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Access to Medicines and Pharmaceutical Patents:
Corporate Responsibility to Respect in the
Pharmaceutical Industry

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Summary

The U.N. Guiding Principles on Business and Human Rights is the final work of the meticulous mandate upheld by the Special Representative of the Secretary-General between 2005 and 2011. It consists of three pillars, namely, the state duty to protect against human rights abuses by third parties, including business, the corporate responsibility to respect human rights, and access by victims to effective remedy. The focus of this thesis is on the second pillar, specifically the corporate responsibility of patent-holding pharmaceutical companies to respect the right to health in access to medicines context.

The research question that this thesis seeks to answer is what meaning the corporate responsibility to respect human rights as framed by the U.N. Guiding Principles signifies for patent-holding pharmaceutical companies in the access to medicines context, more specifically, whether it is comprehensive enough to meet the right to health requirements or not. The thesis initially establishes that the term ‘respect’ is meant to correlate with its meaning in human right law, which refers to non-infringement or ‘doing no harm’. Subsequently, the thesis avails itself of the right to health framework as a reference point to indicate the adverse human rights impacts of patent-holding pharmaceutical companies. As a response to these adverse impacts, specific corporate actions that should be taken are suggested, which often require initiative from companies such as price reductions in life-saving medicines through participation in multi-stakeholder initiatives or engaging in voluntary licensing agreements. Justifications to support the aforementioned actions are also provided to make clear that the scope of corporate responsibility to respect in fact allows for broader interpretation of ‘respect’ in certain circumstances.

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Abbreviations

ARV	Antiretroviral
CESCR	Committee on Economic, Social and Cultural Rights
CSR	Corporate Social Responsibility
DND <i>i</i>	Drugs for Neglected Diseases <i>initiative</i>
GATT	General Agreement on Tariffs and Trade
GSK	GlaxoSmithKline
ICESCR	International Covenant on Economic, Social and Cultural Rights
IHRB	Institute for Human Rights and Business
MPP	Medicines Patent Pool
MSF	Médecins Sans Frontières
NTDs	Neglected Tropical Diseases
OHCHR	Office of the High Commissioner for Human Rights
R&D	Research and Development
SRSR	Special Representative of the Secretary General
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Introduction

1.1 Background

Access to medicines has been at the centre of global health policy debates since the HIV/AIDS epidemic hit the world in the 1980s. Although the efforts in access to AIDS/HIV medicines have been successful thus far, there is still many challenges that lie ahead. According to the UNAIDS Global Report¹, 9.7 million people who receive treatment represents only 34% of the 28.6 million people eligible in 2013. It must be clarified that the access problem cannot be associated with only one type of disease. The challenges of a changing world have placed other diseases such as malaria, drug-resistant tuberculosis, hepatitis C or non-communicable diseases such as cancer or diabetes on the global health policy debates as well.

Access to medicines is a multifaceted problem, which is caused by various actors due to various factors. Indeed, the Working Group on Access to Essential Medicines of the United Nations Millennium Project identified six barriers to access to medicines:

Inadequate national commitment, inadequate human resources, failure of the international community to keep its promises of assistance to developing countries, lack of coordination of international aid, obstacles created by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)² and the current incentive structure for research and development of medicines and vaccines to address priority health needs of developing countries.³ This list clearly indicates that the problems posed by access to medicines are more complex and broader than a claim against the negative

¹ UNAIDS, 'Global Report: UNAIDS report on the global AIDS epidemic 2013' (November 2013) p.46

² Agreement on Trade-Related Aspects of Intellectual Property Rights (15 April 1994) Marrakesh Agreement Establishing the World Trade Organization Annex 1C 1869 U.N.T.S.299

³ Stephen P. Marks, 'Access to Essential Medicines as a Component of the Right to Health' p.82 in: Andrew Clapham *et al.* (eds) *Realizing the Right to Health* Swiss Human Rights Book Vol.3 (rüffer & rub 2009)

impact of pharmaceutical patent rights.⁴ However, the thesis will focus itself on patent-related barriers, specifically the adverse impacts of patent-holding pharmaceutical companies⁵ on the right to health.

Access to medicines is a field in which adverse human rights impacts of business enterprises are felt blatantly. Rapid expansion of the private sector and transnational economic activities⁶ have found its repercussions in this context as well. The most significant manifestation of the U.N. initiative in the human rights and business sphere would be the six year mandate of the Special Representative of the Secretary-General (SRSG), which was concluded in June 2011. Within the mandate, the ‘Protect Respect Remedy’ Framework⁷ (Framework) and the U.N. Guiding Principles on Business and Human Rights⁸ (U.N. Guiding Principles) have shined out and acquired unprecedented level of recognition from a wide range of stakeholders. While the Framework shows *what* should be done in the case of a business related human rights abuse, the Guiding Principles show *how* to do it.⁹ They are based upon three pillars, namely, the state duty to protect against human rights abuses by third parties, including business, the corporate responsibility to respect human rights, and access by victims to effective remedy. The focus of this thesis is on the second pillar, specifically the responsibility of patent-holding pharmaceutical companies to respect right to health in the access to medicines context.

⁴ *Ibid.* p.86

⁵ The terms of company, corporation, business entity or enterprise are used interchangeably throughout the thesis.

⁶ The SRSG, ‘Guiding Principles on Business and Human Rights: Implementing the United Nations “Protect, Respect and Remedy” Framework – Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises’ (21 March 2011) 17th Session Agenda Item 3 UN Doc A/HRC/17/31 p.3

⁷ The SRSG, ‘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’ (7 April 2008) 8th Session Agenda Item 3 UN Doc A/HRC/8/5

⁸ *supra* note 6

⁹ John G. Ruggie, *Just Business: Multinational Corporations and Human Rights* (W.W.Norton & Company 2013) p.81

1.2 Research Question

The research question that this thesis seeks to answer is what meaning the corporate responsibility to respect - as framed in the Pillar II of the U.N. Guiding Principles - signifies for patent-holding pharmaceutical companies in the access to medicines context, more specifically, whether an expectation to 'respect' human rights is comprehensive enough to meet the right to health requirements or not.

The SRSG was inspired by the international human rights law classification of respect, protect and fulfil when formulating the Framework.¹⁰ He makes clear distinction between what is required under the corporate responsibility to respect and what is desirable but not imperative. This thesis critically analyses and challenges this distinction. It challenges it by way of presenting the case of price reductions in life-saving medicines where the positive act - initiative - from the company is needed to make progress in the access problem and therefore, claims that the scope of corporate responsibility to respect needs to be interpreted broadly and the U.N. Guiding Principles in fact allows for this expansion.

1.3 Structure & Method

Access to medicines is a multifaceted problem in which different disciplines play a role. It requires an interdisciplinary approach, which accommodates different fields from human rights, intellectual property or international trade law, to non-legal areas such as voluntary corporate social responsibility schemes. Trilateral cooperation between World Trade Organization (WTO), World Intellectual Property Organization (WIPO) and World Health Organization (WHO) to promote the access to medicines is the proof of this multifaceted nature.¹¹ Therefore, an interdisciplinary approach is covered throughout this thesis.

¹⁰ *Ibid.*

¹¹ WHO, WIPO and WTO, 'Promoting Access to Medical Technologies and Innovation: Intersections Between Public Health, Intellectual Property and Trade' (2012) available at

Chapter II starts with how different disciplines, *i.e.* intellectual property and human rights law approach the access problem whereby a systematic reflection on both disciplines is conducted. At the end, the chapter highlights the state-centric governance focus of both regimes as a shortcoming in international law. The methodology followed in this chapter is mainly a text analysis of primary sources in the two fields. Under the intellectual property heading, the focus is the post-TRIPS period because the TRIPS Agreement is the turning point, which significantly exacerbated the size of the access problem. Therefore, the TRIPS Agreement itself, the WTO mandated Doha Declaration of 2001¹² and the Decision of 30 August 2003¹³ constitute the primary area of focus. Under the human rights context, the focus is limited to the right to health. International Covenant on Economic, Social and Cultural Rights (ICESCR) and general comment No.14 of the Committee on Economic, Social and Cultural Rights (CESCR or Committee), which clarifies the normative content of the right to health and reports of the Special Rapporteur on the right to health (Special Rapporteur), are the main reference points.

Chapter III introduces the reader to corporate responsibility to respect as framed in the U.N. Guiding Principles, specifically the human rights due diligence concept, which is the inherent tool for implementation of the corporate responsibility to respect. For operationalising the corporate responsibility in the patent-holding pharmaceutical industry, the chapter avails itself of the right to health framework as developed in international human rights law. This framework helps to identify more precisely the concrete adverse impacts of patent-holding pharmaceutical companies from access to medicines point of view. It must be clarified that this framework is formulated in relation to state obligations. However, this thesis uses it as a

<http://www.wto.org/english/res_e/booksp_e/pantiwhowipowtweb13_e.pdf> accessed on 23 May 2014

¹² WTO, 'Ministerial Declaration on the TRIPS Agreement and Public Health' (14 November 2001) WT/MIN(01)/DEC//2

¹³ WTO, 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' (30 August 2003) WT/L/540

reference point in order to indicate the adverse impacts of patent-holding pharmaceutical companies.¹⁴

Subsequently, chapter IV questions the boundaries of responsibility to respect and whether what is required of companies can be expanded or not. For this purpose, the example of price reductions in life-saving medicines through participation in multi-stakeholder initiatives and engaging in voluntary licensing agreements is chosen. At the end, the chapter brings justifications that the corporate responsibility to respect needs to be interpreted broadly for the given examples. It refers to the Guiding Principle 19, which provides the appropriate actions expected from companies and several other arguments to support this main point.

