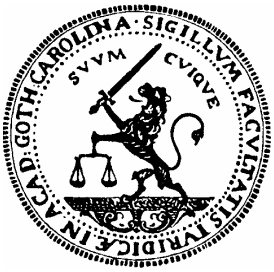

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Is Access To Medicine A Corporate Social Responsibility?

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Contents

Summary

The progress made in the field of patents on pharmaceuticals the last fifteen years, has been of continuous change and adaptation. From the introduction of the TRIPS Agreement in 1995, where patents on pharmaceuticals became a necessity for all Member States of the WTO, to today, where a ratification of the TRIPS Amendment is ongoing, and might be a mean to enhance access to medicine for all people. The aim was to make the flexibilities in TRIPS, i.e. parallel importing and compulsory licensing easier to use, but instead resulted in pharmaceutical companies deciding to lower their prices on pharmaceuticals in developing States. This introduction of price discrimination favouring poor people has lead to enhancing access to medicine, and may be an important step taken towards realising the right to health as a human right.

Aspects of international human rights law relating to health, life and access to medicine are discussed and found to have legal support in the ICESCR and the ICCPR. Two bodies of laws are in conflict: the patents on pharmaceuticals due to the TRIPS Agreement, and the right to access to essential medicine. It is impossible to say that one is superior the other as they are both interdependent human rights. The problem that people do not have access to essential medicine still exists, and an investigation of whether CSR could be a solution was the next step in the analysis. The conclusions indicated that pharmaceutical companies are economical entities, which are obliged to aim for economical profit maximisation. An economical aim may unfortunately not be compatible with a social responsibility. At the same time, social welfare conducts may coincide with economical profit due to the corporation receiving good will and reputation. Still, the obligation of fulfilling access to medicine should be a responsibility of governments, NGOs and economical entities together.

In a newly presented report, made by Oxfam International, tough criticism against the pharmaceutical industry was given. They are claimed not to perform enough in facilitating access to medicine. Instead they are wanted to lower prices, remove patents on essential drugs in developing States and to engage R&D in diseases prevalent in developing countries. Temporary solutions, such as donation programmes, are simply not enough according to the report. The pharmaceutical industry on the other hand claims that the flexibilities in the TRIPS Agreement are sufficient and that the price on medicine probably is not the major reason to lacking access to medicine. The underlying reason is poverty as such, and only pharmaceutical companies cannot be the sole actors in providing this access.

It is impossible to force corporations to give up their economical profit in order to improve global health. Instead, it should be view as a global challenge for everyone to give incentives also for corporations to extent their efforts in increasing access to medicine.

Sammanfattning

De senaste femton årens utveckling av läkemedelspatentering har präglats av kontinuerliga ändringar och anpassningar. Antagandet av TRIPS-avtalet 1995 innebar en obligatorisk patentlagstiftning för läkemedel för samtliga WTO:s medlemsländer. I dagsläget sker även en ratificering av de ändringar som gjorts i TRIPS-avtalet i syfte att öka tillgängligheten för läkemedel, framförallt i utvecklingsländer. Målet var att de flexibiliteter som finns i TRIPS-avtalet, dvs. användandet av parallell import och tvångslicenser, ska bli enklare att använda. Istället bestämde läkemedelsföretagen sig för att sänka sina priser på läkemedel i utvecklingsländer. Den prisdiskriminering som skett i favör för fattiga har lett till ökad tillgänglighet av läkemedel och kan mycket väl vara ett viktigt steg för att uppnå den mänskliga rättigheten till hälsa.

Internationella mänskliga rättigheter såsom rätten till liv, hälsa och tillgång till läkemedel diskuteras i förevarande uppsats. Två olika mänskliga rättigheter står mot varandra. Å ena sidan finns det en rätt till hälsa och å andra sidan har man rättigheter till sitt patent. Det går inte att säga att den ena rätten är överordnad den andra eftersom de är jämbördiga. Problemen för fattiga att få tillgång till läkemedel är dock högst påtagliga och ämnas undersöka huruvida socialt ansvarstagande (CSR) kan vara en möjlig lösning. Slutsatsen pekade på att läkemedelsföretag enbart är enheter med skyldighet att nå maximal ekonomisk vinst för sina aktieägare. Handlingar som stärker den sociala välfärden kan tillika påverka företagens rykte och anseende positivt, som i slutändan ger mer vinst. Samtidigt är det inte enbart läkemedelsföretagens ansvar att främja tillgången till läkemedel, utan detta mål bör uppnås av stater, intresseorganisationer och företag gemensamt.

I en nyligen presenterad rapport av Oxfam International, riktas hård kritik mot läkemedelsbranschen. De anklagas för att i inte tillräcklig utsträckning jobba för en ökad tillgänglighet till läkemedel. Oxfams förslag på lösning är att sänka priserna på läkemedel, ta bort patentskyddet för livsviktiga läkemedel samt att satsa mer utvecklingsresurser på sjukdomar som mest förekommer i utvecklingsländer. Temporära lösningar som exempelvis donationsprogram är helt enkelt inte tillräckliga enligt rapporten. Läkemedelsföretagen hävdar till sitt försvar att de flexibla lösningar som finns i TRIPS-avtalet är tillräckliga samt att prisnivån på mediciner förmodligen inte är den största orsaken till bristen på tillgång till läkemedel. Den underliggande orsaken är den bestående fattigdom som återfinns i utvecklingsländerna.

Det är omöjligt att tvinga företag att ge upp en del av sin vinst för att förbättra den globala hälsan. Istället bör det ses som en utmaning för alla parter att ge även företag incitament att öka sina ansträngningar för en förbättrad tillgång till läkemedel.

Abbreviations

AIDS	Acquired Immune Deficiency Syndrome
CSR	Corporate Social Responsibility
DTI	Department of Trade and Industry
GRI	Global Reporting Initiative
HIV	Human Immunodeficiency Virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economical, Social and Cultural Rights
IHR	International Health Regulations of 2005
ILO	International Labour Organisation
MNEs	Multinational Enterprises
NGO	Non-Governmental Organisation
OECD	Organization for Economic Co-operation and Development
R&D	Research and Development
TB	Tuberculosis
TRIPS	The Agreement on Trade-related Aspects of Intellectual Property Rights
UN	United Nations
UNHCHR	United Nation High Commissioner for Human Rights
UNMD	United Nations Millennium Declaration
WHO	World Health Organization
WTO	World Trade Organization

1 Introduction

> *"The time is ripe for a bold new approach. The industry must put access to medicines at the heart of its decision-making and practices. This is both a more sustainable long-term business strategy and would allow the industry to better play its role in achieving the universal right to health".*

The incentives to invest in developing medicine are based on a potential economical profit. Pharmaceutical corporations have huge sums invested in research, which may lead to finding cures to diseases affecting millions of people worldwide. Patents are of crucial importance within this field, as they serve as a legal prevention to stop others of making use of your findings. With the introduction of the TRIPS Agreement in 1996, it became obligatory for all WTO Member States to adapt their legislation in order to make patents on pharmaceuticals compulsory.

