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The Right to Health and Pharmaceutical Companies in Developing Countries:
Access to Medicines

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Abstract

After extensive debates regarding the status of the right to health as belonging to the category of Economic, Social and Cultural rights (ESCR), today the right to health is considered as a fundamental human right for everyone and should be protected as such. However, at present people living in developing countries are often deprived of their right to health. Among various factors which contribute to this reality this thesis will focus on the conflict between the Intellectual Property (IP) regime as it is currently evolving (TRIPS Agreement, TRIPS-Plus and ISDS provisions) and access to medicines as well as the role of patent-holder pharmaceutical companies within this conflict. Although States' human rights obligations for the realization of the right to health are widely established and the adverse impact of strong IP protection for pharmaceutical products on access to medicines is extensively discussed, this thesis will examine how the corporate-friendly nature of the IP regime combined with the absence of right-to-health responsibilities of the pharmaceutical industry within international law exacerbate the problem of lack of access to medicines in developing countries. A discussion on a theoretical level regarding the conflict between patentability of and access to medicines as well as an elaboration on specific cases will indicate how powerful pharmaceutical companies influence the evolution of the IP regime and are provided with even more power to interfere (directly and indirectly) with the right to health in the name of their purely corporate interests. Based on this analysis, the necessity for right-to-health responsibilities of the pharmaceutical industry will become apparent. Thus, the last part of the thesis places the discussion within the context of the evolving Business and Human Rights (BHR) discourse and attempts to determine the nature and the content of the right-to-health responsibilities of pharmaceutical companies that could contribute to a balance between IP rights and access to medicines in developing countries and to a more right-to-health compliant conduct on the part of the patent-holder pharmaceutical companies.

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List of Abbreviations

BHR	Business and Human Rights
BIT	Bilateral Investment Treaty
CESCR	Committee on Economic, Social and Culural Rights
CPR	Civil and Political Rights
CSR	Corporate Social Responsibility
ESCR	Economic, Social and Cultural Rights
FTA	Free Trade Agreement
HRC	Human Rights Council
ICESCR	International Covenant on Economic, Social and Cultural Rights
ILC	International Law Commission
IP	Intellectual Property
ISDS	Investor-State Dispute Settlement
R&D	Research and Development
TNPC	Transnational Pharmaceutical Companies
TRIPS Agreement	Trade-Related Intellectual Property Rights Agreement
UDHR	Universal Declaration of Human Rights
UN	United Nations
UNGP	United Nations Guiding Principles on Business and Human Rights
VCLT	Vienna Convention on the Law of Treaties
WHO	World Health Organization
WTO	World Trade Organization

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Introduction

The right to health is a recognized universal human right which is included in various UN instruments and its realization has been at the center of discussions in various contexts over the past decades. Initially, health as a fundamental right was explicitly mentioned in the WHO Constitution of 1946, the year the Organization was established. It was stated that 'The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'.[1] The Universal Declaration of Human Rights (UDHR) also states that 'everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services'.[2] The recognition of the right to health continued to expand and has been included in the International Covenant on Economic, Social and Cultural Rights (ICESCR) since 1966, which recognizes 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.[3] It is also included in subsequent treaties such as the Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)[4] and the Convention on the Rights of the Child (CRC)[5], that focus on specific groups of people.

Despite the importance of recognition of health as a fundamental human right for everyone, the right to health faces a variety of threats, especially for people who live in developing countries. While the development of technology within the biomedical and pharmaceutical community has lead to an increase in life expectancy and quality of life due to new medicines

[1] UN International Health Conference, 'Constitution of the World Health Organization' (adopted 22 July 1946, entered into force 7 April 1948) 14 UNTS 185, preamble <http://apps.who.int/gb/bd/PDF/bd48/basic-documents-48th-edition-en.pdf#page=7> accessed 28 June 2019.
[2] United Nation General Assembly (UNGA), 'Universal Declaration of Human Rights' (adopted 10 December 1948, UNGA Res 217 A (III)) (UDHR) art 25 <https://www.refworld.org/docid/3ae6b3712c.html> accessed 28 June 2019.
[3] UNGA, 'International Covenant on Economic, Social and Cultural Rights' (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR) art 12 <https://www.refworld.org/docid/3ae6b36c0.html> accessed 28 June 2019.
[4] UNGA, 'Convention on the Elimination of All Forms of Discrimination against Women' (adopted 18 December 1979, entered into force 3 September 1981) 1249 UNTS 13 (CEDAW) art 12 <https://www.refworld.org/docid/3ae6b3970.html> accessed 28 June 2019.
[5] UNGA, 'Convention on the Rights of the Child' (adopted 20 November 1989, entered into force 2 September 1990) 1577 UNTS 3 (CRC) art 24 <https://www.refworld.org/docid/3ae6b38f0.html> accessed 28 June 2019.

and procedures that can prevent or cure diseases, there remains a significant gap between developed and developing countries. More specifically, life expectancy in developing countries is 18.1 years lower than in developed countries, currently standing 62.7 and 80.8 years respectively, while one in three deaths in developing countries are of children under the age of 5, in contrast to developed countries where most people who die are senior adults.[6] The majority of the 16,000 children who die before their fifth birthday live in Sub-Saharan Africa and die due to pneumonia, malaria or diarrhoea, while 95 and 87 per cent of premature deaths caused by tuberculosis or non-communicable diseases respectively occur within the developing worlds.[7] As most of the diseases that account for these death rates are related to treatable or preventable conditions and diseases, it seems that their right to health is far from being protected and is continuously threatened.

While the right to health of people living in developing countries is connected to and affected by many factors, the focus of this thesis is the lack of access to medicines in developing countries. It will be argued that although States have the primary obligation to realize the right to health of their citizens, external factors related to the current legal reality can interfere with this obligation, particularly with regards to access to medicines. In the following discussion two of these external factors will be examined, namely the ongoing expansion of the Intellectual Property (IP) regime and the absence of international right-to-health obligations for pharmaceutical companies, in order to assess how these two distinct legal realities may exacerbate the problem of access to medicines in developing countries. This will be considered from both an individual but also complementary lens, and will also look at how establishing specific corporate human rights obligations may mitigate, to some extent, the problem of the conflict between pharmaceutical companies' IP rights and access to medicines for people living in developing countries.

In the first chapter it will be analyzed the general impact of the IP regime on access to medicines, the latter being part of the right to health. Firstly, it will be provided a brief overview

[6] World Health Organization (WHO), 'World Health Statistic Overview 2019: Monitoring Health for the SDGs, Sustainable Development Goals' (WHO 2019) (WHO/DAD/2019.1) 4 <https://apps.who.int/iris/bitstream/handle/10665/311696/WHO-DAD-2019.1-eng.pdf> accessed 25 June 2019.
[7] WHO, '10 Facts on Health Inequities and their Causes' (WHO, April 2017) <https://www.who.int/features/factfiles/health_inequities/en/> accessed 25 June 2019.

of the debate and the criticism surrounding the concept that Economic, Social and Cultural rights (ESCR) are concidered to have a lower status than Civil and Political rights (CPR) on the basis of their resource dependent nature and vagueness. This chapter will demonstrate that these arguments do not seem to be valid support for this claim. To that extent, based on, among others, the Committee of Economic, Social and Cultural Rights (CESCR) authoritative interpretation of the right to health, the content and implications of the right to health will be analyzed, focusing on access to medicines as one of its vital components and on what obligations are required for access to medicines, and in extension the right to health, to be realized. Although the focus of this thesis is not States' obligations per se, reference to them is considered necessary and helpful as a basis for the elaboration on how IP norms and their ongoing evolution, influenced by and favoring to a great extent the pharmaceutical industry acting on behalf of their economic interests while not having human rights responsibilities, affects access to medicines in developing countries.

Thus, the first chapter will continue by analyzing the fragmentation of international law and its implications on access to medicines. More specifically, the 1.2 Chapter will consider the evolution of the IP regime in parallel with the Human Rights regime. The main focus will be the inclusion of IP rights in the World Trade Organization (WTO) via the adoption of the Trade-Related Intellectual Property Rights (TRIPS) Agreement.[8] In general, the fragmentation of international law will be illustrated as creating both a problem and an opportunity: a problem by creating conflicting and incompatible legal obligations affecting access to medicines and serving corporate and developed States' interests and an opportunity by creating additional pathways and opportunities for developing countries to challenge existing rules.[9] Both of these possibilities will be demonstrated, starting in the first chapter with the conflict between IP provisions and access to medicines and more specifically how patent provisions for medicines under the TRIPS Agreement, while being influenced and welcomed from the pharmaceutical industry, can deprive people in developing countries from medicines and undermine the protection of their right to health when abused by the said pharmaceutical industry.

[8] WTO, 'Agreement on Trade-Related Aspects of Intellectual Property Rights' (15 April 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 UNTS 299, 33 ILM 11197 (TRIPS Agreement) <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf> accessed 28 June 2019.
[9] Anne Peters, 'The refinement of International Law: from Fragmentation to Regime Interaction and Politicization' (2017) 15 (3) International Journal of Constitutional Law 671 <http://www.mpil.de/files/pdf5/Peters_Refinement_of_IL1.pdf> accessed 20 June 2019.

To that extent, the possible ways and different approaches for avoiding and mitigating, at least at a theoretical level, existing conflicts between different legal regimes shall be discussed. It will be found that the most effective method to avoid and mitigate such conflict is through interpreting each regime in the light of the other and not in isolation from general international law, as also provided by the Vienna Convention on the Law of Treaties (VCLT).[10] As the International Law Commission argued in its report 'Treaty interpretation is diplomacy, and it is the business of diplomacy to avoid or mitigate conflict'[11], a statement which seems to fit perfectly in this context. Following the 'coexistence' approach that will be, among others approaches, analyzed and after reading the TRIPS Agreement's Articles 7 and 8 it will be examined if and how the balance between economic and social welfare that these articles call for can be achieved by taking right-to-health considerations into account when a conflict between IP rights and access to medicines arises. Thus, after discussing the general conflict and elaborating on some approaches for its resolution at a normative level, developments (both positive and negative) regarding IP rights' impact in developing countries will be further discussed in the next chapter.

The second chapter starts by assessing the results of the above theoretical discussion surrounding the conflict and its reconciliation. Although it will be shown to be a positive direction towards right-to-health considerations when interpreting and implementing the TRIPS Agreement, pharmaceutical companies are continuously seeking ways to foster their monopolising power, a fact that disorientates this positive direction. This part of the thesis illustrates a reality that can be accurately described as 'one step forward – two steps back'. Firstly, the discussion starts by analyzing the Doha Declaration on TRIPS and Public Health (Doha Declaration)[12], one of the major developments within the WTO that recognizes the conflict between patentability of and access to medicines, the background of this document's

[10] UN, 'Vienna Convention on the Law of Treaties' (VCLT) (adopted 23 May 1969, entered into force 27 January 1980) 1155 UNTS 331 <https://www.refworld.org/docid/3ae6b3a10.html> accessed 28 June 2019.
[11] International Law Commission (ILC), 'Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law: Report of the Study Group of the International Law Commission: Finalized by Martti Koskenniemi' (13 April 2006) UN doc A/CN.4/L.682 para 37 <http://legal.un.org/ilc/documentation/english/a_cn4_l682.pdf > accessed 28 June 2019.
[12] WTO, 'Declaration on the TRIPS Agreement and Public Health' (Doha Declaration) (adopted 14 November 2001) WTO doc WT/MIN(01)/DEC/2 (20 November 2001) <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 28 June 2019.

adoption and the TRIPS flexibilities that the document highlights. The opportunity that was created for developing countries after the *Pharmaceutical Manufacturers' Association v. The President of the Republic of South Africa*[13](PMA) case to raise awareness within and beyond the WTO and to put concerns surrounding access to medicines and IP rights on the table can be considered as 'a step forward' from a human rights point of view as it led to the adoption of the Doha Declaration. To that extent, I will elaborate on why this document, together with the flexibilities provided by the TRIPS Agreement that it highlights, is of a great importance regarding access to medicines and how, on the other hand, pharmaceutical companies have reacted to it as well as the effects of this reaction.

The second part of this chapter analyzes new trends that are promoted and used by pharmaceutical companies, including TRIPS-Plus and Investor State Dispute Settlement (ISDS) provisions in Bilateral Investment Agreements (BITs) and Free Trade Agreements (FTAs) to which developing countries are gaining a role in. During this analysis it will be stressed the issue that, although there are some positive moves towards taking access-to-medicines considerations into account when implementing the TRIPS Agreement and making use of TRIPS flexibilities, a new reality has been created that undermines the TRIPS flexibilities, and in extension the right to health while at the same time strengthening the pharmaceutical industry. The Elly Lilly[14] case and the tribunals approach will be used for illustrating possible implications of ISDS provisions. Based on the pharmaceutical company's claims and the tribunal's argumentation it will be assessed how ISDS proceedings may undermine States' attempts to comply with their own right-to-health obligations and thus indirectly threaten the right to health and access to medicines. In the author's view, what adds to this situation in addition to the corporate-friendly nature of the current IP system is the fact that pharmaceutical companies, one of the system's basic drivers and beneficiaries, lack human rights obligations under international law. To that extent, the last part of this chapter will

[13] *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* (CCT31/99) [2000] ZACC1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000).
[14] *Elly Lilly and Company v Government of Canada,* ICSID Case No UNCT/14/2 <https://www.italaw.com/sites/default/files/case-documents/italaw8546.pdf > accessed 28 June 2019.

elaborate on the Urbaser case[15] and its contributions both in terms of human rights considerations within ISDS procedures and of corporate human rights obligations.

On the basis of all previous analysis of this paper regarding the interaction between IP rights and access to medicines and the role of pharmaceutical companies in the formation and maintenance of this interaction, the final chapter will elaborate on the right-to-health responsibilities that pharmaceutical companies have, or should have, under international law, and how this could contribute to the improvement of access to medicines in developing countries. At this point, it should be clarified that the focus of this thesis is not the whole spectrum of entities that may constitute what is called the 'pharmaceutical industry'. From the two broad groups of industrial firms that are engaged, according to Graham Dukes, in the pharmaceutical field, namely 'research-based' pharmaceutical companies and 'generic' manufacturers[16], the thesis will focus on the first group, since these companies while being the beneficiaries of patent protection can directly and indirectly affect the right to health. Thus, the discussion will start with some general considerations about the current legal reality regarding who is regarded as possessor of human rights responsibilities, following by an analysis of the evolution of corporate responsibilities, from the traditional Corporate Social Responsibility (CSR) concept to the current Business and Human Rights (BHR) discourse. Finally, the role and human rights responsibilities of pharmaceutical companies in the context of this thesis will be considered. To that extent, in order to assess the nature and content of the right-to-health responsibilities of pharmaceutical companies the thesis will elaborate on, among others, the United Nations Guiding Principles on Business and Human Rights (UNGP) and the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (Hunt Guidelines), and the way that they apply to pharmaceutical companies unique function, focusing mainly on their research and development (R&D) and pricing practices as well as their influence on and use of the IP regime.

[15] *Urbaser et al v The Argentine Republic*, ICSID Case No ARB/07/26 <https://www.italaw.com/sites/default/files/case-documents/italaw8136_1.pdf > accessed 28 June 2019.
[16] Graham Dukes, *The law and Ethics of the Pharmaceutical Industry* (ELSEVIER B.V 2006) 10-14.

CHAPTER 1: Access to Medicines V Intellectual Property Rights

1.1 Access to Medicines as a Human Right

1.1.1 Is the Right to Health in the First place a 'genuine' right? Brief Overview of the Debate

Despite the importance of the recognition of health as a fundamental human right for everyone by a number of UN instruments as well as its inclusion in various national constitutions, the fact that the right to health belongs to the category of ESC rights, which have been for a long time been questioned regarding their content and nature and in extension their justiciability, is one of the factors that makes in the first place the right to health a 'fragile' right. The main focus of the ongoing debate regarding ESCR surrounds their general 'ideological and technical nature' which leads to doubts about whether they are 'genuine rights or mere aspirational targets'.[17] People who differentiate between ESCR and CPR argue that due to both the costly and resource dependent nature and vagueness of ESCR, they are difficult to define in law and thus they cannot be applied or enforced in courts.[18] There are people who take the view that the 'positive' nature of ESCR, meaning that they need action and resources from the part of the State in order to be realized, in contrast with the 'negative' nature of CPR, where the only prerequisite for their realization is that States do not interfere with the right in question, is what constitutes as the main obstacle for courts when adjudicating ECSR, as, it is argued , courts are not the appropriate forum for addressing cost-related issues.[19] However, this statement is misleading, as both sets of rights require both action and inaction in order to be fully implemented, a fact that is also supported by the European Court of Human Rights that, regarding CPR, has argued that 'The fulfilment of a duty under the Convention on occasion necessitates some positive action on the part of the State; in such circumstances, the State cannot simply remain passive.'[20] Thus, as positive action required for CPR has not resulted in

[17] J.K. Mapulanga-Hulston, 'Examining the Justiciability of Economic, Social and Cultural Rights, The International Journal of Human Rights' (2002) 6(4) The International Journal of Human Rights 29, 30 <https://www.tandfonline.com/doi/abs/10.1080/714866691> accessed 28 June 2019.
[18] Ibid 37.
[19] Ibid 40.
[20] Ibid 41.

challenging the justiciability of these rights, challening ESCR on this basis would be inconsistent with existing practice.

It is argued that 'The adoption of a rigid classification of economic, social and cultural rights which puts them, by definition, beyond the reach of the courts would…be arbitrary and incompatible with the principle that the two sets of human rights are indivisible and interdependent'.[21] Indeed the indivisibility and interdependence of the two sets of rights is explicitly recognized within international law and is also supported by many courts' decisions in various jurisdictions at both national and regional levels, where the right to health is connected with a well established constitutional right falling in the category of CPR. For example, the Inter-American Court of Human Rights has connected the violation of the right to health, more specifically the failure to provide access to basic health care to marginalised population, with a violation of the right to life.[22] Similarly, the European Court of Human Rights has held that failure to protect individuals from environmental conditions that can harm health or failure to maintain health care services can also amount to a violation of the right to privacy and family life and the prohibition of cruel, inhuman and degrading treatment respectively.[23] This kind of judicial practice illustrates and reinforces the norm of the interdependence of the two sets of rights and amounts to an indirect way to protect ESCR in general and the right to health in particular.

