schereuer (eds) *The Oxford Handbook of International Investment Law* (Oxford University Press, Oxford, 2008) 259 at 259-303.
[741]Kläger, above n 719, 60.

The most recent formulations of the FET provisions in the IIAs appear to be more detailed and offer specific content as well as limiting the scope of the protection, as illustrated in Chapter 6. Yet, due to the considerably different formulations of the FET, it is not possible to make a precise definition of the FET clause.[742] Similar to the other aspects of investment arbitration, the FET clause and its contents have been shaped by case law and arbitral tribunals play an active role in interpreting the clause. The wording of the FET standard is the key for its interpretation. For instance, as mentioned in the previous paragraph, the treaties that do not make explicit reference to customary international law provide a more expansive scope as opposed to the treaties that do make such a reference.[743] Nevertheless, since the early 2000s, tribunals have started to consider that customary international law is not frozen but rather subject to evolution, leading to a broader interpretation of the FET.[744] As a result of the various formulations of the FET clause, tribunals have developed several FET contents, encompassing but not limited to the followings: denial of justice, due process, due diligence (obligation of vigilance and protection), non-discrimination, lack of arbitrariness, transparency, stability, legitimate expectations and proportionality.[745]

Denial of justice and due diligence have generally been considered integral components of customary international law by tribunals.[746] In *Thunderbird v Mexico*, the tribunal expressed that acts would give rise to a breach of:[747]

> …acts that would give rise to a breach of the minimum standard of treatment prescribed by the NAFTA and customary international law as those that, weighed against the given factual context, amount to a gross denial of justice or manifest arbitrariness falling below acceptable international standards.

In *Genin v Estonia*, the tribunal considered denial of justice together with "bad faith, wilful disregard of due process, or an extreme insufficiency of action".[748]

Transparency, on the other hand, is a new concept that is not traditionally considered as a customary international law.[749] For instance, in *Metalclad Corporation* v *United Mexican*

[742]Tudor, above n 719, at 51.
[743]Yannaca-Small, *Fair and Equitable Treatment Standard in International Investment Law*, above n 728, at 26-39; Yannaca-Small, "Fair and Equitable Treatment Standard: Recent Developments", above n 715, at 113-114.
[744]At 113-114.
[745]At 118-119.
[746]At 118-120.
[747]*International Thunderbird Gaming Corp. v United Mexican States (Arbitral Award)* UNCITRAL, 26 January 2006 at [194].
[748]*Alex Genin, Eastern Credit Limited, Inc. and A.S. Baltoil v Republic of Estonia (Award)* ICSID ARB/99/2, 25 June 2001 at [371].

States, the arbitral tribunal defined transparency as "… all relevant legal requirements for the purpose of investing should be capable of being readily known to all investors".[750] Other contents of the FET such as non-discrimination (based on nationality) and lack of arbitrariness are commonly embodied as different provisions in IIAs; however, some arbitral tribunals have viewed those standards as part of the FET (some grounds such as non-discrimination under FET standards are gender, race, or religious belief).[751] The *MTD v Chile* tribunal stated that the Claimants' argument regarding unreasonable and discriminatory measures is part of FET.[752] Similarly in *PSEG v Turkey*, for tribunal:[753]

> …to the extent supported by the facts, the anomalies that took place in connection with the conduct just referred to are included in the breach of fair and equitable treatment and that there is no ground for a separate heading on liability on account of arbitrariness.

Stability is another concept of the FET standard and requires states to maintain predictable, transparent and consistent legal framework.[754] For instance, in *Occidental v Ecuador*, the arbitral tribunal stated that:[755]

> the stability of legal and business legal framework is thus an essential element of fair and equitable treatment…that fair and equitable is an objective requirement that does not depend on whether the respondent has proceeded in good faith or not.

The flexibility of the FET standard already reduces policy space for states, stabilisation clauses can easily be stretched in a way to restrict regulatory power even more.[756] The stability of law may be necessary to protect foreign investors against potential state interference without justifiable reason or from nationalistic actions. Nevertheless, each state has different needs and considerations, as such; they retain to act in accordance with their

---

[749]Yannaca-Small, *Fair and Equitable Treatment Standard in International Investment Law*, above n 728, at 37.
[750]*Metalclad Corporation v United Mexican States (Award)* ICSID ARB/AF/97/1, 30 August 2000 at [76].
[751]*MTD Equity Sdn. Bhd. and MTD Chile S.A. v Republic of Chile (Award)* ICSID ARB/01/7, 25 May 2004 (hereinafter "*MTD v Chile Award*"); *PSEG Global et al. v Republic of Turkey (Award)* ICSID ARB/02/5, 19 January 2007 (hereinafter "*PSEG v Turkey Award*"); *Saluka Investments BV (The Netherlands) v The Czech Republic (Partial Award)* UNCITRAL, 7 March 2006 (hereinafter "*Saluka v Czech Republic Partial Award*"). On the other hand, the tribunal in *LG&E* v *Argentina* tribunal analysed the non-arbitrariness as a separate matter, distinct from the FET claim: "…characterizing the measures as non-arbitrary does not mean that such measures are characterized as fair and equitable…" *LG&E v Argentina Decision on Liability*, at [162]; CETA, art 8.10.2(d).
[752]*MTD v Chile Award*, at [190-196].
[753]*PSEG v Turkey Award*, at [261].
[754]Yannaca-Small, "Fair and Equitable Treatment Standard: Recent Developments", above n 715, at 123-124; *Occidental Exploration and Production Co v Ecuador (Final Award)* LCIA No. UN 3467, 1 July 2004, (hereinafter "*Occidental v Ecuador Final Award*") at [183-186].
[755]Yannaca-Small, "Fair and Equitable Treatment Standard: Recent Developments", above n 715, at 123-124; *Occidental v Ecuador Final Award*, at [183-186].
[756]Rudolf Dolzer "Fair and Equitable Treatment: A Key Standard in Investment Treaties" (2005) 39(1) The International Lawyer 87 at 106.

particular circumstances. Therefore, stabilisation of the law should not only serve investors' objectives of protecting their investments, but it should also take into account the interests of other stakeholders such as the public or states' regulatory power.

Another concept of the FET clause is legitimate expectation, which is also related to the stability concept. Legitimate expectation requires states to fulfil and respect any commitments or any representation likely to give rise to investor expectation.[757] Arbitral tribunals have played a significant role in the question of what raises legitimate expectations. In the *Continental v Argentina* case, the arbitral tribunal divided legitimate expectation into three sections: "general political declaration, general legislative declaration, and contractual commitments".[758] The strongest source of the legitimate expectation claim stems from contractual commitments or specific assurances while general political declarations do not establish any expectations.[759] Further, a general legislative declaration might potentially raise legitimate expectation, but it should not be combined with stability, since states have right to change, modify, or withdraw the legislations. This concern has also been clarified by tribunals. In the *CMS v Argentina* case, the arbitral tribunal stated that legitimate expectation revolves around determining whether states' actions violate their specific commitments rather than assessing whether the legal framework has changed since legal frameworks are dynamic and adaptable to changing circumstances and should not be considered as frozen.[760] Argentina requested an annulment for this award; however, the Annulment Committee upheld the *CMS v Argentina* decision by respecting the interpretation of the tribunal.[761] Similarly, the arbitral tribunal of *Parkering-Compagniet AS v Republic of Lithuania* put forward similar perspective by stating:[762]

> …the expectation is legitimate if the investor received an explicit promise or guaranty from the host-State, or if implicitly, the host-State made assurances or representation that the investor took into account in making the investment.

[757]Nanteuil, above n 694, at 301-302 [9.039].
[758]At [9.041].
[759]At [9.041].
[760]Yannaca-Small, *Fair and Equitable Treatment Standard in International Investment Law*, above n 728, at 40; *CMS Gas Transmisson Company v The Argentina Republic (Award)* ICSID ARB/01/8, 12 May 2005 at [277].
[761]*CMS Gas Transmisson Company v The Argentina Republic (Decision on Annulment)* ICSID ARB/01/8, 25 September 2007 at [85].
[762]*Parkering- Compagniet AS v Lithuania (Final Award)* ICSID ARB/05/8, 11 September 2007 at [331].

Recent treaties have sought to address concerns regarding legitimate expectations, such as CPTPP Article 9.6.4[763], as discussed in Chapter 6.

Particularly, stability and legitimate expectation pose significant challenges to the regulatory power of states, taking into account the costly nature of ISDS proceedings, especially for Global South countries. While ambiguous concepts can provide room for escape for states, they can also create regulatory chill, as the fear of uncertainty can impede or hinder the implementation of necessary regulatory changes even if they are in public interest. Some examples are given in Chapter 4.5.

In this part, the essential framework of the FET clause is analysed. However, the specific focus of these two standards in relation to patents is discussed in Chapter 4. Furthermore, judicial proportionality analysis is left out here as it is discussed in detailed in Chapter 5.

3.3.3.2. Expropriation

Expropriation is considered possibly one of the most extreme forms of interference that can affect property rights. However, states have the right to expropriate both domestic and foreign property because of their regulatory power.[764] It is imperative to emphasise that this right must be exercised in accordance with the law. Expropriation is permissible as long as it is lawful.

Generally, the situations which are considered lawful expropriation are outlined in the expropriation provisions of IIAs themselves. For instance, USMCA Article 8.14 designates the conditions of the legal expropriation as follows: "…for a public purpose, in a non-discriminatory manner, on payment of prompt, adequate, and effective compensation in… in accordance with due process…".[765] Typically, IIAs are formulated the criteria for lawful expropriation as involving a legitimate public purpose, implementing non-arbitrary/non-discriminatory measures, adhering to the rules of due process, and providing prompt, adequate and effective compensation.[766]

In the context of investment arbitration, investors are permitted to invoke an expropriation claim for only the investments explicitly defined in the IIAs. Additionally, it falls upon the

[763]CPTPP, art 9.6.4.
[764]Dolzer, Kriebaum and Schreuer, above n 634, at 147.
[765]USMCA, Chapter 14 Article 14.8.
[766]Dolzer, Kriebaum and Schreuer, above n 634, at 183.

host state to specify the "nature and extent of property rights" that foreign investors can obtain.[767] In certain cases, the act of taking can appear indirectly, without a formal transfer of title which makes taking less apparent. It is further worth mentioning that, in the modern world, indirect expropriation has become increasingly common as compared to direct expropriation.[768] This trend can be attributed to the fact that most states aim to attract foreign investors while avoiding creating negative investment climate within the state. Additionally, state interference often emerges through obstructing the use of property rather than through explicit acts of expropriation. Therefore, particular emphasis is given to indirect expropriation in this thesis.

Direct expropriation is an act of taking/seizing ownership of a property from foreign investors through transferring its title. On the contrary, in the case of indirect expropriation, foreign investors preserve the title while the investment substantially depreciated equivalent to expropriation or nationalisation.[769] The ISDS system has largely evolved through case law, including expropriation (indirect expropriation). While the concept of expropriation is clear, the question of which situations qualify as indirect expropriation is less clear.[770] Partly because there is no uniformity of the structure in the expropriation clause, arbitral tribunals have interpreted different formulations.[771] Furthermore, determining whether a state activity qualifies as compensable or non-compensable measure, thereby amounting to expropriation, is challenging. The issue of compensable versus non-compensable measures is significant since states might expand the variety of non-compensable measures which can be interpreted as indirect expropriation by investors.[772] This conflict becomes particularly apparent in instances such as the issuance of a compulsory licence for patented products/processes or state intervention in tobacco packaging for public health purposes, as discussed in Chapter 4.

As indicated before, whether state acts lead to expropriation is shaped through case law. Determination is made on a case-by-case basis without any specific rules with regards to the types of states' act.[773] Before examining case law, it is crucial to note that creeping expropriation should be distinguished from "indirect expropriation" or "tantamount to" or

[767]McLachlan, Shore and Weiniger, above n 713, at [8.64].
[768]Bonnitcha, Poulsen and Waibel, above n 43, at 105.
[769]CETA, Chapter 8, Section D, art 8.12 (1) "…either directly or indirectly through measures having effect equivalent to nationalisation or expropriation…"; USMCA, Chapter 14, art 14.8 "…either directly or indirectly through measures having effect equivalent to nationalisation or expropriation...".
[770]McLachlan, Shore and Weiniger, above n 713, at [8.03].
[771]McLachlan, Shore and Weiniger, above n 713, at [8.07].
[772]Dolzer, Kriebaum and Schreuer, above n 634, at 154.
[773]McLachlan, Shore and Weiniger, above n 713, at [8.94].

"equivalent to" expropriation, as *Tecmed v Mexico* and *Feldman v Mexico* tribunals indicated.[774] While creeping expropriation is a type of indirect expropriation, it occurs through a series of measures, gradually, over a period of time.[775]

In assessing whether an act of government leads to indirect expropriation, the examination of certain elements established by tribunals can provide valuable insights. As indirect expropriation is formulated in the form of amount/equivalent to or tantamount to expropriation, it is not surprising that the measure in question should result in "substantial loss of control or value" or "severe economic impact".[776] In *Revere Copper v OPIC*, the arbitral tribunal found that the investor's control of use and operations were deemed ineffective through the measure; thus, the measure constituted an expropriation.[777] On the other hand, in the *Pope& Talbot v Canada*, a NAFTA case, the tribunal refused an indirect expropriation claim since the investor was not prevented from exporting a considerable amount of lumber and making a profit, as stated by the tribunal:[778]

> Even accepting (for the purpose of this analysis) the allegations of the Investor concerning diminished profits. the Tribunal concludes that the degree of interference with the Investment's operations due to the Export Control Regime does not rise to an expropriation (creeping or otherwise) within the meaning of Article 1110. While it may sometimes be uncertain whether a particular interference with business activities amounts to an expropriation, the test is whether that interference is sufficiently restrictive to support a conclusion that the property has been "taken" from the owner.

Similarly, in the *Occidental v Ecuador* case, the arbitral tribunal did not consider indirect expropriation because the investor could still manage day-to-day operations and control investment.[779] In *SD Myers v Canada* case, a temporary ban on exporting certain hazardous waste was not an act tantamount to indirect expropriation.[780]

Another controversial question is whether the taking in question should benefit the state or any other entity. It is argued that, for an act of taking to be considered as indirect

---

[774]At [8.75].
[775]Dolzer, Kriebaum and Schreuer, above n 634, at 180-181.
[776]August Reinisch "Expropriation" in Peter Muchlinski, Federico Ortino and Christoph Schereuer (ed) *The Oxford Handbook of International Investment Law* (Oxford University Press, Oxford, 2008) 407 at 438-439.
[777]*In the Matter of Revere Copper and Brass In v Overseas Private Investment Corporation (Award)* 56 IRL 258, 24 August 1978 at [112- 115].
[778]*Pope & Talbot, Inc v Government of Canada, (Interim Award)* UNCITRAL, 26 June 2000 at [102]; at [88- 105]
[779]*Occidental v Ecuador Final Award*, at [89].
[780]*SD Myers, Inc v Government of Canada (Partial Award)* UNCITRAL, 13 November 2000 (hereinafter "*SD Myers v Canada Partial Award*") at [282- 2823]

expropriation, the state itself does not necessarily need to benefit from this taking.[781] Similarly, *SD Myers v Canada* or *Amco v Indonesia* tribunals expressed that the taking can still be an indirect expropriation if any other legal or natural person benefits from it.[782] In *Tecmed v Mexico*, the arbitral tribunal argued that the focus is on the impact on the foreign investor rather than the benefit derived by the state.[783] However, some tribunals disagreed with this view. For example, in the *Lauder v Czech Republic* case, the arbitral tribunal asserted that neither Czech Republic nor any other person benefitted from the taking, and, as a result, the measure did not amount to expropriation.[784] Similarly, in *Olguin v Paraguay* case, the arbitral tribunal stated that "…whoever performs those actions will acquire directly, or indirectly, control or at least the fruits of the expropriated property.".[785]

The sole effect doctrine is an approach to determine whether state action or omission constitutes indirect expropriation. In this approach, the tribunal does not look at the intention of the state, but instead, it investigates whether the investment is affected. The tribunal in *Tippetts* case clearly specified as follows:[786]

> …the intent of the government is less important than the effects of the measure on the owner, and the form of the measures of control or interference is less important than the reality of their impact.

The primary concern of arbitral tribunals is only the effect of a state's action rather than the intention of a state.[787] Additionally, even if state had a legitimate purpose behind the measure, the arbitral tribunal only considered the impact of the measures on investors.[788] *Bilouna v Ghana*, *Starret Housing v Iran* cases are other examples of how tribunals exercised the sole effect doctrine. In some cases, such as *Tecmed v Mexico* and *Vivendi v Argentina*, even though the tribunals took into account states' intentions, they did not consider intentions as significant as effect.[789] However, the concept of sole effect is highly controversial, as

[781]Reinisch "Expropriation", above n 776, at 442-444.
[782]Reinisch "Expropriation", above n 776, at 442-444; *SD Myers v Canada Partial Award*, at [28]; *Amco Asia Corporation and Others v Republic of Indonesia (Award)* ICSID ARB/81/1, 20 November 1984, 1 ICSID Reports 413.
[783]*Tecmed v Mexico Award*, at [113-115].
[784]*Ronald S. Lauder v The Czech Republic (Final Award)* UNCITRAL, 3 September 2001 at [203].
[785]*Eudoro A Olguin v Republic of Paraguay (Award)* ICSID Case No. ARB/98/5, 26 July 2001 at [84].
[786]*Tippetts, Abbett, McCarthy, Stratton v TAMS-AFFA Consulting Engineers of Iran*, 6 Iran-US CTR 219, 225, 29 June 1984
[787]Reinisch "Expropriation", above n 776, at 444.
[788]At 445; *Phelps Dodge Corp. et al v Iran*, 10 Iran-US CTR 121, 130 (1986-I).
[789]Anne K. Hoffman "Indirect Expropriation" in August Reinisch (ed) *Standards of Investment Protection* (Oxford University Press, New York, 2008) 151 at 156-165.

recognised by scholars since it disregards the purposes of states and focuses solely on the impacts of measures.[790]

The application of sole effect doctrine would raise significant justice problems, particularly in the context of intellectual property rights. By applying the sole effect doctrine, one might claim that measure against a patented product, even if is motivated by a legitimate purpose such as public health, may be deemed as equivalent to expropriation as the investor would financially be impacted. These concerns are addressed in the next chapter. Over time, however, arbitral tribunals have introduced additional factors to be considered, such as the intention of the host state, the legitimate expectation of the investor, the purpose of the measure, or, more recently, the proportionality of the measure.[791] Similarly, some tribunals, as in *Tecmed v Mexico*, or *Azurix v Argentina*, introduced judicial proportionality[792] while acknowledging states' police powers.

The police powers doctrine is another approach which tribunals can apply to determine whether expropriation has occurred, and it reflects states' right to regulate based on their needs. The police powers doctrine implies that if a measure is enacted by means of states' police powers and results in loss of property, it does not qualify as indirect expropriation and, therefore, does not require compensation.[793] The internalisation of the concept of police powers goes to the Harvard Convention on the International Responsibility of States for Injuries to Aliens (Harvard Draft Convention) of 1961 Article 10(5).[794] The concept is further accepted as customary international law, as the OECD states:[795]

> It is an accepted principle of customary international law that where economic injury results from a bona fide non-discriminatory regulation within the police powers of the State, compensation is not required. A state measure will be discriminatory if it results "in an actual injury to the alien …with the intention to harm the aggrieved alien" to favour national companies.

[790]Maryam Malakotipour "The Chilling Effect of Indirect Expropriation Clauses on Host States' Public Policies: a Call for a Legislative Response" (2020) 22(2) International Community Law Review 235 at 239.
[791]Hoffman, above n 789, at 167-168.
[792]The role of judicial proportionality in investment arbitration is thoroughly examined in Chapter 5; therefore, no emphasis is given here.
[793]Catharine Titi "Police Powers Doctrine and International Investment Law" in Andrea Gattini and others (ed) *General Principles of Law and International Investment Arbitration* (BRILL, Leiden, 2018) 323 at 323.
[794]Harvard Convention on the International Responsibility of States for Injuries to Aliens Article 10(5): "*An uncompensated taking of an alien property or a deprivation of the use or enjoyment of property of an alien which results from the execution of tax laws; from a general change in the value of currency; from the action of the competent authorities of the State in the maintenance of public order, health or morality; or from the valid exercise of belligerent rights or otherwise incidental to the normal operation of the laws of the State shall not be considered wrongful*…".
[795]Yannaca-Small, *Fair and Equitable Treatment Standard in International Investment Law*, above n 728, at 5 n 10.

Both sources indicate that police power is not absolute and should be exercised in a non-discriminatory manner, in due process and for public welfare.

Arbitral tribunals have adopted different forms of the police powers doctrine. While some of them have considered the police powers doctrine absolute, some have taken a more moderate approach through proportionality analysis. For instance, the tribunal in *Methanex v United States*, adopted a more absolute approach by stating that:[796]

> …As a matter of general international law, a non-discriminatory regulation for a public purpose, which is enacted in accordance with due process, and which affects, inter alios, a foreign investor or investment is not deemed expropriatory and compensable unless specific commitments had been given by the regulating government to the then putative foreign investor contemplating investment that the government would refrain from such regulation.

Some tribunals, however, have taken into consideration the deference given to states as a result of police powers, introduced *proportionality* (judicial proportionality) in their analysis and have scrutinised whether the measure is "reasonably necessary".[797] A classic example of this decision was rendered by the tribunal in *Tecmed v Mexico*:[798]

> Although the analysis starts at the due deference owing to the State when defining the issues that affect its public policy or the interests of society as a whole, as well as the actions that will be implemented to protect such values, such situation does not prevent the Arbitral Tribunal, without thereby questioning such due deference, from examining the actions of the State in light of Article 5(1) of the Agreement to determine whether such measures are reasonable with respect to their goals, the deprivation of economic rights and the legitimate expectations of who suffered such deprivation. There must be a reasonable relationship of proportionality between the charge or weight imposed to the foreign investor and the aim sought to be realized by any expropriatory measure.

It is worth noting that police powers doctrine can be applicable in the assessment of expropriation, as discussed earlier. In this aspect, some claimed that it curtails protection against indirect expropriation. The concept of public interest operates paradoxically, as explained by Reinisch and Schreurer.[799] On one hand, public interest serves as a standard for

[796]*Methanex v The United States of America (Final Award on Jurisdiction and Merits)* UNCITRAL, 3 August 2005 at Part IV, Chapter D, page 4 [7].
[797]George C. Christie "What Constitutes a Taking of Property Under International Law" (1962) 38 Brit. Y.B. Int'l L. 307 at 338.
[798]*Tecmed v Mexico Award*, at [122].
[799]August Reinisch and Christoph Schreuer *International Protection of Investments: The Substantive Standards* (Cambridge University Press, United Kingdom, 2020) at 393.

determining whether expropriation has taken place.[800] On the other hand, it simultaneously serves as a criterion for legal expropriation.[801] This paradox and complexity was addressed by the tribunal in *Azurix v Argentina* case:[802]

> …the BIT would require that investments not be expropriated except for a public purpose and that there be compensation if such expropriation takes place and, at the same time, regulatory measures that may be tantamount to expropriation would not give rise to a claim for compensation if taken for a public purpose.

The analysis of this decision is provided in Chapter 5, where the role of judicial proportionality in investment cases is discussed.

Expropriation is frequently invoked by investors even when states exercise their sovereignty in line with their international obligations, such as TRIPS Agreement. When states exercise their administrative or judiciary function as a manifestation of their sovereignty, their actions in question might result in expropriation. States have the right to regulate; they should be able to exercise their regulatory power, and such an exercise of power should not automatically result in expropriation or breach an obligation that requires compensation.[803] Given the ambiguity of the application of expropriation, particularly indirect expropriation, states are sometimes cautious before taking/implementing any measures. Further, this situation can occasionally be compounded by ISDS threats from foreign multinational corporations. As a result, despite the measure being necessary or aiming to serve the public interest, such as environmental protection or public health, states might avoid or hesitate to implement measures due to the risk of facing expropriation claims.

3.4. Conclusion

This chapter provided a comprehensive exploration of intellectual property law and international investment law regimes, laying the groundwork for the next chapter. This chapter highlighted that both regimes have originated from Western countries and that they have an impact on human rights like right to health and right to have a clean environment.

---

[800] At 393.
[801] At 393.
[802] *Azurix Corp. v. The Argentina Republic (Award)* ICSID ARB/01/12, 14 July 2006 (hereinafter "*Azurix v Argentina Award*") at [311].
[803] Hoffman, above n 789, at 165-166.

The exploration of IP law, the evolution of international IP, and the flexibilities provided by the TRIPS Agreement have established the complexities of patentability of health resources. This can impact the accessibility and affordability of health resources. While views on the role of patents in promoting or impeding access to medicines and vaccines may vary, the case study of Covid-19-related health technologies has demonstrated the inadequacy of the current system when it comes to equal distribution, even during a global health emergency where access to health technologies is a matter of life and death. By examining the operation of proportionality as a midlevel principle, this thesis seeks to explain why investment protection patented health resources is disproportionate. Through analysis, this thesis determined that mere Merges' deserving core of proportionality by itself fails to serve as a tool for distributive justice. Instead, this thesis suggests that midlevel proportionality exists where the patent system undermines the social function of IP rights. The deserving core of Merges's midlevel proportionality operates to the extent that it harms others. In this respect, as the next chapter will establish, investment protection of patents clearly exceeds just return from a patent protection as it goes beyond the original design intent of patent law.

The analysis of international investment law and its substantive protections under IIAs, with a focus on protections against expropriation and FET, has provided an understanding of how an IIA operates. As it is understood from this chapter, the development of international investment and substantive standards; IIAs, particularly ISDS, can operate as a means to increase profits of multinational corporations at the expense of public interest, health and the environment in the host state. The next chapter specifically addresses this issue in the context of patents and health. The analysis provided here is the legal basis of the analysis in the next chapter, where IP and investment intersections are explored. Understanding this intersection is crucial to be able to evaluate how judicial proportionality operates in case law and to understand why investment protection of patents become disproportionate with midlevel proportionality.

CHAPTER 4- INTELLECTUAL PROPERTY AS AN INVESTMENT

4.1. Introduction

The previous chapters aimed to provide comprehensive understanding of intellectual property law and investment law. The purpose of this chapter is to show the intersection between the two legal areas and the consequent distributive justice challenges. This challenge occurs because the availability of ISDS for patents can hinder the application of the flexibilities under TRIPS, thus access to health-related products/process. Consequently, this thesis argues that investment protection of patents can be disproportional as suggested by midlevel proportionality. The first section of this chapter analyses the concept of investment protection of intellectual property. Next, this chapter scrutinizes the flexibilities within patent law that could potentially violate investment standards: FET and indirect expropriation. Subsequently, this chapter proceeds to two significant IP cases in ISDS that are directly relevant to this thesis and identifies both concerns and positive aspects of tribunals' decisions.

The concept of safeguarding intellectual property rights as an investment is definitely not a new phenomenon.[804] From the earliest bilateral investment treaty signed between Germany and Pakistan, intellectual property rights have been incorporated into the realm of investment in one way or another in the IIAs.[805] However, the intangible nature of intellectual property rights has sparked numerous debates regarding whether intellectual property rights themselves can be investments.[806] This issue is closely linked to the justification of intellectual property rights and their structural arrangements. Although it can be discussed at a theoretical level, in practice, the shift of intellectual property "from incentives to innovate toward the commodification and assetization"[807] is the reality. In the meantime, it shows that the level of the protection of intellectual property law has consistently increased throughout the history of IP.[808]

[804]Though the use of the ISDS for intellectual property rights is new. See, Peter K. Yu "The Investment-Related Aspects of Intellectual Property Rights" (2017) 66(3) The American University Law Review 829 at 842-844.
[805]Germany-Pakistan BIT 1959, art 8(1)(a); Panama-United States of America BIT (1982) (signed 27 October 1982, entered into force 30 May 1991), art I(d)(iv); Agreement between Australia and the Islamic Republic of Pakistan on the Promotion and Protection of Investments (signed 7 February 1998, entered into force 14 October 1998), art1(1)(iv).
[806]Ruth L. Okediji "Is Intellectual Property "Investment"? Eli Lilly v. Canada and the International Intellectual Property System" (2014) 35(4) University of Pennsylvania Journal of International Law 1121at 1125-1126.
[807]Rognstad, above n 196, at 69.
[808]Henning Grosse Ruse-Khan "Protecting Intellectual Property Rights under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?" in Chester Brown and Kate Miles (ed) *Evolution in Investment Treaty Law and Arbitration* (Cambridge University Press, Cambridge, 2011) 485 at 490.

This chapter highlights the impacts of the ISDS mechanism in relation to state sovereignty, particularly in administrative, legislative, or judiciary conducts, which has been already subject to an intense debate especially when public interest is at stake. The ISDS system builds an alternative forum for only foreign investors to challenge states' acts. In the case of intellectual property as an investment, these concerns sparked when the first IP claim was brought to arbitral tribunals, as pointed out by Bryan Mercurio as "awakening the sleeping giant".[809] This sleeping giant further threatens the territoriality principle, a preserved principle under international intellectual property law framework.[810] The following sections discuss the definition of IP as investment, potential expropriation claims and violation of FET standards when patent flexibilities are used. Following that, the discussion will shift to the two significant IP cases brought before the arbitral tribunal under the IIAs. The analysis will suggest how an investor has taken advantage of this protection in the past and may persist in doing so in the future, even in the presence of a pandemic, such as Covid-19. It is important to note that Covid-19 is an exceptional situation. National security exceptions in TRIPS Agreement (yet to what extent this can be revoked is unclear) or the state of necessity defence under the International Law Commission ("ILC") Articles on State Responsibility can be acceptable in such exceptional circumstances.[811] However, the threshold for state of necessity is very high[812] and the requirements for this defence might not be met in the case of every pandemic, epidemic, or other health emergency. Despite the potential applicability of the state of necessity defence or national security exceptions, the legal route itself can be a burden for states. Such power, as developed in the following sections, is considered disproportionate, providing excessive leverage to patent holders, which creates an opportunity for foreign investors to interfere states' regulatory power.

The final part of this chapter illustrates another significant concern: regulatory chill. This thesis defines this regulatory chill, or chilling effect as a "domino effect" since a single legal action or legal warning against one state can influence several others. The analysis in this

[809]Bryan Mercurio "Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements" (2012) 15(3) JIEL 871 at 871.
[810]Cynthia M. Ho "Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions" (2015) 30(1) Berkeley Technology Law Journal 213 at 228-231; Frankel "Interpreting the Overlap of International Investment and Intellectual Property Law", above n 346, at 143.
[811]Emmanuel Kolawole Oke "Can States Invoke the National Security Exception in the TRIPS Agreement in Response to Covid-19" (7 October 2020) <https://www.afronomicslaw.org/2020/10/06/can-states-invoke-the-national-security-exception-in-the-trips-agreement-in-response-to-covid-19/>; *Draft Articles on Responsibility of States for Internationally Wrongful Acts* (A/56/10) GA Res 56/83 (2001), art 25; states can potentially rely on distress (art 24) and force majeure (art 23). These options can be acceptable not only in relation to the Covid-19 but also in other exceptional situations.
[812]*Union Fenosa Gas, S.A. v. Arab Republic of Egypt (Award of the Tribunal)* ICSID ARB/14/4, 31 August 2018 at [8.46]: The tribunal rejected the state necessity defence by stating that "… the "act" was not "the only way" for the Respondent "to safeguard an essential interest against a grave and imminent peril," using the words in Article 25(1)(a) of the ILC Articles."

chapter will show that even if an investor may not bring an investment claim, the availability of ISDS can empower investors to use the mechanism to deter states from enacting measures. This dynamic reflects disproportionate, an excessive, leverage afforded to IP holders through IIAs.

4.2. Intellectual Property Protection under IIAs

Intellectual property rights have been included in BITs in the definition of an investment, while in FTAs (broad economic treaties that include obligations commonly found in BITs[813]) more recently, they have been part of the investment chapter as well as a separate chapter on their own.[814] As exemplified in Chapter 6, these separate IP chapters outline the obligations of states concerning IP rights, mostly including TRIPS-plus obligations. Safeguarding IP rights has always been a focus for the Global West countries (particularly the United States and the European Union) and after the conclusion of the TRIPS Agreement, they have continued to sign bilateral and regional agreements that include substantive intellectual property provisions.[815] Bilateral and multilateral agreements entered into after the TRIPS Agreement have been heavily criticised since they have vast negative impacts on sovereignty and policy flexibilities states have under the TRIPS Agreement.[816]

Intellectual property rights have emerged as a critical part of cross-border economic relations as a result of the loss of the competitive advantages of labour costs and technological capacity[817], as mentioned in Chapter 3. Throughout history, many states have had a key policy goal to the advancement of nationals' private interests in foreign countries by preserving the comparative advantage of intellectual property and maximizing the interest of intellectual property rights owners.[818] For instance, the United States has been applying its very well-known aggressive Section 301 provision as a strategy to enforce intellectual property rights against foreign violations in both pre- and post-TRIPS.[819] The evolution of intellectual property bilateralism has played a significant role in achieving those objectives in

[813]Investment Policy Hub "International Investment Agreements Navigator: Terminology" <https://investmentpolicy.unctad.org/international-investment-agreements>.
[814]Free Trade Agreement between the United States of America and the Republic of Korea (signed 30 June 2007, entered into force 15 March 2012) Chapter 18; The Central American-Dominican Republic Free Trade Agreement (signed 5 August 2004, entered into force 10 March 2007) Chapter 15; ASEAN-Australia-New Zealand Free Trade Agreement (signed 27 February 2009) Chapter 13.
[815]Okediji, "Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection", above n 330, at 128.
[816]At 129; Peter Drahos "BITS and BIPS: Bilateralism in Intellectual Property" (2001) 4(6) The Journal of World Intellectual Property 791 at 791; at 807-808.
[817]Okediji, "Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection", above n 330, at 134.
[818]At 142-143.
[819]Office of the United States Trade Representative "1990 Special Report 301" (27 April 1990); Office of the United States Trade Representative "2023 Special Report 301" (26 April 2023).

agreements both prior to and after the adaptation of the TRIPS Agreement (including FCN treaties).[820] IIAs often incorporate "TRIPS-plus" standards which refer to the standards that go beyond what TRIPS requires. In addition to the TRIPS-plus provisions, which can appear in various forms[821]; the safeguarding of IP as an investment, even without having a separate IP chapter or provision (or by not including flexibilities available under TRIPS)[822], enables an investor-state dispute settlement system. This availability allows private patent holders, or so-called "investors", to bring an investment claim against the state under the private arbitration system. This possibility itself can be classified as TRIPS-plus, representing disproportionate protection of IP rights since it deviates significantly from its design intent, as discussed in the following sections.

However, before fully categorising BITs as a TRIPS-plus (adds more protection than provided in the TRIPS Agreement), it is crucial to differentiate between the meaning of TRIPS-plus as *sensu stricto* and *sensu lato*, as Vanhonnaeker identifies. *Sensu lato* is the commitments that go beyond what is already included or consolidated in the TRIPS Agreement (extension of the scope of application, the inclusion of a new area of IPRs, elimination of advantages available for members under the TRIPS Agreement.).[823] An example of this is the requirement of protecting plant varieties only through the International Union for the Protection of New Varieties of Plants ("UPOV") system, which is an option under the TRIPS Agreement.[824] *Sensu stricto* would regulate the same-subject matter as the TRIPS and add to the latter an additional layer of regulation, thus strengthening what is already included in the TRIPS Agreement. Therefore, the question is whether the TRIPS-plus effect of an IIA constitutes a TRIPS-plus agreement from a *sensu stricto* or *sensu lato* understanding.[825] It is critical to acknowledge that BITs are TRIPS-plus in a *sensu lato* sense since the inclusion of intellectual property operates from a different angle, and they offer investment protection without the intention of functioning as a TRIPS-plus dimension.[826] It is significant to clarify that one of the main purposes of IIAs, particularly BITs, is to safeguard

[820]Okediji, "Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection", above n 330, at 142-143.
[821]Bryan Mercurio "TRIPS-Plus Provisions in FTA's Recent Trends" Lorand Bartels and Federico Ortino (ed) *Regional Trade Agreements and the WTO Legal System* (Oxford University Press, Oxford, 2006) 215 at 219; Drahos, "BITS and BIPS: Bilateralism in Intellectual Property", above n 816, at 792-793.
[822]Bertram Boie *The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is there a TRIPS-plus Dimension?* (Working Paper No 2019/19, November 2010) at 51.
[823]Lukas Vanhonnaeker *Intellectual Property Rights as Foreign Direct Investments: From Collision to Collaboration* (Edward Elgar Publishing, Cheltenham, 2015) at 179.
[824]At 179, n 9.
[825]At 179-180.
[826]Boie, above n 822, at 43.

foreign investment and investors rather than creating a parallel regime by regulating IPRs that overlap the TRIPS Agreement.[827]

Historically, the first BITs or their ancestors, FCN agreements, encompassed IPRs and related provisions and they existed prior to TRIPS Agreement.[828] The interaction of intellectual property law and investment law represents a significant intersection, considering that these areas have developed separately and that they have dissimilar legal regimes.[829] Yet, this intersection remains even if states' actions are consistent with the TRIPS Agreement, which adds an additional layer of legal protection to intellectual property rights distinct from those provided by the local courts or the WTO Dispute Settlement. As discussed later in this chapter, *Eli Lilly v Canada* serves an example of this phenomenon. Despite, changes in patentability requirements that align with the TRIPS Agreement, it did not stop the investor from bringing a claim. *Eli Lilly v Canada* case is significant for this thesis as it concerns a pharmaceutical product and was the first case in which an arbitral tribunal discussed patentability requirements under NAFTA. Similarly, tobacco plain packaging cases constitute another example. *Philip Morris* initiated an investment claim against both Uruguay and Australia, while their plain packaging became a dispute under the WTO[830], for instance. In this respect, investment protection can create non-monetary leverage since it enables the IP holder to bring an investment claim or threat to states with an investment claim, which ultimately provides economic benefit.

As mentioned earlier, from the first BIT till today, many IIAs have included intellectual property rights in the definition of investment. It is a reflection of the significance of protecting intangibles like patents, trade secrets, trademarks, and copyrights in the trade/commercial relations between states.[831] Further, intellectual property rights serve a crucial role in the negotiations of IIAs and represent a strategic resource, especially as a result of advancement in the biotechnology and pharmaceutical industries, both of which heavily rely on patents and know-how.[832] Therefore, states wish to safeguard their industries in overseas commercial interests and the IIAs have emerged as an instrument for this end.

[827]Vanhonnaeker, above n 823, at 182.
[828]At 183.
[829]At 183.
[830]*Australia-Tobacco Plain Packaging*.
[831]United Nations Conference on Trade and Development "Intellectual Property Provisions in International Investment Arrangements" (2007) IIA UNCTAD Monitor No.1 UNCTAD/WEB/ITE/IIA/2007/1 at 2.
[832]At 2.

4.2.1. Inclusion of IP as an Investment

To be able to bring investment claims, claimant investors must meet the criteria outlined in the IIAs. They must demonstrate that they have investment as defined in the IIA, they must qualify as an investor and be able to show the host state consent to arbitration.[833] The definition of investment underlies the answer of the possibility of bringing an investment IP claim. IIAs have been articulated in various formulations, including the definition of investment and intellectual property rights under the definition of investment. In this respect, this section begins with how IP rights are formulated in the definition of investment. It then discusses the Salini approach, which some tribunals employ to assess whether there is an investment. The analysis will show that the question of whether intellectual property qualifies as an investment remains debated. The varied decisions of arbitral tribunals about the definition of investment have contributed little to clarify the issue. This is partly due to the lack of binding precedents in investment arbitration and the diversity of the IIAs texts.

Correa and Vinuales categorise how intellectual property rights have been brought within the definition of the investment term.[834] One possible option of including intellectual property rights as an investment is through a reference to property or assets simply, without any explicit mention of IPRs.[835] Another alternative is making a general reference to either "intellectual property rights" or "intangible property".[836] A noteworthy example of this is NAFTA Article 1139, which lacks specific mention of intellectual property; instead, it contains "intangible" property in the definition of investment.[837] This allowed Eli Lilly to bring an investment claim under NAFTA, as will be discussed in Chapter 4.4.1. Similarly, *Einarsson* brought an investment claim under NAFTA as a result of the disclosure of their seismic data by the Canadian government, which is protected by both copyright and trade secrets.[838]

[833]Zachary Douglas "Property, Investment and the Scope of Investment Protection Obligation" in Zachary Douglas, Joost Pauwelyn and Jorge E. Viñuales (ed) *The Foundations of International Investment Law: Bringing Theory into Practice* (Oxford University Press, Oxford, 2014) 363 at 366.
[834]Carlos Correa and Jorge E. Viñuales "Intellectual Property Rights as Protected Investments: How Open are the Gates?" (2016) 19(1) JIEL 91 At 93
[835]At 93.
[836]At 93.
[837]NAFTA, art 1139.
[838]*Einarsson v Canada Notice of Arbitration*, at [12]. At the time of writing, the arbitral tribunal has not rendered any decision. However, this case and the analysis of tribunal are significant, particularly for sectors relying on data and trade secrets, including the pharmaceutical industry. Please see: Pratyush Nath Upreti *Data, Copyright, and Investor-State-Arbitration: Insights from Einarsson v Canada* (Stanford- Vienna TTLF Working Papers No. 97, 2023) at 21. The decision is even more significant considering the TRIPS-plus commitments related to pharmaceutical data in IIAs, as discussed in Chapter 6.

Further, when IIAs make only general reference to intellectual property, it can create ambiguity regarding which specific types of intellectual property are actually covered by the agreement and whether any future rights that may be established after the conclusion of the IIA can also be included within its scope.[839] In the first instance, it is essential to consider the territoriality principle, a fundamental principle of intellectual property law, ensuring that IIAs do not create new rights.[840] In the second instance, the broad reference to IP poses the risks of encompassing future recognised IP rights and highlights the need for detailed provisions of IIAs if such inclusion is not the intent of states.[841]

A possible third option is categorized where the definition provides a more detailed reference to IP rights which could involve a non-exhaustive or exhaustive list and potentially include rights that are generally not recognized as intellectual property, such as unregistered designs.[842] Where an IIA contains rights that are not recognised by domestic law, such inclusion should not be interpreted as the creation of new rights.[843] Rights referred to in an IIA can only deserve protection if they exist under the domestic law of the host state.[844] The fourth and final option to include intellectual property is mentioning intellectual property rights by, explicitly or not, referring to domestic or international law.[845] However, it is important to note that such reference (domestic or international) is only relevant to the definition of investment, and this does not determine whether IP rights qualify an investment under the treaty.[846]

The qualification of intellectual property rights as an investment is a complex matter. While intellectual property rights are included in the definition of investment in the IIAs, they may not always be deemed an investment. For instance, it is disputable whether mere registration of a patent would qualify as an investment. The *Apotex v USA*[847] tribunal, however,

[839]Carlos Correa "Intellectual Property as Protected Investment: Redefining the Reach of Investors' Rights" in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) 120 at 124-125.
[840]Agreement between the Federative Republic of Brazil and the Federal Democratic of Ethiopia on Investment Cooperation and Facilitation (signed 11 April 2018),art 1.3.(f) states that: "Intellectual property rights such as trademarks, trade names, trade secreta, copyrights, know-how, goodwill associated with an investment, industrial design and technical processes to the extent they are recognized under the law of the Host State and international agreements to which the Contracting Parties are parties."
[841]Correa "Intellectual Property as Protected Investment: Redefining the Reach of Investors' Rights", above n 839, at 124-125.
[842]Correa and Viñuales, above n 834, at 93.
[843]Correa "Intellectual Property as Protected Investment: Redefining the Reach of Investors' Rights", above n 839, at 127.
[844]At 127.
[845]Correa and Viñuales, above n 834, at 93.
[846]At 93, n 8.
[847]*Apotex Inc. v Government of the United States (Award on Jurisdiction and Admissibility)* ICSID ARB (AF)/12/1, 14 June 2013 (hereinafter "*Apotex v USA Award on Jurisdiction and Admissibility*").

distinguished between mere registration and investment. For the tribunal "a company's activities undertaken in its capacity as a foreign exporter of goods into the territory of a NAFTA Party are not addressed by Chapter Eleven".[848] As Dreyfuss and Frankel rightly point out, mere expenses on IP registration should not constitute an investment.[849] Similarly, it is uncertain whether a licencing agreement can meet the requirement of investment. Recently, the *Bridgestone v Panama* tribunal analysed this issue. The case involved two subsidiary companies initiating investment claims before an arbitral tribunal relying on their trademark licencing agreement.[850] The claims were the result of a decision rendered by the Supreme Court of Panama, which determined that Bridgestone's opposition to the registration of the Riverstone trademark by another company was made in bad faith, and awarded the company for the damages.[851] The decision by the Supreme Court of Panama involved claimants' liability to the competitor in opposition proceedings.[852] The arbitral tribunal addressed whether a licence qualifies as an investment through its expedited decision on objections under Article 10.29(f) of the US- Panama Trade Promotion Agreement Article, which employs an asset-based definition of investment.[853] The tribunal answered three significant questions, which potentially could be applicable in cases involving patents:[854]

> 1- In what circumstances does a trademark qualify as an investment?
>
> 2- In what circumstances, if any, are trademark licences capable of qualifying as investments?
>
> 3- Were trademark licence agreements owned and controlled by another subsidiary company?

The tribunal held that, according to domestic law, a licence to use a trademark as a right is recognised as a protected right, and thus, it could constitute an investment if it was exploited similarly to a trademark.[855] The tribunal acknowledged the characteristics of an investment identified by the *Salini* tribunal[856] to answer its first question, as outlined in detail below. For the tribunal, mere trademark registration cannot be considered as an investment; it needs to be exploited.[857] One way of exploitation, as identified by the tribunal, is licencing

[848]At [143].
[849]Dreyfuss and Frankel "From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property", above n 265, at 590.
[850]*Bridgestone v Panama Award of the Tribunal*, at [120-132].
[851]*Bridgestone v Panama Award of the Tribunal*, at [132-133].
[852]At [118-128].
[853]*Bridgestone Licensing Services, Inc. and Bridgestone Americas, Inc. v Republic of Panama (Decision on Expedited Objections)* ICSID ARB/16/34, 13 December 2017 (hereinafter "*Bridgestone v Panama Decision on Expedited Objections*") at [163-218].
[854]At [163-218] (emphasis added).
[855]At [178-180].
[856]At [165].
[857]At [171-172].

the use of the trademark for its own benefit.[858] The tribunal emphasised that such exploitation could be beneficial to the development of the host state.[859] While the tribunal accepted that a simple sale would not be considered an investment and stated that:[860]

> It does not follow that an interrelated series of activities, built round the asset of a registered trademark, that does have the characteristics of an investment does not qualify as such simply because the object of the exercise is the promotion and sale of marked goods.

The tribunal's decision appears to contrast with the decision in *Apotex v United States*, where the tribunal rejected regulatory approval of pharmaceutical products as an investment because the drugs were developed and manufactured outside the United States.[861] For the *Bridgestone* tribunal, it seems like the location of the investment in a trademark, where goodwill (the quality of the product and consumer recognition) attached to the trademark is not significant. The tribunal set a low bar for consideration of benefiting the economic development of the host state by stating that "The activities involved in promoting and supporting sales will benefit the host economy, as will taxation levied on sales.".[862] The question of why benefiting the development of the host state is relevant is considered below.

Even though the *Bridgestone* tribunal rejected the claims, the case certainly reflected neither the purpose of protection of intellectual output nor the goal of investment protection for foreign investors as a commercial dispute became an investment dispute. It illustrates an additional layer of legal protection provided to licence holders for its mere commercial relations. However, it is important to note that the tribunal acknowledged in its cost allocation that the claimants had "over-reacted", and consequently, they were required to reimburse the expended portion of Panama's costs, including advances paid to ICSID, legal fees and expenses.[863] Further, at the very least, the tribunal clarified that a mere licence could not be considered as investment unless it is exploited. Yet, the main issue concerning the economic development of the host state remains. One concern of the case is whether a licensee, who has only the right to use a trademark, can claim to have an investment. According to the tribunal, if the licence does not create a right that is protected by the domestic law, as required by the

[858] At [175].
[859] At [172].
[860] At [176].
[861] *Apotex v USA Award on Jurisdiction and Admissibility* at [143]; at [158]; at [243-244].
[862] *Bridgestone v Panama Decision on Expedited Objections*, at [172].
[863] *Bridgestone v Panama Award*, at [587]; at [589].

relevant IIA, it cannot be considered as investment.[864] However, as the licence is protected as an intellectual property right under domestic law and it is exploited by the licensee, it qualifies as investment.[865] It should be acknowledged that the tribunal respected domestic law, hence adhering to the territoriality principle of IP law. For Panama, BSAM did not own or control the rights (absence of transfer or assign without written approval from the licensor); however, the tribunal rightly concluded that BSAM owned the licence.[866] While this might be a significant aspect of the case, for the current purpose of this thesis, the extent of the licence is less relevant since BSAM owned the licence which provided the right to use the trademark and the goodwill attached to the mark.[867]

Some treaties impose other requirements that need to be fulfilled to be deemed an investment. For instance, Belarus- India BIT 2018 Article 1.4. states that investments should have:[868]

> …the characteristics of an investment such as the commitment of capital or other resources, certain duration, the expectation of gain or profit, the assumption of risk and a significance for the development of the Party in whose territory the investment is made.

As seen here, it incorporates the Salini criteria (as explained below) into its definition of investment.

The territorial nature of intellectual property rights should be kept in mind. Most of the IIAs require that intellectual property rights should be in accordance with the domestic legal framework of the host state.[869] For instance, an invention may not meet the requirements of being an investment until the host state grants a patent for such an invention.[870] Controversially, the opposite approach could be incorporated into the IIAs, and the application process could be an investment.[871] Thus, denial of the patent could even be considered a violation of an investment.[872] The United States-Jamaica BIT can be given as an example to that where agreement protects patentable inventions.[873]

---

[864]*Bridgestone v Panama Decision on Expedited Objections*, at [178].
[865]At [195].
[866]At [183]; [197].
[867]At [184].
[868]Treaty between the Republic of Belarus and the Republic of India on Investments (signed 24 September 2018, entered into force 5 March 2020) (hereinafter "Belarus-India BIT 2018"), art 1(4).
[869]Vanhonnaeker, above n 823, at 15-16.
[870]At 16.
[871]At 16-17.
[872]At 17.
[873]Treaty between the United States of America and Jamaica concerning the Reciprocal Encouragement and Protection of Investment (signed 4 February, entered into force 7 March 1997), art 1(a)(iv).

The answer would also be depending on the mechanism employed to resolve the dispute. For example, where the ICSID mechanism is applied, then an investment should also satisfy the ICSID Convention Art. 25(1): "…any legal dispute arising directly out of an investment"[874] (double-barelled test[875]). Two concepts have been developed to define the investment by tribunals under ICSID. In the first approach, which is called the subjective approach, the meaning of investment is generally found in the definition sections in the IIAs, in the operative part.[876] The second approach, objective approach, as exemplified by the ICSID Convention Article 25, aims to establish a general concept of investment through the interpretation and application by arbitral tribunals and states rather than relying on solely parties' perspectives.[877] In ICSID arbitrations, the determination of the existence of an investment would generally involve a dual analysis, commonly referred as the "double keyhole approach" or "double- barrelled test".[878] It requires an examination of two different elements: satisfy the investment definition under the IIAs, national law, or contract, as well as *investment* requirement under the ICSID Convention Article 25.[879] Yet, Article 25(1) does not provide a definition for the term investment. Thus, in the case of IP rights dispute involving ICSID jurisdiction, determining whether the matter in question constitutes an investment becomes even more challenging.

4.2.2. Salini Test

In time, tribunals operating within the ICSID framework have started to establish criteria defining the concept of investment. The first notable attempt was made by the *Fedex N.V. v Venezuela* tribunal, which formulated five criteria: "…a certain duration, a certain regularity of profit and return, assumption of risk, a substantial commitment and a significance for the host State's development.[880] Afterwards, the *Salini v Morocco* tribunal, in 2001, refined and formulated four criteria, and they became predominant in determining the characteristic of the concept of investment: "a substantial contribution, a certain duration of the operation, risk and contribution to the host State's development".[881] The contribution to the host state might be the most controversial part. The *Salini v Morocco* tribunal add this criterion by relying on

[874]ICSID Convention Article 25.
[875]Dolzer, Kriebaum and Schreuer, above n 634, at 84.
[876]At 84.
[877]At 84.
[878]At 84.
[879]At 84.
[880]*Fedax N.V. v. The Republic of Venezuela (Decision of the Tribunal on Objections to Jurisdiction)* ICSID ARB/96/3, 11 July 1997 at [43].
[881]*Salini Costruttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco (Decision on Jurisdiction)* ICSID ARB/00/4, 23 July 2001 (hereinafter "*Salini v Morocco Decision on Jurisdiction"*) at [52].

the preamble of the ICSID convention and stated that "…In reading the Convention's preamble, one may add the contribution to the economic development of the host State of the investment as an additional condition".[882] Yet, some tribunals have accepted various concepts as a contribution to host state, such as know-how, management, equipment, material, personnel, labour, and services.[883]

Some tribunals have fully applied the *Salini* criteria as a jurisdictional requirement[884] by stating that:[885]

> It is common ground between the parties that the jurisdiction of the Tribunal is contingent upon the existence of an 'investment' within the meaning of Article 25 of the ICSID Convention and of an investment under the BIT.

