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Medical Patents and Access to Medicines

- *How to Incentivize the Search for New Drugs*

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Contents

Summary

Multinational enterprises are private entities run on a voluntary basis; consequently they have only moral responsibilities, and not a state responsibility, to facilitate access to medicines under the right to health. As international human rights law stands today, there are no legal obligations for pharmaceutical companies to ensure, nor improve, the accessibility to medicines for developing countries; this is the obligation of states.

It has been recognized that patents has a vital function in society, and while patents are important in all industries, they are practically indispensable in the pharmaceutical industry. After the implementation of the TRIPS Agreement all WTO members, including developing countries, are obliged to grant pharmaceutical patents for a period of 20 years. It is undisputed that medical patents can, in some circumstances, create barriers to the accessibility of medicines for developing countries, however it is crucially important to recognize that patents are not the root cause of the problem. Access to medicines is impeded by obstacles far greater than medical patents, such as absolute poverty, corrupted governments, poorly educated doctors, nurses, pharmacists and so on. In addition, there is a blatant market failure being the lack of incentive for pharmaceutical companies to invest R&D into neglected diseases, which causes the deaths of millions of people worldwide every year. These diseases strike the poorest of the poor in rural and low- income areas of the world and less than 10% of global health research spending is dedicated to these diseases that afflict 90% of the world´s poorest population.

Demands and pressure on pharmaceutical companies to denounce their IP rights has become a new trend, however it is far from a long-term solution. Instead, focus should be shifted to coping with the real villain, namely: the lack of incentive for pharmaceutical R&D for neglected diseases. There are many initiatives on the way for incentivizing the search for new drugs, including differential pricing strategies and the emergence of new and innovative partnerships, such as the public-private partnerships. The usage of patent pools and prize funds are also an alternative to the unsatisfying market-driven R&D system of today.

As long as there is no legally binding treaty on the subject of pharmaceutical corporate responsibility in relation to access to medicines, it is important to turn to voluntary measures in order to influence the behavior of pharmaceutical companies. The extent of CSR remains unsettled, however, thanks to the guidelines framed by the UN Special Representative on Business and Human Rights: John Ruggie, and of the UN Special Rapporteur on the Right to Health: Paul Hunt, some precision has been achieved in recent years. The guidelines provide a normative foundation upon which a more comprehensive set of binding legal obligations could be built in the future.

Sammanfattning

Multinationella företag är privata enheter som drivs på frivillig basis, varför de endast har ett moraliskt ansvar för att underlätta tillgången till läkemedel inom ramen för rätten till hälsa. Såsom internationell lagstiftning om mänskliga rättigheter står skriven idag, finns det inga rättsliga förpliktelser för läkemedelsföretagen att säkerställa eller förbättra tillgängligheten till läkemedel för utvecklingsländerna, detta är en skyldighet som tillfaller stater.

Patent uppfyller en viktig funktion i samhället och medan patent är viktigt i alla branscher är de praktiskt taget oumbärliga inom läkemedelsindustrin. Efter genomförandet av TRIPS-avtalet är alla WTO-medlemmar, inklusive utvecklingsländer, skyldiga att bevilja läkemedelspatent för en period av 20 år. Det är ostridigt att medicinska patent kan, under vissa omständigheter, skapa hinder för tillgången till läkemedel för utvecklingsländer, dock är det av grundläggande vikt att inse att patent inte är den fundamentala orsaken till problemet. Tillgången till läkemedel hämmas av hinder mycket större än medicinska patent, såsom absolut fattigdom, korrupta regeringar, dåligt utbildade läkare, sjuksköterskor, farmaceuter o.s.v. Dessutom finns det ett uppenbart ”market failure”(= marknadsmisslyckande) nämligen bristen på incitament för läkemedelsföretagen att satsa FoU i s.k. försummade sjukdomar, vilket leder till att miljontals människor över hela världen dör varje år. Dessa sjukdomar drabbar de fattigaste av de fattiga på landsbygden och i låginkomstområden i världen och mindre än 10% av de globala hälsoforskningsutgifterna är tillägnad dessa sjukdomar som drabbar 90% av världens fattigaste befolkning.

Att ställa krav på läkemedelsföretagen att förkasta sina immateriella rättigheter har blivit en trend, men det är långt ifrån en långsiktig lösning. Istället bör fokus skiftas till att handskas med den verkliga boven, nämligen bristen på incitament för farmaceutisk FoU för försummade sjukdomar. Det finns många nya initiativ på väg för att skapa just detta incitament för sökandet efter nya läkemedel, såsom strategier för differentierad prissättning och framväxten av nya och innovativa partnerskap, såsom offentlig-privata partnerskap. Användningen av patentpooler och prisfonder är också ett alternativ till det otillfredsställande marknadsdrivna FoU-systemet som existerar idag.

Då det inte finns något rättsligt bindande fördrag för läkemedelsföretagens ansvar när det gäller tillgång till läkemedel, är det viktigt att vända sig till mer frivilliga åtgärder för att kunna påverka läkemedelsföretags beteende. Omfattningen av CSR är fortfarande oviss, dock har viss klarhet bringats i ämnet de senaste åren tack vare de riktlinjer som har framställts av FN:s särskilda representant för företag och mänskliga rättigheter: John Ruggie, och av FN:s särskilda rapportör om rätten till hälsa: Paul Hunt. Riktlinjerna tillhandahåller en normativ grund för att i framtiden kunna skapa en omfattande uppsättning av bindande rättsliga skyldigheter.

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
ARV	Antiretroviral (drugs)
CESCR	UN Committee on Economic, Social and Cultural rights
CSR	Corporate Social Responsibility
EU	European Union
FN	Förenta Nationerna
FoU	Forskning och utveckling
HIV	Human Immunodeficiency Virus
ICESCR	International Covenant on Economical, Social and Cultural Rights
ICCPR	International Covenant on Civil and Political Rights
ILO	International Labour Organization
IP	Intellectual Property
MNE	Multinational Enterprises
NGO	Non-Governmental Organization
OECD	Organization for Economic Cooperation and Development
PPP	Public- Private Partnerships
R&D	Research and Development
TRIPS	The agreement on Trade-Related aspects of Intellectual Property Rights
UDHR	United Nations Declaration on Human Rights
UN	United Nations
UNDEP	United Nations Development Programme
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1. Introduction

"Expensive medicines are always good: if not for the patient, at least for the druggist."[1]

One of the most promising areas of modern science is the area of medicine. Modern medicines have reduced the deadly threat of many diseases such as malaria, tuberculosis and have lessened the impact of diseases such as AIDS. But are all people receiving the benefits? For several decades the lack of essential medicines has burdened developing countries worldwide and WHO studies has shown that approximately 14 million people per year die from infectious diseases, 90% of whom live in a developing country. Furthermore, children and very young adults in Africa and Southeast Asia bear a heavier burden in relation to infectious diseases and 50% of all deaths are attributable to six diseases, namely: HIV/AIDS, acute respiratory syndrome, diarrheal diseases, malaria, measles and tuberculosis.[2]The real tragedy is that most of these diseases are preventable, treatable or even curable with existing medications. However, these diseases are referred to as "neglected diseases" since they almost exclusively affect populations with little purchasing power, meaning that they offer an insufficient incentive for industry to invest in R&D, causing essential medicines to remain unavailable for the poor. It is simply not profitable for most pharmaceutical companies to develop new medicines or lower the cost of already existing drugs for people living in developing countries. But should they have to? Is it really the pharmaceutical industry´s responsibility to ensure the realization of access to medicines under the right to health?

Pharmaceutical companies, through their patents, have for a long time been accused of creating barriers to access to medicines and being the root cause of the egregious deaths of millions of people. After the implementation of the TRIPS Agreement, this accusation gained more fuel. However, barriers to access to medicines are caused by numerous reasons, such as poverty, market failure, unfair trade practice and weak governance. The market failure referred to is the one associated with medical patents and the lack of incentive to invest R&D into neglected diseases. Lately, too much focus has been placed on blaming the pharmaceutical industry for their patent schemes and not enough focus has been placed on the much more acute problem of lack of incentive.

Pharmaceutical companies are private economical entities driven by profit maximization, and in order for them to invest time and money there must be a prospect of recouping their investment. The existing rules for

[1] Russian Proverb

[2] Wu, Chuan- Feng, *Transnational Pharmaceutical corporations´ legal and moral human rights responsibilities in relation to access to medicines,* Asian Journal of WTO and International Health Law and Policy (2012) p. 77.

[2] Wu, Chuan- Feng, *Transnational Pharmaceutical corporations´ legal and moral human rights responsibilities in relation to access to medicines,* Asian Journal of WTO and International Health Law and Policy (2012) p. 77.

incentivizing[3] pharmaceutical research are morally problematic since they treat health as a mere commodity on the market. But instead of placing the blame on private entities, new and innovative methods that incentivize the search for new drugs must be encouraged in order to overcome this market failure and the question is; how can this incentive be created? If there are no legal obligations for pharmaceutical companies in regards to access to medicines, what is the role of voluntary measures then? Is it possible for soft law and CSR to influence the behavior of pharmaceutical companies for the better?

1.1 Purpose

The purpose of this thesis is first to highlight the market failure caused by the lack of incentives for pharmaceutical R&D for neglected diseases, and second to present a set of measures and solutions that can overcome this market failure. The aim here is to show why it is necessary to re-shift focus into combatting the market failure associated with the lack of incentive for pharmaceutical companies to invest R&D into neglected diseases, instead of focusing blindly at the adverse effects of medical patents and blaming the pharmaceutical industry. The latter will not solve the market failure, while focusing on different measures that incentivize the search for new drugs can potentially save the lives of millions of people living in the poorest areas of the world.

In order to achieve this purpose, it is first necessary to outline the exact obligations that pharmaceutical companies have in relation to access to medicines, if there exists any legal obligations to ensure access to medicines or whether there only exists moral obligations. Entering the field of moral obligations, the thesis will further present voluntary mechanisms such as soft law and guidelines dedicated to the matter, as well as dealing with the related issue of CSR. The aim here is to present a portfolio of good practice that, if adopted by pharmaceutical companies, could potentially improve access to medicines. For the purpose, the general term "medicines" will refer broadly to drugs, vaccines, diagnostics and other medical products.

Seeing that there is a much heated debate on the subject of medical patents and access to medicines, the goal is not to present a complete solution but instead to shed light on the different solutions and reform strategies, seen from a "lack- of- incentive" perspective instead of a "patent-is-bad" perspective. Focusing on the problem will not solve anything, but focusing on the solution might.

The following questions are to be answered in order to fulfill the purpose:

[3] The term "incentivize/incentivizing" will be used for measures that enhance and motivate pharmaceutical R&D, ergo; measures that create incentives.

1. Is there any legal obligation under international human rights law for pharmaceutical companies to facilitate access to medicines under the right to health?

2. How do medical patents affect access to medicines, and what have been the effects of the TRIPS Agreement?

3. How can incentives be created to attract pharmaceutical companies into investing more R&D into neglected diseases?

4. How can voluntary mechanisms, such as soft law and CSR, influence the business conduct of pharmaceutical companies?

1.2 Method

The starting point of the investigation will consist of a brief presentation of international human rights law, such as the UDHR and ICESCR, where the right to health encompassing access to medicine will be outlined. The question to be answered is whether there exist any legal obligations for pharmaceutical companies to ensure access to medicines. Secondly, there will be an overview of the TRIPS Agreement with focus on the flexibilities presented within, as well as an overview of the subsequent Doha Declaration, both frameworks being of crucial importance for pharmaceutical companies. Both initial chapters will be based upon the usage of a traditional legal dogmatic methodology in order to answer the quandaries at issue.

Coming to the focal point of the thesis, there will be a presentation of different reform strategies and measures followed by a thorough analysis of how these methods are actually capable of incentivizing the search for new drugs. Furthermore, voluntary measures and the concept of CSR will be examined, in order to see how they can improve the business conduct of MNEs. Since the aim of this part of the thesis is not to interpret existing law, the usage of traditional legal dogmatic methodology will not be applied. Instead, the usage of a non-formal, law and economic methodology will be applied. The chosen methodology reflects in a better way the aim and purpose of the thesis, since the understanding of a market failure is crucial. Also, the solutions presented are stemming from an economical point of view, instead of merely setting out the positive state of law (de lege lata). The aim is to present alternative solutions and measures that can be as effective as hard-law, by collecting and analyzing different solutions and measures suggested by different scholars and authors.