Chapter V completes the thesis by summing up the findings from the previous chapters. It also makes clear that the critical approach adopted in this thesis should not ignore the positive aspects of the U.N. Guiding Principles.

1.4 Delimitations

Access to medicines is related to various human rights such as the right to life, right not to be tortured, right to non-discrimination, right to an adequate standard of living or the right to enjoy the benefits of scientific progress and its applications. However, this thesis will limit itself within the scope of right to health.

It must be highlighted that the focus of this thesis is access to *essential* medicines. Essential medicines are those that satisfy the priority health-care needs of the population. They are selected with due regard to disease prevalence, evidence on efficacy, safety and comparative cost-effectiveness.¹⁵ Each country is expected to formulate its own national list of essential medicines according to its health-care priorities. The WHO

¹⁴ Joo-Young Lee and Paul Hunt, 'Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines' (2012) *Journal of Law, Medicine & Ethics* p.225

¹⁵ Hans V. Hogerzeil, 'Essential Medicines and Human Rights: What can they learn from each other?' (2006) 84(5) *Bulletin of the World Health Organization* p.371

Model List of Essential Medicines¹⁶, which is updated every two years, serves as a comprehensive guide for the development of such lists.

The focus of the international arena has mostly been on infectious diseases such as AIDS/HIV or malaria, which mainly affect the developing world. However, non-communicable diseases such as cancer, diabetes or cardiovascular diseases also pose a major threat to the developing world, hence, reflected in the WHO Model List of Essential Medicines. Therefore, this thesis does not limit its scope to a particular disease.

Pharmaceutical patents have negative implications on both the innovation and distribution - dispensation - phases of medicines. This thesis uses the access terminology in the broad sense to cover both stages.

Lastly, the responsibility of generic pharmaceutical companies is outside the scope of this thesis. The focus of this thesis is the multinational pharmaceutical companies, which significantly hinder the right to health through their *patent rights*. However, the internal structure of the company such as parent – affiliate company relationships are not considered in this thesis.

¹⁶ WHO Model List of Essential Medicines: 18th List (April 2013) available at<<http://www.who.int/medicines/publications/essentialmedicines/en/index.html>> accessed on 26 May 2014

2 Background of the access problem

2.1 Introduction

In Andrew Clapham's words, "perhaps the most obvious threat to human rights has come from the inability of people to achieve access to expensive medicine, particularly in the context of HIV and AIDS".¹⁷

Access is defined as "having essential medicines continuously available and affordable at public or private health facilities or retail pharmacies that are within one hour's walk from the homes of the population".¹⁸ It is based upon the idea that "medicines are not simply commercial commodities, but basic human needs, fundamental human rights entitlements, and critical components of health care systems".¹⁹

This chapter will have a systematic reflection on both intellectual property, specifically post-TRIPS period and human rights law to present the background of the access problem. The relevance of these different regimes to the access discussion, the way they respond to it, divergences and alignments in their responses will be examined. To achieve this aim, the analysis will begin with the examination of the international legal framework surrounding the access problem. Afterwards, it will be presented that those legal efforts cluster around the state-centric governance mechanisms and that there is not a space for the non-state actors.

¹⁷ Andrew Clapham, *Human Rights Obligations of Non-State Actors* (Oxford University Press 2006) p.175

¹⁸ United Nations Development Group, 'Indicators for Monitoring the Millennium Development Goals' (2003) p.89 available at <http://mdgs.un.org/unsd/mdg/Resources/Attach/Indicators/HandbookEnglish.pdf> accessed on 26 May 2014

¹⁹ Lisa Forman, 'Trade Rules, Intellectual Property, and the Right to Health' (2007) 21 (3) *Ethics & International Affairs* (Wiley-Blackwell) p.337

2.2 International Legal Framework

2.2.1 Trade Related Intellectual Property Law

People have always been deprived of medicines around the world due to several reasons. However, patent related problems have been exacerbated particularly when the TRIPS was adopted in Morocco as an Annex IC to the Marrakesh Agreement Establishing the World Trade Organization²⁰ on 15 April 1994.

TRIPS Agreement itself constitutes a big portion of the problem. Its ‘one size fits all’ or in Peter Yu’s words ‘super size fits all’²¹ approach ignores the fact that an optimal intellectual property system is bound to vary widely from one developing country to another. Each country has different scientific and technological structures.²²

The forum, which is responsible for intellectual property, has been the WIPO since 1967 and relevant treaties were the WIPO administrated Paris Convention for the Protection of Industrial Property²³ and the Berne Convention for the Protection of Literary and Artistic Works.²⁴ However, as global trade started to flourish in the early 1980s, inconsistent levels of patent protection in different markets started becoming very problematic for the developed world industry.²⁵ Thus, the United States (U.S.) and other industrialised countries introduced intellectual property issues into the trade negotiations underway in the General Agreement on Tariffs and Trade

²⁰ Marrakesh Agreement Establishing the World Trade Organization (15 April 1994) 1867 U.N.T.S. 154

²¹ Peter K. Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (2009) 46 (4) Houston Law Review p.981

²² Graham Dutfield, ‘TRIPS and its impact on developing countries’ available at <<http://www.scidev.net/global/policy-brief/trips-and-its-impact-on-developing-countries.html>> accessed on 24 May 2014

²³ Paris Convention for the Protection of Industrial Property (20 March 1883) as last revised in Stockholm on 14 July 1967 and amended in 1979

²⁴ Berne Convention for the Protection of Literary and Artistic Works (9 September 1886) as revised in Paris on 24 July 1971 and amended in 1979

²⁵ Laurence R. Helfer and Graeme W. Austin, *Human Rights and Intellectual Property: Mapping the Global Interface* (Cambridge University Press 2012) p.26 This thesis uses World Bank terminology when it refers to the developed, developing or least-developed country categories.

(GATT).²⁶ The purpose was to shift the forum from WIPO, which mainly serves the interests of developing countries to GATT/WTO.²⁷ In doing so, they managed to get their claims accepted in the TRIPS Agreement.

TRIPS brings 1) a code of minimum intellectual property standards which obliges every country to have patent protection over pharmaceutical products 2) an enforcement mechanism, meaning that countries must not only enact legislation to be in compliance with TRIPS, but must implement domestic enforcement mechanisms as well to ensure that intellectual property rights are upheld²⁸ 3) a dispute settlement mechanism.²⁹ WTO Dispute Settlement Body has the competence to deal with pharmaceutical patents and access related disputes because TRIPS is a WTO agreement.

“Before TRIPS, pharmaceutical patent policies and practices were diverse. For example, many countries did not consider patents on such products as medicines and food to be in the public interest”.³⁰ However, TRIPS Agreement started obliging every WTO-member state to provide patent protection of at least twenty years for pharmaceutical products. Therefore, after TRIPS, the extent of the problem has increased dramatically. No wonder why Jacques Gorlin, a key actor in the business network, said, “we got 95% of what we wanted”.³¹

At the same time, TRIPS Agreement also brings certain safeguards such as Articles 7 and 8, which less developed countries attained as a result of hard-earned bargaining during the TRIPS negotiations.³² Article 7 provides the objective as follows:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer of

²⁶ General Agreement on Tariffs and Trade 1994 (15 April 1994) Marrakesh Agreement Establishing the World Trade Organization Annex 1A 1867 U.N.T.S.187; see also *ibid.* p.27

²⁷ *supra* note 25 p.26-27

²⁸ *Ibid.* p.28

²⁹ Susan K. Sell and Aseem Prakash, ‘Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights’ (2004) 48 *International Studies Quarterly* p.159

³⁰ Ellen ‘t Hoen *et al.*, ‘Driving a Decade of Change : HIV/AIDS, patents and access to medicines for all’ (2011) 14 (1) *Journal of the International AIDS Society* p.2

³¹ *supra* note 29 p.160

³² *supra* note 21

dissemination of technology, to the mutual advantage of producers and user of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.³³

Article 8 provides the interpretative principle of TRIPS Agreement³⁴:

(1) Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

(2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.³⁵

These two provisions play an important role in interpreting and implementing the TRIPS Agreement³⁶ despite certain shortcomings.³⁷ As the WTO panel stated in the case of *Canada-Patent Protection of Pharmaceutical Products*, “both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when [examining the words of the limiting conditions in Article 30]³⁸ as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes”.³⁹ Reichmann explains the power of these two provisions by stating that the safeguard provisions in Articles 7 and 8 may “legitimize ad

³³ TRIPS Agreement Art.7

³⁴ *supra* note 21 p.1008

³⁵ TRIPS Agreement Art.8

³⁶ *supra* note 21 p.1046

³⁷ *Ibid.* p.1014 For example, Article 7 is a ‘should’, Article 8 is a ‘may’ provision and Article 8 is heavily constrained with the TRIPS-consistency requirement.

³⁸ TRIPS Agreement Article 30 brings limited exception possibility when its three-step test requirements are met.

³⁹ WTO, ‘Canada: Patent Protection of Pharmaceutical Products Panel Report’ (2000) WT/DS114/R para.7.26

hoc exceptions and limitations required by overriding national development needs or for reasons of national health, welfare and security”⁴⁰

The WTO also adopted the Declaration on the TRIPS Agreement and Public Health (Doha Declaration) on 14 November 2001, which strongly reinforces the objectives and principles, set forth in Articles 7 and 8 of the TRIPS Agreement⁴¹. It emphasised that the “TRIPS Agreement can and should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health and, in particular, to promote access to medicines for all”⁴². In this connection, member states should be allowed to use the flexibilities brought forth by the TRIPS Agreement such as compulsory licensing option as demonstrated by Article 31. A government can allow someone else to produce the patented product or process without the consent of the patent-owner.⁴³ This flexibility is referred to as ‘compulsory licensing’. Each country itself determines the grounds for issuing a compulsory licensing. Furthermore, the WTO General Council also adopted the Decision of 30 August 2003 to clarify the situation for countries, which lack the necessary manufacturing capacity to benefit from compulsory licensing. This decision, after prolonged negotiations, allows the export of those generic products produced under compulsory licensing to a country with insufficient manufacturing capacity.⁴⁴ This is referred to as the ‘parallel import’ possibility. These two WTO initiatives are very important demonstrating WTO’s affirmative attitude towards the application of Articles 7 and 8 of the TRIPS Agreement.

