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Access to Medicines through Regionally Restricted Licenses

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Preface

90 % of the medicines used to treat children with HIV/AIDS in Africa originate from generic producers located in India.¹ These companies are able to produce copies of patent-protected pharmaceuticals thanks to Indian domestic legislation. In the future, however, these producers may not be able to manufacture these medicines as Novartis, the owner of the patent rights, is currently challenging this legislation in an attempt to enforce its patent in Indian courts.² This clash of interests encompasses several discourses such as economy, law and politics and is particularly interesting as both sides have claims that are both morally and legally just. The conflict in question is the one between owners of pharmaceutical patents and advocates of a right to access to medicines. Usually a corporation holds the patent rights while an international organization or a specific state promotes the right to access to medicines. The conflict arises when the people, in need of a certain medicine, live in a country which cannot afford to purchase the expensive patented drug from the patent-holding company. NGOs and other international organizations become involved as they support, work and aim toward the goal of ensuring access to medicines for everyone.

From a legal point of view, the pharmaceutical companies have very legitimate claims as intellectual property law covers their products. Thus, both the creation of copies as well as the distribution of these counterfeits will amount to a violation of relevant intellectual property laws. One could also argue that enforcing these patent rights is morally sound. Firstly, the pharmaceutical companies spend millions (and often even billions) of dollars on research that is necessary in order to be able to produce these drugs. Secondly, these corporations need to make a considerable profit, as advancements in the medical field will not be possible without adequate

¹ The Bureau of Investigative Journalism, *Analysis: Legal case in India threatens HIV drug access for poorest* by Newman, Melanie, September 12th 2011, accessed 2012-05-14; available at: <http://www.thebureauinvestigates.com/2011/09/12/analysis-legal-case-in-india-threatens-hiv-drug-access-for-poorest/>.

² Id.

financial support. However, both legal and moral arguments support access to medicines for marginalized people as well. The right to health arguably includes a right to access to medicines and, subsequently, creates matching legal obligations (more on this below in section 2.3). In other words, one must strive to enable access to medicines for all. From a moral standpoint it is quite easy to claim that the pursuit of financial gains does not justify compromising the health of human beings.

Solving this conflict is essential for the well-being of countless humans around the world. Even if medical facilities and trained staff are available, adequate treatment will never be possible without the necessary pharmaceuticals. This is perhaps especially true regarding diseases which are treated with drugs that are listed as essential medicines. Nevertheless, one must remember that these drugs, with the exception of government-sponsored medicines, would not exist without the billions of dollars that pharmaceutical companies have spent on research and development. Moreover, this funding was made available by exclusive sales achieved through patent protection. In sum, while solving this conflict one must be careful not to compromise any of the aspects necessary for ensuring human health as well as advancements within the medical field.

Summary

The right to health is a fundamental human right within the international legal sphere. This right includes access to medicines as an essential part that is necessary for its fulfillment. However, millions of people are not provided with the essential medicines that they need, and pharmaceutical companies have a role to play in this context as their patent rights limit the possibilities of manufacturing cheap medicines. With the aim of creating a new solution that can satisfy the needs of all relevant stakeholders, this thesis clarifies the right to health as well as how it applies to both states and corporations, considering the work of John Ruggie within the business and human rights discourse. Adding all these aspects together, the approach of a Regionally Restricted License is presented as a method which may be able to solve the conflict between access to medicines and pharmaceutical patents.

Other solutions, already prevalent within the international community, are presented and assessed within the thesis. These include donations, contributions to research, compulsory licenses and voluntary licensing. However, even though all of these approaches have their benefits, the major obstacles that stand before them will be difficult to overcome. This thesis argues that Regionally Restricted Licenses can surmount these obstacles and provide benefits and incentives that will make the solution both sustainable and applicable in a larger scale.

Abbreviations

CHPS	Community-based Health Planning and Services
CSR	Corporate Social Responsibility
D2P	Duty to Protect
GEMI	Ghana Essential Medicines Initiative
ICESCR	International Covenant on Economic Social and Cultural Rights
IP	Intellectual Property
LDCs	Least Developed Countries
R2R	Responsibility to Respect
RRLs	Regionally Restricted Licences
TRIPS	Agreement on Trade-Related aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UN	United Nations
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

1.1 Background and Overview

Although states are both the creators and subjects of international law, many other actors have had great influence, both for better and for worse, in the international legal sphere. A well-known example of such an actor would be pharmaceutical companies that, rather naturally, have come to play an important role within the field of access to medicines.³ As these companies perform research and development, are holders of the patent rights and are the salesmen of the drugs they create, their actions will inevitably have a huge impact on the state of access to medicines around the world.

The current situation is greatly affected by the World Trade Organization (henceforth referred to as the WTO) and its Agreement on Trade-Related aspects of Intellectual Property Rights (henceforth referred to as TRIPS).⁴ Although many member states of the WTO did not approve of patent protection for neither the process of development nor the pharmaceuticals themselves, it is through TRIPS that pharmaceutical products first became more widely accepted as patentable material. TRIPS merely provides the lowest common denominator for global patent protection but, nevertheless, sets a rather high bar with generous and extensive protection.⁵ However, there has been much tension between TRIPS and the implementation of economic, social and cultural rights, with access to medicines being one of

³ Pogge, Thomas, Rimmer, Matthew. & Rubenstein, Kim (ed.), (2010), *Incentives for global public health: patent law and access to essential medicines*. Cambridge, UK: Cambridge University Press, p. 343.

⁴ *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

⁵ Otterson, Kevin, Should Access to Medicines and TRIPS Flexibilities Be Limited to Specific Diseases?, *American Journal of Law and Medicine*, Vol. 34, 2008, pp. 317-318; Available at SSRN: <http://ssrn.com/abstract=1090270>.

the most relevant aspects.⁶ The problem stems from the one size fits all-structure of TRIPS, which has had a very negative impact on developing countries and their ability to distribute medicines.⁷ An attempt to solve this issue was made through the creation of the Doha Declaration⁸ which unfortunately did not result in much improvement. The Doha Round, with the exception of compulsory licenses (see more under section 5.2), was not a success simply due to lack of consensus. Subsequently, all those trying to use TRIPS in order to address access to medicine issues will face legitimacy problems and much resistance from both pharmaceutical companies and the WTO member states in which they reside.⁹ In other words, integrating human rights into the work of the WTO is still considered controversial and uncertain, even after the Doha Declaration.¹⁰

In human rights circles, access to medicines has been discussed under the umbrella of the right to health. The right to health can be found in many human rights treaties with art. 12 of the International Covenant on Economic, Social and Cultural Rights (henceforth referred to as the ICESCR) being the most known example.¹¹ The discussion has revolved around whether there is a right to access to medicines or whether such access is merely an important part of art. 12. In addition, international customary law might very well include a right to health.¹² If so, one must clarify what such a right to health would entail and, for the purposes of the present paper, whether access to medicines would be included. These

⁶ Helfer, Laurence R., *Human Rights and Intellectual Property: Conflict or Coexistence?*, Minnesota Journal of Law, Science & Technology, Vol. 5, 2003, p. 55; Available at SSRN: <http://ssrn.com/abstract=459120> or doi:10.2139/ssrn.459120.

⁷ Pogge, Rimmer & Rubenstein, supra note 3, p. 36.

⁸ *Declaration on the TRIPS Agreement and Public Health*, WTO Doha Ministerial Conference, 4th Sess., WTO Doc. WT/MIN(01)DEC/2 (2001).

⁹ Pogge, Rimmer & Rubenstein, supra note 3, p. 47.

¹⁰ Helfer, supra note 6, p. 60.

¹¹ UN General Assembly, *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, United Nations, Treaty Series, vol. 993, p. 3.

¹² Niada, Laura, *The human right to medicines in relation to patents in sub-Saharan Africa: some critical remarks*, The International Journal of Human Rights, Vol. 15, No. 5, June 2011, p. 708.

questions will be raised and assessed much more thoroughly under section 2.

The grave consequences of lack of access to medicines, partially resulting from the aforementioned conflict with pharmaceutical patents, are especially well known in the geographical context of Africa.¹³ However, many other regions suffer from lack of access to medicines as the common denominator is not geographical location but financial challenges. The reason for this is that the patent protection under TRIPS has struck hard on those who are infected with poverty-related diseases.¹⁴ According to previous estimates, 80 % of the world population was living in developing countries and that figure has most likely continued growing.¹⁵ In addition, poverty-related diseases amount to 50 % of the burden of healthcare systems in developing countries which is ten times as much as in developed countries.¹⁶ The result is that the TRIPS agreement will negatively impact billions of people seeking treatment for poverty-related illness.

The current situation does not rhyme well with the World Health Organization's (henceforth referred to as the WHO) statement that "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, *economic or social condition*."¹⁷ In sum, the lack of financial means of developing countries, as well as their population, is limiting the possibilities of providing adequate healthcare and the TRIPS

¹³ Yu, Peter K., *Ten Common Questions About Intellectual Property and Human Rights*, Georgia State University Law Review, Vol. 23, 2007, p. 718; Available at SSRN: <http://ssrn.com/abstract=1090241>; see also Commission on Human Rights, resolution 2004/26, *Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria*, 52nd meeting, 16 April 2004.

¹⁴ Pogge, Rimmer & Rubenstein, supra note 3, p. 55.

¹⁵ WHO, *Public Health Innovation and Intellectual Property Rights, A Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (Geneva, 2006) p. 2.

¹⁶ Id., p. 3.

¹⁷ Global strategy and plan of action on public health, innovation and intellectual property, 61st World Health Assembly, WHA61.21, 2008-05-24, p. 7 (emphasis added); Available at: http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

agreement has great influence in this matter as its IP-protection has greatly affected developing states.¹⁸ Kevin Outterson describes the situation very clearly, stating that “The pharmaceutical IP system works to some degree in high-income countries with generous government subsidies and social insurance. It does not work well for the poor in low- and middle-income countries.”¹⁹

Having presented the conflict in question, available solutions will also be briefly introduced. Several pharmaceutical companies have chosen to take action in order to improve access to medicines. It is clear that the business and human rights discourse has had influence in this matter as it has clarified possible gains of a human rights friendly business management. The Access to Medicine Foundation²⁰ has done outstanding work involving stakeholders, such as pharmaceutical companies, in their research. This approach has resulted in transparent reports from said companies, outlining actions taken regarding access to medicines.²¹

Examples of what can be considered as “best strategies”, employed by the world’s largest pharmaceutical companies, include donations (often in cooperation with a foundation), increased transparency, contribution to research and development through, for instance, patent disclosure and innovative solutions such as the application of certain business models and licensing agreements.²² In sum, the main options available are licensing agreements and philanthropic activities. Worthy of mentions is the possibility of simply not enforcing ones patent rights when these are violated by an actor who is trying to ensure access to medicines in an area which does not have considerable purchasing power. These options will be concretized and further elaborated upon in section 5. Moreover, an

¹⁸ Bently, Lionel & Sherman, Brad, (2009), *Intellectual property law*. 3 ed., Oxford: Oxford University Press p. 353.