1.3 Delimitations

The scope of the thesis is fairly broad, seeing that the subject of patents and access to medicine has fueled much heated debates during the last decade. The thesis will however only deal with questions relating to patents and how they affect access to medicine for developing countries, other forms of IP rights are therefore excluded. The TRIPS plus is also excluded since it risks broadening the scope of the thesis and is not as relevant to the perspective of this topic. The thesis will also not deal with questions relating to human rights in general, but focus only on those relating to the right to health and access to medicines.

There exist several suggested measures and strategies for the enhancement of incentive for pharmaceutical R&D, however, this thesis will only deal with measures that are already being applied by some, measures that are believed to be most successful, and for the sake of "thinking-outside-the-box": measures that require an entire reform and that therefore truly enlighten the endless possibilities.

Regarding voluntary measures such as soft law, there have been made much needed delimitations, seeing that there are several guidelines and frameworks dedicated for the purpose of regulating MNEs business conduct. However, this thesis will only deal with guidelines that have been dedicated specifically for pharmaceutical companies, along with general framework that can be applied on pharmaceutical companies and have been endorsed by the international arena, such as the UN Global Compact and the Protect, Respect and Remedy Framework presented by the UN Special Representative John Ruggie.

1.4 Literature

The conflict and relation between medical patents and the right to health has been debated fiercely in legal literature, and even more so since the introduction of the TRIPS Agreement in 1994. *Human Rights and the WTO: The Case of Patents and Access to Medicine* by Holger Hestermeyer and *Human Rights and Intellectual Property: Mapping the Global Interface* by Laurece R. Helfer and Graeme W. Austin have been of great importance for the writing of this thesis. For the subject of incentivizing the search for new drugs, the *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade* by the collaboration of the WIPO, WHO and WTO has been used as a starting point, along with the reform strategies presented by Thomas W. Pogge in *Human Rights and Global Health: a Search Program.* The report by Oxfam International *Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation,* available at the website of Oxfam, has been highly illuminating upon the entire topic of lack of incentive for pharmaceutical R&D for neglected diseases.

There are several articles written on barriers to access to medicines, two articles by Paul Hunt has served to illustrate the tragic situation caused by neglected diseases: *Neglected diseases: A Human Rights Analysis,* along with *Human Rights responsibilities of the Pharmaceutical companies in relation to access to medicines.* The writing of Anand Grover and others in *Pharmaceutical Companies and Global lack of Access to Medicines: Strengthening Accountability under the Right to Health* have helped to shed light on the role that pharmaceutical companies have in regards to access to medicines.

The extent of CSR is a bit unsettled, however some precision has been achieved in recent years thanks to the writings of the UN Special Representative on Business and Human Rights: John Ruggie, and of the UN Special Rapporteur on the Right to Health: Paul Hunt. The Guidelines are not legally binding but serve as a tool for good practice and have been crucial for the topic of voluntary measures. As for a good business conduct portfolio and an illustrative hierarchy pyramid, appraisal goes to the article by Klaus Leisinger, *Corporate Responsibilities for Access to Medicines.* Finally for the purpose of reflecting the entire picture of CSR, the critical writing of Milton Friedman in *The Social Responsibility of Business is to increase its profits* has been very helpful and entertaining.

1.5 Disposition

The outline of the thesis will proceed as follows; chapter 2 will have an overview of the right to health presenting the legal outline for the access to medicines. What the right to health does and does not include and how the right should be understood will also be presented. Finally, the legal obligation to ensure access to medicines and who is primarily responsible for this obligation will be outlined, consequently answering the first question posted.

The third chapter will have a brief presentation of patents in general as well as an overview of the TRIPS Agreement and the declaration on the TRIPS Agreement and public health: the Doha Declaration. The third chapter will contain an answer to the second question posted. There will also be a presentation of the flexibilities of the TRIPS Agreement along with the risks that follows. The recent Novartis decision will also be discussed.

Chapter 4 will outline the concept of neglected diseases and explain the occurring market failure, in addition it will contain a presentation of different solutions and measures that can enhance the incentive for pharmaceutical companies to invest more R&D into neglected diseases. The answer to the third question will be presented in the same chapter.

Chapter 5 and 6 examines voluntary mechanisms that are dedicated for the matter of improving business conduct, chapter 5 contains international

frameworks and guidelines that are dedicated to the cause, while chapter 6 will deal with the concept of CSR and its sources. Question number 4 on how to influence the behavior of MNEs will hence be answered in the two chapters.

Finally, in chapter 7 there will be a last concluding chapter on how to move forward from the situation of today to the solutions of tomorrow for incentivizing the search for new drugs.

2. The Right to Health

2.1 The Legal Outline

The right to the enjoyment of the highest attainable standard of health is a fundamental human right, which every human being is entitled to in order to lead a life in dignity, wherever they may live. The international right to health, as articulated in article 12 of the ICESCR, and further elaborated by General Comments No. 14 of the CESCR, recognizes access to medicines as a core component to the right to health. This is confirmed by the Constitution of the WHO, adopted in 1946, and is also codified and can be found in numerous national constitutions as well as legally binding international human rights treaties. Every country in the world has affirmed, in one treaty or another, the right to health.

The UDHR lays the foundation for the international framework for the right to health; in Article 25.1 it is clearly stated that "*Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services".* The ICESCR further provides the most comprehensive article on the right to health in international human rights law. In accordance with article 12.1 of the ICESCR, states parties recognize "*The right of everyone to the enjoyment of the highest attainable standard of physical and mental health*"[4]. In the general accepted framework of the right to health, access to medicines is an essential component because inaccessibility to medicines prevents individuals from obtaining the medicine they need to prevent or treat medical condition, resulting in them falling below the highest attainable standard of health. Consequently, access to essential medicines is a necessary condition for leading a healthy and dignified life, without which the right to health itself would be meaningless.[5]

However, the right to health is not to be understood as a right to be *healthy.* Good health is merely an aspiration that cannot be ensured by a state, nor can a state provide protection against every possible cause of human ill health. Instead, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health, containing both freedoms and entitlements. The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture,

[4] United Nations Economic and Social Council, *The right to the highest attainable standard of health*, E/C.12/2000/4 General Comments no 14, (article 12 of the International Covenant on Economic, Social and Cultural Rights), 11 August 2000, paragraph 1-3

[5] Wu, Chuan- Feng, *Transnational Pharmaceutical corporations´ legal and moral human rights responsibilities in relation to access to medicines,* Asian Journal of WTO and International Health Law and Policy (2012) p. 91

non-consensual medical treatment and experimentation. By contrast, the entitlements include the right to a system of health protection that provides equality of opportunity for people to enjoy the highest attainable level of health.[6] Within the set of entitlements is the access to essential drugs, which as already stated, constitutes an integral part of the right to health.[7]This means that essential drugs must be *available, accessible* and of *good quality*, not only physically, but also economically to everyone without discrimination.[8]The right to health also requires that much needed new medicines are developed as soon as possible, including those needed to treat diseases, such as tuberculosis and malaria that largely affect the poor in developing countries, the so called neglected diseases.[9]

2.2 The Legal Obligation to Ensure Access to Medicines

Human rights are inspired by moral values, such as dignity, equality and access to justice. However, they are more than moral entitlements since they are legally guaranteed and legally enforceable.[10] Under international human rights law the primary responsibility for ensuring the realization of human rights are placed on states. It is states that have ratified international human rights treaties and thus accepted obligation which are binding under international law. Domestic law also often contains obligations to give effect to human rights. States have therefore both national and international legal obligation to ensure human rights and take action towards the fulfillment of them, as well as remedy any human rights abuses. This applies also to actions that causes or are a result of neglected diseases.

Individuals can be held responsible for a much smaller range of human right abuses such as war crimes, genocide, crimes against humanity, torture, slavery, forced labor and forced disappearance. However, both the ICCPR article 2.1 and ICESCR article 2.1 require "*State parties to the present Covenan*t" rather than non-state parties to "*undertake steps to respect and ensure the full realization of the rights recognized in the Covenant*".

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[6] United Nations Economic and Social Council, *The right to the highest attainable standard of health*, E/C.12/2000/4 General Comments no 14 (article 12 of the International Covenant on Economic, Social and Cultural Rights), 11 August 2000, paragraph 8

[7] Hristova, Mirela, *Are Intellectual Property Rights Human Rights?* Journal of the Patent and Trademark Office Society, Vol. 93 (2011) p. 356

[8] Hunt, Paul, *Neglected diseases, Social Justice and Human Rights: some preliminary observation,* Special topics in social, economic and behavioural research report series: no. 6 (2007) p. 7

[9] Grover, Anand and others, *Pharmaceutical Companies and Global lack of Access to Medicines: Strengthening Accountability under the Right to Health,* Journal of Law, Medicine & Ethics (2012) p. 234

[10] Hunt, Paul, *Neglected diseases, Social Justice and Human Rights: some preliminary observation,* Special topics in social, economic and behavioural research report series: no. 6 (2007) p. 4

Generally speaking, to require that private MNEs to assume human rights responsibilities are hindered by a number of obstacles. Firstly, human rights are traditionally concerned with the relationship between the state and individuals and apply most exclusively to states. Secondly, the regulation of corporate conduct is usually treated as a matter of domestic law. In other words, it is for the state to regulate matters of social importance, such as access to medicines, and for MNEs to obey the law. Since there is no clear standard for human rights to which companies activities can be applied, requiring them to take responsibility for providing affordable medicines is both difficult and confusing.[11]Accordingly, corporations are not the principal targets of human rights concerns; only states can violate international human rights. It therefore rests upon states to do all they reasonably can to make sure that existing medicines are available in sufficient quantities within their jurisdiction. States may also have to make use of the TRIPS flexibilities such as the issue of compulsory licenses and thereby ensuring that medicine reach their jurisdiction in adequate quantities.[12]

In addition, a fulfillment of a positive right such as the right to access to medicines is considered to belong to the public interventions, rather than MNEs. Since positive rights require a specific demand on societal resources for their fulfillment, it is both unreasonable and unrealistic to assign a legal responsibility to corporations that might force them to exhaust their resources to offer social goods or services. In accordance with ICESCR article 2, the right to access to medicines, under the right to health, is subject to the *principle of progressive realization*, meaning that unlike civil and political rights, the state is only obliged to take steps towards the progressive fulfillment of the right on the premise of available resources, and the state can claim scarcity of resources as a legitimate reason for not fulfilling the right. Since the progressive realization of the right to access to medicines means that pharmaceutical accessibility could only be progressively realized over time within available resources, the state has only an obligations to progressively fulfill the right to access to medicines to the extent that resources permit. Accordingly, since the state only has obligations for the fulfillment of the right stemming from so called soft- law obligations that have moral but no legal force, it would prove to be unreasonable and unjustified to place a heavier burden on MNEs, which are designed to serve primary economic purposes of profit maximization.[13]

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[11] Wu, Chuan- Feng, *Transnational Pharmaceutical corporations´ legal and moral human rights responsibilities in relation to access to medicines,* Asian Journal of WTO and International Health Law and Policy (2012) p. 82

[12] United Nations Special Rapporteur Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicine: The sexual and reproductive health context*, Human Rights Center, University of Essex, UN General Assembly in A/63/263, dated 11 August 2008, p.8

[13] Wu, Chuan- Feng, *Transnational Pharmaceutical corporations´ legal and moral human rights responsibilities in relation to access to medicines,* Asian Journal of WTO and International Health Law and Policy (2012) p. 100

2.3 Concluding Comments

Although medical care and access to medicines are vital features of the right to health, almost two billion people lack access to essential medicines. Improving access to medicine could potentially save the lives of 10 million people each year.[14]But traditional international human rights law does not impose any direct or binding obligations on private actors, such as private pharmaceutical companies, even though they can play a major role in the improvement of access to medicines. This is simply because a private entity cannot assume human rights obligations in the same extent as a state.

However, in recent years, there has been growing acceptance that private companies do have some human rights responsibilities.[15]This claim is supported by paragraph 42 of the CESCR General Comment No. 14 which states that: "*While only States are parties to the ICESCR and thus ultimately accountable for compliance with it, all members of society ... [including the private business sector]… have responsibilities regarding the realization of the right to health."*

The human rights responsibilities of MNEs will be discussed further in chapter 5.