The case of *Natco v. Bayer*⁴⁵ from India is an example of how the national authorities can make use of those safeguards. The pharmaceutical company Bayer owns a patent on the drug named Nexavar, which treats liver and

⁴⁰ *supra* note 21 p.1028; see also J.H Reichman, ‘From Free Riders to Fair Followers: Global Competition Under the TRIPS Agreement’ (1997) 29 (11) New York University Journal of International Law and Politics p.35

⁴¹ *supra* note 21 p.995

⁴² *supra* note 12 para.4

⁴³ For the definition

<http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm> accessed on 24 April 2014

⁴⁴ *supra* note 13

⁴⁵ For the case <http://www.ipindia.nic.in/iponew/compulsory_license_12032012.pdf> accessed on 23 May 2014

kidney cancer. However, Natco, the Indian generic drug manufacturer, applied for a compulsory licensing on the ground that the price of the drug was too high and in conflict with the Section 84(1)(b) of the Indian Patent Act of 2005. The Controller of Patents highlighted that the compulsory licensing of the drug will enable Indians suffering from kidney and liver cancer to have greater access to the drug at stake and hence issued compulsory licensing.

2.2.2 Human Rights Law

There does not exist a human right to access to medicines, which is recognised by any international instrument. However, “it is an integral component of the right to health”⁴⁶ both as treatment for epidemic and endemic diseases and as part of medical attention in the event of any kind of sickness.⁴⁷ Several human rights bodies repeatedly asserted that the right to health encompasses a right of access to life-saving medicines.⁴⁸

The WHO Constitution defined health as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” as early as 1946.⁴⁹ From that time, various international, regional and national human rights instruments recognised the right to health.⁵⁰ WHO Alma Ata Declaration of 1978⁵¹ is historically very important in the access to medicines. It strongly emphasized that primary health care must be made accessible to individuals and families at a cost that the community and country can afford to maintain their self-reliance and self-determination. In this regard, it recognised the provision of essential drugs as a component of

⁴⁶ Anand Grover, ‘Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’ (1 May 2013) 23rd Session Agenda Item 3 UN Doc A/HRC/23/42 para.3

⁴⁷ Alicia Ely Yamin, ‘Not Just a Tragedy: Access to Medications as a Right Under International Law’ (2003) 21 (2) Boston University International Law Journal p.336

⁴⁸ *supra* note 25 p.113

⁴⁹ WHO Constitution

⁵⁰ OHCHR and WHO, ‘The Right to Health’ Fact Sheet No.31 (2008) p.9-10

⁵¹ WHO, ‘Declaration of Alma-Ata’ International Conference on Primary Health Care (6-12 September 1978)

primary health care.⁵² Since then, various human rights instruments have referenced the Alma Ata Declaration.

Article 12 of the ICESCR⁵³ and general comment No. 14,⁵⁴ which was issued by the CESCR on 11 August 2000 offers a detailed normative content for the right to health. All health facilities, goods and services must be available, accessible, acceptable and of good quality.⁵⁵ Article 12(2)(d) of the ICESCR requires state parties to create “conditions which would assure to all medical service and medical attention in the event of sickness”.⁵⁶ General comment No.14, under the scope of this provision, specifically refers to access to essential medicines.⁵⁷ It states that access to essential medicines, as defined by the WHO Action Programme on Essential Drugs⁵⁸ is one of the core obligations of the state parties.⁵⁹ This means that it is the minimum essential level of the right to health, which must be immediately satisfied by the state.⁶⁰ Every state is expected to have a national list of essential medicines by taking the WHO list of essential medicines as a model. It is the country’s responsibility to decide which medicines are essential. The CESCR has addressed states’ failures to meet their core obligations in concluding observations.⁶¹ Additionally, the Optional Protocol to the ICESCR⁶², which entered into force on 5 May 2013, brings the possibility of individual communication to the CESCR. It can serve as another forum where the Committee can contribute to the normative content of the right to health.

⁵² *Ibid.*

⁵³ International Covenant on Economic, Social and Cultural Rights (16 December 1966) 993 U.N.T.S.3

⁵⁴ CESCR, ‘General Comment No.14 : The Right to the Highest Attainable Standard of Health’ (11 August 2000) 22nd Session E/C.12/2000/4

⁵⁵ *Ibid.*

⁵⁶ ICESCR Art.12(2)(d)

⁵⁷ *supra* note 54 para.17

⁵⁸ WHO, ‘Action Programme on Essential Drugs: Collaboration Between NGOs, Ministries of Health and WHO in Drug Distribution and Supply’ (1998) WHO/DAP/98.12

⁵⁹ *supra* note 54 para.43

⁶⁰ *Ibid.*

⁶¹ CESCR, ‘Concluding Observations of the Committee on Economic, Social and Cultural Rights: Honduras’ (21 May 2001) UN Doc E/C.12/1/Add.57 para.26; see also *supra* note 47 p.337

⁶² UN General Assembly, ‘Optional Protocol to the International Covenant on Economic, Social and Cultural Rights’ (10 December 2008) A/RES/63/117

General comment No.17⁶³ on Article 15(1)(c) of the ICESCR is also very important in the sense of reflecting the Committee's perspective on the issue despite not explicitly referring to access to medicines:

In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person.⁶⁴

The mandate of the Special Rapporteur is also worth referring to when the access to medicines is at stake. The Special Rapporteur is appointed by the Human Rights Council to present annual reports, monitor the situation of the right to health throughout the world, make country visits to obtain first-hand information, communicate with states and other concerned parties with regard to alleged cases of violations and other issues assigned to him or her.⁶⁵ For example, Paul Hunt who served as the Special Rapporteur from 2002 to 2008 visited the headquarters of GlaxoSmithKline (GSK) in June 2008 and reviewed its policies regarding access to medicines.⁶⁶ He also issued the 'Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines'⁶⁷ among other important reports.⁶⁸ It contains forty-seven detailed guidelines concerning a wide range of topics from transparency, management, monitoring and accountability to neglected diseases, patents, licensing, pricing and donations. The current Special

⁶³ 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 ' (7-25 November 2005) 35th Session E/C.12/GC/17

⁶⁴ *Ibid.*

⁶⁵ For the mandate

<<http://www.ohchr.org/EN/Issues/Health/Pages/SRRrightHealthIndex.aspx>> accessed on 26 May 2014

⁶⁶ Paul Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Health: Mission to GlaxoSmithKline' (5 May 2009) 11th Session Agenda Item 3 UN Doc A/HRC/11/12/Add.2

⁶⁷ Paul Hunt, 'Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines' (11 August 2008) 63rd Session Item 67(b) UN Doc A/63/263

⁶⁸ For the complete list of reports <http://ap.ohchr.org/documents/dpage_e.aspx?m=100> accessed on 20 May 2014

Rapporteur, Anand Grover, pays special attention to the access problem as well since he was appointed in August 2008.⁶⁹

2.3 A shortcoming

Although the efforts mentioned above are welcoming, the access problem still exists due to a wide range of shortcomings.⁷⁰ One major problem is that the responsibilities of non-state actors are very ambiguous. Obligations are mainly placed on states in international law, including international human rights and intellectual property law. For example, the WTO is a member-driven organization, which means that all the decisions are taken by the governments. Non-state actors can have a voice only through their governments. Similarly, international human rights law is established on the idea that human rights are to be claimed against the sovereign power of states because the state is the only actor, which can violate human rights. Therefore, only states are bound by those international instruments previously exemplified. For instance, when the Special Rapporteur Paul Hunt issued a report about the operations of GSK⁷¹, the company stated that “the right to health is an important issue, though not well defined, especially as it relates to non-state actors. Therefore, we do not accept the suggestion — implicit in the development of this report — that GSK’s programme and ongoing commitment is in any way *required* by international legal norms, whether in human rights or other areas”.⁷²

When the responsibility of non-state actors is put under the spotlight, it is mainly rectified within the scope of the state responsibility to ‘protect’ human rights. General comment No. 14 paragraph 42 states that “while only states are parties to the Covenant and thus ultimately accountable for compliance with it, all members of society, including the private business

⁶⁹ *supra* note 46

⁷⁰ For example hard law and soft law discrepancy drawn between intellectual property and human rights legal regimes or the broad terminology used in international human rights law *e.g.* international assistance and cooperation

⁷¹ *supra* note 66

⁷² Suerie Moon, ‘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 & Human Rights: An International Journal* p.36

sector, have responsibilities regarding the realization of the right to health. State parties should therefore provide an environment which facilitates the discharge of these responsibilities”.⁷³ Likewise, paragraph 35 shares the same attitude. “States have the obligation to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services”.⁷⁴

At this point, optional business accountability efforts come to mind. Voluntary self-regulatory business regimes transpired under the heading of corporate social responsibility (CSR).⁷⁵ These approaches can lack a specific reference to human rights. They generally deal with the access problem as part of philanthropy; which is commendable when it takes place but it is entirely optional and can be discontinued or reduced at any time according to the company’s preferences and profit evaluations. As Bilchitz puts it, to ensure that individual rights are realised, it would be entirely ineffective to rely on the contingencies of social pressure or corporate good will.⁷⁶

In summary, this chapter presented the background of the access problem by way of referring to intellectual property and human rights legal regimes. While the TRIPS Agreement has been causing great concern on the ground that it ignores the needs, interests and goals of the less developed member states⁷⁷, it still holds certain safeguards that less developed countries can benefit through Articles 7, 8 or Article 31, which are reinforced by the Doha Declaration and Decision of 30 August 2003.⁷⁸ In international human rights law, access to essential medicines is discussed under the umbrella of right to health. ICESCR and general comment No.14 of the CESCR consider the access to essential medicines as one of the core obligations of the right to health, which requires immediate realisation regardless of whether the state

⁷³ *supra* note 54 para.42

⁷⁴ *Ibid.* para.35

⁷⁵ The UN Global Compact, OECD Guidelines for Multinational Enterprises or ISO26000 are well-known initiatives among many others.