¹⁹ Outterson, supra note 5, p. 338.

²⁰ <http://www.accesstomedicineindex.org/content/about-us>.

²¹ Access to Medicine Foundation, *Access to Medicine Index 2010*, June 2010; available at http://www.accesstomedicineindex.org/sites/www.accesstomedicineindex.org/files/general/Access_to_Medicine_Index_2010.pdf.

²² Id., see for instance pp. 22-24.

original solution to the conflict, Regionally Restricted Licenses (henceforth referred to as RRLs), will be introduced and assessed with the aim of showing the benefits of this approach (see section 4).

1.2 Research Questions

The present paper asks three key questions that encompass all essential aspects necessary to enable the creation or identification of an approach, which can solve the conflict between pharmaceutical patents and access to medicines. *The first question* is whether access to medicines is included in the right to health. Both art 12 of the ICESCR and the right to health found in international customary law, will be discussed in this context. The aim being to clarify their content and question whether one might be able to claim the existence of an independent right to access to medicines. *The second question* is whether it is possible to place obligations regarding human rights on businesses. Answering this question requires further discussion of business and human rights, the responsibility states have regarding the actions of their corporations and whether it is possible, or at least reasonable, to demand action from a business enterprise. *The third and final question* relates to the original concept of RRLs and asks whether this approach is most beneficial and promising when trying to ensure access to medicines, through involvement of the pharmaceutical industry, on a larger scale. In order to adequately answer this question, other available alternatives much also be assessed.

1.3 Methodology

There are mainly two different methodologies used in the present paper. A descriptive method will be applied in order to present and clarify the content of each chapter. This is the method used when presenting the right to health,

the Ruggie Framework²³, RRLs and alternative solutions. Thereafter, an analytical method will be employed in an attempt to establish connections between the different topics and access to medicines. The purpose of this method is to clarify how the right to health, the Ruggie Framework and RRLs can apply and contribute to the field of access to medicines. Moreover, an analytical approach is necessary in order to decide which solution or approach is most suitable when aiming to ensure better access to medicines under conditions that are beneficial, or at least agreeable, to all stakeholders. Finally, in order to ensure the practical value of the solution that is the topic of the present paper, a brief case study method will be applied when describing how to implement RRLs.

1.4 Delimitations

Although it is desirable to provide as wide coverage as possible, certain limitations are necessary. The purpose of this is to enable better and more detailed elaboration on the most important parts of this thesis such as the RRLs. When assessing the right to health, the presentation will be limited to art 12 of the ICESCR and international customary law. Other provisions relating to the right to health may be mentioned briefly but will not be discussed in detail. The Ruggie Framework is expansive, multi-layered and complex; chapter 3 will thus merely summarize the most essential aspects of the Framework before addressing its relevance to ensuring access to medicines.

The greatest restriction, however, is the amount of solutions included in chapter 5. Numerous approaches may serve to facilitate access to medicines, research and development as well as production of generic medicines or strengthen the purchasing power of developing countries. The presentation

²³ Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, *Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework*, UN Doc. A/HRC/17/31, 2011.

will be limited to solutions that include pharmaceutical companies as essential actors. These include compulsory licensing, donations and other philanthropic activities, contributions to research and the option of tolerating violations of patent rights. Finally, the discussion on access to medicines will be limited to the essential medicines as defined by the WHO, in its list which dates back to 1977 that contains medicines considered as integral for promoting public health.²⁴ These drugs are chosen after assessing criteria such as quality, effectiveness and safety.²⁵

²⁴ Krikorian, Gaëlle & Kapczynski, Amy (ed.), (2010), *Access to knowledge in the age of intellectual property*. New York: Zone Books, p. 129.

²⁵ Id.

2 The Right to Health and Access to Medicines

2.1 Article 12 of the ICESCR

The aim of this section is to ascertain whether access to medicines is included in the ICESCR. If so, then states that have ratified the Covenant will be obligated to ensure access to medicines within their jurisdiction in the process of the full realization of the provision. The right to health found in art. 12 of the ICESCR originates from art. 25 of the Universal Declaration of Human Rights (henceforth referred to as the UDHR) which states that “Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care...”.²⁶ Article 25 also includes other rights within the provision, for instance the right to adequate standard of living.

Art. 12 of the ICESCR is more specific, stating that “The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”²⁷ As further definition is clearly necessary, the provision continues by defining which actions are essential to the fulfillment of the right to health. Such steps include:

- “(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
- (b) The improvement of all aspects of environmental and industrial hygiene;
- (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

²⁶ UN General Assembly, *Universal Declaration of Human Rights*, 10 December 1948, 217 A (III), art 25.

²⁷ ICESCR, *supra* note 11, art. 12.

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.”²⁸

Although some degree of specificity is included in art. 12, the provision has many aspects which are vague, unclear and in need of assessment in order to fully describe what the right to health entails. In the following presentation an attempt will be made to provide further clarity with the use of authoritative sources such as the General Comments of the Committee on Economic, Social and Cultural Rights and the reports of the UN Special Rapporteur on the right to health.

2.1.1 General Comment 14

A detailed assessment of the right to health, specifying what standards are laid down and what obligations can be placed on a member state, can be found in General Comment 14²⁹ adopted by the Committee on Economic, Social and Cultural Rights (‘Committee’). The main conditions necessary for the fulfillment of the right to health include Availability of health-related facilities, services and goods (such as pharmaceuticals), Accessibility both in physical and economic context, Acceptability in terms of consideration of ethics as well as culture, and Quality in the sense that the staff must be knowledgeable, the facilities sanitary and adequately equipped and the drugs scientifically approved and unexpired.³⁰ Two of these prerequisites mention medicines as an essential aspect which must be considered when fulfilling the right to health.

Looking at the actual text of art. 12 of the ICESCR, both subparagraph (c) and (d) include language which would suggest that access to medicines must be enabled before the provision can be fully realized. However, the

²⁸ Id.

²⁹ UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12 of the Covenant)*, 11 August 2000, E/C.12/2000/4.

³⁰ Id., para. 12.

Committee merely mentions essential drugs in the context of subparagraph (d).³¹ Nevertheless, this aspect would seem to constitute a part of the provision which strengthens the possibilities of demanding acts of implementation regarding access to medicines. In fact, providing essential drugs is listed as a core obligation of the state parties of the Covenant.³²

Violations of the right to health arise when a state party fails to make use of all available resources in order to take the necessary steps towards full progressive realization.³³ In other words, “A State which is unwilling to use the maximum of its available resources for the realization of the right to health is in violation of its obligations under article 12.”³⁴ Obviously, lack of resources will constitute a formidable obstacle. However, the core obligations mentioned above (such as the provision of essential medicines) must always be enacted as they are considered non-derogable.³⁵ In addition, when entering into other international agreements and treaties, the state parties to the ICESCR must consider their legal obligations under the Covenant.³⁶ Failure in this regard will constitute a violation of the obligation to respect the right to health and a violation of the treaty itself.³⁷ This holds great importance considering the possible conflict between the right to health and the patent protection included in the TRIPS agreement. When such a conflict arises, the provisions related to patent protection must be subjugated to the rights of the Covenant in order to avoid violating the obligation to respect the right to health of art. 12.

³¹ Id., para. 17.

³² Id., para. 43.

³³ Id., para. 47.

³⁴ Id.

³⁵ Id.

³⁶ Id., para. 50.

³⁷ Id.

2.1.2 Reports of the Special Rapporteur

Through resolution 2002/31³⁸, the Commission on Human Rights first appointed a Special Rapporteur with the task of evaluating the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The Special Rapporteur was requested to consult all relevant sources and actors in order to gather and exchange information as well as develop a fruitful dialogue with these stakeholders.³⁹ Moreover, the Special Rapporteur was asked to report on the status of the right to health and to make suitable recommendations for its promotion and protection.⁴⁰ This work was for obvious reasons connected to the UN human rights treaties and General Comment 14 was specifically mentioned as a source to have in mind when working with art. 12 of the ICESCR.⁴¹ Thus, the link to the right to health as stated in the Covenant is both clear and strong.

Paul Hunt was the first Special Rapporteur and was thus given the task of defining the right to health. Doing so, he used international sources and consultation to clarify the right's content in his 2003 report.⁴² The right to health is described as a broad and inclusive right, encompassing several aspects and entitlements such as access to essential medicines.⁴³ In addition, the right was already in 2003 considered as a fundamental human right with a well-established international status.⁴⁴ In the following presentation of the Special Rapporteur, the primary source used in order to define the content of the right to health is General Comment 14. Thus, the 2003 report does not provide us with much new information but mainly includes what can be

³⁸ Commission on Human Rights, Resolution 2002/31, *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*, 49th meeting, 22 April 2002.

³⁹ *Id.*, para. 5.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, UN Doc. E/CN.4/2003/58, 13 February 2003.

⁴³ *Id.*, para. 25.

⁴⁴ *Id.*, para 38.

found in the work of the Committee on Economic, Social and Cultural Rights.

In 2009, the issue of access to medicines became the main topic of the report of the Special Rapporteur.⁴⁵ This came as no surprise as the link between the right to health and access to medicines became highlighted already in resolution 2002/32 which stated that “access to medication (...) is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”⁴⁶.

In the report, the Special Rapporteur stated that healthcare treatment, which includes control and prevention of diseases, depends upon access to medicines.⁴⁷ It is quite apparent neither control nor prevention of diseases will be possible without the necessary medicines. This was affirmed already in the 2006 report which labelled access to essential medicines as an indispensable aspect of the right to health that might also impact other fundamental rights such as the right to life.⁴⁸ The 2009 report continues by stating, in even stronger language, that “States have an obligation under the right to health to ensure that medicines are available, financially affordable, and physically accessible on a basis of non-discrimination to everyone within their jurisdiction.”⁴⁹ Moreover, medicines must not only be available and accessible but must also be of good quality.⁵⁰

⁴⁵ Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Anand Grover, *PROMOTION AND PROTECTION OF ALL HUMAN RIGHTS, CIVIL, POLITICAL, ECONOMIC, SOCIAL AND CULTURAL RIGHTS, INCLUDING THE RIGHT TO DEVELOPMENT*, A/HRC/11/12, 31 March 2009.

⁴⁶ Commission on Human Rights, Resolution 2002/32, *Access to medication in the context of pandemics such as HIV/AIDS*, 49th meeting, 22 April 2002.

⁴⁷ Special Rapporteur 2009, *supra* note 45, para. 10.

⁴⁸ Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, UN Doc. A/61/338, 13 September 2006 para. 40.

⁴⁹ Special Rapporteur 2009, *supra* note 45, para. 11.

⁵⁰ *Id.*, para. 10.