At the same time, people are dying, mostly in developing countries, due to not having access to medicine. This lack of access is apparent in the fact that people simply do not afford to buy essential drugs. For poor people it may be a matter of choice; buying medicine or buying food. It is often argued at patents on pharmaceuticals lead to an increase of price. On the other hand, pharmaceutical corporations argue that prices are set at levels to ensure their investments in research and development are returned.

Governments have the main responsibility for protecting the health of their population, but the fact that transnational corporations control about two thirds of the international commerce and business, indicates that these important global actors also should have a special responsibility in protecting the public health.[2] Campaigns by non-governmental organisations against major pharmaceutical companies over the access to HIV/AIDS medicine have been and still are in constant focus.[3] Do pharmaceutical corporations have a corporate social responsibility to contribute to access to medicine? Is it truly possible to demand of corporations, due to their privileged power-position on the international business market, a change of focus and leave maximization of profit behind them?

1.1 Purpose

The purpose of this thesis is to examine to what extent pharmaceutical corporations have a corporate social responsibility in ameliorating access to

[1] Investing for Life, Oxfam Briefing Paper, November 2007, page 1.
[2] Scholte, Globalization: A Critical Introduction, page 55.
[3] Fidler, A Globalized Theory of Public Health Law, JLMEDETH, page 151.

medicine, with prime focus set in the developing world. The main objective of this thesis is to investigate corporate social responsibility for the pharmaceutical sector on an international level by presenting the flexibilities contained with the TRIPS Agreement.

The goal is not to provide a complete solution, but more to present a discussion from a principal point of view. Due to the subjectivity and political aspects in the discussion on the right to health versus the rights steaming from patented pharmaceuticals, it will be impossible for me to give a clear answer. It is a very debated subject and I can merely provide the reader with the current arguments and the situation today and not with a definite “yes” or “no”. This thesis should therefore be comprehended an investigation of the issues in the ongoing debate on access to medicine and corporate social responsibility, providing the reader with an analytical reflection over the present situation.

The following questions are to be answered to fulfil the purpose:

1. Are there obligations contained within the TRIPS Agreement for the pharmaceutical industry?

2. Are pharmaceutical corporations obliged to take account of international human rights such as the right to life and the right to health?

3. Should pharmaceutical companies go beyond the corporate purpose of profit maximisation and practice corporate social responsibility?

4. To what degree do the pharmaceutical entities, under their respective corporate social responsibility, contribute to access to medicines?

1.2 Method

The starting point of my investigation will consist of a thorough overview of the TRIPS Agreement, the Doha Declaration and the TRIPS Amendment, all being crucial legislation in the field of patents of pharmaceuticals. Secondarily, an investigation of the legislation on international human rights concerning the right to health will be presented. The analysis here will be based on international covenants, general comments and other international legislation. Both these chapters will be based upon the usage of a traditional legal method in order to answer the quandaries at issue.

As there exists no legally binding regulations for pharmaceutical corporations on corporate social responsibility, chapter four is based upon the examination of existing soft law and doctrine within this area. My initial aim was to investigate to what extent pharmaceutical companies apply corporate social responsible conduct practices through interviews with a representative number. The interviews were intended to gain deeper

understanding in the following three areas: pricing, research and development (R&D) and patents. By combining the information obtained in these interviews with publicly available materials, such as the pharmaceutical corporations' websites, the goal was to determine the extent of the corporate social commitments of pharmaceutical corporations. During the research period while writing this thesis, a report made by Oxfam International named *Investing For Life*[4] was encountered. It was completed on very similar purposes as the ones set out by myself. The decision to use the materials and information gathered in Oxfam's report for this thesis was therefore straightforward. An analysis of how far pharmaceutical companies are prepared to take in CSR-aspects, such as providing access to medicine, into their policies and practises will be conducted. It will be based to a large extent on the findings of Oxfam's investigating report and my own investigation of the websites of these corporations. A qualitative method is used here, where focus is put on a dozen of pharmaceutical companies and their respective commitments will be scrutinised and analysed.

1.3 Delimitations

As the scope of this thesis is fairly broad, delimitations have been made. When investigating the legal foundation such as treaties, conventions and covenants within the scope of this thesis, only the most recent are discussed, as this field of law has been expansive during the last decade and is still growing.

Multinational enterprises (MNEs) and *transnational corporations* are two phrases, which are often used in legal literature. Even though there might be some significant difference between the two, they will be used interchangeably in this thesis in order to simplify the understanding of pharmaceutical entities as economic giants, no matter how different sources label them. The concept of *CSR*, i.e. corporate social responsibility, has been chosen to include phrasing such as corporate responsibility, sustainability etc. as the difference between the variations is not relevant. Instead, focus is put into understanding the concept and idea behind CSR.

Emphasise must be put on the fact that Oxfam's report, used as a source in chapter five, only gives one side to the problem and is truly subjective. It does not in any way claim that a complete picture is presented and an effort to balance the subjective opinions in the report against other, has been made continuously throughout the chapter.

1.4 Literature

As the relation between the patent system and pharmaceuticals has been debated fiercely, with intensification since the introduction of the TRIPS Agreement in 1994, a lot of literature has been written on this subject.

[4] Investing For Life, Oxfam Briefing Paper, November 2007.

Several books, in both English and Swedish, deal with the purpose and problems of patents on pharmaceuticals. *Human Rights and the WTO: The Case of Patents and Access to Medicine* by Hestermeyer, *Läkemedel och Immaterialrätt* by Levin and Nilsson, as well as *Accountability and the Right to the Highest Attainable Standard of Health* by Potts are all of great importance for this thesis.

Corporate social responsibility has been increasingly written about the last few years, and there is plenty of material to choose from. The Swedish book *CSR: Företagsansvar i förändring*, is the newest printed material I came across, and was therefore my main reference, together with Samuelsson's contribution to the *Liber Amicorum Reinhold Fahlbeck,* as their information was up to date.

There are also several articles written on this subject such as; Gostin and Hodge's *Global Health Law, Ethics, and Policy,* Banktekas's *Corporate Social Responsibility in International Law*, and Atik and Lidgard's *Embracing Price Discrimination: TRIPS and the Suppression of Parallel Trade in Pharmaceuticals* have all influenced the thesis to a large extent.

The General Comments on, amongst others, the right to the highest attainable standard of health and the right to life, which have been used in order to interpret the International Covenants, are not legally binding and merely aim to give guidance for the Member States. Finally, several reports from various organisations and corporations have been investigated in order to gain some subjective thoughts on the subject of this thesis. The website of WTO offers a coherent fact sheet on the TRIPS Agreement. The report by the Special Rapporteur on Right to Health was also a great cornerstone.