Despite the interdependence of the two categories of human rights and the adjudication of ESCR when connected with CPR, it is argued that the 'lack of doctrinal and jurisprudential development of the right to health within domestic and international law', a lack that is apparent in every ESCR, 'has certainly contributed to the de facto inferior status of social rights' including the right to health.[24] In the case of CPR, it is argued, 'statutory regulations, case law and jurisprudential concepts, all contribute to interpreting and clarifying the content and scope

[21] UN Committee on Economic, Social and Cultural Rights (CESCR) 'General Comment No 9: the Domestic Application of the Covenant' (3 December 1998) E/C.12/1998/24, para 10. <https://www.refworld.org/docid/47a7079d6.html> accessed 28 June 2019.
[22] International Commission of Jurists (ICJ), 'Courts and the Legal Enforcement of Economic, Social and Cultural Rights: Comparative Experiences of Justiciability' (2008) Human Rights and Rule of Law Series No 2, 65-66 <https://www.refworld.org/pdfid/4a7840562.pdf> accessed 3 June 2019.
[23] Ibid.
[24] Lisa Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (2011) 14 (2) The Journal of World Intellectual Property 155, 160 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1804478> accessed 8 June 2019.

of rights' but for ESC rights and thus the right to health this is not the case.[25] In other words, there is a lack of precise rules for courts to have as a reference point in order to adjudicate compliance or non-compliance with these specific norms. The reason behind this absence of case law examples is argued to be the vagueness of ESCR, in terms of their normative content and the legal implications, which in turn reinforces the lack of jurisprudential development. However, vague provisions and unspecific content and limits of rights are present not only in ESC rights; also '"classic" rights such as the right to property, freedom of expression, equal treatment or due process face this hurdle to the same extent as ESC rights' but this has not lead to the denial that they are rights, rather efforts to clarify their meaning have increased.[26] It is argued that 'despite the influence of domestic law concepts of justiciability, the review bodies in international law need not to be courts to accomplish their duties'[27]. To that extend, efforts at the international level have aimed to overcome the absence of jurisprudential development of the right to health. For example, the CESCR, through its General Comments, while not legally binding, has given substance to the content, scope and implications of the right to health and provided with guidance on how the right to health should be interpreted and implemented by the respected and relevant bodies. The following paragraphs will focus on the access to medicines, as a component of the right to health, that seems to be threatened for reasons that will be analyzed below, especially in developing countries.

1.1.2 Access to Medicines: A Vital Component of the Right to Health

Although, as it was demonstrated above, the right to health is a recognized human right which has the same status as CPR, it is argued that there is a 'lack of clarity about the foundations' and an 'incomplete theoretical framework' related to the notion of health in general that creates a confusion and a difficulty when setting priorities for its implementation.[28] At this point, an

[25] International Commission of Jurists (no 22) 21.
[26] Ibid 15.
[27] Michael K Addo, 'The Justiciability of Economic, Social and Cultural Rights' (1998) 14 (4) Commonwealth Law Bulletin 1425, 1426 <https://heinonline-org.ezproxy.nottingham.ac.uk/HOL/Page?lname=&public=false&collection=journals&handle=hein.journals/commwlb14&men_hide=false&men_tab=toc&kind=&page=1425> accessed 8 June 2019.
[28] Audrey Chapman, 'The Foundations of a Human Right to Health: Human Rights and Bioethics in Dialogue' (2015) 17 (1) Health and Human Rights 6, 7 <https://www-jstor-org.ezproxy.nottingham.ac.uk/stable/healhumarigh.17.1.6?sid=primo&origin=crossref&seq=1#metadata_info_tab_contents> accessed 16 June 2019.

elaboration on the actual content and implications of the right to health is considered necessary in order to specify what is required for the right to be realized and how its access-to-medicines component is hindered by external factors that will be analyzed below.

Firstly, Article 12 of the ICESCR could itself be seen as implicitly recognizing access to medicines as a vital component of the right to health. More specifically, in its second paragraph the Article states that States Parties should take steps that ensure 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases' and 'the creation of conditions which would assure to all medical service and medical attention in the event of sickness'.[29] Although 'In early medical science drugs played only a marginal role in the treatment of diseases', the current development of technology and pharmacology has created a new reality where medicines are a vital part of every therapeutic procedure.[30] At this point it is interesting to refer to a relevant statement of the Human Rights Committee (HRC) in its General Comment No 6 regarding the right to life that can be seen as connecting access to medicines with the right to life by demonstrating that the right to life should be interpreted in a broadly rather than 'in a restrictive manner' and that for the right to life to be protected States should 'take all possible measures…to increase life expectancy', a goal that nowadays is achieved, among others, via medicines.[31]

Even though Article 12 does not include the term 'access to medicines' as such, the work of the CESCR regarding the right to health is decisive in overcoming the issue of the alleged vagueness of the right to health and specifying what is expected from States in order to comply with their right-to-health obligations. Generally, the right to health, according to Article 2 of the ICESCR, is subject to the notion of 'progressive realization', meaning that States are given a margin of appreciation to decide the timeframe and the distribution of available resources in order 'to achieving progressively the full realization' of the ESC rights.[32] Despite the flexibility of progressive realization that is provided for ESCR due to the recognized constraints related to States' limited available resources, the Committee in its General Comment 3 takes the view

[29] ICESCR (no 3) Art 12 2 (c), (d).
[30] Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (first published Oxford University Press 2008) 104.
[31] UN Human Rights Committee (HRC), 'CCPR General Comment No 6: Article 6 (Right to Life)' (30 April 1982) para 1, 5 <https://www.refworld.org/docid/45388400a.html> accessed 28 June 2019.
[32] ICESCR (no 3) Art 2.

'that a minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights is incumbent upon every State party'.[33] Thus the Committee, in its General Comment 14, further analyzes and interprets the right to health and enumerates a set of 'core obligations', that will lead to the absolute essential baseline needed in order for this right to be meaningful, and explicitly includes in these obligations that States 'provide essential drugs as from time to time defined under the WHO Action Programme on Essential Drugs'.[34]

At this point, it is interesting to refer to the contribution of Thana Christina de Campos regarding 'basic' and 'non-basic' health needs, that could also be helpful with regards to the prioritization procedure that resource-dependent rights require. She starts the discussion by taking for granted that health is a 'basic human need, simply because it is vital to any human life'.[35] Although she opposes to the 'well-being conception of health' that is supported by the World Health Organization (WHO) and takes the view of the 'decency conception of health', the important and relevant element of her reasoning for the purpose of this thesis is that she stresses that 'basic health needs inherently have a moral urgency', they imply more stringent obligations and require more attention since they are 'indispensable conditions for a minimally decent human existence' that allows '*any* human being to survive within his community'.[36] This idea and distinction between basic and non-basic health needs seems also to be reflected by the core obligations that the Committee sets forth for the achievement of the minimum essential level of the right to health, as well as on the definition of essential medicines, as developed by WHO, as 'those that satisfy the priority health care needs of the population'.[37]

[33] CESCR, 'General Comment No 3: The Nature of States Parties' Obligations (Art. 2 Para. 1, of the Covenant' (14 December 1990) E/1991/23, para 10 <https://www.refworld.org/pdfid/4538838e10.pdf> accessed 28 June 2019.
[34] CESCR, 'General Comment No 14: the Right to the Highest Attainable Standard of Health (Art 12 of the Covenant)' (11 August 2000) E/C.12/2000/4 <https://www.refworld.org/docid/4538838d0.html> accessed 28 June 2019.
[35] Thana Cristina de Campos, 'Health as a Basic Human Need: Would This Be Enough?' (2012) 40 (2) The Journal of Law, Medicine & Ethics 251, 255 <https://journals.sagepub.com/doi/10.1111/j.1748-720X.2012.00662.x#articleCitationDownloadContainer> accessed 9 June 2019.
[36] Ibid 256.
[37] WHO, 'The selection and Use of Essential Medicines-Report of the WHO Expert Committee' (2002) WHO Technical Report Series No 914, section 4.2 Description of Essential Medicines <http://apps.who.int/medicinedocs/en/d/Js4875e/5.2.html> accessed 28 June 2019.

According to a Lancet Commission report 'incorporating strong and strategic essential medicines policies can enable countries, health systems, and global institutions to take major strides towards achieving the highest attainable standard of health and UHC as part of sustainable development for all'.[38] Thus, taking into account the expansion of the science and technology, the definition of basic health needs including to them essential medicines as defined by WHO, and more importantly the contribution of the CESCR, its seems that the vagueness of the right to health is overcoming and that access to medicines is codified as a vital component of the right to health (and in some cases of the right to life), that is not subject to progressive realization, but must be realizated immidiately and thus should be a top priority when policymakers are planning public health policies and considering the allocation of resources.

An interesting report by Hans V Hogerzeil and others in 2006 supports the fact that access to medicines is considered as a vital component of the right to health not only at a theoretical level, but also in practice. According to the report, which analyzed 71 court cases from 12 countries, in 59 cases, mostly from Central and Latin America, access to medicines was found to have been enforced by the courts.[39] Thus, it seems that access to medicines as both a concept and a human right is starting to be globally recognised and consolidated. However, despite the importance of the role of courts in following up the implementation of the right to health, the most important and decisive factor for access to medicines is that States are able to comply with their right-to-health obligations, and for doing so these obligations should be in the first place clear. Thus, in the following paragraphs these obligations will be analyzed for later considering the external factors that may stand as an obstacle to States' compliance.

1.1.3 Obligations Regarding the Right to Health and Access to Medicines

Generally, the CESCR makes it clear that the right to health, like every ESCR and in fact every human right, consists of both positive and negative obligations for being realized. More

[38] Veronica J Wirtz and others, 'Essential Medicines for Universal Health Coverage' (2017) 389 (10067) The Lancet 403, 414 <https://www.thelancet.com/action/showPdf?pii=S0140-6736%2816%2931599-9> accessed 9 June 2019.
[39] Hans V Hogerzeil and others, 'Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health enforceable through the Courts?' (2006) 368 (9532) The Lancet 305, 305-11 <https://www.who.int/medicines/news/Lancet_EssMedHumanRight.pdf?ua=1> accessed 9 June 2019.

specifically the right to health imposes a threefold set of 'general obligations' to States; 'the obligations to *respect*, *protect* and *fulfil'*.[40] Compliance with these obligations with regards to access to medicines may face a number of external obstacles in addition to resource constraints. It is argued, that 'Access to some basic ESC rights…is often left to a great extent to market forces', a fact that 'creates its own tensions for the State, in how it carries out its duties to protect'.[41] That means that, although the obligations regarding the realization of the right to health, including access to medicines, are primarily addressed to States, in the case of access to medicines the role of pharmaceutical companies is a decisive factor that can both positively or negatively contribute to the realization of the right to health. However, under international human rights law, and specifically regarding the right to health, pharmaceutical companies do not have human rights obligations imposed on them. Although the Committee refers to the business sector as having responsibilities for the realization of the right to health, it does not elaborate further on the issue and it ultimately states that only State-parties to the Covenant are accountable for complying with the right to health.[42] This fact, except a missing opportunity within the international human right law (which will be analyzed in the last chapter) has serious implications for the way that States themselves are able to comply with their right to health obligations, in particular access to medicines.

More specifically, regarding the obligation to respect, the negative dimension of the right is that the State should 'refrain from interfering directly or indirectly with the enjoyment of the right to health'[43], similar to the structure of CPR. In other words, States should not act in a way that goes against the right to health, for example by adopting 'policies or laws that contravene the standards set out in article 12 of the Covenant and are likely to result in bodily harm, unnecessary morbidity and preventable mortality'.[44] Importantly, the Committee explicitly refers to situations where States overlook their 'obligations regarding the right to health when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations'[45] as a violation of the right, a case that is increasingly likely to happen due to the emergence and evolution of the IP regime in a way

[40] CESCR General Comment No 14 (no 34) para 33.
[41] International Commission of Jurists (no 22) 45.
[42] CESCR General Comment No 14 (no 34) para 42.
[43] Ibid para 33.
[44] Ibid para 50.
[45] Ibid para 50.

that, as will be illustrated below, creates conflicting obligations for State-parties to both regimes. Moving to the obligations of States to protect the right to health, they include a duty to 'prevent third parties from interfering with article 12 guarantees'.[46] The Committee makes it clear that a 'failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others' consists a violation of the right to health.[47] To that extent, the operations of pharmaceutical companies, that are directly linked with the realization of the right to health and access to medicines, should be very carefully taken into account.

More specifically, their role regarding the right to health consists of the industry's 'core capabilities of researching, developing, and producing medicines…and in helping to ensure their appropriate distribution'.[48] It is important to highlight that access to medicines includes four interrelated and essential elements, namely *availability, accessibility, acceptability and quality.*[49] Thus, on the basis of States' obligation to protect, they should make sure that pharmaceutical companies that have undertaken the production and distribution of medicines they are doing so in a way that complies with the four prerequisites of access to medicines. Finally, the obligation to fulfil calls for States to recognize the right to health in their political and legal systems and to adopt legislative and other necessary measures for ensuring the realization of the specific right, such as 'a national health policy with a detailed plan for realizing the right to health'.[50] But formulating and implementing national policies in line with the provision of the right to health is not always easy, since, as it will be discussed below in detail, States operate within a multileveled and complex system and are subject to various rules and norms that regulate different fields, some of them being driven by corporate interests, a fact that may result with States not considering the right to health when adopting their policies as they should.

[46] Ibid para 33.
[47] Ibid para 51.
[48] Geralyn S Ritter, 'Are Drug Companies Living Up to their Human Rights Responsibilities? The Merck Perspective' (2010) 7 (9) PLoS Medicine e1000343, 1 <https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1000343#s3> accessed 12 June 2019.
[49] CESCR General Comment No 14 (no 34) para 12.
[50] Ibid para 36.

1.2 Intellectual Property Rights Regime – the Theory of the Conflict with Access to Medicines

1.2.2 Fragmentation of International Law: Root Cause of the Conflict?

First of all, the possibility of different treaties to affect a single issue in various ways is not a new problem and neither is it apparent only in the case of trade and human rights. In general, the current international legal reality is characterized by a proliferation of legal regimes, each one of them coming 'with its own principles, its own form of expertise and its own "ethos", not necessarily identical to the ethos of neighbouring specialization'.[51] The number of treaties registered in the United Nation system exceeds 50,000, while only in the 20th century alone 6,000 multilateral treaties were adopted, 30 per cent of which are general treaties, open for all States.[52] This rapid expansion and evolution of new and specialized regimes creates a complex international legal system, an increasing 'fragmentation' of international law, meaning that States will inevitably be 'subjected to specialist systems of international law, such as trade law and human rights law, which have developed largely in isolation from each other', a fact that results at a high possibility of conflicting obligations that need to be addressed.[53] However, fragmentation is not necessarily a negative concept per se. While it 'denotes a process and its results', the process as such, it is argued, by others and this thesis, is a response to globalization and the consequent rise of 'global problems' and new actors that demand global and at the same time specialized rules simultaneously and need regulation in order to be effectively addressed.[54]

Thus, from a practical and functional point of view, as international law is characterized by an 'absence of a central world legislator', the evolution of specialized subfields focusing on 'different issue-areas' and monitored by different institutions, in a similar way to domestic spheres' realities where different governmental departments and administrative authorities negotiate and apply various treaties respectively, is a rational – neither positive nor negative

[51] ILC (no 11) para 15.
[52] ILC (no 11) para 7, footnote 10.
[53] Sarah Joseph, *Blame it on the WTO?: A Human Rights Critique,* (OUP 2011) 47.
[54] Peters (no 9) 673-674.

by itself – consequence.[55] On the other hand, the results of this process may indeed have negative aspects. It is argued that it is the '*coordination* (or lack of it) of fragmented or differentiated institutions that becomes the most important issue' and not the different institutions as such.[56] When distinct rules and norms affecting the same matters are being developed and applied in a vacuum, one cannot expect that these specific matters will remain uninfluenced. Coordination between different systems is necessary for retaining and protecting the coherence and certainty of the international legal system, especially when the driver-actors of the evolution of each system do not have the same interests, which is the case of the IP and human rights regime and the protection of access to medicines.

The reason why coordination between institutions is so important for the effective and desirable function of international law, is what Peters calls the 'ideational' nature of this fragmentation, that is translated to different values and objectives between different legal regimes.[57] It is often argued that the relationship between different regimes is a 'result of a deliberate agenda of powerful states' on the basis of what Peters sees as the 'political causes' of fragmentation.[58] The existence of different values and objectives that are the subject matter of specialized regimes and their respective institutions, when combined with the political causes of the process of fragmentation, may indeed create a problematic situation. Institutional and ideational fragmentation 'flow into each other, assuming that each institution tends to favor the values and objectives of its own regime'[59] and this may lead, as it will be showed in the following paragraphs, to structurally stronger and enforceable regimes which undermine the values of weaker ones. In other words, the creation of different regimes and the way that they interact with each other is a reflection of a negotiation procedure between powerful and less powerful States- and non-states actors with different values and priorities that, in the absence of a coordinating mechanism, may possibly lead to the prevailing of the priorities of powerful States and especially non-state actors and the creation of rules that support them in pursuing their own interests overlooking the common good.

[55] Ibid.
[56] Michael Zürn and Benjamin Faude, ' Commentary: On Fragmentation, Differentiation, and Coordination' (2013) 13(3) Global Environmental Politics 119, 120 <https://pdfs.semanticscholar.org/f153/c8b5c0278d23cd4643a87d103c9842079f62.pdf> accessed 12 June 2019.
[57] Peters (no 9) 675.
[58] Ibid 674.
[59] Ibid 675.

This thesis will focus on the implications that fragmentation of international law, as described, may have on the right to health, particularly access to medicines in developing countries. In particular, how the evolution of two different legal regimes, concerning different policy areas, driven by different interests and dealing with different subject matters (trade/IP and human rights) may create a conflict between required obligations and how this conflict could be mitigated. Access to medicines as an indispensable part of the human right to health was already analyzed. In the rest of this chapter, as well as in the second one, this thesis will follow an analysis of the evolution of the IP regime, from the adoption of the TRIPS Agreement to the Doha Declaration and the subsequent new Agreements with TRIPS-plus and ISDS provisions. It will consider the way that the current IP regime affects the right to health by including patents on medicines within IP protection and whether or not it can be seen that there is a move towards the balancing of the two regimes. Within the whole discussion the great influence of powerful pharmaceutical companies which are concerned mostly with advancing their economic interests have on this evolution will become apparent, a fact that in turn makes not only the adoption of the IP norms but also their interpretation and implementation by courts and States respectively highly driven by corporate interests.