It is quite far-reaching and ambitious to suggest the inclusion of other pharmaceuticals that are not recognized as essential medicines, defined by the WHO. But it would seem that this is what the Special Rapporteur is doing. In addition, using the word “jurisdiction” enables a discussion on extra-territorial activities which might fall under the scope of obligations that a state has under the ICESCR and the right to health. However, pharmaceutical companies do not directly violate the right to health and discussions on extra-territorial application are, therefore, of lesser relevance to the topic of this thesis.

The final report which will be discussed within the present paper is the 2011 report, following consultation with experts on the issue of access to medicines.⁵¹ The title reveals the standpoint of the Special Rapporteur: “Expert consultation on access to medicines as a *fundamental* component of the right to health”⁵² Once again the issue of conflicting norms was raised, with member states being reminded of their legal obligations in relation to the ICESCR and with TRIPS being mentioned as a possible threat to the right to health.⁵³ A participant in the consultation, Steven Marks of the Harvard School of Public Health, referred to Commission on Human Rights resolution 1999/49⁵⁴ which confirmed that states must not be hindered by other international agreements when protecting public health.⁵⁵ In addition, a representative of the WHO, Richard Laing, defined access to medicines as: “a very clear and relatively robust way of measuring a Government’s commitment to fulfilling the right to health.”⁵⁶ In sum, it was yet again reaffirmed that access to medicines is an essential part of the right to health

⁵¹ Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, *Expert consultation on access to medicines as a fundamental component of the right to health*, A/HRC/17/43, 16 March 2011.

⁵² *Id.*, p. 1 (emphasis added).

⁵³ *Id.*, para. 7.

⁵⁴ Commission on Human Rights, resolution 1999/49, *The protection of human rights in the context of human immunodeficiency virus (HIV) and acquired immune deficiency syndrome (AIDS)*, 56th meeting, 27 April 1999.

⁵⁵ Special Rapporteur 2011, *supra* note 51, para. 9.

⁵⁶ *Id.*, para. 12.

as defined in the ICESCR art. 12 and that state parties of the covenant must strive to achieve access for all.

2.2 The Right to Health in Customary Law

There are several reasons for determining the existence and content of the right to health in international customary law. Firstly, norms of such character are of legally binding quality.⁵⁷ Secondly, customary law binds not only those who have contributed to its existence, but applies to all regardless of ratification.⁵⁸ Thirdly, confirming the existence of access to medicines in customary law would motivate greater claims regarding specific actions aimed towards providing complete access for all. This remains true not only regarding states (including those who have not ratified the ICESCR) but for other actors such as pharmaceutical companies who also have responsibilities concerning human rights (more on this in section 3.1-2). Difficulties exist, however, as the task of determining the content of customary law is not an easy one. Both state practice and *opinio juris* must be present in order for a norm to come into existence, and these concepts are neither clear nor very concrete and are therefore difficult to establish.⁵⁹

Some claim that the UDHR constitutes customary law, which would suggest that the same applies for the provision on right to health.⁶⁰ However, art. 25 does not speak specifically of access to medicines but merely of medical

⁵⁷ Kinney, Eleanor, Lecture: *THE INTERNATIONAL HUMAN RIGHT TO HEALTH: WHAT DOES THIS MEAN FOR OUR NATION AND OUR WORLD*, in 34 *Indiana Law Review* 1457, 2001, pp. 5.

⁵⁸ *Id.*

⁵⁹ See for the entire paragraph: art. 38.1 (b) of the Statute of the International Court of Justice; United Nations, *Statute of the International Court of Justice*, 18 April 1946; see also United Nations, *Vienna Convention on the Law of Treaties*, 23 May 1969, United Nations, Treaty Series, vol. 1155, p. 331, preamble and art. 38.

⁶⁰ Universal Declaration, *supra* note 26, art. 25; See also Niada, Laura, *supra* note 12, p. 707, who mentions that it can be argued that the UDHR merely constitutes evidence of *opinio juris*.

care and does therefore not sufficiently address the matter at hand.⁶¹ The UN General Assembly frequently decides on matters that are presented in non-binding resolutions, which usually reflect the general consensus of the member states, and subsequently provide a good indicator for what constitutes customary law.⁶² Some of these were mentioned in section 2.1.2, but worthy of note is also resolution 58/179 on Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria.⁶³ Although customary law is not specifically mentioned within the resolution, it is implied that the right to health constitutes such a norm, and its content is both discussed and defined. Access to medicines constitutes an essential part of the right to health which must be addressed by states through the provision of available, affordable, accessible and qualitative medicines.⁶⁴ Moreover, obligations regarding conflicting international agreements and the facilitation of research and development are mentioned.⁶⁵ In other words, the general consensus of the UN member states is that there is a right to health (even for those who have not ratified the ICESCR), that this right includes access to medicines as an essential aspect and that the work that can be done to ensure such access must not be hindered. Although this does not, independently, prove the prevalence of access to medicines in customary law, it is nevertheless a strong indicator.

Certain authors of available doctrine have arrived at the conclusion that there exists, at the very least, a right to health in customary law.⁶⁶ After similar assessment as the one made in the previous paragraph, Laura Niada stated that “an obligation to respect access to medicines as part of a human right to health – and therefore to respect a ‘human right to medicines’ – can be identified in international customary law.”⁶⁷ However, this right is far

⁶¹ Id.

⁶² Niada, Laura, *supra* note 12, pp. 706-707.

⁶³ United Nations General Assembly, Resolution 179 (2003), UN Doc. A/RES/58/179.

⁶⁴ Id., paras. 1 and 6.

⁶⁵ Id., paras. 8-10.

⁶⁶ Niada, Laura, *supra* note 12; Kinney, Eleanor, *supra* note 57, pp. 5-9, 12.

⁶⁷ Id.

from clear and Niada characterizes it as: “vague and contradictory”⁶⁸, mentioning the difficulties of prohibiting interference with access to medicines while supporting the promotion of IP. Kinney agrees by stating that “Indeed, getting a handle on the content of the right to health is a necessary first step to effective implementation. But this is no easy task.”⁶⁹ In sum, there is a right to health in international customary law, but the content of this right is difficult to ascertain. Nevertheless, due to its key role in the realization of the right to health, the inclusion of access to medicines is inevitable.

2.3 A Right to Access to Medicines?

The question that remains is whether there exists an independent right to access to medicines. It is clear that access to medicines is included in the umbrella of the right to health both in ICESCR art. 12 and arguably also in international customary law. However, even though legal obligations exist regarding the issue, that does not in itself result in an independent right to access to medicines. If such a right exists, it would greatly facilitate the clarification of the discourse and make questionable interpretations by those who oppose the right to health more difficult to justify. Otherwise, States could claim that compliance with the obligations under the right to health does not require providing full access to medicines.

The Special Rapporteur used rights-related language in his 2011 report by stating that there are “positive examples of domestic courts in Latin America, South Asia and South Africa, which have abolished the distinction between civil and political rights, on the one hand, and economic, social and cultural rights, on the other, by recognizing the *individual’s right to have access to medicines*.”⁷⁰ In other words, there are countries who acknowledge the existence of a right to access to medicines. In an earlier report, an entire

⁶⁸ Id.

⁶⁹ Id.

⁷⁰ Special Rapporteur 2011, supra note 51, para. 6 (emphasis added).

section was dedicated to the declaration of a human right to medicines.⁷¹ The essence of this section was that this right constitutes an indispensable part of the right to health.⁷² Moreover, such acknowledgement may, if presented in a larger scale and more uniformly, lead to the creation of a customary norm. Niada considers there to exist a right to medicines in customary law.⁷³ She arrives at this conclusion using the logic that if there is a customary norm regarding the right to health, and this provision includes access to medicines, then indirectly a right to medicines must also exist.⁷⁴

2.4 Chapter conclusion

Regardless of whether one looks at treaty law or international customary law, one will arguably be able to find a right to health that includes access to medicines as an essential component. A right to health in customary law would bind all states regardless of whether they have ratified any human rights treaties. In addition, through the business and human rights discourse and its responsibility to respect (henceforth referred to as R2R), companies will also have responsibilities concerning access to medicines.

The right to health is inclusive, encompassing aspects such as availability and accessibility of healthcare facilities, knowledgeable staff and the provision of qualitative drugs. Moreover, the right demands a high level of compliance from states. When engaging in agreements, states must consider their human rights obligations. Entering into treaties that are in conflict with the right to health is prohibited, and states must ensure that application of their legal obligations never hinder the fulfillment of the right in question.

⁷¹ Special Rapporteur 2006, *supra* note 48, paras. 37-43.

⁷² *Id.*

⁷³ Niada, Laura *supra* note 12, p. 708.

⁷⁴ *Id.*

In addition to the protection provided through the right to health, a specific right to access to medicines may also be present in international customary law. A specific right to access to medicines could strengthen the protection and clarify the responsibilities of states and other actors. However, even though some aspects of the right might still be questioned, the international community would seem to have reached a consensus that access to medicines will always be a fundamental part of the right to health that is indispensable to its fulfillment.

3 The Ruggie Framework

3.1 General Overview and Introduction

Through resolution 2005/69, the Commission on Human Rights requested that a Special Representative of the Secretary-General be appointed to work within the field of human rights and business.⁷⁵ Soon thereafter John Ruggie became Special Representative, and his task was:

- “(a) To identify and clarify standards of corporate responsibility and accountability for transnational corporations and other business enterprises with regard to human rights;
- (b) To elaborate on the role of States in effectively regulating and adjudicating the role of transnational corporations and other business enterprises with regard to human rights, including through international cooperation;
- (c) To research and clarify the implications for transnational corporations and other business enterprises of concepts such as “complicity” and “sphere of influence”;
- (d) To develop materials and methodologies for undertaking human rights impact assessments of the activities of transnational corporations and other business enterprises;
- (e) To compile a compendium of best practices of States and transnational corporations and other business enterprises;”⁷⁶.

Clearly, the mandate was broad and after presenting the ‘Protect, Respect, Remedy’ Framework in his 2008 report⁷⁷ to the Human Rights Council, John Ruggie received an extension of his mandate for an additional three

⁷⁵ Commission on Human Rights, resolution 2005/69, *Human right and transnational corporations and other business enterprises*, 59th meeting, 20 April 2005.

⁷⁶ *Id.*, para. 1.