[14]Hunt, Paul and Joo Young Lee, *Human Rights responsibilities of Pharmaceutical Companies in relation to access to medicines,* Journal of Law, Medicine & Ethics, (2012) p.1

[15]Hunt, Paul, *Neglected diseases: A Human Rights Analysis,* Special topics in social, economic and behavioural research report series; no. 6 (2007) p. 12

3. Medical Patents

3.1 Intellectual Property Law

IP is the overall term for property in the creation of the mind, including inventions, literary and artistic works, but also images and designs.[16] IP is divided in two fields, namely copyright and industrial property, and ensures the protection of ideas and designs in art and technology, in industry and in trade. It is due to the differences between the protection of literary and artistic creations on the one hand and distinctive signs and inventions on the other that there has been a division in IP.[17]

Industrial property relates to objects that can be used in technology and industry, such as trademarks, trade names etc. and inventions in their various forms. Industrial property, unlike copyrights, is characterized by their usefulness and serves a particular economic purpose. From a public health standpoint, the most relevant form of IP is a patent, and it is the means for protection for inventions.[18] Patent is the reward that the state grants the inventor for his contribution to the solution of a problem in technology or industry. Patent rights do not last forever but are specified for a limited period of time. The minimum period specified under article 33 of the TRIPS Agreement is 20 years.

Patent protection for innovations concerning chemical, pharmaceutical and food products has been a very controversial subject in industrial property. The subject of patents protection of pharmaceutical compositions is vitally important, mainly because it is a subject with a strong social implication and touches upon a sensitive matter such as health and the quality of life. Secondly, the pharmaceutical industry relies to a large extent on costly R&D programs, which means that it is more necessary than in other areas to protect them with patent protection. This is also due to the fact that pharmaceutical products are very often relatively easy to copy.[19] If there is no tight control of legal assurance regarding exclusivity of both the process and the resulting product, it is quite easy for second comers or free- riders to replicate the breakthrough drugs in a generic version. For example, with the right information, a second comer can put into the market within a period of about six months a product that took over ten years of pharmaceutical R&D.[20]

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[16] http://www.who.int/topics/intellectual_property/en/ (as accessed on 26 February 2013)
[17] Salazar, Silvia, *Intellectual Property and Human Right,* Intellectual Property and Human Rights, WIPO (1998) p. 67
[18] Ibid p. 68
[19] Ibid p. 71
[20] Oguamanam, Chidi, *Patents and Pharmaceutical R&D: Consolidating Private-Public Partnership Approach to Global Public Health Crises* (2010) p. 556

3.1.1 Adverse Effects of Patents in Relation to Access to Medicines

Medical patents affect access to medicines in two distinct ways, firstly by allowing the patent holder to become a monopoly supplier for a period of 20 years, subsequently creating a barrier to access to medicines for the people who cannot afford the much higher monopoly price. An example that can illustrate this unfortunate situation is the outbreak of the AIDS epidemic. After a series of successful ARV drugs, AIDS has been transformed into a chronic disease instead of deadly as it was before the year 1996. But whereas the accessibility for ARV drugs in North America and Europe for people in need is between 75% and 100%, in Africa it is just 0.1% of the 28.5 million people living with AIDS that have access to the much needed drugs. In these countries over 50% lack access to essential medicines because they cannot afford it.[21] For instance, the cocktail for ARV drugs cost around USD 10,000 per patient per year, and the average income for people in Sub-Saharan Africa is USD 1,600 a year. Now, an Indian manufacturer can offer the same drug for a cost of USD 350, however, this product cannot be sold in many countries because the inventor has a patent there and a generic version of the drug would be an infringement under the international patent system.[22] Until 1994 the problem was not acute, since countries could then decide whether they wanted to grant pharmaceutical patents or not. However, after the implementation of the TRIPS Agreement this situation changed radically since no member state is longer allowed to exclude certain fields of technology from patentability. For many critics it is clear that the patent system, especially after the implementation of the TRIPS Agreement, and the pharmaceutical industry are causing barriers to essential medicine in developing countries.

Medical patents can also affect access to medicine by the way pharmaceutical companies choose to channel their R&D for diseases that predominantly occurs in more affluent countries, since they increase the likelihood for them to recoup their investments. For instance, it is much more profitable for pharmaceutical companies to develop drugs for hair removing cream than develop a cure for African sleeping sickness. This can be illustrated by the Sanofi-Aventis incident in the mid 1990s. Sanofi-Aventis was the first pharmaceutical company to produce a cure for the usually deadly late stage of sleeping sickness, but the company stopped making the drug in 1995 because it was not profitable enough, and instead the drug came to another use as an ingredient in a hair removing cream, a product that was successful in developed countries. The company later got pressured into donating its drug to the WHO, however this does not change

[21] Ley, Björn, *Are Patents really the only Barrier for Good Health Care in Developing Countries?* Human Rights and Intellectual Property Rights: Tensions and Convergences, vol. 2 (2007) p.102
[22] Ibid

the fact that these decisions are consciously being made by pharmaceutical companies, because, simply, the need does not match the market.[23]

3.1.2 Justification Grounds

Inventions are a textbook example of a market failure. An inventor puts time and money into the research and development of a product, especially the pharmaceutical industry depends largely on costly R&D programs and capital investment is primarily directed to research and clinical trials, as opposed to the actual manufacturing process of medications. Newly developed medical treatments often turn out to be unsafe or not effective enough, to have bad side effects, or to fail getting government approval for some other reason, which may lead to the loss of the entire investment.[24] In addition, the culture of medical research emphasizes very early disclosure of inventions, usually long before a resulting product can be placed on the market. This is because scientists working in the field of human pathology have an obligation to share their findings as soon as possible with their peers so that those peers will be able to benefit from the new knowledge in their own research.[25]

The incentive to invest in inventions would decrease if not sufficient return would be received. Patents are a way of resolving this market failure, seeing that the patent holder becomes a monopoly supplier which will give the inventor adequate time to recoup his investment. The bottom line is; patents provide the means whereby the inventor can recover his investment, and without it he would not invest. But does this justify the fact that poor people are being denied access to lifesaving drugs? The answer must sadly be answered in the affirmative. At stake is the balance between the medicine for the diseases of today and those of tomorrow. Any justification on the ground of incentive relies on the fact that patents actually do spur research and innovation in the pharmaceutical industry. The incentive argument therefore discourages any exception to patent law. If exceptions for medicine for serious diseases are made, then the incentive to innovate is lost in the area where it is needed the most.[26]

In addition, access to medicine is multifaceted. There are many impediments to providing individuals in developing countries with access to essential medicines. Proper access to medicines requires a health system with qualified personnel, capacity to distribute the drugs, testing facilities, and other related capacity to effectively administer the drugs. Many countries lack even the basic infrastructure such as access to water. These are

[23] Oguamanam, Chidi, *Patents and Pharmaceutical R&D: Consolidating Private-Public Partnership Approach to Global Public Health Crises* (2010) p. 561
[24] Pogge, Thomas, *Human Rights and Global Health: a research Program,* vol. 36, (2005) p. 185
[25] Hristova, Mirela, *Are Intellectual Property Rights Human Rights?* Journal of the Patent and Trademark Office Society, vol. 93 (2011) p. 357
[26] Hestermeyer, Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (2008) p.158-159

formidable obstacles, and the political leadership of some countries may lack the means and/or the will to overcome them, and the funding necessary to solve these problems is often well above what would be necessary to acquire patented drugs. Therefore, where patents rank on this list of barriers to access can be discussed.[27]

Finally, very few rights are absolute in the sense that any interference with them violates the right. Most human rights provisions can be limited if certain conditions are fulfilled. This means that the interference of patents in developing countries with the right to access to medicine could be justified under human rights law.[28]Accordingly, under a human rights approach the benefits stemming from patents can be distributed without the patent-holder´s authorization in order to meet social needs that are likewise classified as fundamental.[29]

3.2 The TRIPS Agreement

The WTO´s TRIPS Agreement was signed in 1995 and is the leading multilateral treaty regulating the protection of inventions. Its aim is to harmonize the basics of IP law standards and improving the overall framework conditions for the transfer of knowledge and technology in a global marketplace,[30] as well as limiting the risks of unjustified free-riding by securing to inventors and creators a return on their investments from the sale or licensing of innovative knowledge goods anywhere within the global market for goods and services regulated by the TRIPS Agreement.[31]

Before the 1990s there were no patent protections for medicines allowing developing countries to quite freely regulate public health without the interference of international IP law. States could even choose to deny patent protection for pharmaceuticals entirely. Before the TRIPS Agreement entered into force many middle- income developing countries such as Brazil and Argentina had therefore the ability to produce low-cost generic medicines. This made it possible for even poor states to acquire certain low-cost generic medicines on the world market. However, after the implementation of the TRIPS Agreement and the expiration of the transitional periods in 2005 the situation changed radically. All developing countries, except for the least developing countries, must adopt and enforce

[27] Hestermeyer, Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (2008) p.150
[28] Ibid p.152
[29] Dreyfuss, Roshelle C., *Patents and Human Rights: Where is the paradox?* (2010) p.74
[30]Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994, in World Trade Organization, The Legal Texts: The Results of The Uruguay Round of Multilateral Trade Negotiations 321 (1999) available at http://www.wto.org (as accessed on 3 April 2013)
[31] Abbott, Friedrich, *The Doha round´s public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provision,* Journal of International Economic Law (2007) p. 924

all TRIPS patent standards, including standards regulating medicines in all WTO member countries, leaving the availability of medicines dependent on different price-strategies adopted by pharmaceutical companies instead.[32]As long as an invention meets the technical requirements of patentability a patent must be granted for an inventive product, including a pharmaceutical compound, even if it would negatively impact the accessibility of drugs.[33]

The core of the conflict between the TRIPS Agreement and access to medicines is the claim that patents on pharmaceuticals raise prices, and consequently constituting a barrier to the accessibility of drugs. The monopoly of the patent holder allows the pharmaceutical companies to charge excessively high prices for their drugs and this position may lead to the patent owner abusing his exclusive position on the market.[34]

3.3 The Flexibilities of TRIPS

The TRIPS Agreement has some safeguards installed to tackle public health problems. Apart from the more general articles about the desire to balance and facilitate the right to health, there are mainly three solutions that are supposed to facilitate access to cheap medicines in developing countries.

Article 27.1 states that it is no longer possible for member states to exclude medicines from patentability and accordingly allow generic pharmaceuticals. Article 27.2 in the TRIPS Agreement, however, permits states to exclude patentability for inventions if they pose a threat to human life or health. The TRIPS Agreement also provides states discretion in enacting and amending their laws and regulations in order to help them promote public health goals. Furthermore, Article 30 allows states to restrict the exclusive privilege created through patent rights. It should be noted, however, that both article 27.2 and 30 are subject to certain limitations. For instance, under article 30, states may not grant exceptions that unreasonably prejudice the legitimate interest of the patent owner.

The first solution, and the most relevant article in the TRIPS regarding access to medicine, is the right for governments to issue compulsory licenses enshrined in article 31 of the TRIPS Agreement. It authorizes the use of a patented product or process without the patent holder´s consent, provided that adequate remuneration is paid. The state must first attempt to negotiate with the patent holder for a voluntary license, if this fails a member state can then waiver this requirement in the case of a national emergency such as public health. Exercising this right, a government can

[32] Abbott, Friedrich, *The Doha round´s public health legacy: Strategies for the production and diffusion of patented medicines under the amended TRIPS provision,* Journal of International Economic Law (2007) p. 927
[33] Helfer, Laurence and Austin, Graeme W. *Human Rights and Intellectual Property: mapping the Global Interface* (2011) p.120
[34] Hestermeyer, Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (2008) p.138

force down the price of a patented invention by compelling the patent holder to license it to other producers for a set percentage (typically below 10%) of the latter´s sales revenues.[35]Developing countries can thus resort to compulsory licensing—either by threat or actual imposition—in order to persuade pharmaceutical companies to lower the prices of specific medicines to the point where they become available to a mass market consumers in need of them and not just to affluent members of any given community. This situation is a violation of the patent holders´ rights, since it creates competition on the market, however, compulsory licensing is indispensable in situations where the patent holder refuses to supply a market.