Moreover, it is important to emphasise, that the choice to use Oxfam's report as the main source in chapter five is to present the reader with a practical point of view. The aim is to present another view, the tangible daily perspective, than solely the theoretical one in written literature.

1.5 Disposition

Chapter two covers an introduction to the legislation on patents on pharmaceuticals. Answering question number one will be concluded in this chapter. Chapter three deals with posed question number two. Chapter four examines the concept of CSR with its sources and with focus on CSR in the pharmaceutical industry, consequently answering question number three. Finally, chapter five provides the reader with an in-dept knowledge of a chosen assortment of pharmaceutical companies and their respective commitments to CSR. This chapter will answer question number four.

2 Patents on Pharmaceuticals

2.1 The TRIPS Agreement

The introduction of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) in 1994[5] occurred with the aim to strike a balance between, on one hand creating a protection that would give incentives for future research and productions, and on the other hand allowing people to use the existing inventions. The TRIPS Agreement provides minimum standards of protection to intellectual property rights, and obliges Member States to comply with these norms without exceptions. Before TRIPS, several States did not have a patent system on all technology, and out of the excluded items were often pharmaceuticals.[6] Now, TRIPS obliges all WTO Members to enforce patent protection on pharmaceuticals. For reference to the text of the TRIPS Agreement, relevant paragraphs for patents have been placed under Supplement A.

2.1.1 Patents in General

A patent is a right given to the patent owner with the "*legal means to prevent others from making, using, or selling the new invention for a limited period if time, subject to a number of exceptions*".[7] Both products and processes may be patented. In order to qualify for a patent the following three criteria need to be fulfilled: (1) the invention needs to be considered as a *novelty*, (2) contain an *inventive step* and (3) be of *industrial applicability*.[8] There are certain exceptions as well, which if applied, can result in a government refusing to grant patents. One of these is the exclusion of commercial exploiting patents on products or processes, which are needed to protect human, animal or plant life or health, or protect *ordre public* or morality.[9] Methods, including diagnostic, therapeutic and surgical, which are essential to treat humans or animals, cannot be patented.[10] Certain inventions concerning plants and animals should be refused patent protection as well.[11] Finally, there is a safety-exit for nations to refuse granting a patent to inventions, which unreasonably conflict with normal exploitation.[12] All Member States are obliged to offer patents with a minimum of a twenty-years protects.[13]

[5] The TRIPS Agreement entered into force on January 1, 1995.
[6] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 11.
[7] TRIPS and pharmaceutical patents fact sheet, page 2.
[8] Article 27(1) TRIPS.
[9] Article 27(2) TRIPS.
[10] Article 27(3)(a) TRIPS.
[11] Article 27(3)(b) TRIPS.
[12] Article 30 TRIPS.
[13] Article 33 TRIPS.

There are three aspects to patents on pharmaceuticals, which steered the creation of TRIPS: (a) the creation should provide social and technological benefits,[14] which should act as an encouragement for future developments, (b) the aspect of social goals is based on the patented invention being disclosed, and in that way available on the market for everyone. By being "out there" there is no need to invent the same creations twice,[15] and finally (c) the possibility for States to modify the given patent rules in certain circumstances, such as national emergencies or anti-competitive practices.[16] It is the latter of the above-mentioned three that has resulted in the Doha Declaration on TRIPS and Public Health[17] in order to clarify the objectives of TRIPS and especially explain certain exceptions to patents on pharmaceuticals as guidance for the States.

2.1.2 The Flexibilities of TRIPS

TRIPS has since its introduction in 1995 been of great controversy. Questions such as whether the Agreement truly aims to benefit both developed and developing States equally and if not least-developed countries accepted TRIPS because of political pressure have been loud and strong: *"Developing countries accepted the Agreement in many, if not most, cases because of significant political concessions (…). They may not have grasped at the time the full extent of their TRIPS commitments".*[18]

As pointed out in the introduction above, all nations signing the TRIPS Agreement also accepted the fact that patents on pharmaceuticals were an obligatory matter. The Doha Declaration and the decision to amend TRIPS have calmed down several Member States. The WTO themselves claim on their webpage that *"the Decision removes final patent obstacle to cheap drug imports"*.[19] By these legal changes, it has become easier to import cheaper generic drugs, produced under compulsory licensing, for poor countries. There are several flexibilities contained within the TRIPS Agreement, such as limited exceptions,[20] revocation of patents,[21] compulsory licensing and parallel importing, which allows Member States to take measures that limit the rights of the patent holder. Only the two last-mentioned have real potentiality to give patents of pharmaceuticals a tangible flexibility, and are therefore most often discussed. In the aspect of patented pharmaceutical these flexibilities can result in weakening the patent rights and consequently making medicine accessible.

[14] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 31.
[15] Ibid, page 11.
[16] Ibid, page 244.
[17] The November 2001 Doha Declaration on the TRIPS Agreement and Public Health adopted by the WTO Ministerial Conference of 2001 in Doha on November 14, 2001.
[18] Gervais, Intellectual Property, Trade and Development. Strategies to Optimize Economic Development in a TRIPS-Plus Era, page 7-8.
[19] http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.
[20] Article 30 TRIPS.
[21] Article 32 TRIPS.

2.1.2.1 Compulsory License

In the field of patented pharmaceuticals, the term compulsory license is often referred and debated about. A State can grant a compulsory license, without the authorisation of the patent owner, permitting someone else or the government itself, to produce the patented product. This creates competition on the market and such a situation is in violation of the patent holder's right.[22] Compulsory licensing is indispensable in situations where the patent holder refuses to supply a market. Member States are at liberty to decide on what grounds compulsory license may be granted, and even though these grounds are not limited, there are a few commonly suggested grounds. Article 31 of the TRIPS Agreement itself mentions a number of grounds; national emergencies and other situations of extreme urgency are probably the most important in the relation to access to medicine.[23]

Other common grounds are for example insufficient supply of the patented pharmaceuticals, new diseases, public health grounds, or the refusal of the patent holder to work or license the patent. No matter what the grounds are, there is a specific procedure to be undertaken in order to grant a compulsory license. Firstly, authorisation may only occur on *individual merits,*[24] i.e. each individual case needs to be considered and it is not possible to automatically grant compulsory license for all pharmaceuticals. *Efforts to obtain authorization from the right holder*[25] before granting the license must have been made. These efforts should have been reasonable and failure to receive response is considered after *a reasonable period of time*.[26] When a compulsory license is granted, *adequate remuneration,*[27] which is based on the merits of each individual case, must be given. What is considered to be an *adequate* amount depends on factors such as the economic situation of the country granting the license and the interests of the patent holder and the public. According to Hestermeyer, a developing State reacting to a public health crisis by granting a compulsory license may be obliged to solely pay a relatively low, or even symbolic, remuneration.[28]

The scope of rights under compulsory licenses is strict. It allows the *use* of the patented drug, which refers to the same use the patent owner normally is entitled to through his patent. Thus, for pharmaceuticals, it refers to making, using, offering for sale, selling, and importing. A compulsory license is limited to the territory where it is granted,[29] and all entitlements are contained to this territory. A State granting a compulsory license is obliged