⁷⁷ Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, *Protect, Respect and Remedy: a Framework for Business and Human Rights*, UN Doc. A/HRC/8/5, 2008.

years.⁷⁸ This was necessary in order for the Special Representative to be able to continue his work as well as expand it to include aspects such as concrete guidance for states and business enterprises, options and recommendations regarding access to effective remedies and best practices within the field.⁷⁹ Ultimately, the final report on the Guiding Principles on business and human rights which contained specific guidelines and recommendations was unanimously adopted by the Human Rights Council in 2011.⁸⁰

The “protect, respect, remedy” Framework of the 2008 report entails a state duty to protect human rights (henceforth referred to as D2R), a corporate R2R human rights and the issue of ensuring access to remedies.⁸¹ These different parts complement each other while together creating the Framework as a whole.⁸² Access to remedies is of less importance to the topic of the present paper and will, therefore, only be mentioned briefly. Worthy of note is the considerable effort that the Special Representative made as he “convened 14 multi-stakeholder consultations on five continents; conducted more than two dozen research projects, some with the assistance of global law firms and other legal experts, non-governmental organizations (NGOs), international institutions, and committed individuals; produced more than 1,000 pages of documents; received some 20 submissions; and reported twice to the Commission on Human Rights and the Human Rights Council.”⁸³

The D2P human rights falls on the state as a part of its international obligations arising from customary and treaty law and Ruggie considers it as

⁷⁸ Human Rights Council, resolution 8/7, *Mandate of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises*, 28th meeting 18 June 2008.

⁷⁹ *Id.*, para. 4.

⁸⁰ Ruggie Final Report, *supra* note 23; see also Human Rights Council, *Human rights and transnational corporations and other business enterprises*, UN Doc. A/HRC/17/L.17/Rev.1, 2011.

⁸¹ Ruggie 2008 Report, *supra* note 77, para. 9.

⁸² *Id.*

⁸³ *Id.*, para. 4.

a foundation of the international human rights regime.⁸⁴ What is meant here is the obligation to protect from harm that is coming from a third actor, possibly a business enterprise. Ruggie talks of a “corporate culture” which can develop in different ways depending on the actions taken by a state.⁸⁵ According to the Special Representative, the state D2P entails an obligation to ensure that consideration of human rights is included within the corporate culture in question.⁸⁶ Fulfilling this obligation could be done through the application of market pressures on companies or by invoking criminal accountability.⁸⁷ In order for this concept to function within the field of business and human rights, policy alignment and support from the international community will be necessary.⁸⁸ Moreover, special attention must be given to companies that are operating in conflict zones.⁸⁹

The R2R concept entails a responsibility for corporations to be mindful of human rights at the risk of, as Ruggie puts it, being subject: “to the courts of public opinion - comprising employees, communities, consumers, civil society, as well as investors - and occasionally to charges in actual courts.”⁹⁰ What Ruggie successfully impressed during his mandate is that applying state obligations to companies is neither fair nor functional as the business organizations are geared towards economic value creation and have a specific functional role in society.⁹¹ Therefore, something different from the state obligation to protect was needed. The R2R is a baseline expectation that “exists independently of States’ duties. Therefore, there is no need for the slippery distinction between “primary” State and “secondary” corporate obligations - which in any event would invite endless strategic gaming on the ground about who is responsible for what.”⁹² Moreover, the R2R “is not

⁸⁴ Id., para. 9.

⁸⁵ Id., para. 27.

⁸⁶ Id.

⁸⁷ Id., paras. 30-31.

⁸⁸ Id., paras. 33-46.

⁸⁹ Id., para. 49.

⁹⁰ Id., para. 54.

⁹¹ Id., para. 53.

⁹² Id., para. 55.

merely a passive responsibility for firms but may entail positive steps”⁹³. In this context, due diligence plays an essential part and Ruggie states that “To discharge the responsibility to respect requires due diligence. This concept describes the steps a company must take to become aware of, prevent and address adverse human rights impacts.”⁹⁴ The Special Representative outlines the process of due diligence and includes human rights policies, integration of said policies within the company, impact assessments and monitoring procedures as essential to this process.⁹⁵

Access to remedies constitutes the third pillar of the Framework and entails grievance mechanisms which apply both to the D2P and the R2R human rights.⁹⁶ These will be mentioned briefly without going into detail as the third pillar is less relevant to the topic of the present paper. Ruggie states that “State regulation proscribing certain corporate conduct will have little impact without accompanying mechanisms to investigate, punish, and redress abuses.”⁹⁷ These mechanisms can be supervised by the state as well as private actors and can be both judicial and non-judicial.⁹⁸ Ensuring access to such mechanisms as well as the possibility of redress, are two core aspects which must always be present.⁹⁹ In sum, when a person’s rights have been violated, he or she must be able to seek justice from a legitimate source which can offer sanctions and reparations.

⁹³ Id.

⁹⁴ Id., para. 56.

⁹⁵ Id., paras. 59-63.

⁹⁶ Id., para. 82.

⁹⁷ Id.

⁹⁸ Id.; See also paras. 83-103 for more detailed information on different grievance mechanisms.

⁹⁹ Id.

3.1.1 Operationalizing the Framework

The 2008 report was followed by the 2009 and 2010 reports which included more practical advice on how to operationalize the Framework.¹⁰⁰ At this point, the work of the Special Representative had received much attention and acknowledgement from the Human Rights Council, civil society and leading business enterprises.¹⁰¹ As Ruggie stated, “This marked the first time the Council or its predecessor had taken a substantive policy position on business and human rights.”¹⁰² Subsequently, even before the final report and its Guiding Principles, the influence and importance of the “Ruggie Framework” was clear and strong.

Regarding the D2P, the Special Representative noted that although states are the most suitable actor when it comes to regulating the business and human rights field, they have failed in this aspect and integrating human rights concerns in the business sector remains insufficiently addressed.¹⁰³ Clarifying this link and its importance can be considered one of the main tasks of states as regulatory acts may serve to incentivize business corporations to be mindful of human rights.¹⁰⁴ This was one of the concrete recommendations by Ruggie who stated in his conclusion that, “For Governments, the key is to drive the business and human rights agenda more deeply into policy domains that directly shape business practices.”¹⁰⁵

¹⁰⁰ Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, *Business and human rights: Towards operationalizing the “protect, respect and remedy” framework*, UN Doc. A/HRC/11/13, 2009; Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, *Business and human rights: Further steps toward the operationalization of the “protect, respect and remedy” Framework*, UN Doc. A/HRC/14/27, 2010.

¹⁰¹ Ruggie, 2009 report, *supra* note 100, paras. 1, 3-5.

¹⁰² *Id.*, para. 1.

¹⁰³ *Id.*, para. 44.

¹⁰⁴ *Id.*, see also para. 84.

¹⁰⁵ *Id.*, para. 120.

The relevancy of social expectations about corporate social responsibility¹⁰⁶ (henceforth referred to as CSR) was also brought up in the 2009 report. Ruggie noted that companies are always subjected to the scrutiny of civil society and its unwritten norms and that these “can be as important to the success of a business as legal norms.”¹⁰⁷ Today, CSR is a concept that is almost universally acknowledged by civil society, the business sector and NGOs.¹⁰⁸ Moreover, violations of human rights receive global attention and are occasionally subject to different complaint procedures.¹⁰⁹ In other words, CSR is a force to be reckoned with in the business and human rights discourse, and one that is highly relevant to the topic of the present paper as the possible benefits of CSR may yield a solution to the conflict between access to medicines and pharmaceutical patents.

Looking at the 2010 report, it provides additional tools for states and corporations that are striving to fulfill the D2P and R2R. Some innovative examples that are to be found within the report will be included in the following presentation. The problematic aspects of investment treaties and trade agreements were highlighted with the reminder that policy objectives must not hinder the application of human rights agendas.¹¹⁰ In addition, it is well known that states have financial interaction with companies, and this exchange should be used as “the State’s role as an economic actor is a key – but under-utilized – leverage point in promoting corporate human rights awareness and preventing abuses.”¹¹¹

In regard of CSR, the Special Representative clarified its complementary nature to the R2R and the benefits of applying the two together.¹¹² It was also highlighted that superficially philanthropic activities are a way for

¹⁰⁶ Within the context of the present paper, CSR is understood as any corporate act which relates to human rights concerns as well as the non-legal pressures applied by society towards businesses.

¹⁰⁷ *Id.*, para. 46; see also paras. 59-60 which clarify that CSR is not a “negative duty”.

¹⁰⁸ *Id.*, para. 47.

¹⁰⁹ *Id.*

¹¹⁰ Ruggie, 2010 report, *supra* note 100, para. 25.

¹¹¹ *Id.*, para. 32.

¹¹² *Id.*, para. 56.

companies to: “promote their brand, or to develop new business opportunities.”¹¹³ In other words, and without prejudice or negative undertone, what might seem as kindness from businesses may very well be clever ways of achieving financial profitability. It is then a matter of “knowing and showing” rather than “naming and shaming” as Ruggie put it.¹¹⁴ Moreover, due diligence assessments can also be beneficial to corporations as prevention of negative human rights impacts and protection from mismanagement claims will be the result of an adequately employed due diligence policy.¹¹⁵ Regarding legal claims, it was reiterated that although R2R is not a legal concept, it may still entail legal claims where such are made relevant through, for instance, national legislation.¹¹⁶

3.2 Final Report and the Guiding Principles

The Guiding Principles, provided in the 2011 report, are the fruit of the extensive work of the Special Representative. Thanks to investigations and wide stakeholder consultations, the final product had a positive reception and quickly gained authority within the field of business and human rights.¹¹⁷ Ruggie acknowledges that the Guiding Principles can neither solve all issues nor be implemented in the same way across the world.¹¹⁸ Nevertheless, the Principles are both practical and universally applicable when it comes to “the effective prevention of, and remedy for, business-related human rights harm.”¹¹⁹ The Principles will here be presented briefly, with focus on those parts that are relevant to the topic of the present paper.

¹¹³ Id., para. 63.

¹¹⁴ Id., para. 80.

¹¹⁵ Id., para. 86.

¹¹⁶ Id., paras 66-67.

¹¹⁷ Ruggie, Final Report, *supra* note 23, paras. 7-8.

¹¹⁸ Id., para. 15.

¹¹⁹ Id., pars. 15-16.

Ruggie notes that states are obligated to respect, protect and fulfill human rights and that they can therefore be held responsible for acts of private actors when these acts can be attributed to the state or go unpunished and no redress for victims is ensured.¹²⁰ Another innovative principle is that states must make clear the expectation that all companies within their jurisdiction must respect human rights.¹²¹ This most likely relates to the creation of the previously mentioned human rights friendly corporate culture. States are, in addition, encouraged to create legislation and policies, within the field of business and human rights, while promoting communication, utilizing their own influence in the business sector and ensuring that they meet their own human rights obligations originating from international law.¹²²

Corporations should respect human rights which means that “they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved.”¹²³ Concerning which human rights to include in the R2R, guidance is provided in paragraph 12 which includes the bill of human rights and the fundamental rights of the International Labour Organization’s Declaration on Fundamental Principles and Rights at Work.¹²⁴ Subsequently the right to health is included both as it is found in the ICESCR and in the UDHR which reflects the right to health in customary law. In addition, failure to take human rights law into account or to address adverse human rights impacts may result in unlawful behavior in relation to laws regulating corporate behaviour and management duties.¹²⁵ The Principles apply to all companies, which are expected to avoid

¹²⁰ Id., Annex, para. 1, commentary.