Other tribunals have only applied certain elements of the test.[886] Conversely, some ICSID tribunals have entirely rejected the application of the Salini criteria stating concerns about the potential exclusion of certain arbitrary transaction from the ICSID jurisdiction.[887] Conversely, some tribunals have applied Salini even in cases outside the ICSID framework, some tribunals have rejected the applicability of Salini test in non-ICSID cases.[888] While the aim of this present context is not to discuss the objectives of the ICSID Convention or the necessity of the *Salini* for determining whether a disputed matter constitutes an investment, what matters for the sake of this thesis is the implications of those disagreements for disputes concerning the intellectual property rights.

The question of whether intellectual property rights qualify as investments under IIAs or whether the *Salini* test is applicable in the context of intellectual property rights is not absent from controversary. According to Vanhonnaeker, whether the assessment of investment

---

[882] At [52].
[883] *Deutsche Bank AG v Democratic Socialist Republic of Sri Lanka (Award)* ICSID ARB/09/2, 31 October 2012 at [297]; *OI European Group B.V. v. Bolivarian Republic of Venezuela (Award)* ICSID ARB/11/25, 10 March 2015 at [24].
[884] *Patrick Mitchell v. The Democratic Republic of Congo (Decision on the Application for Annulment of the Award)* ICSID ARB/99/7, 1 November 2006 at [15- 33].
[885] *Jan de Nul NV and Dredging International NV v. Arab Republic of Egypt* (hereinafter "*Jan de Nul v Egypt*") *(Decision on Jurisdiction)* ICSID ARB/04/13, 16 June 2006 (hereinafter "*Jan de Nul v Egypt Decision on Jurisdiction*") at [90].
[886] *Saba Fakes v. Republic of Turkey (Award)* ICSID ARB/07/20, 14 July 2010 at [111]: The Tribunal is not convinced, on the other hand, that a contribution to the host State's economic development constitutes a criterion of an investment within the framework of the ICSID Convention. …such as the Salini Tribunal, have mainly relied on the preamble to the ICSID Convention to support their conclusions. … while the preamble refers to the "need for international cooperation for economic development," it would be excessive to attribute to this reference a meaning and function that is not obviously apparent from its wording.".
[887] *Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania (Award)* ICSID ARB/05/22, 24 July 2008 at [314]: "The risks the arbitrary exclusion of certain types of transaction from the scope of the Convention".
[888] *Romak SA (Switzerland) v. The Republic of Uzbekistan (Award)* UNCITRAL Rules PCA AA280, 26 November 2009 at [205-207]; *Alps Finance and Trade AG v. The Slovak Republic (Award)* UNCITRAL, 5 March 2011 at [240–41].

follows the *Salini* criteria or not, intellectual property rights like any other assets can qualify as investments under the ICSID Convention depending on the transaction.[889] In this respect, according to Vanhonnaeker, intellectual property rights can be invested for a certain duration (patents are subject to statutory termination date), they are likely to produce profit and return (monopoly rights provided through patent), they constantly under the risk of infringement by the third parties, they require substantial commitment (the costs related to enforce and protect their rights) and they contribute to the host state's development.[890]

However, there are some challenges in applying *Salini* criteria to patent rights. The first criterion for investment is duration, but there is no definitive standard on the minimum period necessary to meet the criteria (while there is consensus on minimum) and determining the duration for the qualification as an investment is highly subjective.[891] It is true that if an IP is valid, it would be protected for a much longer, for instance 20 years for patents. However, patents are subject to revocation, indicating that their duration may not be absolute. Thus, its legality is more relevant than its duration.[892] When considering the second criterion of *Salini* test, it is worth noting that a patent, may not always generate profit, particularly in situations where the patented product is never exploited in the market since exploitation is not always the requirement under the domestic laws.[893] Yet, IP rights, mainly patents, can generate profits once they enter the market. The extent of the return depends on the market environment, the nature of the product or service and its management.[894]

The third requirement of the *Salini* test is risk. While every economic transaction bear risk and such risks do not automatically qualify the transaction as an investment which is same for IP since not every IP guarantees a profit.[895] This includes potential arguments related to the failure of invention and the costs associated with it. The cost of innovation is considered as only a portion of their whole business, which does not promise any profits, with risks and capital commitments confined to a single state. The cost of innovation can be further viewed a risk undertaken by businesses prior to investment given that obtaining patent is not

[889]Vanhonnaeker, above n 823, at 22-27.
[890]At 26, n 27, n28, n 30.
[891]There seems to be a consensus among tribunals suggesting a minimum requirement of two years. *Salini v Morocco Decision on Jurisdiction*, at [54]: "…with the minimal length of time upheld by the doctrine, which is from 2 to 5 years"; *Jan de Nul v Egypt Decision on Jurisdiction*, at [93]. However, it is questionable why not a minimum of 1.5 years, as it involves more than a one-time transaction.
[892]Upreti, at 97.
[893]At 98.
[894]At 98.
[895]At 98-99.

promised. Hence, this pre-investment activity may not result in receiving IP protection, and consequently, it will not qualify as an investment. The pre-investment activity, the previous assumption of risk, would be irrelevant for the purpose of Salini test. In addition, the issuance of a compulsory licence could potentially be considered a risk for the patent holder since it potentially reduces revenue.[896] Yet, a compulsory licence is a regulatory risk taken by the patent holder rather than an economic risk. Thus, considering this as an economic risk would contravene the most significant feature of IP rights: societal objectives. It would not be suitable to suggest that flexibilities of IP rights, which are also designed to promote societal objectives, such as ensuring access to affordable medicines, constitute an economic risk for the patent holder, even if their revenue is affected.[897]

Finally, the last criterion of the *Salini* test (economic development of the host state) itself is already controversial and there are ongoing debates as to whether intellectual property contributes to the development of states. Some studies suggest that strong intellectual property rights promote further development in a state,[898] whereas others contend that they instead impede local innovation in the states, particularly in economically least-developed countries.[899] The fact that pharmaceutical companies pay taxes and potentially create jobs is not enough since if patents are in fact said to impede local innovation, the debate on economic development persists. Patent may restrict the flow of resources and other investments to the host country, reduce competition, and negatively impact both domestic and other smaller foreign companies, potentially leading to job losses. The analysis of the *Salini* test is not a compulsory one; yet it demonstrates how it does not fit the concept of IP rights.

Where ICSID Convention Article 25(1) needs not to be taken into account (non-ICSID), the mere language of the definition of investment in the IIAs does not seem to be suitable to include intellectual property rights as an investment.[900] The mere existence or acquisition intellectual property rights, such as a patent in our case, does not suffice to be considered as an investment; rather, it only serves a gateway to start importation or enter in a foreign

[896]At 99.
[897]At 99.
[898]*Integrating Intellectual Property Rights and Development Policy* (Report of the Commission Intellectual Property Rights, September 2002) at 11; at 16.
[899]Okediji, "Is Intellectual Property "Investment"? Eli Lilly v. Canada and the International Intellectual Property System", above n 806, at 1127.
[900]Agreement Between the Government of Canada and the Government of the Hong Kong Special Administrative Region of the People's Republic of China for the Promotion and Protection of Investments at (signed 10 February 2016, entered into force 06 September 2016) art 1; Investment Agreement Between the Government of the Hong Kong Special Administrative Region of the People's Republic of China and the Government of the Republic of Chile (signed 18 November 2016, entered into force 14 July 2019) art 1.

market.[901] Dreyfuss and Frankel, further highlight the importance of engaging with the host state law to benefit from protection of investment through the IIAs.[902] In particular, they emphasise how it became so much easier to obtain intellectual property protection in time, in fact, trademark (reputation, becoming well known) or copyright (creation, publication) can be provided even in the absence of activity in the host state.[903] Therefore, simply including IP rights in the definition of investment does not automatically qualify them as an investment.

In the case of patents, for instance, through Patent Cooperation Treaty (PCT)[904], a singular patent application, can provide patent protection in many countries. Thus, mere existence of protection or ownership of a protection should no longer serve as an investment.[905] Similarly, for Okediji, "the answer to the question 'when is IP an investment?" cannot be simply "when the IIA says so".[906] She highlights the necessity of examining domestic law frameworks to resolve what constitutes an investment or intellectual property rights.[907] An assessment of the validity of an IP right under domestic law can also guide what qualifies as an investment and the parameters for invoking an investment arbitration claim.[908] Similarly in IP law, patent infringement, for instance, the court evaluates whether a patent is valid under domestic law.[909] It is claimed that if IIAs and ISDS distorts the national laws like personal property, intellectual property, or contracts, they consequently establish rules of international private law in these specific areas.[910] This conflicts with the principle of territoriality of IP rights. Despite the fact that the TRIPS Agreement serves partial harmonisation of IP rights at the international level, it still gives discretion at the national level and disregarding domestic law would be problematic.

The answer of whether intellectual property rights constitute an investment is still debated as discussed. The varying decisions issued by arbitral tribunals concerning the definition of investment have contributed little to achieving clarity on the matter. It should be noted that

[901]In a similar vein, please see: Rochelle Dreyfuss and Susy Frankel "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?" (2018) 21(2) Vanderbilt JET Law 377; Okediji, "Is Intellectual Property "Investment"? Eli Lilly v. Canada and the International Intellectual Property System", above n 806, at 1125-1126.
[902]Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 901, at 403-404.
[903]At 403-404.
[904]Patent Co-operation Treaty 1160 UNTS 231 (signed 19 June 1970, entered into force 24 January 1978).
[905]Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 901, at 404.
[906]Ruth Okediji "When is Intellectual Property an Investment?" in Christophe Geiger (ed) Research Handbook on Intellectual Property and Investment Law (Edward Elgar, Cheltenham, 2020) 86 at 113.
[907]At 113.
[908]At 114.
[909]At 114.
[910]Julian Arato "The Private Law Critique of International Investment Law" (2019) 113(1) AJIL 1 at 11.

this is partially a result of the absence of binding precedents in investment arbitration, along with the variety of the IIAs texts. Nonetheless, it is crucial to consider fundamental features and underlying theories of intellectual property rights in assessing the classification of intellectual property rights as an investment. While intellectual property rights could technically be protected under IIAs, it should be kept in mind that they also serve societal welfare, human development and public interests. Yet, in practice, the availability of investment arbitration has not always reflected the ideal, as exemplified by instances of creating regulatory chill in Chapter 4.5. Therefore, as detailed in the following section, either patents, particularly those concerning health resources particularly should be non- justifiable before ISDS or the arbitral tribunals should give significant level of deference to state. The availability of ISDS expands the scope of the IP rights, transforming them into a form of investment protection beyond mere ownership. It gives a level of power (as it is described as disproportionate) that can challenge the states' regulatory power under private arbitration tribunal, despite these states being the ones granting the IP rights in the first place. This power remains even if the measures aim to address public welfare or promote the social objectives of IP rights. Consequently, it gives disproportionate power to the IP holder, as detailed in the rest of this Chapter.

Arbitral tribunals are able to include and scrutinise substantial matters in intellectual property rights, which ought to be the within purview of the state sovereign in line with the TRIPS Agreement. Even if scrutinising states' actions is the role of the courts or the arbitral tribunals in some circumstances, there are situations where certain state actions could easily touch upon public health, security, or public needs more generally. In these circumstances, even the possibility of investment claims would represent disproportionate power held by the patent holders and it raises concerns for distributional justice as detailed in the following sections. In this respect, the following parts delve into the possible violation of investment standards by states when enacting laws or interfering the intellectual property rights, in this case, patents. Particular emphasis is given to the concepts of expropriation and fair and equitable treatment, with a specific focus on the issues surrounding compulsory licence and access to health-related resources, which demonstrates how they can undermine the equitable access to affordable health resources.

4.3. Intellectual Property Flexibilities and Potential Violation of Investment Standards

It is significant to highlight the central focus of this thesis once more: This thesis revolves around the incorporation of patent protection within the scope of investments under IIAs and how investment protection of patented health resources can be disproportionate. Now, it is essential to delve into substantive provisions selected in this thesis (indirect expropriation and FET) and their connection to patent law to demonstrate how they could undermine the global distribution of health resources. Following this analysis, this chapter continues with the case law, illustrating how investors can leverage ISDS to challenge domestic IP law, which is further considered against the territoriality principle of IP.[911] Through analysing cases, it becomes tenable that the availability of ISDS for patent law and its potential adverse impact on accessing affordable health resources are not unnecessary fears but rather issues requiring careful consideration in the formulation of future IIAs. Chapter 6 delves into newly concluded regional agreements to demonstrate how the formulation of their investment section has evolved in response to the concerns discussed here.

4.3.1. Expropriation in Intellectual Property Law

As explained in Chapter 3.3.3.2., expropriation can occur directly or indirectly, and this applies to IP-based investments too. Direct expropriation can happen when states transfer the ownership of the legal title of an IP right to themselves. However, the expropriation of an IP-based investment is likely to appear indirectly. Examples of such acts that raise a question of indirect expropriation would be the invalidation of an IP right, issuing a compulsory licence and parallel importation.[912]

More frequently, indirect expropriation takes place as judicial expropriation (liability of actions and decision of the states' courts; further discussed in *Eli Lilly v Canada* case, see Chapter 4.4.1.) or regulatory expropriation (liability of states' regulatory act).[913] It is notable that indirect expropriation is highly relevant to the flexibilities of intellectual property law and such flexibilities are legitimate under the TRIPS Agreement. Being part of the IIA, intellectual property rights may become subject to an expropriation claim even if a state measure is related to public health or falls within the scope of state sovereignty (the right to

[911]Please see the concept of territoriality in definition section in Chapter 1.6.1.
[912]Simon Klopschinski, Christopher Gibson and Henning Grosse Ruse-Khan *The Protection of Intellectual Property Rights Under International Investment Law* (Oxford University Press, New York, 2021) at [7.01]; Valentina Vadi "New Forms of Dialectics between Intellectual Property and Public Health: Pharmaceutical Patent-Related Investment Disputes" (2015) 49(2) The International Lawyer 149 at 157.
[913]Emmanuel Kolawole Oke *The Interface between Intellectual Property and Investment Law: An Intertextual Analysis* (Edward Elgar, Cheltenham, 2021) at 155-156.

regulate). However, as previously discussed in Chapter 3.3.3.2., the mere fact that a state act serves a legitimate public purpose does not necessarily conclude that expropriation has not taken place and, thus, there is no need to compensate.[914] Measures against patents, particularly compulsory licences, represent a very fine line between forms of indirect expropriation that can be considered compensable and those that are considered legitimate and, thus, non-compensable.[915]

Since there is no precedence in the nature of investment arbitration and no formulation to determine expropriation, tribunals make decisions on a case-by-case approach.[916] In doing so, they may consider the sole-effect and police powers doctrine to resolve whether expropriation has occurred or whether a state act has fallen within the state regulatory power, as discussed in Chapter 3.3.3.2.[917] Some writers consider judicial proportionality as one of the assessment methods to determine whether expropriation has taken place.[918] This thesis covers proportionality in a separate chapter, in Chapter 5. Chapter 5 assesses the role judicial proportionality plays in investment arbitration and whether it can safeguard measures that address access to health resources. Where tribunals take the police powers approach, states would not need to compensate as long as the measure taken is non-discriminatory and addresses public health, safety, or public welfare.[919] The police powers doctrine was developed in response to the state's need to have the ability to take executive, legislative, or judicial measures to respond to public needs.[920]

However, this does not remove the risks of the application of the sole-effect doctrine where tribunals assess only the effect of a measure on the investment. That being said, the sole effect doctrine has been applied in various ways, as exemplified in Chapter 3.3.3.2. Another question of the sole effect doctrine is that the possibility of partial expropriation[921] which, particularly, can be an issue concerning intellectual property rights. For instance, in cases where a measure impacts only the intellectual property rights of an investor, but not the rest of the assets, it is controversial whether the measure would constitute partial expropriation.[922]

[914]Klopschinski, Gibson and Ruse-Khan, above n 912, at [7.45].
[915]Christopher Gibson "A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation" (2010) 25(3) AUILR 357 at 380.
[916]Klopschinski, Gibson and Ruse-Khan, above n 912, at [7.45].
[917]At [7.47].
[918]Oke, above n 913, at 165.
[919]Klopschinski, Gibson and Ruse-Khan, above n 912, at [7.50]
[920]At [7.50]
[921]Oke, above n 913, 168.
[922]At 168-170.

It is one of the issues discussed in the *Philip Morris v Uruguay* case, as discussed in Chapter 4.4.2.

As mentioned in Chapter 3.3.3.2., not every taking is illegal as long as it has a legitimate public purpose/interest/benefit, if it is undertaken in a non-discriminatory manner and in due process, and if the investor is compensated. However, the complexity of the elements of expropriation and the elements of police powers can be a problem when states use their power to regulate their domestic laws. It would be unreasonable to claim that every intellectual property that is affected by state measure should be compensated for constituting expropriation. Although these measures may not initially appear to be directly for public purpose, state measures can ultimately serve broader public interest. For instance, the issuance of a compulsory licence to prevent anti-competitive behaviour or to manage the inadequate working of a patent serves public interest; thus, the grounds of a compulsory licence under national law should be regarded as public interest/welfare.[923] Since compulsory licence plays a crucial role in accessing health resources, it is important to explore why a compulsory licence can potentially be considered an expropriation despite the fact that patent holder would be compensated at any rate in line with the TRIPS Agreement. As this thesis argues, this possibility is a disproportionate power provided to the patent holder through IIAs.

4.3.1.1. Compulsory Licence and Expropriation

Compulsory licencing plays a crucial role when public interests are at stake, for instance, when accessing health resources is in question. Details regarding compulsory licences is already discussed in Chapter 3. It is a mechanism which allows governments to authorise the use of a patented product/process without the consent of the patent holder. However, when this patent belongs to a foreign so-called investor and if it is safeguarded through an IIA, the question arises whether the issuance of a compulsory licence constitutes an indirect[924] expropriation. This question itself can affect access to health resources and have significant justice implications, as it adds another layer of protection to the already contentious concept of compulsory licence in intellectual property law.

[923]Carlos M. Correa "Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses" (2004) 26(1) MICH. J. INT'L L. 331 at 349.
[924]Since the legal title of a patent remains with the owner in the case of compulsory licence, it cannot be considered a direct expropriation.

The concept of compulsory licence has existed for more than 140 years, dating back to the adoption of the Paris Convention in 1883 to prevent abusive practices by patent holders.[925] A compulsory licence generally aims to serve public interest or fix anti-competitive behaviours of a patent holder.[926] However, there might be other reasons than those (like lack of working of patent)[927] that can be determined freely by member states according to the Doha Declaration.[928] As discussed in detail in Chapter 3.2, apart from investment protection, there are already complexities in the effective use of compulsory licensing. Yet, compulsory licence can undermine the fundamental interests of private patent holders.[929] This complexity is described by Taubman as:[930]

> …the grant of compulsory licenses is inevitably a contested issue in trade relations, within or beyond the TRIPS regime, because it directly calibrates the boundary between legitimate expectations of patent holders and the public interest…

The compulsory licence issued by the host state may have a substantial impact on the exclusive market opportunity of the patent holder.[931] The issuance of a compulsory license could potentially be considered a form of partial expropriation, as patent-based investments are part of a larger investment.[932] A compulsory license would likely have an economic impact on the patent holder. Although the patent holder retains the right to market the product, the availability of a cheaper alternative and increased market competition during the patent protection period would affect the patent holder's profits. It should be noted that this economic impact does not automatically result in indirect expropriation. This decision would depend on the wording of an IIA and the tribunal's approach (sole effect vs. police powers).

Furthermore, the degree of economic impact depends on multiple factors, such as the duration of the license and the amount of compensation provided to the patent holder.[933] Additionally, as discussed in Chapter 3.2.4., the host state has to pay remuneration to issue a compulsory licence. However, it is disputable if this adequate remuneration would be

[925]Paris Convention, art 5.
[926]Klopschinski, Gibson and Ruse-Khan, above n 912, at 476.
[927]Correa, "Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses", above n 923, at 349.
[928]Doha Declaration para 5(b).
[929]Robert Bird and Daniel R. Cahoy "The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach" (2008) 45(2) American Business Law Journal 283.
[930]Antony Taubman "Rethinking TRIPS:'Adequate Remuneration' for Non-voluntary Patent Licensing" (2008) 11(4) Journal of International Economic Law 927 at 942-943.
[931]Klopschinski, Gibson and Ruse-Khan, above n 912, at 484.
[932]At 484, n 476.
[933]At 485.

sufficient for the relevant IIAs. As detailed in Chapter 3.2.4., the suggested models often focus on the value of the generic product rather than the value of authorisation as required by the TRIPS Agreement. Thus, the suggested models may not meet the TRIPS Agreement standards, not to mention those of IIAs, which often require market value.[934] For some, the reasonable compensation for a compulsory licence under the TRIPS Agreement is more than zero and much less than the royalty needed to fully compensate a patent holder or cover the loss of the monopoly position it might otherwise enjoy.[935] Thus, the adequate remuneration under the TRIPS Agreement may not be satisfactory in the context of international investment law. The patent holder can easily claim that, as experienced in the *Eli Lilly v Canada* case[936], the obtainment of a patent (exclusive right) creates legitimate expectations. This can raise the question of whether issuing a compulsory licence would violate investors' investment-backed legitimate expectations. This question can be evaluated under two scenarios depending on whether the investor receives compensation.[937] It should be accepted that merely granting a patent to an investor by the host state should not create an expectation that the patent would be without limitation or revocation, as this is a well-established concept in intellectual property law. As previously discussed, patents serve a social function, so on the contrary, patent holders would anticipate that their patent might be subject to limitations or revocation. However, the situation changes if a state issues a compulsory licence without any payment or for such an extended period that remuneration becomes insignificant.[938] While compensation is typically expected when a compulsory licence is issued, the amount of compensation is another issue that would be considered based on how the sole effect or police powers doctrine operates.[939]

Moreover, most expropriation provisions include carve-outs for states' measures that are not considered indirect expropriation, such as non-discriminatory measures with legitimate public welfare. However, public welfare is not typically defined in IIAs; states should be given

[934]Agreement between Australia and the Oriental Republic of Uruguay on the Promotion and Protection of Investments (signed 5 April 2019, entered into force 27 January 2022), art 7.2.
[935]Lin, above n 398, at 163.
[936]*Eli Lilly and Company v The Government of Canada (Notice of Arbitration)* ICSID UNCT/14/2, 12 September 2013 at [77-78]: "The expropriations are contrary to the public purpose that is inherent in the grant of a patent, which creates a bargain between the patentee and the government (representing the public interest) pursuant to which the patentee receives an exclusive right to use the invention for a specified period of time in exchange for disclosure to the public of the invention. Canada's failure to fulfil its side of this bargain is unfair and contrary to recognized principles for the protection of intellectual property."
[937]Klopschinski, Gibson and Ruse-Khan, above n 912, at 488.
[938]At 486.
[939]At 490.

considerable deference to determine whether the public welfare criterion is met.[940] So, there might be complexity depending on the purpose of the compulsory licence issued.[941] Further, some IIAs provide carve-out concerning compulsory licenses through reference to the TRIPS Agreement, particularly new regional agreements, as exemplified in Chapter 6. However, the arbitral tribunal would still have a say on the amount of compensation paid even in the case of a pandemic like Covid-19. Perhaps an even more crucial implication of such a layer of protection becomes a deterrent for states due to potential legal and financial repercussions, as exemplified in detail in Chapter 4.5. This is how investment protection of patent can evolve into a non-monetary disproportionate leverage provided to the patent holder.

States may implement measures through legislative, administrative, or judicial acts in relation to patent law for public purposes or on a rational, non-discriminatory basis. This was experienced in *Eli Lilly v Canada* when two drug patents belonging to the investor were invalidated. As explored in detail in Chapter 4.4.1., in this case, the domestic court aimed to prevent patent thicket by a pharmaceutical company which extending the duration of monopoly (an overlapping set of patents, a common practice for pharmaceutical companies) through new patent protection of "new use of patented compounds".[218] Therefore, foreign investors may challenge such conducts if their patent right is affected even if the conduct reflects state policy. The availability to challenge state conduct interferes with the territoriality principle of IP law. For instance, even though Canada won the case against Eli Lilly, the Canadian Supreme Court relaxed the promise/utility doctrine three months after the *Eli Lilly v Canada* decision was rendered by the arbitral tribunal.[942] On the other hand, Upreti stated that in *AstraZeneca v Apotex* case, the patentee clearly demonstrated the utility of the new compound in its patent application, unlike in the *Eli Lilly* case; thus, the Supreme Court decision has no relevance to the arbitral tribunal's decision.[943] However, it should be noted that the Supreme Court's rejection to the promise doctrine was because it was not a good law.[944] This decision was right after the *Eli Lilly v Canada* decision which indicates cause- and -effect relationship. This power appears to show a disproportionate level of power

[940]At 490.
[941]At 492.
[942]Brook K. Baker and Katrina Geddes "The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS" (2017) 49(2) LUCLJ 479 at 505-508; *AstraZeneca Canada Inc. v. Apotex, Inc*. 2017 SCC 36 (hereinafter *AstraZeneca v Apotex)*
[943]Upreti, "Intellectual Property Rights in Investor-State Dispute Settlement: Connecting the Dots Through the Philip Morris, Eli Lilly and Bridgestone Awards", above n 711, at 388.
[944]*AstraZeneca v Apotex,* at [51].

beyond what may be deserved or beyond the social benefits that patent protection can bring. In fact, this power undermines the benefit that a patent system is meant to provide.

It may be challenging to succeed in an expropriation claim; hence, investors often bring an FET claim as an alternative. There is no reason it would be different when the disputed investment is related to IP rights, more particularly patent rights. Given its flexible nature, FET involves many complexities. The subsequent part explores FET claims within the context of patents.

4.3.2. Fair and Equitable Treatment within the Context of Intellectual Property

It is worth noting that FET is one of the treatment standards under the TRIPS Agreement; it is only referred to in the context of enforcing intellectual property rights.[945] Yet, there is a partial overlap between the scope of FET standards under IIAs as well as a fair and equitable process under the TRIPS Agreement. Article 42 of the TRIPS Agreement establishes procedural standards that WTO members must adhere to regarding IP enforcement. These standards may also be applicable in IIAs among WTO members under Article 31.3 (c) of the VCLT.[946]

As mentioned above, the FET standard has predominantly been developed through case law (denial of justice, due process, due diligence (obligation of vigilance and protection), non-discrimination, lack of arbitrariness, transparency, stability, legitimate expectations and proportionality) as a result of different formulations of the standard, which can easily encompass a wide- range scope. Therefore, certain countries, such as India, have adopted a cautious approach towards the wording of the FET. Belarus-India 2018 BIT can be given as example, where the standard is provided under the title of "Treatment of investments" as:[947]

> No Party shall subject investments made by investors of the other Party to measures which constitute a violation of customary international law through:
>
> (i) Denial of justice in any judicial or administrative proceedings; or

[945]TRIPS Agreement, art 41(2): "Procedures concerning the enforcement of intellectual property rights shall be fair and equitable."; art 42 further requires fair and equitable procedures: "Members shall make available to right holders11 civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements."; Vanhonnaeker, above n 823, at 109.
[946]Klopschinski, Gibson and Ruse-Khan, above n 912, at 351-352.
[947]Belarus-India BIT 2018, art 3.

(ii) fundamental breach of due process; or

(iii) targeted discrimination on manifestly unjustified grounds, such as gender, race or religious belief; or

(iv) manifestly abusive treatment, such as coercion, duress and harassment.

In March 2023, the Government of India issued 68 termination notices for their current BITs with renegotiation requests that adhere to its Indian Model BIT 2015.[948] Certainly, their approach may vary depending on the country based on their relationship. As with any other agreement, there must be a mutual agreement, which may not necessarily reflect their 2015 model BIT.

As discussed in Chapter 3.3.3.1, the FET standard lacks uniformity and can be interpreted differently based on the texts of the treaty. Consequently, it has become one of the most frequently invoked claims by investors. In fact, in cases involving intellectual property rights (*Eli Lilly v Canada*, *Philip Morris v Uruguay*), investors asserted that states' measures breached the FET standard under the investment agreement, as discussed below in Chapter 4.4. in detail. Nevertheless, in both cases, FET claims were rejected by the arbitral tribunals. According to Mercurio, the approaches taken by the arbitral tribunal in both *Eli Lilly v Canada* and *Philip Morris v Uruguay* shows that the tribunals respected states' regulatory power and the ambiguity of the FET standard provided tribunals to be deferential to host states.[949] However, the awards of these cases have left an open door for further cases that could create a chilling effect on states seeking to implement their policies within their sovereignty. The analysis of these cases in Chapter 4.4. reveals that different outcomes were possible. Therefore, it is significant to examine the potential FET claims in the context of intellectual property law, mainly patent law.

The emphasis is given to the concepts of legitimate expectation and denial of justice, as they have a high chance to be claimed by investors in relation to patents (for instance, *Eli Lilly v Canada* or *Philip Morris v Uruguay* in the case of trademark). The following part of this section explores legitimate expectations in the context of patents, specifically addressing whether administrative decisions, such as granting patents, can establish legitimate expectations. It further discusses whether there are any grounds for claiming legitimate

[948]Editorial "India Sends Termination Notices to 68 Countries with a Request to Renegotiate" *Investment Treaty News* (online ed, 1 July 2023).
[949]Bryan Mercurio "Keep Calm and Carry On: Lessons from the Jurisprudence on Fair and Equitable Treatment and Intellectual Property Rights" in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) 159 at 180-181.

expectations by relying on domestic IP law or international IP law frameworks. Lastly, the discussion delves into the importance of due process since administrative decisions concerning IP can be subject to judicial review, potentially leading to outcomes that are unsatisfactory for the investor.

4.3.2.1. Legitimate Expectations

The first issue discussed here is the legitimate expectations held by investors concerning their patent rights within the framework of IIAs. To what extent investors expect protection of their patent rights under a FET standard is very controversial. Certainly, the text of the FET is very important, and they are exemplified in Chapter 6, where mega-regional agreements are discussed. Three analysis is required here which can be considered as legitimate expectations: the grant of a patent right, the domestic patent law of the host state, and finally, international intellectual property agreements.

A question arises whether merely granting a patent (or trademark, etc.) would create a legitimate expectation.[950] Typically, patent rights (and other IP rights) are granted by administrative authorities, and they are subject to detailed examination in relation to the conditions of such grants. Investors may think that approval of certain criteria would provide some guarantee that their rights would not be interfered in.[951] This was one of the issues discussed in the *Eli Lilly v Canada* case, which is examined further in Chapter 4.4.1. However, as explained in the case analysis, a mere administrative act of a host state would not establish a legitimate expectation as this grant is bound by the host state's law and its limitations, such as compulsory licences. The mere grant should not provide an unconditional right to the right holder; it is subject to host states' checks and balances.[952]

The reliance on host states' domestic laws stands on the expectation of stability or in other words 'freezing' of the host state legal framework. However, it is not possible to expect that states' laws would remain unchanged as laws are dynamic and will evolve in time depending on circumstances and they will respond to unique situations and societal needs. Predictability, stability, or consistency of law are desirable, but they do not mean that laws will not change at all.[953] 'Reasonable changes' is expected from a host state.[954] In the case of a specific

[950]Klopschinski, Gibson and Ruse-Khan, above n 912, at [6.23]
[951]At [6.23].
[952]At [6.26].
[953]At [6.29].

assurance is provided by the state, circumstances of a discrimination against particular investor, or 'total alteration of the entire regulatory framework for foreign investments' may give rise to liability under FET standard.[955] The concept of specific assurance was discussed in the *Philip Morris v Uruguay* case; and in the *Eli Lilly Canada* case, the degree of such regulatory change was examined (See Chapter 4.4). Consequently, every investor should expect changes or development in the legal framework of host states, which falls into host states' regulatory power.[956] Further, it is important to note that all investors should expect changes (including limitations or flexibilities) within the framework of international intellectual property rights.[957]

The final issue analysed here concerning legitimate expectation is whether it can arise from international intellectual property agreements like the TRIPS Agreement, the Paris Convention and intellectual property chapters in IIAs like NAFTA (today's USMCA, as detailed in Chapter 6) and CETA. In *Eli Lilly v Canada* and *Philip Morris v Uruguay* cases, both investors referred to international agreements as one of their foundations of legitimate expectation. Yet, in those cases, the focus was not the commitment to international IP agreements (See in Chapter 4.4.). In contrast, the claimant in the *Einarsson v Canada* case relies on Berne Convention and the case directly addresses states' commitment to IP obligations.[958] The case is still pending, and the outcome of the case is highly significant for this discussion. While international agreements/treaties can be brought forward by investors, it should be noted that legitimate expectations are linked to the compliance to such agreements.[959] It means that investors should be aware of host states' ability to apply flexibilities and adapt their legal frameworks by complying with these agreements. However, it is important to remind once again that some intellectual property chapters of IIAs[960] may offer stronger protections than those provided in the TRIPS Agreement, particularly enhancing patent and data protections for pharmaceutical products. Chapter 6 provides specific examples of these provisions. Consequently, they might limit the already limited flexibilities of the TRIPS Agreement.

---

[954]*El Paso Energy International Company v. The Argentina Republic (Award)* ICSID ARB/03/15, 31 October 2011 (hereinafter "*El Paso v Argentina Award*") at [370].
[955]Klopschinski, Gibson and Ruse-Khan, above n 912, at [6.29]; at [6.30].
[956]At [6.43].
[957]At [6.43].
[958]Upreti, *Data, Copyright, and Investor-State- Arbitration: Insights from Einarsson v Canada*, above n 838, at [19- 22].
[959]Klopschinski, Gibson and Ruse-Khan, above n 912, at [6.53].
[960]For instance: Trade and Investment Framework Agreement Between the United States of America and the Kingdom of Thailand, The United States-Thailand (signed and entered into force 23 October 2002); for details concerning its implications for Thailand please see: Charles T. Collins-Chase "The Case Against Trips-Plus Protection in Developing Countries Facing Aids Epidemics" (2014) 29(3) U. Pa. J. In t'l L 763.

The expectation of compliance with the TRIPS Agreement raises the question of whether investment arbitration is the appropriate authority to decide on such an issue, as a separate dispute settlement mechanism is already provided under the WTO.[961] However, the WTO dispute system is a state-state mechanism, requiring investors' home state to bring a dispute that does not provide compensation for individual investors. Nevertheless, such an application introduces an additional layer of protection for the WTO rules by allowing investors to challenge states' measures, even if they comply with the TRIPS Agreement[962], such as the issuance of a compulsory licence under Article 31 or bringing an exception under Article 30. It is acknowledged that WTO member states have agreed to participate in these TRIPS-plus agreements with the ISDS mechanism. However, this thesis considers this as a problematic policy decision because ISDS is an additional layer provided to patent holders of health resources, which complicates the use of TRIPS flexibilities by states.

Similarly, changes in national patent law are permissible, given that states have sovereignty over determining their own national law, like patentability requirements or exceptions under Article 27 of the TRIPS Agreement. However, the ability of investors to challenge the national law highlights the disproportionate leverage provided to IP holders by the ISDS system. However, it is even more complicated if the standard is formulated as 'in accordance with customary international law' or 'not below the international minimum standard of treatment' since the TRIPS Agreement is not considered as customary international law even if it is a part of international law.[963] Depending on the interpretation of international minimum standard of treatment, as discussed in Chapter 3.3.3.1, the TRIPS Agreement may be excluded within the concept of the FET standard.[964] Even though it is no longer in force, the NAFTA text provides a notable example. The text provides 'minimum standard of treatment'[965] for its FET protection. Even though there is no explicit reference to customary international law, the NAFTA Free Trade Commission issued a binding interpretation, indicating that the FET article prescribed the customary international law.[966] As a result, the TRIPS Agreement may not be relevant for its FET claim if it is not recognised as a customary international law, despite legitimate expectations being viewed as part of customary

[961]Graham Cook and Hannu Wager "Adjudicating Intellectual Property Disputes at the GATT/WTO: Are There General Lessons for the Investor-State Dispute Settlement System?" in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) 287.
[962]Vanhonnaeker, above n 823, at 111.
[963]At 111.
[964]At 111-112.
[965]NAFTA, art 1105 (1)
[966]Yannaca-Small, *Fair and Equitable Treatment Standard in International Investment Law*, above n 728, at 10.

international law. Nonetheless, the TRIPS Agreement remains a significant source for an analysis conducted on FET. The concept of legitimate expectation potentially requires proportionality analysis, prompting tribunals to create balance between investors' legitimate expectations and states' responsibility and power to regulate for public welfare. This is one of the central issues in this thesis and Chapter 5 addresses it.

4.3.2.2. Denial of Justice

Another concept of the FET standard related to the context of intellectual property is denial of justice. It was also one of the claims brought by both *Eli Lilly* and *Philip Morris*, as discussed in the following section. Domestic courts in host states have significant roles in enforcing intellectual property rights, such as invalidation or revocation cases brought by third parties, and infringement cases.[967] Further, courts have the authority to grant compulsory licence; they deal with cases concerning contractual licenses and IP transfers. [968] An investor can potentially invoke a denial of justice claim even if a court grants a compulsory licence, which is particularly significant for the purpose of this thesis. Yet, TRIPS Article 31 already requires due process.[969] It is further significant to recognise that investment arbitration should not be employed as an appeal mechanism, and arbitral tribunals should not undertake substantial review of domestic court decisions that are against the domestic law of the host state.[970] Similarly, Liddell and Waibel argue that the tribunal should refrain from re-examining domestic courts' interpretation of intellectual property law as long as the rights are not diminished and courts are able to provide a rational basis.[971] Nevertheless, these requirements are already established by the TRIPS Article 41.2 and Article 41.3.[972] Similarly, as mentioned in the beginning of the FET analysis in Chapter 4.3.2., Article 42 of the TRIPS Agreement also provides procedural standards owed by the member parties to WTO on IP enforcement. Articles 41 and 42 of the TRIPS Agreement can potentially be applicable in IIAs among WTO members under the Article 31.3 (c) VCLT.[973]

[967]Klopschinski, Gibson and Ruse-Khan, above n 912, at [6.54].
[968]At [6.54].
[969]TRIPS, art 31.
[970]Klopschinski, Gibson and Ruse-Khan, above n 912, at [6.76].
[971]Kathleen Liddell and Michael Waibel "Fair and Equitable Treatment and Judicial Patent Decisions" (2016) 19(1) JIEL 145 at 173-174.
[972]TRIPS Agreement, art 41.2: "Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly or entail unreasonable time-limits or unwarranted delays."; Article 41.3: "Decisions on the merits of a case shall preferably be in writing and reasoned".
[973]VCLT, art 31.3(c).

The fact that the arbitral tribunals have established a very high threshold concerning denial of justice[974] so far, does not prevent other arbitral tribunals from adopting the opposite approach. Consequently, the availability of FET claims for patent (or expropriation, more generally ISDS, as detailed in Chapter 4.5.) can potentially discourage states from engaging in or implementing limitations or flexibilities of patents or any other intellectual property rights disproportionality. In addition, IIAs do not typically offer limitations concerning IP rights and stability/legitimate expectation within their FET[975] formulation. However, it should be noted that this trend has begun to shift, as identified in Chapter 6. The following section presents two significant cases concerning intellectual property rights and aims to illustrate states' justifiable concerns regarding this system.

4.4. Case Law and Legal Gaps

4.4.1. *Eli Lilly v Canada*

The *Eli Lilly v Canada* case became the first case in which the requirements of patentability were invoked and discussed under an investment arbitration. This case presents significant features for this thesis, as the dispute revolves around patented pharmaceutical products and the authority of a state to determine its own national patent law consistent with international obligations. The case raises questions in relation to broader public considerations, such as preserving states' right to regulate or act, particularly in the event of public interest. Additional questions arise about the impact of a private dispute settlement system on states' right to determine their own IP law as preserved by the TRIPS Agreement. The legal dispute between Eli Lilly and Canada is defined as "the uncomfortable liaison between intellectual property and international investment law"[976] and the decision rendered by the arbitral tribunal has been characterised as "the incredible shrinking victory"[977] by commentators.

It is important to note once more that the TRIPS Agreements establish only minimum protection standard, and it does not obligate a complete harmonisation of IP law among states. States retain their sovereignty over determining their own national laws and the territoriality principle of IP is preserved under the TRIPS Agreement. However, this case

[974]Klopschinski, Gibson and Ruse-Khan, above n 912, at [6.71]; at 362, [6.73].
[975]For instance: Agreement between The Government of the Republic of Colombia and The Government of the Republic of Turkey concerning The Reciprocal Promotion and Protection of Investments (signed 28 July 2014), art 4; Treaty Between the United States of America and the Oriental Republic of Uruguay Concerning the Encouragement and Reciprocal Protection of Investment (signed 4 November 2005, entered into force 1 November 2006), art 5.
[976]Sigrid Sterckx, Lisa Diependaele and Julian Cockbain "Eli Lilly v Canada: The Uncomfortable Liaison Between Intellectual Property and International Investment Law" (2017) 7(3) QMJIP 283 at 283
[977]Baker and Geddes, above n 942.

shows that investors can challenge the territoriality principle of IP law and states' right to regulate accordingly. Despite being classified as a Global North country, Canada's case is an example of powerful companies' control over states' regulatory autonomy provided by their home states.

The dispute between Eli Lilly and Canada under investment arbitration stems from the invalidation of two patents of the pharmaceutical company (Canadian Patent No 2041113, treatment of schizophrenia, the trade name is Zyprexa, and Canadian Patent No 2209735, treatment of Attention Deficit Hyperactive Disorder, the trade name is Strattera) on the grounds of lack of utility or "usefulness", which is an essential condition for patentability.[978] Invalidation of patens results in loss of exclusive rights for patent holder in the market, thereby ending their monopoly.

The story of invalidation of the Zyprexa patent started with Novopharm's regulatory approval of the generic version of Zyprexa by Health Canada.[979] Eli Lilly brought legal action against Novopharm (now Teva) under Section 60 of the Canadian Patent Act; in the same proceeding, the Federal Court, Justice O'Reilly, dismissed the legal action and invalidated Eli Lilly's patent on olanzapine by indicating that the patentee did not establish an invention.[980] After the courts decided on invalidation, Eli Lilly appealed this decision, and the Federal Court of Appeal remitted the case back to the Federal Court for reconsideration; yet again, in 2011, Justice O'Reilly ruled that the Zyprexa patent, olanzapine, was invalid due to lack of utility (did not meet the threshold of usefulness).[981] However, Eli Lilly did not stop and appealed this decision again and the Federal Court of Appeal upheld Justice O'Reilly's decision in 2012. Eli Lilly continued seeking legal action, but their appeal request was denied on 16 May 2013.[982]

The second patent in the *Eli Lilly v Canada* investment case concerned atomoxetine (Strattera). Novopharm initiated proceedings which sought a declaration of the invalidation of the Strattera patent.[983] The Federal Court judge, Justice Barnes, issued a decision in 2010 and invalidated the patent based on lack of utility, as the claimed utility was not established in the

[978]*Eli Lilly v Canada Final Award*, at [63- 94].
[979]*Eli Lilly v Canada Final Award*, at [79] n 33: "C-151, Health Canada, Notice of Compliance Database, Search Results for 'Olanzapine'".
[980]At [80].
[981]At [80-82].
[982]At [84].
[983]At [93].

application by means of sound prediction or demonstration.[984] Eli Lilly appealed the Federal Court decision; however, the Federal Court of Appeal rendered a reasoned judgement dismissing the appeal in 2011.[985] Eli Lilly subsequently sought an appeal; however, their appeal request was denied on 8 December 2011 and Eli Lilly was not able to change the invalidation decision.[986] The promise doctrine can ensure that inventors cannot obtain patent protection based on speculative claims or secure new patents with minor variations of existing patents.[987] This approach aims to prevent high prices for health products and allows generics to enter the market without delay, thereby enhancing access to health resources.[988] By losing its patents, Eli Lilly lost its monopoly in the market and its advantage in pricing.

In accordance with Canadian law, the utility requirement for untested chemical compounds should either be proven by the applicant or be "soundly predicted".[989] The components of this sound prediction were set out in *Apotex v Wellcome*: "a factual basis for the prediction, an articulable and sound line of reasoning from which the desired result can be inferred from factual basis, proper disclosure".[990] Both of Eli Lilly's patents were found invalid as it was decided that they did not fulfil the promise utility doctrine under Canadian law. As a result of domestic courts decisions, Eli Lilly searched other ways to challenge the decision and brought an investment claim under NAFTA Chapter 11. As identified above, the definition of investment and its scope vary significantly in international investment treaties and notably NAFTA Chapter 11 does not make explicit mention of intellectual property rights in the definition of investment. Yet, Eli Lilly, asserted that courts had established a "new, radically different standard for determining whether inventions fulfil that requirement" which resulted in invalidation of two patents.[991] And this resulted in an uncompensated expropriatory act that violated Article 1110 of NAFTA.[992] In addition, Eli Lilly claimed that the constructions of the utility requirement by domestic courts were a violation of NAFTA Article 1105, and, thereby, Canada had breached their particularly three obligations under fair and equitable treatment:

[984]At [93].
[985]At [94].
[986]At [94].
[987]Darren N. Wagner "The Broken Promise Doctrine: *AstraZeneca Canada Inc v Apotex Inc* and the Future of Pharmaceutical Patents" (2022) 27 Appeal 70 at 78-79.
[988]At [78-79].
[989]*Eli Lilly v Canada Final Award*, at [67].
[990]*Apotex Inc v Wellcome Foundation Ltd* 2002 SCR 77 at [70].
[991]*Eli Lilly and Company v The Government of Canada (Claimant Memorial)* ICSID UNCT/14/2, 29 September 2014 at [1].
[992]At [14].

"protection against arbitrary treatment, protection of legitimate, investment-backed expectations; and protection against discriminatory treatment".[993]

Eli Lilly added that they could not have reasonably anticipated Canada's adoption of an exceptional and arbitrary doctrine that contravened Canada's international obligations at the time of investment in the Zyprexa and Strattera patents.[994] Eli Lilly's pursuits of patent protection for those two patents were a result of reliance on Canada's patent law, which in time was issued after careful evaluation by Canadian authorities in the light of the existing law at the time, and the revocation of those patents due to the application of promise utility doctrine was completely and radically contradictory with those expectations.[995] Eli Lilly introduced other noteworthy claims regarding this matter. According to Eli Lilly, Canadian courts applied the promise utility doctrine in a discriminatory manner only to the pharmaceutical sector and Canadian promise utility doctrine diverged significantly from the NAFTA partners.[996] In sum, Eli Lilly asserted that the invalidation of those patents by judicial decisions was a result of the adoption in the mid-2000s of the "promise utility doctrine" that is "radically new, arbitrary and discriminatory against foreign pharmaceutical companies and pharmaceutical products".[997] The doctrine of promise utility is not consistent with NAFTA Chapter 17 and its application was an "unlawful expropriation under NAFTA Article 1110 as well as a breach of Canada's obligation to provide the minimum standard of treatment under NAFTA Article 1105".[998]

Canada objected to all those claims raised by Eli Lilly by stating that the company was treated with due process before Canadian courts, that their decisions did not amount to a violation of the minimum standard of treatment as such a violation would require a high threshold under customary international law, and that a mere interpretation of a domestic statutory interpretation could not serve as grounds for breach of minimum standard of treatment.[999] Canada provided important defences on the other claims by Eli Lilly that were considerably significant and relevant within intellectual property law doctrine. Firstly, Canada was able to defend against Eli Lilly's data analysis to show that discrimination

[993] At [18].
[994] At [20].
[995] At [20].
[996] At [220-222]; at [145-160].
[997] At [5].
[998] At [5].
[999] *Eli Lilly and Company v The Government of Canada (Government of Canada Counter Memorial)* ICSID UNCT/14/2, 27 January 2015 (hereinafter "*Eli Lilly v Canada Government of Canada Counter Memorial*") at [94]; at [106- 115]

against pharmaceutical patent claims lacked merit.[1000] Then, Canada put forward that substantive law (including patentability criteria) was not harmonized as asserted by the claimant.[1001] For instance, while the United States' doctrines of "enablement" and "written description" are comparable to Canada's utility requirement, Mexico has taken a distinct approach to utility requirement.[1002] In addition, all NAFTA partners' patent law has changed since the implementation of NAFTA, as laws are expected to evolve in time rather than remain static.[1003] As a result, such changes in law should not raise investment claims. Canada further referred to the international law of intellectual property, patent law, and their role in the national system. Canada reminded that international intellectual property law did not require same exact rule on substantive law, including TRIPS and NAFTA.[1004] In fact, the patentability requirements of TRIPS is the flexibility of the agreement, as explained earlier in this thesis. Canada added that the Patent Law Treaty and the Patent Cooperation Treaty did not focus on substantive law, but they focused on procedural law.[1005] Particularly, the defence on compliance with TRIPS and NAFTA reminds a discussion that was included in Chapter 4.2. regarding whether IIAs potentially create parallel regime in intellectual property law (NAFTA Chapter 17 was based on the TRIPS draft agreement).

Additionally, and maybe one of the most important considerations for this thesis, is the defence put forward by Canada in relation to its compliance with NAFTA Chapter 11 concerning expropriation claims.[1006] Article 1110 (7) of NAFTA states that:[1007]

> …this Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter 17 (Intellectual Property).

Despite the inclusion of this provision, the arbitral tribunal proceeded to evaluate the case and ultimately rendered an award by disregarding Canada's argument about their lack of jurisdiction to assess the case. This issue highlights the precise risk of incorporating intellectual property rights into the IIAs, particularly for Global South countries, where they have less bargaining power against the Global North. It becomes even crucial if this

[1000] At [135-149]; *Eli Lilly v Canada Final Award*, at [431-442].
[1001] At [181-199].
[1002] At [170-180].
[1003] At [179-180]; at [173].
[1004] At [181-188].
[1005] At [200]; at [184].
[1006] *Eli Lilly and Company v The Government of Canada (Government of Canada Statement of Defence)* ICSID UNCT/14/2, 30 June 2014 at [106-117].
[1007] NAFTA, art 1110(7).

sovereignty is for the pursuit of public interest, such as issuance of compulsory licences by states to promote the dissemination of more pharmaceutical products for public health. When states consent to these agreements, their intention is not to restrict their right to regulate for public purposes but to attract foreign investors by strengthening legal certainty. The ability to bring such claims against states, despite the existence of limitation clauses in IIAs, shows the disproportionate power of IP holders afforded by the ISDS system. The *Eli Lilly v Canada* tribunal prompted concerns among states regarding exercising regulatory authority, even in the case of public health emergencies. Despite the fact that Eli Lilly lost the case, a higher court, Supreme Court, departed from the promise doctrine in *AstraZeneca v Apotex* right after the decision, as highlighted earlier. Such constraints have implications on access to health resources, as they can limit states' capacity to enact laws to distribute adequate needed health products. This situation shows the disproportionate power of patent owners/big pharmaceutical companies as they have the chance to interfere in states' sovereignty even for measures that pertain to public health or interfere in the territoriality of IP law. It should be noted that states respond these concerns either by replacing their existing IIAs, such as NAFTA or, adopting a more nuanced approach in their new IIAs, like CPTPP with respect to investment protection. These agreements are discussed in detail in Chapter 6.