⁷⁶ David Bilchitz, ‘The Ruggie Framework: An Adequate Rubric for Corporate Human Rights Obligations?’ (2010) 7 (12) SUR International Journal on Human Rights p.213

⁷⁷ Susan K. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003)

⁷⁸ *supra* note 21 p.995

has available resources or not. The access problem has also constituted a major part of the mandate of the Special Rapporteur. Lastly, the chapter emphasized the fact that both legal regimes are built on the state-centric governance mechanism, hence, not focused on the role of non-state actors in the access to medicines. This is the stage where the SRSG's mandate will come into play in the following chapter.

3 Corporate Responsibility to Respect Human Rights

3.1 Introduction

“The harms individuals may suffer are not limited to ones where their rights are actively violated by corporations: indeed, lack of access to food, water, healthcare, and legal representation may severely impact upon the lives of individuals”.⁷⁹

The image of pharmaceutical companies was damaged dramatically during the litigations against the South African and Brazilian governments. When the South African government passed the law on compulsory licensing of HIV/AIDS medicines in 1997, thirty-nine pharmaceutical companies brought a court action against the South African government.⁸⁰ When the Brazilian government started following a similar strategy, the U.S. brought a WTO case against Brazil in 2001.⁸¹ However, pharmaceutical companies had to drop their court action and the U.S. government had to withdraw its WTO case against Brazil due to aggressive civil society and media counteractions.⁸²

The SRSB explains the current business and human rights predicament as a result of the “governance gaps created by globalisation-between the scope and impact of economic forces and actors, and the capacity of the societies to manage their adverse consequences”.⁸³ The Framework and the U.N. Guiding Principles emerged in response to those governance gaps.

After presenting the background to the U.N. Guiding Principles, this chapter will clarify the limitations of the ‘respect’ human rights notion as used in the U.N. Guiding Principles. Subsequently, it will avail itself of the human

⁷⁹ *supra* note 76 p.209

⁸⁰ Ahmad Siddiqi, ‘Patents and Pharmaceutical Drugs: The Need for Change’ (2005) Stanford Undergraduate Research Journal p.2

⁸¹ *Ibid.*

⁸² *supra* note 29 p.146

⁸³ *supra* note 7 para.3

rights due diligence concept to interpret ‘respect’ in the context of patent-holding pharmaceutical industry. This will be done by way of referring to the right to health framework drawn by the international human rights authorities.

3.2 Background of the Guiding Principles

As the economic globalisation intensified, the U.N. has been focussing greatly on business-related human rights violations over the past two decades. One initiative was the U.N. Norms on the Responsibilities of Transnational Corporations⁸⁴ (Norms) drafted between 1998 and 2004. However, it resulted in a deeply divisive debate between the business community and human rights advocacy groups while evoking little support from governments.⁸⁵ After the Sub-Commission on the Promotion and Protection of Human Rights submitted the Norms to the Commission on Human Rights (replaced by the Human Rights Council in 2006), the Commission decided not to endorse them.⁸⁶ Therefore, in July 2005, the then U.N. Secretary-General Kofi Annan appointed John Ruggie as Special Representative of the U.N. Secretary-General on the issue of human rights and transnational corporations and other business enterprises to undertake a new process.⁸⁷

Ruggie consulted a wide range of stakeholders⁸⁸ to have a participatory process for reducing the extent of polarisations within the business and human rights discussions. In April 2008, he developed the ‘Protect Respect Remedy’ Framework, which comprises three core pillars: the state duty to

⁸⁴ UN Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, ‘Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with regard to Human Rights’ (26 August 2003) 55th Session Agenda Item 4 UN Doc E/CN.4/Sub.2/2003/12/Rev.2

⁸⁵ *supra* note 6 para.3

⁸⁶ Radu Mares, ‘Business and Human Rights After Ruggie: Foundations, the Art of Simplification and the Imperative of Cumulative Progress’ p.2 in: Radu Mares (ed) *The UN Guiding Principles on Business and Human Rights: Foundations and Implementation* (Martinus Nijhoff Publishers 2012)

⁸⁷ *supra* note 7 para.4

⁸⁸ OHCHR, ‘The Corporate Responsibility to Respect Human Rights: An Interpretive Guide’ (2012) HR/PUB/12/02 p.8; a stakeholder refers to any individual who may affect or be affected by an organization’s activities

protect against human rights abuses by third parties, including business, the corporate responsibility to respect human rights, and the need for more effective access to remedies.⁸⁹ The Framework was unanimously endorsed by the U.N. Human Rights Council and widely welcomed by various stakeholders; individual governments, business enterprises and associations, civil society and workers' organisations, national human rights institutions and investors.⁹⁰

After receiving positive widespread reception⁹¹, the SRSG produced the U.N. Guiding Principles on Business and Human Rights for operationalising the Framework and further defining the key duties and responsibilities of states and business enterprises with regard to business-related human rights abuses.⁹² This is the final report of the SRSG's six year mandate between 2005 and 2011. Similar to the Framework, U.N. Human Rights Council endorsed the Guiding Principles unanimously in June 2011.

3.3 Scope of Respect

Guiding Principle 11 sets the foundational principle of corporate responsibility to respect human rights as follows:

Business enterprises should respect human rights. This means that they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved.⁹³

This is the baseline expectation for all companies in all situations.⁹⁴ The SRSG explains it as a responsibility based on "social expectations-as part of what is sometimes called a company's social license to operate".⁹⁵

Ruggie had to follow a pragmatic strategy during his six year mandate to reduce the existing polarisations and find a focal point where different

⁸⁹ *supra* note 7 para.9

⁹⁰ *supra* note 6 para.7

⁹¹ *Ibid.* para.8

⁹² The UN Working Group on Business and Human Rights, 'The UN Guiding Principles on Business and Human Rights: An Introduction' (2013) p.2

⁹³ *supra* note 6 Guiding Principle 11

⁹⁴ *supra* note 6 para.24

⁹⁵ *Ibid.* para.54

stakeholders' expectations can converge.⁹⁶ As a result, he avoided identifying corporate duties as 'legally' mandated or compulsory, preferring to identify them simply as 'responsibilities' or 'social duties' emanating from the 'social license' businesses need to operate.⁹⁷ According to Paul Hunt, no matter how the relationship between the patent-holder company and society is categorised, "the company holds the patent on express and implied terms. Society has legitimate expectations of a company holding the patent on a life-saving medicine".⁹⁸

The SRSG's responsibility to respect is a result of inspiration from the international human rights law terminology. He adapted the standard human rights definition of 'respect' into the U.N. Guiding Principles.⁹⁹ "Responsibility to respect is defined in terms of the classic human rights meaning of respect: *non-infringement on the rights of others, and addressing harms that do occur*".¹⁰⁰

Respect, as understood in the human rights framework, generally suggests minimum standards of non-infringement. States' positive obligations are widely seen to be embedded in the other two terms within the paradigm of protect and fulfil.¹⁰¹ However, the SRSG claims that corporate responsibility to respect is not necessarily a "mere analogue to a negative duty"¹⁰² and gives examples to prove that. He acknowledges that the responsibility to respect "may entail positive steps - for example, a workplace anti-discrimination policy might require the company to adopt specific recruitment and training programmes".¹⁰³ In his 2009 report, he also points

⁹⁶ *supra* note 6 para.5

⁹⁷ Tara J. Melish and Errol Meidinger, 'Protect, Respect, Remedy and Participate: "New Governance" Lessons for the Ruggie Framework' p.308 in: Radu Mares (ed) *The UN Guiding Principles on Business and Human Rights: Foundations and Implementation* (Martinus Nijhoff Publishers 2012)

⁹⁸ *supra* note 66 para.36

⁹⁹ *supra* note 9 p.94-95

¹⁰⁰ *Ibid.* p.100

¹⁰¹ IHRB, 'Setting Boundaries: Clarifying the Scope and Content of the Corporate Responsibility to Respect Human Rights' (2009) p.3

¹⁰² The SRSG, 'Business and Human Rights: Towards Operationalizing the "Protect, Respect and Remedy" Framework - Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises' (22 April 2009) 11th Session Agenda Item 3 UN Doc A/HRC/11/13 para.59

¹⁰³ *supra* note 7 para.55

out that even the mere fact that companies are required to set up grievance mechanisms where none exist and the existence of the concept of human rights due diligence, requiring companies to become aware of, prevent and address adverse human rights impacts are themselves positive acts.¹⁰⁴ However, this kind of exemplification limited only to a few examples cannot lead one to a comprehensive answer regarding the boundaries of this responsibility in the access to medicines.