¹²¹ Id., Annex, para. 2.

¹²² Id., Annex, paras. 3-6, 8-10.

¹²³ Id., Annex, para. 11.

¹²⁴ Id., Annex, para. 12; see also UDHR, *supra* note 26; ICESCR, *supra* note 11; UN General Assembly, *International Covenant on Civil and Political Rights*, 16 December 1966, United Nations, Treaty Series, vol. 999, p. 171; International Labour Organization (ILO), *ILO Declaration on Fundamental Principles and Rights at Work*, June 1988.

¹²⁵ Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, Addendum, *Human rights and corporate law: trends and observations from a crossnational study conducted by the Special Representative*, UN Doc. A/HRC/17/31/Add.2, 2011, paras. 205, 207.

violating, or contribute to violations of, human rights, seek to mitigate the negative effects of human rights impacts related to their operations and establish internal policies such as those regarding due diligence processes.¹²⁶ In order for such methods to work, businesses should employ means such as tracking, communication and effective integration.¹²⁷

Access to remedies is also regulated but will not be discussed further within the present paper (see sections 3.1-3.1.1). However, the Ruggie Framework and the Guiding Principles need to be assessed in the context of access to medicines in order to clarify in which way the business and human rights discourse may contribute to solving the conflict between access to medicines and pharmaceutical patents. This will be done without going into the specific solutions and what they entail (see sections 4 and 5).

3.3 Significance of the D2P and R2R in Relation to Access to Medicines

As shown above both businesses, including pharmaceutical companies, and states have naturally come to have responsibilities or duties regarding human rights. The question raised in this part of the present paper is how this may affect the field of pharmaceutical patents in relation to the right to health and access to medicines and whether a solution can be born from the fusion of these two discourses. Which methods or approaches are available or suitable with consideration to the business and human rights discourse as well as the work of the Special Representative? The range of solutions will vary depending on whether the actor in question is a state or a company.

The obligations of states are clear but problematic. States are not to enter into conflicting agreements and must always consider their human rights obligations when initiating processes that could hinder their ability to fulfill

¹²⁶ Ruggie, Final Report, supra note 23, Annex, paras. 13-18.

¹²⁷ Id., Annex, paras. 19-21.

the rights in question. Although seemingly simple, this is no easy task as most states are bound by TRIPS (through their WTO membership) which, as discussed above, constitutes an obstacle to the fulfillment of the right to health and access to medicines. What states must do in consideration of the D2P is to ensure that TRIPS is not applied in conflict with their obligation to protect the right to health. Clearly, the same applies for any other agreement or treaty. Taking a stand in this manner is perhaps best done through the internal processes of the WTO itself, but can also be done independently as a response to lobbying or pressure from pharmaceutical companies or other member states. Another approach would be to stimulate a corporate culture with greater tolerance for infringements of IP rights and understanding as well as awareness of human rights and their significance to the business sector. Creating such a culture would be the task of the state, while taking specific action (or avoiding taking action) would fall under the responsibilities of pharmaceutical companies. However, top managers, industry associations and the business education sector could clearly contribute to the development of a better corporate culture.

The Special Rapporteur on the right to health has issued recommendations, for pharmaceutical companies, partially based on the work of John Ruggie up until 2008.¹²⁸ Initially, consultation processes were initiated and discussions were held with multiple stakeholders such as pharmaceutical companies.¹²⁹ The Special Rapporteur quickly noted that although there was a consensus on the duties of states, “pharmaceutical companies’ human rights responsibilities in relation to access to medicines were not clear.”¹³⁰ In order to address this lack of clarity, a collaborative approach including both human rights experts and pharmaceutical company representatives was initiated.¹³¹ However, with only two pharmaceutical companies willing to contribute (Novartis and NovoNordisk) the collaboration ended

¹²⁸ Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, UN Doc. A/63/263, 2008, para. 25.

¹²⁹ *Id.*

¹³⁰ *Id.*, para. 26.

¹³¹ *Id.*, paras. 27-31.

prematurely.¹³² The Special Representative, nevertheless, pursued the objective of clarifying company responsibilities, and did so by constructing draft guidelines and requesting comments on the content of this document.¹³³ The suggestions in the final product included the full acceptance of the use of TRIPS flexibilities, compulsory licenses, provisions of the Doha Declaration and the issuing of voluntary licenses.¹³⁴ Note that this clearly shows the influence of pharmaceutical companies as they are asked to show tolerance and take a stand in the same way as sovereign states (see previous paragraph).

However, the aforementioned consultation with business stakeholders failed and only one corporation was included in the work of the Special Rapporteur.¹³⁵ Thus, the guidelines were not well received which was most likely due to the lack of involvement of the pharmaceutical industry.¹³⁶ Subsequently, there are no authoritative recommendations on the application of R2R to the pharmaceutical industry. Besides the aforementioned options, however, pharmaceutical companies can, and arguably should, avoid enforcing their patent rights when this will harm access to medicines and they should contribute to research and development of generic medicines, or drugs used for treating poverty-related diseases, when possible.¹³⁷ This would be a part of the desirable “corporate culture” mentioned above.

Fulfilling the R2R human rights can be beneficial from a financial point of view if one includes the possible gains from the CSR discourse. Leisinger stated that, “Sustained earnings can only be realized if and when a company uses its resources in a socially responsible, environmentally sustainable and

¹³² Id., para. 32.

¹³³ Id., para. 37.

¹³⁴ Id., Annex, paras. 26-30.

¹³⁵ Id., paras. 33, 38.

¹³⁶ Austin, Graeme W. & Helfer, Laurence R., (2011), *Human rights and intellectual property: mapping the global interface*. Cambridge: Cambridge University Press, pp. 60-61.

¹³⁷ Special Rapporteur, 2008 report, supra note 128, paras. 29-32.

politically acceptable way.”¹³⁸ However, not many available solutions can be said to make a business case for promoting access to medicines. For instance, although charity and donations are greatly appreciated, one will find it difficult to justify them financially. These approaches are classified by Leisinger as belonging to the “can do” dimension, while there are actions that a company ought to or must take in order to be considered as responsible.¹³⁹ Philanthropic activities are, in other words, not included in the R2R concept and a company is not expected to donate medicines or contribute without remuneration to fulfill the R2R and the due diligence criteria.

3.4 Chapter Conclusion

States and companies have duties or responsibilities in relation to international human rights law, in which the right to health and access to medicines is included. While states primarily must ensure that their actions are in conformity with treaty obligations, the task that stands before the business sector is much more vague but also flexible. In addition, the influence of CSR adds yet more variables to the mix as both deterrence and motivation for companies to act within the human rights field is present therein. This aspect is highly relevant to the topic at hand as CSR can not only be a whip, causing businesses to act out of fear, but also a carrot which motivates positive action as there exist possible gains to be found within the discourse. Linking these benefits of CSR to a solution which meets the requirements of the R2R will be the purpose of the following chapter. The aim is to find a solution which can be beneficial to all parties involved and that is practically applicable.

¹³⁸ Leisinger, Klaus M., *Corporate Responsibilities for Access to Medicines*, Journal of Business Ethics, Vol. 85, 2009, p. 5.

¹³⁹ Leisinger, Klaus M., *THE CORPORATE SOCIAL RESPONSIBILITY OF THE PHARMACEUTICAL INDUSTRY: IDEALISM WITHOUT ILLUSION AND REALISM WITHOUT RESIGNATION*, in Business Ethics Quarterly Vol. 15, No. 4, 2005, pp. 583-584.

4 Regionally Restricted Licences

4.1 Definition and Concept

This chapter outlines a proposal for solving the conflict between access to medicines and pharmaceutical patents. The aim is to make use of the due diligence criteria within the R2R concept, which together with the CSR discourse can offer guidance on approaches that can be beneficial to all stakeholders, including pharmaceutical companies. The final product is meant to satisfy the R2R, improve access to medicines and incentivize pharmaceutical companies. If this can be successfully done, then important obstacles will have been overcome in the effort to efficiently provide better access to medicines. In addition, the pharmaceutical industry may take great strides towards fulfilling both the R2R and the demands of society for greater awareness and contribution to the human rights sphere.

The proposal refers to so called Regionally Restricted Licences, abbreviated RRLs, and the name describes well what the solution entails: A license purchased through a one-time cost, used for replicating patented versions of essential medicines within a specific geographical context. The pharmaceutical companies, who own the relevant patent rights, would award licenses to companies, states or regions that do not have the financial means of purchasing larger volumes of the expensive patent-protected drugs. With this license, the recipient would create copies which could then be distributed within that state or region. In other words, the thought behind RRLs is to promote domestic production which avoids the problems of international transport and prevents distribution in other regions that could violate the patent-rights of the pharmaceutical industry (see more under section 4.3). If domestic production is not an option, then a neighbouring country with an adequate pharmaceutical industry will become the distributor.

It is important to differentiate this solution from other approaches. RRLs are not voluntary licenses as only a single financial transaction takes place when the recipient purchases the license in question (see more in section 5.2 on voluntary licenses and fees). Moreover, engaging in RRLs can arguably make business sense for pharmaceutical companies as there are other transactions and possible benefits included in the concept (voluntary licenses without fees make little business sense). RRLs are not the same as compulsory licenses as there is no outside force demanding a license without the right-holders authorization. Instead, the pharmaceutical companies will themselves award RRLs, usually when a state or private actor in the developing world requests the issuing of such a license. One might say that RRLs constitute a business approach to ensuring access to medicines while satisfying the requirements of the R2R and societal demands linked to CSR.

4.2 Application of RRLs

In this part of the present paper, the practical application of the suggested solution will be presented. How to implement RRLs, what is necessary before attempting to apply the solution, incentives for the pharmaceutical industry to engage in the approach and benefits as well as obstacles linked to the concept. The aim is to show the practical value of the solution as it can easily be applied with considerable gains for both human rights advocates and pharmaceutical companies.

4.2.1 Prerequisites

Two questions will arise at this point. Firstly, what will be necessary in order for RRLs to be a viable option? Clearly, several aspects of RRLs necessitate technological advancements, established healthcare infrastructure and other prerequisites before being possible to implement.

Secondly, why would a pharmaceutical company willingly “give up” (poor choice of words but a formulation that would most likely be used by those opposing the solution) their patent rights? It is questionable whether RRLs may lead to the pharmaceutical companies losing potential buyers while creating competing producers. The latter question will be discussed in section 4.2.3 while the prerequisites of RRLs will be discussed in the following.

The most essential requirement is an established pharmaceutical industry, or the possibility of setting one up in the near future. Fortunately, this prerequisite applies to each region as a whole, and therefore only one state in that geographical context needs to have an available pharmaceutical industry. For example, if Brazil would produce a copy of an essential medicine, through the use of a RRL, the drug could be exported to the rest of South America by the crossing of a single border (with the exception of Chile and Ecuador). Subsequently, as long as there is one pharmaceutical industry present in South America, one would be able to implement RRLs in that region.