Eventually the arbitral tribunal rejected all claims of Eli Lilly.[1008] Yet, there was further discussion about the denial of justice. Canada stated that "denial of justice is the only basis on which a domestic court judgment on the validity of a property right could constitute an expropriation"[1009], the existence of which Eli Lilly failed to prove. In the case of minimum standard of fairness, Canada argued that "denial of justice is the only rule of customary international law applicable to State organs exercising an adjudicative function".[1010] The arbitral tribunal disagreed with Canada regarding the narrow interpretation of state responsibility in judicial decisions in the case of both Article 1110 (expropriation) and Article 1105 (fair and equitable treatment), while the tribunal limited itself only for some observations in this issue due to previous analysis on the utility requirement.[1011] In this respect, the tribunal stated that "a judicial act may engage the question of expropriation" and, "manifest arbitrariness" and "blatant unfairness" were included in the definition of the

[1008] *Eli Lilly v Canada Final Award*, at [480].
[1009] At [188].
[1010] At [196].
[1011] At [220-223].

minimum standard of treatment.[1012] Though, the arbitral tribunal highlighted that the ISDS does not serve as an appellate mechanism to domestic court decisions.[1013]

After this analysis, the tribunal proceeded to scrutinise if the utility requirement of Canadian law had undergone a dramatic change both under Canada's national law and in the context of Canada's NAFTA partners.[1014] Despite the fact that the arbitral tribunal differed with Eli Lilly's position on the issue of dramatic change in law, the basis of the tribunal's decision was the lack of evidence establishing a "fundamental or dramatic change".[1015] One of Eli Lilly's arguments was based on the doctrine of "legitimate expectation," where patent rights of the company could be considered as a commitment of the Canadian government.[1016] Eli Lilly claimed that they did not expect a "radical departure" from the utility requirement and it was definitely not an "acceptable margin of change".[1017] In response, Canada claimed that "extensive historical evidence demonstrating the existence of the promise standard in Canadian law long before the Claimant filed its patent or NAFTA entered into force.".[1018] Moreover, even if the promise doctrine was novel/new, its emergence should be considered a jurisprudential development within the ambit of common law, as such, the mere overturn of a prior precedent should not be interpreted as a violation of customary international law.[1019] However, as mentioned above, the only reason for the tribunal to dismiss Eli Lilly's legitimate expectation was based on the lack of evidence of dramatic change and that "it was aware that Canadian patent law required patented inventions to be useful" and that the "alleged promise utility doctrine had a foundation in Canadian law when its patents were filed".[1020]

The concept of legitimate expectation and its legal interpretation by the tribunal show disproportionate power dynamics when the effort put into the investment is considered; in this case, the only investment (effort) was the application of a patent. Further, the company held the patents for more than 10 years, even though its legitimacy was questionable. It should further be kept in mind, as the Canadian government reminded too, that "patents issued by Patent Office are only presumptively valid, subject to challenge and final

[1012]At [221-223].
[1013]At [221]; at [224].
[1014]At [66-120].
[1015]At [387].
[1016]At [261- 269].
[1017]At [269].
[1018]At [274].
[1019]At [306].
[1020]At [383-384].

determination by the judiciary.".[1021] The mere invalidation of a patent by a domestic judiciary as a result of a change in its own national IP law should not be subject to a claim before an investment tribunal. Yet, this possibility underlines the excessive leverage enjoyed by patent holders, even in the event of losing the title. It illustrates how the patent system exceeds its intended purpose as a result of ISDS. This leverage is particularly significant where the issue involves patented health resources, as it can prevent states from acting to promote public health locally or globally. Particularly, using TRIPS Article 31 for compulsory licence and TRIPS Article 31bis might be challenging, especially when a generic company wishes to export the products to countries lacking manufacturing capacities. While there are already formalities regarding the issuance of a compulsory licence under WTO as outlined in Chapter 3.2., investment protection adds an additional layer to these formalities. As exemplified in Chapter 4.5., countries have previously experienced ISDS threats, which undermine global justice. The global regulative structure, developed as a result of interdependence and free trade, should not create legal barriers to accessing affordable products. As highlighted in Chapter 2, advantaged groups shape institutional order, which can have severe human rights consequences, such as the ISDS system for patented health resources.

In the case of the arbitrariness of the promise utility doctrine, the tribunal found that Canada had "asserted a legitimate public policy justification for the promise doctrine", which aimed to secure "the public receives its end of the patent bargain" and "accuracy while discouraging overstatement in patent disclosures".[1022] What the tribunal took into account was whether the Canadian doctrine was "radically connected to these legitimate policy goals" rather than discussing whether the doctrine was the best option.[1023] Additionally, the tribunal stated one more time that Eli Lilly failed to demonstrate the unpredictability or incoherence of Canada's utility requirement.[1024] It is important to recognise that the tribunal acknowledged the need for considerable deference to be given to the conduct and decisions of national courts.[1025] The tribunal further stated that only in cases where "there is clear evidence of egregious and shocking conduct"[1026] could be assessed under NAFTA Chapter 11. This thesis elaborates this aspect further in the next few paragraphs.

[1021] *Eli Lilly v Canada Government of Canada Counter Memorial*, at [219].
[1022] *Eli Lilly v Canada Final Award*, at [423].
[1023] At [423].
[1024] At [424].
[1025] At [224].
[1026] At [224].

The tribunal rejected all the claims brought by Eli Lilly; nevertheless, detailed analysis shows that this win was indeed an "incredible shrinking victory".[1027] Baker and Geddes described this as a shrinking victory because the decision had significant implications, including a chilling effect on states. As noted earlier, the Canadian Supreme Court considered the promise doctrine as bad law right after the *Eli Lilly v Canada* award, which highlighted that Canada's victory was indeed a shrinking one. Furthermore, the arbitral tribunal rejected the claims brought by the company on the grounds of insufficient evidence by considering these patents as investments and taking the national court decisions as basis for the investment claim. While the arbitral tribunal explicitly refused to act as an appeal mechanism and considered the judicial decisions of Canadian courts as within "considerable deference"[1028], it stated that the interpretation of law should follow an "incremental" and "predictable" fashion.[1029]. This thesis acknowledges that the tribunal respected sovereignty, yet, to an extent, and highlighted that ISDS was not an appeal mechanism. However, two problems can arise from the approach of the tribunal. Firstly, by emphasising the concept of considerable deference, the tribunal did not fully acknowledge the judicial sovereignty of courts in interpreting judges' own law; the tribunal should have highlighted a higher degree of deference.[1030] Secondly, this approach can raise questions regarding global justice in the case of a policy that addresses public benefit (like compulsory licence: both public health and preventing anti-competitive behaviour). Because potentially a tribunal would find a breach if a "judicial decision or legislative action is 'dramatic, fundamental, or radical changes' even in the case of a having well-grounded rationality, changing circumstances, or evolving public interests".[1031] With respect to intellectual property, more specifically, patents, these dramatic, fundamental, or radical changes could easily be associated with public interests like accessing affordable medicines or compulsory licences. In such a case, given the analysis of the tribunal in the *Eli Lilly v Canada* case, there is a degree of uncertainty in the event of radical change.

Another concern in the scrutiny of the tribunal is the issue of harmonisation of laws and the comparative analysis of different legal regimes. The arbitral tribunal did not take into account the rules of the TRIPS Agreement which preserves territoriality principle in relation to patentability requirement - similar to those under NAFTA - despite both parties being

[1027]Baker and Geddes, above n 942, at 479.
[1028]*Eli Lilly v Canada Final Award*, at [224].
[1029]At [386]; at [426].
[1030]*Eli Lilly v Canada*: A Pyrrhic Victory Against Big Pharma (26 March 2017) International Economic Law and Policy Blog <https://worldtradelaw.typepad.com/ielpblog/2017/03/eli-lilly-v-canada-a-pyrrhic-victory-against-big-pharma-.html>.
[1031]Baker and Geddes, above n 942, at 502.

members of the WTO. Even if the TRIPS Agreement is not directly applicable, this does not prevent tribunals from recognising international IP law which affords states the freedom to determine their own national IP law as long as states provide minimum standards. Eventually, assessing national law, due to NAFTA provisions, is within the purview of arbitral tribunals. However, this raises questions about appropriate boundaries and parameters of the investment arbitration system. Instead of dismissing Eli Lilly's arguments about the uniqueness of the Canadian utility requirement, the tribunal did consider USTR's Special 301 Report against Canada by stating that:[1032]

> The Tribunal has paid particular attention to the 2014 and 2015 editions of the Special 301 Report of the USTR. In these documents, USTR notes that the United States "has serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied recently". This comment cannot be dismissed outright as a lobbying effort by Claimant, as suggested by Respondent.

While the tribunal suggested that Eli Lilly's comparative analysis would not change the decision made, the tribunal highlighted that it was more than a lobbying effort.[1033] For the tribunal, the fact that the complaint came solely from the United States and not from others meant that silence spoke louder; thus, a comparative analysis would not change the findings.[1034] This type of domestic intellectual property law criticism goes against the territoriality principle of IP law, a principle preserved by the TRIPS Agreement. This comment can easily be interpreted as suggesting that a unique law arising from unique or exceptional circumstances (for instance a special medical need in one country) may indeed become a matter for consideration and potentially leading to breach of an IIA if attracts too many attentions from other countries. Additionally, the arbitral tribunal also stated that the claimant's "claims were not in any sense frivolous, and Claimant pursued them in good faith".[1035] This statement of the tribunal and the tribunal's willingness to analyse state action and judicial change undermine the fact that states have sovereignty over determining their own IP law. This can further raise the question of whether IIAs potentially create parallel regime in intellectual property law (NAFTA Chapter 17 was based on the TRIPS draft agreement[1036]). Although one can suggest that it does not produce a parallel regime (where

[1032] *Eli Lilly v Canada Final Award*, at [378].
[1033] At [378].
[1034] At [378- 379].
[1035] At [455].
[1036] Nathaniel Lipkus and Madison Black "Intellectual Property" in Gibert Gagne and Miechele Rioux (ed) *NAFTA 2.0 From the first NAFTA to the United States- Mexico- Canada Agreement* (eBook, Palgrave Macmillan, 2022) 109 at 110.

there are no similarities or significant differences to the TRIPS Agreement), initiation of a claim of a violation of an intellectual property chapter before an ISDS system can be construed as an indication of a parallel regime of intellectual property law.

As highlighted in the beginning of this section, *Eli Lilly v Canada* is the first case revolving around the patentability requirement, which raised questions about the social function of patents and the territoriality principle of IP law. Despite NAFTA's IP Chapter's mirroring[1037] the TRIPS Agreement and preserving the territoriality, and the exception in Article 1110(7), the arbitral tribunal reviewed the case. The rejection was based on Eli Lilly's failure to prove dramatic, fundamental or radical changes. With respect to these major issues, despite the tribunal's decision in favour of the state, the analysis opened doors for further cases related to patents by not discouraging investors from potential wins. Therefore, the Eli *Lilly v Canada* case itself exemplifies the disproportionate leverage held by the patent holder as the system permits foreign investors to challenge states' regulatory power despite aligning with the TRIPS Agreement and the territoriality principle. This does not imply that foreign investors should not have the right to question states' actions. However, in the context of patent law, it

[1037]There are differences between the text of the TRIPS Agreement and NAFTA IP text, yet in the patentability requirement there are major similarities. NAFTA Article 1709: Patents:
1. Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.
2. A Party may exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent.
3. A Party may also exclude from patentability:
(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
(b) plants and animals other than microorganisms; and
(c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production.
Notwithstanding subparagraph (b), each Party shall provide for the protection of plant varieties through patents, an effective scheme of *sui generis* protection, or both.
TRIPS Article 27: Patentable Subject Matter: 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. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

clearly undermines the intended design of the patent system. It can also harm the social function of IP law and the principle of territoriality by allowing a form of interference in state sovereignty in IP law. Availability of an ISDS system poses a clear risk for justice and fairness, not just in the Global North- Global South context, but also in a global justice perspective. As highlighted in Chapter 2, international institutions like ISDS can have severe human rights consequences for health resources since they have serious implications for states to revise national laws in line with TRIPS flexibilities or to merely use the available flexibilities under the TRIPS Agreement. In line with Dreyfuss and Frankel, the ISDS mechanism can alter the dynamics of IP law and impact how states regulate this area.[1038]

4.4.2. *Philip Morris v Uruguay*

The *Philip Morris v Uruguay* dispute is one of the two cases[1039] brought by Philip Morris (PM) against governments arising from tobacco packaging policies.[1040] Although the case brought against Australia was declined due to lack of jurisdiction, the case brought against Uruguay was scrutinised by the arbitral tribunal, which revealed significant aspects for public health, exercising state sovereignty in regulating public interests, intellectual property rights and development.

In 2010, PM initiated investment arbitration against Uruguay relying on Switzerland-Uruguay BIT 1988 under ICSID arbitration rules.[1041] The tobacco company claimed that Uruguay's measures concerning tobacco packaging, which limits the size of trademark, requires health warning that covers 80% of the front and back of the package (80/80 Regulation) and mandates tobacco companies sell only a single variant for each family brand of their product (the "single representation requirement"- "SPR" - either Marlboro Red or Light) violated their investment protection under the relevant BIT.[1042] PM asserted that Uruguay's anti-smoking legislation constituted indirect expropriation, denied fair and equitable treatment, and the constitutionality decisions of Uruguayan courts about the measures lead to denial of justice.[1043] Before delving into PM's legal claims, the issue of the

[1038]Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 901, at 414.
[1039]*Philip Morris v Uruguay Award.*
[1040]The policies were implemented after the conclusion of the WHO Framework Convention on Tobacco Control. Please see: *WHO Framework Convention on Tobacco Control* (WHO, 2003); *WHO Framework Convention on Tobacco Control: Guidelines for Implementation Article 11* (WHO, FCTC/COP3(10), November 2008).
[1041]*Philip Morris v Uruguay Award.*
[1042]At [9].
[1043]Agreement between the Swiss Confederation and Oriental Republic of Uruguay on the Reciprocal Promotion and Protection of Investments, Switzerland- Uruguay (signed 07 October 1988, entered into force 22 April 1991), art 3(2); art 5.

cost of legal fees and arbitration expenses should be stressed as they could be a considerable burden for a nation like Uruguay. They could have potentially faced with challenges in its payment obligations in the event of an adverse outcome; in fact, Uruguay would not have been able to defend itself if it had not received financial support from Michael Bloomberg.[1044]

The new regulations in question were necessary to fight against tobacco consumption in the country. The WHO and the Pan American Health Organisation (PAHO) emphasized health ramifications of the tobacco industry in the world and particularly Uruguay in their written non-party submission.[1045] "Every year, approximately 5.1 million adults aged 30 years and over die from direct tobacco use, and 603,000 people die from exposure to second-hand smoke".[1046] Uruguay ranked third in Latin America in the highest rate of smoking and the country experienced a high rate of tobacco- related mortality with more than 5,000 deaths annually and diseases like cardiovascular diseases and cancer.[1047] 15% of all deaths of individuals aged 30 and up were related to tobacco consumption or exposure; and as of 2003, 14 people were dying every day.[1048] All these numbers highlighted the importance of implementing strict measures to reduce consumption in the country. It should further be highlighted that Uruguay enacted its tobacco regulations pursuant to the guidelines set forth in the World Health Organisation's (WHO) Framework Convention on Tobacco Control (FCTC), except for single representation.[1049]

According to PM, the SPR measure had a significant impact on the value of the company, while the 80/80 regulation restricted the company's ability to use its legally protected trademark and to exhibit it in a suitable form.[1050] PM argued that Uruguay had violated various obligations under the Switzerland-Uruguay BIT, including Article 3(1) (impairment of the use and enjoyment of investments, Article 3(2) (FET and denial of justice), Article 5

[1044]Kate Kelland "Gates and Bloomberg create $4 million fund to fight Big Tobacco" (19 March 2015) Reuters <https://www.reuters.com/article/us-health-tobacco-fund/gates-and-bloomberg-create-4-million-fund-to-fight-big-tobacco-idUSKBN0ME24C20150318>; Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 901, at 392-393.
[1045]*Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (Written Submission (Amicus Curiae Brief) by the WHO and the Secretariat of the Tobacco Control Convention)* ICSID ARB/10/7, 28 January 2015 (hereinafter *Philip Morris v Uruguay WHO Amicus Brief*"); *Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (Alegato Escrito (Amicus Curiae) de la Organizacion PanAmericana de la Salud)* ICSID ARB/10/7, 28 De Marzo Del 2015 (hereinafter *Philip Morris v Uruguay PAHO Amicus Brief*).
[1046]*Philip Morris v Uruguay WHO Amicus Brief* at [2].
[1047]*PAHO Amicus Brief* at [29-26].
[1048]*PAHO Amicus Brief* at [29-26].
[1049]*Philip Morris v Uruguay Award*, at [38].
[1050]At [10-11].

(expropriation) and Article 11 (pertains to the observance of commitments).[1051] Due to the scope of this thesis, emphasis is only given to the issues pertaining to expropriation, fair and equitable treatment, and denial of justice.

PM claimed that measures taken by Uruguay in relation to SPR and the 80/80 rule had resulted in indirect expropriation of its investment and violated Article 5(1) of the BIT.[1052] According to PM, the implementation of SPR expropriated seven of 13 variants as well as its legal rights stemming from intellectual property, including goodwill.[1053] Further, PM claimed that the 80/80 regulation further impaired the remaining variants by "corrupted representation- (80/80 representation was referred as corrupted)".[1054] PM added that the tribunal should only examine whether measures had significantly reduced the value of the investments rather than look for economic loss entirely to determine if indirect expropriation had taken place.[1055] For PM, it was irrelevant to discuss if a host state had benefited from the expropriatory measure, an intention to expropriate, or if the PM's business stopped entirely because of the expropriatory measures.[1056] According to the claimant, each brand asset (each variant and each brand) constituted an investment and was therefore protected individually; therefore, it was not relevant even if the company still held profit.[1057] PM asserted that the disputed marks had validly been registered and they retained the distinctive nature of the trademark.[1058] Additionally, for PM, a trademark, both at the domestic (under Uruguay law) and international levels, granted owners the right to use and the right to protect their registered trademark.[1059]

However, the most striking claim of the PM was that even if an expropriation was undertaken for a public purpose, adequate compensation was supposed to be paid to meet lawful expropriation.[1060] This argument carries substantial implications with respect to the societal function of intellectual property rights. It shows that the inclusion of intellectual property rights under IIAs has the potential to restrict the fulfilment of societal function as well as the territoriality principle, including states' right to regulate in line with their particular needs.

[1051]At [12].
[1052]At [9-11].
[1053]At [193].
[1054]At [194].
[1055]At [183].
[1056]At [185].
[1057]At [195].
[1058]At [200-203].
[1059]At [204-209].
[1060]At [184].

For PM, neither of these measures could be justified on the basis of the police powers doctrine as their objective was not to reduce tobacco consumption and the government's actions were in contradiction with its particular commitments to investors.[1061] PM further stated that the respondent host state did not conduct "serious, objective and scientific" research concerning these measures and that these measures were not proportional to public interest.[1062]

Uruguay, in its defence, posited that the implemented measures did not have any expropriation effect; therefore, Article 5 was not applicable.[1063] Further, the state argued that the legitimate exercise of police powers should not be considered as expropriation and, hence; it did not require compensation.[1064] A measure would be considered indirect expropriation only if the owner was left with almost no value, rather than just experiencing a mere negative effect.[1065] If "sufficiently positive" value remains, the measure could not constitute expropriation, as established in some cases such as *Archer Daniels*, *LG&E*, *CMS* and *Encana*.[1066] Uruguay highlighted the factual evidences and stated that claimant's net operating income scaled up between the years 2005 and 2012, three years after the SPR and the 80/80 regulations were implemented.[1067] Thus, for the respondent, it was clear that the claimant's business had remained commercially valuable.[1068]

For Uruguay, it would be wrong to asses every brand independently and analysis of expropriation requires to focus on the investment as a whole.[1069] Uruguay rightly defended their measures stating that "if states were held liable for expropriation every time a regulation had an adverse impact, effective governance would be rendered impossible.".[1070] Uruguay defended its policies by stating that safeguarding public health is the only act of police powers that is part of state sovereignty as long as it is *bona fide* and non-discriminatory.[1071] According to Uruguay, the police powers doctrine is part of customary international law and is interpreted according to Article 31 of the VCLT, which does not require compensation.[1072]

[1061]At [199].
[1062]At [199].
[1063]At [187].
[1064]At [188].
[1065]At [189].
[1066]At [190].
[1067]At [211-214].
[1068]At [211].
[1069]At [215].
[1070]At [191].
[1071]At [216-217].
[1072]At [218].

Uruguay further acknowledged that exercise of police powers doctrine had limitations such as the need to "public security, order, health, morality and justice" and, it should be exercised in a non-discriminatory manner and good faith as Uruguay had exercised in its SPR and the 80/80 regulations.[1073] Even if these rights are protected as trademarks, Uruguay also highlighted that Uruguayan intellectual property law, like any other international intellectual property law, safeguarded only against use by others (negative right) rather than providing positive right to use.[1074] Against the claimant's argument, Uruguay defended that mere trademark registration did not raise the protection of the right to use and it did not provide protection against government measures that restricted such use.[1075]

The arbitral tribunal decided in favour of Uruguay and acknowledged that the challenged measures did not affect the legal title of the property.[1076] The tribunal stated that the investment had to be deprived substantially by the state measures to be considered as indirect expropriation.[1077] In this respect, the tribunal addressed three key issues: (i)whether the claimants owned the banned trademarks; (ii)whether a trademark confers a right to use or only a right to protect against use by others; and (iii)whether the challenged measures had expropriated the claimants' investment.[1078] With respect to the first issue, the arbitral tribunal posited that ownership of a trademark had to be decided in line with Uruguayan law and accepted that these trademarks were protected under Uruguayan law.[1079] The issue of whether these trademarks were, in fact, protected under Uruguayan law is the beyond the scope this thesis; therefore, no further analysis is undertaken on this matter. In the case of the second issue, the tribunal found it more beneficial to handle the issue as a question of whether a trademark conferred an absolute versus exclusive right to use rather than whether it conferred right to use versus right to protect.[1080] In the tribunal's view, ownership could entail the right to use against other persons, but this was not an absolute right against the State *qua* regulator under both Uruguayan law and international law.[1081] As Dreyfuss and Frankel rightly identified, while the tribunal acknowledged trademarks as providing owners the right to exclude others from using them (rather than a positive right), they attributed an economic

[1073] At [219-221].
[1074] At [227-232].
[1075] At [232-233].
[1076] At [191].
[1077] At [192].
[1078] At [235].
[1079] At [243]; at [245].
[1080] At [267].
[1081] At [271].

value of negative right and delved into an analysis of measures that potentially could result in expropriation.[1082] In respect, the tribunal stated that:[1083]

> It must be assumed that trademarks have been registered to be put to use, even if a trademark registration may sometime only serve the purpose of excluding third parties from its use…
>
> …The Tribunal concludes that the Claimants had property rights regarding their trademarks capable of being expropriated.

The tribunal disagreed with Uruguay and stated that the lack of a right to use would not necessarily lead to a conclusion that the trademark was not property and was incapable of being expropriated.[1084] The tribunal considered a trademark as a form of property that could be expropriated.[1085] Though, for the tribunal, the 80/80 regulation still gave 20% of space to claimants to provide distinctive elements on packs, thus; the regulation was insufficient to find that it had a substantial effect on the PM's business.[1086] Similarly, for the tribunal, the SPR did not meet the threshold required to constitute indirect expropriation as the Claimant's business was considered as a whole and the impact of the SPR regulation was far from depriving the Claimant's whole business substantively.[1087] It is uncertain, in this case, how much loss would meet the expropriation threshold.[1088] Further, the SPR regulation was not part of the FCTC, which resulted in opposition from one of the arbitrators, as discussed below.

While the arbitral tribunal could have completed its analysis on expropriation, the tribunal addressed the issue of police powers of a state and opined that both measures were valid exercises of police powers.[1089] For the tribunal, in line with Uruguay's argument, the BIT had to be interpreted in accordance with Article 31(3)(c) of the VCLT, and protecting public health was recognised as part of police powers which was also established by the relevant BIT Article 2(1).[1090] The Tribunal highlighted that bona fide exercise of police powers to preserve public order, health, and morality further precludes compensation, even if it harms investors economically as also indicated in some other tribunals such as *Methanex v United*

[1082]Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 901, at 388; *Philip Morris v Uruguay Award*, at [273-274].
[1083] At [273-274].
[1084]*Philip Morris v Uruguay Award*, at [272].
[1085]At [272-273].
[1086]At [276].
[1087]At [283-286].
[1088]Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 901, at 388.
[1089]*Philip Morris v Uruguay Award*, at [287].
[1090]At [290-291].

States or *Chemtura v Canada*.[1091] In addition, the tribunal referred to an arbitral decision that relied on the European Convention for Protection of Human Rights such as *Tecmed v Mexico*.[1092] The tribunal further referred to parties' expert reports and expressed the difficulty on the research that could be carried out on the motivational aspects of tobacco consumption.[1093]

Finally, the tribunal concluded its expropriation analysis by stating that both measures enacted by Uruguay were implemented in good faith, they were non-discriminatory and proportional, and that the measures aimed to fulfil the national and international obligation to protect public health.[1094] While the expropriation decision could be interpreted as a positive result for states, the application of police powers leaves some questions. It remains uncertain how far states can go with this tribunal's analysis of police powers. Despite uncertainty regarding states' regulatory power, the tribunal emphasised that bona fide measures aimed at safeguarding public welfare, as well as non-discriminatory and proportionate measures, would not qualify as indirect expropriation. However, the tribunal, while referring to the OECD's definition of police power as "reasonable bona fide exercise of police powers in such matters as the maintenance of public order, health or morality"[1095], also called for proportionality analysis. This means that even bona-fide non-discriminatory measures adopted for public welfare, can constitute expropriation if they are not proportional. The tribunal appears to have limited the police powers to such an extent that there was an adverse impact on the investment. This might apply to other areas in law, but in IP law, it becomes questionable since the nature of IP rights as an investment (if IP law does not establish a positive right to use) is not certain despite the fact that arbitral tribunals accepted IP rights as investments so far. Moreover, given the design intent of IP and its social functions, there is no guarantee that IP will remain unaffected adversely by states' measures. The tribunal also noted that the measure only restricted the trademark and did not ban the production and sale of tobacco altogether.[1096] The tribunal highlighted the limited economic impact of the measures. Thus, through the application of proportionality and consideration of economic impact on the investment, the tribunal limited the police powers doctrine, and hence, the regulatory power of states.

[1091]At [295-299].
[1092]At [295-296].
[1093]At [306].
[1094]At [302-307].
[1095]At [295].
[1096]At 87, n 405.

Another claim brought by the claimant was that the measures implemented by Uruguay were a violation of the FET provision in Article 3(2) of the BIT. PM claimed that the measures were arbitrary, undermining of PM's legitimate expectation, and destructive for the legal stability on which investors relied with the availability of the BIT.[1097] PM claimed that the SPR regulation was arbitrary because there was no connection between the measures and objectives as there was no scientific evidence on reducing smoking or on that SPR would prevent misleading customers.[1098] Additionally, for PM, again, there was no evidence showing increasing plain packaging from 50% to 80% would be able to raise awareness, and PM claimed that the aim of the 80/80 regulation was to only punish one company.[1099] Further, PM asserted that it had the legitimate expectation that the host state would not enforce restrictive regulations without proper reasoning but it would respect the trademarks, and, thus it would enable PM to effectively capitalise on assets.[1100] According to PM, they had reasonable expectations of accessing a "just, unbiased, and effective domestic court system".[1101] And, yet, for PM, the SPR regulation disrupted its ability to market and capitalise on the trademarks and related goodwill.[1102] In the meantime, the 80/80 regulation hindered the ability to exploit properly and leverage its brand.[1103] Lastly, the claimant asserted that the host state violated the FET claim because Uruguay had the legal obligation to ensure a predictable and stable legal environment, and yet, those measures were in excess of legislative powers and could not be considered as an "acceptable margin of change".[1104]

In response to PM's claims, Uruguay asserted that the measures were not arbitrary; they were consistent with legitimate expectations, and they did not destroy/jeopardise legal stability.[1105] Uruguay stated that the challenged measures were implemented in good faith, there was a logical connection with the goals pursued by the host state, and it was irrelevant to assess whether measures taken by other countries would have been better.[1106] Uruguay argued that both the SPR and the 80/80 measures were in line with the objectives of safeguarding public health.[1107] Further, Uruguay defended its regulations by arguing that the SPR aligned with the

[1097]At [309].
[1098]At [327-334].
[1099]At [335-339].
[1100]At [341].
[1101]At [341].
[1102]At [345].
[1103]At [345].
[1104]At [346].
[1105]At [351-387].
[1106]At [352-356]
[1107]At [359]; at [368].

WHO's recommendations and that the 80/80 measure served the aim of protecting public health since it was widely acknowledged internationally and, thus, was more effective.[1108] For Uruguay, as state had not made any particular promises, no legitimate expectation arose on its part.[1109] The respondent further highlighted that tobacco control was one of the most regulated issues globally, and, thus PM was not supposed to expect that domestic law to remain unchanged.[1110] In particular, for Uruguay, it was not reasonable to presume that regulatory measures would be static over time, given the evolving nature of concerns about public health. Additionally, Uruguay underlined the letter sent by one of the claimants to support the adaptation of tobacco measure.[1111]

The tribunal analysed the arbitrariness involved in the ELSI decision of ICJ: "a wilful disregard of due process of law, an act which shocks, or at least surprises, a sense of juridical propriety" and decided that both measures did not meet the threshold, and thus; they were not arbitrary.[1112] The tribunal acknowledged that the objectives of Uruguay and the effectiveness of the measures were compatible with the WHO and the PAHO Amicus Briefs.[1113] Further, the tribunal recognised the difficulty of gathering evidence by Uruguay and the application of publicly available scientific evidence at global scale.[1114] In addition, the tribunal emphasised the "margin of appreciation" for making public policy decisions and stated that a significant deference had to be given to governments regarding their policy choices and their national interests in line with the *Chemtura v Canada* decision.[1115] When examining the SPR regulation, the tribunal highlighted the issue of misrepresentation in various packaging or labelling of certain variants, a strategy that the claimant PM had also employed.[1116] The tribunal concluded that the SPR regulation, irrespective of the effectiveness of the measure, aimed to address a real health issue about misunderstanding tobacco safety; thus, the measure was not disproportionate and it was implemented in good faith.[1117]

The arbitral tribunal conducted similar analysis in relation to the 80/80 regulation. After the analysis, the tribunal concluded that the determination of the size of warnings fell within the

[1108]At [362]; at [368-374].
[1109]At [375-379].
[1110]At [380].
[1111]At [383].
[1112]At [390-391].
[1113]At [391].
[1114]At [393-396].
[1115]At [398-401].
[1116]At [403-406].
[1117]At [409-410].

purview of national authorities and was left to the discretion of the regulatory authority since the FCTC did not limit size.[1118] The tribunal referred to *EDF v Romania* and *El Paso v Argentina* cases in the context of legitimate expectation and legal stability.[1119] The tribunal stated that no specific commitment was provided by the host state.[1120] In the tribunal's perspective, the tobacco companies could expect regulations to be directed only at the sale and use of tobacco products with the goal to increase awareness of the harmful impact of tobacco products globally.[1121] Ultimately, the arbitral tribunal dismissed the FET claim.

The last significant claim brought by the claimants for the purpose of this thesis was denial of justice (violation of FET). One of the claimants, Abal, had initiated two different proceedings before the Supreme Court of Justice (SCJ) and Supreme Administrative Tribunal, Tribunal de lo Contencioso Administrativo (TCA); however, both disputes ended up with same question: whether the executive would allow more than 50% warnings.[1122] Abal claimed that both decisions of the TCA and the Supreme Court were contradictory and the judicial system of the host state deprived the Claimant's right to a decision on the legality of the 80/80 measure.[1123] The respondent answered these claims by stating that they are co-equal institutions; while TCA rules on administrative acts, the SCJ determines constitutionality of laws.[1124] Further, the host state rejected the contradiction between decisions as the Supreme Court decided that the law was constitutional, and TCA decided the decree was valid. Both institutions dismissed the claimants' arguments, and TCA has no obligation to follow supreme court's legal reasoning or interpretation.[1125] The tribunal analysed the 1952 Constitution of Uruguay and reached a decision that the two judicial bodies were equal and independent in their decisions.[1126] The tribunal added that constitutionality analysis of the Supreme Court would not have any binding effect on the TCA and that it had full discretion to determine the validity of an administrative act.[1127] The tribunal decided that while Uruguay's domestic law system could be unconventional, the claimants were able to challenge the law and obtain a proper decision on the matter.[1128] The tribunal recognised the separation of administrative tribunals in civil law systems and referred to the ECtHR

[1118]At [411-420].
[1119]At [424].
[1120]At [426-429].
[1121]At [429-435].
[1122]At [504-509].
[1123]At [483]; at [506].
[1124]At [510].
[1125]At [511-515].
[1126]At [516-536].
[1127]At [523-524].
[1128]At [527].

jurisprudence; *Nejdet Şahin & Perihan Şahin v Turkey*, to show that separation was accepted by courts.[1129] Furthermore, the tribunal highlighted that the arbitral tribunals were not an appeal mechanism.[1130]

Once again, just like *Eli Lilly v Canada* case, another investment arbitration proceeding was concluded in favour of the respondent state. However, this time, the decision of an arbitral tribunal attracted dissent by one of its arbitrators, Gary Born.[1131] Gary Born, while agreeing with the majority of the award, disagreed with respect to several particular issues in the award. Born, firstly, disagreed with the application of the *Margin of Appreciation* doctrine in investment arbitration proceedings as the doctrine enshrined in ECtHR.[1132] Taking into account this critique, this thesis delves into the question of whether MoA should be applicable in investment arbitration. Born further disagreed with the finding that the SPR regulation did not violate Article 3(2) by reasoning this stance with the fact that SPR was not included in FCTC and that the SPR measure relied on "other reasons than an after-the-fact assessment of the measure's efficacy in reducing smoking".[1133] Finally, Born disagreed with the majority's failure to address the alleged contradictory decisions of Uruguayan courts, which amounted to denial of justice.[1134] Born posited that "quirkiness is not a defence under international law"[1135]. The dissenting opinion expressed by Born has raised significant concerns over the sovereignty of states. It further raised awareness of the threat of accepting a privatised court system (arbitration) that would give almost the decision-making power on public policies to corporate lawyers, as highlighted by some scholars.[1136]

Besides the dissenting opinion of Born, the award rendered by the arbitral tribunal established a significant connection between human rights and police power/state sovereignty. The award acknowledged states' right to regulate to protect public health. These principles should be considered and incorporated into any future dispute involving public health issues. This decision can easily be associated with the circumstances involved in access to health-related

[1129]At [531- 532].
[1130]At [528].
[1131]*Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (Concurrence and Dissent)* ICSID ARB/10/7, 8 July 2016.
[1132]At [180-191].
[1133]At [192-196].
[1134]At [6-81].
[1135]At [62].
[1136]Bernard Caillaud and Ariane Lambert- Mogiliansky *Pro- business Arbitration with ISDS* (HAL Working Paper No 2022-28, December 2023); Amanda Lees and Others "Suitability of ISDS for Societal Challenges" (21 December 2023) Gar <https://globalarbitrationreview.com/guide/the-guide-investment-treaty-protection-and-enforcement/second-edition/article/suitability-of-isds-societal-challenges>.

sources, such as in the case of compulsory licencing. Despite the dissenting opinion, the case is significant for the purpose of this thesis as the arbitral tribunal acknowledged the priority of state sovereignty in implementing regulations that address public health matters.

Investment protection of intellectual property raises questions regarding fairness as it allows big companies like Philip Morris to bring claims under ISDS. This is mainly because the trademark in this case enables protecting a product that poses serious health risks and measures were taken to reduce smoking rates. Here, the main societal goal was to achieve a society with lower smoking rates; however, trademarks created a difficulty against this goal. In this regard, the SPR regulation was merely implemented to correct the perception that certain types of tobacco are less harmful than others. However, the issue at hand transformed into a question of whether a trademark confers a right to use. The claimant was able to leverage its trademark rights by extending the right to use via IIAs disproportionally and challenging public health measures imposed by Uruguay. Investors' stretching trademarks disproportionately via IIAs presents significant distributive justice concerns within the realm of access to health resources or prevention of health risks. The tribunal's jurisdiction over such a case itself has a detrimental effect on other countries' ability to implement similar regulations. This affirms the disproportional power given to the IP holder as exemplified in the following section. Meanwhile, until similar measures are implemented in other countries, companies can continue to reap substantial profits. The impact of these two cases and the inclusion of IP rights in IIAs extend beyond one state. A single legal action against one state or a single warning to one country about their measure can influence multiple others which highlight the disproportionate leverage held by patent holders. The following section explores this implication in depth.

4.5. Domino Effect

It is important to highlight the regulatory chill that investment protection can create, particularly in the context of IP. This thesis characterises this regulatory chill or the chilling effect as a domino effect since a single legal action/warning against one state can influence multiple others. This represents a disproportionate, excessive, leverage provided to IP holders through IIAs. This section aims to identify such examples and highlights why the cases explored in the previous section have a broader impact than mere compensation. These cases potentially deter states from pursuing further regulatory actions or other states from taking similar measures.

Regulatory chill can be defined as: "a restraint of regulators to take certain regulatory actions for fear of arbitration proceedings under ISDS, inter alia, in environmental, labour, health and safety regulations."[1137] For Suzanne Spears, regulatory chill arises "also from the inconsistent legal conclusions and reasoning found in arbitral awards.".[1138] The existence of regulatory chill in investment arbitration has been long highlighted, particularly issues addressing the environment.[1139] Chevron even stated that "the mere existence of ISDS is important as it acts as a deterrent".[1140] For instance, New Zealand banned new offshore oil exploration; it refrained from cancelling existing permits due to the risk of potentially costly ISDS claims.[1141] Another example is France, where regulations on fossil fuel extraction were relaxed after facing threats of ISDS action by a Canadian corporation.[1142] In certain situations, states have paid significant compensation before ISDS proceedings, as in the case of Germany, which paid RWE and LEAG over €4.35 billion to end coal-fired power generation by 2038.[1143] Examples are not limited to the ones mentioned here or to Global North countries which may have managed to mitigate less severe consequences. As Boyd noted in the 2023 Special Report, the Global South received the vast majority of fossil fuel and mining ISDS claims from Global North companies between 1995 and 2021.[1144] At the time of the report, Latin America had faced 327 ISDS claims, 62 percent of which resulting in favour of investors, costing more than $33 billion in damages and negotiated settlements.[1145] In addition to examples related to the environment, several publicly available examples concerning IP are available, particularly in tobacco industry and pharmaceutical sector.

[1137]*Trade and Development Commission: Services, Development and Trade: The Regulatory and Institutional Dimension* UN Doc TD/B/C.I/MEM.4/11 (9 March 2016) at 18.
[1138]Suzanne A. Spears "The Quest for Policy Space in a New Generation of International Investment Agreements" (2010) 13(4) JIEL 1037 at 1040.
[1139]David R. Boyd *Report of the Special Rapporteur on the Issue of Human Rights Obligations Relating to the Enjoyment of a Safe, Clean, Healthy and Sustainable Environment* UN Doc A/78/168 (13 July 2023); *Report of Working Group III (Investor- State Dispute Settlement Reform) on the Work of its Thirty- Seventh Session* UN/CN.9/970 (9 April 2019); Kyla Tienhaara "Regulatory Chill in a Warming World: The Threat to Climate Policy Posed by Investor-State Dispute Settlement" (2018) 7(2) TEL 229; Tim Hagemann "The North-South Divide of Regulatory Chill: A Comparative Analysis of the Impact of Investor-State Dispute Settlement on Policy Makers in Developed and Developing Countries" (2022) 35(1)
[1140]Arthur Nelson "TTIP: Chevron Lobbied for Controversial Legal Rights as 'Environmental Deterrent'" *The Guardian* (online ed, 26 April 2016).
[1141]Boyd, *Report of the Special Rapporteur on the Issue of Human Rights Obligations Relating to the Enjoyment of a Safe, Clean, Healthy and Sustainable Environment*, above n 1138, at [50].
[1142]At [50].
[1143]Fabian Flues *Coal Ransom: How the Energy Charter Treaty Drove up the Costs of the German Coal Phase-Out* (Business& Human Rights Resource Centre, 22 April 2022) at 6.
[1144]Boyd, *Report of the Special Rapporteur on the Issue of Human Rights Obligations Relating to the Enjoyment of a Safe, Clean, Healthy and Sustainable Environment*, above n 1138, at [8].
[1145]At [8].

For instance, it took New Zealand almost four years to introduce plain packaging.[1146] The country made financial calculations regarding potential costs of an investment claim or WTO case and decided to wait until the Australia cases were finalised.[1147] The consultation document in 2012 showed 31 of the submitters out of 292 mentioned the legal implications of such law, some even stated that:[1148]

> Public health justifications would not be a defence if the Government breaches an Investment Treaty through unfair, inequitable and discriminatory conduct. Even if in theory they could be a defence, given the absence of evidence that Plain Packaging would reduce tobacco consumption…

Canada considered plain packing in 1994 even before the WHO convention and came into force in phases from November 2019[1149], right after *Philip Morris v Australia* was concluded, which was 25 years later. It is worth noting that both New Zealand and Canada are economically developed countries. Surely, tobacco companies could make significant profits during the deferment periods. On the other hand, Togo's government eventually withdrew its tobacco measures at the time, indicating a fear of potential investment claim.[1150] Further, it appears that tobacco companies have been engaging in negotiations with host states and seeking specific commitments that would prevent the implementation of tobacco control measures or maintain the legal framework as it is at the time of investment.[1151] This strategy represents another form of regulatory chill. It illustrates a domino-like effect, where one or two initiated cases can significantly impact the regulatory power of many countries. This highlights the excessive leverage held by IP holders as a result of availability of the ISDS mechanism for IP rights.

Colombia desisted from issuing a compulsory licence to Novartis, which could have improved access to medicine for patients who suffer from chronic myeloid leukemia.[1152] A

[1146]Hapai Te Hauro Maori Publi Health "New study finds tobacco industry delayed New Zealand plan packs legislation" (16 April 2018) NZ Doctor Rata Aotearoa <https://www.nzdoctor.co.nz/article/undoctored/new-study-finds-tobacco-industry-delayed-new-zealand-plain-packs-legislation>.

[1147]Cabinet Social Policy Committee *Plain Packaging of Tobacco Products* (27 November 2012).

[1148]Allen and Clarke Policy and Regulatory Specialists Limited "Submissions Analysis on The Proposal to Introduce Plain Packaging of Tobacco Products in New Zealand" (21 November 2012) Ministry of Health <https://www.health.govt.nz/system/files/documents/pages/plain-packaging-submission-analysis-a-c.doc> at 48.

[1149]Government of Canada "Facts about Tobacco Products Regulations (Plain and Standardized Appearance)" (9 January 2020)<https://www.canada.ca/en/healthcanada/services/healthconcerns/tobacco/legislation/federalregulations/productsregulations- plain-standardized-appearance/facts.html>.

[1150]John Oliver "Tobacco: Last Week Tonight with John Oliver (HBO)" YouTube (15 February 2015) <https://www.youtube.com/watch?v=6UsHHOCH4q8>; Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 900, at 393.

[1151]Alverez-Jimenez, above n 204, at 171.

[1152]Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 901, at 393.

leaked letter written by the Embassy of Colombia in Washington to the Minister of Foreign Affairs of Colombia revealed pressure from the pharmaceutical sector and the United States government; thus, Colombia was forced to consider future trade relations.[1153] It highlights the political dimension of IP. Thus, instead of issuing a compulsory licence, the price of medicine was lowered.[1154] While the price was reduced by 44%[1155], the government was not able to touch the monopoly even for a critical health product as ISDS became a political tool to determine what was best for a country instead of the country itself. Additionally, the consideration of a compulsory licence was parallel to the negotiations on pricing with Novartis; however, Novartis ultimately rejected the price reduction.[1156] With a compulsory licence, it was aimed to reduce the price by %77, a percentage which was much lower than what was reached in the end.[1157]

Ukraine deregistered a generic drug competing with Gilead Science's hepatitis C medication.[1158] While the settlement agreement has not been disclosed, a public statement suggested that Ukraine sought discounted deals with the original drugs.[1159] Additionally, Merck& Co's press release following Brazil's issuance of a compulsory licence for a patented anti-HIV medicine was interpreted as a way of threatening with an ISDS claim against countries that have IIAs in place and choose to issue a compulsory licence.[1160] The United States eventually requested a WTO panel by relying on TRIPS Article 27 but withdrew after receiving assurances from Brazil that Brazil would be in consultation with the United States if any products patented by or licenced to companies from United States were subject to compulsory licences in Brazil.[1161] These examples highlight the challenges faced by countries seeking to use TRIPS flexibilities to improve access to medicines. These challenges are the result of this disproportionate protection granted to patent holders, exceeding the *just* return on their patents. It is a non-monetary power they have, ultimately leading to monetary gains as they maintain their monopoly in the market. Thus, it is not surprising that there is a

[1153]"April 27, 2016 Letter from Colombian Embassy regarding Senate Finance, USTR pressure on Novartis compulsory license" (11 May 2016) Knowledge Ecology International < https://www.keionline.org/23082>.
[1154]Corporate Europe Observatory "How Big Pharma Sabotaged the Struggle for Affordable Cancer Treatment" (June 2019) <https://corporateeurope.org/sites/default/files/2019-06/Novartis%20vs%20Colombia.pdf>.
[1155]At 3.
[1156]At 2-3.
[1157]At 3.
[1158]Luke Eric Peterson and Zoe Williams "Gilead Pharma corp withdraws investment arbitration after Ukraine agrees to settlement of dispute over monopoly rights to market anti-viral drug" (16 March 2017) ISDS Platform <http://isds.bilaterals.org/?gilead-pharma-corp-withdraws>.
[1159]Peterson and Williams, above n 1158.
[1160]Mercurio, "Awakening the Sleeping Giant: Intellectual Property in International Investment Agreements", above n 809, at 911-912.
[1161]*Brazil- Measures Affecting Patent Protection.*

hesitancy regarding the use of TRIPS flexibilities, and the issuance of compulsory licences, even in time of need like Covid-19 times. There is no evidence why Canada has not yet approved the compulsory licence request by Biolyse, as mentioned in Chapter 3.2.6.4.

These publicly available examples shed light on power dynamics in the context of ISDS. When weighing two parties -investors and states-, it may appear that investors are at a disadvantaged position as they are bound by host state laws. However, this is often reversed in the context of IP, as exemplified above. It must be highlighted that while regulatory chill is also a reality in other areas of law, such as environmental law, this thesis does not draw any conclusion for these areas. Such analysis is beyond the scope of this thesis.

4.6. Conclusion

The goal of this chapter was to delve into the intersection between intellectual property and investment law, highlighting how it creates excessive leverage and disproportionate power by diverting the intended purpose of IP rights. Moreover, this chapter aimed to highlight the distributive justice implication of the ISDS system with regards to patents as this availability undermines the operation of flexibilities provided under TRIPS by creating additional legal barriers.

Two frequently invoked investment claims (indirect expropriation and FET) are explained to demonstrate how a private investor can challenge a state action through these provisions, even though that action addresses public concerns. Then this chapter looked into two high profile cases: *Eli Lilly v Canada* and *Philip Morris v Uruguay*. Case law illustrated the intersection between investment law and intellectual property law; it also highlighted that the threat is indeed real to states' ability to regulate in public interest despite the fact that none of these IP cases resulted in favour of investors, including *Eli Lilly v Canada* and *Philip Morris v Uruguay*. While the analyses of the tribunals' awards have provided positive aspects, they also underlined the risks, such as limitation on the police powers doctrine and rejection grounds on dramatic changes in law, as explored. Furthermore, these existing decisions, except for some positive outcomes, failed to discourage IP holders from bringing claims due to lack of nuances in IP theories and significant principles upheld by IP law. The availability of ISDS or the way how arbitral tribunals tackled the cases can have implications on both territoriality and social functions of IP law. This can potentially impact access to health-related products/processes, posing a risk to people's health and lives by undermining the

operation of IP flexibilities. While these two tribunals preserved certain aspects of state sovereignty and public health, some missing nuances can have implications on the use of the flexibilities of IP law. The risks should not be dismissed lightly, particularly with regards to access to health resources. This chapter finally highlighted that the availability of ISDS mechanism gives power to investors to use the mechanism to deter states from enacting measures even if it benefits the public, representing another layer of disproportionate leverage held by patent owners/investors.

Transforming intellectual property rights from a trade commodity to an investment without considering states' human rights obligations to citizens and responsible business practices - especially in the pharmaceutical sector- can negatively impact health, particularly among economically disadvantaged communities. As highlighted earlier in Chapter 2, advantaged groups shaped global order. For instance, the bargaining power of the Global North, particularly considering the pharmaceutical sector, influenced the designation of the TRIPS Agreement and efforts to implement TRIPS-plus agreements to increase the level of IP protection. This increased protection of IP impacts the global spread of technologies, including health resources. Since patent holders are generally multinational corporations from the Global North, they control what gets marketed and at what price, leading to unequal distribution of benefits and burdens. Additionally, as provided in this chapter, the investment layer gives power to IP holders to challenge attempts to limit their rights, exacerbating the differences in benefits and burdens. Limited access to health resources has a broader impact on countries already lacking in access to health resources, hindering their development and promoting preferential growth. Hence, as this chapter determined, investment protection becomes disproportionate with respect to midlevel principles, which brings forth the need to mitigate.

This chapter did not include the application of the MoA under ECtHR, Born's dissenting opinion on this matter, and Born's view on the judicial proportionality principle in the *Philip Morris v Uruguay* case. All these issues require in-depth analysis and discussion, which is provided in the next chapter. Thereby, Chapter 5 focuses on the application of judicial proportionality by arbitral tribunals within the context of expropriation and FET claims. The context of proportionality in Chapter 5 differs from its form as a midlevel principle and it is referred to as judicial proportionality in this thesis. The next chapter aims to assess whether the application of judicial proportionality can effectively mitigate the disproportionate

protection of patent rights, safeguard its social function, and promote global justice principles regarding access to health resources.

CHAPTER 5- THE ROLE OF JUDICIAL PROPORTIONALITY IN ISDS

5.1. Introduction

The principle of proportionality has found a place in the realm of ISDS, similar to the jurisdictions of WTO (not explicitly) or ECtHR.[1162] As highlighted in the introductory chapter, methodological proportionality is referred to as judicial proportionality in this thesis. It is further acknowledged that proportionality has become a component of the FET as an independent principle. Notably, in some cases, the tribunals, as discussed in detail below, have referred to the application of the principle by referring to the ECtHR jurisprudence.[1163] It is not surprising that the principle has been incorporated somehow in the context of ISDS. The ISDS system often confronts complex questions as to safeguarding government action that may potentially serve the public interest or protecting investors' interests from government interference in their investments.[1164]

The purpose here is to examine whether the application of judicial proportionality in investment cases can effectively mitigate the disproportional investment protection of patent rights (understood as midlevel proportionality as discussed in Chapter 3.2.7.) when the issue at hand is related to accessing affordable health resources. Hence, the objective is to assess whether the judicial proportionality can preserve distributive justice ideas aimed at promoting access to affordable health resources by mitigating this disproportional investment protection of patented health resources. The analysis involves a thorough examination of case law to identify any existing trends in its application. The case law analysis starts with expropriation claims and then continues with FET claims. With the analysis, it will be concluded that judicial proportionality can undermine discussions prioritising public interest over investment/investor protection (hence the societal function of patent).

It will become clear that tribunals often simply cite the principle without further analysis. Yet, even with proper analysis, this thesis argues that judicial proportionality is unsuitable for international investment arbitration concerning patents, particularly patented health resources as it involves balancing rights that should not be weighed against each other. The judicial proportionality might entail the risk of not affording adequate deference to states that respect

[1162] *Tecmed v Mexico Award*; *EC-Bananas III; Hatton and Others v The United Kingdom* [2003] 37 EHRR 28 (Grand Chamber, ECHR).
[1163] *Tecmed v Mexico Award*, at [122].
[1164] *Philip Morris v Uruguay Award*; *RWE AG and RWE Eemshaven Holding II BV v. Kingdom of the Netherlands* ICSID ARB/21/4; *Eco Oro Minerals Corp. v Republic of Colombia (Decision on Jurisdiction, Liability and Directions on Quantum)* ICSID ARB/16/41, 9 September 2021.

the public's needs. Judicial proportionality further adds extra layers for states to demonstrate as needed by the proportionality test. Therefore, it cannot effectively be used as a tool to mitigate disproportionate investment protection.