Corporate responsibility to respect applies to every business enterprise regardless of their size, sector, operational context, ownership and structure. However, the scale and complexity of the means through which enterprises meet that responsibility may change according to those factors.¹⁰⁵ Ruggie states that “the principles are principles. They are not a toolkit. You do not take it off the shelf and plug it in, and get an answer. Issues of context, issues of industry sector, matter...”¹⁰⁶

What respect signifies will vary considerably depending on where the pharmaceutical company operates, whether it owns any patent rights or how severe its human rights impact is, among others. In other words, the U.N. Guiding Principles’ approach is not a ‘one size fits all’. It applies to 192 United Nations member states, 80,000 transnational enterprises, 10 times as many subsidiaries and countless millions of national firms, most of which are small and medium sized enterprises.¹⁰⁷

The basic requirement, which is common for every industry, is to comply with the national law and international standards in case the former is either absent or not in line with the latter.¹⁰⁸ What is more is the concept of human rights due diligence as a context-dependent tool of operationalisation.

¹⁰⁴ *supra* note 102 para.59

¹⁰⁵ *supra* note 6 Guiding Principle 14

¹⁰⁶ Available at <<http://business-ethics.com/2011/10/30/8127-un-principles-on-business-and-human-rights-interview-with-john-ruggie/>> accessed on 23 April 2014

¹⁰⁷ *supra* note 6 para.15

¹⁰⁸ *supra* note 88 p.77

3.3.1 Human rights due diligence as an implementing tool

Human rights due diligence is the necessary tool for any enterprise to ‘know and show’ that it is respecting human rights in practice.¹⁰⁹ “It is through the human rights due diligence that an enterprise identifies the information it needs in order to understand its specific human rights risks at any specific point in time and in any specific operating context, as well as the actions it needs to take to prevent and mitigate them”.¹¹⁰ A company’s human rights due diligence process must include all the elements set out in the Guiding Principle 17, *i.e.* assessing actual and potential human rights impacts, integrating and acting upon the findings, tracking responses, and communicating how impacts are addressed.¹¹¹

Human rights due diligence is not measured by any absolute standard, but it depends on the relative facts of the specific case.¹¹² “Enterprises of different sizes, in different industries, with different corporate structures and in different operating circumstances will need to tailor their processes to meet those needs”¹¹³

The Framework defines the scope of responsibility in terms of *actual and potential adverse human rights impacts* arising from a business enterprise’s own activities and from the relationships with third parties associated with those activities.¹¹⁴ The company can be involved in those adverse impacts in three ways: it can cause the impact, contribute impact through its own activities or the impact can be directly linked to its operations, products or services by its business relationships.¹¹⁵

“The Committee on Economic, Social and Cultural Rights and others have developed a framework for analysing or “unpacking” the right to health with

¹⁰⁹ *Ibid.* p.32

¹¹⁰ *Ibid.* p.31

¹¹¹ *supra* note 6 Guiding Principle 17

¹¹² *supra* note 88 p.6

¹¹³ *Ibid.* p.32

¹¹⁴ *supra* note 9 p. 97

¹¹⁵ *supra* note 6

a view to making it easier to understand and apply”.¹¹⁶ This thesis will avail itself of this framework to show the *actual and potential adverse human rights impacts* of patent-holding pharmaceutical companies.

3.3.1.1 The right to health framework

Interrelated and essential elements of the right to health are taken as a guideline: All health services, goods and facilities, including medicines, should be made *available, accessible, acceptable and of good quality*.¹¹⁷

(a) Availability

Medicines must be available ‘in sufficient quantities in the countries where they are needed’.¹¹⁸ Availability of medicines is specifically important in the context of neglected tropical diseases. “Neglected tropical diseases (NTDs) are a group of infectious diseases that disproportionately affect the world’s poorest and most vulnerable populations. It is estimated that more than one billion people are affected by NTDs, including roughly 800 million children”.¹¹⁹ Those diseases traditionally receive very little attention because the potential customer cannot afford the excessive drug prices.¹²⁰

It is worth highlighting that this deficiency is in fact a result of current patent regimes, which are driven by commercial concerns of developed countries rather than being a result of actions or omissions of pharmaceutical companies directly. Current pharmaceutical patent regimes channel research and development towards drugs, which could generate revenue for the company, creating a lack of investment for NTDs since those diseases do not present a lucrative market.¹²¹ Therefore, for the purposes of this thesis, the lack of investment in NTDs is not considered as

¹¹⁶ *supra* note 66 para.19

¹¹⁷ *supra* note 46 para.3

¹¹⁸ *supra* note 66 para.22

¹¹⁹ Uniting to Combat NTDs, ‘From Promises to Progress: The First Annual Report on the London Declaration on NTDs’ (2013) p.1

¹²⁰ *Ibid.* p.1

¹²¹ Paul Hunt, ‘The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health – Report of the Special Rapporteur - Addendum: Mission to the World Trade Organization’ (1 March 2004) 60th Session Item 10 UN Doc E/CN.4/2004/49/Add.1 para.44

an adverse impact of patent-holding pharmaceutical companies directly but instead as a deficiency of the overall patent regimes.

(b) Accessibility

Accessibility is the other essential element in the right to health. It has four overlapping dimensions, *i.e.* non-discrimination, physical accessibility, economic accessibility - affordability - and information accessibility.¹²² Physical accessibility means that medicines must be accessible to all parts of a country, in both rural and urban areas.¹²³ To fully ensure accessibility, medicines must be affordable to all, including those living in poverty.¹²⁴ Finally, accessibility of information and transparency regarding the medicine's safety or side effects should be ensured as well.¹²⁵

Patent rights inherently increase the cost of drugs. The *raison d'être* of patents is to encourage more innovation by way of providing monopoly in the market and financial incentive to the original owner. This carries special importance for pharmaceutical companies because "pharmaceutical industry is a science industry for which innovation is the fundamental source of competitiveness".¹²⁶ As a result, the price of a drug includes not only the cost of making it but also R&D and marketing costs.¹²⁷ This makes the drugs unaffordable to segments of the population who could have paid for the drugs had they been sold at their marginal cost of production.¹²⁸

Another concern is the patent-holding companies' efforts to curtail local pharmaceutical production. If this was not prevented, drug prices can become more affordable due to increasing generic competition in the country concerned. The pharmaceutical industry actively participates in

¹²² *supra* note 54 para.12

¹²³ *supra* note 66 para.23 Physical accessibility is very much dependent on states' abilities and willingness as well.

¹²⁴ *Ibid.* para.24

¹²⁵ *Ibid.* para.25

¹²⁶ Constance E. Bagley and Christine D. Tvarno, 'Pharmaceutical Public-Private Partnerships in the United States and Europe: Moving from the Bench to the Bedside' (2013) Lecturer and Other Affiliate Scholarship Series Paper 12, p.9

¹²⁷ Mor Bakhom, 'TRIPS, Patent Rights and Right to Health: "Price" or "Prize" for Better Access to Medicine?' (2009) Max Planck Institute for Intellectual Property, Competition & Tax Law Research Paper No. 10-07 p.7

¹²⁸ *supra* note 25 p.116

persuasive lobbying activities. The practise shows that countries who want to use TRIPS flexibilities such as compulsory licensing or parallel importing are either prevented through TRIPS-plus agreements or are threatened with trade sanctions as well as corporate litigations in bilateral arena as exemplified previously in cases of South Africa and Brazil.¹²⁹

TRIPS-plus agreements refer to bilateral or regional trade agreements, mostly free trade agreements and bilateral investment treaties, in which mainly developed countries sign with the developing world. Those agreements, 1) impose more stringent intellectual property protection standards than TRIPS require such as extending the term of patent protection over twenty years, limiting compulsory licensing, parallel import possibilities or expanding the patentable subject matters excessively 2) oblige developing countries to implement TRIPS before the end of transition periods¹³⁰ that TRIPS brings or 3) require developing countries to conform other multilateral intellectual property agreements.¹³¹ The current European Union - India Free Trade Agreement that has been under negotiation since 2007 is one example. It aims to curtail Indian generic medicine production, which has become to be known as the *pharmacy of the developing world* for years.

Such agreements undermine the generic pharmaceutical production by “strengthening the position of originator-patent holder pharmaceutical enterprises on national markets”.¹³² Generic pharmaceutical production is one of the most effective methods to cut down the price of medicine and overcome access problems in the long term. Therefore, patent-holding pharmaceutical companies are expected to respect the TRIPS Agreement flexibilities and Doha Declaration and Decision of 30 August 2003.

¹²⁹ *supra* note 19

¹³⁰ For transitional periods <http://www.who.int/medicines/areas/policy/wto_trips/en/> accessed on 26 May 2014

¹³¹ *supra* note 25 p.40

¹³² Frederick M. Abbott and Jerome H. Reichman, ‘The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions’ (2007) 10(4) *Journal of International Economic Law* p.963

Responsibility to respect includes not entering into agreements, which destroys the TRIPS flexibilities.¹³³

Companies' patent applications for insignificant changes to existing drugs pose a big concern as well in relation to affordability. Patent-holding pharmaceutical companies developed this ever-greening strategy in order to extend their monopoly in the market. As a result, this delays the generic competition in the country and medicines are sold at higher prices over a longer period. Studies show that research and development is a relatively small part of the budgets of big drug companies; dwarfed by their vast expenditures on marketing and administration, and even smaller than profits.¹³⁴ Furthermore, it can be argued that the pharmaceutical industry is not especially innovative. The great majority of 'new' drugs are not new at all but merely variations of older drugs already on the market.¹³⁵ "While globally, the level of patent protection has increased over the past twenty years, the rate of pharmaceutical innovation has fallen, with an increasing number of 'me-too drugs' of little or no therapeutic gain".¹³⁶ However, if the aim is to incentivise only the genuine research, then companies are expected to be more mindful of economic accessibility and not resort to ever-greening practices.