Another prerequisite is an adequate healthcare infrastructure, ensuring access to healthcare and medicines through the availability of clinics and physicians even in remote areas. This may be the most difficult requirement for many states, but learning from the success of approaches such as the Ghana Initiative for Community-based Health Planning and Services (henceforth referred to as CHPS) and the Ghana Essential Medicines Initiative (henceforth referred to as the GEMI) will enable most states to set up an adequate healthcare infrastructure.¹⁴⁰

¹⁴⁰ See more at: http://ghanachps.org/?page_id=7; Ghana Essential Medicines Initiative, *Lessons Learned from the Ghana Essential Medicines Initiative*, Final Report, Winter 2010; Available at: http://www.popcouncil.org/pdfs/GEMI_FinalReport_Winter2010.pdf.

4.2.2 The Ghana Case

In order to better exemplify how RRLs can be applied, Ghana will be used as an example. Africa is covered by the Banjul Charter on Human and Peoples' Rights which contains a right to health provision stating that:

- “1. Every individual shall have the right to enjoy the best attainable state of physical and mental health.
2. States parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.”¹⁴¹

This right to health in the Banjul Charter, similar to the one in ICESCR art. 12, includes access to medicines as an essential component.¹⁴² Ghana has strived towards ensuring the right to health through the use of different initiatives such as the CHPS and GEMI. The aim of CHPS is to improve healthcare infrastructure as “geographic access is a major barrier to health care”¹⁴³ which is shown by the differences in health between urban and rural areas of Ghana.¹⁴⁴ This issue has been addressed through relocation of primary health care to community locations, using local resources to achieve this.¹⁴⁵ In sum, CHPS entails the placement of nurses and the establishment of clinics in rural areas which, together with visits and consultation, has greatly improved the infrastructure of the healthcare system.¹⁴⁶ CHPS has had great success in the Nkwanta region and the team that worked within the region managed to demonstrate that “this community-based service model could be replicated with limited incremental (...) funding”¹⁴⁷. In

¹⁴¹ Organization of African Unity, *African [Banjul] Charter on Human and Peoples' Rights* (ACHPR), OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force 21 October 1986.

¹⁴² Niada, Laura, *supra* note 12, p. 706.

¹⁴³ THE COMMUNITY-BASED HEALTH PLANNING AND SERVICES (CHPS) INITIATIVE, *THE CONCEPTS AND PLANS FOR IMPLEMENTATION*, December 10, 2002, p. 3; available at <http://www.ghanachps.org/wp-content/uploads/2008/05/concepts.pdf>.

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*, p. 6.

¹⁴⁶ GEMI Final Report, *supra* note 140, pp. 1-3.

¹⁴⁷ CHPS, 2002, *supra* note 143, p. 7.

addition, a consensus on the possibility of “replicating this model on a larger scale”¹⁴⁸ emerged soon thereafter. However, there is still a severe lack of access to medicines, mainly because the necessary drugs are not available.¹⁴⁹ Donations are prevalent, but international transportation is not a viable option in this context as the medicines are often lost, do not arrive or arrive at the wrong location.¹⁵⁰

The GEMI was established in 2007 to address this issue and as a response to the reality “that remote rural communities only have access to a small percentage of the drugs on WHO’s Essential Medicines List.”¹⁵¹ A survey, outlining the efficiency of the CHPS, indicated “that despite the efficiency of CHPS in delivering community-based care, the average rural CHPS clinic in Ghana stocks only 30 drugs, with expiration dates reducing the number of viable drugs considerably.”¹⁵² In other words, healthcare was available but not the essential medicines needed to treat the patients.

Ghana’s domestic pharmaceutical industry is not being used as foreign medicines are being purchased instead.¹⁵³ In order for this to change, the domestic industry needs strengthening.¹⁵⁴ This is especially disturbing as the foreign products are often of bad quality (as the patent-protected original drugs are too expensive to purchase in sufficient amounts) which leads to distribution being without beneficial effects on health.¹⁵⁵ In other African regions, there have even been cases of protests which have resulted from the

¹⁴⁸ Id.

¹⁴⁹ GEMI Final Report, supra note 140, p. 1.

¹⁵⁰ Id., p. 3.

¹⁵¹ Id., p. 1.

¹⁵² Id.

¹⁵³ Ghanaweb, *Moves by Ghana to improve access to medicines*, General News of Thursday, 12 November 2009; Available at: <http://www.ghanaweb.com/GhanaHomePage/NewsArchive/artikel.php?ID=171793&comment=5262766#top>

¹⁵⁴ Id.

¹⁵⁵ GEMI Final Report, supra note 140, p. 3; See also Gauld R, Norris P, Patel A and Rades T., 2010, “*This body does not want free medicines*”: *South African consumer perceptions of drug quality*; Available at: http://heapol.oxfordjournals.org.ludwig.lub.lu.se/content/26/suppl_2/ii92.full.pdf+html.

distribution of low quality medicines.¹⁵⁶ In sum, there exists a healthcare infrastructure and a national pharmaceutical industry, but still the lack of quality pharmaceuticals is impairing the ability to ensure the right to health.

In this context, the application of RRLs could help solving the problem. As shown above, Ghana has some purchasing ability but not enough to buy considerable amounts of the expensive patent-protected pharmaceuticals. Using the available resources, Ghana would purchase a RRL from a pharmaceutical company for the drug that will be produced (this could easily be done in a similar manner for a package of several medicines). With this license, the domestic pharmaceutical industry can be put to use and can produce the medicines. Thereafter, the already established infrastructure will allow for effective distribution. Keeping production within the country, together with the involvement of initiatives such as the GEMI which have support from the international community and the government, will keep costs at a minimum.¹⁵⁷ Applying the allowed flexibilities within TRIPS, would then allow for cooperation with other developing states which could then assist and benefit from the RRL without legal conflict.¹⁵⁸ Note however that the license itself could include these states in order to fully avoid any legal issues related to TRIPS and the WTO.

4.2.3 Benefits, Incentives and Obstacles

This section will explain the benefits of applying a business-oriented solution such as RRLs to the conflict between access to medicines and pharmaceutical companies. In addition, the ways of incentivizing the patent-holding pharmaceutical companies will be presented in order to clarify why RRLs can be a desirable approach even from a corporate point of view. Ultimately, the presentation will entail a discussion on how to solve obstacles such as transfer or lack of technology, inadequate healthcare

¹⁵⁶ Id.

¹⁵⁷ GEMI Final Report, *supra* note 140, pp. 3-4.

¹⁵⁸ Bently, Sherman, *supra* note 18, p. 353.

infrastructure and funding. The aim is that the benefits and lack of obstacles of RRLs (or ways to overcome them) will be clear and convincing at the end of this chapter. This will show why the solution is to be preferred in comparison to other approaches (see chapter 5).

The benefits of national implementation mainly include the avoidance of complications that may arise from international transport (these were mentioned in section 4.2.2). In addition, legal complications and financial pressure or lobbying related to TRIPS will be averted as the solution is neither legal in character nor in conflict with the interests of pharmaceutical companies and their host states. For the state itself, the benefits are self-explanatory as domestic access to quality medicines at low costs will surely benefit the entire country. Moreover, the improved health of the population together with the developed pharmaceutical industry will facilitate long-term economic growth and financial well-being of the state.

Benefits and incentives will be discussed together as these are strongly linked when speaking of what motivates the owners of the patent rights to involve themselves in the solution. Considering that the target state is not a potential buyer, selling a license at a one-time cost will yield a small profit, which is preferable to no profit at all. There are, however, greater financial gains to be found through creative application of the RRLs. The target state can trade its facilities for the RRL. This would enrich the capital worth of the pharmaceutical company while broadening its establishment to regions that, in the future, may become buyers with considerable purchasing power. In other words, the company would gain facilities and reasonably priced staff, which would allow for better access to markets on the rise. When sufficient¹⁵⁹ economic growth and enhanced standard of living (or purchasing power) has appeared and there is no need for discounted pharmaceuticals, the company will get intimate access to a wide range of buyers that are already in favour of the company due to its previous aid.

¹⁵⁹ It would require an additional master thesis to assess what "sufficient" means in this context. The point made is that many developing markets will, eventually, have the ability to purchase the patent-protected original medicines.

The CSR discourse generally states that good managers and directors act responsibly by showing awareness of social factors such as human rights, environmental rights and workers' rights.¹⁶⁰ By incorporating RRLs into its operations, a pharmaceutical company could show such awareness, which would attract both qualitative workforce and investors that are themselves considerate of these rights.¹⁶¹ In other words, applying the solution would be a way of demonstrating good and responsible management and, subsequently, such a company would be desirable from an investor's point of view.¹⁶² For the corporation itself, such an image and related investments will result in long-term profitability. All the aforementioned benefits of CSR as well as those that stem from RRLs would incentivize the pharmaceutical industry to involve itself with the solution. This as both short-term profits (one-time payment and transaction of industrial resources) and long-term profitability (increase of investors due to human rights friendly behaviour, future profitability when purchasing power in nearby regions manifests and low costs for production and transport when supplying these regions with medicines) will be made possible. Through the involvement of pharmaceutical companies due to these incentives, many of the common obstacles will become surmountable.

One issue that is always present in the context of economic, social and cultural rights is the need for funding. As previously mentioned, initiatives such as the GEMI, naturally attract the cooperation of the international community.¹⁶³ However, not much funding will be necessary as purchasing the RRL will be a one-time cost. Thus, funding will not become an obstacle of significance, as the solution is business-oriented and the recipient's contribution amounts to much more than the actual payment.

¹⁶⁰ Leisinger, 2009, supra note 138.

¹⁶¹ Id., p. 6; See also Leisinger, 2005, supra note 139, p. 581 which indicates that successful, major companies are involved in CSR work.

¹⁶² Henderson, Todd M., Malani, Anup, *CORPORATE PHILANTHROPY AND THE MARKET FOR ALTRUISM*, Columbia Law Review, April 2010, p. 10.

¹⁶³ GEMI Final Report, supra note 140, pp. 3-4.

Some technical advancements will be needed for the local pharmaceutical industry to be able to produce complex pharmaceuticals. This would perhaps be the most difficult obstacle to overcome if left to the recipient (target state and its domestic pharmaceutical companies) to deal with on its own. However, the aforementioned incentives of the patent-holding pharmaceutical company, together with the possibility of including the facilities in the transaction, will lead to the natural solution that the pharmaceutical company provides adequate technological transfer. This due to the simple fact that the facilities will become part of the corporation in question, which will ensure that the equipment therein is up to date.

When promoting human rights that are connected to business opportunities, corruption often becomes a problem. However, when implementing RRLs it will become difficult for even a corrupt government to take advantage of the situation. The production will be overseen, or at least influenced by, the patent-holding pharmaceutical company. Moreover, this company has CSR gains related to reputation and goodwill at stake. Inevitably, corruption would render all attempts to benefit from responsible behaviour useless and the corporation would therefore revoke the license under such circumstances. In addition, the contribution of initiatives such as CHPS and GEMI in the process will lead to the involvement of the international community. It is quite unlikely that even a corrupt government will be able to benefit unjustly under these conditions, as it would be demotivated from taking corrupt action due to the consequences of such behaviour.