The tribunals' reference to ECtHR is not limited to proportionality but extends to its MoA doctrine[1165], which entails deference to states. Therefore, it is necessary to include an analysis of the relevance and applicability of ECtHR jurisprudence in the context of investment arbitration. Consequently, this chapter explores the applicability of ECtHR's concepts in ISDS proceedings, with a particular focus on MoA right after the case law analysis involving judicial proportionality. This thesis opposes the applicability of concepts developed in ECtHR jurisprudence within the ISDS and proposes that in cases involving patented health resources, tribunals should employ the police powers doctrine in their expropriation analysis. It also recommends that the tribunals do not need to transfer MoA doctrine in their FET analysis since the well-established police powers doctrine can be applicable.[1166]

5.2. Judicial Proportionality in ISDS Proceedings

Host states can take necessary actions in the public interest, such as for the environment or health, as a result of their human rights obligations under both constitutional and international instruments. This might be the case even if such measures interfere with foreign investments, as experienced in the case of *Philip Morris v Uruguay*.[1167] Thus, in the event of an investment claim against the host states' measures, the states have the option to defend themselves by making human rights arguments before an arbitral tribunal.[1168] The investor, in response to this, can also invoke their human right, like the right to property, along with their investment claim to support their arguments as ECtHR instruments have been employed before in investment arbitration.[1169]

The inclusion of human rights generally does not occur directly. The tribunals might use them in the interpretation of IIAs or in the concept of state obligations through Article 31(3)(c)

[1165]*Philip Morris v Uruguay Award*, at [388].
[1166]It is acknowledged earlier in Chapter 4 that states might invoke the state necessity defence under the ILC in some circumstances. However, the threshold is very high for state necessity and the defence may not be accepted by the tribunals. In addition, relevant IIAs might include non-precluded clauses but not all host States' actions or omissions would fall under these clauses. Existence of these options does not change the fact that police powers should be applied in cases involving patented health resources.
[1167]*Philip Morris v Uruguay Award.*
[1168]Silvia Steininger "What's Human Rights Got to Do with It? An Empirical Analysis of Human Rights References in Investment Arbitration" (2018) 31(1) Leiden Journal of International Law 33.
[1169]Mylly, above n 26, at 407; *Tecmed v Mexico Award*, at [122]; *Mondev International Ltd v. United States of America (Award)* ICSID ARB(AF)/99/2, 11 October 2002 at [138]; at [141-44].

VCLT: "any relevant rules of international law or Article 38(1) of the ICJ Statute "…in accordance with international law".[1170] These references typically involve either the ECHR or international human rights instruments; however, with 80% of the references attributed to the former even if the host state is not bound by it.[1171] Alternatively, some new IIAs incorporate human rights related limitations or rules, as discussed in Chapter 6. In the meantime, although investors can challenge domestic laws addressing public human rights concerns and benefit from human rights analogies, investors' own human rights violations and liabilities are not in any way directly scrutinised within the ISDS framework.[1172] These arguments call for some sort of consideration to decide whether the states' measures are justifiable or breach any IIAs. Some tribunals, therefore, can introduce judicial proportionality. By doing so, some tribunals refer ECtHR jurisprudence as a persuasive authority when applying proportionality.[1173]

In the context of intellectual property rights, human rights considerations can be part of the discussion in an ISDS case, as *Philip Morris v Uruguay* illustrates. Particularly, patent rights, including its exceptions or flexibilities can raise human rights arguments, such as right to health and right to benefit from scientific progress as recognised by the UDHR Article 25 and Article 27(1)[1174] and the ICESCR Articles 12 and 15[1175]. It is further worth considering, any regulatory changes in domestic law can potentially address the social function of IP, in turn, indirectly serving the public interest. For instance, in *Eli Lilly v Canada*, Canada's higher level of utility requirement serves the societal function of IP and, indirectly, public interest, as highlighted in Chapter 4.4.1. Foreign investors, on the other hand, particularly with tribunals' references to EU law, can rely on their property rights under the ECHR, while national investors is not able to do so (unless when the rights are provided under the national constitution, which may differ from the ECHR).[1176] All these issues considered together prompt an assessment of the principle of proportionality (judicial proportionality) in the ISDS proceedings. In the current practice, judicial proportionality can give arbitral tribunals

[1170]VCLT, art 31; ICJ Statute, art 38(1)
[1171]Steininger, above n 1168, at 40.
[1172]Mylly, above n 26, at 412; *Urbaser S.A. and Consorcio de Aguas Bilbao Bizkaia, Bilbao Biskaia Ur Partzuergoa v The Argentine Republic (Award)* ICSID ARB/07/26, 8 December 2016 at [1193-1210]; at [1220]. This thesis acknowledges that the tribunal's recognition of a human rights breach by an investor was a significant step. at [1193] The tribunal stated that: "On a preliminary level, the Tribunal is reluctant to share Claimants' principled position that guaranteeing the human right to water is a duty that may be born solely by the State, and never borne also by private companies like the Claimants."
[1173]*Tecmed v Mexico Award*, at [122].
[1174]UDHR Article 25; Article 27(1).
[1175]ICESCR Article 12; Article 15.
[1176]Mylly, above n 26, at 413.

significant latitude to examine the objectives of states and their decision-making, as almost "second-guessing legislative choices of states".[1177]

Henckels identifies different variations of judicial proportionality within the context of ISDS. In this respect, the principle of proportionality is applied in various ways: (i) European style (legitimacy + three-step test); (ii) least-restrictive means (three-step test without balancing stage); (iii) only proportionality *stricto sensu* analysis; (iv) proportionality with a connection to reasonableness (v) through general statements of proportionality and balancing.[1178] The three-step test assesses the measure's suitability to achieve its objective, necessity considering other alternatives, and proportionality *stricto sensu*.[1179] European style proportionality involves analysing the legitimacy of a measure's objective, assessing whether the measure is suitable to achieve that objective, determining its necessity by considering available alternatives and conducting a *stricto sensu* analysis.[1180] The *stricto sensu* step, a balancing test, assesses the importance of achieving the objective against the importance of preventing harm to the protected right or interest.[1181] Some tribunals applied judicial proportionality without any balancing, *stricto sensu*, stage, while some others applied *strictu sensu* directly without other stages of the test.[1182] Finally, some tribunals simply refer proportionality or balancing without any additional discussion.[1183] This part simply addressed different applications of judicial proportionality, further elaboration on case law will be provided below.

In Chapter 3, the police powers doctrine and the sole effect doctrine are discussed as mechanisms employed by tribunals to assess whether a state's expropriatory measure is justified. Recently, the tribunals have also applied judicial proportionality rather than these two doctrines to allegedly make a more nuanced approach to assess the interplay between the public interest objectives and the impacts such measures may have on private investor/investors.

[1177]At [424- 427].
[1178]Caroline Henckels "Balancing Test (Investment Arbitration)" in H Ruiz Fabri (ed) Max Planck Encyclopaedia of International Procedural Law (OUP, 2019) at 3-10.
[1179]At 8.
[1180]At 3.
[1181]At 3-4; *PL Holdings S.à.r.l. v Republic of Poland (Partial Award)* SCC V 2014/163, 28 June 2017 at [355-391]
[1182]*SD Myers v Canada Partial Award*, at [195], at [215], at [255]; *Tecmed v Mexico Award*, at [118-119], at [121- 124], at [127–128], at [130–139], at [145–147]
[1183]*Charanne and Construction Investments v. Spain (Award)* SCC V062/2012, 21 January 2016 (Unofficial Translation by Mena Chambers) (hereinafter "*Charanne v Spain Award*) at [514].

The shift to applying judicial proportionality is intended to offer some advantages, such as promoting transparent analysis or creating consistent legal reasoning that enhances the legitimacy of the arbitral tribunal.[1184] However, the application of the principle itself has challenges, even if tribunals apply every step of the test, as the interpretation of each step of the test remains subject to the judgement (collegial judgement) of arbitrators. Thus, in practice, the principle still relies heavily on the arbitrators' judgment. Henckels proposes that combining the proportionality test as a method of review with deference could result in a more consistent application of the principle.[1185] According to Henckels, the tribunals can apply the legitimacy, suitability and necessity steps while appropriately deferring to the state, thus avoiding proceeding to the final stage of proportionality *stricto sensu*.[1186] For Henckels, the last stage is already problematic due to its legitimacy implications such as potential uncertainty and negative impact on regulatory autonomy.[1187] Thus, Henckels suggests avoiding the proportionality *strictu sensu* step from the proportionality analysis.[1188]

This thesis agrees with Henckels' argument to the extent that giving deference to states throughout the three steps of the test, as termed institutionally-sensitive approach, could enhance transparent decisions, ensure consistency and offer predictability.[1189] This thesis shares the critique of the *stricto sensu* application of the proportionality principle as it requires a value assessment that is unsuitable for private arbitration mechanisms. This type of assessment results in legitimacy problems since there would be differences in values between the host states and the investors' own home states.[1190] Judicial proportionality introduces a highly subjective dimension arising from decision-makers' own beliefs and assumptions on politics, ideologies and economics.[1191] However, this thesis differs with Henckels' institutionally-sensitive approach in the context of patented health resources. This is because it imposes additional burdens (particularly cumulative application of judicial proportionality) on states to demonstrate that their measure was legitimate, suitable and necessary, regardless of the degree of deference given to the states. As detailed in Chapter 3, the TRIPS Agreement

[1184]Benedict Kingsbury and Stephan W Schill "Public Law Concepts to Balance Investors' Rights with State Regulatory Actions in the Public Interest – the Concept of Proportionality" in Stephan W Schill (ed) *International Investment Law and Comparative Public Law* (Oxford University Press, New York, 2010) 75 at 88.
[1185]Caroline Henckels *Proportionality and Deference in Investor-State Arbitration: Balancing Investment Protection and Regulatory Autonomy* (Cambridge University Press, Cambridge, 2015) at 194.
[1186]At 171.
[1187]At 193.
[1188]At 173.
[1189]At 126; at 194
[1190]Valentina Vadi *Proportionality, Reasonableness and Standards of Review in International Investment Law and Arbitration* (Edward Elgar, Cheltenham, 2018) at 271-272.
[1191]Caroline Henckels "Balancing Investment Protection and the Public Interest: The Role of the Standard of Review and the Importance of Deference in Investor-State Arbitration" (2013) 4(1) Journal of International Dispute Settlement 197 at 207.

provides flexibility to states to determine their own patent law and it gives states the power to use flexibilities like compulsory licence despite the procedural difficulties and formalities under the TRIPS Agreement. States are not required to demonstrate the legitimacy, suitability, or necessity in the changes of patentability requirements, for instance. The three-step test is relevant for Article 30 of the TRIPS Agreement[1192], yet as identified by many scholars, the article does not indicate a strict cumulative application of judicial proportionality.[1193] In certain instances, the TRIPS Agreement may not be directly applicable, like in *Eli Lilly v Canada*; nevertheless, the agreement remains influential as it shapes the domestic IP laws of the WTO member countries. The tribunals are likely to accept IP as an investment and find past awards with respect to IP persuasive. However, such analysis should not even extend to these three-steps in the context of patent law as the test imposes additional burdens on states, conflicting with the societal function of IP law. As long as state measure adheres patent standards provided by the TRIPS Agreement, states have freedom to determine their own domestic law and implement any measure. In addition, as highlighted by Vadi, particularly the necessity test renders the given measure invalid as the tribunal can always envisage alternatives given the advantage of hindsight.[1194] This does not mean that an arbitral tribunal would identify the alternative measures, but it implies that the state may begin the case in a disadvantaged position if the investor identifies specific alternatives that were allegedly available to the host States. Once the investors have identified the measure it switches burden of proof to respondent states to prove that the alternatives not available. Similarly, Henckels also highlights that the necessity test can potentially allow decision-makers to substitute their perspective for the measure that has been chosen.[1195]

The next part shows how the tribunals have applied judicial proportionality in expropriation or FET claims so far. It becomes clear that the tribunals have indeed applied judicial proportionality in different ways. While this is very expected as a system that has no doctrine of precedence, the lack of clarity in the methodology of investment arbitration can create unpredictability for states and this may have a deterrence impact on the measures that serve

[1192]TRIPS Agreement, art 30: "Members may provide (i) limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions (ii) do not unreasonably conflict with a normal exploitation of the patent and (iii) do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.
[1193]*Canada- Patent Protection of Pharmaceutical Products* at [7.20]; at [7.44]; at [7.38]; at [7.59]; Matthias Lamping and others *Declaration on Patent Protection Regulatory Sovereignty Under TRIPS* (Max Planck Institute for Innovation and Competition Research Paper No. 14-19, 15 April 2014) at [22-23].
[1194]Vadi, *Proportionality, Reasonableness and Standards of Review in International Investment Law and Arbitration*, above n 1190, at 246.
[1195]Henckels, *Proportionality and Deference in Investor-State Arbitration: Balancing Investment Protection and Regulatory Autonomy*, above n 1185, at 149.

the societal function of IP. An argument can be made that employing a proportionality test including *stricto sensu* or a test suggested by Henckels could yield more reliable outcomes in the context of IP instead of relying solely on police powers. Since both approaches (full tests of judicial proportionality or institutionally sensitive approach) involve interpretation, the judicial proportionality might entail the risk of not affording adequate deference to states that respect the public's needs. In addition, the judicial proportionality, particularly cumulative application of three-step test, adds extra layers for states to demonstrate, which is not needed by patent provisions under the TRIPS Agreement. Therefore, it cannot effectively be used as a tool to mitigate disproportionate investment protection.

5.2.1. Case Law in Expropriation Claims

Before analysing the case law in relation to arbitration claims, it should be borne in mind that in the context of intellectual property rights, patents in this case, the nature of the claim would be revolving around indirect expropriation rather than direct expropriation. Within the realm of patent law, interference often occurs through legislative, administrative, or judicial acts that do not necessarily involve a formal transfer of title. Yet, even where these measures align with public or broader societal objectives, the principles of international investment law may require compensation if the host states' action results in a breach of the relevant IIA. Judicial proportionality has emerged as an instrument employed by tribunals to determine whether an expropriation has taken place. Since judicial proportionality has become a very common practice, it is likely that judicial proportionality can be used in patent-related disputes.

Tecmed v Mexico[1196] is considered as a leading case in discussions surrounding proportionality within the framework of indirect expropriation. Its significance is underscored by the fact that many tribunals have invoked and referred to this case.[1197] Therefore, the analysis first, explores the *Tecmed* decision. Subsequently, the examination extends to a review of other relevant cases that invoked judicial proportionality. *Tecmed* is further significant as the first explicit reference to the ECtHR jurisprudence was introduced by the *Tecmed* tribunal. However, the ramifications of this practice and its applicability is discussed in below Chapter 5.3.

[1196] *Tecmed v Mexico Award*, at [122].
[1197] *LG& E v Argentina Decision on* Liability, at [127]; *Azurix v Argentina Award* at [311-312]; *Philip Morris v Uruguay Award*, at [305].

The *Tecmed v Mexico* case revolved around the operations of a hazardous waste landfill, wherein the investor encountered challenges emanating from the facility's proximity to the city of Hermosillo and its consequent implications on the local populace.[1198] During the course of negotiations with local authorities for potential relocation, Mexico's environmental regulatory body declined to renew the operational license, resulting in the cessation of the landfill's activities.[1199] Though, during the landfill operation, the claimant investor breached a series of conditions of their permit, and the non-compliance was validated by the federal agency PROFEPA.[1200] The issue centered around the location of landfill, along with the logistical aspects related to waste transportation and disposal.[1201] Notably, the negotiations aimed at facilitating the relocation of the landfill indicated this underlying issue. The matter received community attention, covered by the media, and the population further monitored closely the operation.[1202] Consequently, the state rejected the renewal of the license and provided justifications behind their decision in detail.[1203] Afterwards, the investor initiated proceedings under the Agreement on the Reciprocal Promotion and Protection of Investments signed by the Kingdom of Spain and the United Mexican States through ICSID and claimed that Mexico's actions amounted to an expropriation.[1204] At the end of their examination, the tribunal concluded that declining the renewal of the licence would result in closing the landfill permanently and irrevocably, and the resolution adopted by the state was not primarily reasoned of socio-political concerns.[1205] For the tribunal, since there were no other way to use the landfill, ultimately resulted in losing its value, the decision of the Mexican authority was not proportional to the protected public interest.[1206] Despite recognising states' regulatory power for public interest, like environmental issues, the tribunal overweighed the negative impacts of the measure on investors, by referring the *Santa Elena v Costa Rica*:[1207]

> Expropriatory environmental measures – no matter how laudable and beneficial to society as a whole – are, in this respect, similar to any other expropriatory measures that a state may take in order to implement its policies: where property is expropriated, even for environmental purposes, whether domestic or international, the state's obligation to pay compensation remains.

[1198] *Tecmed v Mexico Award*, at [35-51].
[1199] At [43].
[1200] At [123].
[1201] At [108-137].
[1202] At [108].
[1203] At [105-110].
[1204] At [93].
[1205] At [117]; at [147-151].
[1206] At [122-151].
[1207] At [121].

The tribunal applied judicial proportionality, drawing inspiration from the ECtHR.[1208] According to the tribunal:[1209]

> …in order to determine if they are to be characterized as expropriatory, whether such actions or measures are proportional to the public interest presumably protected thereby and to the protection legally granted to investments, taking into account that the significance of such impact has a key role upon deciding the proportionality…

The manner in which the tribunal considered proportionality appears to be similar to the sole effect doctrine, as it attributed substantial significance to the impact of a regulatory decision on the investor's interests. Similarly, the tribunal highlighted the negative impact on the claimant as a result of the state's denial of renewal the licence by stating that:[1210]

> …for the purpose of establishing whether the Respondent breached Article 5(1) of the Agreement, to evaluate such reasons as a whole to determine whether the Resolution is proportional to the deprivation of rights sustained by Cytrar and with the negative economic impact on the Claimant arising from such deprivation.

The focus of the tribunal was more on the community pressure on the government rather than environmental considerations as the underlying reasons for such pressure.[1211] A similar application to a patent dispute would be highly problematic due to the complexities of patent law. For example, in the event of patent invalidation, as in *Eli Lilly v Canada*, the patent holder would be economically impacted due to the loss of the market monopoly. Similarly, in the case of compulsory licence, investors could bring claims opposing the actual reasons behind the issuance of a licence, such as public health concerns, national security and other local protectionist purposes.[1212] Similarly, technically, factors like the adequate remuneration requirement, length and terms of the licence could be brought as an investment claim.[1213] As highlighted earlier, the proposed models for the calculation of the compensation might fall short under the TRIPS Agreement if it is based on the value of generic products. In that case, this shortfall is even more likely under the IIA, given that monopoly companies charge significantly higher prices. Even if the compensation meets the TRIPS standards, the

[1208]At [122].
[1209]At [122-123].
[1210]At [132].
[1211]Henckels, *Proportionality and Deference in Investor-State Arbitration: Balancing Investment Protection and Regulatory Autonomy*, above n 1185, at [108-110].
[1212]Gibson, "A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation", above n 915, at 391.
[1213]At 398.

presence of a competitor in the market would economically impact the patent holder. If the tribunal applies judicial proportionality and assesses the proportionality of the measure concerning the protected public interest, it could technically result in indirect expropriation. In the case of a compulsory licence for anti-competitive practices, the amount paid to the patent holder might be lower, as highlighted in Article 31(k)[1214] of the TRIPS Agreement. However, this amount may fall short of the investment arbitration if it comes to the consideration of the compensation stage, considering IIAs most of the time refer to the fair market price.[1215] In any case, the availability of ISDS contradicts with the societal function of patents by hindering the use of TRIPS flexibilities. Applying judicial proportionality, subject to three-step test, exacerbates this conflict by comparing societal aspect of IP law with economic impact on foreign investor. In such scenarios, investors would likely be economically harmed. While harm might not be enough for expropriation, merely focusing on economic impact would undermine rationales of patent protection. Applying judicial proportionality in situations where patented health resources are at hand, similar to the approach in *Tecmed*, without considering the importance of the measure would undermine access to health resources. Particularly, considering that states have obligations to protect public health, including promoting access to health resources, it is crucial for tribunals to consider the obligations under national constitutions and international commitments.[1216]

As it is discussed in more detail, in Chapter 5.3., a fundamental structural challenge emerges in the application of ECtHR jurisprudence and judicial proportionality within the practice of investment arbitration. However, it is important to mention some key issues about *Tecmed* and highlight differences between investment expropriation and ECHR. Firstly, it is suggested that reference to *James and Others v The United Kingdom* by the *Tecmed* tribunal was very strategic[1217] in a way that highlights the vulnerability of foreign investors to national laws. The *Tecmed* tribunal did not find any issue with extending this case, which

[1214]TRIPS Agreement, art 31(k): "The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases".
[1215]Agreement between Japan and Georgia for the Liberalisation, Promotion and Protection of Investment (signed 29 January 2021) art 11: "The compensation shall be equivalent to the fair market value of the expropriated investments at the time when the expropriation was publicly announced or when the expropriation occurred..."
[1216]This thesis acknowledges that in some situations, states' aim may not be promoting access to health resources in relation to patents. There might be disputes between states and pharmaceutical companies that may not have a direct impact on the public. An example is experienced between Russian company Sputnik and Bolivia, where Bolivian authorities decided not to pay the second batch of Covid-19 vaccines against their contract with Sputnik. The dispute was recently settled. See: Ciar Global "Bolivia Descarte El Arbitraje De 27 MUSD Con Rusia Por Vacunas Sputnik" (12 Mayo 2024) <https://ciarglobal.com/bolivia-descarta-el-arbitraje-de-27-musd-con-rusia-por-vacunas-sputnik/> (translation: Bolivia Rules Out 27M USD Arbitration With Russia Over Sputnik Vaccines).
[1217]Henckels, *Proportionality and Deference in Investor-State Arbitration: Balancing Investment Protection and Regulatory Autonomy*, above n 1185, at 110.

dealt with the protection of private landlords, to a multinational corporation involved in landfill operations of hazardous industrial waste.[1218] In fact, the parts where the ECtHR discussed a wide MoA for legislatures concerning social and economic policies are missing in the *Tecmed* decision.

In addition, as Bücheler highlights, in investment arbitration cases, tribunals encounter the all-or-nothing practice, which means that if there is no expropriation, the investor receives no compensation.[1219] In contrast, in ECtHR jurisprudence, the compensation paid to the claimant would be relevant to the proportionality of an expropriation.[1220] Furthermore, the all-or-nothing structure of expropriation in investment arbitration renders the application of judicial proportionality analysis susceptible to a process that weighs private investors over public interest as experienced in *Tecmed* decision. Similarly, in the context of intellectual property, particularly in cases involving patents, prioritising the societal function of IP or public health through judicial proportionality would be very challenging. This is due to the fact that one of the primary purposes of IIAs is to protect foreign investments. Tribunals may overlook some of the layers of a dispute, including the broader societal goals of a patent system and the various stakeholders of such system, which was experienced in the decision of *Eli Lilly v Canada* as highlighted in Chapter 4.4.1. The decision to introduce a higher level of utility requirement in domestic law, in line with the TRIPS Agreement, lies with the state. The issue should not be left in the hands of arbitrators when the IIAs are formulated by the states as their state policy. The reasoning for the decision in *Eli Lilly* was based on the fact that the investor was not able to prove the dramatic change in the domestic law, which might otherwise have led to a consideration of the invalidations as expropriation.

The concept of judicial proportionality is vulnerable to a consideration of on the one hand, the public interest and on the other hand so-called property, in the case of patent, as if it is possible to strike such a balance between them. It poses a risk of hindering a potential discussion that can weigh the social goals of IP and the public interest of a particular country over investment in the context of IP. Some scholars have pointed out that the tribunals tend to view the property as something states should protect rather than recognise as having limitations, which reflects the mismatch in the application of ECtHR principles.[1221] In

[1218]Mylly, above n 26, at 425.
[1219]Gebhard Bücheler *Proportionality in Investor-State Arbitration* (Oxford University Press, New York, 2015) at 147.
[1220]At 148.
[1221]Upreti, at 210; Mylly, above n 26, at 426.

addition, while judicial proportionality has its origins in Western constitutional law, its global application involves values attributed to individual and community interests, making them subjective.[1222] This thesis supports both arguments and asserts that the judicial proportionality analysis would undermine discussions prioritising public interest over investment, which requires broad regulatory space for a particular nation. Specifically, in the context of patents, prioritising investment and a negative impact of a measure on the investor would jeopardise using IP flexibilities aimed at ensuring affordable health resources, hence equal distribution.

The tribunal in *Azurix v Argentina* invoked the *Tecmed* decision and judicial proportionality, stating that the public purpose criteria should serve as supplemental elements.[1223] Despite the fact that the tribunal did not find expropriation, the reason was that the investor had not been impacted substantially. There was no detailed analysis of judicial proportionality and proportionality was only mentioned briefly. Thus, the case fails to provide a thorough insight into the application of the principle. Similarly, in the decision on liability of *LG&E v Argentina*, the tribunal referred judicial proportionality to determine whether there had been an indirect expropriation. The tribunal of *LG&E* identified some elements to be considered like the economic impacts of the measure and its duration, as well as the societal or general welfare objectives of the measure.[1224] Further, the tribunal concentrated on the economic impacts of the measure while referring *Pope& Talbot v Canada* case which is known as a persuasive authority for the application of the sole effect doctrine.[1225] The arbitral tribunal concluded that Argentina's measures did not constitute expropriation, reasoning the limited impact of those measures.[1226] The decision does not offer significant guidance for the application of judicial proportionality in the context of expropriation, since the tribunal stated that:[1227]

> With respect to the power of the State to adopt its policies, it can generally be said that the State has the right to adopt measures having a social or general welfare purpose. In such a case, the measure must be accepted without any imposition of liability, except in cases where the State's action is obviously disproportionate to the need being addressed.

[1222]Vadi, Proportionality, Reasonableness and Standards of Review in International Investment Law and Arbitration, above n 1190, at 31-53.
[1223]*Azurix v Argentina Award*, at [291]; at [311].
[1224]*LG&E v Argentina Decision on Liability*, at [190-196].
[1225]*LG&E v Argentina Decision on Liability*, at [190]: "…one must analyze the measure's economic impact"; at [191]: "In considering the severity of the economic impact, the analysis focuses on whether the economic impact unleashed by the measure…The impact must be substantial in order that compensation may be claimed for the expropriation."; at [198].
[1226]In *LG&E v Argentina*, the tribunal accepted Argentina's state necessity defence for the period between 1 December 2001 and 26 April 2003, and exempted Argentina from paying compensation for damages incurred during that time. See: at [226-266]; at [267 (d)].
[1227][195].

While acknowledging the tension between investors' interests and public welfare, the extent to which a measure would significantly impact remains uncertain, as it is determined on a case-by-case basis. It raises the question of why a significant impact can outweigh the public interest, potentially leading to expropriation. This is especially significant in the case of patents for health resources. As demonstrated earlier in this chapter, the flexibilities can significantly affect the investors' profits. However, prioritising profit over societal goals or public interest would contradict the principles of global justice, the right to health and access to health resources, the right to live a life in dignity and the right to benefit from scientific progress under the UDHR and the ICESCR, as highlighted earlier. Ultimately, the flexibilities afforded by the TRIPS Agreement are designed to uphold societal values embedded in IP rights and to benefit society by facilitating the creation of affordable products. These values, which initially reflected Global South values but benefit everyone today, should not be subject to a limitation by a principle originating from Aristotelian distributive justice that does not fully address today's designation of patent law and justice principles.

Similarly, the *Continental v Argentina* tribunal's assessment was solely concerned with impacts of the state measure on the claimant's investment.[1228] The tribunal in *Glamis v United States* took similar approach to *LG&E* tribunal and posited that the weighing assessment of the extent of the interference with the property right and the underlying governmental objective was not necessary as the measure in question did not create a significant economic impact on the investment.[1229]

It should be noted that the tribunal of *Philip Morris v Uruguay*[1230], which concerns trademark as discussed above in detail, referred to judicial proportionality in its expropriation claim. The tribunal stated that:[1231]

> the action must be taken bona fide for the purpose of protecting the public welfare, must be non-discriminatory and proportionate. In the Tribunal's view, the SPR and the 80/80 Regulation satisfy these conditions.

[1228] *Continental Casualty Company v The Argentine Republic (Award)* ICSID ARB/03/9, 14 July 2006 at [276].
[1229] *Glamis Gold, Ltd. v. United States of America (Award)* UNCITRAL, 8 June 2009 (hereinafter "*Glamis Gold v USA* Award") at [365]; at [536].
[1230] *Philip Morris v Uruguay Award.*
[1231] At [305].

As explained in Chapter 4.4.2., the tribunal concluded concerning expropriation claim by stating that both measures enacted by Uruguay were implemented in good faith, were non-discriminatory and proportional, and the measures were "effective means to protecting public health".[1232] In this case, while the tribunal applied judicial proportionality, they actually connected it with the police powers doctrine. In the meantime, the tribunal's analysis can also be interpreted as even bona-fide non-discriminatory measures adopted for public welfare, can constitute expropriation if they are not proportional. The analysis of judicial proportionality presented is once again vague and unclear, leaving uncertainty about what would constitute disproportionate measures. As highlighted earlier, applying a similar approach by the tribunal in patent cases would undermine societal functions, especially taking into account the tribunal' analysis of whether investment have been deprived substantially from the state measure.[1233] The tribunal's decision in favour of state does not eliminate the concerns regarding judicial proportionality. It should be kept in mind that, in any case, the territoriality principle in IP underscores a state's authority to determine its own national policies as long as it complies with the TRIPS Agreement. Therefore, even if the measure lacks proportion, however they assess, as long as it adheres to TRIPS, private arbitrators should not challenge or scrutinise in debt whether the measure strike a balance between public interest and investors' property.

The concept of judicial proportionality is susceptible to an analysis that strikes a balance between public interest and property. It further poses a risk of hindering a potential discussion that can weigh the social goals of IP and the public interest of a particular country over an investment. It requires a value judgement that involves assessing the significance of public welfare against the impact on the investment. Such analysis should not be within the purview of an investment tribunal in the context of IP. The TRIPS Agreement already empowers states to use flexibilities or determine their own laws, even though the TRIPS flexibilities, like compulsory licence, can involve difficult procedures and formalities, as detailed in Chapters 3.2.4. and 3.2.5.

State measures can have a substantial impact on the investor where state actions pertaining to patents, such as the invocation of a patent, as observed in *Eli Lilly v Canada*, or issuance of a compulsory licence. For instance, in case of the issuance of compulsory licences means that

[1232] At [302-307].
[1233] At [192].

there would be cheaper options available manufactured by other companies or the revocation would mean that the patent holder would lose its monopoly entirely. As a result, such actions could lead to significant financial consequences for investors. The application of judicial proportionality analysis runs the risk of potentially neglecting the importance of such measures in serving public welfare or broader societal goals of the state.

The following section explores the application of the judicial proportionality principle within the context of FET claims, where more intricate, challenging, and problematic analyses transpire to ascertain if a similar conclusion can be drawn. More case law exists in the tribunals' analysis of FET as proportionality is also developed as a component of FET.

5.2.2. Case Law in FET Claims

Several cases have expressly referred to judicial proportionality in their FET analysis, particularly becoming very popular in the renewable energy regulation cases.[1234] However, it is important to note that, unlike indirect expropriation, the FET can be violated even if the states' conduct on the investment does not amount to a substantial deprivation.[1235] This implies that if state conduct falls short of constituting expropriation, it could still potentially breach FET. Therefore, the judicial proportionality analysis should be examined within this respect, especially when the tribunals evaluate the economic impact on the investor. As analysed by the following case law, particularly in cases initiated against Spain, FET has become an analysis similar to expropriation, where indirect expropriation cannot be upheld; the tribunals used FET to find a breach, applying judicial proportionality as its justification.

Potentially, the incorporation of judicial proportionality could contribute to the interpretive process in cases where there are competing interests, like the interests of the public versus the investor.[1236] According to Bücheler, arbitral tribunals should be cautious when considering the application of the judicial proportionality principle for assessing potential breaches of FET since there are potential ramifications such as judicial activism, arbitrary outcomes, or a decision that goes against the rule of law.[1237] Within this view, Bücheler highlights the inherent nature of the principle how actually its application is unpredictable rather than a

[1234]Bücheler, above n 1219, at 193-194; Filip Balcerzak *Renewable Energy Arbitration-quo vadis?: Implications of the Spanish Saga for International Investment Law* (Brill, Leiden, 2023).
[1235]Bonnitcha, Poulsen and Waibel, above n 43, at 108.
[1236]Benedict Kingsbury and Stephan Schill *Investor-State Arbitration as Governance: Fair and Equitable Treatment, Proportionality and the Emerging Global Administrative Law* (IILJ Working Paper 2009/6 Global Administrative Law Series 2009) at 21.
[1237]Bücheler, above n 1219, at 193-197

systemic method. The application of judicial proportionality becomes more pronounced when the principle is employed in the assessment of FET claims considering the certain degree of ambiguity. While Bücheler ultimately recognises judicial proportionality as a valuable tool in the process of balance, this thesis questions this conclusion as the associated risks outweigh any potential benefits in the context of patented health resources. Additionally, as Henckels highlighted rightly, proportionality itself has become a principle within FET, obliging states to act in a proportionate manner towards investors.[1238] However, the content is not clearly explained by tribunals.

Further, it is often presented as a legal rationale by simply citing the term "proportionality" without engaging in further analysis, regardless of whether the tribunal ultimately rules in favour of the state or the investors.[1239] However, as highlighted earlier, even when properly applied, this thesis contends that judicial proportionality is ill-suited for the context of international investment arbitration concerning IP rights because it involves rights that are difficult to be balanced against each other. The incommensurability problem of the judicial proportionality principle is highly acknowledged.[1240] The structural problems of FET should not automatically prompt the inclusion of a judicial proportionality analysis, which involves balancing or weighing certain benefits, particularly where the dispute concerns patents for health resources.

In *EDF v Romania* case, proportionality was considered as a stand-alone element of FET standard.[1241] The tribunal referred *Azurix v Argentina* tribunal's *James and Others v the United Kingdom* quotation and stated that:[1242]

> …proportionality would be lacking if the person involved bears an individual and excessive burden…the requirement was met as shown by the fact that the adverse effect of this measure regarding Claimant was limited…

This analysis reminds the tribunal's economic impact analysis about expropriation, as the notion of individual and excessive burden very relevant to economic impact on the investors. Therefore, similar concerns regarding patents would be applicable here. For instance, in the event of patent invalidation, the patent holder could face an excessive burden due to the loss

[1238] At 71.
[1239] *Philip Morris v Uruguay Award*, at [305].
[1240] Cass R. Sustein "Incommensurability and Valuation in Law" (1993) 92(4) Michigan Law Review 779.
[1241] *EDF (Services) Limited v Romania (EDF v Romania) (Award)* ICSID ARB/05/13, 8 October 2009 at [286]; at [293].
[1242] At [293].

of the market monopoly, depending on the how close the patent is to its expiration. Likewise, in the scenario of compulsory licencing, the patent holder could be bearing an individual and excessive burden in the pursuit of ensuring affordable access by the government.

In *Arif v Moldova*, the tribunal refers balancing exercise in the FET standard, but highlights that even if there is reasonable public policy behind the state action, state should respect legitimate expectation of investor.[1243] The tribunal gives responsibility to state in due process as well as ameliorate the effects on the investor.[1244] While states should always follow due process, how or to what extent the effects can be ameliorated pose interesting questions. In *Total v Argentina* case, the arbitral tribunal linked the proportionality and reasonableness by stating that:[1245]

> The circumstances and reasons (importance and urgency of the public need pursued) for carrying out a change impacting negatively on a foreign investor's operations on the one hand, and the seriousness of the prejudice caused on the other hand, compared in light of a standard of reasonableness and proportionality are relevant.

Hence, for the arbitral tribunal FET breach can be determined trough "a weighing of the Claimant's reasonable and legitimate expectations on the one hand and the Respondent's legitimate regulatory interest on the other.".[1246] In relation to pesification of the gas tariffs and their adjustments according to the US dollars, the arbitral tribunal considered the reasons behind its adaptation (subjective good faith, proportionality to the aims and legitimacy of the latter according to parallel practice) and decided that due to the good faith and non-discriminatory manner, it was not a breach of FET.[1247] Though the tribunal distinguish pesification of US dollar from failure to readjusting the tariffs since 2002 and held that was a breach of FET.[1248] Concerning claims on power generation, the arbitral tribunal referred proportionality and balancing between investors' expectations, and *bona fide* measures one more time.[1249] Eventually, the tribunal held that Argentina breached FET standard due to "their negative impact on the investment and their incompatibility with the criteria of economic rationality, public interest, reasonableness and proportionality".[1250] Yet, in both

[1243] *Mr. Franck Charles Arif v Republic of Moldova (Arif v Moldova) (Award)* ICSID ARB/11/23, 8 April 2013 at [537].
[1244] At [537].
[1245] *Total S.A. v. The Argentina Republic (Decision on Liability)* ICSID ARB/04/01, 27 December 2010 at [123]; at [309 (h)].
[1246] At [123].
[1247] At [159-165].
[1248] At [166-175]; at [179].
[1249] At [309 (h)], at [309 (f)].
[1250] At [333].

analyses, there was no step-by-step analysis of proportionality, but mere acknowledgement of the principle. Additionally, in the FET claim for the measures after 2002, there was a focus on negative impacts on the investment. If there is an economic harm, the investor would be compensated. However, economic harm should not necessarily indicate a breach of FET, provided that there is no legitimate expectation, manifest arbitrariness, discrimination, denial of justice and due process.

The tribunal also rejected Argentina's necessity defence by stating that Argentina failed to show that "the peril is grave and imminent and that the action is 'the only way' to safeguard the essential interest at stake".[1251] It should be noted that the tribunal highlighted the prices set by Argentina after 2002 did not adequately compensate the claimant or allow for a reasonable profit.[1252] The pricing structure led to increased electricity consumption, ultimately requiring Argentina to import energy to meet the demand.[1253] Further, the tribunal stated that Argentina should have paid the receivables after the crisis as it was not related to the economic crises anymore but merely due to Argentina's decision.[1254] Therefore, it appears that the rationale behind the decision of the tribunal was based more on absence of public interest after 2002.

A more clear and explicit application of proportionality in the analysis of FET is identified in the *Occidental v Ecuador* II[1255] case. The tribunal considered Ecuador's termination of a contract as disproportionate, thereby constituting a breach of FET. Notably, this decision resulted in one of the largest publicly known awards at the time, amounting to $1.8 billion in favour of the investor[1256], apart from the tribunal fees. The arbitral tribunal conducted a very extensive proportionality analysis, nearly 37 pages.[1257] The background is very significant in this case as it illustrates the extent to which the decision punished the state's policy aimed at preventing ecological and health issues within the Amazon.[1258] Ecuador had granted Occidental the permission to explore and extract oil, with the understanding that Occidental could not unilaterally transfer its right to a third party without proper authorisation from

[1251]At [484].
[1252]At [327-332].
[1253]At [327-332].
[1254]At [333-334].
[1255]*Occidental Petroleum Corporation and Occidental Exploration and Production Company v. The Republic of Ecuador (Award)* ICSID ARB/06/11, 5 October 2012 (hereinafter "*Occidental v Ecuador* II *Award*").
[1256]At [876].
[1257]At [384- 456].
[1258]Public Citizen Memorandum "*Occidental v Ecuador* Award Spotlights Perils of Investor-State System: Tribunal Fabricated a Proportionality Test to Further Extend the FET Obligation and Used "Egregious" Damages Logic to Hit Ecuador with $2.4 Billion Penalty in Largest Ever ICSID Award" at 2.

Ecuador.[1259] If Occidental were to transfer its rights to oil production to another company without governmental authorisation, Ecuador could terminate their contract.[1260] The underlying intent of this clause was to retain state control over companies that had enjoyed certain privileges in the region before granting them rights to prevent ecological and health problems. However, Occidental did proceed to transfer 40% of its oil concession to another company, without requisite authorisation, leading Ecuador to terminate the contract.[1261] Subsequently, Occidental sought compensation through ISDS. The tribunal accepted that Occidental breached its contract and broke Ecuadorian law yet decided that Ecuador had violated its obligations under the treaty through a proportionality assessment.[1262]

The arbitral tribunal considered all those claims under the judicial proportionality principle and indicated that:[1263]

> …the argument is not that the State must prove harm, but that any penalty the State chooses to impose must bear a proportionate relationship to the violation which is being addressed and its consequences…The test at the end of the day will remain one overall judgement, balancing the interests of the State against those of the individual, to assess whether the particular sanction is a proportionate response in the particular circumstances.

In the analysis, the tribunal also listed alternative options to termination.[1264] However, the availability of alternative measures, if there are any at the time, should not necessarily be seen as a treaty violation in the context of patented health resources. States have the discretion, as permitted by the TRIPS Agreement, to decide what is best for their national patent policy. In particular, in the context of IP, the availability of other measures does not alter the fact that international IP law upholds the principle of territoriality, which allows states to make their own choices.

What the tribunal did was not applying a judicial proportionality principle but extending the obligation of protecting foreign investment by a host state under the international law. For the tribunal:[1265]

[1259] *Occidental v Ecuador* II *Award*, at [120-121].
[1260] At [120].
[1261] At [134].
[1262] At [456].
[1263] At [416-417].
[1264] At [433].
[1265] At [450].

> the price paid by the Claimants- total loss of an investment worth many hundreds of millions of dollars- was out of proportion to the wrongdoing alleged against OEPC, and similarly out of proportion to the importance and effectiveness of the deterrence message which the Respondent might have wished to send to the wider oil and gas community.

Very clear that the tribunal decision was based on some assumptions, yet the tribunal found a breach of FET. Further, their very short decision on expropriation was particularly concerning, as it almost suggested that a breach of FET would almost automatically constitute a breach of protection against expropriation. The expropriation analysis was conducted after FET claim by the tribunal and the tribunal stated that:[1266]

> Having found in the previous Section of the present Award that the Caducidad Decree was issued in breach of Ecuadorian law, in breach of customary international law and in violation of the Respondent's Article II.3(a) obligation to accord fair and equitable treatment to the Claimants' investment, the Tribunal now has no hesitation in finding that, in the particular circumstances of this case which it has traversed earlier, the taking by the Respondent of the Claimants' investment by means of this administrative sanction was a measure "tantamount to expropriation" and thus in breach of Article III.1 of the Treaty.

The expropriation decision is problematic in many ways. The tribunal applied judicial proportionality automatically by suggesting that a breach of FET means that the measure was tantamount to expropriation for the tribunal. More substantially, it is well known in investment arbitration, the threshold for expropriation is much higher than that for FET, which apparently is not so much for the tribunal. The host state requested an annulment, one of the issues was the application of judicial proportionality by claiming that the principle of proportionality is not encompassed in the contract between countries, in Ecuadorian law, or in customary international law.[1267] The committee confirmed the tribunal's practice of judicial proportionality analysis within the FET context, noting that the threshold for annulment of a decision due to the misapplication or misinterpretation of law is very high and that the tribunal did not make any gross or egregious error of law.[1268] As against the committee decision, for this thesis applying a principle that does not suit every legal system can hinder achieving a proper balance between interests. For Bücheler, the case offers no clear guidance on whether judicial proportionality may limit states' exercise of rights; however, Bücheler

[1266] At [455].
[1267] *Occidental Petroleum Corporation and Occidental Exploration and Production Company v. The Republic of Ecuador* (*Decision on Annulment Award)* ICSID ARB/06/11, 2 November 2015 (hereinafter "*Occidental v Ecuador Decision on the Annulment of the Award*") at [349].
[1268] At [350].

cautious against tribunals too readily to apply judicial proportionality in similar situations.[1269] Henckles highlighted that the decision was questionable and the fact that arbitrators have broad scope to assess the proportionality of measures as the tribunal considered acting proportionately as a norm of general international law and customary law.[1270] For this thesis, the broadness/vagueness of FET along with the judicial proportionality analysis led to a decision that undermined the state sovereignty and lacked a consideration of weighing competing values. Instead, it led to expansion of states obligation under international investment law. Such practices become even more contentious if the disputed matter is a compulsory licence and raises concerns as it is very difficult to determine whether the issuance of that particular compulsory licence with the particular commercial terms: duration, amount of the product or remuneration is proportionate.

Proportionality in FET has been widely applied in cases where the relevant investment agreement is ECT. It is mostly as a result of formulation of the FET in ECT, mainly states that:[1271]

> Each Contracting Party shall, in accordance with the provisions of this Treaty, encourage and create stable, equitable, favourable and transparent conditions for Investors of other Contracting Parties to make Investments in its Area.

The FET claim in ECT is very detailed and includes explanations, annexes, and reservations and the FET formulation explicitly includes stable conditions for investors.[1272] To balance this so called stable legal framework and states' regulatory power, the concept of legitimate expectations has played a significant role. And applying principle of proportionality in the concept of legitimate expectations, the tribunals aim to establish whether the states' purposes are excessive taking into account the means employed to achieve this end.[1273]

Similarly, in *Electrabel v Hungary* case, Electrabel claimed that the state act was unreasonably disproportionate and cited some other relevant cases where proportionality were applied since there would not be proportionality if an investor bore an individual and

[1269]Bücheler, above n 1219, at 206.
[1270]Henckels, *Proportionality and Deference in Investor-State Arbitration: Balancing Investment Protection and Regulatory Autonomy*, above n 1185, at 83.
[1271]ECT, art 10(1).
[1272]ECT, art 10.
[1273]Balcerzak, above n 1234, at 224-225.

excessive losses.[1274] The case concerned Hungary terminating a power purchase agreement with the investor, allegedly as part of Hungary's initiative to liberalise its electricity market in accordance with European Union laws on state aid following its accession to the European Union.[1275] For Electrabel, failure to compensate fully was unjust, arbitrary, abusive, inconsistent and disproportionate.[1276] The tribunal considers disproportionality as arbitrariness, irrationality, unreasonable and inequitable under the FET standard under the ECT and collectively addresses them as arbitrariness.[1277] According to the Electrabel tribunal:[1278]

> A challenged measure must also be reasonable. That is, there needs to be an appropriate correlation between the state's public policy objective and the measure adopted to achieve it. This has to do with the nature of the measure and the way it is implemented. In the Tribunal's view, this includes the requirement that the impact of the measure on the investor be proportional to the policy objective sought.

At the end of the day, the tribunal rejected the FET claim as Electrabel was unable to prove that "state's conduct bore no reasonable relationship to that purpose or was, in another word, disproportionate".[1279] However, probably the most significant part of the award for the purpose of this thesis is that the tribunal highlighted:[1280]

> …a State has a wide scope of discretion to determine the exact contours of the measure. That requires a balancing or weighing exercise so as to ensure that the effects of the intended measure remain proportionate in regard to the affected rights and interests. Provided that there is an appropriate correlation between the policy sought by the State and the measure, the decision by a State may be reasonable under the ECT's FET standard even if others can disagree with that decision. A State can thus be mistaken without being unreasonable.

The tribunal analysis underscored the significance of the relationship between the policy and the measure in determining its reasonableness, emphasising that mere mistakes would not render the measure or the state unreasonable. It can be said that regardless of Electrabel's claims, the tribunal at least did not primarily focus on whether the investor

[1274] *Electrabel S.A. v. Republic of Hungary (Award)* ICSID ARB/07/19, 25 November 2015 (hereinafter "*Electrabel v Hungary Award*") at [124]; at [132].
[1275] *Electrabel S.A. v. Republic of Hungary (Decision on Jurisdiction, Applicable Law and Liability)* ICSID ARB/07/19, 30 November 2012 at [2.24].
[1276] *Electrabel v Hungary Award*, at [127].
[1277] At [167].
[1278] At [179].
[1279] At [168].
[1280] At [180]; at [186].

bore an excessive burden. In the meantime, the tribunal accepted the amount paid by Hungary, concluded that the payment of the full amount could not be deemed proportionate and the fact that arriving at a different figure if the tribunal were in Hungary's position irrelevant.[1281] While this conclusion is noteworthy, it is important to consider that the amount already paid by Hungary as a state aid during the agreement was significantly high, totalling 85%. The tribunal considered the state aid paid to the investor, which the investor was supposed to repay due to the European Commission decision.[1282] By choosing not to expect this repayment and merely terminating the agreement without making any payment, Hungary exercised its discretion.[1283] It remains uncertain whether the same conclusion would have been reached if the amount were considerably lower. The risk in potential cases involving patents and the compulsory licence is that proportionality analysis may prompt questions about whether the compensation provided by the state to the patent holder is adequate, an issue that should ideally fall outside the scope of a private tribunal as the TRIPS Agreement initially allows host states to determine the calculation of the compensation.[1284] Even if an IIA does not incorporate the TRIPS Agreement, the TRIPS Agreement remains relevant as it shapes many states' domestic IP law.

In *Charanne v Spain*, the arbitral tribunal accepted that the State should not act unreasonably, disproportionately or contrary to the public interest to amend laws since investor has a legitimate expectation.[1285] The tribunal relied on the UNCTAD study for the definition of legitimate expectation:[1286]

> (a) specific commitments personally, for example in the form of stabilization clause, or (b) rules that are not specifically addressed to a particular investor, but which are put in place with a specific aim to induce foreign investment and on which the foreign investor relied in making his investment.

Further, the tribunal considered that as long as the changes in law are not "capricious or unnecessary and do not amount to suddenly and unpredictably eliminate the essential

[1281]At [219].
[1282]At [185-186]
[1283]At [185-186].
[1284]World Trade Organisation "Compulsory Licencing of Pharmaceuticals and TRIPS" <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm#:~:text=The%20TRIPS%20Agreement%20does%20list,holder%20on%20reasonable%20commercial%20terms.>.
[1285]*Charanne v Spain Award*, at [514].
[1286]At [489].

characteristics of the existing regulatory framework", the principle of proportionality would be satisfied.[1287] For the tribunal, in the absence of a specific commitment, there can be no legitimate expectation on the fact that rules remain unaltered.[1288] Subsequent changes, though, should be implemented fairly, consistently and predictably while considering the circumstances of the investment.[1289] The importance of predictability was seen in *Eli Lilly v Canada*. The tribunal of *Eli Lilly v Canada* even highlighted in judicial interpretation and application of some level of unpredictability is expected.[1290]

The *Charanne v Spain* decision represents a more well-thought-of application of proportionality and shows an actual weight to certain interests of the public. This sort of analysis could benefit where the subject matter is patent like patent revocation or compulsory licencing. In both circumstances, it is acceptable that any patent owner can project that government may issue a compulsory licence, or revocation if there is a disproportionate benefit to the patent owner through a patent registration, similar to the predictability discussion in *Charanne v Spain*.[1291] However, though, it should be considered that any investor would expect some sort of changes in the legislation at some point in the host state. In the analysis, there is little information on the parameters that need to be assessed to determine when such legislative changes have gone too far. Another issue that the *Charanne v Spain* tribunal highlighted was the regulatory changes did not limit the fundamental benefits for the investors.[1292] Where the subject matter is patent, neither revocation of a patent nor compulsory licence would impact commercialising the product in the market, even though the patent owners have to compete with other products. While the *Charanne v Spain* case can provide some beneficial outcomes for cases where states make *bona fide* acts, the tendency is to use proportionality as legitimise the decision.

The *Novenergia II v Spain* tribunal referred to the *Saluka* and *Electrabel* decisions in terms of balancing exercise in FET.[1293] In its balancing exercise, the tribunal made a very troublesome statement:[1294]

[1287]At [517].
[1288]At [499-500].
[1289]At [499-500].
[1290]*Eli Lilly v Canada Final Award*, at [421].
[1291]*Charanne v Spain Award*, at [530-534].
[1292]At [533].
[1293]*Novenergia II – Energy & Enviroment (SCA) (Grand Duchy of Luxembourg), SICAR v The Kingdom of Spain (Final Award)* SCC 2015/063, 15 February 2018 (hereinafter "*Novenergia II v Spain Final Award*") at [657 -658].
[1294]At [694].

> the assessment of whether the FET standard has been breached is a balancing exercise, where the state's regulatory interests are weighed against the investors' legitimate expectations and reliance. It is not simply sufficient to look at the economic effect that the challenged measures have had. Destruction of the value of the investment is clearly determinative in the assessment of whether a state has breached Article 13 of the ECT, but it is but one of several factors to consider when determining whether a state has breached Article 10(1) of the ECT. Nevertheless, in the Tribunal's opinion, the economic effect on a claimant's investment is an important factor in the balancing exercise pursuant to Article 10(1) as well, as it can go towards showing a change in the essential characteristics of the legal regime relied upon by investors in making long-term investments.

The tribunal considered the economic impact on the investor as one of the reasons for the FET breach and did not refrain from mentioning similarities with the expropriation claim.

RREF v Spain tribunal also considered proportionality as an element of FET.[1295] The analysis of proportionality one time focused on the loss suffered by the investor:[1296]

> …the determination of a violation of the principles of proportionality and reasonableness is inseparable from an assessment of the damages – if any – endured by the Claimants as a consequence of the measures taken by the Respondent.