The second option under the TRIPS Agreement is parallel trade. Parallel trade occurs when a product covered by IP rights sold by, or with the right holder´s consent in State A, is re-sold in another State B without the right holder´s permission. This may occur when there is a significant difference in price. The TRIPS Agreement leaves the decision to allow parallel imports on the states.[36]

Another option available under the TRIPS to facilitate access to medicines is the use of price controls. The TRIPS Agreement does not prohibit the use of price controls and it is already a feature of the pharmaceutical industry in rich and poor countries. Price controls affect the profits of manufacturers in a similar way as compulsory licensing, however, the right owners are more willing to abide to price controls since they retain the control over distribution.[37]

3.4 The Doha Declaration

The unanimously concluded Doha Declaration on the TRIPS Agreement and Public Health reflects a series of unrelated and unexpected events, instead of a true convergence of opinion. A few months before the Doha meeting, developed countries and pharmaceutical companies continued to insist that issues besides patents were the true hurdles to access to medicine.[38]After the expiry of the TRIPS transition periods a social tension was created due to the restrictions on access to generic medicine in developing countries, especially after the AIDS pandemic. In a response to the growing crisis that was threatening the stability of the WTO itself, the WTO adopted the Doha Declaration in November 2001. The Declaration reconfirms many of the flexibilities built into the TRIPS Agreement,

[35] Pogge, Thomas, *Human Rights and Global Health: A research Program,* vol. 36, (2005) p.187
[36] See article 6 of the TRIPS Agreement
[37] Ley, Björn, *Are Patents really the only Barrier for Good Health Care in Developing Countries?* Human Rights and Intellectual Property Rights: Tensions and Convergences, vol. 2 (2007) p. 121
[38] Ho, Cynthia, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (2011) p. 337

including the right for member states to issue compulsory licenses to produce low- cost drugs in national health emergencies, while at the same time acknowledging that states with insufficient domestic manufacturing capabilities cannot make effective use of such licenses.[39]

The language in the preamble of the Declaration is consistent with the general premise that patents are not inherently in conflict with public health. In addition, the declaration confirms that TRIPS does in fact "*contribute to the availability of medicines*", accordingly since it provides an incentive for the development of drugs, focus being on future development rather than current access. The fact that there is a higher cost for patented drugs is discreetly sanctioned by the statement that "strong" protection is necessary as strong protection generally means there will be no or only minimal exceptions to patent rights.[40]

The Declaration also clarifies that TRIPS can and should be interpreted and implemented in a manner supportive of the WTO Member´s right to protect public health and in particular to promote access to medicine for all. It also allowed the least developing countries to defer from the obligation to extend patent protection for pharmaceutical products until 2016.

Paragraph 6 of the Declaration reflects the international consensus that the TRIPS Agreement posed a barrier to providing low-cost generic drugs to some poor countries and that the TRIPS Council should take action. However, the impact of that article was to be radically affected by unexpected events. At the terrorist attacks on the United States on 9/11 2001, there was a bioterrorism threat involving mailed anthrax. Canada initially stated it would issue a compulsory license on the patented antibiotic to ensure adequate supplies to treat anthrax inhalation, and a US official stated the United States was contemplating a similar move. Although no compulsory licenses were ultimately issued, the United States was widely mocked for its hypocrisy. The United States had condemned the use of compulsory licenses to treat HIV pandemics, but considered issuing a compulsory license for its own use to address an unrealized threat of limited scope.[41]

Although the Declaration was unanimously concluded, competing views of patents remains in the form of divergent interpretations of the Declaration.

[39] Helfer, Laurence and Austin, Graeme W. *Human Rights and Intellectual Property: mapping the Global Interface* (2011) p. 123
[40] Ho, Cynthia, *Access to Medicine in the Global Economy: International Agreements on Patents and Related Rights* (2011) p. 338
[41] Dyer, Geoff and Michaels, *A Bitter Pill for Drug Makers,* The Financial Times (London), (2001) p. 27

3.5 The Risks of Compulsory Licenses

The use of TRIPS flexibilities, such as the issue of compulsory licenses, can lead to significant cost savings and increases in coverage. However, an important matter to raise regarding the possibilities for a member state to issue compulsory licenses is the political risks that these actions can cause.

In 2006 and 2007 Thailand issued a total of seven compulsory licenses for a combination of ARVs and medicines used to treat cardiovascular disease and cancer, and in 2007 Brazil followed with a single compulsory license for HIV/AIDS. Even though it was permitted under the TRIPS, criticism of the compulsory licenses issued by Thailand came from several sources, such as the EU Trade Commissioner, United States Senators, The Wall Street Journal and even the WHO Director General who retaliated by withdrawing seven pending applications for registration for new medicines from Thai Food and Drug Administration. Brazil faced similar opposition. In 2005 Brazil announced that they were considering issuing a compulsory license for tenofovir[42]. After their announcement, Brazil was criticized by a number of US Congressmen, the CEO of PhRMA[43] as well as Executive President of the Brazilian Federation of Pharmaceutical Industry. Brazil tried to first negotiate with the patent holder for lower prices, but when this failed it turned to the flexibilities and issued a compulsory license. This lead to criticism from Merck, which was "*profoundly disappointed*" as well as from the Brazil Council that stated that it was "*a major step backward*" and that it would discourage investment in Brazil.[44]

Despite the Doha Declaration´s confirmation of the right to use the TRIPS flexibilities, taking advantage of the same requires both the legal capacity and the political ability to resist external pressure.

3.6 The Novartis Decision

On 1 April 2013 the Supreme Court of India delivered judgment on an appeal by Novartis against rejection by the India Patent Office of a product patent application for a specific compound used to treat chronic leukemia, which was marketed by Novartis as "Glivec".[45] The judgment ended a seven- year battle by the Swiss drug-maker to get a patent in India on its leukemia drug. The medication, which was approved for use in the USA

[42] A crucial virus enzyme in HIV and hepatitis B virus infections used to block reverse transcriptase.
[43] PhRMA: Pharmaceutical Research and Manufacturers of America is probably the most powerful, effective and influential industrial interest and pressure group.
[44] So, Anthony and Sachs, Rachel, *Making Intellectual Property work for Global Health,* Harvard International Law Journal (2012) p. 113-114
[45] Judgement of the India Supreme Court as delivered on 1 April 2013, *Novartis AG vs. Union of India & Others,* CIVIL APPEAL Nos. 2706-2716 OF 2013, sections 3-5.

back in 2001, has been produced generically by Indian pharmaceuticals for years at a fraction of the Swiss drug´s cost.[46]

The Supreme Court rejected the claim from Novartis and the reasoning behind the decision was that the latest version of the drug Glivec did not differ enough from the previous version. The ruling of the Court should be interpreted that new innovative medicines will still be able to be granted patent protection in India, however, pharmaceutical companies will no longer be able to be granted patents for minor alterations on a drug.

Indian drug companies and health activists have welcomed the delivered judgment by the Supreme Court. The latter has called the decision a win for patients seeking cheaper treatment and being against pharmaceutical companies making minor tweaks to an already existing drug in order to prolong the company´s patent protection in order to deny other firms to produce the drug as a cheaper generic version once the patent has expired.

The effects of the decision are yet to be seen, however, the fact that India is creating a tough environment for global companies to continue to invest in new drugs is a cause of criticism for the Court ruling. In a statement, Novartis said that the Supreme Court´s decision "*discourages innovative drug discovery essential to advancing medical science for patients"* and that the decision "*discourages further innovation within the pharmaceutical field".*[47]According to Novartis, 95% of the more than 16 000 patients who are prescribed Glivec in India already receive it free of charge through the company´s donation program.[48]

3.7 Concluding Comments

States must according to the ICESCR guarantee the economic accessibility of medicines, and developing countries can only do so by guaranteeing a reasonable price level. Providing corporations with the possibility to patent pharmaceuticals goes against that obligation, since it results in a higher price level of those products. Given the effect on price that patents may have, patents would then indeed interfere with the right to access to medicine at least in developing countries, as higher prices reduce the accessibility of the medicine for the poor. More importantly, this effect cannot be compensated by developing countries, since they lack the resources to pay for the higher prices themselves.[49]

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[46] Mahr, Krista, *The Novartis Decision: Is the Big Win for Indian Pharma Bad news for Investment?* Available at http://world.time.com (as accessed on 1 April 2013)

[47] http://www.sydsvenskan.se/varlden/dom-oppnar-for-lagprismedicin/ (as accessed on 2 April 2013)

[48] http://world.time.com/2013/04/01/the-novartis-decision-is-the-big-win-for-indian-pharma-bad-news-for-investment/#ixzz2QafdyF99 (as accessed on 1 April 2013)

[49] Hestermeyer, Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (2008) p.138

There is therefore an inherent conflict between patent rights for pharmaceutical companies and access to medicines. Some authors argue that the flexibilities built into the TRIPS Agreement are sufficient to provide the necessary balance between access to medicine and patent protection.[50] However, it is quite clear that neither the TRIPS nor the Doha Declaration managed successfully to facilitate the balance required between IP law and access to medicines. Essentially, what the TRIPS Agreement achieved was to introduce a 20-year patent protection worldwide, however it failed manifestly to boost R&D in pharmaceuticals to satisfy the needs of developing countries. Furthermore, the risks that the state issuing compulsory licenses exposes itself to, political and economical, economical in the sense that the issuing country will have trouble attracting foreign investments, it might be necessary to rethink the flexibilities of the TRIPS Agreement and instead focus on other solutions not strictly related to patents.

The recent Novartis decision can be seen as a victory for the Indian drug industry, but it might also be seen as a victory for the right to health and access to medicines, since the pharmaceutical company was denied a patent allowing a much cheaper generic medicine to be sold for cancer patients. What will be the consequences of this judgment then? Most likely it will have a devastating affect on foreign investments in India, and the judgment has already been described as a stunning defeat for IP rights in India.

However, the decision might also be leading a world where judicial decisions from countries such as China, India and Brazil have an increasing global reach and can contribute to shaping global approaches to IP. The decision may also bring focus on the growing role played by the judiciary in developing countries in the implementation of international IP rules, such as the TRIPS Agreement and the Doha Declaration, which both affirm that the Agreement can and should be interpreted and implemented in a way consistent with the right to protect public health, and, in particular, to promote access to medicines for all. The growing role of the judiciary on IP matters in developing countries could also bring changes to the extent these countries are willing to go beyond the minimum standards that are contained in TRIPS.[51]

[50] Ibid p.169- 170

[51] Abdel Latif, Ahmed, *The Novartis Decision: A Tale of Developing Countries, IP and The Role Of The Judiciary,* published on 15 April 2013, also available at http://www.ip-watch.org/ as accessed on 16 April 2013

4. Neglected Diseases and the Lack of Incentive

4.1 The Concept of Neglected Diseases

The term "neglected diseases" refers to diseases that continue to burden the poorest of the poor. They have by the WHO been defined as those diseases primarily affecting those living in poverty, especially in rural areas in low-income countries and they include diseases such as river blindness, leprosy, African sleeping sickness and dengue. In recent years HIV/AIDS, tuberculosis and malaria are also being regarded as neglected diseases.[52]

Neglected diseases can further be divided into three main categories: Type I diseases are found in both rich and poor countries and affect large numbers of vulnerable populations in both. Examples of type I diseases are measles, hepatitis B, cardiovascular diseases, diabetes and tobacco-related illnesses. Type II diseases can be found in both rich and poor countries, but a substantial proportion of cases, over 90%, occurs in poor countries. Examples of such diseases include HIV/AIDS and tuberculosis. Type III diseases are those that are overwhelmingly or exclusively incident in developing countries. Examples of such diseases include African sleeping sickness and African river blindness.[53]

Neglected diseases are both a cause and consequence of human rights violations. The unavailability of medical technologies to effectively address these neglected diseases is one of the major problems associated with tackling this human health tragedy. The situation has been characterized by a chronic lack of investment in R&D to find effective treatments for neglected diseases. An R&D system exclusively based on IP does not generate sufficient economic incentives for pharmaceutical companies to develop medicines needed predominantly in poor countries. Today, funding for R&D for these diseases comes predominantly from the public sector.[54]