[22] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 239.
[23] See Supplement A for the entire text of the patent-relevant paragraphs in the TRIPS Agreement.
[24] Article 31 (a) TRIPS.
[25] Article 31 (b) TRIPS.
[26] Article 31 (b) TRIPS.
[27] Article 31 (h) TRIPS.
[28] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 249.
[29] Article 31 (f) TRIPS.

to *limit its scope and duration*.[30] Furthermore, compulsory licenses must be *non-exclusive* and *non-assignable*.[31]

2.1.2.2 Parallel Import

If the patent owner gives permission to market and sell the patented product on a specific market of a State, and this occurs correctly, then the principle of *exhaustion* is manifested, meaning that the buyer of the product is free to re-sell the product as he or she wishes.[32] Control or decisions can no longer be claimed after the sales transactions. This implies that the product is free to circulate on the market; it can be re-sold, destroyed or modified freely. The aspects of parallel imports are of importance for pharmaceuticals, as the patent holder may have decided to place identical products on separate markets at different price-levels. Reasons behind these different levels of prices are closely connected to the economical possibilities of buyers. People living in the developed world may afford to pay more for their medicine due to health-care insurances. Citizens of developing States often do not have access to neither health-care insurances nor the possibility to spend their savings on essential medicines. For them, it will be a choice between the needed pharmaceuticals or something else, which is essential to living, such as food. Pharmaceutical companies strive to gain their investments back through profit, and this economical gain may be attained from the higher price-levels on their pharmaceuticals in the western world.

An eye-opening case in the pharmaceutical field touching upon parallel imports is the *South African Case.*[33] The South African government signed for the South African 1997 Medicines Act,[34] empowering the Health Minister to override patent laws in established health emergencies. The HIV/AIDS situation in South Africa is of extreme urgency. One in eight South Africans has HIV/AIDS.[35] The Act aimed to make more medicine available in the country, primarily with reference to HIV/AIDS drugs, as South Africa is the country with the largest number of infections in the world.[36] By enacting this law, the South African government could buy the life-saving pharmaceuticals on other States' markets, where they were sold cheaper, import them back to South Africa, and re-sell them at the same low price. Tens of pharmaceutical companies jointly objected to this act and claimed the South African government was violating the protection of patents on their HIV/AIDS drugs. The government, on the other hand, stated

[30] Article 31 (c) TRIPS.
[31] Article 31 (d) and (e) TRIPS.
[32] Drahos and Mayne, Global Intellectual Property Rights; Knowledge, Access and Development, page 43.
[33] High Court of South Africa (Transvaal Provincial Division), *Pharmaceutical Manufacturers' Association of South Africa et al v President of the Republic of South Africa*, Case No 4183/98, Notice of Motion (1998).
[34] The Medicines and Related Substances Control Amendment Act, No. 90 of 1997.
[35] Drahos and Mayne, Global Intellectual Property Rights; Knowledge, Access and Development, page 190.
[36] UNAIDS: Sub-Saharan Africa, AIDS Epidemic Update, Regional Summary, 2007, page 3. Found on UNAIDS webpage: http://data.unaids.org/pub/Report/2008/jc1526_epibriefs_ssafrica_en.pdf

that the Act was not aiming to undermine patent rules, but solely a mean to protect the public health of the South African population. Can patent rights be limited by decisions made by the Health Minister? What should prevail: right to health or the right to intellectual property? These questions could have been given interesting answers if the case would have been given a verdict as a final outcome. Instead, the pharmaceutical companies withdrew their actions and a settlement was reached before a sentence was given, due to pressure from NGOs and other countries. The pharmaceutical companies have since offered HIV/AIDS drugs to African countries at a fraction of the prices in the developed nations.[37] Their decisions were probably based on the effort to diminish the use of parallel imports.

As the case was settled, no answer was given to whether HIV should be considered a national emergency. Where States free to use parallel importing under the TRIPS Agreement? This question was of importance when the Doha Declaration was adopted. In the Declaration clarification was made on the fact that it is acceptable for a company or a person to try to buy the needed pharmaceuticals on a market in a cheaper country, and thereafter import it to the home country.[38] Nothing in the provisions of TRIPS excludes these possibilities, and the Doha Declaration gives the Member States the answer that it is up to them to decide how exhaustion shall be dealt with nationally.[39]

2.2 The Doha Declaration

Since TRIPS came into force and became obligatory for all WTO members, several have raised questions on how certain issues should be interpreted and have asked for guiding clarification. During a conference in November 2001 emphasis was put on the interpretation of TRIPS, in a manner supporting public health, both in access to existing pharmaceuticals as well as to future pharmaceuticals.[40] Member States are, through the Doha Declaration on TRIPS and Public Health,[41] reminded of the flexibility of TRIPS such as making use of compulsory licensing and parallel importing. Several developing countries[42] are facing an HIV crisis, which is argued to be comparable with a *national emergency*[43], but is this really the case? HIV mostly affects the working population, i.e. people who are sexually active and often have grown to the age of having a family to support. As HIV hits the working population, the whole economy of the affected countries becomes imbalanced. How many percent must affect the population with HIV in order for a State to classify as being in a national emergency? It is

[37] http://www.wsws.org/articles/2001/apr2001/aids-a21.shtml
[38] TRIPS and pharmaceutical patents fact sheet, page 5.
[39] Article 6 TRIPS and Article 5(d) Doha Declaration.
[40] TRIPS and pharmaceutical patents fact sheet, page 5.
[41] The text of the Doha Declaration is placed under Supplement B.
[42] South Africa has the largest population of HIV patients in the world, followed by Nigeria and India.
[43] Article 5(c) Doha Declaration.

not clear what constitutes a national emergency, and as the debate was difficult to settle, the WTO came with guidelines in the Doha Declaration.

It establishes the following: (a) compulsory license can be granted by Member States without any restrictions, on grounds determined by themselves[44] (b) the use of parallel import is under the discretion of each Member State,[45] (c) each State has the possibility of using the flexibilities, e.g. parallel imports and compulsory licensing contained in TRIPS,[46] and finally (d) States are free to decide whether HIV may be considered as a national emergency.[47]

In conclusion, there is no requirement for a State to ask for authorisation for issuance of compulsory license or allowance of parallel imports. The Doha Declaration fails to answer how compulsory license could be of help to a country lacking economical resources[48], fighting against a high percentage of HIV-affected amongst its nationals. How shall the compulsory license be paid?[49] Can third countries (if they have manufacturing capacity) be asked to produce the pharmaceuticals, and then let the country-in-need import?