Despite the tribunal considered that proportionality weighing should "seek a fair balance competing interests and/or principles affected by the regulation", the regulation interference should be minimized.[1297]

Another case that was initiated against Spain was RWE Innogy.[1298] According to the tribunal, while Spain did not create legitimate expectations, it acted disproportionately. The proportionality analysis focused on "whether the changes were suitable and necessary to achieve the legislative intent, and whether an excessive financial burden was shifted to claimant" and the tribunal questioned if any margin of appreciation could be accorded to the state.[1299] The tribunal applied a proportionality test, examined the suitability of the measure and the availability of less restrictive measures to achieve the same objective, and finally discussed *sensu stricto*. In the analysis, similar to the *Electrabel* and *EDF* decision, the

[1295]*RREEF Infrastructure (G.P.) Limited and RREEF Pan- European Infrastructure Two Lux S.á.r.l v. Kingdom of Spain (Decision on Responsibility and on the Principles of Quantum)* ICSID ARB/13/30, 30 November 2018 (hereinafter *RREEF v Spain Award*") at [260]; at [324].
[1296]At [472].
[1297]At [465].
[1298]*RWE Innogy GmbH and RWE Innogy Aersa S.A.U. v Kingdom of Spain (Award of the Tribunal)* ICSID ARB/14/34, 18 December 2020 (hereinafter "*RWE Innogy v Spain Award of the Tribunal*").
[1299]At [551].

tribunal focused more on the burden borne by the investor rather than the reasons behind the decision and the analysis was similar to an expropriation analysis. As mentioned above, a state conduct/measure can breach a FET, if the impact falls short of amounting to a substantial deprivation. This type of analysis of FET claim, very similar to expropriation, often finds a breach through the proportionality. This approach poses significant risks in the context of patents related to health resources as defined in this thesis. For example, in cases involving compulsory licence, as the patent holder would be compensated in line with the TRIPS Agreement, the economic impact may not meet the threshold for expropriation. However, it could still be deemed a breach of FET due to the significant burden that the patent holder would be bearing.

Similar to the RWE decision, in *Muszynianka v Slovakia*[1300], the tribunal applied the proportionality principle and considered *stricto sensu* as "requires weighing the effects of State measure on investor's rights or interests and significance of the purpose pursued by the measure.".[1301] In addition, the tribunal added that the *sricto sensu* step would not be met if "a measure imposes an excessive burden on an investor's rights in relation to the aim of the measure".[1302] Despite such consideration, the tribunal's *stricto sensu* analysis represents an example of weighing public interest over investor and the analysis did not solely focus on the impact on the investor.[1303]

Other cases initiated against Spain further included proportionality analysis.[1304] It can be said that in FET analysis, proportionality has been used as a balancing tool to limit the states regulatory power. Most of the cases initiated against Spain in relation to renewable energy regulations suggest that FET in nature calls for a balancing of different interests.[1305] Some of these tribunals considered this balancing as a part of the proportionality principle, some

[1300]*Spoldzielnia Pracy Muszynianka v. Slovakia Republic (Muszynianka v Slovakia) (Award)* UNCITRAL 2017-08, 7 October 2020.
[1301]At [573].
[1302]At [574].
[1303]At [575].
[1304]*Watkins Holdings S.á.r.l and others v. Kingdom of Spain (Award)* ICSID ARB/15/44, 21 January 2020 (hereinafter "*Watkins v Spain Award*") at [601-603]; Hydro Energy 1 *S.á.r.l and Hydroxana Sweden AB v. Kingdom of Spain (Decision on Jurisdiction, Liability and Directions on Quantum)* ICSID ARB/15/42, 9 March 2020 (hereinafter "*Hydro Energy v Spain Decision on Jurisdiction, Liability and Directions on Quantum*") at [573-574]; *BayWa r.e. Renewable Energy GmbH and BayWa r.e. Asset Holding GmbH v. Spain* ICSID ARB/15/16, 2 December 2019 at [460- 463]; at 480; *Stadtwerke München GmbH, RWE Innogy GmbH, and others v. Kingdom of Spain (Award)* ICSID ARB/15/1, 2 December 2019 (hereinafter "*Stadtwerke v Spain Award*") at [323- 355]; *AES Solar and others (PV Investors) v The Kingdom of Spain (Final Award)* UNCITRAL 2012-14, 28 February 2020 (hereinafter "*PV Investors v Spain Final Award)* at [627-630]; *SolEs Badajoz GmbH v Kingdom of Spain (Award)* ICSID ARB/15/38, 31 July 2019 (hereinafter "*SolEs v Spain Award*") at [308- 328]
[1305]*Novenergia II v Spain Final Award*, at [694]; *Hydro Energy v Spain Decision on Jurisdiction, Liability and Directions on Quantum*, at [583]; *RWE Innogy v Spain Award of the Tribunal*, at [53]; *Watkins Holdings S.á.r.l and others v. Kingdom of Spain (Dissent on Liability and Quantum of Prof. Héléne Ruiz Fabri*) ICSID ARB/15/44, 9 January 2020 at [5]

applied the three-step test, while others directly applied proportionality by linking it to reasonableness.[1306] Some of the cases also included the margin of appreciation doctrine developed by the ECtHR.[1307] The applicability of this doctrine will be discussed in the following part. Yet, none of those cases were able to bring so many positive outcomes in the system of international investment arbitration, in fact they raised even more significant questions, particularly in relation to the concept of FET and the judicial proportionality. The balancing exercise of tribunals mostly revolved around economic impact of such measures on the investor. When the economic impact could not meet the threshold for expropriation, FET claims often came into play. As mentioned above, some of the tribunals did not even refrain from mentioning similarities. The cases initiated against Spain particularly prove that FET turn into an analysis similar to the expropriation. Where indirect expropriation cannot be upheld, the tribunals used FET to find a breach and judicial proportionality was applied as its justificatory.

The assessment of three-step or reasonableness can overlook the policy priorities of the host state. Particularly, the cases initiated against Spain exemplify this. Judicial proportionality or balancing cannot serve as a tool for weighing different values in either expropriation or FET claims, particularly in cases involving patented health resources. The concept of judicial proportionality requires an analysis that attempts to balance between public interest and investors' right as if they were comparable or interchangeable. This can be possible in some areas of law or other judiciary contexts, but in investment law, judicial proportionality risks impeding discussions that prioritise the social objectives of IP and the public welfare of a particular country over an investment. Judicial proportionality requires a value judgment that involves weighing the importance of public welfare against the impact on the investment or significant burden borne by an investor. If IP, in particular patent concerning health resources, falls under the jurisdiction of an investment tribunal, the tribunal should avoid a value judgment through judicial proportionality. The TRIPS Agreement already permits states to use flexibilities or determine their own laws, even though one can discuss the effectiveness of these flexibilities in safeguarding access to health resources under the TRIPS Agreement.

[1306] *SolEs v Spain Award*, at [317]; *RWE Innogy v Spain Award of the Tribunal*, at [568-571]; *Watkins v Spain Award*, at [601-603]; *Hydro Energy v Spain Decision on Jurisdiction, Liability and Directions on Quantum*, at [573-574]; *Stadtwerke v Spain Award*, at [354].
[1307] *RREEF v Spain Award*, at [238]; at [243]; [283], *RWE Innogy v Spain*, at [551- 554]; at [567]; at [571]; at [589]; at [599]; at [647]; *PV Investors v Spain Final Award*, at [583]; at 193, n 790; *Hydro Energy v Spain Decision on Jurisdiction, Liability and Directions on Quantum*, at [589 590].

The purpose of IIAs is not only to protect foreign investors but also, they are expected to benefit the development of the host state through foreign investment.[1308] Therefore, tribunals have a role in the interpretation of investment treaties to consider not only strong investor and investment protection but also other aspects of investment treaties, such as the prosperity and development of the host state.[1309] In particular, when the issue involves patented health resources, tribunals should avoid balancing investors' economic burdens against state needs, as judicial proportionality or balancing analysis of various needs and objectives has no a priori outcome. Aiming to provide deference to the state in FET claims, the tribunals transferred MoA doctrine from ECtHR jurisprudence. Yet, this practice has received some concerns from arbitrators and scholars, as identified in the following section. Therefore, this thesis suggests the possibility of application of the police powers doctrine instead of transferring MoA, taking into account major oppositions to this practice and conceptual differences between investment arbitration and ECtHR.

5.3. ECtHR Jurisprudence in Investment Arbitration

Since the first explicit reference to the principle of proportionality, there has been a gradual integration of ECtHR's concepts into investment arbitration, including margin of appreciation ("MoA").[1310] This is mostly a result of the growing presence of human rights concepts within the area of investment arbitration. A predominant feature is the inclusion of the ECHR and its case law, regardless of whether the respondent states are parties to that regional agreement. The MoA discussion is significant for this thesis, as it was recently applied by the *Philip Morris v Uruguay* tribunal to provide deference to the state. However, this practice received opposition from one of the arbitrators and from scholars, which this thesis recognises the rationales behind it. A question might arise about what arbitrators should do. This thesis argues that the tribunals do not need to transfer concepts from ECtHR like MoA since the police powers doctrine is already available and well developed in the context of investment arbitration. While so far, it is associated with expropriation, this thesis finds no problem in extending police powers to FET, in line with Viñuales.[1311]

[1308]Sornarajah, above n 633, at 55.
[1309]Federico Ortino "Investment Treaties, Sustainable Development and Reasonableness Review: A Case Against Strict Proportionality Balancing" (2017) 30(1) Leiden Journal of International Law 71 at 78-79.
[1310]*Chemtura Corporation (formerly Crompton Corporation*) *v Government of Canada (Award)* PCA 2008-1, 2 August 2010 at [133-134]; *Glamis Gold v USA Award*, at [779]
[1311]Jorge E. Viñuales "Sovereignty in Foreign Investment Law" in Zachary Douglas, Joost Pauwelyn and Jorge E. Viñuales (ed) *The Foundations of International Investment Law: Bringing Theory into Practice* (Oxford University Press, Oxford, 2014) 317 at 332-333; at 344.

As highlighted earlier, when IP is a subject matter, just as other issues human rights considerations can easily play a role in the discussion, similar to *Philip Morris v Uruguay.* In IP-ISDS debate, several studies have tackled the intersection with human rights.[1312] Some criticised existing agreements for their failure to address human rights imbalances while highlighting the challenges of states in relying on human rights and police powers to justify their measures.[1313] Perhaps, the integration of MoA can be seen as a reflection of this. The integration of both the judicial proportionality principle and MoA doctrine can be displayed in different forms, either by adopting VCLT Article 31 or by applying 'relevant principles of international law' as prescribed by several BITs and Article 38(1) ICJ Statute.[1314] This integration can facilitate the application of judicial proportionality or MoA doctrine. In fact, both proportionality and MoA are regarded as general principles of international law.[1315] However, the integration of MoA particularly received much attention.[1316]

The first explicit reference to ECtHR in investment arbitration, as highlighted earlier was made in *Tecmed v Mexico* case; the arbitral tribunal referred to *Matos e Silva, Lda., and Others v. Portugal*, *Mellacher and Others v. Austria*, *Pressos Compañía Naviera, and Others v. Belgium* cases to assess whether the state's measure was proportional concerning protect public health protection. As mentioned in Chapter 4.4.2., *Philip Morris v Uruguay* represents an example where the tribunal referenced ECtHR jurisprudence. Notably, the tribunal incorporated the MoA in fair and equitable treatment claim and proportionality within the expropriation claim. Despite the tribunal's dismissal of the investor's claims, it is significant to highlight that one arbitrator dissented, emphasising references to ECtHR jurisprudence

[1312]Cynthia Ho "Intersection of ISDS and TRIPS Flexibilities" in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) 207; Cynthia Ho "Reexamining *Eli Lilly v Canada*: A Human Rights Approach to Investor-State Disputes?" (2018) 21(2) Vanderbilt Journal of Entertainment and Technology Law 437; Cynthia Ho "Inside Views: TRIPS Flexibilities Under Threat from Investment Disputes: A Closer Look at Canada's "Win" Against Eli Lilly" (27 April 2017) Intellectual Property Watch <https://www.ip-watch.org/2017/04/27/trips-flexibilities-threat-investment-disputes-closer-look-canadas-win-eli-lilly/>; Daniel Gervais "Investor State Dispute-Settlement: Human Rights and Regulatory Lessons from *Lilly v Canada* (2018) 8 (3) UC Irvine Law Review 459.

[1313]Dreyfuss and Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?", above n 901, at 389.

[1314]Application of VCLT art 31: *Hesham T.M. Al-Warraq v. Republic of Indonesia (Final Award)* UNCITRAL, 15 December 2014 at [177]; at [183]; Application of IIA and ICJ art 38(1): *Channel Tunnel Group Limited and France-Manche SA v United Kingdom and France (Award)* PCA 2003-06, 30 January 2007 at [114]; *El Paso v Argentina Award*, at [419-420].

[1315]Yuval Shany "Toward a General Margin of Appreciation Doctrine in International Law?" (2006) 16(5) EJIL 907; Eric De Brabandere and Paula Baldini Miranda da Cruz "The Role of Proportionality in Investment Law and Arbitration: A System-Specific Perspective" (2020) 89 NIJHOFF 471.

[1316]Giovanni Zarra "Right to Regulate, Margin of Appreciation and Proportionality: Current Status in Investment Arbitration in Light of Philip Morris v. Uruguay" 2017 14(2) Revista de Direito Internacional 95; Julian Arato "The Margin of Appreciation in International Investment Law" 2014 54(3) Va. J. Int'l L 545; Yuka Fukunaga "Margin of Appreciation as an Indicator of Judicial Deference: Is It Applicable to Investment Arbitration?" 2019 10(1) Journal of International Dispute Settlement 69; Erlend M. Leonhardsen "Designing Deference: Towards a Thin Margin of Appreciation Doctrine in International Investment Law" 2022 European Yearbook of International Economic Law 151.

connected to the MoA within his dissenting opinion. As included in the dissenting opinion, ECHR, as a regional agreement, developed within a distinct historical context. Some scholars, aligning with this opinion, oppose integrating judicial proportionality within ISDS proceedings, including that the IP is recognised as a human right to property within ECHR.[1317] This thesis supports this stance, not solely because IP is recognised as a right to property under ECHR. One of the reasons for questioning ECtHR principles, both judicial proportionality and MoA, is that they are rooted in specific and historical contexts.[1318] The recognition of IP as a human right to property under ECHR is different from the purpose of protection of expropriation in investment arbitration law which reflects this historical difference.

Judicial proportionality under ECtHR is a tool for decision-makers to determine whether their actions that constrain human rights are required.[1319] Further, judicial proportionality generally addresses conflicts between diverse human rights and interests, encompassing both private and public concerns.[1320] Decision-makers, hence, evaluate these rights and interests against each other, eventually giving weight one over the other.[1321] The purpose of ECHR is to safeguard human rights across member states, which may potentially interpret these rights differently. As a result, these differences can lead to distinct perspectives on prioritising or limiting the rights protected under the convention.[1322] That is not the focus of investment tribunals. Their analysis is focused on resolving the disputes between foreign investors and states and determining whether there has been a breach of the IIA.

However, since judicial proportionality is widely applied in different contexts (criminal law, administrative law, or constitutional law), it may not be difficult to recognise as part of international law, while MoA lacks comparable influence. The doctrine of MoA is justified as protecting "supranational judges from charges that they are violating the wishes of democratic polities particularly legislatures".[1323] It aims to manage the relationship between Strasbourg judges and national democracies.[1324] However, this purpose is not applicable to

[1317]Mylly, above n 26, at 436-437.
[1318]Raymond Yang Gao "What are We Talking About When We Talk About Deference in Investment Treaty Arbitration?" (2022) 13(3) Journal of International Dispute Settlement 472 at 482-483.
[1319]Kristina Trykhlib "The Principle Of Proportionality in the Jurisprudence of the European Court of Human Rights" (2020) 4 ECLIC 128 at 129.
[1320]At 129-130.
[1321]At 129-130.
[1322]Zarra, above n 1316, at 110.
[1323]Gao, above n 1318, at 482.
[1324]At 483.

investment tribunals, whose role is to resolve the dispute between foreign investor and state rather than managing relationship between states' conducts and themselves. In addition, as Zarra analyses, the structure of all rights where MoA is acknowledged in the ECHR (*i.e.* Article 8: Right to respect for private and family life; Article 9: Freedom of thought, conscience and religion; Article 10: Freedom of expression, Article 11: Freedom of assembly and association; Article 15: Derogation in time of emergency) is quite similar, their first paragraphs draw the protected right and the second paragraphs explain the conditions in presence which a state may limit the enjoyment of such a right.[1325] This does not apply to IIA, even though there are limitations to the substantive protections provided to investors. It is important to note that while there is only one ECHR, there are many IIAs in force, each formulated in multiple ways, representing the different intentions of states. Therefore, the application of MoA may not be well suited to investment arbitration.

Additionally, the purpose of investment tribunals is to determine whether governmental interference with foreign investments constitutes a breach of an IIA (might be arising out of a contract between state and investor). In contrast to human rights courts, investment tribunals are not designed to adjudicate human rights violations. When a state measure addresses public human rights, the state merely employs human rights as a defence, as it serves as the underlying purpose behind the measure. Human rights are the nature of the public policy objectives and a result of constitutional obligation to citizens and to the state itself (environmental protection or safety). The inclusion of human rights, either derived from international or regional agreements or constitutions, underpins state activity or public considerations, thus it constitutes a component of state defence. In line with this, according to Gervais, the arbitral tribunals should not interpret IIAs in conflict with states' human rights obligations.[1326] While this does not legitimise any human rights violations against foreigners, investment tribunals are not the appropriate forum to adjudicate such claims. This highlights that the purpose of the investment tribunals and ECtHR differ, thus ECtHR doctrine cannot fit well within the investment arbitration.

While the host states must justify their interference that serves the public interest, the nature of these interests arises from public human rights considerations. The concept of ISDS is a mechanism where foreign investors can seek protection (not human rights protection) only to

[1325]Zarra, above n 1316, at 110.
[1326]Gervais, "Investor State Dispute-Settlement: Human Rights and Regulatory Lessons from *Lilly v Canada*, above n 1312, at 506-509.

the extent IIAs allow. Besides, it is very clear that IIAs are not human rights agreements, they are a mechanism to prevent or change certain behaviours of the host state. One of the purposes of IIAs is to establish some limitation on state sovereignty to encourage foreign capitals to invest[1327], though only up to a point, like public measures. The standards of treatment for foreign investors within IIAs do not represent a similar structure to the rights outlined in ECHR[1328] and the purpose of ECHR.

In the *Philip Morris v Uruguay* case, the arbitral tribunal applied the MoA doctrine in examining the FET claim. This approach was rejected by Born and it was claimed that the proportionality principle should have been applied instead.[1329] According to Born, the SPR regulation was disproportionate and violated the FET standard.[1330] As previously explained, this thesis also rejects the application of judicial proportionality when IP is the subject matter, which raises the question of how to assess an FET claim. As previously highlighted, this thesis finds that there is no need to transfer concepts from the ECtHR to the ISDS context. In the case of expropriation, the answer is relatively straightforward, as police powers can come into play. In the context of FET, it is more complex. Mylly suggests that *deference* should be given to the state through MoA.[1331] Since this thesis acknowledges the concerns about the application of MoA, the question of how deference can operate in FET claims with a wide degree remains a significant one.

Schill explains the different notions of deference under the investment arbitration well.[1332] It is important to highlight that here deference refers to giving a "space for maneuver"[1333] so that state conduct is exempt from full review by the tribunals. Technically, deference has a similar meaning to MoA; however, as elaborated above, MoA has developed under ECtHR for a specific purpose. The concern regarding deference in the context of investment arbitration arises from the absence of consensus on how to conceptualise it, the degree of deference to afford when evaluating different types of states' conduct and the factors influencing whether deference should be afforded.[1334] Another concern is that if the degree of deference granted to the state remains unknown, it may inevitably lead to invoking judicial proportionality, since it

[1327]Zarra, above n 1316, at 110-111.
[1328]At 111.
[1329]*Philip Morris v Uruguay* Dissenting Opinion, at [129-139].
[1330]At [129].
[1331]Mylly, above n 26, at 429.
[1332]Stephan W. Schill "Deference in Investment Treaty Arbitration: Re-Conceptualising the Standard of Review" (2012) 3(3) Journal of International Dispute Settlement 577 at 581-582.
[1333]At 582.
[1334]At 585.

requires weighing non-investment interests. For instance, the tribunal in *S.D Myers v Canada* stated that:[1335]

> The Tribunal considers that a breach of Article 1105 occurs only when it is shown that an investor has been treated in such an unjust or arbitrary manner that the treatment rises to the level that is unacceptable from the international perspective. That determination must be made in the light of the high measure of deference that international law generally extends to the right of domestic authorities to regulate matters within their own borders.

However, this may not be always the case. This uncertainty poses risks for the regulatory space and flexibilities provided under the TRIPS Agreement when the issue concerns IP rights. This underscores the need to consider the applicability of police powers within the context of FET. Extending police powers to FET may not be a straightforward effort in safeguarding states' regulatory power as the police powers doctrine is associated with expropriation.[1336] In fact, Argentina attempted to extend police powers to FET as a defence in *Suez v Argentina*. However, the tribunal rejected it by stating that police powers is a concept that can be applicable only in relation to the expropriation, not to other standards.[1337] However, as Viñuales puts rightly, also highlighted in Chapter 3.3.3.2, the police powers doctrine is recognised as a norm of customary international law and it can operate autonomously from treaty or contract.[1338] This means that the application of the police powers doctrine does not rely on, nor is it a component of, any specific investment discipline.[1339] Additionally, there are no limitations as to interferences that are lesser than expropriation, like FET, which can be justified through the police powers doctrine.[1340] Viñuales highlights well that restricting or characterising the police powers doctrine to expropriation alone allows claimants to neutralise state sovereignty.[1341] An alternative option, probably a better option, is to prevent bringing FET claims for the IP rights entirely. This alternative option aligns with Gervais's emphasis on how the language of agreements, which highlights limiting the scope

[1335] *SD Myers v Canada Partial Award*, at [261].
[1336] Jorge E. Viñuales *Foreign Investment and the Environment in International Law* (Cambridge University Press, New York, 2012) at 379.
[1337] *Suez, Sociedad General de Aguas de Barcelona S.A., and InterAguas Servicios Integrales del Agua S.A. v The Argentine Republic (Decision on Liability)* ICSID ARB/03/17, 30 July 2010 at [148].
[1338] Viñuales, "Sovereignty in Foreign Investment Law", above n 1311, at 344.
[1339] At 344.
[1340] At 334.
[1341] At 332.

of ISDS or recognising the states' regulatory power, can prevent the tribunals from interfering with states' regulatory power.[1342]

5.4. Conclusion

This chapter examined the judicial proportionality principle in indirect expropriation and FET analysis by tribunals to determine whether the application can effectively mitigate the disproportional investment protection of patented health resources. The analysis highlighted that judicial proportionality in cases involving patented health resources entails the risk of not affording adequate deference to states that possess a deeper understanding of the public's needs, as well as adding extra layers for states to demonstrate as needed by the three-step test. This chapter emphasised that judicial proportionality is ill-suited for international investment arbitration concerning IP rights, particularly patented health resources. This analysis involves weighing investors' economic burdens against state needs, with the risk of placing greater emphasis on the impact on the investors. Therefore, this chapter concluded that judicial proportionality cannot mitigate disproportionate (as understood from midlevel proportionality) investment protection of health resources. The application of judicial proportionality runs the risk of potentially neglecting the importance of such measures in serving public welfare or broader societal goals of patent law. Therefore, the application of proportionality should be avoided in investment cases involving patents, as it cannot adequately assess public welfare or societal goals of patent law.

This chapter further examined the applicability of ECtHR, as tribunals have employed judicial proportionality as well as the MoA doctrine by a reference to this regional human rights court, even when the host state is not a party to the ECHR. In this respect, this chapter highlighted the distinct purposes and historical developments of the ECtHR and ISDS. Consequently, this thesis opposes the applicability of ECtHR concepts within the ISDS. Having argued against applying judicial proportionality, this thesis recommends that tribunals handling cases involving patented health resources should employ the police powers doctrine in their expropriation and FET analysis.

The formulation of IIAs is crucial in determining the potential success of an investor/patent holder in the ISDS case, ultimately influencing the decision to bring a claim in the first place and the principles/doctrines that the tribunal might apply. The text of IIAs has the power to

[1342]Gervais, "Investor State Dispute-Settlement: Human Rights and Regulatory Lessons from *Lilly v Canada* above n 1312, at 506-509.

discourage states from implementing necessary public measures or, conversely, discourage investors from bringing claims. In this respect, it can be observed that the new IIAs, particularly mega-regional IIAs, potentially signify a more considerate inclusion of investment protection for IP rights. Subsequently, the following chapter of this thesis aims to scrutinise these agreements to determine whether they adequately incorporate the social functions of patent rights and scale back from disproportionate investment protection of health resources. This analysis encompasses the United State-Mexico-Canada Agreement (USMCA), the EU-Canada Comprehensive Economic and Trade Agreement (CETA), and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP).

CHAPTER 6- PROPORTIONALITY WITHIN THE REGIONAL IIAs

6.1. Introduction

The new emerging IIAs, particularly the mega-regional IIAs, indicate a more nuanced approach to the availability of investor-state dispute settlement for IP chapters and confirm the concerns raised in this thesis are addressed by the countries. As a result, this chapter examines these agreements to evaluate how effectively they incorporate the social aspects of patent rights. This analysis will encompass the United States-Mexico-Canada Agreement (USMCA)[1343], the European Union-Canada Comprehensive Economic and Trade Agreement (CETA)[1344] and the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP)[1345]. In the analysis of these agreements, emphasis is given to patent regulations in the intellectual property chapters, as well as expropriation and FET rules under the investment chapters. At times, the analysis includes comparisons with model BITs from Global South countries to highlight the core concerns of states regarding ISDS, which have led them to implement certain changes.

It will become evident that states have taken specific steps to avoid the ISDS mechanism for patent protection and have adopted certain limitations in the agreement. The purpose of this chapter is to assess parts relevant to IP-investment, which involve scaling back from the disproportionate reward provided to IP holders. In this regard, the focus will be on evaluating whether this balancing can prioritise global justice principles that promote access to health resources. Proportionality here is the use of the midlevel principle in treaty-making and differs from its application in investment arbitration, constitutional courts, or the ECtHR as judicial proportionality. Here, it primarily involves analysing the conflict between two elements: access to affordable health resources (social function of IP) and investment protection of patents, with proportionality being considered within the midlevel principle. As identified earlier, proportionality in its midlevel form can reveal itself in the design of the IP rights and its limitations.[1346]

The analysis shows that the USMCA has notably limited the scope of ISDS, especially regarding the controversial substantive standards of FET and indirect expropriation. Within the context of patent protection, this limitation can be interpreted as an embodiment of

[1343]USMCA.
[1344]CETA.
[1345]CPTPP.
[1346]Wallot, "The Proportionality Principle in the TRIPS Agreement", above n 627, at 232; Merges, above n 22, at 160.

midlevel proportionality, addressing the disproportionate investment protection of patent law that undermines the social function of the IP law, leading to its restriction. While CETA does not eliminate the indirect expropriation and FET claims entirely, it provides substantial limitations in both provisions aiming at mitigating disproportional investment protection of health resources. The limitations on the substantive principles, along with the detailed preamble and the shift from ISDS to an investment court system, address the critiques presented in this thesis. The limitations and restrictions can also be found in CPTPP, and most controversial IP provisions are suspended. Theoretically, CPTPP safeguards states' regulatory measures ensuring affordable access to health resources. The limitations provide states with more leeway to implement their own patent law or use TRIPS flexibilities. Yet, the *chilling effect* of patent protection as an investment remains in CPTPP. It should be noted, as explored in Chapter 6.4, that some states have been excluded from ISDS through side letters.

Here, the focus is on examining how the design of patent rights is structured concerning their investment protection. Midlevel proportionality reveals itself either in the formulation of a single provision or in reading provisions collectively in the agreement. It should be noted that while the analysis here includes IP chapters, which largely involve TRIPS-plus provisions, the primary focus here is on their investment protection, mainly protection against indirect expropriation and fair and equitable treatment. The analysis in this chapter encompasses the North American region and extends to Oceania. Within this respect, this chapter starts with the overall background of USMCA, the replacement of NAFTA, CETA, and CPTPP. The goal here is to offer a wide regional overview, showcasing the trends, movements, or steps taken by the states concerning patents, access to health resources, and ISDS.

6.2. The United States- Mexico- Canada Agreement (USMCA)

The USMCA replaced NAFTA and came into effect on 1 July 2020.[1347] A transitional period of 3 years was agreed upon by the parties only for investments made before the USMCA took effect, which concluded on 30 June 2023.[1348] In this way, those investors were able to resort to the ISDS mechanism of NAFTA during that transition period. It should be noted that this new trade agreement exempts Canada from the ISDS; making it available solely between the United States and Mexico under USMCA.[1349] However, this does not prevent both Mexican

[1347]Office of the United States Trade Representative "Unites States- Mexico- Canada Agreement" < https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement>.
[1348]USMCA, Annex 14-C Paragraph 3.
[1349]USMCA, Annex 14-C Paragraph 3; Annex 14-D.

and Canadian investors from initiating an ISDS procedure against states through CPTPP.[1350] Through the analysis, starting from the preamble to the IP and investment chapters of the agreement, it appears that USMCA member states have managed to mitigate risks and critiques of ISDS, particularly with respect to indirect expropriation or FET.

The intellectual property chapter of USMCA is very detailed and long, encompassing almost 65 pages including its annexes, while the investor chapter is 40 pages with annexes.[1351] Thus, it should be kept in mind that the analysis is only limited to patent protection of health resources and their availability to be brought before the ISDS mechanism. Other issues concerning states' regulatory powers on sustainability and the environment or concerns in relation to indigenous rights or biodiversity[1352] are beyond the main question of this thesis.

According to the VCLT Article 31.2, preambles have roles in the interpretation of a treaty.[1353] As highlighted by UNCTAD, many preambles of the IIAs emphasise investment protection as the primary objective and purpose of the treaties, which led some tribunals to prioritise interpretations that focus on investors' interests.[1354] The preamble can play a role that ultimately leads tribunals to give significantly more weight to investors' interest, as experienced decades ago in *SGS v Philippines.*[1355] In this aspect, the USMCA preamble, which can contribute to the interpretation of its provisions, when necessary, offers balanced positions. The agreement acknowledges states' right to regulate and protects their flexibility in establishing legislative and regulatory priorities, as well as safeguards states' public welfare objectives, like health, as long as they are "in accordance with the rights and obligations in the agreement".[1356] While it is difficult to claim that states can enjoy complete freedom to undertake whatever actions are necessary to safeguard their public welfare objectives, this part of the preamble is valuable for the purpose of interpreting the agreement when there are conflicting interests. The USMCA preamble aims to ensure that states retain

[1350]CPTPP, Chapter 9.
[1351]USMCA, Chapter 20; Chapter 14.
[1352]Richard A. Morgan "Three Countries, One Environment: Environmental Cooperation and Free Trade in North America" (28 July 2021) IISD <https://www.iisd.org/articles/environmental-cooperation-free-trade-north-america>; Shannon Hale "Indigenous Rights and Trade: the USMCA and Contemporary Issues" in Dwight Newman (ed) Research Handbook on the International Law of Indigenous Rights (Edward Elgar, Cheltenham, 2022) 280.
[1353]VCLT, art 31.2.
[1354]UNCTAD *IIA Issues Note- Interpretation of IIAs: What States Can Do* (December 2011) at 9; *SGS Société Générale de Surveillance S.A. v Republic of Philippines (Decision on Jurisdiction)* ICSID ARB/02/6, 29 January 2004 (hereinafter "*SGS v Philippines Decision on Jurisdiction*") at [116].
[1355]*SGS v Philippines Decision on Jurisdiction*, at [116]: "…According to the preamble it is intended 'to create and maintain favourable conditions for investments by investors of one Contracting Party in the territory of the other' It is legitimate to resolve uncertainties in its interpretation so as to favour the protection of covered investments."
[1356]USMCA, Preamble Paragraph 9.

flexibility to safeguard public goals, such as access to health resources. Thus, it starts introducing a balanced protection of foreign investors to the extent that public welfare is at stake. When compared with the NAFTA preamble, which only states "preserve their flexibility to safeguard the public welfare"[1357], the USMCA offers broader protection of states' right to regulate and a more proportional approach to investment protection. The issue to be discussed alongside the treaty's relevant provisions is whether the preamble and the text of the agreement can address the global justice concerns regarding access to health resources.[1358]

This chapter on intellectual property rights in USMCA draws significantly from the TTP text, which the latter did not come into force following the United States withdrawal. The objective of the IP chapter and its principles are derived from the TRIPS Agreement Article 7 and Article 8[1359], which represent the flexibilities of the TRIPS Agreement, as discussed in Chapter 3.2. These articles reflect the concerns of the Global South and are further embedded in the USMCA IP chapter through Article 20.2 and Article 20.3.[1360] Article 20.2, mirroring TRIPS Agreement Article 7, explicitly seeks to strike a balance between rights and obligations, emphasising the mutual advantage of both IP holders and users while taking into account social and economic welfare.[1361] Article 20.2 states that:[1362]

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

As highlighted by Ruse-Khan in relation to Article 7 of TRIPS, in this case, Article 20.2 of USMCA also requires the promotion of technological innovation on one hand, and transfer and dissemination on the other.[1363] The requirement to strike a balance of rights and obligations underscores the need to weigh different stakeholders.[1364] The influence of midlevel proportionality comes into play, offering regulatory flexibility to states to consider

[1357]NAFTA, Preamble Paragraph 12.
[1358]As discussed in detail in Chapter 2, although the agreements are regional, regional agreements can address global justice concerns since global justice deals with individuals' claim from one country to another.
[1359]TRIPS Agreement, art 7; art 8.
[1360]USMCA, art 20.2; art 20.3.
[1361]USMCA, art 20.2.
[1362]USMCA, art 20.2.
[1363]Henning Grosse Ruse-Khan "Proportionality and Balancing within the Objectives" in Paul L.C. Torremans (ed) *Intellectual Property and Human Rights: Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer, Netherlands, 2008) 161 at 173-174.
[1364]At 173-174.

both public interest (social function) and domestic market[1365], which can be relied on in the interpretation of the treaty.[1366] In line with Ruse-Khan, this thesis suggests that this provision calls for a proportional investment protection, fostering a balanced system.[1367] The provision gives the same weight to both IP holders and its users, the public, emphasising that Article 20.2 in the IP chapter has the same power as the substantive rights.

Article 8 of TRIPS is mirrored in Article 20.3 of the USMCA, emphasising the states' right to regulate for the protection of public health and the promoting public interest in sectors of vital importance to their social-economic and technological development.[1368] It also serves to prevent the abuse of intellectual property rights,[1369] like not using a patented product. By safeguarding public health, promoting public interest in social-economic and technological development, aligning with the IP chapter, as well as preventing abusive behaviour of patent holders, it underscores a proportion between the social function of patent and patent protection. Moreover, the first paragraph should be interpreted as emphasising global justice values in a regional agreement, eliminating barriers to enhance development, where access to health resources is a key component of these developmental values. However, it should be noted that the IP chapter introduces TRIPS-plus obligations. The TRIPS-plus obligations in the IIAs, as explored further below, require states to offer higher levels of IP protection than mandated by TRIPS. This shift undermines the balance between IP holders and the public by giving greater protection to IP holders. However, the investment protection of the IP chapter is the main issue for this thesis, which highlights that states have introduced certain balances.

The Articles 7 and 8 of the TRIPS Agreement have been previously applied by the WTO panel.[1370] The WTO panel interprets the TRIPS Agreement, emphasising the role of Articles 7 and 8 within the TRIPS Agreement itself. However, it remains to be determined whether USMCA Articles 20.2 and 20.3 can or should function in a similar manner, as it was particularly interpreted as a tool to balance the rights and obligations under the TRIPS Agreement in *Australia- Tobacco Plain Packaging* case. The panel highlighted that:[1371]

[1365]Wallot, "The Proportionality Principle in the TRIPS Agreement", above n 627, at 222.
[1366]Ruse-Khan, "Proportionality and Balancing within the Objectives", above n 1363, at 181.
[1367]At 178.
[1368]USMCA, art 20.3.
[1369]USMCA, art 20.3.
[1370]*Australia-Tobacco Plain Packaging* at [7.2403]; at [2.2404]; *EC-Trademarks and Geographical Indications* at [7.245]; *Canada- Patent Protection of Pharmaceutical Products* at [7.26].
[1371]*Australia-Tobacco Plain Packaging*, at [7.2403]; at [2.2404].

> Article 7 reflects the intention of establishing and maintaining a balance between the societal objectives mentioned therein. Article 8.1, for its part, makes clear that the provisions of the TRIPS Agreement are not intended to prevent the adoption, by Members, of laws and regulations pursuing certain legitimate objectives, specifically, measures "necessary to protect public health and nutrition" and "promote the public interest in sectors of vital importance to their socio-economic and technological development", provided that such measures are consistent with the provisions of the Agreement…
>
> …Specifically, the principles reflected in Article 8.1 express the intention of drafters of the TRIPS Agreement to preserve the ability for WTO Members to pursue certain legitimate societal interests, at the same time as it confirms their recognition that certain measures adopted by WTO Members for such purposes may have an impact on IP rights, and requires that such measures be "consistent with the provisions of the [TRIPS] Agreement".

The panel highlighted the importance of TRIPS Articles 7 and 8, noting that the weight given to IP holders by the TRIPS Agreement can be adapted through these articles. A comparable analysis would be relevant in the context of USMCA. Similarly, IIAs give considerable weight to IP holders/investors, which, in certain situations, can be considered disproportionate, and the reflection of TRIPS Articles 7 and 8 in USMCA as Articles 20.2 and 20.3 can address this disproportion.

One notable revision was the changes in the text of patentability subject matter in Article 20.36, with the amendment dated 10 December 2019.[1372] Removing "new uses of a known product, new methods of using a known product, or new processes of using a known product" wording in the text, which was in the text of TPP, was crucial.[1373] Keeping the text as *new uses of a known product, new methods of using a known product, or new processes using a known product* would have encouraged evergreening[1374] and required an obligation on states to protect such practices. Article 20.11 clarifies that there has been no TRIPS-plus

[1372]Protocol of Amendment to the Agreement Between the United States of America, the Mexican States, and Canada (10 December 2019), art 3.
[1373]Australian Government Department of Foreign Affairs and Trade "CPTPP suspensions explained" <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-suspensions-explained>.
[1374]Pooja Tidke and others "Evergreening of Patents" (19 May 2023) Lexology <https://www.lexology.com/library/detail.aspx?g=aacfd802-52e1-4468-b71e-6a6a2d2c513b> Evergreening: "a minor modification is made to an existing product claimed as a new invention".

commitment in the context of exhaustion of IP[1375] and states are still free to determine its' conditions in their domestic law.[1376]

Notably, it is possible to find references to the TRIPS Agreement, the Doha Declaration and health related issues in various parts of this chapter, starting from Article 20.6, Article 20.40 and in Subsection C, where there is a special part for pharmaceutical patents.[1377] The agreement affirms states' right to protect public health and promote access to affordable medicines, as well as the right to determine "what constitutes a national emergency or other circumstances of extreme urgency", in line with TRIPS Article 31bis. The agreement further safeguards future amendments or waivers in the TRIPS Agreement concerning health issues.[1378] This can be interpreted as aiming to offer proportional protection to the patent holder without undermining the social function of IP. Yet, the complexities of using flexibilities, as identified in Chapter 3.1 in detail, would be applicable here.

It is also quite easy to identify TRIPS-plus commitment in the IP chapter. For instance, Article 20.44 requires a patent term adjustment for "unreasonable authority delays".[1379] Article 20.44.4 details the time frames that can be at least considered unreasonable: "five years from the date of filing of the application, or three years after a request for examination of the application has been made, whichever is later."[1380] In addition to that a specific provision is added for pharmaceutical products, which requires an adjustment of the patent term for the unreasonable or unnecessary delay in the marketing approval process through a "*sui generis* protection which confers the rights conferred by the patent".[1381] These provisions undermine access to affordable health protection by extending the protection of patented products. This compromises global distributive justice values through a regional agreement, as it hinders the entry of generics into the market, thereby limiting the availability of affordable products.

[1375]Exhaustion of IP rights can be defined as "Once the product is placed on the market, rights to control the marketing of the particular products entailing IP end." For details please see Thomas Cottier "Parallel Trade and Exhaustion of Intellectual Property in WTO Law Revisited" in Henning Grosse Ruse-Khan and Axel Metzger (ed) *Intellectual Property Ordering beyond Borders* (Cambridge University Press, Cambridge, 2022) 189 at 191.
[1376]USMCA, art 20.11.
[1377]USMCA, art 20.6; art 20.40; art 20.48.3.
[1378]USMCA, art 20.6; art 20.40.
[1379]USMCA, art 20.44.
[1380]USMCA, art 20.44.4.
[1381]USMCA, art 20.46, n 39; The purpose of patent term extensions is to compensate for the reduced effective patent duration for pharmaceuticals, which is often shortened due to delays in securing patent grants and/or marketing approval from authorities.

Further, the USMCA extends beyond TRIPS standards by safeguarding "undisclosed test or other data"[1382]. This requirement prevents generic companies from utilising patent holders' test data (regarding safety or efficiency or both) for a minimum of five years following the market approval of the new pharmaceutical products. This provision directly delays the entry of generic products into the market, hence delays in the accessibility of affordable pharmaceutical products. While Canada and the United States do not need to make any changes, Mexico needs to revise its domestic law.[1383] This change shall be done within five years from the date the agreement entered into force, and Mexico still has time for implementation.[1384] However, Mexico was still on the United States watch list in its 301 Special Report in 2023, which urges Mexico to implement USMCA fully, including protection of pharmaceutical- related IP.[1385] Trade practices, such as the 301 Special Report of the United States, contradict the objectives and principles of both TRIPS and the IP chapter of USMCA, undermining states' freedom to determine their own development objectives.

Article 20.50[1386] in USMCA also includes the "patent linkage" requirement as in other FTAs.[1387] It requires a link between the patent status and the marketing approval process for generics, potentially leading to delays in the entry of generics if a dispute arises as the market approval authority needs to notify the patent holder.[1388] A similar provision was not included in NAFTA. In addition to those provisions, Article 20.51 provides a distinction between market exclusivity and patent terms.[1389] It provides that the market exclusivity in Article 20.48 (or Article 20.45 related to agricultural chemical products) is to continue even after the patent expires.[1390] This provision implies that the patent holders can maintain their market exclusivity, monopoly, even after their patent expires, resulting in delays in generics entering the market, reduced competition, and consequently, delayed access to affordable products.

In the final provisions of this chapter, Article 20.89.3 outlines the transition period, commencing the date from the agreement's entry force, since the agreement requires

[1382]USMCA, art 20.48.
[1383]USMCA, art 20.89.3.
[1384]USMCA, art 20.89.3(d).
[1385]Office of the United States Trade Representative "2023 Special Report 301" (26 April 2023) at 79.
[1386]USMCA, art 20.50.
[1387]Free Trade Agreement between Australia and the United States of America (signed 18 May 2004, entered into force 1 January 2005), art 17.10.
[1388]APEC Intellectual Property Rights Experts Group "Patent Linkage System for Intellectual Property Rights and Public Health Harmonisation" (July 2023) <https://www.apec.org/docs/default-source/publications/2023/7/223_ipeg_patent-linkage-system-for-intellectual-property-rights-and-public-health-harmonisation.pdf?sfvrsn=bc4d2712_2> at 3.
[1389]USMCA, art 20.51.
[1390]USMCA, art 20.51.

modification in the national legislation. According to this, Mexico is mandated to implement Article 20.46 within 4.5 years and Article 20.48 within five years, while Canada should implement Article 20.44 in 4.5 years. There is no question that the United States does not have to make such modifications. The agreement refers to the TRIPS Agreement, implements TRIPS objectives and principles, yet introduces additional protections not required under the TRIPS, thereby undermining the balanced objectives and principles of the TRIPS among USMCA parties. Thus, the operation of midlevel proportionality in the investment protection of IPRs becomes even more substantial in the face of expansion of TRIPS standards. To safeguard access to affordable health resources, investment protection (investment chapter) should respect states' determination of their own domestic laws based on their own development agenda.

Intellectual property rights are covered as an investment in the Investment Chapter 14.[1391] Article 14.8 regulates expropriation and how compensation should be paid.[1392] It refers to Annex 14-B[1393] for the determination of what constitutes indirect expropriation. The annex provides guidelines to determine the existence of an indirect expropriation. The factors that should be considered are:[1394]

> ...adverse effect on the economic value (yet mere establishment of the economic impact not enough), the extent to which the government action interferes with distinct, reasonable investment-backed expectations, and the character of action, including its object, context, and intent.

In the annex, it is stipulated that non-discriminatory measures aimed at addressing public welfare, like health, will not be deemed as an indirect expropriation.[1395]

Article 14.8 further refers to the TRIPS Agreement and Chapter 20 of USMCA, specifying that it does not apply to the issuance of compulsory licences as long as they adhere to TRIPS requirements.[1396] Similarly, it extends this exclusion to revocation, limitation, or creation, provided that they are in line with Chapter 20 of the agreement and the TRIPS Agreement.[1397] The purpose of the paragraph is to safeguard the right to regulate the state parties as well as address public health issues. Thereby it aims to scale back from the disproportionate

[1391]USMCA, art 14.1.
[1392]USMCA, art 14.8.
[1393]USMCA, art 14.8.5.
[1394]USMCA, Annex- 14B.
[1395]USMCA, Annex- 14B 3(b).
[1396]USMCA, art 14.8.6.
[1397]USMCA, art 14.8.6.

investment protection of IP rights. However, the challenges of using the flexibilities of TRIPS as discussed in detail in Chapter 3.3.3., coupled with the existence of TRIPS-plus commitments, reduce the practical value. In practice, such clauses may not necessarily prevent bringing an ISDS claim, as experienced in *Eli Lilly v Canada*, where NAFTA included a similar clause.[1398]

Article 14.6 addresses the minimum standard of treatment, encompassing both FET and full protection of security, connecting them with customary international law.[1399] A further restriction is made in the article by specifying that a "breach of another provision of the agreement or of a separate international agreement" does not automatically imply a breach.[1400] Finally, in the last paragraph, the article affirms that mere inconsistency with the investors' expectations through the action or inaction of a state would not amount to a breach.[1401] The article does not specify the source of these legitimate expectations. However, based on NAFTA practice, it can be presumed that they arise from the conduct and representations of the host state, particularly relied on by the investor when making the investment.[1402] Nevertheless, even if this is the case, the mere inconsistency of these legitimate expectations would not be considered a breach of FET. With this formulation, particularly the last paragraph, achieving results similar to *Bilcon v Canada*[1403] may not be always viable, as now the threshold is higher for a breach. As can be seen, party states intended to limit the scope of the FET standard. In addition, the Chapter includes corporate social responsibility in Article 14.17.[1404] Although the provision does not impose an obligation on corporations, it serves as a tool to be used by the tribunals to interpret the treaty in ways that can limit the scope of protection the USMCA provides to investors under Chapter 14.

Certainly, Canada's most significant relief is its exemption from the ISDS. Consequently, any measures against a patent holder or failure to provide protection in line with Article 20

[1398]NAFTA, art 1110(7) stated that: "This Article does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property).".
[1399]USMCA, art 14.6.1.
[1400]USMCA, art 14.6.3.
[1401]USMCA, art 14.6.4.
[1402]*Mobil Invs. Canada Inc. v Canada (Decision on Liability and on Principles of Quantum)* ICSID ARB(AF)/07/4, 22 May 2012 at [152- 154]; *International Thunderbird Gaming Corp. v United Mexican States (Arbitral Award)* UNCITRAL, 26 January 2006 at [147]; Kendra Leite "The Fair and Equitable Treatment Standard: A Search for a Better Balance in International Investment Agreements" (2016) 32(1) AUILR 363 at 375.
[1403]*Bilcon of Delaware et al v. Government of Canada (Award on Jurisdiction and Liability)* UNCITRAL PCA 2009-04, 17 March 2015 at [455- 594].
[1404]USMCA, art 17.

(potentially), as detailed above, foreign investors/patent holders from Mexico and the United States can only initiate a case against Mexico and the United States. This can be interpreted as a response to *Eli Lilly v Canada* case and the fact that Canada has been facing investment claims from the United States' investors almost every year.[1405] In addition, the United States and Mexico imposed restrictions on the ISDS mechanism. According to 14.D.3, investors are no longer able to initiate indirect expropriation and FET claims against the host state. Restricting indirect expropriation and FET is particularly significant for an agreement with many TRIPS-plus provisions. Providing data exclusivity, safeguarding undisclosed tests or other data, could become a tool for investors/IP holders, especially in light of the decision *Einarsson v Canada*, considering what analysis will be made by the tribunal about when and to what data can be considered as an investment.

The investor dispute settlement mechanism is only available for national treatment and most-favoured-nation treatment and direct expropriation claims. Clearly departing from NAFTA, the USMCA has notably limited the scope of ISDS, especially in the controversial substantive standards, as discussed in Chapter 3.3.3. and Chapter 4.3., FET and indirect expropriation. This limitation, within the context of patent protection, can be viewed as an embodiment of midlevel proportionality. It addresses the disproportionate investment protection of patent law that undermines the social function of the IP law, leading to its restriction.

Another approach can be seen in the Indian Model BIT 2015, it is evident that India already aims to remove FET provisions from its IIAs; an approach followed in the Comprehensive Economic Cooperation Agreement between the Republic of India and the Republic of Singapore ("India-Singapore CECA").[1406] However, the model agreement only refers the treatment of investment, with very restricted components of FET. On the other hand, the Indian Model BIT includes protection against indirect expropriation, but it exempts compulsory licences issued in line with TRIPS obligations from the scope of the treaty.[1407] While this does not prevent an investor from bringing a case before an arbitral tribunal, the model requires the exhaustion of local remedies first. Another example is the Brazil Model BIT, titled Cooperation and Facilitation Investment Agreement ("CIFA"), which excludes the

[1405]UN Trade& Development, Investment Policy Hub, Investment Dispute Settlement Navigator "Cases as Respondent State: Canada" (1 December 2023) <https://investmentpolicy.unctad.org/investment-dispute-settlement/country/35/canada>.
[1406]Indian Model BIT 2015; Comprehensive Economic Cooperation Agreement between The Republic of India and the Republic of Singapore (signed 29 June 2005, entered into force 01 August 2005).
[1407]Indian Model BIT 2015, art 2.4 (iii)

ISDS mechanism and does not include FET.[1408] However, it is worth noting that Brazil has not ratified any IIAs that include the ISDS mechanism or adhere to ICSID.[1409] The purpose is not to extensively discuss either the Indian or Brazil Model BITs, but to demonstrate the different approaches taken by states recognising the negative impacts of the ISDS system. In the context of IP rights, particularly in cases like *Eli Lilly v Canada* and *Philip Morris v Uruguay*, attention has been given to safeguarding sovereignty over the designation of domestic IP law and the use of the TRIPS flexibilities, removing barriers to that. In this respect, the different approaches prove that while ensuring the protection of IP rights (higher than TRIPS) at least state-state dispute settlement level, states aim to limit the power that investors had previously.

From the preamble to its IP and investment chapters, the USMCA offers provisions to safeguard states regulatory frameworks, aiming to reduce the excessive leverage held by the patent holder/investors. The exceptions and limitations against bringing an ISDS claim are so much more detailed compared to NAFTA. Particularly significant is the inclusion of Articles 7 and 8 of the TRIPS Agreement within the USMCA in Articles 20.2 and 20.3, especially considering the higher level of patent protection compared to the TRIPS Agreement. The exceptions or flexibilities embodied in the USMCA represent proportionality as a midlevel principle in action within the design investment protection of IP rights.

The most significant aspect of the USMCA is the complete elimination of ISDS for Canada and removing indirect expropriation and FET from the scope of ISDS between Mexico and the United States. While this is a significant step for Canada and to some extent for Mexico, the difference between them in ISDS coverage underscores the power dynamics between Global North and Global South countries. The varying dynamics may further reflect differing levels of adherence to the rule of law by the respective judicial systems. However, it also indicates that Global North countries are shifting away from resolving indirect expropriation and FET claims under ISDS. For the context of this thesis, all parties to the USMCA have managed to prevent themselves from facing indirect expropriation and FET claims in a private arbitration system regarding IP rights, thus removing the excessive power previously held by the IP holders/investors with respect to investment protection. The approach taken by

[1408]Cooperation And Facilitation Investment Agreement Between the Federative Republic of Brazil (Brazil Model BIT 2015) <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/4786/download>.
[1409]Geraldo Vidigal and Beatriz Stevens "Brazil's New Model of Dispute Settlement for Investment: Return to the Past or Alternative for the Future?" (2018) Journal of World Investment & Trade 475 at 485.

the USMCA countries responds to the critiques made in this thesis regarding the risks associated with ISDS, particularly concerning indirect expropriation and FET. As mentioned earlier, their availability under ISDS prevents the implementation of necessary measures, which hinder access to affordable health resources and contradicts the global justice principles. By removing indirect expropriation and FET from the scope of ISDS between Mexico and the United States- Canada is already exempted from ISDS entirely- members took a step towards promoting the societal goals of IP, which refers the interest of community, without the risks of facing indirect expropriation and FET claims under ISDS.