When medicines are available, there must be a way to distribute these within the state or region affected by the RRL. For this to be possible, an adequate healthcare infrastructure must be present. The difficulty of overcoming this obstacle will solely depend on the will of the recipient state to spend time and resources on the matter. As previously mentioned, even less developed states can attain this prerequisite by applying methods that have proven to be successful for other countries. Once again, many lessons can be learned from the work in Ghana and its CHPS initiative. Already in 2010, the CHPS initiative had: “attracted a large number of international partners interested

in the CHPS model as a sustainable primary health care intervention.”¹⁶⁴ These included senior health officials and policy makers from Northern Nigeria, Ethiopia, Tanzania, Sierra Leone, and Burkina Faso who wished to extend the “lessons learned” from Ghana to their own countries.¹⁶⁵ A continuation of this development would render obstacles related to healthcare infrastructure insignificant.

4.3 Chapter Conclusion

RRLs constitute an original solution, created with the aim of satisfying the needs of all relevant stakeholders while avoiding obstacles such as legal and political pressure. The approach is applicable in practically any context as long as there is a state with a pharmaceutical industry, and an adequate healthcare infrastructure, present within that region. Obstacles are surmountable through the joint effort of initiatives such as GEMI, the naturally involved international community and the pharmaceutical company that is rewarding the license. This cooperation enables learning from best practices and will result in substantial benefits for all parties involved.

What previous solutions have failed to do is sufficiently incentivize corporations to engage in human rights. Within the concept of RRLs, there are several benefits which will motivate pharmaceutical companies to engage in the solution. This is crucial, as the support of the financial forces of the developed world is necessary in order to be able to deal with the problem in an adequate manner. Without it, any solution (see for example compulsory licensing within the TRIPS agreement) will be prevented from reaching its full potential, as economic and political pressure will amount to an insurmountable obstacle of successful implementation.

¹⁶⁴ Id., p. 3.

¹⁶⁵ Id.

5 Alternative Solutions

5.1 Introduction

Although the aim of this thesis is to introduce a new, original solution to the conflict between access to medicines and pharmaceutical patents, and promoting this solution, other approaches remain present and influential. Therefore, these will be discussed in order to assess their benefits and downsides. Moreover, a comparison to RRLs will be present all throughout the chapter with the purpose of reiterating the practical value of the solution and the effective avoidance of problems and obstacles that limit the usefulness of other options. The solutions included in this chapter are categorized as philanthropic activities, contributions to research, approaches available through TRIPS and the possibility of abstaining from enforcing one's patent rights.

5.2 Philanthropic Activities

Donations, cooperation with foundations¹⁶⁶, and voluntary license agreements can be, among other things, included within the scope of philanthropic activities. What these methods have in common is that they entail a one-sided transfer of information or resources from the pharmaceutical company to a recipient. Already at this point, one might ask why a company would engage in such activities as they are, in nature, philanthropic.¹⁶⁷ Answers vary and include explanations such as unwillingness to return money to shareholders, the realization of charity as a business opportunity and that improving others' lives makes one feel

¹⁶⁶ See for instance the Clinton foundation: <http://www.clintonfoundation.org/what-we-do/clinton-health-access-initiative>; and the Bill & Melinda Gates foundation: <http://www.gatesfoundation.org/Pages/home.aspx>. Both are active within the field of access to medicines and cooperate with businesses, NGOs and governments.

¹⁶⁷ Henderson, Malani, supra note 162, p. 1.

good.¹⁶⁸ In the current context, it must be noted yet again that although certain research contributions and other forms of philanthropic cooperation may play a part within the CSR discourse, such actions are not included in the R2R. Thus, one cannot consider donations as something that a pharmaceutical company is obligated to do. Responsible and good management cannot rely on philanthropic activities as the main way of facilitating access to medicines; at the extreme, large scale charity might even be prohibited considering the legal managerial duty of ensuring profitability and pursuing the corporation's interests. Worthy of note is that other solutions, such as RRLs, can be included within the R2R concept, especially when establishing a link to due diligence.

Nevertheless, trillions of dollars are spent on donations and it is evident that there is what Henderson and Malani calls a "Market for Altruism."¹⁶⁹ So what are companies doing within the context of philanthropic activities? Donations are frequent, both through programmes and as a response to request from individual governments and NGOs.¹⁷⁰ Similar to RRLs, successful donations require an established healthcare infrastructure, and pharmaceutical companies can be incentivized to contribute to this development with the prospect of improved access to future markets.¹⁷¹ The most successful companies, according to the Access to Medicine Index, all operate single-drug donation programmes (widely considered as the best from of donating medicines, targeting specific diseases or geographical areas) and contribute to the healthcare infrastructure in their target areas.¹⁷² Companies at the forefront within this field include Merck & Co. Inc., GlaxoSmithKline PLC and Pfizer Inc.¹⁷³

Voluntary licenses are perhaps not completely suited under the heading of philanthropic activities as there are opportunities for the patent-holding

¹⁶⁸ Id.

¹⁶⁹ Id.

¹⁷⁰ Access to Medicine Index, *supra* note 21, p. 161.

¹⁷¹ Id., p. 162.

¹⁷² Id., pp. 161-163.

¹⁷³ Id.

company to charge fees for rewarding the license.¹⁷⁴ In this sense, this is the solution most similar to RRLs. The separation from compulsory licensing and TRIPS is, however, necessary for structural purposes of the present paper. The benefits are considerable as “voluntary licensing can help the originator companies focus on their competitive advantage of innovative research while benefiting from the low cost and increasingly high quality production capacity and distribution channels of the generics companies.”¹⁷⁵ However, generic companies are usually not located within the countries where the pharmaceuticals are needed the most. Moreover, the lack of inclusion of governments and the international community limits the resources needed to further affect the situation and aspects such as healthcare infrastructure. It can also be claimed that applying a voluntary license, which is fee-based, would result in nearly as demanding financial requirements from the recipient as if the original drug was purchased. On the other hand, without the fee there is little financial incentive for the patent-holding company to engage in voluntary licensing.

5.3 Contributions to Research

A viable option for pharmaceutical companies when discharging CSR, is the cooperation with generic companies, NGOs and other actors that may influence access to medicines. Contributions to research mainly aim at developing the capability of dealing with neglected diseases. Companies can engage in research and development of neglected and poverty-related diseases and can refrain from applying IP protection while choosing to share their information with, for instance, generic companies.¹⁷⁶ This can be achieved by allowing third party access to what is called “compound libraries” and through general company disclosure.¹⁷⁷

¹⁷⁴ Id., p. 140.

¹⁷⁵ Id.

¹⁷⁶ Id., pp. 108-110.

¹⁷⁷ Id., pp. 110-111.

The problem with this approach is that “As there is a lack of developed world markets for these products, there is currently a weak business case for R&D in this area.”¹⁷⁸ In other words, the financial incentives present in solutions such as RRLs are not prevalent when it comes to research and development of neglected diseases and information disclosure. While contribution to research can be of great aid when battling neglected and poverty-related diseases, the solution cannot be used when attempting to address the issue of lack of access to medicines in a systematic and sustainable manner. The ability to satisfy such requirements is the strength that makes RRLs worthy of note.

5.4 TRIPS and Compulsory Licencing

The best known approach to access to medicines is included within the WTO and its TRIPS agreement, namely compulsory licenses. Article 31 of TRIPS regulates use of a patent without the right-holders authorization.¹⁷⁹ The provision states that “such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions” unless “a national emergency or other circumstances of extreme urgency” is at hand.¹⁸⁰ The remaining parts of article 31 includes additional constraints placed on the user of the patent such as limiting distribution to the domestic market, demanding remuneration paid to the right-holder and subjecting the use of the patent to judicial review.¹⁸¹

As compulsory licenses have been strongly opposed by the WTO, improvement from a human rights perspective was needed.¹⁸² This came in the form of the Doha Declaration, a response to social pressure that

¹⁷⁸ Id., p. 108.

¹⁷⁹ Trips, supra note 4, art. 31.

¹⁸⁰ Id., art. 31 (b).

¹⁸¹ Id., art. 31 (f)-(j).

¹⁸² Austin, Helfer, supra note 136, p. 41.

highlighted flexibilities within TRIPS as well as how these can be used in order to promote the right to health.¹⁸³ Paragraph 4 of the Doha Declaration states that the “TRIPS Agreement does not and should not prevent Members from taking measures to protect public health.”¹⁸⁴ Moreover, “the 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.”¹⁸⁵ This leaves the reader rather optimistic together with paragraph 5 (b) which states that “Each Member has the right to grant compulsory licences”¹⁸⁶ and paragraph 5 (c) which provides that “Each Member has the right to determine what constitutes a national emergency”¹⁸⁷. Thus far, compulsory licenses would seem to offer a rather satisfactory solution to the lack of access to medicines as promotion of public health, the possibility of using patents during emergencies and the right to determine within one’s own state whether there is such an emergency at hand.

Unfortunately, the main concern within the WTO would seem to be that compulsory licenses will affect prices in high-income markets.¹⁸⁸ Arguably, the concern that TRIPS might limit access to medicines needs to be voiced in this context. The aforementioned attitude in the WTO has resulted in the solution barely being used at all.¹⁸⁹ Moreover, although paragraph 6 acknowledges the issue of insufficient technological advancements, the solution provided therein is only superficial and any substantive results will remain elusive.¹⁹⁰

¹⁸³ Id., p. 42.

¹⁸⁴ Doha Declaration, supra note 8, para. 4.

¹⁸⁵ Id.

¹⁸⁶ Id., para. 5.

¹⁸⁷ Id.

¹⁸⁸ Outterson, supra note 5, p.318.

¹⁸⁹ Srinivas, Krishna Ravi, *TRIPS, Access to Medicines and Developing Nations: Towards an Open Source Solution*, November 2006, p. 3; Available at SSRN: <http://ssrn.com/abstract=952435>.

¹⁹⁰ Id., pp. 3-4.