The most important issue the Doha Declaration presents, but does not resolve, is the scenario of countries with an established national emergency such as a public health crisis,[50] not having national manufacturing capacity, but still in need of pharmaceuticals. They are unable to make use of a compulsory license.[51] In fact, more issues than merely manufacturing capacity are apparent in developing counties: lack of know-how, education and technology all add on to the lack of national infrastructure.[52] The question is whether it in such case is acceptable for that State to import generic copies of the needed pharmaceuticals from another countries? It has in various literature been referred to as the *"paragraph 6"* issue.[53] As discussed above, TRIPS gives a right to produce pharmaceuticals on a compulsory license *"predominately for the domestic market"*.[54] This formulation implies two things: (a) countries that have a manufacturing capacity encounter no problems, (b) countries that do not have manufacturing capacity are in a difficult situation as there is no chance for

[44] Article 5(b) Doha Declaration.
[45] Article 5(d) Doha Declaration.
[46] Article 4 and 5 Doha Declaration.
[47] Article 5(c) Doha Declaration.
[48] Article 6 Doha Declaration.
[49] Atik and Lidgard, Embracing price discrimination: TRIPS and the suppression of parallel trade in pharmaceuticals, UPAJIEL, page 1049.
[50] Article 5(c) Doha Declaration.
[51] Article 6 Doha Declaration.
[52] Atik and Lidgard, Embracing price discrimination: TRIPS and the suppression of parallel trade in pharmaceuticals, UPAJIEL, page 1050.
[53] The expression can be found in for example: TRIPS and pharmaceutical patents fact sheet, page 5, and on the WTO website: http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm,
[54] Article 31(f) TRIPS.

them to import from other countries, as the latter only produces an amount corresponding to their own national need.[55]
Several questions arose as for example whether article 30 TRIPS needs to be interpreted extensively, implying a solution is already found. Also, whether an amendment of article 31 TRIPS is needed in order to create a legal ground to allow countries lacking manufacturing capacity to import pharmaceuticals. These resulted in wonders whether compulsory license should be issued not only for the need of domestic matters but also to allow issuance for nations on other member states' markets, who have manufacturing capacity. The TRIPS Council was therefore requested to find a solution to those nations who lack manufacturing capacity, in order to make TRIPS useful for all member nations.[56]

2.3 The TRIPS Amendment

All WTO members agreed on a decision on 30 August 2003[57] proposed by the TRIPS Council, often referred to as the *"2003 waiver"*[58], which aims at resolving the above-discussed problem. First of all, any WTO Member State with manufacturing capacity, holding a compulsory license on a pharmaceutical may export to importing countries in need. In other words, the obligation under article 31(f) of the TRIPS Agreement, i.e. that production of supply should solely satisfy the need of the domestic market, is waived in this decision.[59]

The importing country must first be classified as an *eligible importing country*.[60] Important to notice here is that the exporting country does not need to use the drugs themselves. It is sufficient if it only manufactures and directly exports these to other States. Secondly, only the exporting State pays the remuneration to the patent holder. This choice was made in order to avoid double payment, from both the exporting and importing country.[61] Finally, all constraints associated with the export of generic pharmaceuticals are waived for developing and least-developed countries,[62] simply to make it easier for them to use the system. Extension for national legislation on pharmaceutical patents has been given to the least-developed countries until 2016.[63]

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[55] Levin and Nilsson, Läkemedel & Immaterialrätt, page 80.
[56] Atik and Lidgard, Embracing price discrimination: TRIPS and the suppression of parallel trade in pharmaceuticals, UPAJIEL, page 1069.
[57] The text of the TRIPS Amendment is placed under Supplement C.
[58] Expression used on WTO website: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm, and TRIPS and pharmaceutical patents fact sheet, page 6.
[59] TRIPS and pharmaceutical patents fact sheet, page 6.
[60] Should be included on the list in Annex II of Council Regulation 953/2003, To Avoid Trade Diversion into the European Union of Certain Key Medicines.
[61] TRIPS and pharmaceutical patents fact sheet, page 6.
[62] According to WTO website there are 50 classified least-developed countries, of which 32 are WTO members: http://www.wto.org/English/thewto_e/whatis_e/tif_e/org7_e.htm.
[63] TRIPS and pharmaceutical patents fact sheet, page 5.

Certain rules or conditions apply to the generic pharmaceuticals produced for export to States with no manufacturing capacity, in order to identify the products and protect the patent holder. Both the exporting and the importing country have obligations to deal with before the transactions take place. The importing country needs to inform the community[64] by notifying the TRIPS Council with certain information such as the name and expected quantity, proof of established or non-sufficient manufacturing capacity (presumed that least-developed countries lack manufacturing capacity) and a confirmation of granted or intention to be granted a compulsory license.[65] The exporting State, on the other hand, is obliged to provide information on the conditions attached to the compulsory license, such as name and address of the licensee, quantities to each destination,[66] designated importing country and the duration of the license.[67] Also, the product aimed to export, is to be clearly identified through specific labelling or marketing so that suppliers can distinguish it through for example its shape, colour or packaging.[68] All these notifications are to be made public on the WTO website. The reason to these strict regulations surrounding such transactions is the make sure the pharmaceuticals reach their designated recipient and to prevent the drugs from being re-imported or reaching the underground economy.

These waivers were adopted as an amendment made to TRIPS in 2005, and will come into force when two thirds of the WTO Members accept it. The amendment will then only apply to those who have accepted it.[69] Since the introduction of this possibility, solely one country has announced compulsory license to export generic drugs, namely Canada on October 4, 2007. Canada has agreed to manufacture a triple combination of AIDS therapy drugs called *TriAvir* and to export these to Rwanda, which has no manufacturing capacity to produce them.[70] Rwanda also notified the WTO on July 17, 2007, of its intentions to import the Canadian generic drug and has estimated the quantity to 260 000 packs over two years.[71]

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[64] TRIPS and pharmaceutical patents fact sheet, page 6.
[65] Details to be notified each time: paragraph 2(a) of the 2003 Decision and of the 2005 annex to the TRIPS Agreement.
[66] Subparagraph 2(b)(i) of the 2003 Decision and of the 2005 annex to the TRIPS Agreement.
[67] Paragraph 2(c) of the 2003 Decision and of the 2005 annex to the TRIPS Agreement.
[68] Subparagraph 2(b)(ii) of the 2003 Decision and of the 2005 annex to the TRIPS Agreement.
[69] The following have accepted the TRIPS amendment so far: United States (17 December 2005), Switzerland (13 September 2006), El Salvador (19 September 2006), Rep. of Korea (24 January 2007), Norway (5 February 2007), India (26 March 2007), Philippines (30 March 2007), Israel (10 August 2007), Japan (31 August 2007), Australia (12 September 2007), Singapore (28 September 2007), Hong Kong, China (27 November 2007), China (28 November 2007), European Communities (30 November 2007), Mauritius (16 April 2008), Egypt (18 April 2008), Mexico (23 May 2008), Jordan (6 August 2008).
[70] http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm.
[71] http://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm.