4.2 Overcoming the Market Failure: the Challenge of Neglected Diseases

The debate on access to medicines has so far been centered on the claim that patents held by pharmaceutical companies are a significant contributor to

[52] UN Special Rapporteur Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicine: The sexual and reproductive health context,* (2008) p.14
[53] WTO, WIPO and WHO, *Promoting access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade* (2013) p. 115
[54] Ibid p.116

the miserable health outcomes experienced by people in the poorest parts of the world. This claim is based on the premise that pharmaceutical companies use their patents to withhold drugs from poorer people in order to maximize their profits. However, this premise is not completely true, seeing that 95 % of the WHO´s essential drugs have never been or are no longer patented and most AIDS, malaria and tuberculosis medications is not patented in the countries that are hardest hit. Pharmaceutical companies need to patent drugs where there are manufacturing capacity in order to prevent others from manufacturing the drugs without consent; many developing countries lack the capacity to manufacture.[55]

Patent protection means little when there is no significant market at the end of the process, which results in grossly underfinanced R&D where it is needed the most. To put it roughly: poor countries benefit from R&D mainly when the rich also suffers from the same diseases.[56] A new drug will therefore remain unavailable for a majority of the world´s population that resides in developing countries and least developing countries, creating a "10/90 gap", meaning that only 10% of the global health research is devoted to conditions that account for 90% of the global disease burden.[57] The current situation can be illustrated by numbers that make it even clearer: The UNDP has stated that only 0.2% of the global health-related R&D goes to pneumonia, diarrheal diseases and tuberculosis which account for 18% of the global disease burden.[58]The global disease burden is defined by measures using a disability-adjusted life year, which combines years of life lost due to premature mortality, and years of life lost due to time lived in states of less than full health.[59]

There are mainly three barriers that hinder progress in developing new medicines. First of all it is *insufficient financing*, meaning that R&D for neglected diseases receives only $1 out of every $100,000 spent worldwide on biomedical research and product development, and only 16% of funding for product development partnerships is provided by governments of rich countries. Secondly, it is the *lack of bold and creative thinking about incentive mechanisms*, new mechanisms such as product-development partnerships and orphan drug programs, should be applauded for their support to crucial R&D and are evidence of an openness to new ideas. Thirdly, it is the *absence of coordination concerning R&D,* since without coordination within and between countries, resources are used less efficiently and important needs are being neglected.[60]

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[55] Hestermeyer, Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (2008) p.150
[56] Ibid p.152
[57] Helfer, Laurence and Austin, Graeme W. *Human Rights and Intellectual Property: mapping the Global Interface* (2011) p. 140
[58] Hestermeyer, Holger, *Human Rights and the WTO: The Case of Patents and Access to Medicine* (2008) p.162
[59] http://www.who.int/topics/global_burden_of_disease/en/ (as accessed on 9 April 2013)
[60] Oxfam Briefing Paper, *Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation,* Oxfam International (2008) p. 2

4.3 Incentivizing the Search for New Drugs

The exclusive reliance on patent monopolies as the only mechanism for innovation remains a major barrier to R&D for neglected diseases. However, there are new approaches under discussion that improve knowledge sharing and follow-on innovation, or which are dedicated to avoid the reliance on patent-based monopolies as an incentive mechanism for private firms. These incentives involve a diverse group of actors and a large number of collaborative partnerships that are working to address the lack of medical innovation for neglected diseases. While many proposals are under discussion, various new measures are already being applied.

4.3.1 Patent Pools and Prize Funds

One such mechanism under consideration at the WHO Global Strategy is the use of patent pools. A patent pool is an agreement between two or more parties to license one or more of their patent to a collective "pool" which then can be used by any third party. The use of patent pools have many benefits, first of all it enables collective management of IP for use by third parties for a licensing fee, it facilitates follow-on innovation for appropriate formulations and "fixed-dose" combinations, as well as reducing medicine prices through generic competition. A patent pool overcomes the hurdle of patents that prevents researchers from sharing and using knowledge to develop new clues for vaccines or medicines; in addition it can improve access to existing medicines.[61]

The use of prize funds is another mechanism that is designed to expand incentives for R&D beyond those that support the existing system of IP ownership. The system offers innovators a cash prize that reflects the contribution of a product aimed to public health. Prizes are particularly effective for promoting access since they do not require that the expenditures of R&D to be recouped through excessive medicine prices. Prizes constitute an innovative "pull" mechanism that is aimed to overcome the link of innovation and drug prices. Inventors are offered a cash prize that reflects the product´s contribution to public health. While prizes enable an inventor to maintain a patent, it also requires the recipient of a prize to surrender the monopoly rights in exchange for the reward, consequently ensuring generic competition, which will lead price reductions. The use of prize funds can also stimulate follow-on innovation since prizewinners are asked to place their scientific knowledge in the public domain.[62]

In addition to incentives, building a scientific capacity of the developing world could potentially lower the costs of drug development, create new centers of innovation, broaden the range of diseases targeted by

[61] Oxfam Briefing Paper, *Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation,* Oxfam International (2008) p. 21
[62] Ibid

pharmaceutical R&D, and finally ensure that R&D costs are shared more equitable between all countries. The development of local and regional manufacturing, clinical-trials capacity and scientific expertise would eventually repay the investment.[63]

4.3.2 The TRIPS Solution

The classic solution for the market failure of lack of pharmaceutical R&D is enshrined in the TRIPS agreement, which is simply patent protection for 20 years. The ability to exclude competitors from copying and selling newly invented drugs during that period the patent holder will be able to sell it at a profit-maximizing monopoly price well above the marginal cost of production. Through this, the patent holder can recoup his research and overhead expenses as well as some of the cost of other research efforts that failed to bear fruit.

This solution corrects the market failure of undersupply of medical innovation, however its monopoly features create another. During the patent´s duration the monopoly pricing will cause a barrier to access the medicine because of its excessively high prices.

4.3.3 The Differential- Pricing Strategy

The differential-pricing strategy comes in different variants. One version is to have the inventor firms themselves offer their propriety drugs to different customers at different prices (positive price- discrimination) and in that way realizing a large profit margin from sales to the more affluent without having to renounce sales to poorer buyers at a lower margin. Another version is the state government's right to issue compulsory licenses under the TRIPS Agreement.

In order for the differential- pricing strategy to be successful, different categories of buyers must be prevented from knowing about the prices for other categories. If a drug would be sold at a lower price to some, then many buyers who are willing and able to pay the higher price will find a way to buy at a lower price. This would create an incentive to divert, and instead smuggle drugs sold cheaper back into more affluent countries leading to great losses.[64] The knowledge of this has led to many pharmaceutical companies shying away from adopting differential-pricing methods, resulting in the exclusion of poor people who are willing and able to pay a price above the marginal cost of the drugs, but who cannot afford the much higher monopoly price. Such exclusions are accepted for other IP rights, however it is morally problematic regarding essential drugs.

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[63] Oxfam Briefing Paper, *Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation,* Oxfam International (2008) p. 3

[64] Pogge, Thomas, *Human Rights and Global Health: a research Program,* vol. 36 (2005) p. 187

4.3.4 The Public Goods Strategy

The public goods reform strategy is based on the idea that the results of any successful effort to develop a new essential drug are to be provided as a public good that all pharmaceutical companies may use free of charge. This reform would eliminate the market failure associated with high monopoly pricing by allowing competition to bring prices of new essential drugs down close to their marginal cost of production. In order for this reform to be successful it is necessary for it to be global in scope, because implemented in only a few countries this reform strategy would suffer the same problems as the ones associated with the differential- pricing strategy, that is; cheaper drugs produced in countries adhering the public goods strategy will seep back into countries adhering to the monopoly- patent regime.[65]

Another feature of the reform strategy is that inventor firms should be rewarded for their patent of essential drugs (during the life of the patent) out of public funds, in proportion to the impact on their invention on the global disease burden. This will lead to a massive shifting in incentive in a highly desirable way, since disease which have a great impact on the global disease burden, such as neglected diseases, will suddenly be highly attractive to treat.[66]

The downside of this strategy lies with the issue of classification. This can be exemplified by the concept of "drug cocktails" that combine various drugs that frequently have been developed by different companies. To make it work, the reform strategy must formulate clear and transparent rules for distributing the overall reward, based on the impact of the drug cocktail, among the inventors of the drug it contains.[67]

Effective implementation of this strategy would require that most of its costs to be borne by the industrialized countries, not an overall heavy burden considering that 16 % of the world´s population control about 81 % of the global social product. The taxpayers must however be given compelling reasons as to why to support it, since they are the ones paying. The benefits of this reform strategy, would it be implemented, are many. For starters, taxpayers of the more affluent countries will gain considerable benefits for themselves in form of lower drug prices, since under the current regime affluent persons in need of essential drugs pay high prices for them, either directly or through their contributions to insurance companies. The public goods regime would benefit less-healthy citizens at the expense of the healthier ones. The fair distribution of the effects of luck is morally appealing, since fortunate persons can have the peace of mind knowing that they would have access to cutting- edge medical knowledge would they ever

[65] Pogge, Thomas, *Human Rights and Global Health: a research Program,* vol. 36 (2005) p. 187
[66] Ibid
[67] Ibid p. 192

need it.[68] Secondly, the idea of allowing poor people to free-ride on the pharmaceutical research conducted for the benefit of citizens in the affluent countries is morally compelling. Thirdly, leaving the moral aspect, the reform would actually create top-notch medical- research jobs in the industrialized countries. It would enable the developed countries to respond better to future public-health emergencies by increasing and having a more diversified arsenal of medical knowledge. In addition, better human health around the world would reduce the risk of invasive diseases transiting from poor countries in to the developed countries, such as the SARS and swine flue outbreak. The current neglect of the medical needs of the poor populations leaves the developed countries unprepared to deal with such problems when suddenly confronted with them.[69]

4.3.5 The R&D Treaty

The current system for R&D of new medicines does not adequately meet the needs of the majority of the world´s population. The idea of a binding international convention on R&D has been debated since at least 2004, and in April 2012 the WHO Consultative Expert Working Group on R&D recommended that governments begin to negotiate over a global medical R&D convention to address some of the problems caused by lack of incentive in a systemic way. The aim of the proposal is to create a new global framework for supporting priority medical R&D, based on the fair and equitable sharing of costs, access to benefits of R&D, and incentives to invest in needs- driven R&D consistent with human rights and with the goal of all sharing in the benefits of scientific advancement.[70]

The shortcoming of the current regime is that patents are today used as a method to drive investments into medicine R&D. Prior to the TRIPS Agreement, there was a great variation amongst countries in the types of length of the patent life, on average industrialized countries granted longer patent protection (15-17 years) while developing countries offered shorter patent protection (5-10 years) and many countries made special exceptions for food, medicines and agricultural technologies. As a result of the implementation of the TRIPS Agreement this regime changed dramatically, and medical patents must now be granted a 20-year protection in most WTO member states.[71]

An R&D Treaty could complement and build on existing initiatives, but needs to address four areas that remain particularly weak, namely: affordability, sustainable financing, efficiency and equitable governance.

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[68] Pogge, Thomas, *Human Rights and Global Health: a research Program,* vol. 36 (2005) p. 192-193
[69] Ibid, p. 193
[70] WTO, WIPO and WHO, *Promoting access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade* (2013) p. 119
[71] Moon, Suerie and others, *Innovation and Access to Medicines for Neglected Populations: Could a Treaty Address a Broken Pharmaceutical R&D System?* PLoS Medicine, Vol. 9 Issue 5 (2012) p. 1

Affordability: Currently there exists no system that ensures that new medicines will be affordable to the majority of people who need them. A treaty could therefore include measures to ensure affordability, such as new incentive mechanisms that incorporate the principle of de-linkage, meaning that pharmaceutical companies can include licensing through the medicines patent pools or the use treaty-generated funds to reward a prize to a successful drug-developer, both measures will allow competitive generic production of drugs.[72]

Sustainable finance: Currently there are no mechanisms to ensure sufficient predictable financing for R&D to meet the health need in developing- and least developing countries. Donor governments and non-profit entities, such as the Gates Foundation, have indeed invested significantly into neglected diseases; as a result 140 products have been developed for the combat of neglected diseases. An R&D Treaty could include binding obligations on governments to contribute to R&D and thereby addressing the free-rider problem while at the same time establishing an equitable burden-sharing arrangement.