In addition to economic accessibility, accessibility of information, which means the right to seek, receive and impart information and ideas concerning health issues,¹³⁷ is also an essential part of the right to health. It has particular importance when transparency is threatened during TRIPS-plus negotiations. Parties in those agreements mostly ignore the public's right to information and participation in the conduct of public affairs, which are both very critical for the full realisation of right to health.¹³⁸ For instance, the European Union - India Free Trade Agreement or rather the

¹³³ *supra* note 72 p.38

¹³⁴ Available at < <http://www.nybooks.com/articles/archives/2004/jul/15/the-truth-about-the-drug-companies/>> accessed on 25 March 2014

¹³⁵ *Ibid.*

¹³⁶ *supra* note 30 p.7

¹³⁷ *supra* note 54 para.12

¹³⁸ For Anand Grover's comments

<<http://www.ohchr.org/EN/NewsEvents/Pages/GenericMedicines.aspx>> accessed on 20 May 2014

Trans-Pacific Partnership Agreement¹³⁹ processes have been conducted secretly. The little that the public knows is through leaked information. Another common concern regarding the accessibility of information is the test data exclusivity practices of patent-holding pharmaceutical companies. Before the marketing of a pharmaceutical product, companies are legally required in most countries to provide data regarding the safety, quality and efficacy of new medicines, validated through medically and ethically valid clinical trials.¹⁴⁰ However, the practise shows that trial data are not made public by companies on grounds of protecting their commercial information. In some situations, even if they do disclose information, they tend to show only positive results, which is misleading and detrimental to patients.¹⁴¹

(c) Acceptability and Quality

Acceptability and quality are other essential elements of the right to health. While *acceptability* means that medicines and associated processes such as clinical trials must be respectful of medical ethics, culturally appropriate, sensitive to gender as well as life cycle issues, the *quality* element refers to the responsibility to ensure that their medicines are of good quality, safe and efficacious. An important point in this regard is the confusion between poor-quality drugs and generic drugs. Some countries even take unilateral actions against legitimate generic medicines as being counterfeit due to this misinterpretation.¹⁴² This type of policy deviates considerably the promotion of local production of medicines and public health efforts.

3.4 Conclusion

In summary, this chapter introduced the reader to the background of the U.N. Guiding Principles and showed what motives it had behind its existence. The concept of human rights due diligence provided the necessary guidance and flexibility to envision the adverse human rights impacts of patent-holding pharmaceutical companies. In doing so, the

¹³⁹ For the negotiator countries <<http://tppinfo.org/>> accessed on 26 May 2014

¹⁴⁰ *supra* note 46 para.63

¹⁴¹ *Ibid.*

¹⁴² *Ibid* para.66

chapter took the guidance of the right to health framework. Those adverse impacts can vary from the lack of investment in research and development of NTDs to companies' strong lobbying activities to maintain high drug prices and ever-greening practices. The aim was not to make an exhaustive list of impacts one by one, but instead to give a glimpse of how pharmaceutical patents influence the access to medicines. This was specially necessitated by the fact that the following chapter will refer to those adverse impacts while challenging the boundaries of corporate responsibility to respect.

4 More than respect?

4.1 Introduction

When adverse impacts of pharmaceutical companies are investigated, it appears that some of them necessitate certain positive acts on behalf of companies. The question is whether those acts have any standing in the U.N. Guiding Principles.

In the access problem, for the U.N. Guiding Principles to offer any efficacy, they need to be interpreted in a way covering positive measures as well. Companies must be required to take certain initiative and act upon their adverse impacts. Lack of access to essential medicines differs from other areas of business related human rights violations such as the environmental harms caused by large-scale oil extraction, racial or religious discrimination in the workplace, right to privacy in the information technology domain or respecting patients' right to health in clinics.

According to the SRSG, “companies may undertake additional commitments voluntarily or as a matter of philanthropy. Moreover, some have developed new business opportunities by offering goods and services more closely aligned with basic needs, as in bottom-of-the-pyramid strategies and other types of inclusive business models. These are worthy endeavours that may contribute to the enjoyment of human rights. But what it is desirable for companies to do should not be confused with what is required of them”.¹⁴³ At this point, the question arises as to which acts are within the scope of ‘respect’, and which ones lie outside and fall into the domain of desired but not required acts.

The aim of this chapter is to challenge the boundaries set for corporate responsibility to respect and prove that it is indeed possible to expand the interpretation in certain cases. For this purpose, the chapter will initially present the case of price reductions in life-saving medicines where the narrow understanding of corporate responsibility to respect is insufficient.

¹⁴³ *supra* note 102 para.62

In doing so, it will avail itself of current practices of patent-holding pharmaceutical companies such as participation in multi-stakeholder initiatives and voluntary licensing agreements. Afterwards, the thesis attempts to justify that there is in fact opportunity for broader interpretation by referring to both the concept of human rights due diligence and other supportive arguments.

4.2 Cases

4.2.1 Price reductions in life-saving medicines

When the U.N. Declaration of Commitment on HIV/AIDS¹⁴⁴ was endorsed by the General Assembly in 2001, it recognised that pharmaceutical companies are central to reducing the cost of HIV/AIDS medicines and ensuring the availability thereof.¹⁴⁵ It provides that:

“The cost, availability and affordability of drugs and related technology are significant factors to be reviewed and addressed in all aspects and that there is a need to reduce the cost of these drugs and technologies in close collaboration with the private sector and pharmaceutical companies”.¹⁴⁶

Companies have a wide range of options available to them to reduce the prices of life-saving drugs, *e.g.* offering differential pricing, participating in multi-stakeholder initiatives, or engaging in voluntary licensing agreements. For example, Abbott and Novartis focus on delivering low-cost medicines through differential pricing strategies.¹⁴⁷ However, this chapter will only focus on the participation in multi-stakeholder initiatives and voluntary licensing agreements, which offers a long-term solution for the ‘steady supply of essential medicines’.¹⁴⁸

¹⁴⁴ UN General Assembly, ‘Declaration of Commitment on HIV/AIDS’ (2 August 2001) 26th Session Agenda Item 8 UN Doc A/RES/S-26/2

¹⁴⁵ *supra* note 76 p.212

¹⁴⁶ *supra* note 144

¹⁴⁷ Access to Medicine Foundation, ‘Access to Medicine Index’ (November 2012) p.62

¹⁴⁸ UNCTAD, ‘Local Production of Pharmaceuticals and Related Technology Transfer in Developing Countries: A Series of Case Studies by the UNCTAD Secretariat’ (2011) UNCTAD/DIAE/PCB/2011 p.6

4.2.1.1 Participation in multi-stakeholder initiatives

The Institute for Human Rights and Business (IHRB) observes that as ‘some problems go beyond national borders’, developing governance mechanisms that are effective beyond borders ‘may require non-State actors’ participation, with corresponding delineation of rights and responsibilities’.¹⁴⁹

Multi-stakeholder initiatives have been offering a promising increase in access to HIV/AIDS medicines by pulling down the drug prices. For example, “in July 2013, UNAIDS joined with WHO, the US President’s Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria and other partners to launch the *Treatment 2015* initiative, which aims to ensure that the world reaches its 2015 HIV treatment target as a critical stepping-stone towards universal access treatment”¹⁵⁰. The goal is to provide ARV therapy to 15 million people by 2015.

Initiatives of the Global Fund to Fight AIDS, Tuberculosis and Malaria also have been offering very successful examples since 2002. For instance, its Affordable Medicines Facility for Malaria allows people to buy life-saving malaria treatment for less than one U.S. dollar. Comparable malaria medicines outside the program cost up to ten to twenty times as much.¹⁵¹

Multi-stakeholder initiatives play a major role in research and development for NTDs as well. For example, DNDi is a product development partnership founded in July 2003, which includes numerous partners from the pharmaceutical industry such as AbbVie (formerly Abbott), Astra Zeneca, Bristol Myers Squibb, CIPLA, GNF Novartis, Merck & Co., Pfizer Limited and many more.¹⁵² In 2007, DNDi brought out its first product: a simple, affordable and effective anti-malarial fixed-dose combination, combining

¹⁴⁹ *supra* note 14 p.223; see also *supra* note 101 p.8

¹⁵⁰ *supra* note 1 p.46

¹⁵¹ Available at <http://www.theglobalfund.org/en/mediacenter/newsreleases/2012-04-25_Global_Fund-led_initiative_slashes_cost_of_anti-Malaria_medicines_in_many_African_countries/> accessed on 25 May 2014

¹⁵² For the partners <<http://www.dndi.org/partnership/partners.html#Pharmaceuticals>> accessed on 30 April 2014

two anti-malarials in a single pill. Since then, it has given rise to a total of four new products onto the market, a second new treatment for malaria and treatments for Visceral Leishmaniasis and Human African Trypanosomiasis (HAT)/ sleeping sickness.¹⁵³

In Paul Hunt's words, while the company cannot be expected to make an overall loss, it can sometimes be expected to operate, with respect to some of its activities, on a not-for-profit basis.¹⁵⁴

4.2.1.2 Voluntary licensing agreements as a tool to encourage local production

There is a new focus on local production as a means of contributing to the overall goals of promoting innovation, building capacity and improving access.¹⁵⁵