1.2.3 The Conflict Between Access to Medicines and Intellectual Property Rights

1.2.3.1 Origins of the Conflict

From the above analysis it is obvious that there is a normative expansion of the human rights law regarding ESCR in general, and the right to health in particular. The clarification of the scope, content and implications of the right to health and the recognition of access to medicines as a human right based on the right to health is, among others, a reflection of this expansion. However, as was mentioned in the introduction, a great number of people in developing countries lack access to affordable and effective medicines and their right to health is therefore being threatened. At this point the evolution of another legal regime, namely the Intellectual Property (IP) regime, will be analyzed focusing on its impact on access to medicines. As Helfer argued, this expansion that human rights law experiences, in combination with the parallel expansion of the IP transnational legal order, particularly the expansion ‘of the legal and geographic scope of pharmaceutical patents’ through ‘the incorporation of IP into the WTO as

embodied in the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)' results in a conflict between access to medicines and IP rights and renders access to medicines directly influenced by the new IP rules.[60] Thus, 'a blurring of the demarcation between the two fields, creating dense policy spaces where previously unrelated sets of principles, norms and rules increasingly overlap in incoherent and inconsistent ways' is created.[61] To that extent, the purpose of the following part of the thesis is to reflect on how this reality of different legal orders affects access to medicines, especially for people who live in developing countries where States may already lack the adequate capacity to realize the right to health.

Following the 'wide notion of conflict' that the International Law Commission (ILC) adopts within its report about the fragmentation of international law, a conflict is created when a treaty or sets of rules 'frustrate the goals of another treaty without being any strict incompatibility between their provisions'.[62] Therefore, it is obvious that a conflict between the IP and the human rights regime exists. According to the ILC, 'two rules or principles suggest different ways of dealing with a problem' due to their aiming 'at divergent ends' and their differing raison d'être.[63] In this case, 'the problem' (and the issue in focus) is the access to medicines (of the lack of it) in developing countries, an issue that is affected both by IP rights and the human right to health and is treated differently within each of these rights, mainly because of the different values and objectives of the two regimes that these these rights are part of. When looking at the different values and objectives between these two regimes the great influence of the pharmaceutical industry on the evolution of IP protection under the WTO regime should be noted as one of the reasons that contributed to this difference. Thus, on the one hand the the right to health, as part of the human rights regime, aims to protect the dignity of every human being.[64] On the other hand, 'TRIPS is an annex to the *Marrakesh Agreement*, which established the WTO, and this context locates TRIPS firmly within a legal system driven by the telos of

[60] Laurence R Helfer, 'Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines', in Terence C Halliday and Gregory Shaffer (eds), *Transnational Legal Orders* (NY Cambridge University Press 2015) 312.
[61] Jeniffer Anna Sellin, 'Does One Size Fit All? Patents, The Right to Health and Access to Medicines' (2015) 62 (3) Netherlands International Law Review 445, 447 <https://link.springer.com/article/10.1007%2Fs40802-015-0047-5> accessed 28 June 2019.
[62] ILC (no 11) para 24.
[63] Ibid paras 24-25.
[64] UDHR (no 2) preamble.

free trade'.[65] To that extent, States that are part of both legal orders may be in the position where for complying with the obligation to provide patent protection for a medicine may mean that the State may have to set aside their right to health obligations, as a patent, as it will be discussed below, will likely affect the economic accessibility of the medicines. The opposite may also be true; to fulfil the obligation of protecting the right to health, a State may have to reject a patent application and thus failing to comply with their trade obligations.

1.2.3.2 Post- and After TRIPS Reality

It is well known that 'TRIPS dramatically expanded intellectual property protection standards'[66], whose existence and scope was until then a domestic policy's function. Before the TRIPS Agreement, adopted in 1994, governments 'were left free to determine the scope of protection as regards patents' and a number of developed as well as developing countries, such as Brazil, India and Mexico, did not provide patent protection to pharmaceutical products.[67] They were free to evaluate their needs and priorities and based on this evaluation to choose whether they will include pharmaceutical patents within their national laws that 'are exclusively territorial in scope'.[68] When, and if, countries adopted laws for patents on medicines they were able to choose between 'product' and 'process' patents, that grant 'the owner exclusive rights over the chemical compound itself' or apply just on 'the means by which that compound is made' respectively.[69] Process patents gave the freedom to generic pharmaceutical companies of respective countries to proceed to the manufacture of a medicine that was already patented in another country, as the compound itself was not protected. For example, this was the situation in India, where under the Patents Act of 1970, pre-amendment,

[65] Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (no 24) 164.
[66] Laurence R Helfer, 'Regime Shifting in the International Intellectual Property System' (2009) 7(1) Perspectives on Politics 39, 39 <https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2605&context=faculty_scholarship> accessed 18 June 2019.
[67] Harrison Mwakyembe and George Mpundu Kanja, 'Implications of the Trips Agreement on the Access to Cheaper Pharmaceutical Drugs by Developing Countries: Case Study of *South Africa v. The Pharmaceutical Companies'* (2002) 34 Zam L J 111. <https://heinonline.org/HOL/Page?handle=hein.journals/zambia34&div=7&g_sent=1&casa_token=&collection=journals> accessed 28 June 2019.
[68] Helfer, 'Pharmaceutical Patents and the Human Right to Health: The Contested Evolution of the Transnational Legal Order on Access to Medicines' (no 60) 314.
[69] Ibid 314.

Indian pharmaceutical companies could produce generic medicines, for lower prices than patented ones.[70] In this way, product patents were providing 'absolute monopolies' while process patents provided only 'relative monopolies'.[71] After the Uruguay Round however, countries did not have the freedom to choose whether or not to include pharmaceutical products under IP protection according to their needs, and the 'cherry picking' situation was transformed, by the adoption of TRIPS Agreement, to a 'package deal', meaning that States who wanted to be members of the WTO community and benefit from it, automatically had to adhere to the TRIPS Agreement and all of its provisions.[72]

The flexibility of deciding whether and when to provide patent protection to pharmaceutical products created an inconsistent and unstable environment for the research-based pharmaceutical industry that was operating at an international level. Its has been argued that 'As the proliferation of counterfeit, pirated, and other infringing products posed great concern for manufacturers of original products, the importance of IPR protection in trade was recognized'.[73] Additionally, without patent protection, competing generic companies 'could free ride on the efforts of the inventor, copying the invention through reverse engineering and saving the research and development costs while reaping the benefits of the inventor's effort', a fact that would logically result in a lack of a motivation from the part of research-based pharmaceutical companies to invest time and money into the development of new medicines due to the absence of a return on this investment that eventually would lead to a 'market failure.[74] To that extent, 'The TRIPS Agreement is the first international agreement to comprehensively set out substantive and procedural minimum standards for the protection of IPRs'.[75]

The TRIPS Agreement actually binds IP rights and patent protection in the trade regime in order to ensure 'that measures and procedures to enforce intellectual property rights do not

[70] Mwakyembe and Kanja (no 67)111.
[71] UN Human Rights Council (HRC), 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover' (31 March 2009) A/HRC/11/12 para 18< https://www.refworld.org/docid/49faf7652.html> accessed 28 June 2019.
[72] Mwakyembe and Kanja (no 67) 112.
[73] Yoshiko Kojo, 'Global Issues and Business in International Relations: Intellectual Property Rights and Access to Medicines' (2018) 18(1) International Relations of the Asia Pasific 5, 9 <https://academic-oup-com.ezproxy.nottingham.ac.uk/irap/article/18/1/5/4924531> accessed 28 May 2019.
[74] Hestermeyer (no 30) 142.
[75] Sellin (no 61) 453.

themselves become barriers to legitimate trade'[76], such as in the above mentioned case where generic manufacturers produce and sell a medicine at a cheaper price than the inventor although they have never had to bear R&D costs. Under the TRIPS Agreement 'patents shall be available for any inventions, whether products or processes, in all fields of technology' and owners of patents have the exclusive right 'to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing' the respective patented product or the use of process for the development of a product, for a duration of 20 years.[77] Proponents of the TRIPS Agreement argue that the existing patent system achieves the desirable innovation and creativity due to the incentives and rewards that provides to the inventors.[78] Thus, from this point of view, patent protection for pharmaceutical products is a great step and advantage provided to the reseasch-based pharmaceutical industry. However, although it supposedly contributes to the sustainability of the market by providing incentives to inventor pharmaceutical companies to develop new medicines, there are also other implications that can adversely affect people living in developing countries.

While the pressure for the adoption of the TRIPS Agreement mainly came from developed countries who wanted to expand their industries and the pharmaceutical industry itself, developing countries were more reluctant to negotiate and adopt the Agreement. Developing countries were concerned that including pharmaceutical products within patent protection would not be actually beneficial rather it would interfere with the right to health and the welfare of people.[79] However, an economic argument was set forward from proponents of the TRIPS Agreement who argued that introducing the minimum standards of IP protection for every field of technology into their domestic laws would lead to increased foreign domestic innovation and technology transfer.[80] This argument, interestingly, was mainly made by the pharmaceutical sector and developed countries and seems to be only part of an effort towards international IP standards for advancing their own interests since, according to Mwakyembe's and Mpundu Kanjia's point, there is no evidence that premises of the argument are actually taking place. They argue for example that, under TRIPS's Article 27 'removal of the obligation

[76] TRIPS Agreement (no8) preamble.
[77] Ibid art 27, 28, 33.
[78] Joseph (no 53) 220-221.
[79] Mwakyembe and Kanja (no 67) 112.
[80] Joseph (no 53) 232.

to work the pharmaceutical patent locally, for it to be protected', a patent holder has the option of simply import its products to another country instead of actually starting a manufacturing procedure in case of 'no economic viability' to the particular market, a fact that, in combination with the inability of developing countries to compete, leads in the end to no foreign direct investment or transfer to technology in developing countries.[81]

If we take the example of India which, as previously mentioned, provided only for process patents, the impact of product patents in pharmaceutical products on access to medicines for people in developing countries becomes obvious. After India amended its patent rules in 2005 to fully implement the TRIPS Agreement, the populations of developing countries were affected 'in two ways; directly by undercutting the supply of affordable medicines and indirectly by removing the generic competition that reduced the cost of brand-name medicines'.[82] To that extend, pharmaceutical patents are described as 'a source of capital and a source of power' that is reflected on 'the concentrated handful of pharmaceutical companies that through patents receive the privilege of monopolistic profits'.[83] Although a detailed and technical analysis of the function of the pharmaceutical industry's market is out of the scope of this thesis, Holger Hestermeyer, when comparing how competitive and monopolistic markets function, explains how including medicines under patentable subject matters and precluding competition within pharmaceutical industries' markets results in higher prices and lower quantity of medicines sold than in the case of a competitive environment.[84] Thus, while one of the obligations of States, as provided by the above mentioned CESCR General Comment 14, is to ensure economic accessibility of medicines, 'providing corporations with the possibility to patent pharmaceuticals is…counterproductive…,since it results in a higher price level of those products'.[85]

[81] Mwakyembe and Kanja (no 67) 118.
[82] Doris Schroeder, 'Does the Pharmaceutical Sector Have a Coresponsibility for the Human Right to Health?' (2011) 20(2) Cambridge Quarterly on Healthcare Ethics 298, 304 <https://doi-org.ezproxy.nottingham.ac.uk/10.1017/S0963180110000952> accessed 28 June 2019.
[83] Lee C Moerman and S L van der Laan, 'TRIPS and the Pharmaceutical Industry: Prescription for profit?' (2006) 17(8) Critical Perspectives on Accounting 1089, 1099 <https://doi.org/10.1016/j.cpa.2005.09.001> accessed 28 June 2019.
[84] Hestermeyer (no 30) 142-5.
[85] Ibid 138.

The initial argument in favor of the adoption of the TRIPS Agreement and the provision of pharmaceutical patent protection was the avoidance of free riders and thus the promotion of innovation. However, doubt can be cast as to whether meaningful innovation is actually promoted through patents. Although patent protection may indeed incentivize R&D of - at least some - medicines through protecting innovators' rights, there are some methods used by the pharmaceutical industry within the current patent system that give rise to certain concerns regarding the extent to which current R&D priorities and innovation are meaningful from a right-to-health perspective. To that extent it is argued that 'Patents are increasingly used as strategict assets to influence the conditions of competition rather than as a defensive means to protect research and development outcomes'.[86] Firstly, pharmaceutical companies are driven by their for-profit nature and seek to benefit as much as possible from the monopoly that is provided by the TRIPS Agreement. They delay the generic competition through 'evergreening' of patents that 'refers to the practice of obtaining new patents on a patented medicine by making minor changes to it' before the patent period of the initial medicine expires.[87] This leads to what Donald Light and Joel Lexchin refer to as 'the real innovation crisis' which 'stems from current incentives that reward companies for developing large numbers of new drugs with few clinical advantages over existing ones'.[88] A study by Robin Feldman published in 2018 supports this argument, showing that '78% of the drugs associated with new patents in the FDA's records were not new to the market, but existing drugs', a percentage which is estimated to increase to 80% in the following years.[89]

Another issue that is related to the concern over whether the existing incentives for innovation are compatible with the right to health, is connected to the 'neglected diseases' and the amount of R&D efforts directed towards markets where the purchasing power is limited, namely developing countries. Lee C Moerman and A.L van der Laan define 'neglected diseases' as 'a

[86] Matthias Lamping and others, 'Declaration on Patent Protection - Regulatory Sovereignty under TRIPS' (2014) 45(6) IIC - International Review of Intellectual Property & Competition Law 679, 1; Max Planck Institute for Innovation & Competition Research Paper No 14-19 <http://dx.doi.org/10.2139/ssrn.2500784> accessed 28 June 2019.
[87] HRC, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover' (no 71) para 34.
[88] Donald W Light and Joel R Lexchin, 'Pharmaceutical Research and Development: What Do We Get for All That Money?' (2012) 345 British Medical Journal 22, 22 <https://www.bmj.com/bmj/section-pdf/187604?path=/bmj/345/7869/Analysis.full.pdf> accessed 8 June 2019.
[89] Robin Feldman, 'May your Drug Price Be Evergreen' (2018) 5(3) Journal of Law and the Biosciences 590, 617-8 <https://academic.oup.com/jlb/article/5/3/590/5232981> accessed 31 May 2019.

group of diseases that attract little or no research and development, and in some cases, a cessation of manufacture of drugs or vaccine' and they categorize such diseases into two groups: diseases for which 'effective treatment is not available' at all and 'diseases which have treatments but for reasons of access and affordability are not available' in developing countries.[90] According to the WHO Commission Report on Intellectual Property Rights, Innovation and Public Health, 'Poverty affects purchasing power, and the inability of poor people to pay reduces effective demand, which in turn affects the degree of interest of for-profit companies.'[91] Thus, it is very likely that the monopolies provided by the TRIPS Agreement will drive R&D towards diseases that are more likely to generate profit rather than towards diseases which are prevalent in developing countries, where people have the highest needs for such R&D. On this basis it seems then that 'The argument that intellectual property rights are a tortured solution to providing a social good, but alas necessary, does not work for those poor who may die because of the TRIPS regime.'[92]

1.2.3.3 Resolving the Conflict

It is obvious that, although the nature of the TRIPS Agreement is a very 'technical' one that functions like a 'vehicle' to 'foster international trade', it 'has significant impacts beyond trade and intellectual property areas', especially when the object of TRIPS protection are medicines.[93] Remembering the 'institutional' and 'ideational' types of fragmentation of international law, in this case it seems that it is the combination of both that creates the conflict, meaning that different regimes within different institutions and treaties (such as the IP/Trade regime, WTO, TRIPS and Human Rights Law, CESCR, ICESCR) will focus on and favor their own different values and objectives. This can create a structural and normative tension, which is reinforced by the 'the rise of new actors beside states' within the international arena who are trying to advance their own interests, while also being bound by different obligations.[94] In other

[90] Moerman and van der Laan (no 83) 19.
[91] WHO, 'Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health' (WHO 2006) 2 <https://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf?ua=1> accessed 12 June 2019.
[92] Doris Schroeder (no 82) 304.
[93] Philippre Cullet, 'Patents and Medicines: The Relationship between TRIPS and the Human Right to Health' (2003) 79(1) International Affairs 139, 144 <https://academic-oup-com.ezproxy.nottingham.ac.uk/ia/article/79/1/139/2434795> accessed 22 June 2019.
[94] Peters (no 9) 673-675.

words, access to medicines is not just a basic component of the right to health which is subject to the human rights regime, but it also becomes an issue that is affected by the TRIPS Agreement and trade regime, that is in turn influenced by corporate interests. Thus, efforts to resolve the conflict between access to medicines and IP rights are necessary for the protection of the right to health and the achievement of global access to medicines. Both policy makers and legal judges or arbitrators should deal with this conflict both while prioritizing different objectives when they adopt domestic policies or during the actual adjudication of an alleged violation respectively.[95] To this extent, the following paragraphs will analyze proposals for the mitigation of the conflict, in order to to identify the most appropriate and effective path, at least on a theoretical level. Although, as it will be demonstrated, the 'coexistence' approach is the proposal that seems to have contributed the most to the move towards health concerns within the TRIPS regime, a brief analysis of the other approaches is helpful to better understand the relationship between the two different sets of rights that are in conflict.

Les Posterior - Lex Specialis

To begin with, one set of traditional juridical principles applying in cases of conflicting norm arising from international treaties 'are the priority of the *lex* specialis (the treaty that deals more specifically with a matter shall prevail), and the priority of the *lex* posterior (the treaty later in time shall prevail)'.[96] Thus, one may argue that the TRIPS Agreement, should be given a priority based on the fact that the former was adopted after the adoption of the ICESCR (lex posterior) or the fact that it provides for more specific obligations than right to health obligations (lex specialis). However, the fact that the international legal system is characterized by a decentralized norm production, these principles do not have the same effect as they are when applied in domestic contexts.[97] Different actors who are parties to the negotiations for the adoption of the respective different treaties and rules, as well as the different subjects matters of each legal system make the application of these principles inappropriate when resolving the conflict.

[95] Ibid 676.
[96] Ibid 682.
[97] Ibid 683.

Thus, different ways of approaching the relationship and the possible conflict between the trade and human rights regime and the respective rights they provide for should be analyzed and evaluated. Richard Gold presents three different approaches regarding the interface between patents and human rights. Each of these approaches have different implications in terms of how these rights interact with each other and how a possible conflict should be solved. These are the 'integrating', the 'subjugation' and the 'coexistence' approach.[98] Although in the end Gold rejects all of these approaches as being ineffective on the basis that 'international human rights law and patent law are radically different' and that he does not regard the 'the international legal order as the appropriate forum for resolving the human rights-patent tension'[99], this thesis will use them as a reference point to reflect on the various attempts to address this conflict. While realistically it is each individual State that has the responsibility for implementing the rules of a regime, one can not deny that the root of the conflict lies at the international level and the way that these international regimes evolve and interact.