Nevertheless, it should be acknowledged that the patent section of USMCA offers higher protection than the TRIPS Agreement and state-state dispute settlement[1410] will be available in case of non-compliance. Although investors would not be compensated, states can step- in to ensure compliance with the agreement. Yet, an adverse impact on one investor would not be enough for their home state to initiate inter-state proceedings. Considering the TRIP-plus provisions in the IP Chapter, even if it requires that pharmaceutical companies' home states initiate proceedings against host states, the state-state dispute settlement mechanism can still be seen as a powerful tool.

The following section delves into the agreement between the European Union and Canada, providing insights into the distinctions between Canada's partnership with the European Union and North America. The analysis then continues with CPTPP. The following explanations are more concise as they compare the provisions in these agreements with those of USMCA, focusing on the nuances between them.

6.3. Canada- European Union Comprehensive Economic and Trade Agreement (CETA)

CETA is an agreement between Canada and the European Union, signed on 30 October 2016 and provisionally entered into force on 21 September 2017.[1411] In the preamble, the agreement recognises states' right to regulate to achieve their policy objectives like public health or public morals, while also ensuring the protection of investments without compromising the public interest.[1412] It should be noted once more that the VCLT Article 31.2, preambles play role in the interpretation of a treaty. While CETA's preamble does not

[1410]USMCA, art 31.2(c).
[1411]Government of Canada "View the timeline" (26 October 2023) <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/view_timeline-consultez_chronologie.aspx?lang=eng>.
[1412]CETA, Preamble Paragraph 6; Paragraph 8.

elaborate as extensively as the USMCA on safeguarding states' regulatory power, it still advocates for a proportional protection of an investment when public welfare is in jeopardy. It highlights two different interests: on one hand, investment protection, and on the other hand, public welfare. Particularly, the preamble provides that:[1413]

> ...provisions of this Agreement protect investments and investors with respect to their investments, and are intended to stimulate mutually-beneficial business activity, without undermining the right of the Parties to regulate in the public interest within their territories.

As mentioned earlier regarding the USMCA, the preamble can play a role in interpreting the agreement in disputes involving the interests of investors versus public interests.

While not as extensive as the USMCA, the IP Chapter of CETA still comprises 50 sub-articles. Article 20.2 clarifies that the agreement complements the TRIPS Agreement and states have the freedom to decide how to implement the obligations under this agreement.[1414] Additionally, Article 20.3 makes reference to the Doha Declaration and its amendments to reaffirm the public health flexibilities of IP.[1415] Similar to the USMCA, CETA also explicitly states that the agreement would not impact the freedom of determining the exhaustion of IP.[1416] These provisions advocate for a proportional protection of patent as an investment, even if not explicitly articulated.

During the negotiations, the difference between Canadian and European Union patent laws emerged as one of the key issues, requiring Canada to align more closely with the EU regime.[1417] Probably one of the most controversial commitments is Article 20.27, which provides a *sui generis* protection for pharmaceutical products. This aspect of the agreement patent holders to obtain *sui generis* protection for a pharmaceutical product protected by a basic patent, if it meets the specified requirements:[1418]

> …a)an authorisation has been granted to place the product on the market of that Party as a pharmaceutical product (referred to as "marketing authorisation" in this Article); b) the product has not already been the subject of a period of sui generis protection; and c)the marketing

[1413]CETA Preamble.
[1414]CETA, art 20.2.
[1415]CETA, art 20.3.
[1416]CETA, art 20.4.
[1417]House of Commons Canada *Negotiations Toward a Comprehensive Economic and Trade Agreement (CETA) Between Canada and The European Union: Report of the Standing Committee on International Trade* (March 2012) at [20-21]
[1418]CETA, art 20.27.2.

> authorisation referred to in subparagraph (a) is the first authorisation to place the product on the market of that Party as a pharmaceutical product.

As outlined in Article 20.27.4, this *sui generis* protection becomes effective at the end of the basic patent, thereby extending the overall protection period.[1419] The duration of that *sui generis* protection will be the time between the filing date of a patent and the grant of market authorisation, reduced by a period of five years.[1420] The duration can be reduced between two to five years, if it is associated with a specific target population.[1421] This article creates additional protection for a patented product, essentially serving as a patent term extension, even in cases where the applicant is deemed responsible for any delay. The absence of action on the part of a patent applicant only results in reduction of the overall duration.[1422] Before CETA, Canada did not have this form of patent extension.

Similar to USMCA, CETA also contains linkage regulation in Article 20.28 and provides data protection for pharmaceutical products.[1423] However, Article 20.28 does not impose an implementation of a patent linkage, as stated:[1424]

> If a Party relies on "patent linkage" mechanisms whereby the granting of marketing authorisations (or notices of compliance or similar concepts) for generic pharmaceutical products is linked to the existence of patent protection, it shall ensure that all litigants are afforded equivalent and effective rights of appeal.

It is worth reminding that patent linkage is a system which connects the market approval of generic medicines to the protection of patents and prevents marketing approval until the expiration of the patent. An appeal mechanism means a longer litigation process, ultimately extending the market exclusivity.[1425] While Canada adjusted its domestic law due to its existing patent linkage legislation, the European Union did not need to do so as patent linkage is already prohibited under European Union law and Article 20.28 does not require an appeal mechanism if the state party has no patent linkage legislation already.[1426]

[1419]CETA, art 20.27.4.
[1420]CETA, art 20.27.5.
[1421]CETA, art 20.27.6.
[1422]CETA, art 20.27.7.
[1423]CETA, art 20.28; art 20.29. For the definition of pharmaceutical product, see in Article 20.6.
[1424]CETA, art 20.28.
[1425]Joel Lexchin and Marc-Andre Gagnon *CETA and Intellectual Property: The Debate over Pharmaceutical Patents CETA* (Policy Brief Series, October 2013) at 5.
[1426]K.D. Raju "Patent Linkages and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries" in Carlos M. Correa and Reto M. Hilty (ed) *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (eBook, Springer, 2022) 329 at 335-338; Simon Hitchens and David Turgeon "The Impact of

The wording of undisclosed data protection is very similar to the USMCA. It extends beyond the provisions of the TRIPS Agreement and even the UMSCA by providing six years of protection from the date of authorisation against reliance on such data and preventing the granting of authorisation to those relying on that data for eight years.[1427] This implies that someone other than the person who submitted the data can rely on that data after six years,[1428] but the person cannot be granted authorisation for another two years,[1429] resulting in an additional eight years of market exclusivity.

Once more, another TRIPS-plus and disproportional objective is the inclusion of IP as an investment in the investment chapter and the agreement defines IP rights by explicitly stating which rights are to be considered as IP. Yet, the section of investment protection starts with the reaffirmation of states' "right to regulate within their territories to achieve legitimate policy objectives, such as the protection of public health, safety, the environment or public morals, social or consumer protection…"[1430] as outlined in Article 8.9. While this thesis interprets the reaffirmation as encompassing access to health resources or the societal function of IP, adjudicators may not necessarily share the same interpretation. To clarify, this reaffirmation should cover similar claims to *Eli Lilly v Canada* or *Philip Morris v Uruguay*, although that might not be the case for any arbitral tribunal. Further clarification is provided under CETA in the same article, which states that:[1431]

> ...the mere fact that a Party regulates, including through a modification to its laws, in a manner which negatively affects an investment or interferes with an investor's expectations, including its expectations of profits, does not amount to a breach of an obligation...

This formulation limits the chances of success of claims.

Article 8.10 regulates FET together with full protection and security[1432], as opposed to the USMCA or any other traditional formation of FET; it does not refer to customary international law or international law. As Unuvar highlighted the arbitral experience has resulted in the development of a context specific framework rather than relying on a reference

---

CETA and Bill C-30 on Canada's IP Landscape: Important Changes to Canadian Patent and Trademark Laws" (5 December 2016) Fasken <https://www.fasken.com/en/knowledge/2016/12/intellectualpropertybulletin-20161205>.
[1427]CETA, art 20.29.
[1428]CETA, art 20.29.2 (a).
[1429]CETA, art 20.29.2 (b).
[1430]CETA, art 8.9.1.
[1431]CETA, art 8.9.2.
[1432]CETA, art 8.10.

to principles.[1433] In this respect, the second paragraph explicitly enumerates acts that constitute a breach with the possibility of reviewing the content of the FET obligation by the request of parties in the third paragraph of the same article.[1434] The following paragraph stipulates that the tribunal can consider the legitimate expectations of the investors if the host state has made a "specific representation".[1435] This list has faced criticism. For instance, Kriebaoum highlighted that stability, despite being recognised as a component by the tribunals under the FET standards, is not listed in CETA.[1436] However, the formulation of the FET in CETA is evidently a response to critiques of FET as well as states' own experiences. The vagueness and different interpretations of FETs, with investors utilising FET claims as a substitute for indirect expropriation, have prompted countries to adopt a more restrictive formulation of FET. As a result of this text, the disproportionate investment protection of IP, particularly patents, has been mitigated by the parties.

Expropriation is outlined in Article 8.12.[1437] Similar to most of the expropriation clauses, expropriation is not prohibited under CETA; rather, states only need to fulfil specific requirements for it to be considered lawful.[1438] The interpretation of expropriation in CETA refers to its' Annex 8-A.[1439] In the Annex, similar to USMCA, indirect expropriation (which is the key for expropriation of a patent) is explained as "a measure or series of measures of a Party has an effect equivalent to direct expropriation"[1440] and that should "substantially deprives the investor of the fundamental attributes of property in its investment".[1441] In the subsequent section of the Annex, it clarifies additional factors to be taken into consideration, starting with economic impact.[1442] Nevertheless, the provision explicitly clarifies that sole adverse economic impact would not suffice to establish an indirect expropriation.[1443] The provision almost eliminates the application of the sole effect doctrine[1444] and can also shift focus from economic impact when the tribunals apply judicial proportionality. With this text,

[1433]Güneş Ünüvar "The Vague Meaning of the Fair and Equitable Treatment Principle in Investment Arbitration and New Generation Clarifications" in Anne Lise Kjaer and Joanna Lam (ed) *Language and Legal Interpretation in International Law* (Oxford University Press, New York, 2002) 271 at 284.
[1434]CETA, art 8.10.2; art 8.10.3.
[1435]CETA, art 8.10.4.
[1436]Ursula Kriebaum "FET and Expropriation in the (Invisible) EU Model BIT" (2014) 15(3-4) 454 at 454-483.
[1437]CETA, art 8.12.
[1438]Christian Riffel "Indirect Expropriation and the Protection of Public Interests" (2022) 71(4) The International and Comparative Law Quarterly 945 at 946; Güneş Ünüvar "Is CETA the Promised Breakthrough? Interpretation and Evolution of Fair and Equitable Treatment and (Indirect) Expropriation" (iCourts, Working Paper Series No.97, 2017) at 22.
[1439]CETA, Annex 8-A
[1440]CETA, Annex 8-A.1(b).
[1441]CETA, Annex 8-A.1(b).
[1442]CETA, Annex 8-A 2.
[1443]CETA, Annex 8-A 2(a).
[1444]Riffel, above n 1438, at 947.

it appears that the disproportionate investment protection of patented health resources can be mitigated.

In the third and final part of the Annex, exceptions from indirect expropriations are outlined, if measures are non-discriminatory and serve legitimate public welfare[1445]. Though, further clarification with regards to IP rights is provided in Article 8.12, paragraphs 5 and 6.[1446] The article explicitly states that issuance of a compulsory licence in line with TRIPS would not be considered expropriation.[1447] Similar to the USMCA, CETA also stipulates that as long as measures are consistent with the TRIPS Agreement and IP chapter of the agreement, those measures would not constitute an indirect expropriation.[1448] Going beyond USMCA, it explicitly states that the "determination that these measures are inconsistent with the TRIPS Agreement or Chapter 20 does not establish an expropriation.".[1449] It appears that CETA aimed to limit the possibility of bringing claims against the state in regard to patents. This also signifies the goal of ensuring proportional investment protection of patents, considering its social function. Additionally, in an effort to provide further clarification, the parties to the agreement issued a joint declaration regarding Article 8.12.6 in Annex 8-D. According to that "domestic courts of each party are responsible for the determination of the existence and validity of intellectual property rights" and "that each party shall be free to determine the appropriate method of implementing the provisions of this agreement regarding intellectual property within their own legal system and practice.".[1450] Dreyfuss states that this provision can change the trajectory of disputes similar to *Eli Lilly v Canada*.[1451] In line with this, for this thesis, it certainly seeks to protect states' regulatory power to implement TRIPS or CETA in accordance with their domestic market and societal goals, and aims at almost closing doors to expropriation claims like *Eli Lilly v Canada*.

Furthermore, in response to critiques on costs and legitimacy of arbitration, CETA introduces an investment court system with an appellate mechanism instead of appointed arbitration tribunal by the parties.[1452] Nevertheless, the majority of the investment chapter,

[1445]CETA, Annex 8-A 3.
[1446]CETA, art 8.12.5; art 8.12.6.
[1447]CETA, art 8.12.5.
[1448]CETA, art 8.15.6.
[1449]CETA, art 8.15.6.
[1450] CETA, Annex 8-D
[1451]Rochella Dreyfuss "Hedging Bets with BITS: The impact of Investment Obligations on Intellectual Property Norms" in Jonathan Griffiths and Tuomas Mylly *Global Intellectual Property Protection and New Constitutionalism: Hedging Exclusive Rights* (Oxford University Press, Oxford, 2021) 157 at 170.
[1452]CETA, art 8.29; Issam Hallak "Multilateral Investment Court: Framework Options" European Parliament Briefing (June 2021); Shilpa Singh Jaswant "Analyzing Features of Investment Court System under CETA and EUIPA: Discussing

encompassing expropriation and investment dispute mechanism, is not in effect yet.[1453] Thus, it remains to be seen how responsive it will be once it is operational. Certainly, succeeding in a claim related to IP rights would be challenging due to the existence of proportional investment protection of patents.

While dispute settlement provisions of CETA do not restrict bringing investment claims against the state concerning indirect expropriation and FET, unlike USMCA, the formulation of these substantive protections, their limitations, and the specific and detailed reference to TRIPS in its indirect expropriation provision, when considered together with its preamble, all reflect the critiques presented in this thesis. The introduction of an investment court system can be seen as aiming for an institutional change in the ISDS mechanism. Considering everything, it can be argued that the agreement aims to safeguard the societal function of IP laws, which highlights the community interest. The formulations of FET and indirect expropriation highlight the importance of preserving states' regulatory power, the territoriality principle of IP rights and aims at upholding global justice principles in terms of availability of accessible health resources for everyone. Yet, it remains to be seen if this would be the case once the investment court becomes effective. Similar to USMCA concerns related to the inclusion of TRIPS-plus provisions remains in CETA as TRIPS-plus provisions would likely lead to higher price levels for a longer period of time due to the extended amortisation period.[1454]

6.4. The Comprehensive and Progressive Agreement for Trans- Pacific Partnership (CPTPP)

The CPTPP is a free trade agreement between Canada, Mexico, Australia, Brunei, Chile, Japan, Malaysia, New Zealand, Peru, Singapore, and Vietnam.[1455] It incorporates the provisions of TPP.[1456] Following the withdrawal of the United States from TPP, the remaining

---

Improvement in the System and Clarity to Clauses" (8 February 2019) Kluwer Arbitration Blog <https://arbitrationblog.kluwerarbitration.com/2019/02/08/analyzing-features-of-investment-court-system-under-ceta-and-euvipa-discussing-improvement-in-the-system-and-clarity-to-clauses/>.

[1453]Council Decision (EU) 2017/38 of 28 October 2016 on the provisional application of the Comprehensive Economic and Trade (CETA) between Canada, of the one part, and the European Union and its Member States, of the other part L 11/1080, 14 January 2017 (The Council of the European Union).

[1454]Joel Lexchin and Marc-Andre Gagnon "CETA and Pharmaceuticals: Impact of the Trade Agreement between Europe and Canada on the Costs of Prescription Drugs" (2014) 30 Globalisation and Health.

[1455]Government of Canada "CPTPP explained" (28 August 2023) <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/cptpp_explained-ptpgp_apercu.aspx?lang=eng>.

[1456]New Zealand Foreign Affairs & Trade "Comprehensive and Progressive Agreement for Trans-Pacific Partnership texts" <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text-and-resources/>.

countries negotiated the CPTPP and signed it in March 2018.[1457] In July 2023, the CPTPP parties signed an accession protocol with the United Kingdom, and expected to be ratified in October 2024.[1458] The preamble of the CPTPP recognises the right of states to regulate, using very similar language to the USMCA; therefore, the explanations provided there would be applicable here. It offers a proportional protection of foreign investors when public welfare is in jeopardy. The IP chapter of the agreement is notably concerning, especially provisions related to pharmaceuticals. The parties largely incorporated TPP provisions, yet some of them are suspended. The section begins with an analysis of the IP chapter and then continues with the investment chapter.

The IP chapter of the CPTPP is extensive and detailed, covering 75 pages, more than the USMCA.[1459] Starting from the general provisions of the agreement, similar to USMCA, CPTPP also incorporates TRIPS Articles 7 and 8 in Articles 18.2 and 18.3.[1460] Similar explanations are applicable here as their incorporation underscores midlevel proportionality between the social function of the patent and investment protection of the patent. These principles should be interpreted as emphasising global justice values, striking a balance between rights and obligations, emphasising the mutual advantage of both IP holders and users, and eliminating barriers for the Global South to enhance their development, where access to health resources is a key component of these developmental values. Article 18.6 specifically addresses measures related to protecting public health.[1461] The article explicitly mandates that the IP chapter should not impede any measures concerning public health and that the chapter should be interpreted and implemented in a manner that safeguards public health and promotes access to medicine.[1462] With reference to the TRIPS Agreement and the Doha Declaration, the agreement aims to preserve the flexibilities of TRIPS in relation to public health.[1463] Parties to CPTPP will consult to adjust the IP Chapter accordingly in the event of any waiver or amendment to the TRIPS Agreement if these waiver or amendments contradict the IP chapter of CPTPP.[1464]

[1457]New Zealand Foreign Affairs & Trade "Comprehensive and Progressive Agreement for Trans-Pacific Partnership" <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/cptpp-overview/>.
[1458]Government of Canada "About the Comprehensive and Progressive Agreement for Trans-Pacific Partnership" (23 January 2024) <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/backgrounder-document_information.aspx?lang=eng>.
[1459]CPTPP, Chapter 18.
[1460]CPTPP, art 18.2; art 18.3.
[1461]CPTPP, art 18.6.
[1462]CPTPP, art 18.6.1(a).
[1463]CPTPP, art 18.6.1(b).
[1464]CPTPP, art 18.6.1(c).

However, similar to other multilateral agreements it is not hard to find TRIPS-plus in the IP chapter. The wording of the patentability requirement is similar to the TRIPS Agreement, except the second paragraph where it requires member states to provide patent protection "at least one of the following: new uses of a known product, new methods of using a known product, or new process of using a known product".[1465] This requirement definitely is a way to allow secondary patents. Yet, the paragraph has been suspended until party states agreed otherwise the transition from TPP to CPTPP.[1466] Article 18.40[1467] of the chapter incorporates the TRIPS Article 30 and assessments concerning this can be found in Chapter 3.2.4 of this thesis. Article 18.41[1468] directly refers to TRIPS compulsory licence. Similar to other regional agreements, CPTPP also introduces a patent term adjustment provision to address unreasonable delays in the procedure; however, it is worth noting that this is one of the provisions that has been currently suspended.[1469]

Subsection C of the IP chapter is dedicated specifically to measures relating to pharmaceutical products. Within this subsection, a patent term adjustment is specifically outlined for pharmaceutical products. If there are any unreasonable and unnecessary delays in the market approval stage, the owner should be compensated through an adjustment of the unreasonable curtailment of the patent term.[1470] This subsection also incorporates provisions for undisclosed data protection, specifically for pharmaceutical products and biologics.[1471] However, all the mentioned provisions in this paragraph are suspended in the transition from TPP to CPTPP[1472], which alleviates the concerns associated with such provisions for now. Under the title of "Measures relating to the Marketing of Certain Pharmaceutical Products", the CPTPP also introduces a patent linkage mechanism which requires creating a system to notify the patent holder if a third person relies on information provided by the patent holder

[1465]CPTPP, art 18.37.2.
[1466]CPTPP, art 18.37.2; Australian Government "CPTPP Suspension Explained" <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-suspensions-explained#:~:text=What%20are%20the%20suspended%20provisions%3F&text=Each%20CPTPP%20Party%20has%20agreed,at%20%241%2C000%20under%20Australian%20law.>.
[1467]CPTPP, art 18.40.
[1468]CPTPP, art 18.41.
[1469]CPTPP, art 18.46; CPTPP Annex II- List of Suspended Provisions.
[1470]CPTPP, art 18.48.
[1471]CPTPP, art 18.50; art 18.51.
[1472]Australian Government Department of Foreign Affairs and Trade "CPTPP Suspension Explained" (January 2019) <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-suspensions explained#:~:text=What%20are%20the%20suspended%20provisions%3F&text=Each%20CPTPP%20Party%20has%20agreed,at%20%241%2C000%20under%20Australian%20law.>.

or alternatively to preclude reliance on patent-related information for market approval by a third party unless patent holder provides consent or acquiescence.[1473]

The current position of the CPTPP mitigates the negative impacts on access to health products, more specifically medicines or vaccines, since the most controversial provisions are currently suspended, such as lowering patentability standards or protection of undisclosed data. While the mere suspension may not be indefinite, and as emphasised earlier, their operation requires all 12 members, now with the United Kingdom, to agree on that. Yet, the patent linkage is not one of the suspended provisions and potentially it can delay generics into the market.

It is unsurprising that intellectual property rights are included in the definition of investment.[1474] Although the investment chapter is shorter in comparison to its IP chapter, it covers the ISDS mechanism for private parties. While there are substantial restrictions on ISDS in USMCA or CETA, this is not the case for CPTPP. The disproportionate power of IP holders arising from IIAs remains there. However, it should be noted that some states have excluded ISDS through reciprocal side letters. These side letters can be categorised as a modification of the agreement between some countries under Article 31(2)(b) of the VCLT.[1475] New Zealand is one of them. Through the side letters, they excluded the ISDS mechanism from 80% of their overseas investment from CPTPP countries.[1476] Australia and the United Kingdom also concluded side letters to exclude the ISDS system from each other.[1477] These instances serve as clear indications that even Western countries, Global North, are moving away from the ISDS mechanism. On the other hand, the situation was different for Chile. While Chile attempted to sign side letters to exclude ISDS, as far as publicly available information shows, it has only succeeded in doing so with New Zealand.[1478] Chile ranks 29th in the Corruption Perception Index with a score of 66, not far away from another party, Australia, which ranks 16th with a score of 73, or the United

[1473]CPTPP, art 18.53.
[1474]CPTPP, art 9.1.
[1475]VCLT, art 31(2)(b).
[1476]New Zealand Foreign Affairs& Trade "Investment and ISDS" <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/understanding-cptpp/investment-and-isds/>.
[1477]Australian Government Department of Foreign Affairs and Trade "CPTPP Text and Associated Documents" <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/official-documents>.
[1478]Tony Dymond, Cameron Sim and Tiffany Chan "Dispute settlement mechanisms under the CPTPP and the RCEP" (27 May 2022) Global Arbitration Review <https://globalarbitrationreview.com/review/the-asia-pacific-arbitration-review/2023/article/dispute-settlement-mechanisms-under-the-cptpp-and-the-rcep>; Letter from Michael O'Shaughnessy to Jose Miguel Ahumana Franvco (17 February 2023) <https://www.subrei.gob.cl/docs/default-source/tratado-tpp11/nz-cl-(isds).pdf?sfvrsn=ce9347e_2>.

Kingdom, which ranks 20th with a score of 71 in 2023.[1479] In fact, from 2012 to 2023, Chile's score has been between 72 to 66, better than some European countries or Israel.[1480] The quality and effectiveness of legal systems are closely related to the level of corruption. In this sense, Chile is performing strongly compared to other Global South countries, very close to Western nations. Yet, Chile was not able to fully close the door on ISDS with other Global North countries, which underscores the different political power between the Global South and North.

FET is provided under Article 9.6.[1481] The wording of the article is very similar to USMCA. The article addresses FET with full protection and security, linking it to customary international law.[1482] Similar to the USMCA, it restricts FET by stating that a breach of another provision of this agreement or a separate agreement, merely taking a measure, or failing to take a measure that is not in line with a legitimate expectation would not establish a breach.[1483] In addition to what is provided in USMCA, CPTPP also introduces limitations to FET by stating that "the mere fact that a subsidy or grant has not been issued, renewed, or maintained, or has been modified or reduced" would not constitute a breach.[1484] The FET provision, especially; with respect to patents should be interpreted with reference to Article 18.6, where the IP chapter refers to the public health measures concerning TRIPS. In relation to patent protection and the FET limitations, it could be said that actions such as patent revocation or the issuance of a compulsory licence could easily be discussed within the sphere of legitimate expectation, as claimed by the patent holder in *Eli Lilly v Canada*, or in decisions related to maintaining, modifying or reducing a grant. However, the above-mentioned limitations under CPTPP aim to prevent such claims and scale back from the disproportionate leverage of IP holders.

Article 9.8 protects investors against expropriation.[1485] The fifth paragraph of the expropriation provision refers to intellectual property, the TRIPS Agreement, and, specifically, compulsory licences.[1486] It explicitly states that the issuance of compulsory licence in line with the TRIPS Agreement or the revocation, limitation, or creation of IP

[1479]Transparency International "Corruption Perception Index" < https://www.transparency.org/en/cpi/2023>.
[1480]Transparency International "Corruption Perception Index: Chile" <https://www.transparency.org/en/cpi/2023/index/chl>.
[1481]CPTPP, art 9.6
[1482]CPTPP, art 9.6.1.
[1483]CPTPP, art 9.6.3.
[1484]CPTPP, art 9.6.5.
[1485]CPTPP, art 9.8.
[1486]CPTPP, art 9.8.5.

rights will be exempted from the provision as long as it is consistent with the TRIPS Agreement and IP chapter of the agreement.[1487] Annex 9-B of the agreement provides details about indirect expropriation, very similar wordings to USMCA and CETA.[1488] However, bringing indirect expropriation is closed under USMCA and for now under CETA. Therefore, Article 9.8.5 aimed at preventing excessive leverage holds greater importance in CPTPP.

It is important to highlight that CPTPP excludes "an order or judgement entered in a judicial or administrative action"[1489] from the definition of investment. In this respect, technically, any decision made by patent offices or judicial decisions against patents, similar to *Eli Lilly v Canada*, should not be regarded as investment by the arbitral tribunal. Even if it is regarded as an investment, it should not constitute expropriation since Article 9.8.6 excludes the 'decision not to issue, renew or maintain a subsidy or grant, or decision to modify or reduce a subsidy or grant' (revocation of patent) from expropriation.[1490] Bringing claims similar to *Eli Lilly v Canada* under CPTPP appears to be almost closed, giving the chance of winning the case is highly unlikely.

All the restrictions and limitations theoretically safeguard states' regulatory measures ensuring affordable access to health resources. They offer greater playing grounds for states to implement their own patent law or use TRIPS flexibilities. While the challenge of winning a case discourages patent holders from initiating a claim, this is not an absolute comfort. The *chilling effect* of patent protection as an investment still remains in CPTPP.

6.5. Conclusion

The protection of foreign investments is significant for the home states of investors, investors themselves and host states, as it can attract foreign investors and ultimately contribute to the domestic economy and development. However, this protection should be limited to ensure that it does not undermine public welfare and deter states from safeguarding public health. This chapter specifically delved into the investment protection of patents in recently concluded mega-regional trade agreements to examine how the protection of foreign investment is weighed against public welfare, such as health and access to health resources. It is aimed to determine whether USMCA, CETA and CPTPP can mitigate disproportional

[1487]CPTPP, art 9.8.5.
[1488]CPTPP, Annex 9-B
[1489]CPTPP, art 9.1. Similar limitation is available USMCA under Article 14.1; however, since FET and indirect expropriation is not available under ISDS, it is not explicitly mentioned in Chapter 6.2.
[1490]CPTPP, art 9.8.6.

investment protection patented health resources. In this respect, this chapter delved into IP and investment chapters of these three trade agreements.

It might be argued that ensuring access to health resources is the responsibility of home states through their national health policies, but international policies play a crucial role to not to hinder such efforts. In the context of IP, particularly patent, which Upreti puts well, the TRIPS Agreement provides a "minimum ceiling for exceptions and limitations" and states can offer beyond them.[1491] Consequently, international investment treaties should not become a tool to impede the implementation of these exceptions or limitations. Investment protection undermines the social function of IP rights as it confines IP only to its economic value, monetary profit that an IP right can generate.[1492] However, IP has significant political and bargaining value in the trade agreements, making it challenging to reverse. The inclusion of IP as an investment gives leverage to IP holders, potentially leading to a regulatory chill on states and creating a disproportionate power dynamic. Reversing from that power is required not only in the Global South, but also in the Global North. Countries should also be mindful and negotiate with the aim of addressing the limitations, particularly regarding indirect expropriation and FET claims for patent protection in their IIAs.

USMCA illustrates this point very well. Canada closed the ISDS door with the United States. While Canada had significant negotiating power with the United States in the trade deals, it is essential to acknowledge that not every country has that influential participation in the international regime, making it challenging to achieve similar results as Canada could. Yet, Mexico successfully excluded FET and indirect expropriation from ISDS with the United States, even if not able to exclude itself from ISDS entirely. In CETA, another trade deal involving Canada and the European Union, the impact of *Eli Lilly v Canada*, and others, are reflected in substantial limitations of FET and indirect expropriation in the treaty. In addition, CETA, the quasi-judicial inspired system of investor-dispute settlement represent significant a step for reforming ISDS system. Even CPTPP has a more traditional approach compared to USMCA or CETA; limitations on FET and clarifications of expropriation claims are in place and most of the TRIPS-plus protections are suspended.

These trade deals reflect a proportional protection of patents towards promoting the global justice principles in the availability of affordable health resources, considering the restriction

[1491]Upreti, above n 708, at 159.
[1492]At 116-121.

of the additional layer provided by the ISDS system. The limitations and exclusions address the concerns this thesis highlighted. These three mega-regional trade deals offer a more nuanced approach to the protection of patents as an investment and the availability of ISDS for patent holders/foreign investors. These three trade deals, related to the investment protection of patented health resources, have mostly addressed the concerns identified in this thesis regarding the human right to health. They have either removed or mitigated the legal layer of ISDS, aligning with promoting access to health resources as an essential enjoyment component of having a healthy life and a life with dignity in line with UDHR Article 3, UDHR Article 25; ICESCR Article 12; ICCPR Article 6.[1493] However, it is noteworthy that concerns about regulatory chill remain in CPTPP. The power differences between the Global South and North are also visible, notably in USMCA and CPTPP. While Mexico has not entirely eliminated the ISDS mechanism, Canada was successful in doing so. In CPTPP, as a Global South country, Chile, despite being comparable to Global North countries in terms of the quality and effectiveness of its legal system, only managed to exclude ISDS in mutual agreement with New Zealand.

It is further crucial to mention one more time that the IP chapters in these trade deals have a negative effect on accessing health resources. This thesis acknowledges that IP chapters would potentially lead to increased prices and delayed market entry for generic products. Non-compliance to the IP chapters would be resolved through state-state dispute mechanisms, which is beyond the purpose of this thesis.

[1493]UDHR, art 3; UDHR, art 25; ICESCR, art 12; ICCPR, art 6.

CHAPTER 7- CONCLUSION AND RECOMMENDATIONS

7.1. General Conclusion and Suggestions

The purpose of this thesis was to emphasise the disproportionate nature of investment protection for patented health resources. In this respect, this thesis argued that investment protection for patent rights extends beyond the original intent of intellectual property rights. This research is significant because, as long as patented health resources receive investment protection under the IIAs and investors are able to bring investment claims against states, the issues addressed in this thesis remain highly relevant for preserving states' efforts in promoting access to health resources. In this respect, this thesis aims to contribute to and deepen the ongoing debates on the interaction between IP and investment law, particularly regarding their impact on access to affordable health resources.

As highlighted in the introduction, while there is existing literature on the intersection between intellectual property and investment law, few studies focus on the concept of proportionality. To date, none of them has provided a comprehensive study of proportionality, particularly considering the midlevel facet of the proportionality principle. Midlevel principles in the context of intellectual property are also underdeveloped. However, the midlevel facet of proportionality can advance the social function and territoriality principle within IP and investment contexts and support global justice principles aiming at ensuring access to affordable health resources. Midlevel proportionality can help identify and remove the additional layers imposed by the ISDS system in patent law, thereby preserving states' rights to create their own laws based on their needs. This thesis benefitted from theories of global justice as the underlying theory for promoting access to health resources.

Moreover, although some studies have used TWAIL to explore IP and international investment law, not many studies have analysed their intersection from the TWAIL perspective. Additionally, as noted in the introduction, the proportionality principle has not been explicitly criticised through the lens of TWAIL. The absence of this analysis may be a result of the extensive reach of the proportionality principle worldwide, despite variations in its interpretation. Yet, applying proportionality in the global sphere requires a cautious approach and the TWAIL perspective highlights the foundational roots of the principle.

This thesis argues that the current structure of IIAs can undermine the equitable distribution of health resources. As detailed in Chapter 2, this thesis engages with global justice theories

and benefits from each theory of cosmopolitanism. This chapter argued that pursuing global distributive justice and cooperative theories provide significant perspectives to consider when adapting new policies in relation to investment protection of patented health resources. Drawing from Beitz and Pogge's arguments, this thesis emphasises the necessity of improving economic, political, and legal institutions to achieve global justice, particularly in the context of IP protection under investment agreements. Designing international agreements is heavily influenced by politics and international relations. Consequently, these legal norms need to be adjusted to address today's distribution problems of affordable health resources. Supporters of a duty-based approach would advocate for an enforceable human rights mechanism within the international IP rights system. What is crucial for this thesis is that the human right to health, to life and to enjoy a life with dignity, achieved through access to health resources, should be preserved, particularly in the formulation of IIAs. This can be achieved by either making specific references to IP flexibilities concerning access to health resources, thereby excluding them from the context of ISDS, or by completely removing IP rights from the scope of ISDS, particularly with regard to indirect expropriation and FET.

The capability approach highlights the requisite to re-evaluate and adjust the international patent system concerning health resources, as health is one of the fundamental dimensions that enables individuals to flourish and achieve a life they value. This approach acknowledges and emphasises the broader social and cultural impacts of IP rights as opposed to the economic perspective on IP, which often overlooks these aspects. Luck egalitarians' goal is to reduce inequalities resulting from people's luck, such as their place of birth, which is often factor in the difficulty of accessing vaccines or medicines in Global South countries. This argument can also be applied to the IP-investment debate. Yet, it should be noted that this thesis solely relies on this theory to reduce or eliminate luck as a factor in accessing health resources. Finally, Singer, as a utilitarian, seeks to maximise marginal utility. With regards to IP rights, he argues that they "must be assessed by reference to the common good of humankind"[1494], which directly aligns with the objective of this thesis.

Global justice theories advocate and aim to achieve the equitable distribution of patented health resources. However, investment protection of patents can pose significant barrier to this goal. The ISDS system provides an additional legal layer which can lead to disputes even when countries intend to act in the interest of the public. The existing international patent law

[1494]Schroeder and Singer, above n 200, at 6.

system already creates a global justice problem, and ISDS exacerbates it even more. Patent protection enables patent holders to set prices and monopolise the market, affecting access to affordable patented health resources, especially for those financially disadvantaged. Investment protection worsens this problem even more by undermining the TRIPS flexibilities that could otherwise foster affordability. ISDS can undermine the TRIPS flexibility as the system enables IP patent holders/investors to initiate an investment claim through a private arbitration system. Investment protection allows patent holders/investors to challenge state measures related to patent rights or laws shaped based on states' evolving needs. The availability of challenging state measures undermines the TRIPS flexibilities intended to promote the social function of IP rights and requires rebalancing interests between patent holders and the public.

To address this, this thesis delved into the proportionality principle, aiming to rebalance the interests between patent holders and the public. To highlight this imbalance, this thesis argued that investment protection of patented health resources is considered disproportionate as suggested by *midlevel proportionality*. This thesis further suggested that if investors have access to bring claims for patents in relation to health resources, the arbitrators should provide maximum level of deference to states. To this end, this thesis examined case law in investment arbitration where *judicial proportionality* is applied to determine whether *judicial proportionality* can mitigate with this imbalance. To achieve this rebalancing effectively, this thesis drew on TWAIL critiques since, historically, both IP and investment law have reflected the interests of Global North and proportionality has its roots in Western traditions.

As identified in Chapter 2, TWAIL engages with three themes: a critical analysis of international legal frameworks that prioritise the interests of capital over the fundamental needs of the Global South, a commitment to historical analysis to reveal the realities and social functions embedded within the international legal system and a call to reform and reconceptualise international law to challenge the deeply rooted traditions of colonialism.[1495] The critiques of TWAIL shed light on the historical engagement of IP and investment law, as well as the concept of proportionality. They assist in understanding why investment protection of patents is disproportionate and raises concerns about global justice. In this respect, this thesis examined the intersection of IP and investment law, focusing on the role of

[1495]Gathii, "The Agenda of Third World Approaches to International Law (TWAIL)", above n 223, at 158-161.

proportionality by taking into account TWAIL critiques and aiming for global justice to ensure affordable access to health resources worldwide.

Considering the above explanations, this thesis addressed three main questions, with the goal of achieving global justice in accessing health resources, drawing on critiques from TWAIL.

1- Why and how has the investment protection of patented health resources become disproportionate through midlevel principles from the perspective of global distributive justice (cosmopolitanism)?
2- Can the application of judicial proportionality by arbitral tribunals assist in scaling back from this disproportionate protection in ISDS cases involving patented health resources to preserve global justice?
3- How do some newly concluded regional agreements mitigate the disproportionate investment protection of patented health resources?

The first question originated from the analysis in Chapter 2 and Chapter 3. The analysis started with the development of an international legal framework of IP law, followed by an exploration of investment law. This chapter highlighted the influence of industrial lobbyists in the creation and formulation of these areas. Given the extensive nature of IP law, the IP analysis solely focused on patent law, its flexibilities and its implications on accessing affordable health resources. This chapter further explored the midlevel proportionality. The principle served as the basis for understanding the disproportionate nature of investment protection for patent rights. According to Merges, the midlevel facet of proportionality aims to remove disproportional rewards resulting from a power beyond what is rightfully deserved.[1496] As explained in detail in Chapter 3, this thesis differed from Merges's understanding of the core of the principle. For Merges, disproportion arises from a power that exceeds what is rightfully deserved. However, this thesis argued that disproportionate leverage stems not only from what is deserved but also from the extent of the impact on the social function of IP rights. For this thesis, it is not only the technological advancement (contribution) that matters, but also the source of financing for the invention, the labour invested, the beneficiaries of such protection and primarily whether patent protection harms global society. Thus, the valuation of proportionality considers whether the level of patent protection negatively impacts the social function of intellectual property rights. Consequently,

[1496]Merges, above n 22, at 150-151.

this thesis argued that investment protection of patents is disproportionate as was explored in detail in Chapter 4.

Further, in Chapter 3, a case study concerning Covid-19 was employed to demonstrate the challenges of accessing health resources due to their patentability. The availability of investment protection for patents adds another challenging layer. Chapter 3 further explored the substantive protection provided by the IIAs to illustrate the reasons for these challenges concerning patents in Chapter 4. In this respect, this thesis limited itself to examining indirect expropriation and FET claims as they are absolute and independent investment standards. This analysis particularly highlights the challenges posed by stability and legitimate expectations to the regulatory power of states, even if they address public interest. Given the ambiguity surrounding the application of expropriation (sole effect doctrine, police powers, or proportionality), particularly indirect expropriation, states are more cautious before implementing any measures. The availability of both standards is further complicated by ISDS threats from large corporations. Consequently, states might avoid implementing it entirely due to the risk of facing claims even if a measure is necessary or intended to serve the public interest, such as environment, cultural heritage, or public health.

Considering the development of IP rights and investment law at the global level, Chapter 4 explored their intersection. The analysis consisted of the scope of IP protection as an investment and why states' measures regarding patent flexibilities, such as compulsory licencing, may violate treaty standards. In this respect, this chapter answered the first thesis question by demonstrating the disproportionate power held by IP owners, facilitated by the availability of ISDS. This power ultimately impacts the accessibility of affordable health resources. It determined that the availability of ISDS for patents restricts states from implementing regulatory measures related to public health and empowers investors/IP holders to bring claims, even if those measures fall within the scope of states' sovereignty. In this regard, ISDS adds a legal layer that deters implementing/taking necessary measures, which has been considered disproportionate as it goes beyond the design intent of patent rights. This chapter analysed the *Eli Lilly v Canada* and *Philip Morris v Uruguay* cases, which strengthened the argument concerning the disproportionate power of investors since these cases addressed issues of state sovereignty and public health, respectively. Finally, this chapter provided examples to illustrate the regulatory chill created by ISDS in the context of IP law, further highlighting the disproportionate impact on the public.

This thesis explored proportionately in two different contexts to address this disproportionate/excessive power: within the arbitral tribunal in its analysis of the indirect expropriation and FET, and within the formulation of IIAs. These are examined in Chapter 5 and Chapter 6, which answered the last two questions of this thesis, respectively. The second question aimed to explore the application of *judicial proportionality* within investment arbitration to assess whether it can help to reduce the disproportionate protection of patents. In this respect, Chapter 5 delved into the role judicial proportionality in investment disputes and sought to determine whether its application should be maintained, considering global justice perspectives on access to health resources. This investigation involved analysing ISDS case law where judicial proportionality (derived from the ECtHR jurisprudence) was applied in expropriation and FET claims. This was necessary to understand the practice of arbitral tribunals. It is determined that judicial proportionality test within the investment arbitration might risk not giving adequate deference to states that possess a deeper understanding of the public's needs. Additionally, it adds extra layers for states to demonstrate as required by the test. Therefore, this chapter argued that arbitral tribunals should apply the police powers doctrine in cases where investors bring expropriation and FET claims related to patented health resources.

Furthermore, Chapter 5 explored the relevance of the ECtHR jurisprudence, especially the MoA doctrine, which has become highly debated, particularly in the context of IP. This chapter highlighted the different purposes of the ECtHR and ISDS. Therefore, applying judicial proportionality and MoA cannot have the same impact in both contexts. It is highlighted that investment tribunals are designed to determine whether governmental interference with foreign investments constitutes a breach of investment protection. On the other hand, human rights courts are specifically designed to adjudicate human rights violations. When a state takes measures related to human rights considerations of the public, human rights only become a defence in an investment case as it serves as an underlying purpose behind the measure rather than being content of the dispute. This chapter suggested that judicial proportionality should not be preserved as it may adequately address the disproportionate investment protection of patents. Similarly, this chapter suggested that arbitral tribunals need not adopt the MoA doctrine, given the critiques of its application in ISDS and its specific purpose in the ECtHR. The police powers doctrine is well established in investment arbitration and can effectively safeguard states' regulatory powers for measures

that serve the public interest. While the police powers doctrine is well established in cases of indirect expropriation, this chapter highlighted that there are no limitations on its applicability in assessing FET claims. This would ensure that an appropriate level of deference is given to states in patent-related disputes.

The most effective approach to address this disproportionate investment protection of patent rights is through the formulation of IIAs. This aspect answers the final question of this thesis: How do some newly concluded regional agreements mitigate the disproportionate investment protection of patented health resources? Chapter 6 explored emerging trends in IIAs, particularly the mega-regional IIAs, which suggest a more nuanced approach to ISDS mechanism for IP chapters. This chapter analysed USMCA, CETA and CPTPP to assess how effectively they incorporate the social aspects of patent rights within investment protection. It primarily focused on patent provisions in IP chapters, as well as expropriation and FET rules in the investment chapters. At times, comparisons with model BITs from Global South countries were provided to highlight the main concerns about ISDS. This chapter examined proportionality as its midlevel facet, analysing the conflict between accessing the societal function of IP, community interest and investment protection of patents.

The analysis in Chapter 6 determined that the removal of indirect expropriation and FET from ISDS in USMCA, the substantial limitations of FET and indirect expropriation in CETA, along with the quasi-judicial system of investor-dispute settlement, reflect a proportional investment protection of patents towards promoting the global justice principles in availability of affordable health resources. In addition, although CPTPP takes a more traditional approach than USMCA or CETA, it includes significant limitations on FET and clarifies expropriation claims. Furthermore, most of the TRIPS-plus protections are suspended. All these factors serve as significant deterrents against investors bringing a claim. These trade deals restrict the additional layer provided by the ISDS system substantially. Countries should carefully negotiate their future IIAs to incorporate these limitations, particularly regarding indirect expropriation and FET claims for patent protection in their IIAs. This thesis finally urges states to renegotiate their current IIAs in a way that more effectively addresses the social function of patents.

7.2. Suggestions for Future Research

Chapter 6 examined the role of proportionality in the formulation of IIAs, in particular, USMCA, CETA, and CPTPP. This chapter acknowledged that IP chapters of these trade deals, which include TRIPS-plus provisions, have negative impacts on accessing health resources, leading to higher prices and delayed market entry for generics. These agreements include the protection of trade secrets and monopolies on clinical trial data. Similar research can be conducted aimed at determining the disproportionateness of these protections. This thesis provides a step toward such analysis, engaging with midlevel principles concerning intellectual property rights and promoting its social function.

BIBLIOGRAPHY

Laws

-Civil Code of the Russian Federation Part 4 2006 (Russia)
-Federal Constitutional Law of 6 November 2020 (Russia)
-Republic of South Africa Government Gazette Medicines and Related Substance Act 1997 (South Africa)
-Russian Constitution
-United States Constitution

International Treaties/Declarations/Model Bits/Rules

-2012 Model Text for the United States Bilateral Investment Agreement <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/2870/download>

-2015 Model Text for the Indian Bilateral Investment Agreement (hereinafter "Indian Model BIT 2015") <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/3560/download>

-Agreement between Australia and the Islamic Republic of Pakistan on the Promotion and Protection of Investments (signed 7 February 1998, entered into force 14 October 1998)

-Agreement between Australia and the Oriental Republic of Uruguay on the Promotion and Protection of Investments (signed 5 April 2019, entered into force 27 January 2022)

-Agreement between Japan and the Arab Republic of Egypt Concerning the Encouragement and Reciprocal Protection of Investment (signed 28 January 1977, entered into force 14 January 1978)

-Agreement Between the Government of Canada and the Government of the Hong Kong Special Administrative Region of the People's Republic of China for the Promotion and Protection of Investments at (signed 10 February 2016, entered into force 06 September 2016)

-Agreement between the Government of the Kingdom of Cambodia and the Government of the Republic of Cuba Concerning the Promotion and Protection of Investments (signed 26 September 2001)

-Agreement between The Government of the Republic of Colombia and The Government of the Republic of Turkey concerning The Reciprocal Promotion and Protection of Investments (signed 28 July 2014)

-Agreement between the Republic of Lebanon and the Republic of Hungary for the Promotion and Reciprocal Protection of Investments (signed 22 June 2001, entered into force 23 July 2002)

-Agreement between the Swiss Confederation and Oriental Republic of Uruguay on the Reciprocal Promotion and Protection of Investments, Switzerland- Uruguay (signed 07 October 1988, entered into force 22 April 1991)

-Agreement on Reciprocal Encouragement and Protection of Investments Between the People's Republic of China and the Kingdom of the Netherlands (signed 26 November 2001, entered into force 01 September 2004)

-Arbitration Rules of the Arbitration Institute of the Stockholm Chamber of Commerce (entered into force 1 January 2023)

-*Arbitration Rules on United Nations Commission on International Trade Law*, UN Doc A/31/98 (15 December 1976)

-ASEAN-Australia-New Zealand Free Trade Agreement (signed 27 February 2009)

-Australia-Thailand Free Trade Agreement (signed 5 July 2004, entered into force 1 January 2005)

-Berne Convention for the Protection of Literary and Artistic Works 828 UNTS 211 (opened for signature 9 September 1886, entered into force 4 December 1887)

-Bilateral Agreement for the Promotion and Protection of Investments Between the Government of the Republic of Colombia and the Government of the People's Republic of China (hereinafter "China- Colombia BIT") (signed 22 November 2008, entered into force 02 July 2013)

-Comprehensive and Progressive Agreement for Trans-Pacific Partnership (signed 8 March 2018, entered into force 30 December 2018)

-Comprehensive Economic Cooperation Agreement between The Republic of India and the Republic of Singapore, India-Singapore (signed 29 June 2005, entered into force 01 August 2005)

-Convention for the Protection of Human Rights and Fundamental Freedoms 213 UNTS 222 (opened for signature 4 November 1950, entered into force 4 November 1953)

-Convention on the Rights of the Child 1577 UNTS 3 (opened for signature 20 November 1989, entered into force 2 September 1990)

-Convention on the Settlement of Investment Disputes between States and Nationals of other States 575 UNTS 159 (opened for signature 18 March 1965, entered into force 14 October 1966)

-Cooperation And Facilitation Investment Agreement Between the Federative Republic of Brazil (Brazil Model BIT 2015) <https://investmentpolicy.unctad.org/international-investment-agreements/treaty-files/4786/download>.