Efficiency in innovation: There is considerable room for the improvement of the efficiency innovation process. For instance, by impeding the free flow of information, IP rights can impede the gathering of common knowledge that drives scientific progress forward. A treaty could therefore establish rules that would improve efficiency in innovation and could do so by global norms regarding research priorities and transparency in investment decisions. A treaty could further establish rules that would foster creativity such as incentives for faster global knowledge sharing.

Equitable health-focused governance: Today, it is market incentives, and sadly not health needs, that drives private R&D investments. A treaty could here establish rules on governance arrangements to ensure that public interest drives innovation, instead of market-generated profits. As an example, treaty rules could structure financial rewards for innovation so that they are equal with a medicine´s health benefit.[73]

Finally, a global health and pharmaceutical R&D treaty would elaborate on a framework for drug pricing within PPP initiatives that would ensure a realistic and leaner pricing regime that focuses on a PPP model rather than to a direct market regime.[74]

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[72] Moon, Suerie and others, *Innovation and Access to Medicines for Neglected Populations: Could a Treaty Address a Broken Pharmaceutical R&D System?* PLoS Medicine, Vol. 9 Issue 5 (2012) p. 2

[73] Ibid p. 3

[74] Oguamanam, Chidi, *Patents and Pharmaceutical R&D: Consolidating Private-Public Partnership Approach to Global Public Health Crises,* (2010) p. 572

4.3.6 Public- Private Partnerships

The concept of PPPs is usually used to describe collaboration between a government and at least one private-sector company. The collaboration is sometimes also referred to as product-development partnerships. Today, such partnerships manage a large proportion of all neglected diseases drug development projects worldwide. PPPs are characterized by the fact that they: integrate public-sector and private-sector approaches by generally using industry practices in their R&D activities, manage neglected diseases R&D portfolios and targets at least one neglected disease, are created for the purpose of pursuing public health objectives rather than commercial gains, as well as providing funding to cover existing research gaps and finally they ensure that the developed products are affordable.[75]

The advantages that PPPs have is that they are able to complete the entire cycle of R&D at a far lower cost that the pharmaceutical industry working alone, and they can do so in a more transparent manner. Also, as non-profit entities, PPPs can take the matter of access into account. Non-patented products will encourage generic competition and lead to price reductions.[76]

Due to the emergence of PPPs over the last 15 years there has been a major development in efforts to focus R&D towards neglected diseases. These partnerships have significantly increased the number of products in development for neglected diseases and they play an important role in identifying pathways to new research for these diseases.

4.3.6.1 The Gates Foundation

The Gates foundation is a perfect example of a successful PPP that have lead to significant improvement in access to medicines in developing countries. The innovative partnership between the government of Botswana, the Bill & Melinda Gates Foundation and Merck, managed for the first time in Africa to present a successful national effort to treat those living with HIV, to slow the transmission of the virus and to minimize the impact of the epidemic. The numbers of the new collaboration speak clearly as more than 50% of those who can benefit from ARVs, and 85% of those with advanced HIV infection, are now receiving lifesaving drugs. These are the highest rates in Africa.

The main reason for the success story of Botswana was that the country had a relatively well-developed health care system and a political stability, supported by a President who was personally committed to the cause. Before the partnership, Botswana had one of the world´s highest rates of HIV infection; 33% among people aged 15-49. When researchers estimated in 2001 that half of all women in Botswana would die in AIDS in their 20s,

[75] WTO, WIPO and WHO, *Promoting access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade* (2013) p. 120
[76] Oxfam Briefing Paper, *Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation,* Oxfam International (2008) p. 14

the President of Botswana claimed that his country was "threatened with extinction".[77]

The wisdom gained by the collaborative PPP in Botswana is that it is difficult, yet possible, to scale up a national ARV program and save lives, despite what the critics say. Working closely with a national government can sometimes slow down a project; however, working directly with the government enables a collaboration to build up a nation with its own capacity.

4.3.6.2 WIPO Re:Search

In October 2011 WIPO started a collaboration between public-sector and private-sector researchers and BIO Ventures for Global Health was started, that launched a new consortium called WIPO Re:Search. With WIPO Re:Search, public-sector and private-sector organizations can share IP and expertise with the global health research community in order to promote development of new medicines, vaccines and diagnostics to treat neglected diseases. Trough an innovative model, selected IP assets are available under royalty-free licenses to researchers anywhere in the world. The WIPO Re:Search aims to foster collaborations to advance and stimulate R&D for medicines, vaccines, and diagnostics for neglected diseases and the resources are aimed at facilitating new partnerships.

In addition to pharmaceutical companies, members of WIPO Re:Search include universities and research centers from all over the world. Of particular importance are the research centers in Africa whose participation is an important component to the development of new and better treatments for neglected diseases. The products come to market will in turn be royalty-free in all least developed countries, and royalties will be subject to negotiations for developing countries.

WIPO Re:Search is grounded in voluntary agreements and operates on the basis of voluntary licenses. It is based on the belief that IP and knowledge can be used creatively to stimulate more investment in R&D for new health solutions while ensuring access for the most disadvantaged population. By October 2012, WIPO Re:Search had 62 members and had facilitated 11 research collaborations or agreements between WIPO Re:Search and members.[78]

The main tools that the WIPO Re:Search has developed will guarantee transparency and accessibility of information and facilitate collaboration and cross-sector partnerships. Its Public database contains IP assets that different providers have chosen to make available and accessed without registration.

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[77] Bill & Melinda Gates Foundation, *Working with Botswana to confront its devastating AIDS crisis* (2006) p. 2, available at http://www.gatesfoundation.org/whatwerelearning

[78] WTO, WIPO and WHO, *Promoting access to Medical Technologies and Innovation Intersections between public health, intellectual property and trade* (2013) p. 123

4.3.7 Orphan Drug Schemes and Tax Credits

Orphan Drug schemes are used in the USA and EU and offers additional market exclusivity and financial benefits for new medicines for neglected diseases, or for diseases that affect relatively few people in the country that awards the benefit. The credits reward a manufacturer with tax benefits and an extended patent term. However, an issue is that extended market exclusivity under an Orphan Drug scheme may lead to abuses of the monopoly position in terms of unaffordable prices.

Tax credits are often provided as a part of a package of benefits within the Orphan Drug scheme. For instance, in the USA, a tax credit is provided for 50% of the cost of clinical trials that are conducted for R&D for rare diseases. Some countries have introduced additional tax credits in order to boost R&D on specific diseases that are for the time viewed as ”priority” diseases for developing countries. An example is the United Kingdom, which has an existing program that provides tax credits for R&D for HIV/AIDS, tuberculosis and malaria.[79]

These schemes provide important private incentives in order to encourage new pharmaceutical R&D. However, it is unlikely that they will function effectively on their own to create incentives for neglected diseases. The WHO noted that the Orphan Drug schemes are insufficient to stimulate sufficient innovation for neglected diseases, since the extended market exclusivity does not take into account the absence of a market in the developed country. Tax credits on the other hand, function effectively as an incentive only where there are anticipated profits. Consequently, in order to ensure that tax credits function effectively, countries could consider designing credits that work together with other incentive schemes, such as credits that target contributions made by pharmaceutical companies to PPPs. These could then work across countries to build incentives to encourage private-sector research.

4.4 Concluding Comments

It is undisputed that more public financing for drug development for neglected diseases is needed, and this should be an obligation of both rich and poor countries. The different solutions presented above all have different strengths and weaknesses, some more clear and others still remain to be discovered. None of the solutions are perfect, nor do they solve the market failure completely, however, they do offer a major improvement of the situation of today.

For instance, the differential pricing strategy is an example of a measure that has already been adopted and several pharmaceutical companies have applied differential pricing to medicines for neglected diseases and for

[79] Oxfam Briefing Paper, *Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation,* Oxfam International (2008) p. 17

products that the WHO regards as essential.[80]This has lead to an improvement for developing countries to access essential medicines, since the positive price discrimination has allowed poorer countries to acquire the drug without the pharmaceutical companies having to renounce their profit.

However, existing R&D mechanisms supported by developed countries remains severely under-funded. Public financing for R&D requires inputs both to ”push” and to ”pull”. Push financing means paying for basic scientific research that is translated into new medicine, or directly paying costs associated with bringing a medicine to the market, such as the usage of prize funds. Pull financing involves creating financial or market incentives for the private sector, or a public-private entity. The development of PPPs is a method of pull financing.

Over the past decade, numerous PPPs have been launched to develop new medicines and vaccines, through a combination of resources from the public sector, philanthropy, and the pharmaceutical industry. While PPPs have certain problems that limit their effectiveness, they should be supported as one approach to generate R&D for neglected diseases. However, rich countries provide only 16% of funding for PPPs and philanthropic foundations provide the rest. For instance, the Gates Foundation provided 79% of the overall financing for the PPP in Botswana. Some countries, such as Germany, have given no money whatsoever, while the European Commission, as the primary funding source on behalf of the entire EU, has provided little support.[81]

PPPs have been praised as the ideal solution to the lack of medicines for neglected diseases since they have proved effective in promoting and initiating considerable R&D activity. However, it is essential that funding is to be provided from other sources, and not primarily relied on philanthropically oriented foundations. This is where a potential R&D Treaty can step in and play a major role for the funding of PPPs or for pharmaceutical R&D in general. If a future R&D Treaty would be successfully implemented, then it would meaningfully overcome the market failure of neglected diseases.

[80] Leisinger, Klaus, *Corporate Responsibilities for Access to Medicines,* Journal of Business Ethics (2008) p. 17
[81] Oxfam Briefing Paper, *Ending the R&D Crisis in Public Health: Promoting pro-poor medical innovation,* Oxfam International (2008) p. 9

5. Voluntary Mechanisms

5.1 A wolf in sheep's clothing?

As already stated in chapter 2, there is no legally enforceable obligation under international human rights law for MNEs, including pharmaceutical companies, to ensure the protection and realization of human rights. The human rights responsibilities referred to in paragraph 42 of the CESCR General Comment No. 14 claim that all actors of society have a responsibility regarding the realization of the right to health. However, the same paragraph affirms that it is only states that can ultimately be held accountable, leaving the effectiveness of the claim to be a matter of discussion. Also, the nature and content of MNEs responsibilities is not defined any further in the Comment. Furthermore, a distinction must be made between on the one hand MNEs human rights responsibility to avoid infringing the human rights of others, and on the other a positive obligation to ensure access to medicines, which would require that private firms are to actively pursue and realize human rights. These are two different actions and must be treated as such.

In order to improve corporate behavior and align it with international human rights law, focus must be turned to voluntary mechanisms that have been designed to promote good practice for businesses.

Voluntary mechanisms serve a variety of purposes, to the extent that they are in conformity with market-based incentives, voluntary mechanisms may be effective in guiding corporate behavior. Voluntary guidelines formulated by multilateral institutions, including the UN, may operate as soft law and promote increased human rights accountability. Such mechanisms are an improvement of self-imposed codes to the extent that they align with the international human rights regime and are more comprehensive in scope than self-imposed codes of conduct. Soft law may also serve as a stepping-stone toward more concrete legal obligations or hard law.[82]

Being "only" soft law, the question of interest is whether these voluntary measures really can influence the behavior of MNE´s, or if they only pose as a wolf in sheep´s clothing?

5.2 The UN Global Compact

In an attempt to promote greater corporate accountability for human rights violations the UN Secretary-General Kofi Annan proposed in 1999 the Global Compact, which is a voluntary initiative that requires companies to

[82] Grover, Anand and others, *Pharmaceutical Companies and Global lack of Access to Medicines: Strengthening Accountability under the Right to Health,* Journal of Law, Medicine & Ethics (2012) p. 241

commit themselves to ten principles relating to human rights, protection of the environment and labor law. The Secretary-General initiated the initiative in an attempt to codify CSR. According to the two human right principles, businesses should support and respect the protection of internationally proclaimed human rights and make sure that they are not complicit in human rights abuses.

It is a simple procedure to become a member of the Global Compact, which has led to approximately 7,000 businesses being currently members of the Compact. The Global Compact has generated a lot of criticism mostly from NGOs claiming that the UN´s positive image is made vulnerable to being sullied by corporate criminals, while companies get a chance to "blue-wash" their image by wrapping themselves in the flag of the UN.[83] The Compact does not have a method of enforcement and the only penalty for a corporation not abiding the ten principles is simply exclusion from the Compact.