Integrating Approach

First to be considered is the 'integrating approach'. It is argued that 'Human rights law…provides the overarching context in which patent law is to be elucidated', which means that any conflict between patent rights and the right to health may be resolved under human rights law and that any interference may be justified under said human rights law.[100] According to this view, protection of intellectual property rights is seen as a genuine human right and an interference with the right to health may be justified, on the basis that most human rights are not absolute. Therefore 'a limitation of the rights of one person by the rights of others is inherent in the concept of rights'.[101] Thus, if IP rights, in particular patents, are to be classified as human rights then a possible infringement of another human right, in this case the right to health, could be permissible in the name of IP protection if the limitation aims in 'promoting the general welfare in a democratic society'.[102] Article 15 of the ICESCR provides the right to everyone 'to enjoy the benefits of scientific progress and its application'[103] and 'to benefit from

[98] Richard E Gold, 'Patents and Human Rights: A Heterodox Analysis' (2013) 41(1) The Journal of Law, Medicine & Ethics 185-198 <https://journals.sagepub.com/doi/pdf/10.1111/jlme.12013> accessed 10 June 2019.
[99] Ibid 193.
[100] Ibid 187.
[101] Hestermeyer (no 30) 152.
[102] ICESCR (no 3) art 4.
[103] Ibid art 15(1)(b).

the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'.[104] One could understand from this that it allows ill people to 'benefit from the development of new drugs', yet also 'the "right" of pharmaceutical companies to earn a profit from the drugs they develop' respectively.[105] From such an understanding it follows that Article 15 indicates that patent rights are human rights and thus patent-holders, in this case pharmaceutical companies, are protected under human rights law.

However, the CESCR in its General Comment 17 makes it clear that this Article 'does not protect patents as such, nor does it protects pharmaceutical companies'.[106] It highlights that 'human rights are fundamental as they are inherent to the human person as such', a fact that distinguishes Article 15 from IP rights that are 'means by which States seek to provide incentives for inventiveness and creativity'[107]. Thus, the fundamental nature of human rights contrasts with the instrumental nature of the IP rights, which in turn implies the 'timeless' nature of the former contrary to the 'temporary' nature of the latter.[108] Finally the Committee stated that only an 'individual or group of individuals…can be the beneficiary of the protection of article 15, paragraph 1(c)'[109] while 'intellectual property regimes primarily protect business and corporate interests and investments'.[110] On this basis, it is really important that 'pharmaceutical patents are rarely owned by the inventor' but rather they are owned by the 'corporation he works for' and since Article's 15 protection is only granted to individual inventors for the protection of their livelihoods, it is obvious that modern IP rights and patents are not human rights, and the claim of justified interference with the human right to health is not valid.[111] Thus, as Farida Shaheed, the Special Rapporteur in the field of cultural rights, has stated: the right provided by Art 15(1)(c) of the ICESCR 'does not establish a human right to

[104] Ibid art 15(1)(c).
[105] Stephen P Marks, 'Access to Essential Medicines as a Component of the Right to Health', in Andrew Clapham and Mary Robinson (eds), *Realizing the Right to Health* (Rüfer & Rub, the Swiss Human Rights Book Series 2012) 89.
[106] Hestermeyer (no 30) 158.
[107] CESCR 'General Comment No 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (art 15 para 1(c) of the Covenant)' (12 January 2006) E/C.12/GC/17 para 1 <https://www.refworld.org/docid/441543594.html> accessed 28 June 2019.
[108] CESCR General Comment No 17 (no 107) para 2.
[109] Ibid para 7.
[110] Ibid para 2.
[111] Hestermeyer (no 30) 157.

patent protection', while at the same time, 'it does provide a human rights framework within which to consider patent policy'.[112] That means that alleging a human right to patent protection is not a valid claim that can function as a justification for the interference with the right to health, but in fact the opposite may be more likely. This brings us to the second approach which views human rights as the basis upon which trade and patent rules should be applied.

Subjugation Approach

The second approach that Richard Gold analyzes is what he names the 'subjugation approach'. This approach suggests that in cases of conflict between patents and human rights, 'human rights considerations trump patent rights'.[113] This approach reflects another traditional conflict resolution technique of international law, where 'In a system of normative hierarchy, the higher norm is applied, and the other not at all'.[114] Although the subjugation approach could be an acceptable approach from an ethical and idealistic point of view, having in mind the fundamental nature of human rights and their goal, the current reality does not reflect that this approach is followed in practice. Although the 'primacy of human rights law' has been broadly supported in various contexts, from the European Court of Justice which, in the *Kadi and Al Barakaat International Foundation v Council of the European Union*[115] case, 'placed human rights high in the hierarchy of European Union law, even above the commercial obligations which originally gave birth to the regional grouping', to the Vienna Declaration and Plan of Action of 1993 where 'States themselves declared the primacy of their human rights obligations', the current reality and practice within the WTO do not seem to reflect a supremacy of the human right to health over trade interests and patent rights.[116]

Although it seems that there is, or that it should be, a normative hierarchy of human rights over patents and trade rules based on the fact that former are 'goals or ends in themselves, whereas free trade rules are means by which certain ends…are to be achieved'[117], there is no such

[112] UNGA, 'Cultural Rights: Note by the Secretary-General: Report of the Special Rapporteur in the Field of Cultural Rights' (4 August 2015) UN doc A/70/279 para 5 <https://www.un.org/en/ga/search/view_doc.asp?symbol=A/70/279> accessed 28 June 2019.
[113] Gold (no 98) 186.
[114] Peters (no 9) 683.
[115] Joint Cases C-402/05 P and C-415/05 P *Yassin Abdullah Kadi and Al Barakaat International Foundation v Council of the European Union and Commission of the European Communities* (2008) ECR I-06352 para 304.
[116] Joseph (no 53) 48-50.
[117] Ibid 49.

established hierarchy under general international law between the two legal regimes and their norms. There are mainly three 'sources of hierarchically superior norms' that trump any treaty obligation: *jus cogens, erga omnes* and section 103 of the *Charter of the United Nations* but the right to health does not seem to fall within these categories for being regarded as a prioritized norm.[118] Thus, it logically follows that 'the norms are of equal value' and so each regime will give a priority to its own system and will apply its own rules based on its own objective when considering a case.[119] The crucial issue at this point is the strict enforcement mechanism of the WTO regime. The fact that 'TRIPs is a member of the family of World Trade Organization (WTO) treaties' means that the Agreement is linked to the strong enforcement mechanism of the WTO regime, the WTO dispute settlement body.[120] A similar strong monitoring and enforcement mechanism is something that is missing from the human rights regime, which is likely to lead in a 'factual hierarchy' in favor of patents, since States are more likely to comply with WTO rules and their trade obligations due to the possibility of facing trade sanctions for non-compliance.[121]

Consequently, not only it is unlikely that the WTO enforcement mechanism will give priority to right-to-health considerations over TRIPS rules, but when States are confronted with a choice between complying with one rule for the sake of another, they will prefer to comply with the regime with a stronger structure and institution rather than a normative superior provision that has nevertheless no actual sanctioning power. Indeed, 'TRIPS cases have been criticized as largely interpreting the object, purpose and context of TRIPS in favor of protecting intellectual property rights, and giving little weight to arguments about public welfare'.[122] The existence of an 'international judicial system in international law' and more specifically the establishment of 'a reference procedure by granting the ICJ jurisdiction to render advisory opinions requested by other international tribunals', as Anne Peters argues, functioning as 'an institutional supplement to normative hierarchy' would most likely result in distinct institutional enforcement mechanisms, courts and tribunals, to take into account norms and

[118] Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (no 24) 157-162.
[119] Joseph (no 53) 50.
[120] Helfer, 'Regime Shifting in the International Intellectual Property System' (no 66) 39.
[121] Sellin (no 61) 456.
[122] Forman 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (no 24) 165.

objectives from different regimes and thus connect different regulatory regimes to be connected.[123] However, such a procedure does not exists and it does not seem likely to be established and thus, a different approach to the reconciliation of the conflict is necessary.

Coexistence Approach

From the approaches which have been analyzed above, it is clear that IP rights, while they may strengthen the human right of innovators, are not within in the category of human rights. Thus a justification of the interference of patents to access to medicines based on the human rights discourse is not valid. In contrast, relying on the normative superiority of human rights has proven an unrealistic approach to protect the right to health when access to medicines and IP norms are in conflict. Thus, this thesis turns to the third of Richard Gold's approaches to solve the conflict between IP rights and human rights that translates to a conflict of access to and patentabilty of medicines, namely the 'coexistence' approach. This third approach appears to be more promising as it recognizes and is based on the fact that 'patent and human rights law are distinct' while at the same time 'share a basic concern: the optimal amount of patent protection to stimulate and put into practice socially useful innovation' that will eventually benefit the right to health as well.[124] In other words, the interpretation of TRIPS' provisions should be done in a way which supports development, serving not only trade objectives and corporate interests but also complementing right-to-health and access-to-medicines policy goals in order to enhance the livelihoods of people across the world.

This approach is in line with the 'presumption against conflict' that exists in international law and the 'principle of systemic integration', a principle of interpretation that implies that 'when states create new obligations under international law, they do not derogate from their already existing obligations'.[125] This principle has been characterized as a 'de-fragmentation' technique that works as a linking device between different specialized legal regimes, meaning that 'international law-applying bodies' when interpreting 'their body of law' do so 'in the light of a different regime's special rules, or in conformity with general international law'.[126] It is stated in the Vienna Convention on the Law of Treaties (VCLT), a treaty interpretation 'shall

[123] Peters (no 9) 684-5.
[124] Gold (no 98) 187.
[125] Sellin (no 61) 460.
[126] Peters (no 9) (692)

be taken into account, together with the context…any relevant rules of international law applicable in the relations between the parties'[127]. In the context of this thesis, that signifies that the right to health, as being established before the adoption of TRIPS and being part of public international law, should be taken into account during the application and interpretation of the TRIPS Agreements. To that extent, it is argued that Article 31 of the VCLT 'opens the door to non-WTO law and thus to human rights law'.[128] Thus, although the WTO dispute settlement system is not entitled to directly apply human rights law and is very unlikely to do that as its objective is the promotion of trade, the WTO Appellate Body in the *United States - Standards for Reformulated and Conventional Gasoline* case stated that 'the *General Agreement* is not to be read in clinical isolation from public international law'.[129] On the contrary, 'WTO law should be interpreted according to customary rules of treaty interpretation'.[130]

Article 31 of the VCLT also states that 'A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its subject and purpose'.[131] To that extent, it can be understood that the subject and purpose of the TRIPS Agreement, as stated in its provisions, is among others 'the promotion of technological innovation and…the transfer and dissemination of technology…in a manner conductive to social and economic welfare' and that States should be able, when applying TRIPS requirements, to 'adopt measures necessary to protect public health'.[132] Indeed, reading the provisions of Articles 7 and 8 it seems that the purpose of the Agreement could actually contribute to the realization of the right to health rather than hindering access to medicines. However, the current patentability and trade system, the way that is used by pharmaceutical companies and the kind of innovation that promotes, as it was analyzed above, has been

[127] VCLT (no 10) art 31 (3) (c).
[128] Hestermeyer (no 30) 220.
[129] WTO, *United States-Standards for Reformulated and Conventional Gasoline—Appellate Body Report and Panel Report* (20 May 1996) WT/DS/9, 17 <https://www.wto.org/english/tratop_e/dispu_e/2-9.pdf> accessed 28 June 2019.
[130] Sellin (no 61) 461.
[131] VCLT (no 10) art 31 (1).
[132] TRIPS Agreement (no 8) art 7, 8 (1)

challenged and an 'international consensus is building that patents in poor countries serve no innovative function in motivating the development of drugs for diseases prevalent there'.[133]

One of the main concerns of this section was that by 'internationalizing legal protection for pharmaceutical patents and enabling companies to charge monopoly pricing for twenty years in all countries globally, irrespective of the disease burden or level of development of such countries' may lead to a lack of access to medicines and obscure the protection of the right to health that would have a disprportionate effect on people living in developing countries.[134] Thus, as Sellin argues the 'one size fits all' approach for IP rights and patent protection is not desirable as the impact of TRIPS is country specific, meaning that it depends on each country's level of development and specific needs.[135] In this regard, the TRIPS Agreement encompasses a wide range of flexibilities, the so called 'TRIPS flexibilities', that developing countries are encouraged to use when interpreting and implementing IP rights, in order for the objective of articles 7 and 8 to be realized in developing countries.[136]

In other words, by using the provisions of Articles 7 and 8 as a framework and as a compass when States apply the TRIPS requirements within their national laws, the conflict between health needs and patent rules could be avoided by enabling States 'to define a balanced regime of protection, to mutual advantage of producers and users of technological knowledge'.[137] Therefore, States would be able to realize the right to health for their citizens. To this end, the Doha Declaration that will be analyzed bellow, although not a binding document, 'could be construed as a subsequent agreement that should guide the interpretation of a treaty as envisaged in article 31.3.a of the Vienna Convention', as it highlights the importance and priority that should be given to Articles 7 and 8 when interpreting the TRIPS Agreement.[138] In the next chapter, the TRIPS flexibilities and the extent to which it is possible for countries to

[133] Lisa Forman, '"Rights" and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines?' (2009) 10(2) Health and Human Rights: An International Journal 37, 46 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1353221> accessed 2 July 2019.
[134] Lisa Forman and Jillian Clare Kohler (eds) *Access to Medicines as a Human Right: Implications for Pharmaceutical Industry Responsibility* (University of Toronto Press 2012) 8.
[135] Sellin (no 61) 464.
[136] Cullet (no 93) 145.
[137] Mwakyembe and Kanja (no 67) 120.
[138] Forman, 'An Elementary Consideration of Humanity? Linking Trade-Related Intellectual Property Rights to the Human Right to Health in International Law' (no 24) 166.

take advantage of them will be also examined, as well as new trends that have been adopted by pharmaceutical companies in order to strengthen their IP rights and commercial interests, often overlooking their impact on access to medicines and consequently the right to health in developing countries.

CHAPTER 2: TRIPS Developments and New Trends: 'One Step Forward-Two Steps Back'

Having analyzed firstly the content and normative force of the right to health and then the legal commitments that States have regarding both access to medicines for the realization of the right to health and the protection of IP rights, in addition to the conflict that arises between these two commitments, this chapter will present and elaborate on various developments in the direction of taking a more human rights friendly approach when interpreting and applying IP rules in line with what the coexistence approach calls for. However, although there are indeed some efforts within the WTO to take into account the access-to-medicines impacts of the TRIPS Agreement, especially for developing countries, the reaction on the part of the patent-holders, namely pharmaceutical industries, will be examined in order to illustrate how they are both hindering the implementation of the TRIPS flexibilities and are pushing instead towards stricter IP rules, factors which result to the indirect undermining of the right to health in developing countries.

2.1 Doha Declaration and TRIPS Flexibilities - 'One Step Forward'

2.1.1 Background of the Adoption: The Case of South Africa

The Doha Declaration is a document that is one of the major developments that recognizes and highlights the impact that strong patent protection may have on access to medicines in developing countries while highlighting the flexibilities that States are encouraged to use for

mitigating this impact. Before going into an analysis of the Doha Declaration, however, it is worth referring to the *Pharmaceutical Manufacturers' Association v. The President of the Republic of South Africa* case that Lisa Forman regards as the 'tipping point' in the struggle of better the situation of access to HIV medicines in developing countries which led to the adoption of the Doha Declaration.[139] The situation of HIV/AIDS in sub-Saharan Africa was, and still is, highly problematic. According to the UN Programmme on HIV/AIDS (UNAIDS), in 2008, sixty-seven percent of people living whith HIV and seventy-two percent of deaths related to AIDS occured in that area.[140] In 1997, the government of South Africa, in an effort to improve and protect the health of its citizens enacted the Medicines and Related Substances Control Amendment Act No 90 (the Medicines Act).[141] One of the many effects on this act was to provide permission for 'the manufacture of generic HIV/AIDS drugs', 'price control measures' and to empower 'the country's Minister of Health to determine whether to permit parallel imports of patented drugs'.[142] This amendment became the reason for a 5 years 'battle' between the Pharmaceutical Manufacturers' Association of South Africa (PMA) which was composed of 40 multinational pharmaceutical companies, and the South Africa government supported by the Treatment Action Campaign (TAC), a non-governmental organisation.[143] While the aim of the government was to provide 'the country a new drug policy which would facilitate availability of affordable medicines to the majority of South Africans', pharmaceutical companies, as well as US and European governments, who regarded the Amendment 'as a blatant violation of intellectual property rights under both domestic and international law', exercised trade pressure and court litigation to deter the Medicines Act.[144]

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[139] Forman, '"Rights and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines? (no 133) 44.

[140] Joint United Nations Programme on *HIV/AIDS* (UNAIDS)**, '**Report on the Global AIDS Epidemic (July 2008*)* UNAIDS/08.27E/JC1511E 5 <http://data.unaids.org/pub/globalreport/2008/jc1511_gr08_executivesummary_en.pdf> accessed 28 June 2019.

[141] South Africa's Medicines and Related Substances Control Amendment Act No 90 (12 December 1997) <https://www.gov.za/sites/default/files/gcis_document/201409/a90-97.pdf> accessed 2 July 2019.

[142] Erika George, 'The Human Right to Health and HIV/AIDS: South Africa and South-South Cooperation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines' (2011) 18(1) Indiana Journal of Global Legal Studies 167, 182 <https://www.repository.law.indiana.edu/cgi/viewcontent.cgi?article=1440&context=ijgls> accessed 28 June 2019.

[143] Forman, '"Rights and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines? (no 133) 44.

[144] Mwakyembe and Kanja (no 67) 130-1.

Pharmaceutical companies claimed that the proposed legislation and its provisions did not comply with the TRIPS Agreement and South Africa's constitutional property protection, and therefore that the Medicine Act would decrease their incentives to develop new and innovative medicines.[145] The government of South Africa, in contrast, denied the industry's claim and 'South Africans living with HIV and AIDS opposed the industry lawsuit, asserting that industry efforts to block legislation intended to increase access to medicines would threaten their right to health, dignity, and life'.[146] The principal opponent of the pharmaceutical industry, TAC, and its advocacy against the industry's Medicines Act challenge was one of the most important factors that contributed to the positive outcome of the case, as, by drawing on the country's constitution, it 'brought human rights arguments drawn from international and domestic law' and argued that the right to health was a recognized protected constitutional right and a 'legal interest that should be prioritized over corporate property rights'.[147] The case was never been decided by the Court as the pharmaceutical companies withdrew in 2001, which has been attributed to international public outrage that would have led to a reputational damage and economic loss. Despite the withdrawal, the case is regarded as 'instrumental in putting the access to medicines issue on the international human rights and public health agendas'.[148] Although this case demonstrates a clear image of the resistance and negative reaction of pharmaceutical companies when States adopt laws and policies for the protection of the right to health that may undermine their corporate interests, it had a positive outcome as well.