-European Union-Canada Comprehensive Economic and Trade Agreement (signed 30 October 2016, provisionally applied since 21 September 2017)

-Free Trade Agreement between Australia and the United States of America (signed 18 May 2004, entered into force 1 January 2005)

-Free Trade Agreement between the United States of America and the Republic of Korea (signed 30 June 2007, entered into force 15 March 2012)

-International Centre for Settlement of Investment Disputes Additional Facility Arbitration Rules ICSID/11/Rev.3 (amended 1 July 2022)

-International Convention on the Elimination of all Forms of Racial Discrimination 660 UNTS 195

-International Covenant on Civil and Political Rights UNTS 999 (opened for signature 16 December 1966, entered into force 23 March 1976)

-International Covenant on Economic, Social and Cultural Rights 993 UNTS 3(16 December 1966)

-Investment Agreement between the Government of the Hong Kong Special Administrative Region of the People's Republic of China and the Government of the Republic of Chile (signed 18 November 2016, entered into force 14 July 2019)

-Investment Agreement Between the Government of the Hong Kong Special Administrative Region of The People's Republic of China and the Government of the Republic of Chile (signed 18 November 2016, entered into force 14 July 2019)

-Marrakesh Agreement Establishing the World Trade Organization 1867 UNTS 3 (opened for signature 15 April 1994, entered into force on 1 January 1995)

-Marrakesh Agreement Establishing the World Trade Organization 1867 UNTS 3 (opened for signature 15 April 1994, entered into force on 1 January 1995), annex 1C (Agreement on Trade-Related Aspects of Intellectual Property Rights)

-Panama-United States of America BIT (1982) (signed 27 October 1982, entered into force 30 May 1991)

-Paris Convention for the Protection of Industrial Property 828 UNTS 305 (opened for signature 20 March 1883, entered into force 7 July 1884)

-Patent Co-operation Treaty 1160 UNTS 231 (signed 19 June 1970, entered into force 24 January 1978)

-Protocol of Amendment to the Agreement Between the United States of America, the Mexican States, and Canada (10 December 2019)

-Rules of Arbitration of the International Chamber of Commerce (entered into force 1 January 2021)

-Statute of the International Court of Justice 33 UNTS 993 (18 April 1946)

-The Central American-Dominican Republic Free Trade Agreement (signed 5 August 2004, entered into force 10 March 2007)

-*The Doha Declaration on the TRIPS Agreement and Public Health* WT/MIN (01)/DEC/2 20 November 2001, (WTO Ministerial Document)

-The Energy Charter Treaty (adopted 1 December 1994, opened for signature 17 December 1994, entered into force 16 April 1998)

-The North American Free Trade Agreement (signed 1992, entered into force 1 January 1994)

-Trade and Investment Framework Agreement Between the United States of America and the Kingdom of Thailand, The United States-Thailand (signed and entered into force 23 October 2002)

-Treaty between the Republic of Belarus and the Republic of India on Investments (signed 24 September 2018, entered into force 5 March 2020)

-Treaty between the United States of America and Jamaica concerning the Reciprocal Encouragement and Protection of Investment (signed 4 February, entered into force 7 March 1997)

-Treaty Between the United States of America and the Oriental Republic of Uruguay Concerning the Encouragement and Reciprocal Protection of Investment (signed 4 November 2005, entered into force 1 November 2006)

-Treaty for the Promotion and Protection of Investments Germany and Pakistan, 457 UNTS 24 (signed 25 November 1959, entered into force 28 April 1962)

-United States-Mexico-Canada Agreement (signed 30 November 2018, entered into force 1 July 2020)

-*Universal Declaration of Human Rights* GA Res217 (1948)

-Vienna Investment Arbitration and Mediation Rules (entered in force 1 July 2021)

Case Law

-*AES Solar and others (PV Investors) v The Kingdom of Spain (Final Award)* UNCITRAL 2012-14, 28 February 2020

-*Alex Genin, Eastern Credit Limited, Inc. and A.S. Baltoil v Republic of Estonia (Award)* ICSID ARB/99/2, 25 June 2001

-*Alps Finance and Trade AG v. The Slovak Republic (Award)* UNCITRAL, 5 March 2011

-*Amco Asia Corporation and Others v Republic of Indonesia (Award)* ICSID ARB/81/1, 20 November 1984, 1 ICSID Reports 413

-*Amco Asia Corporation and others v. Republic of Indonesia (Award in Resubmitted Proceeding)* ICSID ARB/81/1, 10 May 1988

-*Azurix Corp. v. The Argentina Republic (Award)* ICSID ARB/01/12, 14 July 2006

-*Bayindir Insaat Turizm Ticaret ve Sanayi A.S. v Islamic Republic of Pakistan (Decision on Jurisdiction)* ICSID ARB/03/29, 14 November 2005

-*Bayindir Insaat Turizm Ticaret Ve Sanayi AS v. Islamic Republic of Pakistan* (Decision on Jurisdiction) ICSID ARB/03/29, 14 November 2005

-*BayWa r.e. Renewable Energy GmbH and BayWa r.e. Asset Holding GmbH v. Spain* ICSID ARB/15/16, 2 December 2019

-*beIN Corporation v. Kingdom of Saudi Arabia (Notice of Arbitration)* UNCITRAL, 01 October 2018

-*Bilcon of Delaware et al v. Government of Canada (Award on Jurisdiction and Liability)* UNCITRAL PCA 2009-04, 17 March 2015

-*Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania (Award)* ICSID ARB/05/22, 24 July 2008

-*Brazil-Aircraft* WT/DS46/ARB, 28 August 2000 (Decision by the Arbitrators)

-*Bridgestone Licensing Services, Inc. and Bridgestone Americas, Inc. v Republic of Panama (Decision on Expedited Objections)* ICSID ARB/16/34, 13 December 2017

-*Bridgestone Licensing Services, Inc. and Bridgestone Americas, Inc. v Republic of Panama (Request for Arbitration)* ICSID ARB/16/34, 7 October 2016

-*Bridgestone Licensing Services, Inc. and Bridgestone Americas, Inc. v Republic of Panama (Award of the Tribunal)* ICSID ARB/16/34, 14 August 2020

-*Channel Tunnel Group Limited and France- Manche SA v United Kingdom and France (Award)* PCA 2003-06, 30 January 2007

-*Charanne and Construction Investments v. Spain (Award)* SCC V062/2012, 21 January 2016 (Unofficial Translation by Mena Chambers)

-*Chemtura Corporation (formerly Crompton Corporation*) *v Government of Canada (Award)* PCA 2008-1, 2 August 2010

-*CMS Gas Transmisson Company v The Argentina Republic (Award)* ICSID Case No. ARB/01/8, 12 May 2005

-*CMS Gas Transmisson Company v The Argentina Republic (Decision on Annulment)* ICSID Case No. ARB/01/8, 25 September 2007

-*Continental Casualty Company v The Argentine Republic (Award)* ICSID ARB/03/9, 14 July 2006

-*Deutsche Bank AG v Democratic Socialist Republic of Sri Lanka (Award)* ICSID ARB/09/2, 31 October 2012

-*EC-Bananas III* WT/DS27/ARB, 9 April 1999 (Decision by the Arbitrators)

-*EDF (Services) Limited v Romania (EDF v Romania) (Award)* ICSID ARB/05/13, 8 October 2009

-*El Paso Energy International Company v. The Argentina Republic (Award)* ICSID Case No. ARB/03/15, 31 October 2011

-*Electrabel S.A. v. Republic of Hungary (Award)* ICSID ARB/07/19, 25 November 2015

-*Electrabel S.A. v. Republic of Hungary (Decision on Jurisdiction, Applicable Law and Liability)* ICSID ARB/07/19, 30 November 2012

-*Eli Lilly and Company v The Government of Canada (Award)* ICSID UNCT/14/2, 16 March 2017

-*Eli Lilly and Company v The Government of Canada (Claimant Memorial)* ICSID UNCT/14/2, 29 September 2014

-*Eli Lilly and Company v The Government of Canada (Government of Canada Counter Memorial)* ICSID UNCT/14/2, 27 January 2015

-*Eli Lilly and Company v The Government of Canada (Government of Canada Statement of Defence)* ICSID UNCT/14/2, 30 June 2014

-*Eli Lilly and Company v The Government of Canada (Notice of Arbitration)* ICSID UNCT/14/2, 12 September 2013

-*Eudoro A Olguin v Republic of Paraguay (Award)* ICSID Case No. ARB/98/5, 26 July 2001

-*Fedax N.V. v. The Republic of Venezuela (Decision of the Tribunal on Objections to Jurisdiction)* ICSID ARB/96/3, 11 July 1997

-*Glamis Gold, Ltd. v. United States of America (Award)* UNCITRAL, 8 June 2009

-*Hatton and Others v The United Kingdom* [2003] 37 EHRR 28 (Grand Chamber, ECHR)

-*Hesham T.M. Al-Warraq v. Republic of Indonesia (Final Award)* UNCITRAL, 15 December 2014

-*Holdings S.à.r.l. v Republic of Poland (Partial Award)* SCC V 2014/163, 28 June 2017

-*Hydro Energy 1 S.á.r.l and Hydroxana Sweden AB v. Kingdom of Spain (Decision on Jurisdiction, Liability and Directions on Quantum)* ICSID ARB/15/42, 9 March 2020

-*İ .A. v Turkey* ECHR 42571/98, 13 September 2005

-*In the Matter of Revere Copper and Brass In v Overseas Private Investment Corporation (Award)*, 24 August 1978, 56 IRL 258

-*International Thunderbird Gaming Corp. v United Mexican States (Arbitral Award)* UNCITRAL, 26 January 2006

-*International Thunderbird Gaming Corp. v United Mexican States (Arbitral Award)* UNCITRAL, 26 January 2006

-*Jan de Nul NV and Dredging International NV v. Arab Republic of Egypt* (hereinafter "*Jan de Nul v Egypt*") *(Decision on Jurisdiction)* ICSID ARB/04/13, 16 June 2006

-*Klöckner Industrie- Anlagen GmbH er al. v United Republic of Cameroon and Societe Camerounaise des Engrais (Decision of the Ad-Hoc Committee Unofficial English Translation)* ICSID ARB/81/2, 3 May 1985

-*LG&E Energy Corp, LG& E Capital Corp, and LG& E International, Inc. v. The Argentina Republic) (Decision on Liability)* ICSID ARB/02/1, 3 October 2006

-*Metalclad Corporation* v *United Mexican States (Award)* ICSID ARB/AF/97/1, 30 August 2000

-*Methanex v The United States of America (Final Award on Jurisdiction and Merits)* UNCITRAL, 3 August 2005

-*Military and Paramilitary Activities in and against Nicaragua (Nicaragua v. United States of America) (Merits)* [1986] ICJ Rep 14

-*Mobil Invs. Canada Inc. v Canada (Decision on Liability and on Principles of Quantum)* ICSID ARB(AF)/07/4, 22 May 2012

-*Mondev International Ltd v. United States of America (Award)* ICSID ARB(AF)/99/2, 11 October 2002

-*Mr. Franck Charles Arif v Republic of Moldova (Arif v Moldova) (Award)* ICSID ARB/11/23, 8 April 2013

-*MTD Equity Sdn. Bhd. and MTD Chile S.A. v Republic of Chile (Award)* ICSID ARB/01/7, 25 May 2004

-*Novenergia II – Energy & Enviroment (SCA) (Grand Duchy of Luxembourg), SICAR v The Kingdom of Spain (Final Award)* SCC 2015/063, 15 February 2018

-*Occidental Petroleum Corporation and Occidental Exploration and Production Company v. The Republic of Ecuador* (*Decision on Annulment Award)* ICSID ARB/06/11, 2 November 2015

-*Occidental Petroleum Corporation and Occidental Exploration and Production Company v. The Republic of Ecuador (Award)* ICSID ARB/06/11, 5 October 2012

-*OI European Group B.V. v. Bolivarian Republic of Venezuela (Award)* ICSID ARB/11/25, 10 March 2015

-*Oil Platforms (Islamic Republic of Iran v. United States of America) (Judgment)* [2003] ICJ Rep 161

-*Otto-Preminger-Institut v Austria* (1994) Series A no 295/A

-*Parkering- Compagniet AS v Lithuania (Final Award)* ICSID ARB/05/8, 11 September 2007

-*Patrick Mitchell v. The Democratic Republic of Congo (Decision on the Application for Annulment of the Award)* ICSID ARB/99/7, 1 November 2006

-*Phelps Dodge Corp. et al v Iran*, 10 Iran-US CTR 121, 130 (1986-I).

-*Philip Morris Asia Limited v The Commonwealth of Australia (Award)* UNCITRAL PCA 2012-12, 17 December 2015

-*Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (Written Submission (Amicus Curiae Brief) by the WHO and the Secretariat of the Tobacco Control Convention)* ICSID ARB/10/7, 28 January 2015

-*Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (Alegato Escrito (Amicus Curiae) de la Organizacion PanAmericana de la Salud)* ICSID ARB/10/7, 28 De Marzo Del 2015

-*Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (Concurrence and Dissent)* ICSID ARB/10/7, 8 July 2016

-*Philip Morris Brands Sarl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay (Award)* ICSID ARB/10/7, 8 July 2016

-*Pope & Talbot, Inc v Government of Canada, (Interim Award)* UNCITRAL, 26 June 2000

-Production Card Case No. AKPI21-303 (04 January 2021) <https://vsrf.ru/lk/practice/cases/11085980>

-*PSEG Global et al. v Republic of Turkey (Award)* ICSID ARB/02/5, 19 January 2007

-*Romak SA (Switzerland) v The Republic of Uzbekistan (Award)* UNCITRAL Rules PCA AA280, 26 November 2009

-*Ronald S. Lauder v The Czech Republic (Final Award)* UNCITRAL, 3 September 2001

-*RREEF Infrastructure (G.P.) Limited and RREEF Pan- European Infrastructure Two Lux S.á.r.l v. Kingdom of Spain (Award)* ICSID ARB/13/30, 11 December 2019

-*RWE AG and RWE Eemshaven Holding II BV v. Kingdom of the Netherlands* ICSID ARB/21/4; *Eco Oro Minerals Corp. v Republic of Colombia (Decision on Jurisdiction, Liability and Directions on Quantum)* ICSID ARB/16/41, 9 September 2021

-*RWE Innogy GmbH and RWE Innogy Aersa S.A.U. v Kingdom of Spain (Award of the Tribunal)* ICSID ARB/14/34, 18 December 2020

-*Saba Fakes v. Republic of Turkey (Award)* ICSID ARB/07/20, 14 July 2010

-*Salini Costruttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco (Decision on Jurisdiction)* ICSID ARB/00/4, 23 July 2001

-*Saluka Investments BV (The Netherlands) v The Czech Republic (Partial Award)* UNCITRAL, 7 March 2006

-*SD Myers, Inc v Government of Canada (Partial Award)* UNCITRAL, 13 November 2000

-*SGS Société Générale de Surveillance S.A. v Republic of Philippines (Decision on Jurisdiction)* ICSID ARB/02/6, 29 January 2004

-*SolEs Badajoz GmbH v Kingdom of Spain (Award)* ICSID ARB/15/38, 31 July 2019

-*Spoldzielnia Pracy Muszynianka v. Slovakia Republic (Muszynianka v Slovakia) (Award)* UNCITRAL 2017-08, 7 October 2020

-*Stadtwerke München GmbH, RWE Innogy GmbH, and others v. Kingdom of Spain (Award)* ICSID ARB/15/1, 2 December 2019

-*Suez, Sociedad General de Aguas de Barcelona S.A., and InterAguas Servicios Integrales del Agua S.A. v The Argentine Republic (Decision on Liability)* ICSID ARB/03/17, 30 July 2010

-*Tecnicas Medioambientales Tecmed, S.A. v The United Mexican States (Award)* ICSID ARB(AF)/00/2, 29 May 2003

-*Theodore David Einarsson, Harold Paul Einarsson and Russell John Einarsson, Geophysical Service Incorporated v Government of Canada (Notice of Arbitration)* ICSID UNCT/20/6, 18 April 2019

-*Tippetts, Abbett, McCarthy, Stratton v TAMS-AFFA Consulting Engineers of Iran*, 6 Iran-US CTR 219, 225, 29 June 1984

-*Total S.A. v. The Argentina Republic (Decision on Liability)* ICSID ARB/04/01, 27 December 2010

-*Union Fenosa Gas, S.A. v. Arab Republic of Egypt (Award of the Tribunal)* ICSID ARB/14/4, 31 August 2018

-*Urbaser S.A. and Consorcio de Aguas Bilbao Bizkaia, Bilbao Biskaia Ur Partzuergoa v The Argentine Republic (Award)* ICSID ARB/07/26

-*Watkins Holdings S.á.r.l and others v. Kingdom of Spain (Award)* ICSID ARB/15/44, 21 January 2020

-*Watkins Holdings S.á.r.l and others v. Kingdom of Spain (Dissent on Liability and Quantum of Prof. Héléne Ruiz Fabri*) ICSID ARB/15/44, 9 January 2020

-*Wena Hotels Limited v Arab Republic of Egypt (Decision on Annulment)* ICSID ARB/98/4, 5 February 2002.

UN Documents

-*Committee on Science and Economic, Social and Cultural Rights Statement on the Coronavirus Disease (COVID-19) Pandemic and Economic, Social and Cultural Rights* UN Doc E/C.12/2020/1 (17 April 2020)

-David R. Boyd *Report of the Special Rapporteur on the Issue of Human Rights Obligations Relating to the Enjoyment of a Safe, Clean, Healthy and Sustainable Environment* UN Doc A/78/168 (13 July 2023)

-*General Comment No.24 (2017) on State Obligations under the International Covenant on Economic, Social and Cultural Rights in the Context of Business Activities* UN Doc E/C.12/GC/24 (10 August 2017)

-*General Comment No.25 (2020) on Science and Economic, Social and Cultural Rights (article 15(1) (b), (2), (3), and (4) of the International Covenant on Economic, Social and Cultural Rights)* UN Doc E/C.12/GC/25 (30 April 2020)

-Paul Hunt *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health - Annex: Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* UN Doc A/63/263 (11 August 2008)

-*Report of the Covenant on Civil and Political Rights Human Rights Committee for 2019 General comment No. 36 on Article 6: Right to Life* UN Doc CCPR/C/GC/36 (3 September 2019)

-*Report of the United Nations Secretary- General's High-Level Panel on Access to Medicines: Promotion innovation and Access to health Technologies* (14 September 2016)

-*Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: General Comment No. 14(2000)*, Un Doc E/C.12/2000/4 (11 August 2000)

WTO Documents

-Amendment of the TRIPS Agreement, Decision of the General Council of 6 December 2005, WT/L/641, 8 December 2005

-*Australia- Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging* WT/DS435/R, WT/DS441/R, WT/DS458/R, and WT/DS467/R 28 June 2018 (Panel Report)

-*Brazil- Certain Measures Concerning Taxation and Charges* WT/DS472/R WT/DS497/R 30 August 2017 (Reports of the Panel)

-*Brazil- Measures Affecting Patent Protection* WT/DS199/4, G/L/454, IP/D/23/Add.1 19 July 2001 (Notification of Mutually Agreed Solution)

-*Canada- Patent Protection of Pharmaceutical Products* WT/DS114/R 17 March 2000 (Panel Report)

-*European Communities- Measures Prohibiting the Importation and Marketing of Seal Products* WT/DS400/AB/R, WT/DS401/AB/R 22 May 2014 (Reports of the Appellate Body)

-*European Communities- Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* WT/DS174/R 15 March 2005 (Panel Report)

-Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, WT/L/540, 1 September 2003

-*India-Patent Protection for Pharmaceutical and Agricultural Chemical Products* WT/DS50/R 5 September 1997 (Report of the Panel)

-*Korea- Measures Affecting Imports of Fresh, Chilled and Frozen Beef* WT/DS161/AB/R WT/DS169/AB/R 11 December 2000 (Report of the Appellate Body)

-Ministerial Decision on the TRIPS Agreement, Adopted on 17 June 2022 WT/MIN(22) /WT/L/1141, 22 June 2022 (Ministerial Conference 12 Session, Geneva)

-*Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods-Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for The Protection of Intellectual Property* MTN.GNG/NG11/W/24, 5 May 1988 (Note prepared by the International Bureau of WIPO)

-Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19 IP/C/W/669, 2 October 2020 (Council for Trade-Related Aspects of Intellectual Property Rights)

-Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, Revised Decision Text IP/C/W/669/Rev.1, 25 May 2021 (Council for Trade-Related Aspects of Intellectual Property Rights)

-Waiver from Certain Provisions of The TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19, IP/C/W/684 30 September 2021 (Council for Trade-Related Aspects of Intellectual Property Rights)

-WTO Analytical Index GATT 1994 Article XX (DS Report)

Books

-Abbe E. L. Brown and others *Contemporary Intellectual Property: Law and Policy* (5th ed, Oxford University Press, Oxford, 2019)

-Adam D. Moore *Intellectual Property and Information Control: Philosophic Foundations and Contemporary Issues* (Routledge/ Transaction Publishing, New York, 2004)

-Amaka Vanni *Patent Games in the Global South Pharmaceutical Patent Law Making in Brazil, India and Nigeria* (Hart, Great Britain, 2019)

-Amartya Kumar Sen *Development as Freedom* (Knopf, New York, 1999)

-Amartya Sen *The Idea of Justice* (The Belknap Press, Cambridge, 2009)

-Andrea K. Bjorklund and Lukas Vanhonnaeker "Applicable Law in International Investment Arbitration" C. L. Lim *The Cambridge Companion to International Arbitration* (Cambridge University Press, 2021)

-Andreas Von Gunten *Intellectual Property is Common Property: Arguments for the Abolition of Private Intellectual Property Rights* (Buch & Netz, Zurich, 2015)

-Antony Anghie *Imperialism, Sovereignty and the Making of International Law* (Cambridge University Press, Cambridge, 2005)

-Antony Anghie *The Third World and International Order: Law, Politics, and Globalization* (Martinus Nijhoff, Leiden 2003)

-Antony Taubman, Hannu Wager and Jayashree Watal *A Handbook on the WTO TRIPS Agreement* (2nd ed, Cambridge University Press, Cambridge, 2020)

-Aristotle *The Nicomachean Ethics* (M.A. F. H. Peters (translator),10th ed, Kegan Paul, Trench Trübner & Co Ltd., London, 1906)

-Arnaud de Nanteuil *International Investment Law* (Edward Elgar Publishing, Northampton, 2020)

-August Reinisch and Christoph Schreuer *International Protection of Investments: The Substantive Standards* (Cambridge University Press, United Kingdom, 2020)

-Campbell McLachlan, Laurence Shore and Matthew Weiniger *International Investment Arbitration: Substantive Principles* (2nd ed, Oxford University Press, Oxford, 2017)

-Carlos M. Correa *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2nd ed, Oxford University Press, Oxford, 2020)

-Caroline Henckels *Proportionality and Deference in Investor-State Arbitration: Balancing Investment Protection and Regulatory Autonomy* (Cambridge University Press, Cambridge, 2015)

-Charles R. Beitz *Political Theory and International Relations* (Princeton University Press, Princeton, 1999)

-Congyan Cai *The Rise of China and International Law: Taking Chinese Exceptionalism Seriously* (eBook, OUP, 2019)

-Cynthia Ho *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (Oxford University Press, Cary, 2011)

-Daniel Gervais *The TRIPS Agreement- Drafting History and Analysis* (2nd ed, Sweet & Maxwell, UK, 2003)

-Darrel Moellendorf *Cosmopolitan Justice* (Westview Press, Boulder, CO, 2002)

-David I. Bainbridge *Intellectual Property* (9th ed, Pearson Education Limited, Harlow, 2012)

-David Miller *On Nationality* (Clarendon, Oxford, 1997)

-Dwight Newman (ed) Research Handbook on the International Law of Indigenous Rights (Edward Elgar, Cheltenham, 2022)

-Emmanuel Kolawole Oke *The Interface between Intellectual Property and Investment Law: An Intertextual Analysis* (Edward Elgar United Kingdom, 2021)

-Filip Balcerzak *Renewable Energy Arbitration-quo vadis?: Implications of the Spanish Saga for International Investment Law* (Brill, Leiden, 2023)

-G. A. Cohen *Rescuing Justice and Equality* (Harvard University Press, Cambridge 2008)

-Gebhard Bücheler *Proportionality in Investor-State Arbitration* (Oxford University Press, New York, 2015)

-Graham Allison Destined for War: Can America and China Escape Thucydides's Trap? (Brunswick, Scribe, 2017)

-Hege Elisabeth Kjos Applicable Law in Investor-State Arbitration the Interplay Between National and International law (Oxford University Press, Oxford, 2013)

-Henning Grosse Ruse-Khan *The Protection of Intellectual Property in International Law* (Oxford University Press, United Kingdom, 2016)

-Henry Shue *Basic Rights: Subsistence, Affluence, and U.S. Foreign Policy: 40th Anniversary Edition* (Princeton University Press, New Jersey, 2020)

-Ioana Tudor *The Fair and Equitable Treatment Standard in the International Law of Foreign Investment* (Oxford University Press, Oxford, 2008)

-John Rawls *A Theory of Justice* (revised ed, The Belknap Press, Cambridge, 1999)

-John Rawls *Justice as Fairness: A Restatement* (2nd ed, Harvard University Press, United States of America, 2001)

-John Rawls *The Law of Peoples with "The Idea of Public Reason Revisited"* (4 ed, Harvard University Press, United States of America, 2002)

-Jonathan Bonnitcha, Lauge N. Skovgaard Poulsen and Michael Waibel *The Political Economy of the Investment Treaty Regime* (Oxford University Press, Oxford, 2017)

-Jorge E. Viñuales *Foreign Investment and the Environment in International Law* (Cambridge University Press, New York, 2012)

-Joseph E. Stiglitz *Globalisation and Its Discontents Revisited: Anti-Globalization in the Era of Trump* (W.W. Norton & Company, New York, 2018)

-Jules L Coleman *The Practice of Principles: In Defence of a Pragmatist Approach to Legal Theory* (Oxford University Press, New York, 2001)

-Katia Yannaca-Small "Fair and Equitable Treatment Standard: Recent Developments" in August Reinisch (ed) *Standards of Investment Protection* (Oxford University Press, New York, 2008)

-Kevin K. W. Ip *Egalitarianism and Global Justice: From a Relational Perspective* (Palgrave Macmillan US, New York, 2016)

-Kok-Chor Tan *Justice Without Borders Cosmopolitanism, Nationalism, and Patriotism* (Cambridge University Press, New York, 2004)

-Lionel Bently and others *Intellectual Property Law* (5th ed, Oxford University Press, Oxford, 2018)

-Lukas Vanhonnaeker *Intellectual Property Rights as Foreign Direct Investments: From Collision to Collaboration* (Edward Elgar Publishing, Cheltenham, 2015)

-M. Sornarajah *The International Law on Foreign Investment* (2nd ed, Cambridge University Press, Cambridge, 2004)

-Madhavi Sunder *From Goods to a Good Life: Intellectual Property and Global Justice* (Yale University Press, New Haven 2012)

-Martha C. Nussbaum *Frontiers of Justice: Disability, Nationality, Species Membership* (The Belknap Press, Cambridge, 2006)

-Mārtiņš Paparinskis *The International Minimum Standard and Fair and Equitable Treatment* (Oxford University Press, Oxford, 2013)

-Mathias Risse *On Global Justice* (Princeton University Press, United States of America, 2012)

-Michael A. Newton and Larry May *Proportionality in International law* (Oxford University Press, New York, 2014)

-Michael Boylan *Morality and Global Justice: Justifications and Applications* (Westview Press, New York, 2011)

-Michael Spence *Intellectual Property* (Oxford University Press, Oxford, 2007)

-Milton Friedman "A Friedman Doctrine- The Social Responsibility of Business is to Increase its Profits" *The New York Times* (online ed, New York, 13 September 1970)

-Milton Friedman and with the assistance of Rose D. Friedman *Capitalism and Freedom* (40th ed, University of Chicago Press, Chicago, 2002)

-Moshe Cohen-Eliya and Iddo Porat *Proportionality and Constitutional Culture* (Cambridge University Press, New York, 2013)

-Norrie Macqueen *Colonialism* (Routledge, London, 2007)

-Oisin Suttle *Distributive Justice and World Trade Law: A Political Theory of International Trade Regulation* (Cambridge University Press, Cambridge, 2018)

-Olasupo Owoeye *Intellectual Property and Access to Medicines in Africa: A Regional Framework for Access* (Routledge, Milton, 2019)

-Ole-Andreas Rognstad *Property Aspects of Intellectual Property* (Cambridge University Press, Cambridge, 2018)

-Onora O'Neill *Bounds of Justice* (Cambridge University Press, Cambridge, 2000)

-Paul Goldstein and Bernt P. Hugenholtz *International Copyright: Principles, Law and Practice* (2nd ed, Oxford University Press, Oxford, 2010)

-Peter Drahos *A Philosophy of Intellectual Property* (eBook, Anu eText, 2016)

-Peter Singer *Famine, Affluence, and Morality* (Oxford University Press, Oxford, 2016)

-Pratyush Nath Upreti *Intellectual Property Objectives in International Investment Agreements* (Edward Elgar, London, 2022)

-Rami M. Olwan *Intellectual Property and Development: Theory and Practice* (Springer, Heidelberg, 2013)

-Robert M. Sherwood *Intellectual Property and Economic Development* (Routledge, New York 1990)

-Robert P. Merges *Justifying Intellectual Property* (Harvard University Press, Cambridge, 2011)

-Roland Kläger *Fair and Equitable Treatment' in International Investment Law* (eBook ed, Cambridge University Press, 2011)

-Rudolf Dolzer, Ursula Kriebaum and Christoph Schreuer *Principles of International Investment Law* (3rd ed, Oxford University Press, New York, 2012)

-Simon Caney *Justice Beyond Borders: A Global Political Theory* (Oxford University Press, Oxford, 2005)

-Simon Klopschinski, Christopher Gibson and Henning Grosse Ruse-Khan *The Protection of Intellectual Property Rights Under International Investment Law* (Oxford University Press, New York, 2021)

-Stephan Schill *The Multilateralization of International Investment Law* (Cambridge University Press, Cambridge, 2009)

-Thomas Pogge *World Poverty and Human Rights: Cosmopolitan Responsiblities and Reforms* (Polity Press, Cambridge, 2008)

-Thomas W. M. Pogge *Realizing Rawls* (Cornell University Press, Ithaca, 1989)

-Peter Singer Practical Ethics (3rd ed, Cambridge University Press, Cambridge 2011)

-Valentina Vadi *Proportionality, Reasonableness and Standards of Review in International Investment Law and Arbitration* (Edward Elgar, Cheltenham, 2018)

-Yael Tamir *Liberal Nationalism* (Princeton University Press, Princeton, 1995)

Chapters in Edited Books

-Andreas Kulick "Narrating Narratives of International Investment Law: History and Epistemic Forces" in Stephan W. Schill, Christian J. Tams, and Rainer Hofmann (ed) *International Investment Law and History* (Edward Elgar, United Kingdom, 2018) 41

-Anne K. Hoffman "Indirect Expropriation" in August Reinisch (ed) *Standards of Investment Protection* (Oxford University Press, New York, 2008) 151

-Antonius R. Hippolyte “Aspiring for a Constructive TWAIL Approach towards the International Investment Regime” in Stephan W. Schill, Christian J. Tams and Rainer Hofmann *International Investment Law and Development: Bridging the Gap* (Edward Elgar, Cheltenham, 2015) 180

-August Reinisch “Expropriation” in Peter Muchlinski, Federico Ortino and Christoph Schereuer (ed) *The Oxford Handbook of International Investment Law* (Oxford University Press, Oxford, 2008) 407

-B.S. Chimni “Critical Theory and International Economic Law: A Third World to International Law (TWAIL) Perspective” in John Lineralli (ed) *Research Handbook on Global Justice and International Economic Law* (Edward Elgar, Cheltenham, 2013) 251

-Benedetta Cappiello “Applicable Law in Investment Arbitration” in Julian Chaisse, Leila Choukroune and Sufian Jusoh (ed) *Handbook of International Investment Law and Policy* (Springer, online ed, 2021) 1123

-Benedict Kingsbury and Stephan W Schill “Public Law Concepts to Balance Investors’ Rights with State Regulatory Actions in the Public Interest – the Concept of Proportionality” in Stephan W Schill (ed) *International Investment Law and Comparative Public Law* (Oxford University Press, New York, 2010) 75

-Bryan Mercurio “Keep Calm and Carry On: Lessons from the Jurisprudence on Fair and Equitable Treatment and Intellectual Property Rights” in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) 159

-Bryan Mercurio “TRIPS-Plus Provisions in FTA’s Recent Trends” Lorand Bartels and Federico Ortino (ed) *Regional Trade Agreements and the WTO Legal System* (Oxford University Press, Oxford, 2006) 215

-Carlos Correa “Intellectual Property as Protected Investment: Redefining the Reach of Investors’ Rights” in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) 120

-Carlos M. Correa “Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing” in Carlos M. Correa (ed) *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (South Centre, Geneva, 2013) 1

-Catharine Titi “Police Powers Doctrine and International Investment Law” in Andrea Gattini and others (ed) *General Principles of Law and International Investment Arbitration* (BRILL, Leiden, 2018) 323

-Christophe Geiger “The Social Function of Intellectual Property Rights, or How Ethics Can Influence the Shape and Use of IP Law” in Graeme B. Dinwoodie (ed) *Methods and Perspectives in Intellectual Property* (Edward Elgard Publishing, Cheltenham, 2013) 153

-Cynthia Ho “Intersection of ISDS and TRIPS Flexibilities” in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) 207

-Eric Engle “The General Principle of Proportionality and Aristotle” in Liesbeth Huppes-Cluysenaer and Nuno M. M. S. Coelho *Aristotle and The Philosophy of Law: Theory, Practice and Justice* (Springer Netherlands, Dordrecht, 2013) 265

-Graham Cook and Hannu Wager “Adjudicating Intellectual Property Disputes at the GATT/WTO: Are There General Lessons for the Investor-State Dispute Settlement System?” in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020) 287

-Güneş Ünüvar “The Vague Meaning of the Fair and Equitable Treatment Principle in Investment Arbitration and New Generation Clarifications” in Anne Lise Kjaer and Joanna Lam (ed) *Language and Legal Interpretation in International Law* (Oxford University Press, New York, 2002) 271

-Henning Grosse Ruse-Khan “Protecting Intellectual Property Rights under BITs, FTAs, and TRIPS: Conflicting Regimes or Mutual Coherence?” in Chester Brown and Kate Miles (ed) *Evolution in Investment Treaty Law and Arbitration* (Cambridge University Press, Cambridge, 2011) 485

-Henning Grosse Ruse-Khan “Proportionality and Balancing within the Objectives” in Paul L.C. Torremans (ed) *Intellectual Property and Human Rights: Enhanced Edition of Copyright and Human Rights* (Wolters Kluwer, Netherlands, 2008) 161

-Iddo Porat “Some Critical Thoughts on Proportionality” in Giorgio Bongiovanni, Giovanni Sartor and Chiara Valentini (ed) *Reasonableness and Law* (Springer Netherlands, Dordrecht, 2009) 243

-James Thuo Gathii “The Agenda of Third World Approaches to International Law (TWAIL)” in Jeffrey L. Dunoff and Marka A. Pollack (ed) *International Legal Theory: Foundations and Frontiers* (eBook ed, Cambridge University Press, 2022) 153

-Joost Pauwelyn “Rational Design or Accidental Evolution? The Emergence of International Investment Law” in Zachary Douglas, Joost Pauwelyn and Jorge E. Viñuales (ed) *The Foundations of International Investment Law: Bringing Theory into Practice* (Oxford University Press, Oxford, 2014) 11

-Jorge E. Viñuales “Sovereignty in Foreign Investment Law” in Zachary Douglas, Joost Pauwelyn and Jorge E. Viñuales (ed) *The Foundations of International Investment Law: Bringing Theory into Practice* (Oxford University Press, Oxford, 2014) 317

-Julie Clague ““Patent Injustice”: Applying Sen's Capability Approach to Biotechnologies” in Mathias Nebel and Nicholas Sagovsky Severine Deneulin (ed) *Transforming Unjust Structures: The Capability Approach* (Springer Netherlands, Dordrecht, 2006) 177

-K.D. Raju “Patent Linkages and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries” in Carlos M. Correa and Reto M. Hilty (ed) *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (eBook, Springer, 2022) 329

-Karin Timmermans “Ensuring Access to Medicines in 2005 and Beyond” in Pedro Roffe, Geoff Tansey and David Vivas-Eugui (ed) *Negotiating Health: Intellectual Property and Access to Medicines* (Routledge, London, 2006) 41

-Larry S. Temkin “Illuminating Egalitarianism” in Thomas Christiano and John Christman (ed) *Contemporaty Debates in Political Philosophy* (Wiley-Blackwell, Malaysia, 2009) 154

-Malcolm Langford and others “Regime Responsiveness in International Economic Disputes” in Szilárd Gáspár-Szilágyi and others (ed) *Adjudicating Trade and Investment Disputes: Convergence or Divergence?* (Cambridge University Press, United Kingdom, 2020) 244

-Marsha S. Cadogan “A TWAIL-Constructivist Critique of the IP and Development Divide in the Age of Innovation – Has the Protection of Place Based Goods Changed the Narrative for the Caribbean?” in Susy Frankel (ed) *The Object and Purpose of Intellectual Property* (Edward Elgar, Cheltenham, 2019) 57

-Max Wallot “The Proportionality Principle in the TRIPS Agreement” in Hanns Ullrich and others *TRIPS plus 20: From Trade Rules to Market Principles* (eBook, Springer Nature, 2016) 213

-Nathaniel Lipkus and Madison Black “Intellectual Property” in Gibert Gagne and Miechele Rioux (ed) *NAFTA 2.0 From the first NAFTA to the United States- Mexico- Canada Agreement* (eBook, Palgrave Macmillan, 2022) 109

-Ole Spiermann “Applicable Law” in Peter Muchlinski, Federico Ortino and Christoph Schereuer (eds) *The Oxford Handbook of International Investment Law* (Oxford University Press, Oxford, 2008) 89

-Olunmiloda Olabode “A TWAIL Approach to Reforming the International Investment Regime” in Mariela de Amstalden and others (ed) *International Economic Law: New Approaches and Issues”* (eBook, Springer, 2023) 93

-Pedro Roffe, Christoph Spennemann, and Johanno von Brawn “From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health” in Pedro Roffe, Geoff Tansey and Vivas-Eugui (ed) *Negotiating Health: Intellectual Property and Access to Medicines* (Routledge, London, 2006) 9

-Rochella Dreyfuss “Hedging Bets with BITS: The impact of Investment Obligations on Intellectual Property Norms” in Jonathan Griffiths and Tuomas Mylly *Global Intellectual Property Protection and New Constitutionalism: Hedging Exclusive Rights* (Oxford University Press, Oxford, 2021) 157

-Ruth Okediji “When is Intellectual Property an Investment?” in Christophe Geiger (ed) Research Handbook on Intellectual Property and Investment Law (Edward Elgar, Cheltenham, 2020) 86

-Saïda El Boudouhi “Barcelona Traction Re-Imagined: The ICJ as a World Court for Foreign Investment Cases?” in Ingo Venzke and Kevin Jon Heller (ed) *Contingency in International Law: On the Possibility of Different Legal Histories* (Oxford University Press, New York, 2021) 406

-Sigrid Sterckx “Patents and Access to Drugs in Developing Countries: An Ethical Analysis” in Michael J.Selgelid Thomas Pogge (ed) *Health Rights* (Routledge, London, 2016) 297

-Simon Caney “Cosmopolitanism and Justice” in Thomas Christiano and John Christman (ed) *Contemporary Debates in Political Philosophy* (Wiley-Blackwell, Oxford, 2009) 387

-Thomas Cottier “Parallel Trade and Exhaustion of Intellectual Property in WTO Law Revisited” in Henning Grosse Ruse-Khan and Axel Metzger (ed) *Intellectual Property Ordering beyond Borders* (Cambridge University Press, Cambridge, 2022) 189

-Thomas Pogge “Global Ethics and Global Justice” in Jean-Marc Coicaud and Lynette E. Sieger *Conversations on Justice from National, International, and Global Perspectives: Dialogues with Leading Thinkers* (Cambridge University Press, New York, 2018) 167

-Todd J Grierson-Weiler and Ian A. Laird “Standards of Treatment” in Peter Muchlinski, Federico Ortino and Christoph Schereuer (eds) *The Oxford Handbook of International Investment Law* (Oxford University Press, Oxford, 2008) 259

-Tuomas Mylly “Human Rights and Intellectual Property in Investor to State Dispute Settlement” in Christophe Geiger (ed) *Research Handbook on Intellectual Property and Investment Law* (Edward Elgar, Cheltenham, 2020)

-Tzen Wong and Graham Dutfield (ed) *Intellectual Property and Human Development: Current Trends and Future Scenarios* (Cambridge University Press, New York 2011) 198

-Yas Banifatemi “The Law Applicable in Investment Treaty Arbitration” in Katia Yannaca-Small (ed) *Arbitration under International Investment Agreements: A Guide to the Key Issues* (Oxford University Press, Cary, 2010) 191

-Yousuf A. Vawda “Compulsory Licenses and Government Use: Challenges and Opportunities” in Carlos M. Correa and Reto M. Hilty (ed) *Access to Medicines and Vaccines: Implementing Flexibilities Under Intellectual Property Law* (eBook, Springer, 2022) 73

-Zachary Douglas “Property, Investment and the Scope of Investment Protection Obligation” in Zachary Douglas, Joost Pauwelyn and Jorge E. Viñuales *The Foundations of International Investment Law: Bringing Theory into Practice* (Oxford University Press, Oxford 2014) 363

Journal Articles

-“Remdesivir”: Decision of the Supreme Court of the Russian Federation 27 May 2021 – Case No. АКПИ21-303” (2021) 52(9) IIC Int Rev Ind Prop Copyr Law

-Alberto Alverez-Jimenez “Tobacco Control Measures and International Investment Law after *Philip Morris v. Australia* and *Philip Morris v.* Uruguay” (2018) 29(2) ARIA 147

-Alec Stone Sweet and Jud Mathews “Proportionality Balancing and Global Constitutionalism” (2008) 47(1) Colum. J. Transnat'l L 72

-Allen Buchanan “Rawls's Law of Peoples: Rules for a Vanished Westphalian World” (2000) 110(4) Ethics 697- 194

-Amitaya Banerjee “Who has Responsiblity for Access to Essential Medical Drugs in the Developing World?” (2006) 4(2) Ethics and Economics 1

-Antony Anghie “Rethinking International Law: A TWAIL Retrospective” (2023) EJIL 34(1) 7

-Antony Anghie “The Evolution of International Law: Colonial and Postcolonial Realities” (2006) 27(5) Third World Quarterly 739

-Antony Anghie “Time Present and Time Past: Globalization, International Financial Institutions, and the Third World” (2000) 32 N.Y.U. J. Int’L. & Pol. 243

-Antony Taubman “Rethinking TRIPS: ‘Adequate Remuneration’ for Non-voluntary Patent Licensing” (2008) 11(4) Journal of International Economic Law 927

-Asavari Raut and Others “Acceptance, Hesitancy and Refusal towards Covid-19 Vaccination” (2023) 21 Clin Epidemiol Glob Health.

-B. S. Chimni “Capitalism, Imperialism, and International Law in the Twenty-First Century” (2012) 14(1) Oregon Review of International Law 17

-B. S. Chimni “The International Law of Jurisdiction: A TWAIL Perspective” (2022) 35(1) LJIL 29

-B. S. Chimni “The Past, Present and Future of International Law: A Critical Third World Approach” (2007) 8(2) MJIL 499

-B.S. Chimni “Third World Approaches to International Law: A Manifesto” 2006 8(1) International Community Law Review 3

-Brian Angelo Lee “Making Sense of "Moral Rights" in Intellectual Property” (2011) 84(1) TLR 71

-Brian Barry “Nationalism versus Liberalism? ” (1996) 2(3) Journal of the ASEN 430

-Brook K. Baker and Katrina Geddes “The Incredible Shrinking Victory: Eli Lilly v. Canada, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS” (2017) 49(2) LUCLJ 479

-Bryan Mercurio “Awakening the Sleeping Giant: Intellectual Property Rights in International Investment Agreements” (2012) 15(3) JIEL 871

-Calvin Wai Loon Ho “Utilitarianism and Patents: Justification and Change” (2010) 2(3) Asian Bioethics Review 202

-Carlos Correa and Jorge E. Viñuales “Intellectual Property Rights as Protected Investments: How Open are the Gates?” (2016) 19(1) JIEL 91

-Carlos M. Correa “Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses” (2004) 26(1) MICH. J. INT'L L. 331

-Caroline Henckels “Balancing Investment Protection and the Public Interest: The Role of the Standard of Review and the Importance of Deference in Investor-State Arbitration” (2013) 4(1) Journal of International Dispute Settlement 197

-Caroline Henckels “The Ostensible ‘Flexibilities’ in TRIPS: Can Essential Pharmaceuticals Be Excluded From Patentability in Public Health Crises?” (2006) 32(2) Monash Law Review 335

-Cass R. Sustein “Incommensurability and Valuation in Law” (1993) 92(4) Michigan Law Review 779

-Charles Beitz “The Moral Rights of Creators of Artistic and Literary Works” (2005) 13(3) JOPP 330

-Charles N. Brower and Stephan W. Schill “Is Arbitration a Threat or a Boon to the Legitimacy of International Investment Law?” (2009) 9(2) Chi J Intl L 473

-Charles T. Collins-Chase “The Case Against Trips-Plus Protection in Developing Countries Facing Aids Epidemics” (2014) 29(3) U. Pa. J. In t'l L 763

-Christian Riffel “Indirect Expropriation and the Protection of Public Interests” (2022) 71(4) The International and Comparative Law Quarterly 945

-Christoph Schreuer “Jurisdiction and Applicable Law in Investment Treaty Arbitration” (2014) 1(1) MJDR 1

-Christopher Gibson “A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation” (2010) 25(3) AUILR 357

-Colin Crawford “The Social Function of Property and the Human Capacity to Flourish” (2011) 80(3) Fordham L. Review 1089

-Congyan Cai “New Great Powers and International Law in the 21st Century” (2013) 24(3) EJIL 755

-Cynthia Ho “Reexamining *Eli Lilly v Canada*: A Human Rights Approach to Investor-State Disputes?” (2018) 21(2) Vanderbilt Journal of Entertainment and Technology Law 437

-Cynthia M. Ho “Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions” (2015) 30(1) Berkeley Technology Law Journal 213

-Dan L. Burk and Mark A. Lemley “Policy Levers in Patent Law” (2003) 89(7) Va. L. Rev. 1575

-Daniel Gervais “International Intellectual Property and Development: A Roadmap to Balance?” (2005) 2(4) Journal of Generic Medicines 327

-Daniel Gervais “International Property, Trade & (and) Development: The State of Play” (2005) 74(2) Fordham Law Review 505

-Daniel Gervais “Investor State Dispute-Settlement: Human Rights and Regulatory Lessons from *Lilly v Canada* (2018) 8 (3) UC Irvine Law Review 459

-Darren N. Wagner “The Broken Promise Doctrine: *AstraZeneca Canada Inc v Apotex Inc* and the Future of Pharmaceutical Patents” (2022) 27 Appeal 70

-Doris Schroeder and Peter Singer “Access to Life-Saving Medicines and Intellectual Property Rights: An Ethical Assessment” (2011) 20(2) Cambridge Quarterly of Healthcare Ethics 1

-Duncan Matthews “WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?” (2004) 7(1) JIEL 73

-Edwin C. Hettinger “Justifying Intellectual Property” (1989) 18(1) Philosophy & Public Affairs 31

-Ellen 't Hoen and others “Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All” (2011) 14(1) Journal of the International AIDS Society 15

-Emmanuel Oke “Territoriality in Intellectual Property Law: Examining Goals and Treating Intellectual Property Law: Examining the Tension between Securing Societal Goals and Treating Intellectual Property as an Investment Asset” (2018) 15(2) Scripted 3135

-Enakshi Jha “TWAIL and Investment Law: The Perpetual Struggle” (2016) 5(2) NLIU L. Rev 217

-Eric De Brabandere and Paula Baldini Miranda da Cruz “The Role of Proportionality in Investment Law and Arbitration: A System- Specific Perspective” (2020) 89 NIJHOFF 471

-Erlend M. Leonhardsen “Designing Deference: Towards a Thin Margin of Appreciation Doctrine in International Investment Law” 2022 European Yearbook of International Economic Law 151

-Federico Ortino “Investment Treaties, Sustainable Development and Reasonableness Review: A Case Against Strict Proportionality Balancing” (2017) 30(1) Leiden Journal of International Law 71

-G. A. Cohen “On the Currency of Egalitarian Justice” (1989) 99(4) Ethics 906

-G. Krishna Tulasi and B. Subba Rao "A Detailed Study of Patent System for Protection of Inventions" (2008) 70(5) Indian Journal of Pharmaceutical Sciences 547

-George C. Christie "What Constitutes a Taking of Property Under International Law" (1962) 38 Brit. Y.B. Int'l L. 307

-Geraldo Vidigal and Beatriz Stevens "Brazil's New Model of Dispute Settlement for Investment: Return to the Past or Alternative for the Future?" (2018) Journal of World Investment & Trade 475

-Gillian Brock "Liberal Nationalism versus Cosmopolitanism: Locating the Disputes" (2002) 16(4) PAQ 307- 27

-Giovanni Zarra "Right to Regulate, Margin of Appreciation and Proportionality: Current Status in Investment Arbitration in Light of Philip Morris v. Uruguay" 2017 14(2) Revista de Direito Internacional 95

-Hanns Ullrich "TRIPS: Adequate Protection, Inadequate Trade, Adequate Competition Policy" (1995) 4(1) Pac.Rim L.& Pol'y J 153

-Haochen Sun "The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health" (2004) 15(1) EJIL 123

-Ikechi Mgbeoji "The Comprador Complex: Africa's IPRs Elites, Neo-Colonialism and the Enduring Control of African IPR Agenda by External Interests" (2014) 26 IPJ 313

-James T. Gathii "TWAIL: A Brief History of Its Origins, Its Decentralized Network, and a Tentative Bibliography" (2011) 3(1) Trade L. & Dev. 26

-Jean Raymond Homere "Intellectual Property Rights Can Help Stimulate the Economic Development of Least Developed Countries" (2004) 27 (2) Columbia Journal of Law and Arts 277

-Joel Lexchin and Marc-Andre Gagnon "CETA and Pharmaceuticals: Impact of the Trade Agreement between Europe and Canada on the Costs of Prescription Drugs" (2014) 30 Globalisation and Health

-Johannes Kniess "Must We Protect Foreign Investors?" (2018) 5(2) MOPP 205 at 205

-José Juan Moreso and Chiara Valentini "In the Region of Middle Axioms: Judicial Dialogue as Wide Reflective Equilibrium and Mid-level Principles" (2021) 40(5) Law and Philosophy 545

-Joseph E. Stiglitz "Economic Foundations of Intellectual Property Rights" (2008) 57(6) Duke Law Journal 1693

-Julian Arato "The Margin of Appreciation in International Investment Law" 2014 54(3) Va. J. Int'l L 545

-Julian Arato "The Private Law Critique of International Investment Law" (2019) 113(1) AJIL 1

-Julio S. Solis Arce and Others "Covid-19 Vaccine Acceptance and Hesitancy in Low- and Middle- Income Countries" (2021) 27(8) Nature Medicine 1385

-Justine Pila "Pluralism, Principles and Proportionality in Intellectual Property" (2014) 34(1) Oxford Journal of Legal Studies 181

-Kathleen Liddell and Michael Waibel "Fair and Equitable Treatment and Judicial Patent Decisions" (2016) 19(1) JIEL 145

-Kendra Leite "The Fair and Equitable Treatment Standard: A Search for a Better Balance in International Investment Agreements" (2016) 32(1) AUILR 363

-Kenneth Einar Himma "The Justification of Intellectual Property: Contemporary Philosophical Disputes" (2008) 59(14) Journal of the American Society for Information Science and Technology 1143

-Kenneth W. Abbott and Duncan Snidal "Hard and Soft Law in International Governance" (2000) 54(3) International Organisation 421

-Kristina Trykhlib "The Principle Of Proportionality in the Jurisprudence of the European Court of Human Rights" (2020) 4 ECLIC 128

-Kwadwo Appiagyei-Atua “Ethical Dimensions of Third-World Approaches to International Law (TWAIL): A Critical Review” (2015) 8(3-4) AJLS 209

-Kyla Tienhaara “Regulatory Chill in a Warming World: The Threat to Climate Policy Posed by Investor-State Dispute Settlement” (2018) 7(2) TEL 229

-Makau Mutua and Antony Anghie “What Is TWAIL?” (2000) 94 JSTOR 31

-Manuel Knoll “The Meaning of Distributive Justice for Aristotle’s Theory of Constitutions” (2016) 1 Pege 57

-Margaret Chon “Intellectual Property “from below”: Copyright and Capability for Education” (2007) 40(3) U.C. Davis Law Review 803

-Margaret Chon “Intellectual Property and the Development Divide” (2006) 27(6) Cardozo Law Rev. 2821

-Mark A. Lemley “Property, Intellectual Property, and Free Riding” (2005) 83 Texas L. Rev. 1031

-Mark A. Lemley “Taking the Regulatory Nature of IP Seriously” (2014) 92 TE X. L. RE V. 68

-Maryam Malakotipour “The Chilling Effect of Indirect Expropriation Clauses on Host States’ Public Policies: a Call for a Legislative Response” (2020) 22(2) International Community Law Review 235

-Mathumalar Loganathan Fahrni “Management of Covid-19 Vaccines Cold Chain Logistics: A Scoping Review” (2022) 15(1) Journal of Pharmaceutical Policy and Practice

-Mehr Muhammad Adeel Riaz and others “Global Impact of Vaccine Nationalism during COVID-19 Pandemic” (2021) 49(1) Tropical Medicine and Health 101

-Michael Boylan “Medical Pharmaceuticals and Distributive Justice” (2008) 17(1) Camb. Q. Healthc. Ethics 30

-Michael P. Ryan “Knowledge-Economy Elites, the International Law of Intellectual Property and Trade and Economic Development” (2002) 10 Cardozo J. Int'l & Comp. L. 271

-Muhammad Z.Abbas and Shamreeza Riaz “WTO “Paragraph 6” System for Affordable Access to Medicines: Relief or Regulatory Ritualism?” (2018) 21(1-2) The Journal of World Intellectual Property 32

-Nerina Boschiero “Covid-19 Vaccines as Global Common Goods: An Integrated Approach of Ethical, Economic Policy and Intellectual Property Management” (2021) Global Jurist 1

-Nicholas G. Vincent “Trip-ing Up: The Failure of Trips Article 31Bis ” (2020) 24(1) Gonzaga Journal of International Law 1

-Obiora Chinedu Okafor “Critical Third World Approaches to International Law (TWAIL): Theory, Methodology, or Both?” (2008) 10(4) ICLR 371

-Onora O’Neill “The Dark Side of Human Rights” (2002) 81(2) International Affairs 427-

-Peter Drahos “BITS and BIPS: Bilateralism in Intellectual Property” (2001) 4(6) The Journal of World Intellectual Property 791

-Peter Drahos “Developing Countries and International Intellectual Property Standard-Setting” (2002) 5(5) The Journal of World Intellectual Property 765

-Peter Drahos “Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines” (2007) 28(1) Liverpool Law Review 11

-Peter K. Yu “Currents and Crosscurrents in the International Intellectual Property Regime ” (2004) 38(1) Loy. L.A.L. Rev. 323

-Peter K. Yu “The Investment-Related Aspects of Intellectual Property Rights” (2017) 66(3) The American University Law Review 829

-Peter M. Beattie “The (Intellectual Property Law &) Economics of Innocent Fraud: The IP & Development Debate” (2007) 38 (1) IIC 6

-Prabhash Ranjan and Pushkar Anand “The 2016 Model Indian Bilateral Investment Treaty: A Critical Deconstruction” (2017) 38(1) Nw. J. Int'l L. & Bus 1

-Pratyush Nath Upreti “A TWAIL Critique of Intellectual Property and Related Disputes in Investor-State Dispute Settlement” (2022) 25(1) J World Intellect Prop 220

-Pratyush Nath Upreti “Intellectual Property Rights in Investor-State Dispute Settlement: Connecting the Dots Through the Philip Morris, Eli Lilly and Bridgestone Awards” (2020) 31(4) ARIA 338

-R. A. Mahshelkar “Intellectual Property Rights and the Third World” (2001) Current Science 81(8) 955

-R. J. Arneson “Primary Goods Reconsidered” (1990) 24(3) Noûs (Bloomington, Indiana) 429

-Raymond Yang Gao “What are We Talking About When We Talk About Deference in Investment Treaty Arbitration?” (2022) 13(3) Journal of International Dispute Settlement 472

-Richard T. Eastman and others “Remdesivir: A Review of Its Discovery and Development Leading to Emergency Use Authorization for Treatment of COVID-19” (2020) 6(5) ACS central science 672

-Robert Bird and Daniel R. Cahoy “The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach” (2008) 45(2) American Business Law Journal 283

-Robert P. Merges “The Relationship Between Foundations and Principles in IP law” (2012) 49(4) The San Diego Law Review 957

-Rochelle Dreyfuss and Susy Frankel “From Incentive to Commodity to Asset: How International Law is Reconceptualizing Intellectual Property” 2015 36(4) MIJL 557

-Rochelle Dreyfuss and Susy Frankel “Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It?” (2018) 21(2) Vanderbilt JET Law 377

-Rudolf Dolzer “Fair and Equitable Treatment: A Key Standard in Investment Treaties” (2005) 39(1) The International Lawyer 87

-Ruth L. Okediji “Is Intellectual Property “Investment"? Eli Lilly v. Canada and the International Intellectual Property System” (2014) 35(4) University of Pennsylvania Journal of International Law 1121

-Ruth L. Okediji “The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System” (2003) 7 SGJ IInt Comp Law 315

-Ruth Okediji “Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection” (2003-2004) 1 UOITJ 125

-Sigrid Sterckx, Lisa Diependaele and Julian Cockbain “Eli Lilly v Canada: The Uncomfortable Liaison Between Intellectual Property and International Investment Law” (2017) 7(3) QMJIP 283

-Silvia Steininger “What’s Human Rights Got to Do with It? An Empirical Analysis of Human Rights References in Investment Arbitration” (2018) 31(1) Leiden Journal of International Law 33

-Simon Caney “Global Interdependence and Distributive Justice” (2005) 31(2) RIS 389

-Simon Caney “International Distributive Justice” (2001) 49(5) Political Studies 974

-Siva Thambisetty and others “Addressing Vaccine Inequity During The Covid-19 Pandemic: The TRIPS Intellectual Property Waiver Proposal and Beyond” 2022 57(1) Cambridge Law Journal 1

-Stavros Tsakyrakis “Proportionality: An Assault on Human Rights?” (2009) 7(3) International Journal of Constitutional Law 468

-Stephan W. Schill “Deference in Investment Treaty Arbitration: Re-Conceptualising the Standard of Review” (2012) 3(3) Journal of International Dispute Settlement 577 at 581

-Susan D. Franck “The Legitimacy Crisis in Investment Treaty Arbitration: Privatizing Public International Law Through Inconsistent Decisions” (2005) 73(4) Fordham LR 1521

-Susy Frankel “Interpreting the Overlap of International Investment and Intellectual Property Law” (2016) 19(1) JIEL 121

-Suzanne A. Spears “The Quest for Policy Space in a New Generation of International Investment Agreements” (2010) 13(4) JIEL 1037

-Thomas Cottier and others “The Principle of Proportionality in International Law: Foundations and Variations ” (2017) 18 BRILL NIJHOFF 628

-Thomas Pogge “Are we Violating the Human Rights of the World’s Poor?” (2011) 14(2) 1

-Thomas Pogge and Krishen Mehta “A New Deal After COVID-19” (2022) 19(3) Globalizations 497

-Thomas W Pogge “An Institutional Approach to Humanitarian Intervention” (1992) 6(1) North American Philosophical Publications 89

-Thomas W. Pogge “Cosmopolitanism and Sovereignty” (1992) 103(1) Ethics 4

-Tim Hagemann “The North-South Divide of Regulatory Chill: A Comparative Analysis of the Impact of Investor-State Dispute Settlement on Policy Makers in Developed and Developing Countries” (2022) 35(1)

-Tom G. Palmer “Are Patents and Copyrights Morally Justified- The Philosophy of Property Rights and Ideal Objects” (1990) 13(3) Harv. J. L.& Pub. Pol. 817

-Tsai-Yu Lin “Compulsory Licences for Access to Medicines, Expropriation and Investor- State Arbitration Under Bilateral Investment Agreements- Are There Issues Beyond the TRIPS Agreement?” (2009) 40 Int’L Rev. Intell. Prop. & Competition Law 152

-Ursula Kriebaum “FET and Expropriation in the (Invisible) EU Model BIT” (2014) 15(3-4) 454

-Valentina Vadi “New Forms of Dialectics between Intellectual Property and Public Health: Pharmaceutical Patent-Related Investment Disputes” (2015) 49(2) The International Lawyer 149

-Wenhua Shan “From ‘North-South Divide’ to ‘Private-Public Debate’: Revival of the Calvo Doctrine and the Changing Landscape in International Investment Law” 2007 27(3) Northwestern Journal of International Law & Business 631

-Yuka Fukunaga “Margin of Appreciation as an Indicator of Judicial Deference: Is It Applicable to Investment Arbitration?” 2019 10(1) Journal of International Dispute Settlement 69

-Yuval Shany Toward a General Margin of Appreciation Doctrine in International Law?” (2006) 16(5) EJIL 907

Websites/ News/Press Releases

-“BioNTech, Pfizer Sue Curevac in U.S. Over COVID-19 Vaccine Patent Claims” *U.S. News* (online ed, 26 July 2022)

-“Covid-19 Related Information” (2022) Supreme Court of the Russian Federation <https://vsrf.ru/lk/practice/cases/11085980>

-“Energy Charter Treaty: Council gives final green light to EU’s withdrawal” Council of the EU (30 May 2024).