Firstly, local production can increase price-based competition in the market, contributing and ensuring lower drug prices and greater affordability.¹⁵⁶ Secondly, local production can in the future fill an important gap for developing country needs in case Indian generic companies continue to shift their focus to developed country markets and needs. With improved production and R&D capacities, Indian firms have started targeting more affluent markets and their specific disease patterns.¹⁵⁷ Mergers and acquisitions of large Indian companies with global pharmaceutical companies and other political economy factors such as free trade agreements threaten the future of generic drug manufacturing.¹⁵⁸ Thirdly, generic pharmaceutical companies have extensive distribution networks. Most local companies are adept at using context-relevant strengths for distributing their products and in creating newer modes of distribution for their medicinal products.¹⁵⁹

¹⁵³ Available at <<http://www.msfaaccess.org/our-work/driving-medical-innovation/article/1354>> accessed on 24 May 2014

¹⁵⁴ *supra* note 66 para.39

¹⁵⁵ *supra* note 148 p.5

¹⁵⁶ *Ibid.* p.13

¹⁵⁷ *Ibid.*

¹⁵⁸ *Ibid.* p.6

¹⁵⁹ *Ibid.* p.13-14

Non-exclusive voluntary licenses have the most potential to encourage generic drug competition, especially when they are accompanied with the necessary technology transfer. However, only a few companies make use of them. Gilead, GlaxoSmithKline and Merck & Co. are the most advanced, with Gilead openly recognising the value of engagement with the generic industry's capacity to produce high volumes of low-cost and high-quality medicines.¹⁶⁰ At this point, the absorptive capacity, availability of human skills to engage in production, management, marketing and relevant scientific and physical infrastructure should be taken into consideration when transferring technology.¹⁶¹

4.2.1.2.1 Medicines Patent Pool

A voluntary licensing initiative is the Medicines Patent Pool (MPP), which aims to reduce the prices of HIV medicines and facilitate the development of better-adapted HIV medicines in developing countries.¹⁶²

When a company aims to produce generic drugs, it can acquire a license from the MPP in return for a certain amount of royalty. The notion behind the MPP mechanism is that it would reduce drug prices by encouraging the generic competition and alleviate the access problem considerably. A Pool would also make the development of more adapted medicines easier. For instance, a company wanting to combine drugs in a new fixed-dose combination - when several drugs are integrated into a single pill - will only have to deal with the patent pool – and not all the patent-holding companies.¹⁶³

The method that the MPP uses is voluntary licensing, *i.e.* voluntary licensing of key HIV medicine patents. Fixed-dosed combination drugs are what the MPP promotes for local production. It proved to simplify treatment for people living with HIV and facilitate scaled-up treatment in developing

¹⁶⁰ *supra* note 147

¹⁶¹ *supra* note 148 p.15

¹⁶² Available at <<http://www.medicinespatentpool.org/>> accessed on 20 May 2014

¹⁶³ Available at <<http://www.msfacecess.org/our-work/driving-medical-innovation/article/1354>> accessed on 2 May 2014

countries.¹⁶⁴ Since 2010, a number of companies with relevant HIV drugs in their portfolios have entered into formal negotiations with the MPP.¹⁶⁵

4.3 Justification for broader interpretation

4.3.1 Analysis within the scope of human rights due diligence

The human rights due diligence concept, which is tightly embedded in the responsibility to respect, must be approached according to certain steps. When a company's operational area is resource-poor as well as prone to a certain disease, *e.g.* hepatitis C in India, then this operational area exhibits particular risks for which the company should consider when assessing its actual and potential adverse impacts, act upon these risks, track whether the response is effective and communicate externally how those impacts are addressed.¹⁶⁶ Throughout these defined steps, the company is highly expected to engage with affected stakeholders.

Guiding Principle 19 states that:

In order to prevent and mitigate adverse human rights impacts, business enterprises should integrate the findings from their impact assessments across relevant internal functions and processes, and take appropriate action.¹⁶⁷

Appropriate action will vary depending on the company's involvement in the adverse impact. When a pharmaceutical company offers excessive drug prices to a resource-poor country, then it can be involved in the adverse impact by different ways depending on the specifics of each case. At this point, Guiding Principle 19 provides the appropriate actions expected from companies according to degree of their involvement: when the company causes or may cause the adverse impact, it then should take the necessary steps to cease or prevent it. When the company contributes or may contribute to it, it should similarly take the necessary steps to cease or

¹⁶⁴ Available at <<http://www.medicinespatentpool.org/about/>> accessed on 20 May 2014

¹⁶⁵ *supra* note 147

¹⁶⁶ *supra* note 7 para.60-64

¹⁶⁷ *supra* note 6 Guiding Principle 19

prevent its contribution and use its leverage¹⁶⁸ to mitigate any remaining impact. Lastly, in more complex situations, even though the company has not contributed to the adverse impact, it can still be expected to act upon it when the impact is linked to its operations, products or services by its business relationship with another entity.¹⁶⁹ This entity can be business, governmental or non-governmental.¹⁷⁰

The leverage over the entity plays a crucial role when a business relationship is involved in the situation. If a company has leverage, it then should exercise it. Even when the company does not have it, it is still expected to find a way such as offering capacity-building or collaborating with other actors to increase the leverage.¹⁷¹ Where the company lacks the leverage and is unable to increase it, it then should end its relationship with the entity. However, the SRSR clearly suggest that ending the relationship is an option only when the company is unable to increase its leverage. Therefore, the notion of leverage in fact outweigh the disengagement option.¹⁷² This provision imposes a responsibility to act on behalf of the company. It can be claimed that this requirement clearly goes beyond the traditional meaning of ‘respect’ in the human rights regime. In a way, it subtly embeds a ‘protect’ nature in corporate responsibility to respect. This represents the SRSR’s pragmatic strategy to achieve the convergence of stakeholder expectations.¹⁷³

Patent-holding multinational pharmaceutical companies are the key players in global health policies due to their financial and political powers, as previously explained. This thesis has advocated certain corporate actions to reduce the prices of essential medicines by way of participating in multi-stakeholder initiatives and engaging in voluntary licensing agreements accompanied by transfer of technology. Within the light of Guiding

¹⁶⁸ *supra* note 88 p.48; Leverage means the ability to effect change in the wrongful practices of the party that is causing or contributing to the impact.

¹⁶⁹ *Ibid.*

¹⁷⁰ *Ibid.* p.49

¹⁷¹ *Ibid.*

¹⁷² Radu Mares, ‘Respect’ Human Rights: Concept and Convergence’ (2014) Forthcoming in *Law, Business and Human Rights: Bridging the Gap* (Robert C. Bird, Daniel R. Cahoy & Jamie Darin Prenekert, eds. Elgar Publishing Ltd. 2014) p. 18-19

¹⁷³ *Ibid.*

Principle 19, the company is expected to incentivise the entity to improve its right to health performance in terms of future business, reputational advantage or transfer of knowledge and technology.¹⁷⁴ Business associations and multi-stakeholder initiatives can be effective as well in increasing the leverage.¹⁷⁵ Therefore, this thesis claims that corporate actions that this thesis has advocated can be justified as appropriate actions under Guiding Principle 19, which attaches a significant importance to the concept of leverage. Indeed, the strong emphasis on the stakeholder involvement throughout the human rights due diligence process supports this claim as well.

4.3.2 Supportive Arguments

“An examination of human rights responsibilities beyond the duty to respect is critically important because the pharmaceutical sector has highly distinctive functions directly impacting upon the life, health and prosperity of countless individuals and communities”.¹⁷⁶

Firstly, “why are policies and processes required as in the Guiding Principle 15 if this is just a question of avoiding harm?” The OHCHR explicitly acknowledges that “respecting human rights is not a passive responsibility: it requires action on the part of businesses”¹⁷⁷ The SRSG builds the corporate responsibility to respect on the concept of “social expectations-as part of what is sometimes called a company’s social license to operate”.¹⁷⁸ This social expectation naturally varies depending on the circumstances.

By limiting the scope of corporate responsibility only to respect and asserting that this responsibility is sourced in societal expectations, Guiding Principles would actually be claiming that our societal expectations of pharmaceutical companies do not extent to a responsibility to help render such life-saving medicines affordable to those who need them.¹⁷⁹

¹⁷⁴ *supra* note 88 p.49

¹⁷⁵ *Ibid.*

¹⁷⁶ *supra* note 14 p.224

¹⁷⁷ *supra* note 88 p.23

¹⁷⁸ *supra* note 7 para.54

¹⁷⁹ *supra* note 76 p.212

“The agreement between society and patent holder includes a responsibility on the patent holder to take these steps, expeditiously and effectively, by way of deliberate, concrete and targeted measures...Of course, the success of the patent holder’s actions will sometimes depend upon states, donors and others in the pharmaceutical sector fulfilling their responsibilities. Nonetheless, the patent holder has a right-to-health responsibility to do what it can”.¹⁸⁰

Secondly, the IHRB suggested that the activities of certain industries such as companies who provide healthcare facilities, food distribution, water provisions, and power generation or telecommunications are closely tied with the fulfilment and realisation of specific rights. Therefore, these companies should have responsibilities beyond respect.¹⁸¹ The IHRB highlighted that this must be the case especially in circumstances where the state is unable to meet its human rights obligations.¹⁸² However, the SRSG objected to this idea on the ground that this proposition would “encourage endless strategic gaming by states and companies alike about who was responsible for what in particular situations”.¹⁸³

The SRSG often refers back to the Norms in claiming that the responsibilities of companies should not reflect the state obligations:

“Corporations are not democratic public interest institutions and that making them, in effect, co-equal duty bearers for the broad spectrum of human rights- and for “the obligation to promote, secure the fulfilment of, respect, ensure respect and protect” those rights, as the General Obligations of the Norms put it-may undermine efforts to build indigenous social capacity and to make Governments more responsible to their own citizenry”.¹⁸⁴