The whole reaction on the part of developed countries, mainly deriving from pharmaceutical companies, and the subsequent answer and resistance of civil society lead to a global awareness about the adverse effects that strong IP protection and patentability of medicines may have on the right to health of populations living in developing countries, especially in the case of the patent system's abuse. To that extent it seems that, although the complexity of legal regimes created both a substantive and a procedural conflict between patentability of and access to medicines, at the same time the fragmentation of international law functioned as an opportunity for developing countries to advance their interests. In this case of South Africa it is illustrated

[145] Forman, '"Rights and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines? (no 133) 44.
[146] George (no 142) 183.
[147] Forman, '"Rights and Wrongs: What Utility for the Right to Health in Reforming Trade Rules on Medicines? (no 133) 44.
[148] George (no 142) 187.

how, in Peter's words, 'institutional dispersal…helps to prevent abuse because it constitutes a separation of powers with the possibility of checks and balances'.[149] Access to medicines, and more specifically IP protection for essential medicines, became an issue of great concern not only within the WTO but was also debated within the UN System, but here with a focus on human rights discourse. The increasing and intense discussions within these forums resulted in the adoption of the Doha Declaration in 2001, the year when the PMA case ended, the importance of which is assessed below.

2.1.2 Doha Declaration and TRIPS Flexibilities

The Doha Declaration is regarded as a milestone regarding its impact on access to medicines and the interpretation of TRIPS Agreement. The Declaration recognizes 'the gravity of public health problems affecting many developing and least-developed countries'[150] and calls for the TRIPS Agreement 'to be part of the wider national and international action to address these problems'.[151] These two provisions could be seen as reaffirming the above analyzed 'purpose' and 'objective' of the TRIPS Agreement as they aim to confirm that trade policies should not stand as a barrier for the development and the advanced livelihoods of people around the world, but rather that they support other public policy goals. The Declaration then continues by recognizing the concerns about the TRIPS Agreement's impact on prices and consequently on access to medicines. It highlights that it 'should not prevent Members from taking measures to protect public health' and reaffirms the importance of the Agreement being 'interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all'.[152] This statement is of great importance since, as was illustrated in the PMA case and will be further highlighted below, companies often are challenging national laws and regulations that threaten their corporate interests. These provisions also are also in line with Article 31(3)(c) of the VCLT about the appropriate procedure of treaty interpretation. The significance of the Doha Declaration is perfectly illustrated by Ellen 't Hoen, policy and advocacy director of the Médecins sans Frontières, who stated that:

[149] Peters (no 9) 681.
[150] Doha Declaration (no 12) para 1.
[151] Ibid para 2.
[152] Ibid paras 3, 4.

> 'The Doha Declaration signalled a sea change in thinking about patents and medicines, and is at the root of a cascade of activities aimed at reformulating IP protection as a social policy tool for the benefit of society as a whole, rather than a mechanism to protect only limited commercial interests. The Doha Declaration provided an authoritative interpretation of the TRIPS flexibilities, gave political backing to countries that wanted to use these provisions, and created new rights for LDCs not to grant or enforce pharmaceutical product patents until at least 2016.'[153]

The flexibility provided by paragraph 7 of the Doha Declaration for the least-developed countries to postpone granting or enforcing patent rights regarding pharmaceutical products until 2016 was recently extended until 2033.[154] Another frequently utilised flexibility is the use of a patent 'without authorization of the right holder', known as 'compulsory licencing', a procedure that must however follow certain requirements which are set out in the TRIPS Agreement.[155] That means that a government is able to allow someone else, usually a generic manufacturer, to produce a patented medicine of process without the patent holder's consent or to use the patent-protected medicine itself.[156] According to the Medicines Law & Policies Database about the use of TRIPS flexibilities, as of 2001 there have been 104 instances of compulsory licences, under Article 31 of the Agreement, of medicines by 52 countries and 46 instances of non-enforcement of patents by 30 countries using paragraph 7 of the Doha Declaration.[157] Additionally, Article 27 which states that 'patents shall be available for any inventions,…provided that they are new, involve an inventive step and are capable of industrial application'[158] but does not specify any particular patentability criteria and implicitly provides a flexibility for States to apply their own criteria according to their needs, is also a tool that

[153] Ellen F M 't Hoen, *The Global Politics of Pharmaceutical Monopoly Power: Drug Patents, Access, Innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB Publishers 2009) 85.
[154] WTO, 'Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, Decision of the Council for TRIPS' (6 November 2015) WTO doc IP/C/73 <https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm> accessed 2 July 2019.
[155] TRIPS Agreement (no 8) art 31.
[156] WTO website FAQ 'Compulsory Licencing of Pharmaceuticals and TRIPS' <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed 28 June 2019.
[157] Medicines Law & Policy: TRIPS Flexibilities Database <http://tripsflexibilities.medicineslawandpolicy.org> accessed 2 July 2019.
[158] TRIPS Agreement (no 8) art 27 (1).

may function also as a preventive measure for the above mentioned 'evergreening' of patents that pharmaceutical companies often make.[159]

Another significant recent development that has favored access to medicines for developing countries is an amendment to the TRIPS Agreement through the Protocol of 6 December 2005 that entered into force on 23 January 2017, after ratification of two thirds of WTO Members, and inserted a new Article 31bis into the Agreement.[160] This amendment increased the flexibility of compulsory licence. Until this point, under Article 31(f) of the TRIPS, compulsory licences were permitted only 'for the supply of the domestic market of the Member authorizing such use'.[161] That meant that for countries with no or limited pharmaceutical manufacturing capacity the flexibility was meaningless in practice. A decision in 2003[162] had made a first move towards the improvement of this provision by introducing a waiver of Article 31(f), however it was still difficult for those countries who could not produce medicines domestically to import generic medicines. However, in 2017, the first amendment to a multilateral trade agreement in the WTO transformed the waiver to a norm rather than just an exception. An important aspect regarding the content of the Doha Declaration as a whole is, as Erica George notes, that it 'is crafted in the language of rights', meaning that according to the Declaration States are granted an actual right to make use of the TRIPS flexibilities in the context of exercising their regulatory autonomy of policy planning according to their needs.[163]

It is argued that 'The TRIPS flexibilities provide a legal basis for poor countries to avoid the consequences of the patent system with regard to their capacity to make essential medicines available to their populations.'[164] However, despite the explicit endorsement of the Doha Declaration encouraging States to make full use of them, there is 'limited and declining usage of TRIPS flexibilities', a fact that 'is attributable at least in part to economic, legal and diplomatic pressure from industry and their host governments' which deters countries from

[159] Joseph (no 53) 227.
[160] WTO, 'Amendment of the TRIPS Agreement' (adopted 6 December 2005, entered into force 23 January 2017) WTO doc WT/L/641 <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm> accessed 28 June 2019.
[161] TRIPS Agreement (no 8) art 31(f).
[162] WTO, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (30 August 2003) WTO doc WT/L/540 <https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> accessed 28 June 2019
[163] Erica George (no 142) 190.
[164] Steven P Marks (no 105) 88.

taking advantage of them.[165] There are various examples of this kind of deterrent reactions when countries used or attempted to use TRIPS flexibilities. For example, in 2006, Thailand was elevated by the US Trade Representative on its 301 Priority Watch List on the basis that its compulsory licences on antiretroviral medicines were an 'indication of "a weakening of respect for patents"' and the pharmaceutical company threatened the government with withdrawal of the country's market of essential medicines.[166] India was also placed in the US priority Watch List after two cases, one related with a compulsory licence that India awarded to a generic version of Bayer's cancer drug and one where the Indian Supreme Court, based on the section 3 (d) of its Patent Act that 'prohibits the patenting of trivial modifications of existing drugs', ruled against Novartis and rejected its application for a patent on Glivec.[167] However, despite the challenges that India faced, it managed, as Jacqui Wise reports, to inspire countries such as Indonesia, Thailand and Brazil to challenge the patent system and reform their patent laws in order to improve access to medicines.[168]

Thus, one cannot deny that the recognition of the possible conflict between access to medicines and patent protection, within the WTO and beyond, has resulted in an increasing number domestic regulations and court decisions with the aim of fostering public health policies and various developments regarding the TRIPS Agreement itself in an attempt to reconcile the conflict and the achievement of the initial purpose of trade agreements in general, and TRIPS Agreement in particular, to promote economic and social welfare, without stand as impediment to other public policy areas. However, at the same time governments of developing countries, when trying to adopt policies and laws for promoting access to medicine and complying with their right to health obligations , are confronted with pharmaceutical companies' and their government's resistance which is translated to a variety of actions, such as actual or potential

[165] Lisa Forman and Gillian Macnaughton, 'Moving Theory into Practice: Human Rights Impact Assessment of Intellectual Property Rights in Trade Agreements' (2015) 7(1) Journal of Human Rights Practice 109, 113 <https://academic-oup-com.ezproxy.nottingham.ac.uk/jhrp/article/7/1/109/2191146> accessed 28 June 2019.
[166] Lisa Forman, 'From TRIPS-Plus to Rights-Plus?: Exploring Right to Health Impact Assessment of Trade-Related Intellectual Property Rights Through the Thai Experience' (2012) 7(2) Asian Journal of WTO & International Health Law and Policy 347, 368 <https://heinonline-org.ezproxy.nottingham.ac.uk/HOL/Page?lname=&public=false&collection=journals&handle=hein.journals/aihlp7&men_hide=false&men_tab=toc&kind=&page=347> accessed 28 June 2019.
[167] Emannuel Kolawole Oke, 'Using the Right to Health to Enforce the Corporate Responsibilities of Pharmaceutical Companies with Regard to Access to Medicines' (2013) 1(2) Journal of Health Diplomacy 8-10 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2332604> accessed 28 June 2019.
[168] Jaqui Wise, 'Patent Wars: Affordable Medicines Versus Intellectual Property Rights' (2014) 348 BMJ 15, 16 <https://www-bmj-com.ezproxy.nottingham.ac.uk/content/348/bmj.g1533> accessed 28 June 2019.

trade sanctions or threats against medical innovation and the removal of essential medicines from the market of the respective country, facts that eventually may lead to an undermining of the right to health for their citizens.

2.2 New Trends for Strengthening Corporate Interests - 'Two Steps Back'

From the above analysis regarding the conflict between the two legal regimes and the TRIPS flexibilities and the positive steps towards a right-to-health friendly use of the Agreement, it seems that there are two parallel realities regarding how rules and cases are considered and decided and how interests of various stakeholders are taken into account between international trade institutions on the on hand and domestic forums on the other. As Emmanuel Kolawole Oke observes, 'While multinational pharmaceutical companies can successfully lobby for stronger patent protection at international trade forums, poor patients and local NGOs usually rely on domestic courts to ensure that their rights are protected at the domestic level.'[169] In other words, the TRIPS Agreement restricted States sovereignty by including a duty to adopt minimum level of protection. Therefore, States had to take this into account when considering and deciding their own IP policies and protection depending on their own capacities and needs. However, there is some space provided by TRIPS flexibilities for States to balance IP/trade and health priorities. While developments of the TRIPS Agreement that enhance access to medicines protection are welcomed from developing States, patients and civil society, pharmaceutical companies have shown concern and look for new ways to protect their corporate interests that depend on strong IP protection.

2.2.1 TRIPS-Plus Provisions

As the UN Special Rapporteur on the right to health notes in his report in 2009, developed countries and their pharmaceutical industry, in an effort to achieve 'the universal harmonization of IP law according to their standards' while viewing TRIPS flexibilities as an impediment to this goal, are continuously pushing for stronger IP protection, a fact that resulted

[169] Oke (no 167) 10.

in many developing countries signing or negotiating 'on extensive trade agreements, including bilateral investment treaties (BITs), FTAs, economic partnership agreements (EPAs) etc'.[170] If previous minimum requirements contained in TRIPS Agreement were hindering access to medicines, despite the flexibilities, one can imagine the adverse effect that these new generation agreements, containing the so called 'TRIPS-plus' provisions, may have on the human right to health. The Special Rapporteur urges both developed and developing States to be cautious about agreements containing TRIPS-plus provisions, stating that developed States should not push for this kind of agreements with developing countries, while the latter should avoid introducing TRIPS-plus provisions in their national laws.[171] However, developing countries often 'sign agreements to gain desired market access without fully understanding the implications of the intellectual property provisions'[172], which usually are to 'undermine the safeguards and flexibilities that developing countries sought to preserve under TRIPS'.[173]

For example, the US-Morocco FTA among others, in contrast with the TRIPS Agreement that provides States the possibility to 'exclude from patentability…(b) plants and animals other than micro-organisms'[174], expands the scope of patentable subject matters by stating that 'Each Party shall make patents available for the following inventions: (a) plants, and (b) animals'[175]. Another way that TRIPS-Plus provisions expand patent protection is by requiring States to provide patents 'for any new uses or methods of using a known product'.[176] This has the effect that, in contrast to the flexibility that is provided by TRIPS Article 27 unspecified patentability criteria, that allowed for example India not to grant patents for non genuine innovations if it does not prove to have a significant advantage, countries which have agreed to TRIPS-plus provisions do not have this discretion. Other TRIPS-plus provisions included in FTAs, such as

[170] HRC, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover' (no 71) paras 23, 68.
[171] Ibid para 108.
[172] Cynthia M Ho, 'A Collision Course Between TRIPS Flexibilities and Investor-State Proceedings' (2016) 6(3) UC Irvine Law Review 395, 402 <https://www.law.uci.edu/lawreview/vol6/no3/Ho.pdf> accessed 23 June 2019.
[173] HRC, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover' (no 71) para 69.
[174] TRIPS Agreement (no 8) art 27 (3) (b).
[175] US-Morocco Free Trade Agreement Art 15 (9) (2) <https://ustr.gov/trade-agreements/free-trade-agreements/morocco-fta/final-text> accessed 2 July 2019.
[176] UN Secretary-General's High-Level Panel on Access to Medicines, ' Report on Promoting Innovation and Access to Health Technologies (14 September 2016) 25 <http://www.unsgaccessmeds.org/final-report> accessed 28 June 2019.

as Article 17 (10) (1) and Article 15 (10) (1) of the US-Chile and US-Morocco FTAs respectively, introduce test data exclusivity periods, meaning that 'Drug regulatory authorities cannot use or rely on clinical studies and data developed by the originator company to register the generic equivalent of a medicine for a given period of time following registration'.[177] This can lead to a delay of the circulation of a cheaper medicine on the market or an increase of its price if a generic manufacturer must repeat all the necessary studies for the respective drug, which in turn can adversely affect the right to health. Finally, another provision from the TRIPS Agreement that can be restricted or even prohibited by TRIPS-Plus provisions is the issuance of compulsory licences, which can be limited and allowed under very specific circumstances.[178] Thus, it is obvious how TRIPS-plus provisions within new FTAs and BITs agreements can in general satisfy both state- and non-state actors who are dissatisfied with and worried about the weaker than the desired IP protection under TRIPS and the TRIPS flexibilities. This does, however, make access to medicines, especially in developing countries, even more difficult.

2.2.2 Investor-State Dispute Settlement (ISDS)

Except for the actual content of IP protection discussed above, relating to stricter IP rights for pharmaceutical companies, another vital development towards the enhanced protection of pharmaceutical companies's IP rights under new FTAs or BITs is that they often include 'dispute settlement mechanisms that establish arbitration processes outside of national courts and allow private firms to challenge national laws for depriving them of future profits', namely Investor-State Dispute Settlement (ISDS).[179] Although investment agreements have existed for decades, it was not always the case that an IP right was considered and as an investment and was protected as such. Until recently, any disagreement related with IP rights was subject to state-to-state dispute settlement within the WTO. In this context 'TRIPS is often considered to have built- in flexibilities that permit compliance with TRIPS while also recognizing domestic priorities'.[180] In these cases, a State's regulatory autonomy for a balance between private economic and health rights was partly supported by the TRIPS flexibilities and was taken into

[177] Ibid.
[178] Ibid 26.
[179] Ibid 19.
[180] Ho (no 172) 397.

account when deciding if a violation of an IP norm had taken place. This does not seem to correlate with the concept of IP protection being subject to ISDS provisions.

It is a fact that companies, being 'private right holders have no standing in fora where states can adjudicate compliance with international IP norms' nor are they often allowed by domestic courts 'to invoke international IP norms directly or even to challenge a domestic IP provision as inconsistent with the forum state's international IP obligations'.[181] That has the result that companies can not invoke IP rights abroad and challenge national laws and policies, as the TRIPS Agreement does not create international rights per se, but rather IP norms that should be interpreted and transferred to each member State's national laws. However, within the current reality, in cases where investors, namely private pharmaceutical companies, can not lobby their host state to invoke an IP violation and file a WTO case, international agreements that include an ISDS provision 'permit foreign investors to bring unique claims against a country before a tribunal of three typically private attorneys, in a so-called "investor-state" arbitration proceeding' that is alleged to aim to a level playing field between foreign and domestic investors.[182]

Daniel J. Gervais effectively criticized the emergence of ISDS as providing for exactly the opposite to what is provided to States in the 1974 Charter of Economic Rights and Duties of States adopted by the UN General Assembly, namely a right to regulate and supervise transnational companies operating within their jurisdiction as well as a duty on these companies 'not to intervene in the internal affairs of a host State'.[183] Although a detailed analysis of the investment regime is not possible within this thesis due to limitations of length, Henning Grosse Ruse – Khan, in his Article, summarizes the various routes that are provided to investors under new trade and investments treaties for bringing an IP claim in ISDS and argues that this new reality 'offers a truly unique and unprecedented opportunity for private right holders to challenge national IP laws in a way not seen before'.[184] In other words, ISDS provisions

[181] Henning Grosse Ruse-Khan, 'Challenging Compliance with International Intellectual Property Norms in Investor-State Dispute Settlement' (2016) 19(1) Journal of International Economic Law 241, 242 <https://academic-oup-com.ezproxy.nottingham.ac.uk/jiel/article/19/1/241/2357954> accessed 28 June 2019.
[182] Ho (no 172) 397, 404.
[183] Daniel J Gervais, 'Investor-State Dispute Settlement: Human Rights and Regulatory Lessons from Lilly v Canada' (2017) UC Irvine Law Review (2018, Forthcoming) Vanderbuilt Law Research Paper 17, 9-10 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3061996> accessed 28 June 2019.
[184] Ruse-Khan (no 181) 10.

provide a tool for companies to overcome national courts and directly challenge any measure which may have an impact on the company's investment, patents being regarded as such, to private arbitration. This, in turn, can fairly been considered as a move back with regards to human rights in relation to what is provided from the TRIPS Agreement and its flexibilities and is an additional threat to the right to health and access to medicines.