When developing countries cannot use a solution due to insufficient manufacturing capabilities, and no way to deal with this issue is presented, one will find it difficult to claim that the approach is successful. Even when application of compulsory licenses is practically possible, political and economic pressure will inhibit the success of the solution. In addition, compulsory licenses are arguably in conflict with the TRIPS Plus agreements (generally bilateral treatments which tend to strengthen the patent protection within TRIPS) from a legal point of view.¹⁹¹ Despite the considerable efforts of finding a solution to issues concerning access to medicines through the application of TRIPS, neither the flexibilities nor the compulsory licenses within the agreement can adequately deal with the situation.¹⁹² In sum, there is much controversy and resistance prevalent in the context of compulsory licenses and the Doha Declaration has had little influence beyond constituting a mere political statement regarding the relation between TRIPS and the right to health.¹⁹³

Compulsory licenses are, practically, not very different from RRLs. The differences lie in the approach and thought behind the solutions as well as the lobbying included within the WTO umbrella. RRLs engage pharmaceutical companies as potential partners that can benefit from the solution. Due to its nature of being a business-oriented approach, political pressure, legal obstacles and lobbying will hardly prevent implementation of RRLs. Moreover, although it is possible for the patent-holding pharmaceutical to receive remuneration through compulsory licensing, there are fewer financial incentives prevalent than within the RRL concept. In other words, compulsory licenses have potential to aid in solving the conflict between pharmaceutical patents and access to medicines, but have too much controversy, legal disputes and uncertainties surrounding them for successful application to be possible.

¹⁹¹ Austin, Helfer, *supra* note 136, pp. 124-125.

¹⁹² Srinivas, *supra* note 189, p. 3.

¹⁹³ Krikorian & Kapczynski, *supra* note 24, pp. 152-153.

5.5 Not Enforcing Patent Rights

Although an unconventional approach, the option of not enforcing one's patent rights is, nevertheless, valid and of importance to the topic at hand. As mentioned in the preface of the present paper, Novartis is currently pursuing a lawsuit in India with the aim of strengthening their patent protection with the possible outcome that the source for 90 % of the AIDS medicines designated for African children will be suspended indefinitely.¹⁹⁴ In fact, if Novartis wins the case, large parts of the entire developing world will be negatively affected.¹⁹⁵ As Leena Menghaney from Doctors Without Borders stated: "India is literally the lifeline of patients in the developing world, especially in the poorest parts of Africa"¹⁹⁶. And she has reason to worry as approximately 80 % of the pharmaceuticals used by Doctors Without Borders (when treating HIV) comes from Indian generic companies.¹⁹⁷ This is the most obvious way in which pharmaceutical companies can enforce their patent protection, and the tremendous effects this might have need no explanation.

One can question whether tolerating interference with one's financial interests, motivated by human rights concerns, is not at the very core of an obligation to respect human rights. The concept of the R2R would surely include not instigating legal conflict when this prevents the fulfillment of fundamental human rights, as a simple yet effective way to show proper respect and awareness. However, the situation is often far more complex and it may often be difficult to assess where to draw the line for patent right enforcement.

¹⁹⁴ The Bureau of Investigative Journalism, *supra* note 1.

¹⁹⁵ Pharmatimes, *Novartis again urged to drop India patent lawsuit* by Grogan, Kevin, February 24 2012, accessed at 2012-05-14; available at: http://www.pharmatimes.com/article/12-02-24/Novartis_again_urged_to_drop_India_patent_lawsuit.aspx.

¹⁹⁶ The Bureau of Investigative Journalism, *supra* note 1.

¹⁹⁷ Pharmatimes, *supra* note 195.

In the Access to Medicine Index 2010 report, 13 of 20 originator companies had policies regarding enforcement of their patents in the least developed countries (henceforth referred to as LDCs).¹⁹⁸ However, the level of commitment varies and, as previously mentioned, production of these vital medicines is often located outside the poor countries that need them.¹⁹⁹ Subsequently, litigations can proceed while maintaining a human rights friendly policy and not directly enforcing one's patent rights in the LDCs. Nevertheless, the suppliers will be affected and the indirect result of such litigations will be the lack of access to medicines in the poorest parts of the world. As stated in the Access to Medicine Index 2010 Report: "Regardless of their result, such litigations and controversies compromise the regulatory environment for the companies and can make stakeholder engagement and collaboration more difficult."²⁰⁰

Looking at similarities and differences between not enforcing patent rights and applying RRLs, one will find that although tolerating infringements will be valuable in preventing access to medicines from declining, it will rarely provide financial incentives for the pharmaceutical companies to engage actively in the solution and aid with healthcare infrastructure or technology transfer. Moreover, not harming the current state of access to medicines is hardly the same as improving it, and the healthcare infrastructure and access to medicines needs to take great strides forward before sufficient fulfillment of the right to health can be achieved. This is partially the reason for applying RRLs, as the solution includes all the benefits for the recipient while ensuring that pharmaceutical companies are incentivized to participate and contribute.

¹⁹⁸ Access to Medicine Index, *supra* note 21, p. 145.

¹⁹⁹ *Id.*

²⁰⁰ *Id.*, p. 146.

5.6 Chapter Conclusion

For a solution to be completely suitable to the conflict between access to medicines and pharmaceutical patents, in the context of business and human rights, it must satisfy requirements included within the R2R and due diligence as well as take into account the societal demands linked to CSR. In addition, financial profitability and other incentives must be included as to ensure the active involvement of patent-holding pharmaceutical companies. Finally, the solution must yield sufficient results and improvement in the fulfillment of access to essential medicines within the target state or region. Although all solutions presented within this chapter have their respective benefits and uses, none of them succeed in addressing all these aspects. This is what differentiates RRLs from these approaches.

While prevention of patent rights enforcement allows human rights work to progress, it does not improve the situation systematically. Compulsory licenses could be used for progress but lack the support of the necessary actors. Finally, philanthropic activities surely alleviate some burdens included in the fulfillment of human rights, but make little business sense due to lack of incentives. The ability to improve access to medicines while providing considerable incentives for corporations, will allow RRLs to gain the support of both pharmaceutical companies and domestic governments and initiatives. Therefore, the solution might succeed where others have failed.

6 Conclusions and Recommendations

6.1 Acknowledging the Right to Health and Access to Medicines

Within international law, there exists an encompassing right to health which includes access to medicines as a key component. In fact, its vital role indicates that there may even be an independent right to medicines, in international law, as well. This binding right creates both duties for states and responsibilities for corporate entities. Regarding the D2P, governments must protect the right to health and ensure that healthcare is available, accessible, acceptable and of high quality. In this context, the provision of access to essential medicines is crucial. States must protect from violations by third parties, such as business entities, while striving for the full progressive realization of the right to health. Moreover, it must be ascertained, by the government, that no other agreement or the application of it comes in conflict with its human rights obligations.

As the right to health and access to medicines arguably constitute part of international customary law, no state can claim that the right does not apply to them. Neither treaty ratification nor any other form of acknowledgement is necessary; the right is binding to all. This however, raises the issue of pharmaceutical companies. These private entities are not subjects of international law in the way that states are. Nevertheless, companies will be affected and international law and CSR instruments will give rise to corporate responsibilities related to the human right to health and access to medicines. Business must now decide how to respond in order to meet these expectations.

6.2 Protect and Respect the Right to Health and Access to Medicines

Considering the development within the business and human rights field, how states need to deal with negative impacts on human rights originating from business behaviour, was clarified. Governments can issue laws on disclosure and reporting that will pressure corporations to apply best practices and responsible management. In addition, governments must be aware of their own human rights obligations and not violate them through state-owned companies, but instead apply the aforementioned best practices themselves. States should strive to influence their corporate culture, raising awareness not only of human rights per se, but how businesses can benefit from applying such concerns to their operations. Companies will neither contribute to, nor benefit from the protection of human rights and access to medicines until they have realized the potential that lies within the discourse. It is the task of governments to ensure that such realization manifests within the business sector.

Corporate entities have a R2R human rights. When defining the scope of this responsibility (namely specifying which human rights companies must respect), the bill of rights and the provisions therein is used. These are the human rights which a company must consider when fulfilling its R2R. The texts of the bill of rights encompass not one, but two health-related rights and, subsequently, the right to health is without a doubt included in the human rights framework applicable to businesses. Companies must ensure that they are diligent in their operations so that they do not violate human rights, contribute to such violations or fail to assess risks and impacts of human rights harm. In doing so, modern business must also take into account societal demands related to the CSR discourse. It is imperative, however, that not only the duties of due diligence and socially responsible management are conveyed to companies. Possible gains and benefits must also be included in the communication so that corporations will be incentivized to commit to acting responsible in the context of human rights.

6.3 Recommendations

Pharmaceutical companies have a broad range of approaches available to choose from, when fulfilling their R2R human rights. Philanthropic activities in the form of donations, contribution to research through disclosure, acceptance and application of TRIPS flexibilities including compulsory licenses, the option of showing tolerance in the face of patent right infringements and the application of RRLs are merely a few of the tools prevalent within the discourses of CSR, business and human rights and the R2R. However, these are some of the main trends that have proven to be useful and appreciated by certain pharmaceutical companies as well as human rights advocates.

The task that remains is to create a solution which is accepted by a broader audience of stakeholders and that can be applied in a larger, long-term perspective. This could be done both through the development of prevalent approaches and by molding a new solution, better suited for all relevant demands and requirements. The latter has been the choice advanced in the present paper that supports RRLs. Pharmaceutical companies should apply this approach as a business strategy, beneficial both financially and socially. Worthy of note is, however, that social benefits linked to CSR may allow for long-term economic profitability and are therefore not necessarily separate from financial gains. Moreover, RRLs can satisfy requirements related to both the R2R and CSR, and although the solution will not be applicable without some adaption to national particularities, it is an approach that can be implemented in virtually any context.

Ultimately, specific recommendations on how to solve the conflict between access to medicines and pharmaceutical patents will be issued. These recommendations include states as well as corporations and the actions that these actors should take to fulfill obligations that arise from international human rights law and the business and human rights regime. These recommendations are issued without prejudice to the solutions preferred by individual actors and with the utmost respect for the importance of allowing

a certain margin of appreciation for states and business executives in their decision-making. Nevertheless, there are certain core aspects that will always relate to the fulfillment of human rights and, therefore, the following recommendations are issued for states and corporations in the context of the right to health and access to medicines.

States should:

1. Acknowledge the importance of access to medicines and its inclusion in the right to health.
2. Ensure the avoidance of conflicts between human rights obligations and duties that arise from other agreements.

Pharmaceutical companies should:

3. Apply best practices in promoting access to medicines and improving healthcare infrastructure through the aid of the international community.
4. Incorporate approaches aimed at fulfilling the R2R in code of conducts or other internal policies of the company. Such approaches include:
 - (a) Philanthropic activities such as donations and disclosure of research and patent information.
 - (b) Acceptance of TRIPS and cooperation in the process of awarding compulsory licenses.
 - (c) Tolerance of patent right infringements within LDCs, and the states supplying them with discounted drugs, when these are aimed at improving access to medicines and fulfilling the right to health. This recommendation does not apply to distribution outside of the LDCs.
 - (d) The application of RRLs as a business strategy applied to developing markets.

These can be applied together in moderation, or more intensively with focus on one of these solutions. However, implementing RRLs will allow for inclusion of the other approaches as a part of implementation adapted to national particularities. The aim and result of such application will be a systematic and sustainable solution that is beneficial for the world economy as well as the international human rights regime.

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