However, the Global Compact was never intended to be a regulatory arrangement, even less a legally binding code of conduct. The critics therefore wish it to be something that it is not, since the Global Compact never claimed to be anything else than a learning platform intended to promote good practice.

5.3 Protect, Respect and Remedy Framework

Globalization has contributed to the increasingly central role of MNEs in domestic and international economic orders. The world´s 300 largest companies account for 25% of the world´s total productive assets. MNEs also hold 90% of all technology and products patents worldwide and are involved in 70% of world trade. These companies have therefore greater economic power over markets than do states in the international trade era.[84] In some instances, the profits of large MNEs have outgrown the GDP of many states. For instance, in 2010 the revenues of Pfizer, the world's largest pharmaceutical company, were larger than the GDP of approximately two-thirds of the countries in the world.[85]

It is quite apparent that the nature and scope of pharmaceutical companies´ human rights responsibilities in relation to access to medicines are not crystal clear. However, it has been confirmed by the CESCR that the private

[83] Bruno, Kenny and Karliner, Joshua, *Tangled up in Blue: Corporate Partnerships at the United Nations*, Transnational Resource and Action center (2000) p.2
[84] Wu, Chuan- Feng, *Transnational Pharmaceutical corporations´ legal and moral human rights responsibilities in relation to access to medicines,* Asian Journal of WTO and International Health Law and Policy (2012) p. 85
[85] Grover, Anand and others, Pharmaceutical Companies and Global lack of Access to Medicines: *Strengthening Accountability under the Right to Health,* Journal of Law, Medicine & Ethics (2012) p. 238

business sector has in fact responsibilities regarding the realization of the right to health, but it has not taken any further steps to specify these responsibilities. In an attempt to do so, the UN Special Representative of the Secretary-General, John Ruggie, developed a policy framework for business and human rights, and called it the "Protect, Respect and Remedy Framework".

The Framework rests on differentiated but complementary responsibilities and comprises three core principles, namely: the State duty to protect against human rights abuses by third parties, including businesses; the corporate responsibility to respect human rights; and the need for more effective access to remedy.[86]The second pillar is the corporate responsibility to respect. What it essentially clarifies is that the corporate responsibility to respect human rights means that corporations should avoid infringing on the human rights of others, to put it simply: to do no harm.[87]

A company has to become aware of, prevent and address human rights impact and it can do so through four steps: adopt a human rights policy; conduct human rights impact assessment; integrate human rights policies throughout the company; and track performance. Essentially it means that the company has to perform a due diligence throughout the entire life of the project in order to acquire knowledge about human rights impacts and to act upon that information. According to the Framework, MNEs should address adverse human rights impacts with which they are involved.[88]

5.4 The Human Rights Guidelines for Pharmaceutical Companies

Whereas the Protect, Respect and Remedy Framework and the UN Global Compact are general human rights standards for all business entities, the Human Rights Guidelines for Pharmaceutical Companies in relation to access to medicines[89] drafted by former UN Special Rapporteur Paul Hunt, identify with greater care the responsibilities of pharmaceutical companies in relation to access to medicines.[90]

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[86] Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, Human Rights Council, 7 April 2008, paragraph 9

[87] Ibid paragraph 54-55

[88] Mares, Radu, *A gap in the Corporate Responsibility to Respect Human Rights,* Monash University Law Review, Vol. 36, No 3 (2009) p. 41

[89] United Nations Special Rapporteur Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicine: The sexual and reproductive health context,* Human Rights Center, University of Essex, published by UN General Assembly in A/63/263, dated 11 August 2008

[90] Hunt, Paul and Joo-Young Lee, *Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines,* Journal of Law, Medicine and Ethics (2012) p. 224

The human rights responsibilities for pharmaceutical companies are of course not identical to those obligations of states, such a duty cannot fall upon a private entity. Nonetheless, the Guidelines provide a useful tool for clarifying the right-to-health responsibilities of corporations.[91] The aim of the Guidelines is to provide practical, constructive and specific guidance to pharmaceutical companies and other interested parties. The language used throughout the Guidelines is deliberately set to "should" instead of "must" in order to avoid the controversial doctrinal question "*Are businesses legally bound by international human rights la*w?"

While the Guidelines recognize that companies have a responsibility to enhance shareholder value, it states that companies also have a human rights responsibility to extend access to medicines for all, even to the disadvantaged poor people. In this context, pricing has a critical role to play. According to the Guidelines, lower prices do not necessarily mean lower profits. Sometime the goal to enhancing access to medicines coincides with commercial interests. For instance, there are numerous arrangements that may reduce prices and increase sales, and since the lives and health of millions are at stake, companies must approach such arrangements with urgency and boldness.[92]Pharmaceutical companies are therefore required to do all they reasonably can to ensure that medicines are available in sufficient quantities in the countries where they are needed. They can therefore not arbitrarily withhold supply of medicines over which they have a patent, or manufacture, from a particular country or group of people.

In order to combat neglected diseases, the Guidelines require that a company should make a public commitment to contribute R&D for these kinds of diseases. The company should also either provide in-house R&D or support external R&D for neglected diseases. In addition, the company should consult with the WHO and other relevant organizations with the aim of enhancing its contribution to R&D for neglected diseases. Since R&D has given insufficient attention to neglected diseases, it is important to provide an incentive for companies to invest R&D, in order for the IP regime to make a major contribution to the discovery of new medicines and to potentially save lives. In that context the Guidelines demand that all companies provide in-house R&D for neglected diseases, since the right to the highest attainable standard of health not only requires that existing medicines are accessible, but also that essential new medicines are developed as soon as possible.[93]

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

[92] United Nations Special Rapporteur Paul Hunt, *Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicine: The sexual and reproductive health context,* Human Rights Center, University of Essex, published by UN General Assembly in A/63/263, dated 11 August 2008, paragraph 33 and commentary

[93] Ibid paragraph 23-25

A pharmaceutical company that develops a life-saving medicine places an important responsibility on the patent-holder, due to its critical social function. Having developed a life-saving medicine, the company has an additional human rights responsibility to take all reasonable steps to make the medicine as accessible as possible, as soon as possible, to all those in need. Patent-holding pharmaceutical companies have a responsibility to ensure that their policies and practices do not negatively impact access to life-saving medicines. According to the Protect, Respect and Remedy Framework a company is required to "*avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved"*. In order to meet this responsibility, companies should place policies and processes, including a policy commitment to meet their responsibility to respect human rights, human rights due diligence, and a process to enable the "remediation" of any adverse human rights impact they cause to which they contribute. This responsibility applies to patent-holding pharmaceutical companies.[94]

The conclusion of the Special Rapporteur is that the status of innovator companies would be immensely enhanced if they would not treat their patents as their "crown jewels", but instead choose to publicly recognize their critically important social function and right- to-health responsibilities. They must prevent or address negative impacts of their pricing and licensing policies on access to medicines, and must do everything possible within their sphere of influence to fulfill their human rights responsibilities. Presently, this is not happening.[95]

5.5 Concluding Comments

One must not neglect the importance of soft law in an area of law where legally binding acts remain unavailable. Just because soft law is not legally enforceable, does not mean that they do not have any legal importance. The Protect, Respect and Remedy Framework presented by UN Special Representative John Ruggie rely on soft law to draw its legitimacy for the responsibility to respect doctrine. Both the OECD Guidelines and the ILO Tripartite Declaration states that companies should respect the human rights of those affected by their activities. Essentially, the Special Representative implies that the responsibility to respect as stated in the Framework, has acquired a near-universal recognition and has been with us long enough to be accepted as legitimate.[96]Although unanimously endorsed by the UN when presented in 2008, the Framework received its share of criticism; especially from NGOs claiming that the Framework is silent on the point of accountability and that is has no legal effect. However, the Framework

[94] Hunt, Paul and Joo-Young Lee, *Human Rights Responsibilities of Pharmaceutical Companies in Relation to Access to Medicines,* Journal of Law, Medicine and Ethics (2012) p. 228
[95] Ibid p. 231
[96] Mares, Radu, *A gap in the Corporate Responsibility to Respect Human Rights,* Monash University Law Review, Vol. 36, No 3 (2009) p. 36

deliberately kept the language to "should" in order not to make the same mistake as the predecessor UN Norms[97], which failed miserably since it placed the same responsibility on MNEs as on states.

Unfortunately, the Human Rights Guidelines for Pharmaceutical Companies suffer from the same weakness as both self-imposed codes of conducts and external voluntary mechanisms as they do not go far enough towards establishing any direct legal obligations for pharmaceutical companies under the right to health. The preamble of the Guidelines refers to the Special Representative´s work and establishes that the "private business sector has human rights responsibilities" which is further refined in the text paragraph which states that "*pharmaceutical companies, including innovator, generic and biotechnology companies have human rights responsibilities in relation to access to medicines*". The nature and extent of theses responsibilities, however, is not clearly defined.

However, the Guidelines and Framework do represent an important contribution to the development of soft law addressing access to medicines under the right to health. Also, they provide a useful tool for clarifying the right-to-health responsibilities of corporations. But unfortunately, even if all the guidelines were to be adopted by pharmaceutical companies, they would simply take the form of self-imposed codes of conduct. Therefore, in a way, voluntary measures can be perceived as a wolf in sheep´s clothing, since they portray an image of binding regulatory acts, but when it comes to establishing an effective accountability mechanism by which to regulate the behavior of pharmaceutical companies, they fall short.

[97]Norms on the responsibilities of transnational corporations and other business enterprises with regard to human rights, adopted by the Sub-Commission on the Promotion and Protection of Human Rights at its 22nd meeting on August 13, 2003, UN Doc. E/CN.4/Sub.2/2003/12/Rev.2, August 26, 2003

6. Corporate Social Responsibility

6.1 Sources of CSR

Self-imposed codes of conduct, including CSR initiatives, declaration principles, human rights guidelines and other voluntary mechanisms have all emerged to address the human rights impact of MNEs and the corresponding lack of accountability. As a result of external pressure, mainly from costumers and civil society, MNEs have adopted a set of CSR measures meant to address human rights issues. Many of these measures fall under the umbrella of CSR movement, which can be broadly defined as "any attempt to get corporations to behave responsibly on a voluntary basis out of ethical or bottom-line considerations".[98]

The sources of CSR cannot be drawn from international or national law, inspiration is instead drawn from guidelines and frameworks that promote good practice. The most notable sources of CSR comes from the OECD – the OECD Guidelines for Multinational Enterprises that flesh out MNEs responsibility to "*respect the human rights of those affected by their activities consistent with the host government´s international obligations and commitments*". The already mentioned Respect, Protect and Remedy Framework and the elaborate Human Rights Guidelines for Pharmaceutical Companies are of course of great value for CSR inspiration. Other institutions are the ILOs Tripartite Declaration of Principles Concerning Multinational Enterprises and Social Policy. In addition to international institutions, MNEs have adopted their own code of conduct since they have an economic interest of bringing their practice into conformity with at least some essential human rights standards.[99]

6.2 The "Nice to have´s"

The role of a pharmaceutical company in a global economy is to make research, develop, and produce innovative medicines that make a difference to sick people´s quality of life and it is their duty to do so in a profitable way. No other societal actor assumes this responsibility. Many pharmaceutical corporations, however, perceive a moral obligation to do more, whenever possible, to help alleviate health problems of poor people