2.4 Concluding Comments

With its new amendment, TRIPS clearly permits compulsory manufacturing licensing with the aim to facilitate supply of needed pharmaceuticals to States without manufacturing capacity. Several years have past since August 2003, and still virtually no States (except Rwanda) have resorted to make use of this possibility. Instead of increasing usage of compulsory licensing and parallel imports, patent holding pharmaceutical companies have chosen to lower their prices on HIV/AIDS drugs significantly on the markets of developing countries. It appears that the flexibilities are not used, but the mere threat of the widespread possibility to use them, served as an encouragement to lower prices on pharmaceuticals.

TRIPS has not created any obligations for pharmaceutical corporations, but due to its mere existence and to the possibilities for States to make use of the flexibilities contained within, it has lead to policy changes in these corporations. Something of important virtue has happened. The WTO community and the pharmaceutical companies have embraced a new policy of differential prices, which in fact means price discrimination. Pharmaceuticals are offered to low prices on developing markets, which makes them affordable to poor people suffering from e.g. HIV/AIDS, but prices for the same drugs remain high on the developed markets. The high prices should be maintained in developed States in order to cover the costs of research and development of medicine. By applying different price levels, the developing markets may gain something extraordinary: access to essential medicine at a cost they can afford. This so-called market segregation maximises profit for the pharmaceutical patent holders, as it is adapted to the possibilities each consumer has and effectively targets and captures the surplus on markets where demand is strong, i.e. developing States with a high percentage of HIV/AIDS infected. It is true that such an act is pure discrimination, affecting developed States only. Balancing the different interests in this debate gives us a picture, which we cannot ignore; price discrimination could be a way of providing access to medicine to people who are in great need of it.

The willingness by pharmaceutical companies to distribute pharmaceuticals at lower prices entirely depends on the trust and confidence that the drugs will not be re-imported back onto the developed markets and sold at competing prices. The aim of these pharmaceuticals is to be distributed to the people suffering from public health emergencies. It appears to be a decision based on good faith to protect public health. It could perhaps imply a sense of corporate social responsibility, which will be discussed in chapter four.

3 Does a Human Right to Access to Medicines Exist?

3.1 A Right to Health and its Sources

The right to health is a fundamental human right. It does not imply that a right to be healthy exists. The right to health requires States to progressively aim towards establishing the highest attainable standard of health for their population, which is a process that takes time and requires resources for its accomplishment. This implies that governments are under the pressure to continuously improve the enjoyment of the right to health and must point out clear strategies, plans of action, benchmarks and indicators so that the process is transparent to everyone.[72]

The right to health is a widespread right with several interlinked rights and obligations. Basics such as available, accessible and acceptable health facilities, essential goods and services that are appropriate and of good quality are prime examples. Non-discrimination, accountability mechanisms and remedies are also included. Governmental obligation to respect, protect and fulfil the right to health is as well contained within.[73]

The right to health is both a civil and political right, as well as an economical, social and cultural right. The right can be found at international, national and regional levels, whereas the choice has been made to only present the international due to its superiority.

3.1.1 Economical, Social and Cultural Rights

The right to health can be found in article 12 of the International Covenant of Economical, Social and Cultural Rights (ICESCR), which reads:

> *1) The State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*
> *2) The steps to be taken by the State Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:*
> *a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;*
> *b) The improvement of all aspects of environmental and industrial hygiene;*

[72] Potts, Accountability and the Right to the Highest Attainable Standard of Health, page 10.
[73] Ibid, page 9.

> *c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;*
> *d) The creation of conditions, which would assure to all medical service and medical attention in the event of sickness.*

States have the *obligation of conduct*, meaning action is required with the clear aim to enable its citizens the enjoyment of rights. Secondly, the *obligation of result* pressures states into setting targets of achievement, so that the process of achievement is visible. These obligations lean on three parts: the obligations 1) to respect, 2) to protect and 3) to fulfil the rights in the Covenant.[74] The implementation of the rights given in the Covenant can be found in article 2, paragraph 1, which reads:

> *Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures.*

Important to note here is that this article is an accessory article, and therefore it can only be breached or violated with other articles of the Covenant, such as article 12 on the right to health. States are required to *"take steps"*[75], meaning that there is an obligation to begin immediately, and steps should be deliberate, concrete and targeted.[76] These steps should be undertaken *"through international assistance and cooperation"*[77], where emphasise is given to the fact that *all* States have this obligation. For a State to guarantee enjoyment of rights resources are needed and these are scarce. Therefore the obligation of a State can merely be up *"to the maximum of its available resources"*[78], and if there is an inadequacy, then the most vulnerable rights must be the priority of protection.[79] The prospect of full fulfilment of rights is important and States should take all the above measures and steps *"with a view to achieving progressively the full realization of the rights"*[80]. Of course, full achievement at once is near to impossible, and should therefore be seen as of progressive nature, but States may not indefinitely delay efforts aimed at realising the rights. Even if resources are limited, they must make the best possible use of those available to them. Finally, States themselves should decide the means for

[74] The Commission of Human Rights, Report by Mr. Hatem Kotrane, E/CN.4/2003/53, I.A.
[75] ICESCR article 2.1.
[76] The Commission of Human Rights, Report by Mr. Hatem Kotrane, E/CN.4/2003/53, I.A.
[77] ICESCR article 2.1.
[78] ICESCR article 2.1.
[79] The Commission of Human Rights, Report by Mr. Hatem Kotrane, E/CN.4/2003/53, I.A.
[80] ICESCR article 2.1.

realisation, and these could be legislative measures, as well as judicial remedies and administrative measures.[81]

The right to health is not to be understood in a utopian significance, i.e. the right to be healthy, as this is impossible to grant due to the biological preconditions of individuals. There is an obligation for States to actively work towards realising the highest *attainable* standard of health. In order to reach a satisfactory level of health in the sense this Covenant is striving for, factors such as adequate food and housing and access to health care, as well as access to medicine, being a necessity for the prevention and treatment of most diseases, must be taken into account Health care is difficult to accomplish without the provision of pharmaceuticals.[82]

Access to medicine is stated to contain the following four elements: (a) the availability of medication in sufficient quantities; (b) the accessibility of the medication to everyone; (c) the acceptability of the treatment with respect to the culture and ethics of the individual; and (d) an appropriate quality of medication.[83] Obviously, not all pharmaceuticals are classified to fall under the right to medicine; only such that are understood to be essential drugs, which the WHO keeps a regularly updated list of.[84] They are defined as *"those that satisfy the priority health care needs of the population"*.[85] Unfortunately, the poorest, or least-developed States are disproportionately burdened with the worst effects of poor health.[86] Premature deaths and diseases often affect the world's poorest regions, but infectious diseases may spread across national borders, as seen historically with pandemics. A collective health security is therefore a concern for every country.