What can be proven problematic from a right-to-health point of view is that investor claims, are more likely, if not certain, to be decided in favor of the investor. This is because such claims characterized by a complete 'lack of competing language in the treaty to promote public interest goals'[185], such as health interests, in contrast with the TRIPS Agreement. The lack of reference to interests that go beyond purely investment concerns in new trade and investment agreements is of course welcomed from and promoted by private actors who are mainly concerned about their corporate interests and are relying on a corporate-friendly investor-state tribunal aiming to promote their economic goals. To that extent, it is argued that ISDS is 'a way to achieve indirectly what a corporation cannot do directly'[186], which may sound true if one considers the reluctance and resistance that the pharmaceutical industry has shown to the TRIPS flexibilities and right-to-health friendly national policies.

2.2.2.1 Human Rights Considerations in ISDS: Elly Lilly Case- 'Win of the Battle, not the War'

The Elly Lilly case is an example of where a pharmaceutical company made use of ISDS procedure and submitted a dispute related to IP protection to international private arbitration. By referring to both the company's claims and the tribunal's decision, it will be shown how this kind of dispute settlements which is both favored by and favors pharmaceutical companies, could have an adverse effect on the regulatory sovereignty of States, on TRIPS flexibilities and the balance that States aim to achieve between trade and health objectives and in turn to access to medicines. In this case the pharmaceutical company challenged the decision of the Canadian court, which based on Canada's 'promise utility doctrine', part of its patent law, resulted in the invalidation of two drug patents the company owned on Canada. The company claimed that

[185] Ho (no 172) 409.
[186] Gervais (no 183) 20.

the specific doctrine and the way that it was applied was 'radically new, arbitrary and discriminatory against pharmaceutical companies and products' and thus makes it 'inconsistent with Respondent's obligations related to patent protection under NAFTA Chapter 17' to which Canada is part of.[187] According to the Canadian Patent Act, an 'invention' is defined as 'any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter'.[188]

To that extent, the main subject matter of the dispute was the term 'useful' that, according to the Canadian government, 'is not defined in the Patent Act and its meaning has therefore necessarily evolved through jurisprudence'.[189] The promise of utility doctrine that constitutes the applicable requirement for patent application to be valid, according to the Court's reasoning in this case, 'only applies when a patent applicant, such as Eli Lilly, "promises" that an invention will have a particular purpose' and the doctrine is satisfied if a patent application 'discloses data to support the promise'.[190] This evolution of the notion of utility, and in extension the patent law itself, is what the company is challenging by taking the 'position that its legitimate expectations were violated as a result of a dramatic change in the law'.[191] However, the tribunal regards that the 'evolution of the law through court decisions is natural, and departures from precedent are to be expected'.[192] Although the case was decided in favor of the State of Canada and the tribunal dismissed all the claims of the Eli Lilly company, it did so on the basis that the claimant (the pharmaceutical company) failed to meet its burden of proving a '"dramatic" change in the utility requirement in Canada' or 'a violation of its legitimate expectations' and in general on the basis that the Claimant 'has failed to establish the factual premise of its claims' as well as 'that there was not an arbitrary or discriminatory measure in violation of NAFTA Article 1110 or NAFTA Article 1105'.[193]

However, dismissing the company's claims based on the fact that it did not provide sufficient data probably means that if it did have sufficient proof, the outcome of the case would be

[187] *Elly Lilly and Company v Government of Canada* (no 14) para 5.
[188] Canada's Patent Act R.S.C., 1985, c. P-4 <https://laws-lois.justice.gc.ca/eng/acts/p-4/page-1.html> accessed 2 July 2019.
[189] *Elly Lilly and Company v Government of Canada* (no 14) para 270.
[190] Ho (no 172) 441.
[191] *Elly Lilly and Company v Government of Canada* (no 14) para 306.
[192] Ibid para 310.
[193] Ibid paras 307, 308, 385, 469.

different. More specifically, it is has been argued by Professor Brook K. Baker and Katrina Geddes that the justification for the tribunal 'failed to close the door to the possibility that invalidation of intellectual property rights ("IPRs") under domestic law could constitute a violation of international investment law in the future'.[194] They criticize the fact that 'the Tribunal considered Eli Lilly's criticism of the "uniqueness" of Canada's law (relative to other jurisdictions) as a valid argument' and the fact that it characterized the company's claims as insufficient rather than irrelevant as it should do, in order to honor Canada's 'long-standing national sovereignty over domestic public health policy'.[195] Indeed, as Cynthia M. Ho argues, 'Canada's promise doctrine can be considered a type of TRIPS flexibility', under which States are provided with the discretion to interpret and apply IP norms in ways that they consider to be appropriate for their own legal system and needs.[196] By leaving the door open for investors to challenge domestic patent laws and patentability criteria, regardless of whether the former has sufficient evidence to support their challenge or not, and overlooking each country's national sovereignty, has a negative effect on how developing countries decide to make use of the TRIPS flexibilities. It is created a situation that is described by Baker and Geddes as a 'chilling effect of investor-state arbitration' on the implementation TRIPS flexibilities.[197] They also present two further IP-related investor disputes, where 'two other Big Pharma companies, Novartis and Gilead, have filed or threatened to file ISDS claims against Colombia and Ukraine respectively based on putative IP-investment rights'[198], that 'reflect the extraordinary power given to corporations to challenge national sovereignty over both domestic IP policy and health, and to promote the private arbitration of public interests'.[199]

It is argued that 'The potential conflict between ISDS and human rights exacerbates the risk that tenuous bridges built to allow states to enforce human rights when those rights conflict with trade commitments will collapse'.[200] In other words, the positive developments regarding access to medicines within the WTO, namely the Doha Declaration and TRIPS flexibilities,

[194] Brook K Baker and Katrina Geddes, 'The Incredible Shrinking Victory: *Eli Lilly v. Canada*, Success, Judicial Reversal, and Continuing Threats from Pharmaceutical ISDS' (2017) Loyola University Chicago Law Journal Northeastern University School of Law Research Paper No 296/2017 (last revised May 2018) 479, 480 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3012538> accessed 28 June 2019.
[195] Ibid 502.
[196] Ho (no 172) 442.
[197] Baker and Geddes (no 194) 488.
[198] Ibid 487.
[199] Ibid 513.
[200] Gervais (no 183) 36.

are clearly threatened by TRIPS-plus and particularly ISDS provisions. The involvement and the vital role of pharmaceutical companies on the creation and maintenance of this situation is an issue that cannot and should not be overlooked. While pharmaceutical patent protection under the TRIPS Agreement 'reflects both private and private interests' and allows for a balancing between right to health and trade commitments, 'in an ISDS…the singular focus on the protection of private interests' in combination with the fact that 'a party to the dispute is a multinational company' it is problematic.[201] One main explanation for this problematic reality is that pharmaceutical companies, when provided with such a powerful tool for advancing their interests, will of course make use of it especially in the absence of human rights obligations. Thus, after referring to the current reality regarding human rights considerations in ISDS contexts, the last chapter of this thesis is dedicated to discussing what this thesis considers is decisive for access to medicines under the existing circumstances. That is, what kind of right-to-health responsibilities pharmaceutical companies have, or should have, under international law and if they are applicable in situations when they seem to abuse the patent system and indirectly affect access to medicines by affecting the extent to which States are able to comply with their commitments and protect the right to health.

2.2.2.2 Human Rights Considerations in ISDS: Urbaser Case-a Way Forward?

A study by Silvia Steininger which was based on 46 awards by investment tribunals shows that although human rights references in investment arbitration are present, it is most likely that they will be taken into account 'when the rights invoked could serve investment concerns'.[202] More specifically, it is clear from the results of the study that while the respondent, namely States, is the one to introduce human rights references in most investor-state arbitrations as a defence in order 'to justify its non-compliance with the investment treaty in place', human rights references introduced by the claimant, namely the investor, for his benefit 'have a stronger impact than those introduced by the respondent' and thus it is more likely to be taken into account and be addressed.[203] As the study reaffirms, 'human rights in the sense of third

[201] Ibid 34-27.
[202] 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, 52 <https://doi.org/10.1017/S0922156517000528> accessed 28 June 2019.
[203] Ibid 42-43.

party interests (in particular economic and social rights as well as third-generation human rights) only played a very limited role in investment arbitration'[204], and thus the overall situation for human rights protection from investors' claims that act only on behalf of their corporate interests is disappointing. However, some more recent cases seem to be optimistic.

In 2018 Stefanie Schacherer published a compilation of 10 investment arbitration cases related to issues of sustainable development, that in the author's view 'has become the global paradigm guiding the ongoing reform of international investment law', including, among others, human rights.[205] Among the presented cases, that are used to elaborate on the complexity of balancing investment and non-investment interests within the ISDS context, two are relevant with the subject of this chapter, as well as the whole thesis, as they are cases where socio-economic rights were successfully brought forward. These cases focus on the right to health and the right to water in *Philipp Morris* v. *Uruguay*[206] and *Urbaser v. Argentina* respectively, and are of great importance as they 'provoked significant public awareness of the critical implications of investor-state dispute settlement and investment treaties'.[207] More specifically, in the Philipp Morris case the tribunal 'recognized the right to regulate and a wide margin of appreciation for states in adopting measures concerning public health'[208], a fact that reinforces what is provided by the TRIPS flexibilities. The Urbaser case on the other hand, although not directly related to the right to health, but to the right to water, constitutes a great development in terms of human rights considerations in ISDS contexts as well as a unique case where corporate human rights obligations were discussed. Thus a closer look at this case will provide a valuable basis for the discussion of the last part of this thesis.

Urbaser Case

While a detailed and technical analysis of this case will be not conducted due to limitations of length, there are two elements to the tribunal's approach of importance. First of all, until now

[204] Ibid 56.
[205] Stefanie Schacherer, 'International Investment Law and Sustainable Development: Key cases from the 2010s' (Nathalie Bernasconi-Osterwalder and Martin Dietrich Brauch eds 2018) Published by the International Institute for Sustainable Development 1 <https://www.iisd.org/sites/default/files/publications/investment-law-sustainable-development-ten-cases-2010s.pdf> accessed 2 July 2019.
[206] *Philip Morris Brands SÀRL, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay*, ICSID Case No ARB/10/7.
[207] Stefanie Schacherer (no 205) 43.
[208] Ibid.

thesis has been concerned with the corporate-friendly approach of the IP system in general and the prioritization of IP and economic interests over non-economic ones, especially in agreements with ISDS provisions. The ISDS system in general is characterized, as Kevin Crow and Lina Lorenzoni Escobar state, by an 'asymmetrical nature'; from the one hand 'procedural' since it 'provides a cause of action for investors against the host States to protect their investments' without providing the same for States while refuting 'attempts by States to bring counterclaims against investors', and 'substantive' by imposing obligations only to States in contrast to investors who are being granted rights without any obligations.[209] Consequently, this reality is more than possible to undermine human rights obligations of States. However, the Urbaser case and the tribunal's approach to accept jurisdiction over a State's human right counterclaim can be seen as partly mitigating this asymmetry and as a sign 'that non-investment concerns are creeping up on the side-lines of investment arbitration' while, at the same time, acknowledging that States bear additional rights and obligations under international law and a 'right to regulate' taking them into account.[210] It does so also by referring to the VCLT and the rules of interpretation that it sets out, which the tribunal should take into account when interpreting and applying this or any other Convention, and stating that the 'The BIT has to be construed in harmony with other rules of international law of which it forms part, including those relating to human rights'.[211] It further 'rejected the position that a human rights claim was inherently beyond its jurisdiction, as it was not convinced that a human rights counterclaim and an investment dispute were mutually exclusive'.[212] However, while an innovative step was taken by the tribunal as 'it has simplified the jurisdictional requirements for ICSID counterclaims' and broadened the space for human rights considerations, its discussion of the merits of the counterclaim is more complex and challenging.[213]

This brings us to the second important contribution of the Urbaser case that is related to the final chapter of this thesis; corporations' human rights obligations. Despite the fact that the

[209] Kevin Crow and Lina Lorenzoni Escobar, 'International corporate obligations, human rights, and the *Urbaser* Standard: Breaking New Ground?' (2017) 35 BU Int'l L J 87, 89 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2984987> accessed 28 June 2019.
[210] Silvia Steininger (no 202) 53.
[211] *Urbaser et al v The Argentine Republic* (no 15) para 1200.
[212] Edward Guntrip, '*Urbaser v Argentina:* The Origins of a Host State Human Rights Counterclaim in ICSID Arbitration' (10 February 2017) EJIL: Talk Blog of the European Journal of International Law https://www.ejiltalk.org/urbaser-v-argentina-the-origins-of-a-host-state-human-rights-counterclaim-in-icsid-arbitration/ accessed 2 July 2019.
[213] Ibid.

counterclaim in this case was accepted in terms of jurisdiction, the actual content of the counterclaim: the 'Claimants' alleged failure to provide the necessary investment into the Concession, thus violating its commitments and its obligations under international law based on the human right to water'[214] was more controversial. Importantly, the tribunal departed from the traditional view that investors and corporations, as non-state actors, 'are by nature not able to be subjects of international law' and thus do not bear human rights responsibility, a view that it regarded as having 'lost its impact and relevance' within the current reality.[215] It is argued that 'ISDS is the result of a move towards recognizing the role of multinational corporations as international legal persons' who 'are given a right to sue states in binding and mandatory arbitration proceedings'.[216] Taking the same line of argumentation, the tribunal regards the rights being conferred by the BIT to companies as a valid basis upon which to reject the idea 'that a foreign investor company could not be subject to international law obligations'.[217] However, although only the fact that the Tribunal explicitly recognizes the possibility that companies could have human rights obligations under international law is a fact of great significance, 'it ultimately did not hold the investor liable for not effectively ensuring the human right to water, reasoning that, in this case, related international obligations applied to states only'.[218]

In other words, although the tribunal recognizes the negative obligations for companies to abstain from human rights violations, after exploring traditional human right treaties, it argued that 'the investor's obligation to perform…does not find its legal ground in general international law', rather 'has as its source domestic law', over which the tribunal had no jurisdiction.[219] This has two pottential meanings. On the one hand, as the tribunal stated: 'The situation would be different in case an obligation to abstain, like a prohibition to commit acts violating human rights would be at stake. Such an obligation can be of immediate application, not only upon States, but equally to individuals and other private parties.'[220] On the other hand though, it could mean that the outcome of the case could also be different in the case of more

[214] *Urbaser et al v The Argentine Republic* (no 15) para 36.
[215] Ibid para 1194.
[216] Gervais (no 183) 8-9.
[217] *Urbaser et al v The Argentine Republic* (no 15) para 1194.
[218] Stefanie Schacherer (no 205) 2.
[219] *Urbaser et al v The Argentine Republic* (no 15) 1195-1210.
[220] Ibid 1210.

explicit and specific human right obligations for companies under international law. The tribunal was willing and indeed took an innovative approach, both in terms of accepting jurisdiction and considering a human rights counterclaim, as well as by departing from a state-centric view of human rights obligations. The above case was selected for illustrating both a positive approach within the ISDS context and the problem caused by the lack of corporate human rights obligations under international law. Thus, based on the great power that companies are given within the ISDS system that is now part of many agreements with IP provisions, a more detailed elaboration on their human rights obligations is crucial for their more effective protection. More specifically, returning to the subject matter of this thesis, the focus of the discussion in the next and final chapter will be on the pharmaceutical companies, their existing right-to-health responsibilities and the potential that their special nature and function may provide for additional responsibilities.

CHAPTER 3: Pharmaceutical Companies' Role and Right-to-Health Responsibilities

The above analysis showed how human rights and IP interests interact with each other when the corporate interests of pharmaceutical companies are involved. More specifically, it was demonstrated that the strong enforcement mechanism within trade and investment regimes in contrast to the weaker enforcement of human rights instruments, especially ESCR, often results in the undermining of the right to health and access to medicines in developing countries. Furthermore, except for the fact that the marker-driven nature of the IP regime as such favors the corporate interests of transnational pharmaceutical companies (TNPCs), the latter, as non-state actors, are regarded as not having any, at least internationally recognized, human rights obligations. The implications of this became apparent in the above mentioned Urbaser case. It is often argued that 'The complex interplay of these factors, that is the lack of binding international norms for TNPCs or a lack of regulation of TNPCs, the patent system and pricing mechanisms of the TNPCs are intermingled with an unnecessary deprivation of the "right to

health"'.[221] The patent system and its implications on the economic accessibility of medicines has been broadly discussed in the previous chapters. At this point the issue that should be studied closer is the role of the pharmaceutical companies, what this role may imply for their right-to-health responsibilities and what international law provides for in this regards.