-“Finalisation of the negotiations on the Modernisation of the Energy Charter Treaty” (24 June 2022) ECT<https://www.energychartertreaty.org/modernisation-of-the-treaty/>

-“Fiocruz Releases first 100% Brazilian COVID-19 Vaccine” Fiocruz (press release, 22 February 2022)

-“Gilead Sciences Announces Steps to Expand Availabilit of Remdesivir in India” Gilead Sciences (press release, 26 April 2021)

-“Key Finding: Access Strategies: Less than Half of Key Products are Covered by Pharma Companies’ Access Strategies in Poorer Countries” (2021) Access to Medicine Foundation <https://accesstomedicinefoundation.org/access-to-medicine-index/results/less-than-half-of-key-products-are-covered-by-pharma-companies-access-strategies-in-poorer-countries>

-“Merck Signs Deals with Five Indian Firms to Boots supply of oral Covid-19 Drug” *Pharmaceutical Technology* (online ed, 28 Aril 2021)

-“Merck Signs Deals with Five Indian Firms to Boots supply of oral Covid-19 Drug” *Pharmaceutical Technology* (online ed, 28 Aril 2021)

-“More than half of Canada’s AstraZenaca vaccine doses expired, will be thrown out” *CTV News* (online ed, Canada, 6 July 2022)

-“Remdesivir: Five Indian and Pakistani Firms to Make Drug to ‘Fight Coronavirus’” *BBC News* (India 14 May 2020); Gilead Sciences “Gilead Sciences Announces Steps to Expand Availabilit of Remdesivir in India” (press release, 26 April 2021)

-“Remdesivir: Five Indian and Pakistani Firms to Make Drug to ‘Fight Coronavirus’” *BBC News* (India 14 May 2020)

-“Russia Allows Domestic Pharmaceutical to Continue Producing U.S. Company’s Covid-19 Drug” (31 December 2021) <https://www.rferl.org/a/russia-remdesivir-generic-patent/31634198.html>

-“Sanofi to Provide Manufacturing Support to Johnson& Johnson for their COVID-19 Vaccine to Help Address Global Supply Demands” (press release, 22 February 2021) <https://www.sanofi.com/en/media-room/press-releases/2021/2021-02-22-10-40-00-2179318>

-“Update: Ukrainian company Darnitsa signs sublicence agreement with MPP bringing to 36 the number of generic manufacturers to produce generic versions of Pfizer’s oral Covid-19 treatment” *Medicines Patent Pool* (online ed, 22 March 2022)<https://medicinespatentpool.org/news-publications-post/update-ukrainian-company-darnitsa-signs-sublicence-agreement-with-mpp-bringing-to-36-the-number-of-generic-manufacturers-to-produce-generic-versions-of-pfizers-oral-covid-19-treatment>

-“What to Know About the Different Covid-19 Vaccines” *Medical News Today* (29 March 2022) <https://www.medicalnewstoday.com/articles/which-covid-vaccine-is-best#summary>

-“WHO Covid-19 Dashboard” <https://data.who.int/dashboards/covid19/deaths?n=c>

-“WHO’s Tedros says COVID-19 Vaccine Inequity Creates ‘Two-Track’ Pandemic” (8 June 2021) Reuters

-“Why We’re Excited to Partner on Johnson & Johnson’s COVID-19 Vaccine” (10 March 2021) <https://www.merck.com/stories/why-were-excited-to-partner-on-johnson-and-johnsons-covid-19-vaccine/>

-*A Double Dose of Inequality* (Amnesty International, POL 40/4621/2021, 22 September 2021)

-Allen and Clarke Policy and Regulatory Specialists Limited “Submissions Analysis on The Proposal to Introduce Plain Packaging of Tobacco Products in New Zealand” (21 November 2012) Ministry of Health <https://www.health.govt.nz/system/files/documents/pages/plain-packaging-submission-analysis-a-c.doc>

-Amy Maxmen “The WHO’s Push for Global mRNA Vaccine Access: Will the WHO hub Realise its Vision Before the Next Global Health Crisis?” (26 February 2024) Think Global Health <https://www.thinkglobalhealth.org/article/whos-push-global-mrna-vaccine-access>

-Angus Liu “BioNTech, Fosun Pharma eye 1B doses of COVID-19 Vaccine Capacity with new China JV” (10 May 2021) Fierce Pharma <https://www.fiercepharma.com/manufacturing/biontech-fosun-pharma-eye-1b-doses-covid-19-vaccine-capacity-new-china-jv>

-Anna Holmes “A company that bought Theranos’ Patents is using them to sue a health Start-up Working on coronavirus tests” (18 March 2020) Insider <https://www.businessinsider.com/theranos-patents-fortress-labrador-diagnostics-lawsuit-biofire-coronavirus-tests-2020-3?r=US&IR=T>

-APEC Intellectual Property Rights Experts Group “Patent Linkage System for Intellectual Property Rights and Public Health Harmonisation” (July 2023) < https://www.apec.org/docs/default-source/publications/2023/7/223_ipeg_patent-linkage-system-for-intellectual-property-rights-and-public-health-harmonisation.pdf?sfvrsn=bc4d2712_2>

-April 27, 2016 Letter from Colombian Embassy regarding Senate Finance, USTR pressure on Novartis compulsory license” (11 May 2016) Knowledge Ecology International < https://www.keionline.org/23082>.

-Arthur Nelson “TTIP: Chevron Lobbied for Controversial Legal Rights as ‘Environmental Deterrent’” *The Guardian* (online ed, 26 April 2016).

-Ashleigh Furlong “Moderna to Share Vaccine tech, Commits to Never Enforce COVID-19 Jab Patents” *Politico* (online ed, 8 March 2022)

-AstraZeneca “Serum Institute of India Obtains Emergency Use Authorisation in India for AstraZeneca’s COVID-19 vaccine” (press release, 6 January 2021)

-Australian Government “CPTPP Suspension Explained” <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-suspensions-explained#:~:text=What%20are%20the%20suspended%20provisions%3F&text=Each%20CPTPP%20Party%20has%20agreed,at%20%241%2C000%20under%20Australian%20law.>

-Australian Government Department of Foreign Affairs and Trade “CPTPP suspensions explained” <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-suspensions-explained>

-Australian Government Department of Foreign Affairs and Trade “CPTPP Suspension Explained” (January 2019) <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/outcomes-documents/Pages/cptpp-suspensions explained#:~:text=What%20are%20the%20suspended%20provisions%3F&text=Each%20CPTPP%20Party%20has%20agreed,at%20%241%2C000%20under%20Australian%20law.>

-Australian Government Department of Foreign Affairs and Trade “CPTPP Text and Associated Documents” <https://www.dfat.gov.au/trade/agreements/in-force/cptpp/official-documents>

-Bernard Caillaud and Ariane Lambert- Mogiliansky *Pro- business Arbitration with ISDS* (HAL Working Paper No 2022-28 December 2023); Amanda Lees and Others “Suitability of ISDS for Societal Challenges” (21 December 2023) Gar <https://globalarbitrationreview.com/guide/the-guide-investment-treaty-protection-and-enforcement/second-edition/article/suitability-of-isds-societal-challenges>

-BioNTech “BioNTech and Fosun Pharma form COVID-19 Vaccine Strategic Alliance in China” (press release, 16 March 2020)

-Blake Brittain “Pfizer, BioNTech Countersue Moderna over Covid-19 Vaccine Patents” (2 December 2022) <https://www.reuters.com/legal/pfizer-biontech-countersue-moderna-over-covid-19-vaccine-patents-2022-12-05/>

-Bob Herman “Biden admin warns Moderna to “Step-Up” Global Vaccine Supply” (14 October 2021) AXIOS <https://www.axios.com/2021/10/13/covid-vaccine-moderna-biden-global-supply-covax>.

-Businesswire “Governments Spent at Least €93bn on COVID-19 Vaccines and Therapeutics During the Last 11 Months” (11 January 2021) <https://www.businesswire.com/news/home/20210110005098/en/Governments-Spent-at-Least-€93bn-on-COVID-19-Vaccines-and-Therapeutics-During-the-Last-11-Months>

-Carl Zimmer and Rebecca Robbins “Pfizer’s Covid Pill Works Well, Company Confirms in Final Analysis” *The New York Times* (online ed, 14 December 2021)

-Carmen Paun and Ashleigh Furlong “Poorer countries hit with higher price tag for Oxford/AstraZeneca vaccine” *Politico* (online ed, 22 February 2021)

-Christopher Rowland and Laurie McGinley “Merck will help make Johnson & Johnson Coronavirus Vaccine as Rivals team up to help Biden accelerate shots” *The Washington Post* (3 March 2021)

-Ciar Global “Bolivia Descarte El Arbitraje De 27 MUSD Con Rusia Por Vacunas Sputnik” (12 Mayo 2024) <https://ciarglobal.com/bolivia-descarta-el-arbitraje-de-27-musd-con-rusia-por-vacunas-sputnik/>

-Corporate Europe Observatory “How Big Pharma Sabotaged the Struggle for Affordable Cancer Treatment” (June 2019) <https://corporateeurope.org/sites/default/files/2019-06/Novartis%20vs%20Colombia.pdf>.

-CureVac “CureVac Files Patent Infringement Lawsuit in Germany Against BioNTech” (press release, 5 July 2022)

-Cynthia Ho “Inside Views: TRIPS Flexibilities Under Threat from Investment Disputes: A Closer Look at Canada’s “Win” Against Eli Lilly” (27 April 2017) Intellectual Property Watch < https://www.ip-watch.org/2017/04/27/trips-flexibilities-threat-investment-disputes-closer-look-canadas-win-eli-lilly/>

-Daniel Boffey “EU threatens to block Covid Vaccine Exports amid AstraZeneca Shortfall” *Guardian* (online ed, Brussels, 25 January 2021)

-Daniel Hurst, Paul Karp and Christopher Knaus “Scott Morrison calls on European Union to supply outstanding AstraZeneca Covid vaccine doses” *Guardian* (online ed, 7 Wednesday 2021)

-Dave Keating “EU Governments Under Pressure to Quit Energy Charter Treaty” (10 December 2019) Forbes <https://www.forbes.com/sites/davekeating/2019/12/10/eu-governments-under-pressure-to-quit-energy-chartertreaty/#323ad9bf63ed>

-David Goldman Alabama Just Tossed 65,000 Vaccines. Turns Out It’s Not Easy To Donate Unused Doses” *NPR* (online ed, 10 August 2021) <https://www.npr.org/sections/goatsandsoda/2021/08/10/1025463260/alabama-just-tossed-65-000-vaccines-turns-out-its-not-easy-to-donate-unused-dose?t=1659105449311>

-David Meyer “Its COVID-19 Vaccine Bogged down in trials, Sanofi to Manufacture BioNTech/Pfizer Doses” *Fortune* (11 September 2021)

-Debevoise& Plimption “From NAFTA to USMCA: Main Changes to the Investor- Dispute Settlement System” (7 May 2020) <https://www.debevoise.com/insights/publications/2020/05/from-nafta-to-usmca-main-changes-to-the-investor>

-Deborah Gleeson and Brigitte Tenni “While Australians line up for COVID-19 boosters, low vaccination rates in poor countries continue to cost lives” *Conversation* (online ed, 18 July 2022)

-Donato Paolo Mancini “AbbVİe Drops Patent Rights for Kaletra Antiviral Treatment” *Financial Times* (UK 23 March 2020) <https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b>

-Donato Paolo Mancini, Hannah Kuchler and Mehreen Khan “Pfizer and Moderna raise EU vaccine prices” *Financial Times* (online ed, 1 August 2021)

-Editoral 1Covid-19: India Records New Case High as Brazil Registers Deadliest Month1 *EuroNews* (India, 30 April 2021) <https://www.euronews.com/2021/04/30/covid-19-india-records-new-case-high-as-brazil-registers-deadliest-month>

-Editorial “India Sends Termination Notices to 68 Countries with a Request to Renegotiate” *Investment Treaty News* (online ed, 1 July 2023)

-Editorial “India Sends Termination Notices to 68 Countries with a Request to Renegotiate” *Investment Treaty News* (online ed, 1 July 2023)

-*Eli Lilly v Canada*: A Pyrrhic Victory Against Big Pharma (26 March 2017) International Economic Law and Policy Blog <https://worldtradelaw.typepad.com/ielpblog/2017/03/eli-lilly-v-canada-a-pyrrhic-victory-against-big-pharma-.html>

-Emergency “Pharmaceutical Companies Reaping Immoral Profits from Covid Vaccines yet Paying Low Tax Rates” (15 September 2021)<https://en.emergency.it/press-releases/pharmaceutical-companies-reaping-immoral-profits-from-covid-vaccines-yet-paying-low-tax-rates/>

-Emmanuel Kolawole Oke “Can States Invoke the National Security Exception in the TRIPS Agreement in Response to Covid-19” (7 October 2020) <https://www.afronomicslaw.org/2020/10/06/can-states-invoke-the-national-security-exception-in-the-trips-agreement-in-response-to-covid-19/>

-Eric Sagonowsky “After Pfizer deal, Sanofi offers a hand to Johnson& Johnson for COVID-19 vaccine production” (22 February 2021) <https://www.fiercepharma.com/pharma/after-pfizer-deal-sanofi-offers-a-hand-to-johnson-johnson-for-covid-19-vaccine-production>

-Eric Sagonowsky “Pfizer eyes higher prices for COVID-19 vaccine after the pandemic wanes: exec, analyst” (23 February 2021) Fierce Pharma <https://www.fiercepharma.com/pharma/pfizer-eyes-higher-covid-19-vaccine-prices-after-pandemic-exec-analyst>

-Fabian Flues *Coal Ransom: How the Energy Charter Treaty Drove up the Costs of the German Coal Phase-Out* (Business& Human Rights Resource Centre, 22 April 2022)

-Fraiser Kansteiner “J&J pauses COVID-19 vaccine production at Dutch plant in temporary pivot to RSV shot: NYT” (8 February 2022) Fierce Pharma <https://www.fiercepharma.com/manufacturing/j-j-temporarily-freezes-covid-19-vaccine-production-at-key-leiden-plant-report>

-Fraiser Kansteiner “Moderna Mounts Defense in Covid-19 Vaccine Patent Feud with Arbutus, Gevenant” (10 May 2022) Fierce Pharma <https://www.fiercepharma.com/pharma/moderna-mounts-defense-covid-19-vaccine-patent-feud-arbutus-genevant>

-Fraiser Kansteiner “U.K. inspects AstraZeneca vaccine partner’s India manufacturing, setting stage for supply boost” (16 February 2021) Fierce Pharma <https://www.fiercepharma.com/manufacturing/serum-institute-india-up-for-british-audit-as-astrazeneca-looks-to-boost-covid-19>

-Fraser Kansteiner “Moderna Mounts 2 New Patent Lawsuits Against mRNA Rivals Pfizer, BioNTech: Report” (11 July 2023) Fierce Pharma <https://www.fiercepharma.com/pharma/covid-vaccine-patent-war-heats-moderna-mounts-additional-infringement-lawsuits-against>

-Gavi “Gavi and Moderna Reach Agreement for Additional Supply to COVAX” (10 December 2021) <https://www.gavi.org/news/media-room/gavi-and-moderna-reach-agreement-additional-supply-covax>

-Gilead Sciences “Gilead Sciences Announces Steps to Expand Availabilit of Remdesivir in India” (press release, 26 April 2021)

-Gordon Brown “The World is Making Billions of Covid Vaccine Doses, so Why is Africa Not Getting Them?” *Guardian* (16 August 2021)

-GOV.UK “Covid-19: Epidemology, Virology, and Clinical Features” (17 May 2022) <https://www.gov.uk/government/publications/wuhan-novel-coronavirus-background-information/wuhan-novel-coronavirus-epidemiology-virology-and-clinical-features>

-Government of Canada “About the Comprehensive and Progressive Agreement for Trans-Pacific Partnership” (23 January2024)<https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/backgrounder-document_information.aspx?lang=eng>

-Government of Canada “CPTPP explained” (28 August 2023) < https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/cptpp-ptpgp/cptpp_explained-ptpgp_apercu.aspx?lang=eng>

-Government of Canada “Facts about Tobacco Products Regulations (Plain and Standardized Appearance)” (9 January2020) <https://www.canada.ca/en/healthcanada/services/healthconcerns/tobacco/legislation/federalregulations/productsregulations-plain-standardized-appearance/facts.html>

-Government of Canada “View the timeline” (26 October 2023) <https://www.international.gc.ca/trade-commerce/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/view_timeline-consultez_chronologie.aspx?lang=eng>

-Government of the Russian Federation Order No.3718-r (31 December 2020) <http://actual.pravo.gov.ru/text.html#pnum=0001202101050003>

-Hannah Balfour “Gilead to Support Indian Covid-19 Crisis with Donation of Remdesivir” *European Pharmaceutical Review* (online ed, 27 April 2021)

-Hapai Te Hauro Maori Publi Health “New study finds tobacco industry delayed New Zealand plan packs legislation” (16 April 2018) NZ Doctor Rata Aotearoa <https://www.nzdoctor.co.nz/article/undoctored/new-study-finds-tobacco-industry-delayed-new-zealand-plain-packs-legislation>

-Heidi Ledford “What the Moderna- NIH COVID Vaccine Patent Fight Means for Research” (30 November 2021) Nature <https://www.nature.com/articles/d41586-021-03535-x>

-Helen Lock “Vaccine Nationalism: Everything You Need to Know” (12 February 2021) Global Citizen <https://www.globalcitizen.org/en/content/what-is-vaccine-nationalism/>

-IISD “9th Annual Forum of Developing Country Investment Negotiators” < https://www.iisd.org/events/9th-annual-forum-developing-country-investment-negotiators>

-International Monetary Fund “Globalisation: A Brief Overview” (May 2008) <https://www.imf.org/external/np/exr/ib/2008/053008.htm>

-Investment Policy Hub “International Investment Agreements Navigator: Terminology” <https://investmentpolicy.unctad.org/international-investment-agreements>

-James Love “Remuneration Guidelines for Non- Voluntary Use of a Patent” (WHO/TCM/2005.1,2005) WHO/UNDP<https://iris.who.int/bitstream/handle/10665/69199/WHO_TCM_2005.1_eng.pdf>

-Jillian Deutsch “Moderna Accused of Parking Vaccine Profits in Tax Heavens: Report” (13 July 2021) Politico < https://www.politico.eu/article/moderna-vaccine-profits-tax-havens/>.

-Joe Miller “German City Reaps Tax Windfall from BionTech’s Covid Vaccine Success” (26 December 2021) Financial Times <https://www.ft.com/content/5a705ebc-ce1f-4525-8406-d2875a32c473>

-John Oliver “Tobacco: Last Week Tonight with John Oliver (HBO)” YouTube (15 February 2015) < https://www.youtube.com/watch?v=6UsHHOCH4q8>

-Kate Kelland “Gates and Bloomberg create $4 million fund to fight Big Tobacco” (19 March 2015) Reuters <https://www.reuters.com/article/us-health-tobacco-fund/gates-and-bloomberg-create-4-million-fund-to-fight-big-tobacco-idUSKBN0ME24C20150318>

-Katherine Tai “Statement from Ambassador on the Covid-19 TRIPS Waiver” (press release,05 May 2021) <https://ustr.gov/about-us/policy-offices/press-office/press-releases/2021/may/statement-ambassador-katherine-tai-covid-19-trips-waiver>

-Kerry Cullinan “Pfizer and Medicines Patent Pool Reach ‘Ground-breaking’ Voluntary Licensing Deal for New COVID-19 Treatment Pill” (16 November 2021) Health Policy Watch <https://healthpolicy-watch.news/pfizer-and-medicines-patent-pool/>

-Kevin Dunleavy “CureVac’s Patent Infringements Case against BioNTech has $500 M of ‘Potential Upside’: Analyst” (12 July 2022) Fierce Pharma <https://www.fiercepharma.com/pharma/curevacs-patent-infringement-case-against-biontech-has-500-million-potential-upside-analyst>

-Kevin Dunleavy “Merck plant in Durham, N.C. gets $105M to upgrade for J&J Vaccine Production” (11 March 2021) Fierce Pharma <https://www.fiercepharma.com/manufacturing/merck-plant-durham-n-c-set-to-produce-bulk-substance-for-j-j vaccine#:~:text=Manufacturing,Merck%20plant%20in%20Durham%2C%20N.C.%20gets%20%24105M,upgrade%20for%20J%26J%20vaccine%20production&text=On%20Wednesday%20afternoon%20President%20Joe,million%20shots%20from%20the%20drugmaker>

-Kevin Dunleavy “Moderna, amid mounting pressure to address vaccine inequality, says it’s working on new COVAX deal” (16 November 2021) <https://www.fiercepharma.com/pharma/under-pressure-moderna-talks-to-pledge-covid-19-vaccines-to-poor-countries-report>

-Kevin Dunleavy “Moderna, U.S. clash in patent dispute over origins of COVID-19 vaccine: report” (10 November 2021) Fierce Pharma <https://www.fiercepharma.com/pharma/moderna-u-s-clash-patent-dispute-over-development-covid-19-vaccine-report>

-Knowledge Portal on Innovation and Access to Medicines “Covid-19 Vaccine R&D Investments” (8 July 2021) <https://www.knowledgeportalia.org/covid19-r-d-funding>

-Leng Shumei “China Approves 7th Self-Developed Covid-19 Vaccine, can Cross-Neutralize Variants” *Global Times* (online ed, China) <https://www.globaltimes.cn/page/202106/1225877.shtml>

-Letter from Michael O’Shaughnessy to Jose Miguel Ahumana Franvco (17 February 2023) <https://www.subrei.gob.cl/docs/default-source/tratado-tpp11/nz-cl-(isds).pdf?sfvrsn=ce9347e_2>

-Luke Eric Peterson and Zoe Williams “Gilead Pharma corp withdraws investment arbitration after Ukraine agrees to settlement of dispute over monopoly rights to market anti-viral drug” (16 March 2017) ISDS Platform <http://isds.bilaterals.org/?gilead-pharma-corp-withdraws>

-Make Medicines Affordable “MPP- Merck Molnupiravir License Reveals the Limits of Voluntary Measures During a Pandemic” (29 October 2021) <https://makemedicinesaffordable.org/mpp-merck-molnupiravir-license-reveals-the-limits-of-voluntary-measures-during-a-pandemic/>

-Maria Chaplia “TRIPS: Developing countries will not benefit from IP waived vaccines” (15 June 2022) The Parliament <https://www.theparliamentmagazine.eu/news/article/trips-developing-countries-will-not-benefit-from-ip-waived-vaccines>

-Marijn Vernoef “Which Information Matters Most? Transparency by Pharma that Builds Access to Medicine Plus Trust and Engagement” (2 October 2020)<Access to Medicine Foundation https://accesstomedicinefoundation.org/news/which-information-matters-most-transparency-by-pharma-that-builds-access-to-medicine-plus-trust-and-engagement#:~:text=Greater%20transparency%20brings%20direct%20benefits,can%20lead%20to%20new%20solutions.>

-Marisa Woutersen “BioNTech Wins Latest Round in Covid-19 Patent Clash” (21 December 2023) LSIPR <https://www.lifesciencesipreview.com/big-pharma/biontech-wins-latest-round-in-covid-19-patent-clash-5328>

-Mark Peterson “Global Vaccine Divide- More Science Collobarotaion Needed” *University World News* (Global, 2 April 2021) <https://www.universityworldnews.com/post.php?story=20210402151906225>

-Max Roser and Hannah Ritchie “HIV/AIDS is one of the world’s most fatal infectious disease” (November 2014, revised November 2019) Our World in Data < https://ourworldindata.org/hiv-aids>

-Médecins Sans Frontières “1998: Big Pharma versus Nelson Mandela” (20 February 1998) <https://www.msfaccess.org/1998-big-pharma-versus-nelson-mandela>

-Medicines Patent Pool “27 Generic Manufacturers Sign Agreements with MPP to Produce Low-Cost Versions of COVIP-19 Antiviral Medication Molnupiravir for Supply in 105 Low-and- Middle- Income Countries” (20 January 2022) <https://medicinespatentpool.org/news-publications-post/27-generic-manufacturers-sign-agreements-with-mpp-to-produce-molnupiravir>

-Medicines Sans Frontières “Compulsory Licences, the TRIPS Waiver, and Access to COVID-19 Medical Technologies, MSF Briefing Document” (May 2021) <https://msfaccess.org/compulsory-licenses-trips-waiver-and-access-covid-19-medical-technologies>

-Medicines Sans Frontières “License between Merck and Medicines Patent Pool for global production of promising new Covid-19 drug Molnupiravir disappoints in its access limitations” (27 October 2021) <https://msfaccess.org/license-between-merck-and-medicines-patent-pool-global-production-promising-new-covid-19-drug>

-Medicines Sans Frontières “Moderna posts billions in profit from Covid-19 vaccine but won’t share technology” (4 November 2021) <https://www.doctorswithoutborders.org/latest/moderna-posts-billions-profit-covid-19-vaccine-wont-share-technology>

-Medicines Sans Frontières “South Africa should override patent on key HIV medicine after widespread stock out problem” (27 October 2015) <https://www.msf.org/south-africa-should-override-patent-key-hiv-medicine-after-widespread-stock-out-problem>

-Micheal Safi “Oxford/AstraZeneca Covid Vaccine Research ‘was 97% Publicly Funded’” *Guardian* (online ed, 15 April 2021)

-MSF “MSF welcome Fiocruz’s step Towards Transparency of AstraZenaca Deal” MSF (press release, 3 November 2020)

-Myre Davies “Michael Bloomberg fights big tobacco in Uruguay” *BBC* (Rio de Janeiro, 7 April 2015)

-Nature “Covid vaccine IP waiver agreed” (online ed, 13 April 2022)

-New Zealand Foreign Affairs & Trade “Comprehensive and Progressive Agreement for Trans-Pacific Partnership texts” <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/comprehensive-and-progressive-agreement-for-trans-pacific-partnership-text-and-resources/>

-New Zealand Foreign Affairs & Trade “Comprehensive and Progressive Agreement for Trans-Pacific Partnership” <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/cptpp-overview/>

-New Zealand Foreign Affairs & Trade “CPTPP vs TPP” <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/understanding-cptpp/cptpp-vs-tpp/>

-New Zealand Foreign Affairs& Trade “Investment and ISDS” <https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/understanding-cptpp/investment-and-isds/>

-New Zealand Intellectual Property Office “History of IP in New Zealand” (2024) <https://www.iponz.govt.nz/about-iponz/history-of-ip-in-new-zealand/>

-NHS “Coronavirus (COVID-19) vaccine” <https://www.nhs.uk/conditions/coronavirus-covid-19/coronavirus-vaccination/coronavirus-vaccine/>

-Nicole Wetsman “A SoftBank-owned company used Theranos patents to sue over COVID-19 tests” (19March 2020) The Verge https://www.theverge.com/2020/3/18/21185006/softbank-theranos-coronavirus-covid-lawsuit-patent-testing OCHA “MSF Responds to FDA Approval of COVID-19 Treatment Nirmatrelvir/Ritonavir” (22 December 2021)ReliefWeb<https://reliefweb.int/report/world/msf-responds-fda-approval-covid-19-treatment-nirmatrelvirritonavir>

-Novartis “Novartis Signs New Initial Agreement with BioNTech to Support Fill and Finish of the mRNA Pfizer- BioNTech COVID-19 Vaccine” (21 October 2021) <https://www.novartis.com/news/media-releases/novartis-signs-new-initial-agreement-biontech-support-fill-and-finish-mrna-pfizer-biontech-covid-19-vaccine>

-Office of the United States Trade Representative “Unites States- Mexico- Canada Agreement” < https://ustr.gov/trade-agreements/free-trade-agreements/united-states-mexico-canada-agreement>.

-Othoman Mellouk “The Covid Treatment Pill is here- and Big Pharma will Ultimately Decide Who Gets it” *Guardian* (online ed, 20 February 2022)

-Our World in Data “Coronavirus (COVID-19) Vaccinations” <https://ourworldindata.org/covid-vaccinations>

-OXFAM International “COVID-19 Death toll Four times Higher in Lower- Income Countries than Rich One” (press release, 3 March 2022)

-Pearl Cohen Zedek Latzer Baratz “IP Rights for COVID-19 Vaccines: Worldwide Stakes of Israeli Compulsory Licences” (19 July 2021) Lexology <https://www.lexology.com/commentary/intellectual-property/israel/pearl-cohen-zedek-latzer-baratz/ip-rights-for-covid-19-vaccines-worldwide-stakes-of-israeli-compulsory-licences>

-Peter Sullivan “Biden official warns Moderna to ‘step up’ on vaccine doses for the world” *The Hill* (online ed, 13 October 2021)

-Phil Taylor “BioNTech Wins Round in CureVac mRNA Patent Dispute” (20 December 2023) Pharmaphorum <https://pharmaphorum.com/news/biontech-wins-round-curevac-mrna-patent-dispute#:~:text=Shares%20in%20CureVac%20have%20plummeted,COVID%2D19%20vaccines%20was%20invalid.>

-Pooja Tidke and others “Evergreening of Patents” (19 May 2023) Lexology <https://www.lexology.com/library/detail.aspx?g=aacfd802-52e1-4468-b71e-6a6a2d2c513b>

-Public Citizen Memorandum “*Occidental v Ecuador* Award Spotlights Perils of Investor-State System: Tribunal Fabricated a Proportionality Test to Further Extend the FET Obligation and Used “Egregious” Damages Logic to Hit Ecuador with $2.4 Billion Penalty in Largest Ever ICSID Award.”

-Rebecca Robbins “Analysis: Moderna, Racing for Profits, Keeps COVID Vaccine Out of Reach of Poor” *Next Billion* (online ed, 13 October 2021)

-Records New Case High as Brazil Registers Deadliest Month1 *EuroNews* (India, 30 April 2021) <https://www.euronews.com/2021/04/30/covid-19-india-records-new-case-high-as-brazil-registers-deadliest-month>

-Reuters “Gilead Says Signed Non-Exclusive Voluntary Licencing Agreements with 5 Generic Pharmaceutical Manufacturers based in India, Pakistan to Further Expand Supply of Remdesivir” (14 May 2020) <https://www.reuters.com/article/idUSFWN2CU0RP/>

-Reuters “Russia Extends Production of Covid-19 Drug Remdesivir without Patent for a Year” (30 December 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/russia-extends-production-covid-19-drug-remdesivir-without-patent-year-2021-12-30/>

-Reuters “South Africa’s Biovac to Start Making Pfizer- Biontech COVID-19 vaccine in early 2022” (7 December 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/south-africas-biovac-start-making-pfizer-biontech-covid-19-vaccine-early-2022-2021-12-06/>

-Reuters “South African Firm to Help make Pfizer/BioNTech COVID Vaccine” (22 July 2021) <https://www.reuters.com/business/healthcare-pharmaceuticals/pfizerbiontech-strike-south-africa-covid-19-manufacturing-deal-with-biovac-2021-07-21/>

-Richard A. Morgan “Three Countries, One Environment: Environmental Cooperation and Free Trade in North America” (28 July 2021) IISD < https://www.iisd.org/articles/environmental-cooperation-free-trade-north-america>

-Richard Llyod “After Theranos suit, Fortress makes Patent available on Royalty-Free Basis for COVID-19 Tests” (17 March 2020) IAM <https://www.iam-media.com/article/after-theranos-suit-fortress-makes-patents-available-royalty-free-basis-covid-19-tests>

-Rosa Balfour, Lizza Bomassi and Marta Martinelli *Coronavirus and the Widening Global North-South Gap* (Carnegie Europe, April 2022)

-Russian Government Advised- ‘Issue Compulsory Licence to Make Generic Covid-19 Drug Available’”(6 November 2020) -Make Medicine Affordable <https://makemedicinesaffordable.org/russian-government-advised-issue-compulsory-license-to-make-generic-covid-19-drug-available/>

-Saba Aziz “With Millions of Covid-19 Doses Wasted, Has Canada Kept its Donation Promises?” *Global News* (online ed, 9 December 2022)

-Samuel Lovett “An absolute scandal’: UK threw away 600,000 vaccine doses after they passed expiry date” *Independent* (online ed, 15 November 2021); Joshua Eaton “The U.S. has wasted over 82 million Covid vaccine doses” *NBC News* (online ed, 6 June 2022)

-Sanofi “Sanofi to Provide Support to BioNTech in Manufacturing their COVID-19 Vaccine to help Address Public Health needs” (press release, 27 January 2021)

-Sanofi “Sanofi- GSK Next Generation COVID-19 Booster Delivers Strong Immune Response against Variants of Concern, including Omicron” (press release, 13 June 2022)

-Selin Sinem Erciyes “Determination of Royalty in Case of Compulsory Licence” (03 March 2022) Gun + Partners <https://gun.av.tr/insights/articles/determination-of-royalty-in-case-of-compulsory-license>

-Shilpa Singh Jaswant “Analyzing Features of Investment Court System under CETA and EUIPA: Discussing Improvement in the System and Clarity to Clauses” (8 February 2019) Kluwer Arbitration Blog <https://arbitrationblog.kluwerarbitration.com/2019/02/08/analyzing-features-of-investment-court-system-under-ceta-and-euvipa-discussing-improvement-in-the-system-and-clarity-to-clauses/>

-Simon Hitchens and David Turgeon “The Impact of CETA and Bill C-30 on Canada’s IP Landscape: Important Changes to Canadian Patent and Trademark Laws” (5 December 2016) Fasken <https://www.fasken.com/en/knowledge/2016/12/intellectualpropertybulletin-20161205>

-Stefan Anderson “No Pandemic Accord Without Intellectual Property Protection, says German Health Minister” Health Policy Watch (16 October 2023) <https://healthpolicy-watch.news/no-pandemic-accord-without-intellectual-property-protection-says-german-health minister/#:~:text=%E2%80%9CFor%20countries%20like%20Germany%20and,property%20rights,%E2%80%9D%20said%20Lauterbach>

-Stefan Riegler, Dalibor Valincic and Borna Dejanovic “Applicable Law in Investment Treaty Arbitration” (14 January 2022) GAR Global Arbitration Review < https://globalarbitrationreview.com/guide/the-guide-investment-treaty-protection-and-enforcement/first-edition/article/applicable-law-in-investment-treaty-arbitration>

-Stephanie Pilkington “Insight: Remdesivir and the Role of Patents in Tackling Covid-19” *Bloomberglaw* (online ed, 17 July 2020)

-Thiru “Hungarian Compulsory License for Remdesivir Raises a Stir with BIO, PhRMA and the US Chamber of Commerce” (8 March 2021) KEI < https://www.keionline.org/35558>

-Tony Dymond, Cameron Sim and Tiffany Chan “Dispute settlement mechanisms under the CPTPP and the RCEP” (27 May 2022) Global Arbitration Review <https://globalarbitrationreview.com/review/the-asia-pacific-arbitration-review/2023/article/dispute-settlement-mechanisms-under-the-cptpp-and-the-rcep>

-Transparency International “Corruption Perception Index: Chile” <https://www.transparency.org/en/cpi/2023/index/chl>

-Transparency International “Corruption Perception Index” < https://www.transparency.org/en/cpi/2023>

-UN “WHO Chiefs Declares end to COVID-19 as a Global Health Emergency” (5 May 2023) <https://news.un.org/en/story/2023/05/1136367>

-UN Trade& Development, Investment Policy Hub, Investment Dispute Settlement Navigator “Cases as Respondent State: Canada” (1 December 2023) < https://investmentpolicy.unctad.org/investment-dispute-settlement/country/35/canada>

-UNCTAD Investment Policy Hub “International Investment Agreement Navigator” <https://investmentpolicy.unctad.org/international-investment-agreements/model-agreements>

-Victoria Rees “Gilead Prices Remdesivir at $2,340 per Patient for Developed Countries” *European Pharmaceutical Review* (online ed, 30 June 2020)

-William Honaker “NIH’s fight for Ownership of Moderna’s COVID-19 Patent Highlights Hazards of Business Collaborations (31 March 2022) IP Watch Dog <https://www.ipwatchdog.com/2022/03/31/nihs-fight-ownership-modernas-covid-19-patent-highlights-hazards-business-collaborations/id=148040/#>

-World Health Organisation “Global Observatory on Health R&D” (2021) <https://www.who.int/research-observatory/why_what_how/en/>

-World Health Organisation “Health Inequities and Their Causes” (22 February 2018) <https://www.who.int/news-room/facts-in-pictures/detail/health-inequities-and-their-causes>

-World Health Organisation “Listing of WHO’s response to Covıd-19” (29 January 2021) <https://www.who.int/news/item/29-06-2020-covidtimeline>

-World Health Organisation “Pandemic prevention, preparedness and response accord” (23 June 2023) <https://www.who.int/news-room/questions-and-answers/item/pandemic-prevention--preparedness-and-response-accord>

-World Health Organisation “The Moderna COVID-19 Vaccine: What you need to Know” (18 August 2022) <https://www.who.int/news-room/feature-stories/detail/the-moderna-covid-19-mrna-1273-vaccine-what-you-need-to-know>

-World Health Organisation “The Oxford/AstraZeneca COVID-19 Vaccine: What you Need to Know” (13 June 2022) <https://www.who.int/news-room/feature-stories/detail/the-oxford-astrazeneca-covid-19-vaccine-what-you-need-to-know>

-World Health Organization “WHO recommends highly successful COVID-19 Therapy and Calls for wide Geographical Distribution and Transparency from Originator” (22 April 2022) <https://www.who.int/news/item/22-04-2022-who-recommends-highly-successful-covid-19-therapy-and-calls-for-wide-geographical-distribution-and-transparency-from-originator>

-World Intellectual Property Organisation “Paris Convention for the Protection of Industrial Property” < https://www.wipo.int/treaties/en/ip/paris/#:~:text=This%20international%20agreement%20was%20the,were%20protected%20in%20other%20countries.>

-World Intellectual Property Organisation “What is Intellectual Property?” <https://www.wipo.int/about-ip/en/>

-World Trade Organisation “Compulsory Licencing of Pharmaceuticals and TRIPS” <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm#:~:text=The%20TRIPS%20Agreement%20does%20list,holder%20on%20reasonable%20commercial%20terms>

-World Trade Organisation “TRIPS and Public Health” <https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm>

-World Trade Organization “Members and Observers” (26 July 2016) <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm>

-World Trade Organization “TRIPS, the Intellectual Property System and Covid-19” (2023) <https://www.wto.org/english/tratop_e/trips_e/trips_and_covid19_e.htm>

-Zachary Snowdon Smith “Johnson& Johnson Reportedly Pauses Covid Vaccine Production Despite Sharp Need in Developing Countries” *Forbes* (9 February 2022)

-Zoey Becker “Alnylam Sticks with Aggressive Litigation Strategy against Pfizer and Moderna, filing yet another Patent Lawsuit” (30 May 2023) <https://www.fiercepharma.com/pharma/alnylam-hopes-third-times-charm-another-covid-19-vaccine-suit-against-pfizer-moderna>

-Zoey Becker “Alnylam to Appeal Covid-19 Vaccine Patent Ruling in Moderna Case” (28 August 2023) <https://www.fiercepharma.com/pharma/alnylam-appeal-covid-19-vaccine-patent-ruling-moderna-case>

-Zoey Becker “Clash of the titans: Moderna Sues Pfizer, BioNTech for mRNA Patent Infringement” (26 August 2022) Fierce Pharma <https://www.fiercepharma.com/pharma/clash-titans-moderna-sues-pfizer-and-biontech-patent-infringement>

-Zoey Becker “Moderna Loses a Covid Vaccine Patent in Europe Amid Heated Clash with BioNTech, Pfizer” (21 November 2021) <https://www.fiercepharma.com/pharma/covid-19-patent-war-rages-biontech-win-moderna-european-patent-ruled-invalid>

-Zoey Becker “Moderna Nabs a Win in Arbutus Patent Case as Appeals Court Upholds Prior Invalidation” (12 April 2023) <https://www.fiercepharma.com/pharma/moderna-prevails-again-over-arbutus-appeals-court-upholds-2018-decision-strike-arbutus>

Others

-“Dispute Settlement: Appellate Body” World Trade Organization <https://www.wto.org/english/tratop_e/dispu_e/appellate_body_e.htm>; Peter Van den Bossche *The Demise of the WTO Appellate Body: Lessons for Governance of International Adjudication?* (World Trade Institute, Working Paper No. 02/2021)

-Bertram Boie *The Protection of Intellectual Property Rights through Bilateral Investment Treaties: Is there a TRIPS-plus Dimension?* (Working Paper No 2019/19, November 2010)

-Caroline Henckels “Balancing Test (Investment Arbitration)” in H Ruiz Fabri (ed) Max Planck Encyclopaedia of International Procedural Law (OUP, 2019)

-Catherine Yannaca-Small, *Fair and Equitable Treatment Standard in International Investment Law* (OECD, Working Papers on International Investment Number 2004/3, September 2004)

-Fred Feldman and Brad Skow “Desert” in Edward N. Zalta (ed) (Winter 2020) The Stanford Encyclopedia of Philosophy <https://plato.stanford.edu/cgi-bin/encyclopedia/archinfo.cgi?entry=desert>

-Fred Miller “Aristotle’s Political Theory” in Edward N. Zalta and Uri Nodelman (ed) (1 July 2022) The Stanford Encyclopedia of Philosophy <https://plato.stanford.edu/archives/fall2022/entries/aristotle-politics/>

-Gillian Brock and Nicole Hassoun “Global Justice” in Edward N. Zalta (ed) (Fall 2017 Edition) The Stanford Encyclopedia of Philosophy < https://plato.stanford.edu/entries/justice-global/#GlobInteJust >

-*Guidelines on Intellectual Property and Private International Law* Res 6/200 (13 December 2020)

-Güneş Ünüvar “Is CETA the Promised Breakthrough? Interpretation and Evolution of Fair and Equitable Treatment and (Indirect) Expropriation” (iCourts, Working Paper Series No.97, 2017)

-Intellectual Property & Development (Commission Intellectual Property Rights). Available at http://www.iprcommission.org/papers/pdfs/final_report/Ch1final.pdf (accessed 15 March 2022)

-International Law Commission, Draft Articles on Responsibility of States for Internationally Wrongful Acts (A/56/10)

-Issam Hallak “Multilateral Investment Court: Framework Options” European Parliament Briefing (June 2021)

-Joel Lexchin and Marc-Andre Gagnon *CETA and Intellectual Property: The Debate over Pharmaceutical Patents CETA* (Policy Brief Series, October 2013)

-Julian Lamont and Christi Favor “Distributive Justice” in Edward N. Zalta (ed.) (Winter 2017 Edition) The Stanford Encycloaedia of Philosophy <https://plato.stanford.edu/archives/win2017/entries/justice-distributive/ >

-Kate Miles “Imperialism, Eurocentrism and International Investment Law: Whereto from Here for Asia?” Submission for the Second Biennial General Conference of the Asian Society of International Law

-Licence Agreement between PF Prism Holdings B.V and Medicines Patent Pool Foundation <https://medicinespatentpool.org/licence-post/pf-07321332>

-License Agreement between Merck Sharp & Dohme Corp and Medicines Patent Pool Foundation< https://medicinespatentpool.org/licence-post/molnupiravir-mol>

-Merck Sharp & Dohme Corp. and Medicines Patent Pool Foundation License Agreement (signed and entered into force 26 October2021)<https://medicinespatentpool.org/uploads/2021/10/2021-10-26-MPP-MSD-Head-license-Executed-agreement-1.pdf>.

-Michael Boylan “Global Distributive Justice” in Deen K. Chatterjee (ed) (2011) Encyclopedia of Global Justice <https://link.springer.com/content/pdf/bfm%3A978-1-4020-9160-5%2F1.pdf>

-Muhammed Zaheer Abbas “Canada’s Political Choices Restrain Vaccine Equity: the Bolivia- Biolyse Case” (South Centre, 136, September 2021)

-*OECD Guidelines for Multinational Enterprises on Responsible Business Conduct* (OECD, 2023)

-Pedro Caro de Sousa, *Licensing of IP Rights and Competition Law* (OECD, DAF/COMP (2019), 3 April 2019)

-Peter Beyer “Report of the Medicines Patent Pool Expert Advisory Group on the Proposed Licence Agreement with Merck Sharp& Dohme (MSD) on Molnupiravir” Medicines Patent Pool (25 October 2021)

-Pratyush Nath Upreti *Data, Copyright, and Investor-State- Arbitration: Insights from Einarsson v Canada* (Stanford-Vienna TTLF Working Papers No. 97, 2023)

-*Report of Working Group III (Investor- State Dispute Settlement Reform) on the Work of its Thirty- Seventh Session* UN/CN.9/970 (9 April 2019)

-Robert C. Hockett and Mathias Risse *Primary Goods Revisited: The “Political Problem” and Its Rawlsian Solution* (Cornell Law Faculty Publications Legal Studies Research Paper Series No. 06-30, 2006)

-S.R. Ratner *Ethics and International Law: Integrating the Global Justice Project(s)* (Public Law and Legal Theory Research Paper Series Paper No. 315, 2013)

-Thomas Cottier and others *The Principle of Proportionality in International Law* (NCCR Trade Regulation Working Paper No 1212/38, December 2012)

-*Trade and Development Commission: Services, Development and Trade: The Regulatory and Institutional Dimension* UN Doc TD/B/C.I/MEM.4/11 (9 March 2016)

-UNCTAD *IIA Issues Note- Interpretation of IIAs: What States Can Do* (December 2011)

-UNCTAD *IIA Issues Note: Reform of Investor-State Dispute Settlement: In Search of a Roadmap* (June 2013)

-UNCTAD *IIAs Issue Note: Review Of 2021 Investor–State Arbitration Decisions: Insights for IIA Reform* (July 2023)

-United Nations Conference on Trade and Development "Intellectual Property Provisions in International Investment Arrangements" (2007) IIA UNCTAD Monitor No.1 UNCTAD/WEB/ITE/IIA/2007/1

-Wayne P. Pomerleau "Western Theories of Justice" Internet Encyclopedia of Philosophy < https://iep.utm.edu/justwest/#SH1b>

-*WHO Framework Convention on Tobacco Control* (WHO, 2003)

-*WHO Framework Convention on Tobacco Control: Guidelines for Implementation Article 11* (WHO, FCTC/COP3(10), November 2008)

-World Health Organization Proposal for Negotiating Text of the WHO Pandemic Agreement, Seventh Meeting of the Intergovernmental Negotiating Body to Draft and Negotiate a WHO Convention, Agreement or Other International Instrument on Pandemic Prevention, Preparedness and Response A/INB/9/3 13 March 2024