Can non-compliance be justified with the lack of financial means? The ICESCR takes account of the fact that States have limited budgetary means with the phrasing *"to the maximum"*. States need to take steps up to the level possible for them specifically. If the level they succeed in attaining does not satisfy the minimum core of human rights, such as the non-derogable right to life, the State is obliged to seek international assistance in the matter.[87] It is therefore not possible to excuse non-compliance due to lack of resources. A State must demonstrate that every effort has been made to use the resources available with an aim to satisfy the minimum obligations. States need to continuously strive towards realising the right to health, monitoring progress and protect their most vulnerable members of society. Hestermeyer argues that those States, which are financially unable to provide their population with access to medicine, have to guarantee

[81] The Commission of Human Rights, Report by Mr. Hatem Kotrane, E/CN.4/2003/53, I.A.
[82] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 104.
[83] E/C.12/2000/4, General Comment no. 14 on the Right to the Highest Attainable Standard of Health, paragraph 12.
[84] WHO, Essential Drugs and Medicines Policy found at: http://www.who.int/countries/eth/areas/medicines/en/ (last visited on 8 December 2008).
[85] Ibid.
[86] Gostin and Hodge, Global Health Law, Ethics, and Policy, JLMEDETH, page 519.
[87] Ibid.

economical accessibility by other means. According to his opinion, States have an obligation within the right to health, to change their patent legislation if patents influence the price of essential drugs. Changing legislation does not require financial resources, but does contribute to facilitating access to medicine.[88] On the other hand, it is highly controversial to claim that altering legislation, *de facto* weakening patent protection on pharmaceuticals, is an acceptable route to choose. The interests of patent owners must still be taken account of and a State has responsibility not to discriminate their citizens on any grounds.

What the right to health includes and what concrete obligations States have are discussed further in General Comment no 14 on the Right to Health.[89] It is stated that global health is virtually impossible without a collective response.[90] According to the General Comment, health is crucial in order to live a life in dignity.[91] The highest attainable standard of health is founded upon the individual's biological preconditions and the available resources of the State.[92] Not only adequate health care is included in the right to health; also availability in the sense of access to safe potable water, adequate housing, healthy environmental conditions and access to health-related education is included. Furthermore, accessibility, without discrimination, especially aiming at making the right to health affordable for everyone in need, is contained within the right.[93] Finally, the General Comment emphasises upon the three levels of obligations for States, i.e. the obligations to respect, protect and fulfil, discussed above in this same section,[94] which should result in transparent health indicators and benchmarks to identify the targets to strive for.[95]

3.1.2 Political and Civil Rights

In comparison with economical, social and cultural rights, which do not have a strong status in the international community mainly due to the lack of an Optional Protocol enabling a complaint mechanism, civil and political rights are viewed differently. Article 6 of the International Covenant on Civil and Political Rights (ICCPR) contains the right to life in the following wording:

[88] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 112.
[89] General Comments are not legally binding instruments. They are aimed at facilitating interpretations and clarify the purpose of the rights given in the Covenants for state organs and individuals.
[90] Gostin and Hodge, Global Health Law, Ethics, and Policy, JLMEDETH, page 522.
[91] E/C.12/2000/4, General Comment no. 14 on the Right to the Highest Attainable Standard of Health, paragraph 1.
[92] Ibid, paragraph 9.
[93] Ibid, paragraph 12.
[94] Ibid, paragraphs 33-37.
[95] Ibid, paragraphs 57-58.

> *Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.*

This Covenant has tangible force partly due to many States having ratified it[96] and that an Optional Protocol may be ratified together with it, enabling a complaint mechanism. The right to life is the essence of human rights, as it is a prerequisite for the enjoyment of all other human rights. But does the right to life include access to medicine? Some argue that the right to life is limited to penal laws on murders and prohibition of capital punishment. They argue that it does not include access to appropriate standard of living, food, housing or medical care.[97] Others claim that in order to make the right effective, it has to be extended to including basic conditions of life, i.e. necessary components for survival. Access to life-saving medicine should be understood to be one of these, and therefore access to medicine is argued to fall under article 6 of the ICCPR.[98] The Human Rights Committee, in its General Comment, has adopted the later view.[99]

Article 6 of the ICCPR is clear. It does establish the right to life and also explicitly demands the right to be protected by law. There are two obligations contained within this right; (1) there is a positive duty for States to fulfil legal obligations and to protect their individuals against violations by the State and by private actors;[100] and (2) States have a negative obligation to refrain from violating the right to life. Again the obligations to respect, protect and fulfil are encountered, as discussed above under 3.1.1. State Parties are obliged to create a legal order where access to life-saving medicine is guaranteed.[101]

3.2 Accountability

> *"An institution as complex and important as a health system – and a human right as complex and extensive as the right to the highest attainable standard of health – require a range of effective, transparent, accessible, independent accountability mechanisms."*[102]

Accountability is a central concept within human rights as it creates the strength for them to become something else than just beautiful words and

[96] In December 2008, 163 nations had ratified it, and 111 of them were also parties to the First Optional Protocol.
[97] Gostin and Hodge, Global Health Law, Ethics, and Policy, JLMEDETH, pages 521-524.
[98] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 116.
[99] A/37/40, General Comment no. 6 on the Right to Life.
[100] CCPR/C/21/rev.1/add.13., General Comment no. 31 on the nature of general legal obligation imposed on States Parties to the Covenant, paragraphs 5 ff.
[101] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 119.
[102] A/63/263, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Section III, paragraph 11.

visions. Accountability gives a foundation for individuals and governments to call upon human rights both as being rights and obligations. As a process it requires States to justify how their obligations regarding the right to the highest attainable standard of health have been fulfilled.[103] It is concerned with ensuring that health systems are improving, and that the right to the highest attainable standard of health is being progressively realised for all.[104] If mistakes in fulfilling obligations occur, accountability sometimes makes it possible to require redress.[105]

In the health sector, accountability often relates to the financial accountability, i.e. whether the national funds are spent in an adequate way on health, or to the political accountability, meaning that there are mechanisms to control that the government fulfils its obligations.[106] Monitoring is an important part of accountability as it enables rights-holders to receive information on the progress of fulfilment of rights. Through monitoring, areas of focus are targeted to reach the realisation of the right to health. The government is obliged to make the results of monitoring public, as they are important tools in accountability.[107] Reports on the health status of the State, made on periodic basis, could be sufficient way to fulfil this obligation.[108]

3.3 Who is Bound by International Human Rights Law?

As already concluded, it is obvious for States that have signed the relevant Covenants to be bound by it, and all States are bound by general international law. This is a rather undisputable statement. The question is whether other State actors, such as multinational corporations are to be included into having these obligations? The growth and extent of corporations have increased and is still increasing. Corporate power is therefore also increasing, and various sectors, such as the pharmaceutical market in a society, are under an interdependent pressure from both the State and corporate powers.[109]

Both States and private parties may violate international human rights. Nevertheless, State practice in the application of the Covenants does not support direct human rights obligations for corporation and therefore it is

[103] Potts, Accountability and the Right to the Highest Attainable Standard of Health, page 13.
[104] A/63/263, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Section III, paragraph 12.
[105] Ibid paragraph 8-9 and Potts, Accountability and the Right to the Highest Attainable Standard of Health, page 7.
[106] Potts, Accountability and the Right to the Highest Attainable Standard of Health, page 7.
[107] Article 16 (1) of the ICESCR.
[108] Potts, Accountability and the Right to the Highest Attainable Standard of Health, page 15.
[109] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 95.

highly unlikely that corporate human rights obligations ought to be acknowledged. Furthermore, even though there is no direct bondage for private parties with international human rights, it does not indicate that there is no relationship between the two. Pharmaceutical corporations have a huge influence on the access to medicine due to pricing, patents, research and development, all areas which will be dealt with in detail below in chapter five. Initiative and development of voluntary guidelines for multinational corporations in the aspect of international human rights has been made[110] and these are discussed below in section 4.2.