3.1 Who has Human Rights Responsibilities? General Considerations

The primary duty barriers for the protection and realization of human rights are States. As it was analyzed in the first chapter, States have the responsibility to protect their citizens from the conduct of private actors, including corporations, through legislative and other measures. Thus the obligations that non-state actors have, according to international human rights law, is 'a matter of domestic civil or criminal law, backed by the international legal obligation of the State'.[222] In other words, the human rights obligations of non-state actors derives from the State's obligation to protect and consequently companies are not 'the direct holder of human rights obligations under international law'.[223] However, there are cases where the State is either not able or not willing to comply with their human rights obligations and, as it was shown, this inability or unwillingness is often exacerbated by conflicting IP obligations. Furthermore, the exclusive right provided to companies by ISDS provisions provides them with the unique opportunity to challenge national laws adopted for the protection of public policy issues, such as health, outside of national courts, a fact that renders the protection of human rights difficult even if the State is able and willing to do so. It is argued that the existing 'state-centric framework of international human rights law' remains 'partially blind to the opportunity to speak more directly to influential non-state actors including corporations' despite the fact that their 'size, revenues and global reach' makes their impact over people and societies comparable

[221] Janna Greve, 'Healthcare in developing countries and the role of business: a global governance framework to enhance the accountability of pharmaceutical companies' (2008) 8(4) Corporate Governance: The International Journal of Business in Society 490, 493 <https://www.emerald.com/insight/content/doi/10.1108/14720700810899220/full/html> accessed 28 June 2019.
[222] Eric De Brabandere 'Human Rights and Transnational Corporations: The Limits of Direct Corporate Responsibility' (2010) 4(1) Human Rights & Internationall Legal Discourse 66, 74 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1992945> accessed 28 June 2019.
[223] Ibid 74.

with that of States, a fact that seems to be not appropriate and effective within the current reality.[224]

Although the fact that there is no consensus on whether the wording 'all organs of society' of the UDHR was intended, at the time of its adoption, to make transnational companies (TNCs) addressees of the UDHR's human rights obligations, one should consider the fact that, even if it was supposed to exclude them in the time of writing, 'the financial and cultural influence of TNCs has expanded significantly since the drafting of the Declaration'.[225] Thus, on the basis of companies' evolution and increasing influence over a great range of aspects of peoples lives, the way that international law deals with non-state actors and their responsibilities needs to be reevaluated and changed. As was reaffirmed by the tribunal's reasoning in the above-mentioned Urbaser case, companies should be regarded as having, at least, negative human rights obligations. In the context of pharmaceutical companies' activities, could we say that abusing the patent system, or challenging States measures that aim to the protection of their citizens' right to health fall within the realm of not interfering with the right to health? And if they do, can the explicit recognition of corporate responsibilities to, at least, respect human rights achieve a balance between IP and access to medicines rights? To this end, although under international human rights law, the main duty bearers of human rights obligations seem to be exclusively States, there are a number of soft law instruments that are adapting to the changing reality by taking a more innovative approach and, by recognizing the changing nature of companies, attempt to provide a tool and a framework in order to specify their human rights responsibilities. Before elaborating on these documents and their added value in the human rights and right-to-health discourse, focusing on the UNGP and the Hunt guidelines, it is helpful to analyze the evolution of the view regarding the responsibilities that companies were perceived to have and the transition from the traditional corporate social responsibility (CSR) concept, to the Business and Human rights (BHR) discourse, or in other words the inclusion of

[224] Justine Nolan 'Mapping the Movement: The Business and Human Rights Regulatory Framework', in Dorothée Baumann-Pauly and Justine Nolan (eds) *Business and Human Rights: from Principles to Practice* (2016 Routledge) 34.
[225] Anand Grover and others, 'Pharmaceutical Companies and Global Access to Medicines: Strengthening Accountability Under the Right to Health' (2012) 40(2) Journal of Law, Medicine & Ethics 234, 239 <https://journals.sagepub.com/doi/abs/10.1111/j.1748-720X.2012.00661.x> accessed 28 June 2019.

human rights considerations within CSR practices, in order to illustrate how there is indeed a change in how companies are generally perceived.

3.2 Who Should Have Human Rights Responsibilities? Evolution of CRS and BHR Concepts

The traditional understanding of what businesses were responsible for in the past was, as Friedman stated in 1962, 'to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition without deception or fraud'.[226] This means that at this time it was considered that the only responsibility of a company was supposed to be profits maximization for its shareholders and to compete in good faith with each other without any further considerations of whether and how they may affect other aspects of society. However, society as a whole is composed on a set of 'subsystems' with 'various players and sets of rules', each one of them is subject to specific expectations, and these expectations have changed both in terms of number and content.[227] After the gradual recognition of companies' actual impact, the focus of the discussions about CSR have changed and a debate started regarding what CSR means not just for the company itself but also for society as a whole.

Since the beginning of this debate, 'the corporation was equated with monopoly, and monopolies posed great opportunities for abuse' as well as great power.[228] In the case of pharmaceutical companies and the patentability of medicines, the implications of this monopoly is extremely apparent. On this basis, the role of corporations began to be revaluated. There was a growing recognition among the business community that the impact that they have is reflected not only in economic practices but also in environmental and societal issues and that this impact should also be part of their concern. Thus, people argued that 'the proper target

[226] Fiona Harris, 'Brands, Corporate Social Responsibility and Reputation Management' in Aurora Voiculescu and Helen Yanacopulos (eds), *The Business of Human Rights: an Evolving Agenda for Corporate Responsibility* (Zed Books, The Open University 2011) 47.
[227] Klaus M Leisinger, 'Corporate Responsibilities for Access to Medicines' (2009) 85(sup 1) Journal of Business Ethics 3, 10 <https://link-springer-com.ezproxy.nottingham.ac.uk/article/10.1007/s10551-008-9944-4> accessed 28 June 2019.
[228] A A Sommer Jr, 'Whom Should the Corporation Serve? The Berle-Dodd Debate Revisited Sixty Years Later' (1991) 16 Del J Corp L 33, 36 <https://perma.cc/FCQ2-NGGJ> accessed 20 June 2019.

of directorial attention should be *stakeholders* and not just stockholders'[229], meaning that not only the interests of people who had a direct economic interest in a company, such as its owners, should be taken into account, but also other affected peoples' or groups of peoples' interests should be part of the overall decision making process of a company.

In general, some of the companies' social responsibilities are precisely defined and prescribed by law, but others are not. Regarding these different features of CSR, Carroll's 'pyramid of responsibilities' illustrates what is expected from companies: at the base of the pyramid are the economic and legal requirements, meaning firstly to be profitable and secondly to obey the law; the second level is the expected ethical operation of a company and at the top of the pyramid is the discretionary social responsibility required of being a good corporate citizen.[230] The latter type of CSR is in line with the US conception of CSR, where 'philanthropic giving, community service and marketing' is emphasized.[231] Doris Schroeder refers also to CSR as 'Either a duty is instructed by law (e.g., health and safety for workers) or self-interest (e.g., continuous education of staff) or benevolence (e.g., donations) or a mixture of the three'. [232] Although there is a more inclusive understanding of what it means for a company to be socially responsible, every action is still taken bearing in mind and examining the corporation's best interest and it seems to be a missing point regarding the meaning and importance of progressing CSR one step ahead by including human rights considerations into a business's agenda.

First of all it is argued that 'Instrumental CSR emphasizes the value of CSR as a tool or instrument for the advancement of economic interests of the company'.[233] This means that companies may take their impact on affected stakeholders into account, as long as these stakeholders are directly linked to the corporation (e.g. workers) or are powerful enough to to affect in turn the operation of the company. Additionally, 'the business case' for environmentally sustainable practices, such as energy savings or alternative energy sources, are easier to be measured, analyzed and justified than human rights, since they are positively

[229] ibid 38.
[230] Harris (no 226) 45.
[231] Dorothée Baumann-Pauly and Justine Nolan (eds), *Business and Human Rights: from Principles to Practice* (Routledge 2016) 77.
[232] Doris Schroeder (no 82) 305.
[233] Florian Wettstein, 'Human Rights as a Critique of Instrumental CSR: Corporate Responsibility Beyond the Business Case' (2012) 18 (106) Notizie di Politeia 18, 20 <https://perma.cc/AA8J-BH8A> accessed 20 June 2019.

connected with a company's financial performance and thus 'a win-win situation for society and the company' is created.[234] Instead, when dealing with human rights challenges a company has 'to make additional investments in training social compliance audits or enhanced infrastructure'.[235] Such features add costs rather than profits, that then must be explained and justified to the relevant shareholders of the corporation, and thus are often overlooked. The same applies in the case of pharmaceutical companies, where for example lower drug prices may often translate to a company's financial loss but at the same time they may contribute to a population's access to medicines and the protection of their right to health.

It is argued that 'CSR, as defined, may encompass some aspects of human rights – in particular labor and social rights – but the focus of CSR has been broader and not explicit about human rights as an end goal'.[236] However, the content and driving force for CSR needs to be revaluated. At this point the BHR discourse fills the gap that exists between companies, CSR and human rights. While CSR is a voluntary concept, human rights are fundamental and imply specific obligations, and while CSR is very often focused on the distribution of profits, 'BHR and some European concepts of CSR, in contrast, are more focused on where companies derive profits and how core operations affect human rights'.[237] Having in mind the fundamental nature of human rights, their purpose to protect right-holders, and the power that companies have gained to affect not only the global economy but also peoples' lives, it is vital to make it clear that the corporate responsibility to address and respect human rights during operations is 'a normative imperative and that no economic rationale is needed for companies to devote resources' to do so.[238] Thus, although until now the rationale of corporations for adopting CSR practices has been based on powerful stakeholders and economic factors, corporate responsibility to respect human rights needs to be approached in a different way.

[234] Dorothée Baumann-Pauly and Michael Posner, 'Making the Business Case for Human Rights: An Assessment' in Dorothée Baumann-Pauly and Justine Nolan (eds), *Business and Human Rights: From Principles to Practice* (Routledge 2016) 13.
[235] Ibid.
[236] Anita Ramasastry, 'Corporate Social Responsibility Versus Business and Human Rights: Bridging the Gap Between Responsibility and Accountability' (2015) 14 (2) J Hum Rts 237, 239 https://ssrn.com/abstract=2705675 accessed 28 April 2019
[237] Bauman-Pauly and Nolan (no 232) 77.
[238] Bauman-Pauly and Michael Posner (no 235)14.

To this end, because of the confusion surrounding the meaning and function of corporate responsibility to respect human rights and the increased number of allegations of human rights violations from companies, various soft law instruments have been developed within the international community. While voluntary in nature these instruments attemt to build an international consensus on what it actually means for a corporation to behave in line with human rights within a globalised economy and provide practical guidance to this end. As there are no international legally binding human rights obligations placed upon companies, the discussion that will follow regarding the pharmaceutical companies right-to-health responsibilities, will be based mainly on the UNGP, as this is regarded as one of the most comprehensive documents dealing with corporate human rights responsibilities, as well as the Hunt Guidelines which are specifically addressed to the pharmaceutical industry.

3.3 The Case of the Pharmaceutical Industry

It has been argued that 'Human rights already have become a permanent part of the international political agenda – and it is necessary that they become a regular part of the international economic agenda too.'[239] Some of the various ways that a research-based pharmaceutical company may affect the right to health and in particular access to medicines has been discussed in the previous chapters. At the same time, the fact that they are not legally bound by international human rights law in combination with the provision of great power they hold within various forums to promote their corporate interests, was identified as exacebrating the conflict between IP righst and access to medicines when pharmaceutical companies are abusing the monopoly which is provided by the IP system. To that extent, it is argued that 'the direct and indirect negative impact of TNPCs on the accessibility of vital medicines automatically justifies the demand for human rights obligations of the TNPCs'.[240]

At this point, the UNGP, attempting to provide a general framework regarding corporate human rights obligations, makes it clear that 'The responsibility to respect human rights is a

[239] Greve (no 221) 494.
[240] Ibid.

global standard of expected conduct for all business enterprises wherever they operate'[241], meaning that businesses must make sure that they do not infringe on the human rights of others during their ordinary operations. It is important to note that the responsibility to respect is not just a passive concept but rather requires action from companies. Thus, except expressing 'their commitment to meet this responsibility through a statement of policy'[242], the UNGP set out a wide range of steps that companies should actively take in order to comply with their responsibility, one of them being that they 'should carry out human rights due diligence' that is defined as a process that includes 'assessing actual and potential human rights impacts, integrating and acting upon the findings, tracking responses, and communicating how impacts are addressed.'[243] The responsibility to respect, and everything that it encompasses according to the UNGP 'is the baseline expectation for all companies in all situations'[244], including pharmaceutical companies. However, as Ruggie argued, 'There are situations in which companies may have additional responsibilities - for example, where they perform certain public functions'.[245] On this basis, it is necessary to address if pharmaceutical companies fall within this category and how the UNGP apply to them.

At this point, it is worthy to refer to some criteria that David Bilchitz considers important for defining the nature of human rights obligations of companies. He argues that 'corporations cannot exclusively focus on achieving business goals such as maximizing profits in a manner that inhibits the advancement of human rights'.[246] According to him there are some factors that justify additional duties that are directly addressed to certain corporations. When we consider if and what kind of obligations a company has in relation to human rights, some necessary elements that we should take into account are 'the extent to which the sphere of activity of a

[241] HRC, 'UN Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework' (UNGP) (United Nations 2011) HR/PUB/11/04 Guiding Principle 11, Commentary https://www.ohchr.org/documents/publications/GuidingprinciplesBusinesshr_eN.pdf accessed 28 June 2019
[242] Ibid Guiding Principle 16.
[243] Ibid Guiding Principle 17.
[244] HRC, 'Protect, Respect and Remedy: a Framework for Business and Human Rights: Report of the Special Representative of the Secretary-General on the issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie' (7 April 2008) UNdoc A/HRC/8/5 para 24 <https://www.business-humanrights.org/sites/default/files/reports-and-materials/Ruggie-report-7-Apr-2008.pdf> accessed 28 June 2019.
[245] Ibid.
[246] David Bilchitz, 'Corporate Obligations and a Treaty on Business and Human Rights' in David Bilchitz and Surya Deva (eds) *Building a Treaty on Business and Human Rights: Context and Contours* (Cambridge University Press 2017) 204.

corporation is closely connected to the realization of human rights', 'the structure of the market and dominance of a corporation therein' and 'the extent to which corporate activity affects the ability of government organs to realize the state's positive obligations'.[247] Thus, based on these variables, we must consider what unique characteristics pharmaceutical companies have that may call for more specific responsibilities.

First of all, the nature of the product or service that a corporation provides for should be taken into account. Although the primary responsibility of every company is towards their shareholders and they are mainly concerned with profit maximization, a distinction should be made regarding the profit from products that are vital for peoples wellbeing and luxury products. It is argued that 'an essential commodity such as health care is analogous to the primary social goods considered by Rawls since it is so crucial for one's self-determination'.[248] For such essential social goods as medicines there is a distinction between what constitutes 'a morally reasonable profit' and 'an economically reasonable profit', the former usually being lower than the latter.[249] Thus, based on Rawls rationale, 'pharmaceutical firms must be prepared to impose some restraints on profits for the sake of distributive justice', meaning 'the fair distribution of society's benefits and burdens'.[250] The issue of reasonable prices and profit will be also discussed below, in the context of the need for transparency. In general, based on theories of morality, it seems more than obvious that the unique function and goods that the pharmaceutical industry provides for justify the need for additional concerns and balance of for-profit and social function.

To that extent Leisinger, accepting the responsibility of pharmaceutical companies to respect human rights, but also additional – in terms of morally required – responsibilities, provides a hierarchy model, similar to Caroll's pyramid, that establishes priorities regarding the potential corporate access-to-medicines obligations.[251] According to what he calls the 'must' dimension,

[247] Ibid 205.
[248] Richard A Spinello, 'Ethics, Pricing and the Pharmaceutical Industry' (1992) 11(8) Journal of Business Ethics 617, 625 <https://www-jstor-org.ezproxy.nottingham.ac.uk/stable/25072314?seq=1#metadata_info_tab_contents> accessed 28 June 2019.
[249] David B Resnik, 'Developing Drugs for the Developing World: An economic, legal, moral, and political dilemma' (2001) 1(1) Developing World Bioethics 11, 26 <https://onlinelibrary.wiley.com/doi/epdf/10.1111/1471-8847.00004> accessed 28 June 2019.
[250] Spinello (no 248) 621-625.
[251] Leisinger (no 227) 13-17.

'the primary responsibility of a pharmaceutical company arises in the context of its normal business activity' and consists of R&D and distribution of innovative medicines in the market in order to contribute to the 'reduction of premature mortality', the 'prevention and cure of diseases' and the advance of 'the quality of life of sick people', while actions and practices of pharmaceutical companies that 'respond to broader public expectations that go beyond legal minima', especially in countries with weak legal norms, or actions of 'corporate philanthropy' such as donations, fall within the realm of, what he calls, the 'ought to' and 'can' dimension respectively.[252] An aspect of Leisinger's this thesis considers particularly important is that although there is an increase of good practices taken up by pharmaceutical companies, such as differential prices, donations and R&D for neglected diseased, these fall within the 'can' or 'ought to' dimension.[253] He further criticizes the fact that, despite the increase of good practices, there is a tendency from the part of activists to continuously 'raise the "demand bar"', a fact that can have as a result a 'responsibility fatigue'.[254]

Indeed, a hierarchy between primary and additional responsibilities is necessary and pharmaceutical companies cannot be expected to act as charities. Nevertheless, it is necessary to make sure that, regardless as to whether they adopt this kind of good practices, they always respect the right to health during their operations and clarify what 'respect' means in the context of pharmaceutical companies' operations. To this extent, it seems that Leisinger's analysis is more focused on the responsibilities of pharmaceutical companies that are related with the direct way that a company may contribute to the realization of access to medicines, the actual manufacture and distribution of medicines. Although he mentions that 'companies must strive to ensure that their activities do not contribute directly or indirectly to the neglect of respect, protection and fulfilment of the right to health'[255], he does not specify what exactly is meant by that.

In this respect, the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines, drafted by the UN Special Rapporteur Paul Hunt in 2008 (Hunt Guidelines), is a useful guidance tool for assessing pharmaceutical companies' responsibilities

[252] Ibid 13-17.
[253] Ibid 16-17.
[254] Ibid 17.
[255] Ibid 15.

in this context. Unlike the UNGP that applies to to all corporations the Hunt Guidelines 'identify with a greater degree of operational specificity: the human rights responsibilities of one sector…in relation to one area of sectoral activity.'[256] While Hunt's report and his Guidelines consider a wide variety of issues, including transparency, management, accountability, patents, licencing and pricing, and is addressed both to patent-holding and generic companies, for the purpose of this thesis the most relevant and important regarding pharmaceutical companies' practices and policies that directly and indirectly affect access to medicines will be focused on. More specifically, although Leisinger argues that 'patents do not form a significant obstacle to access to essential medicines'[257], the two previous chapters demonstrated that they do not only have an impact on pricing and R&D policies of pharmaceutical companies but the general patent and IP system also provides them with great power to challenge national laws. Recalling Schroeder's CSR conception, he argues that pharmaceutical companies that benefit 'from a system that imposes direct harm' and 'from patents on goods required to satisfy basic needs, a fourth realm must be added, namely, a duty of redress for harm from which one benefits.[258] Or, in Joo-Young Lee and Paul Hunt words, 'society has a legitimate expectation that the patent holder of a life-saving medicine will not only enjoy the privileges arising from the patent but also fulfill the corresponding responsibilities'.[259] To this extend, patent-holders pharmaceutical companies are clearly benefiting from a system that by itself obscures access to medicines, and the fact that they are not legally bound by human rights responsibilities increases the degree of the conflict that is created.