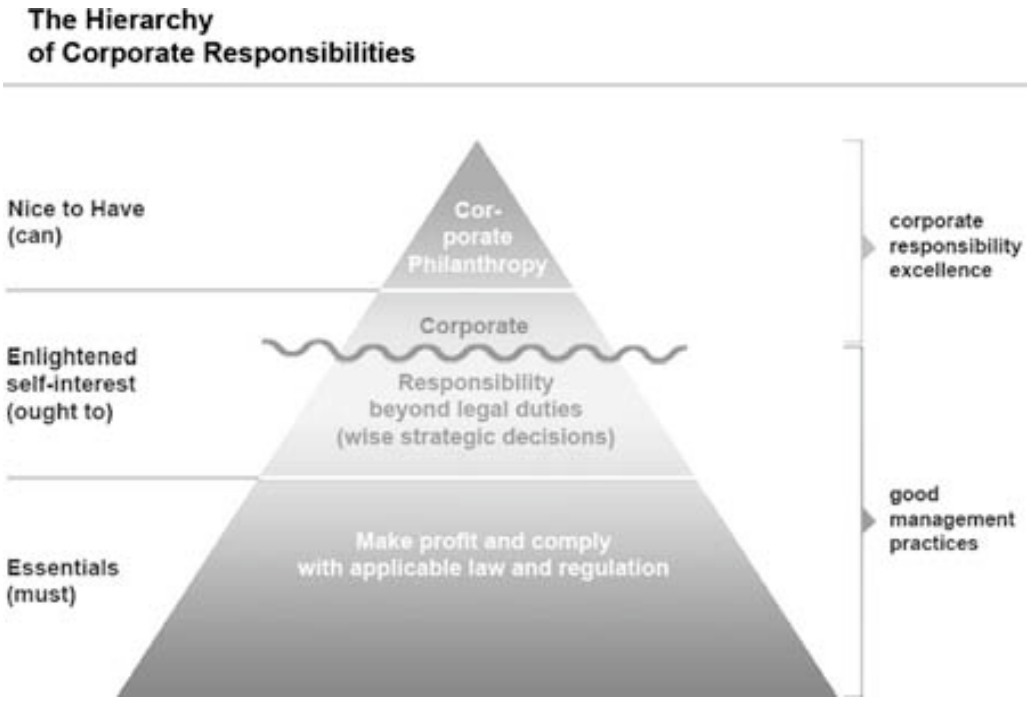
[98] Grover, Anand and others, Pharmaceutical Companies and Global lack of Access to Medicines: *Strengthening Accountability under the Right to Health,* Journal of Law, Medicine & Ethics (2012) p. 240

[99] Wu, Chuan- Feng, *Transnational Pharmaceutical corporations´ legal and moral human rights responsibilities in relation to access to medicines,* Asian Journal of WTO and International Health Law and Policy (2012) p.88

all over the globe. Such corporate actions are, however, of a voluntary nature and should remain so. The discrepancies between public expectations and the financial market-driven objectives of businesses have resulted in a "legitimacy gap" and a hostile attitude towards MNEs in general. To help establish priorities on any potential obligations with regards to human rights and corporate responsibilities in general, a hierarchy of responsibilities can be helpful.[100]

The following figure is intended to illustrate systematic analysis of corporate responsibility in regards to access to medicines.

Figure 1: Leisinger´s hierarchy pyramid of corporate responsibilities.



The model distinguishes between three degrees of corporate obligations. In the "must" dimension, there are the non-negotiable mandatory regulations on the respective industry. In the "ought" dimension, there are the good corporate responsibility standards which are particularly relevant in sensitive business areas or in countries where the qualities of law is insufficient or inadequately enforced. Finally in the "can" dimension, there are the voluntary measures of additional responsibility according to capacity.[101]

As for the "must" dimension, a fulfillment of a pharmaceutical company´s core responsibility is required and must be done in a legitimate way, that is, in compliance with all laws and regulations concerning healthy workplaces,

[100] Leisinger, Klaus, *Corporate Responsibilities for Access to Medicines,* Journal of Business Ethics (2008) p. 7
[101] Ibid p.13

environmental protection and the safety and efficiency of products and services. Also making part of the ‘‘must’’-dimension is the obligation to adhere to ethical principles and transparency concerning clinical trials, as laid down in the Declaration of Helsinki[102] and in the WHO Guidelines for good clinical practice for trials on pharmaceutical products.[103]

The “ought” to dimension is of particular importance where the quality of local legal norms is insufficient, then companies ought to apply higher standards such as fair labor conditions and wages that allow employees to lead a decent life and cover their basic needs. Leading pharmaceutical companies have established for their employees a comprehensive program of medical services that include free or heavily subsidized facilities for diagnosis or treatment and psychosocial care of workers with HIV/AIDS or other neglected diseases. Other actions for workers include free or heavily subsidized meals, nursery schools for single mothers, free training opportunities using company infrastructure and scholarships programs for the children of low-income employees. In regards to prices for life-saving medicines, responsible pharmaceutical companies are willing to adjust the price, on a case-by-case basis, for patients living in individual or collective poverty. Finally, most pharmaceutical companies provide donations in cases of acute emergency, for example the 2004 tsunami. This leads to the “can” dimension of corporate endeavors to protect, respect and fulfill the right to health.[104]

Business services in the “can” dimension mainly involves corporate philanthropy, as stated in figure 1, but can in modern terms of today be called CSR. They are defined as those expenditures beyond a company´s business activity and have no direct corporate advantages or any financially measurable reward. Corporate philanthropy, or CSR, belongs to the discretionary business responsibilities, which are purely voluntary guided only by business´ desire to engage in social activities that are not required by law. It is therefore simply something that is “nice to have” for a company, since it may have many benefits, but is far from compulsory.

6.3 A Portfolio of Good Practice

If a pharmaceutical company would be dedicated to the cause of improving access to medicines for people living in developing countries within their sphere of corporate philanthropy, there is a body of good practices in which pharmaceutical companies can adopt. It includes the following steps:

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[102] World Medical Association Declaration of Helsinki, *Ethical Principles for Medical Research Involving Human Subjects*, adopted by the 18th WMA General Assembly, Helsinki, Finland, June 1964, and final amendment in Seoul, 2008, available at: http://www.wma.net/en/30publications/10policies/b3/ (as accessed on 8 May 2013)
[103] Leisinger, Klaus, *Corporate Responsibilities for Access to Medicines,* Journal of Business Ethics (2008) p.13
[104] Ibid p.13

- Differential pricing to reduce tenders for selected drugs against poverty-related and neglected diseases for use in least- developed countries, particularly for drugs which are patent protected or exclusive.
- Donations for disease abolition programs or emergencies, adhering to WHO Guidelines for Drug Donations.
- R&D investments for neglected diseases.
- Support for broader health and development goals in developing countries.
- Works with stakeholders in countries where they operate to ensure that access to medicines initiatives are integrated correctly.
- Exploring opportunities for production in developing countries through wholly- owned subsidiaries and the use of voluntary licenses in order to increase sustainable access to essential medicines.[105]

This set of body would definitely elevate the company into corporate responsibility excellence, and place the company in the top of the pyramid of corporate responsibilities.

6.4 Can the Fox Guard the Henhouse?

It is easy to forget that a corporation is an artificial person, a legal creation, and cannot in itself be said to have any social responsibilities. The individuals who are to be responsible are businessmen, which means individual proprietors or corporate executives. A corporate executive can of course be either male or female, but for the sake of linguistic simplicity the term “he” and “his” will be used.

A corporate executive has a direct responsibility towards his employers. That responsibility is to conduct business in a way that is in conformity with their desires, which generally will be to make as much money as possible, while conforming to the basic rules of society, both those embodied in law and in ethical custom. To say that a corporate executive has a “social responsibility” in his capacity of a businessman is to say that he is to act in some way that is not in the interest of his employers. For instance, if he would to refrain from increasing price of the product in order to contribute to the social objective of preventing inflation, even though an increase of price would benefit the shareholders. Or if he would to spend money on reducing pollution, or another given cause, beyond the amount that is the best interest of the corporation, or if he would hire unemployed personnel instead of better qualified available employers to contributing to the social objective of reducing poverty. In each of these cases, the corporate executive would be spending someone else´s money for a general social

[105] Leisinger, Klaus, *Corporate Responsibilities for Access to Medicines,* Journal of Business Ethics (2008) p.17

interest. If his actions due to the "social responsibility" reduce returns to stockholders, he is spending their money. If his actions raise the price to customers, he is spending the customers' money. And finally if his actions lower the wages of some employees, he is spending their money.[106]

Adopting CSR measures within a company´s business conduct is not cheap. It requires a set of self-monitor, transparency and various donation programs. These expenditures go beyond what is necessary for the corporation, and can be seen as a cost without any return in monetary value. In addition, allowing a corporation to monitor itself and expecting it to penalize itself if found guilty to a human rights abuse, is an excellent example of allowing the fox to guard the henhouse.

6.5 Concluding Comments

CSR is characterized by its voluntarism and lack of legal enforceability. Therefore, a corporation cannot be held responsible for not realizing basic human rights; this is once again the duty of states. CSR also fails to provide remedies for the affected individuals and groups, as required under international human rights law.

CSR is a perfect example of allowing the fox to guard the henhouse. Corporations are not required to adopt a code of conduct and as a result many corporations do not have codes at all. In addition, if adopted CSR measured would prove to be successful in highlighting bad corporate behavior, the corporate accountability would unlikely have any significant effects due to the unavailability of any external accountability mechanisms. Thus, CSR suffers from the same weaknesses as soft law and other voluntary mechanisms, namely; there is no organ of control, hence no accountability.

However, CSR should not be viewed in such a narrow perspective. CSR can have very positive effects on a corporation. CSR measures can lead to improved goodwill, attract better and more qualified employees as well as attract new investors. Today, it is evident that the pharmaceutical industry is taking the matter of CSR very seriously. This is mainly because if CSR is not at the centre of the company´s operations, there is a fundamental risk to the business. Within the pharmaceutical industry these risks range from the medical profession refusing to prescribe drugs, potential investors deciding not to invest or current investors selling their shares. Any of these issues can lead to negative media coverage, and seeing that the pharmaceutical industry is already suffering from a bad reputation, it is very important for them to try to maintain a good image.[107]Therefore, CSR is a very strong

[106] Friedman, Milton, *The Social Responsibility of Business is to Increase Its Profits,* The New York Times Magazine (1970) p. 1
[107] Esteban, Diego, *Strengthening Corporate Social Responsibility in the pharmaceutical industry,* Journal of Medical Marketing, vol.8 (2008) p. 77

influence for the behaviour of pharmaceutical companies and can improve the access of medicines in a meaningful way. The different donation schemes and medical aid for employees that most pharmaceutical companies offer, as shown in the “ought to” dimension, illustrates the fact that pharmaceutical companies are in fact aware of their responsibilities and provide for basic human rights, even though they are not obliged to.

7. How to Move Forward

There are many fundamental obstacles to the improvement of access to medicines for the world´s poor. The most obvious ones are absolute poverty, lack of good governance leading to deficits in health infrastructure, lack of well-trained doctors, nurses and pharmacists. These obstacles have for some reason been placed in the backseat and focus has instead shifted to blaming the pharmaceutical industry. They now face pressure and demands to denounce their IP rights, to make the latest patented medicines available at lower prices, or even free of charge, and criticism for the market-oriented R&D have become a new trend. This new approach can result in costly interferences for the pharmaceutical industry, without even solving the market failure. In order to move forward and overcome the challenge of the market failure, focus must be re-shifted towards the systemic deficits and political inadequacies that lie at the root of the access to medicines issue.

My belief is that a long-term solution on better access to medicines for the poor should not simply consist of demands on corporate property. Instead, new and innovative solutions must be encouraged, measures to improve incentives for pharmaceutical R&D must be adopted and methods of public funding should be applied. I also believe that IP protection is a precondition for successful R&D, patents are therefore not up for negotiation in the access to medicines debate. Patents contribute to meet the needs of future patients and helps to find new solutions and cures for health needs, they are also crucial for securing future business existence for research oriented companies. Therefore, the solution for the lack of incentive for neglected diseases lies not in the abolition of the patent system, but in an intelligent mix of public and private research. The corporate responsibility challenge is therefore to find innovative and creative channels for the responsible use of patents under the conditions of market failure.

The Guidelines formulated by the former Special Rapporteur, Paul Hunt, on the right to health is incomplete, yet it provides a normative foundation upon which could be built a more comprehensive set of binding legal obligations for pharmaceutical companies under the right to health in relation to access to medicines. Presumably, as long as there is no legally binding instrument, the right to health and access to medicines will not be improved, since self-imposed codes of conduct and voluntary guidelines have yet been incapable of improving access to medicines under the right to health. Voluntary mechanisms and CSR have for a long time aspired to improve access to medicines for the world´s poor, but has yet failed to do so in a significant way, since millions of people still die every year due to the neglect of the developed world. CSR measures such as donation programs and discounts are unquestionably good, but can however be terminated for numerous reasons and unexpectedly. Therefore, innovative and stable methods are not only necessary, but also essential for the well being of all peoples.

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