It must be clarified that this thesis is aware of the sensitivity of calling for responsibilities beyond respect. It does not claim that further responsibilities

¹⁸⁰ *supra* note 66 para.41

¹⁸¹ *supra* note 101 p.5; see also *supra* note 14 p.223

¹⁸² *Ibid.*

¹⁸³ *supra* note 9 p.97

¹⁸⁴ The SRSG, ‘Interim Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises’ (22 February 2006) 62nd Session Agenda Item 17 UN Doc E/CN.4/2006/97 para.68

should be assigned in a way, “which risks detracting attention away from state obligations, making it easier for governments to shirk their own obligations”.¹⁸⁵

This thesis does acknowledge though, the overall success can be achieved by states and companies together. For example, regarding the physical accessibility of drugs, many factors such as local infrastructure or distribution capacities depend on the state.¹⁸⁶ Another example is the expectation that companies should waive test data exclusivity or refrain from applying for patents ‘for insignificant or trivial modifications of existing medicines’ at low and middle- income countries.¹⁸⁷ However, this is more likely to happen when states disallow data exclusivity and patents on trivial modifications of existing medicines in their national laws¹⁸⁸ such as India. Indian Supreme Court rejected to uphold the patent on Gleevec, the cancer drug developed by Novartis, on the ground that the patent application could not satisfy the strict novelty requirement brought by the Indian patent law.¹⁸⁹

The SRSR also states that these additional responsibilities ‘undermine corporate autonomy, risk taking and entrepreneurship’.¹⁹⁰ Philip Alston asks, “if the private sphere is distinguished from the public sphere by virtue of its emphasis on autonomy, risk-taking, entrepreneurship, and the rational pursuit of self-interest, what are the consequences of saddling it with all of the constraints, restrictions and even positive obligations which apply to government?”¹⁹¹ Bilchitz’s argument is worth highlighting at this point:

¹⁸⁵ *supra* note 72 p.37; see also *ibid.*

¹⁸⁶ *supra* note 66 para.23

¹⁸⁷ *supra* note 72 p.40

¹⁸⁸ *Ibid.*

¹⁸⁹ Available at < <http://www.project-syndicate.org/commentary/the-impact-of-the-indian-supreme-court-s-patent-decision-by-joseph-e--stiglitz-and-arjun-jayadev>> accessed on 25 May 2014

¹⁹⁰ John Ruggie, ‘Business and Human Rights: The Evolving International Agenda’ (2007) Corporate Social Responsibility Initiative Working Paper No.38 p.11; see also *supra* note 77 p.213

¹⁹¹ Philip Alston, ‘The ‘Not-a-Cat’ Syndrome: Can the International Human Rights Regime Accommodate Non-State Actors?’ p.14 in: Philip Alston (ed) *Non-State Actors and Human Rights* (Oxford University Press 2005); *supra* note 76 p.213

“Imposition of some positive obligations upon corporations would not saddle them with all of the obligations that apply to government”.¹⁹² Nevertheless, he accepts that at a certain point, the company may claim that it has no reason to continue to invest in research and development if it is faced with overly onerous positive obligations, which causes a diminishment of profits. However, this does not provide a case against his argument. Instead, what it shows is that a balance is necessary if one wishes to gain both the traditional benefits of the market-place and additional social advantages for the realisation of human rights.¹⁹³ He refers to ‘push programmes’ through which government may help subsidise such research and ‘pull programmes’ which reward developers for producing a product with strong social benefits.¹⁹⁴

“What is needed is thus a movement away from the traditional assumption embedded in the Ruggie framework that only governments are responsible for the realisation of rights and the recognition that, in many cases, it will be necessary to involve wider social actors in this task”.¹⁹⁵

Another important point is the renouncement of the phrase ‘doing no harm’ in the U.N. Guiding Principles. The Framework states that the responsibility to respect means not to infringe on the rights of others. Put simply: to do no harm.¹⁹⁶ However, when one delves in more in-depth into the U.N. Guiding Principles, it appears that the phrase of ‘doing no harm’ which is used in the Framework has disappeared.¹⁹⁷ It instead explains the responsibility to respect as to avoid infringing and to address human rights impacts with which they are involved.¹⁹⁸ According to Mares, this shift is deliberately done to prevent the misinterpretation of the phrase ‘doing no harm’ as a purely negative responsibility to avoid or to refrain in order not to harm.¹⁹⁹

¹⁹² *supra* note 76 p.213

¹⁹³ *Ibid.* p.214

¹⁹⁴ *Ibid.*

¹⁹⁵ *Ibid.* p.215

¹⁹⁶ *supra* note 7 para.24

¹⁹⁷ *supra* note 172 p.15

¹⁹⁸ *supra* note 6 Guiding Principle 11

¹⁹⁹ *supra* note 172 p.15

This change of terminology might alone not be a strong indicator. However, it certainly opens the doors to interpret the Pillar II in a broader manner.

Finally, when analysing typologies, Shue's words should be recalled:

“Now, almost everyone involved in these discussions realizes that typologies are not the point. Typologies are at best abstract instruments for temporarily fending off the complexities of concrete reality that threaten to overwhelm our circuits. Be they dichotomous or trichotomous, typologies are ladders to be climbed and left behind, not monuments to be caressed or polished”.²⁰⁰

In this regard, the label of responsibility to *respect* is not the point. Therefore, the interpretation of the Pillar II should not be strictly limited within the typology.

4.4 Conclusion

This chapter challenged the boundaries set by corporate responsibility to respect with the help of specific examples. For the Pillar II to be effective, the sphere of required acts should be expanded in favour of access to medicines. When the question arises as to whether the proposed solutions such as multi-stakeholder initiatives or promoting the local production through licenses bring a permanent solution to the access problem, the answer would be negative. The cancellation of the Global Fund Round II²⁰¹ serves a good example in this regard. “With the Global Fund, unprecedented levels of donor money were channelled towards saving lives. But ten years on, global health is suffering from a sudden shortfall in funding, as donor countries leave the Fund in dire financial straits”.²⁰² Therefore, those efforts offer practical solutions for particular situations. However, it is very difficult to claim that they bring an end to the clash of patent rights and human right to health.

²⁰⁰ Henry Shue, *Basic Rights: Subsistence, Affluence and U.S. Foreign Policy* (Princeton University Press, 1996) p.160

²⁰¹ Available at http://www.msfaaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_briefing_LosingGround_ENG_2012.pdf accessed on 23 May 2014

²⁰² Available at <http://www.msfaaccess.org/10stories2011> accessed on 23 May 2014

5 Concluding Remarks

The research question that this thesis sought to answer was the meaning of corporate responsibility to respect human rights with regard to patent-holding pharmaceutical companies, more specifically, whether the corporate responsibility to respect as framed by the U.N. Guiding Principles is comprehensive enough to meet the right to health requirements in the access to medicines or not. In answering the research question, the thesis suggested that corporate responsibility to respect has the potential to enable greater access to essential medicines and allows for broader interpretation of *respect*, requiring positive actions from pharmaceutical companies in certain situations, *e.g.* price reductions in life-saving medicines.

Different disciplines, in particular, intellectual property and human rights legal regimes have been searching for a stable and feasible solution to the access problem. It is often claimed that a balance needs to be achieved between pharmaceutical patents and the right to health.²⁰³ This thesis has approached the problem by putting forward the corporate responsibility to respect, which can serve as a means to finding a balance.

Human rights due diligence is the prime element in operationalising the corporate responsibility to respect. It clearly requires companies to assess their actual and potential adverse human rights impacts. In this regard, the thesis has indicated how pharmaceutical companies adversely influence the essential elements of right to health through their patent rights. In close connection to these impacts, the thesis has advocated that the corporate responsibility to respect should not be confined to the traditional meaning of *respect* as framed in international human rights law. The example of price reductions in life-saving medicines is given to suggest that in certain situations, corporate responsibility to respect requires companies to take positive actions such as participating in multi-stakeholder initiatives or engaging in voluntary licensing agreements. This claim has been reinforced

²⁰³ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (Oxford University Press 2007) p.51

by the concept of human rights due diligence which requires companies to take appropriate actions to prevent and mitigate their adverse human rights impacts. This requirement is valid even in the situations where the company is involved in the adverse impact solely due to its *business relationship* with another entity. The company is expected to use every means available to prevent and mitigate adverse impacts such as by exercising leverage over the entity as well as increasing leverage in cases where it lacks. The thesis invoked the notion of *social expectation*, which lies behind the very existence of corporate responsibility to respect as well. Company's social license to operate necessitates the responsibility to *act* in certain situations, e.g. price reductions in life-saving medicines through different corporate actions. At the same time, the thesis also highlighted that calling for expansion in the domain of non-state actors' responsibilities should not be understood as deviating attention away from state obligations.²⁰⁴ Overall success can only be achieved by involvement of both states and companies in the process.

Consequently, it must be made clear that this thesis does not claim that imposing further responsibilities on patent-holding pharmaceutical companies will put an end to the access problem. However, it will contribute to an improvement in the overall process. The SRSG has already achieved a compelling task by simplifying the responsibilities of different actors, which was previously a complicated area and helped outline future debates. The field of business and human rights will follow a clearer path as the implementation of the U.N. Guiding Principles proceeds and underdeveloped areas are clarified. Indeed, the SRSG explained further expectations by stating that the Council endorsement of the U.N. Guiding Principles will “mark the end of the beginning: by establishing a common global platform for action, on which cumulative progress can be built, step-by-step, without foreclosing any other promising longer-term developments”.²⁰⁵

²⁰⁴ *supra* note 72 p.37; see also *supra* note 184

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