At this point, it is useful to have in mind Moon's review of the the Hunt Guidelines in the light of the UNGP. Moon sought to assess what respecting the right to health means for the pharmaceutical industry, and to achieve his aim categorized the 47 Hunt Guidelines into four different realms, namely 'respect', 'protect', 'grey areas' and 'fulfil', each one of them falling, in his view, under a corporate responsibility, a State obligation or under a grey area that

[256] Joo-Young Lee and Paul Hunt, 'Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines' (2012) 40(2) The Journal of Law, Medicine& Ethics 220, 222 <https://journals.sagepub.com/doi/pdf/10.1111/j.1748-720X.2012.00660.x> accessed 28 June 2019.
[257] Leisinger (no 227) 17.
[258] Doris Schroeder (no 82) 305.
[259] Lee and Hunt (no 256) 228.

involves both.[260] First of all, in line with the UNGP due diligence requirement, the Hunt Guidelines call all pharmaceutical companies to have in place mechanisms that specifically 'assess the impact of the company's strategies, policies, programmes, projects and activities on access to medicines, especially for disadvantaged individuals, communities and populations'[261]. In this way, companies will be able to evaluate their potential actions and decisions, to identify possible negative outcomes regarding specific target populations, such as developing countries, and to adopt right-to-health compliant policies, appropriate for the respective population. Regarding specifically patent-holding companies, the focus of this thesis, the Guidelines state that they should contribute to the R&D of neglected diseases[262], provide voluntary licenses[263], waive data exclusivity[264], not apply for second uses patents[265] and in general aiming at ensuring that the medicines they develop are 'affordable to as many people as possible'[266]. However, Moon argues that all of these practices are likely to be impossible to be initiated by the pharmaceutical companies themselves without state action and regards them as falling within the category of State obligations to 'protect' and 'fulfil' access to medicines objectives that can be achieved 'more likely when governments decisively deploy a range of policy tools for this purpose'[267].

At this point, however, one of the above mentioned Bilchitz's criteria regarding companies' responsibilities comes into play, that is the level of influence that a company has on the ability of a State to comply with its positive obligations. Pharmaceutical companies have the power, as it was discussed in the previous chapter, by relying on ISDS forums to challenge, or threaten to challenge, whichever national access-to-medicines initiative may hinder their corporate

[260] Moon Suerie, 'Respecting the right to access to medicines: Implications of the UN Guiding Principles on Business and Human Rights for the Pharmaceutical Industry' (2013) 15(1) Health and Human Rights 32, 38 <https://www-jstor-org.ezproxy.nottingham.ac.uk/stable/healhumarigh.15.1.32?seq=1#metadata_info_tab_contents> accessed 28 June 2019.
[261] UNGA, 'The Right to Health: Note by the Secretary-General: Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health' (11 August 2008) UNdoc A/63/263 Annex 'Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines' (Hunt Guidelines) para 14 (a) <https://www.refworld.org/docid/48e35af12.html> accessed 28 June 2019.
[262] Ibid para 23.
[263] Ibid para 30.
[264] Ibid para 31.
[265] Ibid para 32.
[266] Ibid para 33.
[267] Suerie (no 260) 40.

objectives, and thus negatively affect how States protect and fulfil the right to health. To that end, the Hunt Guidelines explicitly address this issue by stating that companies 'should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994)', 'make and respect a public commitment not to lobby for more demanding protection' such as TRIPS-Plus and ISDS provisions and generally 'respect the letter and the spirit of the Doha Declaration'.[268] According to Moon's categorization, these provisions clearly fall under the 'respect' principle's umbrella and consequently constitutes what Ruggie calls a 'baseline expectation' of the industry. Having in mind the above mentioned provisions of the Hunt Guidelines and Moon's categorization, even if making medicines affordable requires coordination between the State and the companies, not interfering with the right and obligation of the State to regulate in favor of access to medicines, such as in the above mentioned cases, translates into not interfering with the right to health and should be regarded as an established obligation of the pharmaceutical industry.

Another important element that Hunt regards as vital for the effective respect and protection of access to medicines is that 'the company should be as transparent as possible'.[269] In general, there is a tendency to naturalize high drug costs on the basis of high costs of R&D. High prices on the other hand should not make medicines inaccessible since this translates to a violation of the right to health. A 'reasonable price' is often defined as 'a price that allows the company to earn its money but also promotes accessibility and equity'.[270] However, the data that exists for assessing if a claim of high R&D costs is valid is controversial due to a lack of transparency. An often cited study conducted by Joseph DiMasi, Ronald Hansen and Henry Grabowski at the Tuftis Center showing that the costs for R&D of a new drug was more than $1.3billion in 2006 (a figure that was expected to be continuously increasing) has been subject to a lot of criticism due to the fact that the Center has continuously received industry funding and thus is regarded as biased.[271] Interestingly, the GlaxoSmithKline CEO itself has characterized the

[268] Hunt Guidelines (no 261) paras 26-29.
[269] Ibid para 6.
[270] Resnik (no 249) 19.
[271] Donald Light and Rebecca Warburton, 'Demythologizing the High Costs of Pharmaceutical Research' (2011) 6(1) BioSocieties 34, 36 <https://search-proquest-com.ezproxy.nottingham.ac.uk/docview/1030868876?accountid=8018&rfr_id=info%3Axri%2Fsid%3Aprimo> accessed 28 June 2019.

$1billion R&D costs figure for the development of a new drug as 'one of the great myths of the industry'[272]. On the other hand, there are many who argue that the pharmaceutical industry spends more on Marketing and Sales(M&S) than on R&D. For example, a study prepared by the Institute for Health and Socio-Economic Policy in 2016 shows, among others, that 'out of the top 100 pharmaceutical companies in 2015, 89 spent more on M&S than on R&D'.[273] Many NGOs advocate against 'the arbitrary nature of price setting by pharmaceutical corporations, with no rationale other than profit-maximisation made possible by abuse of the patent system'[274] and argue that the 'lack of transparency gives pharmaceutical corporations the upper hand in price negotiations, keeping prices as high as possible while overstretched health systems and people in need of lifesaving medicines lose out'.[275] Another fact that creates doubts about whether patents and high drug drug prices are justified on the basis of innovation is the already mentioned concern of 'evergreening' of patents and the extend of which new medicines have indeed a beneficiary function. Thus, the importance of requiring pharmaceutical companies to have a level of transparency about their R&D priorities as well as their pricing and their overall policies, as required by the Hunt Guidelines 6 to 8, for assessing what a fair return on R&D investment is and generally if the company is complying with its right-to-health responsibility, becomes apparent.

Thus, it becomes clear that a pharmaceutical company's responsibility to respect the right to health and access to medicines relates both to the activities of the company that are directly linked with R&D priorities and pricing setting but also to the degree that they allow or hinder governments' attempts to live up to their own already established human rights obligations. On the one hand, R&D priorities and pricing policies seem to fall to each company's discretion to act in a responsible manner and it is hard to require and oblige pharmaceutical companies to set low prices or to follow good practices on a regular basis considering their for-profit nature.

[272] Ellen 't Hoen, 'Private Patents and Public Health: Changing Intellectual Property Rules for Access to Mesicines' (Health Action International 2016) 17 <http://accesstomedicines.org/wp-content/uploads/private-patents-and-public-health.pdf> accessed 28 June 2019.
[273] Institute or Health and Socio-Economic Policy, 'The R&D Smokescreen: The Prioritization of Marketing & Sales in the Pharmaceutical Industry' (20 October 2016) <https://nurses.3cdn.net/e74ab9a3e937fe5646_afm6bh0u9.pdf> accessed 28 June 2019.
[274] Médecins Sans Frontières, 'Medicines Shouldn't Be a Luxury: It's Time to Stop Big Pharma's Profiteering' (8 May 2019) Opinion Article <https://msfaccess.org/medicines-shouldnt-be-luxury-its-time-stop-big-pharmas-profiteering> accessed 28 June 2019.
[275] Candice Sehoma and Gaelle Krikorian, 'MSF: Secret Medicine Prices Cost Lives' (Health E-News 10 April 2019) <https://www.health-e.org.za/2019/04/10/msf-secret-medicine-prices-cost-lives/> accessed 28 June 2019.

Nevertheless, monitoring their performance by establishing transparency requirements that aim for example to the avoidance of the abuse of the legal monopoly that is provided by patents, seems more possible – and in fact necessary - than setting actual uniform international requirements about R&D and pricing issues. On the other hand, pharmaceutical companies should be legally bound to respect the State's human rights obligations, meaning they must comply with the domestic legal norms and policies of the respective State and not arbitrarily challenge legislations and regulations that aim to the protection of the right to health of citizens. Having in mind both the UNGP and the Hunt Guidelines, trying to challenge and undermine a State's right-to-health laws and policies for the sake of their corporate interests amounts to a corporate violation of the right to health and should be taken into account both in domestic courts but even more so in international ISDS arbitration proceedings which tend to favor corporate interests.

It seems by the tribunal's approach in the Urbaser case, analyzed in the previous chapter, that corporate human rights obligations (at least in their negative dimension) are indeed possible to be taken into account in cases of investor-States disputes. Having accepted and established an international corporate responsibility to respect of the above mentioned nature can indeed reinforce the positive direction that the Urbaser tribunal already took. Discussions and negotiations for a legally binding treaty on BHR have already taken place and such a development could mitigate the conflict between IP rights and access to medicines or, in other words, between corporate interests and human rights. A BHR treaty wich codified the obligation to respect could provide an additional instrument to rely upon when corporations challenge States on the basis of legislative or other reforms. Such a codification 'may offer such an opportunity by striking a better balance between states' legitimate role in safeguarding human rights and the need to protect investors' rights'.[276] David Bilchitz considered two different possible models of such a treaty, a 'direct' model addressed directly to companies and an 'indirect' model that is focused on the State's obligation to protect their citizens, and argued in favor of a direct model that would 'involve recognizing that there are in fact direct obligations imposed upon corporations by international human rights law or that such

[276] Surya Deva, 'Conclusion-Connecting the Dots' in David Bilchitz and Surya Deva (eds) *Building a Treaty on Business and Human Rights: Context and Contours* (Cambridge University Press 2017) 481.

obligations should be created by states'.[277] The precise nature of such a future BHR treaty, while a topic worthy of further study, is out of the scope of this thesis. However, regardless to whether a future BHR treaty would specifically include for example 'an obligation on signatory states to include a BHR clause in all future IIAs, and to amend existing agreements to include one'[278] as Peter Muchlinski calls for or whether it will be directly or indirectly addressed to corporations, the recognition of human rights obligations by an international BHR treaty could still be regarded as a great positive step that may result in a more cautious and responsible conduct on the part of pharmaceutical companies and their access-to-medicines (direct and indirect) influence as well as in a more effective balance between corporate IP rights protection and access to medicines for people in developing countries.

Conclusion

This thesis provided an extensive analysis of how the two distinct legal realities of strong corporate IP protection and the lack of pharmaceutical companies' human rights responsibilities within the international legal order lead to the deprivation of the right to health for people living in developing countries by undermining access to medicines. The whole discussion of this thesis demonstrated a clear conflict between the current strong corporate IP protection (under TRIPS, TRIPS-plus and ISDS provisions) and access to medicines. On this basis, it sought to determine the role of the pharmaceutical companies to the evolution of the IP regime and the implementation of its provisions. The results of this elaboration according to the author call for specific right-to-health responsibilities of the pharmaceutical industry in order for a balance between corporate and human rights interests, and in extension IP rights and access to medicines in developing countries to be achieved.

Thus the first chapter conducted an overall analysis of the content, normative force and legal implications of the right to health and the interference between IP rights and access to medicines in developing countries as well as an assessment on how the conflict which is created

[277] David Bilchitz (no 246) 187.
[278] Peter Muchlinski, 'The Impact of a Business and Human Rights Treaty on Investment Law and Arbitration' in David Bilchitz and Surya Deva (eds) *Building a Treaty on Business and Human Rights: Context and Contours* (Cambridge University Press 2017) 374.

can be resolved, at least at a theoretical level. Starting with an analysis of ESCR it was clarified that the right to health is a fundamental human right, consolidated among various legal instruments and there is no normative or legal basis for challenging this status. Access to medicines is implicitly and explicitly defined as a vital component of the right to health according to Article 12 ICESCR and the CESCR General Comment 14 respectively. The 'access to medicines' inclusion in the core States' right-to-health obligations renders it subject to immediate realization and thus should be protected and promoted as such. Despite a superficial reference to the business sector as having right-to-health responsibilities in the General Comment 14 the fact that the CESCR does not further elaborate on the issue has serious implications on how States can comply with their obligations to respect, protect and fulfil the right to health and on how the pharmaceutical industry affects access to medicines.

These implications became apparent in the context of conflicting obligations of States which are subject to both the IP and the human rights regime and have to balance IP and access to medicines rights. This situation was firstly examined in the light of the general reality of the fragmentation of international law and it was made clear that the fact that two different specialist legal systems with different values and objectives developed in isolation from each other is very likely to result to an adverse effect on access to medicines if the application of IP standards which are being established continues to take place in isolation from the right to health. It was demonstrated that the initial goal of including pharmaceutical products under IP protection to promote innovation and contribute to the sustainability of the market is not reflected on the current reality, since the monopoly power that the TRIPS Agreement provides to pharmaceutical companies does not always incentivise meaningful R&D and often results to high prices which in turn negatively affect the accessibility of medicines. To this extent it is clear that the expansion of the IP regime disproportionately affects access to medicines in developing countries.

Thus, on the basis of the TRIPS Agreement's significant impact beyond trade and intellectual property protection and the conflict between patentability of and access to medicines it was considered necessary to examine possible ways to mitigate and resolve this conflict. Although not all of these approaches were proved effective, they were helpful in order to better understand the relationship between the access-to-medicines and IP norms. Firstly, no

appropriate reference point exists for applying traditional judicial principles such as the *les specialis* and *lex posterior* principles. Additionally, considering IP rights as human rights (integrating approach) and approaching the conflict with access to medicines under human rights law in order to justify a possible interference of IP rights with access to medicines is not a valid approach since patent rights are not human rights. Nor can we rely on a normative hierarchy of the right to health over patents on the basis of human rights' fundamental nature (subjugation approach) for the resolution of an actual conflict, since the strong enforcement mechanism of the WTO regime creates an actual structural and procedural hierarchy in favor of IP rights both within the WTO system as well as when States are confronted with a prioritization decision between IP and right-to-health norms.

The last approach that was analyzed is considered to be the more appropriate and realistic as it recognizes the different nature between IP rights and the right to health and the more promising from a human rights point of view as it calls for interpreting the TRIPS Agreement in the light of the right to health (integrating approach). According to this approach which is in line, with the principle of systemic integration of international law, specialized trade and IP provisions should not stand as an obstacle to the realization of the right to health, rather their interpretation should take into access to medicines. Also by reading Articles 7 and 8 of the TRIPS Agreement in the light of Article 31 of the VCLT it was argued that these two provisions of the Agreement could be used as a framework when States adopt TRIPS requirements with a view to balance economic and social welfare objectives, at least at a theoretical level.

The second chapter evaluated various developments, both positive and negative, within the IP regime and their implications on access to medicines in developing countries. Firstly, it examined how the global awareness raised after the South Africa case regarding the impact of strong IP protection of pharmaceutical products on access to medicines led to the adoption of the Doha Declaration which is regarded as one major 'step forward' towards a more right-to-health friendly interpretation and implementation of the TRIPS Agreement. The TRIPS flexibilities that the Doha Declaration highlights and urges States to use are the main, and probably the only tool for developing countries to achieve a balance between IP with access to medicines obligations. However, although a willingness within the WTO order for a more right-to-health friendly approach when interpreting the TRIPS Agreement, the fact that

powerful non-state actors, pharmaceutical companies, who have great corporate interests and no international human rights obligations, are involved in this conflict, decreases the possibility of the effective implementation of TRIPS flexibilities.

To that extent the thesis elaborated on new trends of enhanced IP protection that the author characterizes as 'two steps back' regarding access to medicines in developing countries. Aggressive pressure from the part of the pharmaceutical companies has resulted to negative developments from a right-to-health perspective, which decreased the space provided by the TRIPS flexibilities for States to balance access to medicines with IP rights protection. Firstly, TRIPS-plus provisions in new trade and investment agreements undermine the TRIPS flexibilities by expanding patentable subject matters, introducing test data exclusivity requirements and restrict or prohibit compulsory licences. At the same time ISDS provisions under FTAs or BITs which was illustrated as diminishing the willingness of States to make use of the TRIPS flexibilities and adopt right-to-health friendly laws and policies. The Elli Lilly case was used as an example where the ISDS tribunal, although it dismissed the company's claims, it left the door open for private companies to challenge national patent laws and TRIPS flexibilities, a fact that was illustrated as creating a deterrent effect on future attempts by other countries to adopt laws and policies in order to promote the right to health.

The absence of corporate human rights obligations explains why pharmaceutical companies are so willing to oppose to right-to-health friendly laws and policies, especially when the corporate-friendly IP system itself provides them with such an opportunity. To this extent, the Urbaser case which was discussed in the the second chapter was described as a positive development within ISDS contexts from a general human rights point of view. The acceptance of jurisdiction over a respondent's (the Argentinian State) human rights counterclaim as well as the tribunal's departure from the traditional view that non-state actors are not and should not be subject of human rights obligations could be a great step forward towards the more effective protection of human rights. However, the lack of precise and internationally established corporate human rights obligations remains a problem which the last chapter attempted to address.

It was argued that although States are the primary addressees of human rights obligations, the changing nature of corporations and the way that they can affect human rights requires a different approach regarding their corporate responsibilities. It was shown that there is an ongoing (positive) evolution regarding the conception of corporations' role and responsibilities, from the traditional CSR concept that was mainly based to a voluntary nature of social and environmental good practices to the BHR discourse that calls for companies' stricter human rights responsibilities. On the basis of the BHR discourse and drawing, among others, on the UNGP as well as the Hunt Guidelines the final part of this thesis attempted to assess and define the nature and content of right-to-health obligations that pharmaceutical companies should have in order for access to medicines to be more effectively protected in the context of the strong and corporate-friendly IP system.

On the basis of pharmaceutical companies' unique social function that renders their activity directly connected to the realization of the right to health as well as the great power which is provided to them by the IP system to interfere with the ability of States to comply with their right-to-health responsibilities the author stressed the need for more precise and stricter right-to-health responsibilities of pharmaceutical companies. Stricter transparency requirements for better monitoring pharmaceutical companies' activities and the obligation to respect developing countries' right to make use of the TRIPS flexibilities when they adopt their national law and policies were highlighted as two of the most important aspects of respecting the right to health that in the author's view could improve access to medicines in developing countries. As both the WTO and ISDS forums seem to consider international law when they evaluate and decide cases, establishing international human rights obligations for corporations, including the pharmaceutical industry, are necessary. A legally binding BHR treaty could function as a tool for decreasing the possibility of the right to health to be sacrificed for the sake of corporate interests by biased, in favor of companies, outcomes in IP forums. In that way a more cautious approach by the pharmaceutical companies when challenging States' right-to-health compliant laws and policies and when adopting their own R&D and pricing policies could be achieved that in turn could contribute to the enhanced protection of access to medicines and the right to health for people living in developing countries. To that extent, the precise nature of such a treaty in order to be more effective is considered to be a matter worthy of further study.

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