To give an answer to the question posed in the title of this section, only States are bound by international human rights law within the field of access to medicine and the right to health. Whether a widening of obligations is possible, to also include corporations, will be discussed in the sense of corporate social responsibility under chapter four below.

3.4 The Conflicts between Patents and Access to Medicine

According to the microeconomic theory, a market, which is perfectly competitive and unregulated, has prices set by the *"invisible hand"*[111], the workings of the laws of supply and demand, with the aim to use the resources in the most efficient way. A perfectly competitive and unregulated market is a market without patents. In such a situation, the prices are set where the demand and supply intersects, i.e. the goods would be priced at their marginal cost. Inventions, such as pharmaceuticals, require time and money to be put into the research and development. If these costs are not taken into account, a market failure will occur, were competitors could take advantage of efforts made by the inventor, by coping the drug.[112] The copied drug could thereafter be put on the market at a lower price than the original of the inventor, as the competitor would have lower costs of production. The incentive to invest in inventions would decrease because not sufficient return would be received. Patents are a way of resolving this market failure, as the patent holder becomes a monopoly supplier. The idea of patents is to uphold the incentives to invest into new pharmaceuticals and to enhance those already existing on the market. To claim that there is an economical validation for patents on pharmaceuticals is rather safe.

Patents are not the sole factor to the level of pricing on pharmaceuticals. National regulations on health care, such as government price controls may influence prices. Availability of health insurance also helps individuals, as

[110] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, pages 97-99.
[111] A metaphor coined by the economist Adam Smith in *The Wealth of Nations.*
[112] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, pages 141-142.

insurance systems impose a limit on the price. Nevertheless, patents have a significant influence on prices of drugs.[113]

The question of justification is of essence in this discussion. Most human rights may be limited if certain conditions are fulfilled, for example interference of patents in developing countries with the right to access to medicine can potentially be justified due to article 4 of the ICCPR:

In the time of public emergency which threatens the life of the nation and the existence of which is officially proclaimed, the States Parties to the present Covenant may take measures derogating from their obligations under the present Covenant to the extent strictly required by the exigencies of the situation…[114]

Also article 4 of the ICESCR is vital with its general limitations clause:

… in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only due to limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.[115]

The centre here is the identification of balancing the protection of the material interests of the inventor against access to medicine. There is no easy answer to how this balance is to be established. To my knowledge there is no answer to the economical problem of patenting medicine is the developing world. The fact is that the pharmaceutical industry maintains lobbying for making patents available in developing countries. Fear of leakage, i.e. parallel imports, to the developed world is the main reason. Pharmaceutical companies often keep (way too) high prices, in order to minimize parallel imports, even though this excludes a big portion of the target market from economical access to medicines.[116]

3.5 Concluding Comments

As can be deducted from above, pharmaceutical companies do not have any legal obligations to fulfil the international human rights to life and health. These are only obligations for States. Two bodies of laws are in conflict: the patents on pharmaceuticals due to the TRIPS Agreement and the right to access to essential medicine. The right to essential medicine is contained within the right to health and the right to life-saving medicine in the right to life. The patent system, on the other hand, aims to provide incentives for the development of pharmaceuticals. It has been argued that without this system

[113] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 146.
[114] Article 4 (1) of the ICCPR.
[115] Article 4 of the ICESCR.
[116] Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, pages 165-166.

the innovation process will vanish. Finding a balance between these two interests seems to require one side to make some significant sacrifices and so far neither one is ready to do so.

Based on an interpretation of the sources used in this chapter, it seems this situation has reached a status quo in the aspect of law. To say that one stands above the other is impossible as such a bold statement are merely personal opinions or interpretations without legal support in conventions or agreements. Both rights are interdependent and must therefore be considered as equals. If there is no legal base for one of the right to be superior the other, the next step of investigation must seek new other sources. Below, chapter four on corporate social responsibility will present the reader with a possible bridge between the right to access to medicine contra the rights of a patent owner, which potentially may be the solution to finding the balance.

4 Corporate Social Responsibility

This chapter aims to investigate the linkage, or perhaps the clash, between patents on pharmaceuticals and the international human right to access to health and medicine. Is corporate social responsibility the solution to providing access to medicine?

4.1 The Historical Development of Corporate Social Responsibility

Corporate social responsibility (CSR) is not a new concept. It emerged during the times of industrialisation in Europe and has since constantly gained acknowledgment. In the beginning, CSR served to render the belief that good working-conditions, such as humane working-hours, health and medical care offered to employees, safety at work etc. would result in content workers. All these items were in addition to normal salary.[117] Content and happy workers would in turn perform their tasks more efficiently and with a higher quality.[118]

According to Milton Friedman companies only have one sole responsibility, namely an economical one:

> *"There is one and only one social responsibility of business – to use its resources and engage in activities designed to increase its profits so long as it stays within the rules of the game, which is to say, engages in open and free competition without deception or fraud".*[119]

Friedman argued that companies do not have a social responsibility, but only an economical one and instead of engaging in philanthropic activities, the company should focus on profit, as economical gains has positive outcome on the development of the State as a whole.[120]

Today, the debate is often based on the linkage between the engagement of corporations in social responsibility and profit. Some claim there is no correlation between the two, as social responsibility goes against the free market and is therefore a threat against capitalism, as a company is an economical societal institution that should focus on profit in order to satisfy

[117] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 28.
[118] Bantekas, Corporate Social Responsibility in International Law, BUILJ, page 339.
[119] Friedman, New York Times Magazine, 13 September 1970.
[120] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 32.

their stakeholders.[121] The other side claims that the interest of the stakeholder is closely linked with demands on profit, and increased profit can be an outcome from adhering to more than just economic responsibility. Engaging in social responsible acts and activities may therefore be contributing to more profit.[122]

4.2 Corporate Social Responsibility in Multinational Enterprises

The total of the top-ten pharmaceutical corporations in the world today have a massive overturn, which can easily be compared to the GDP of Denmark. Global corporations dominate the political economy of developing countries. There is no simple answer to what corporate social responsibility is today, due to the lack of a coherent definition of CSR. It has become a matter for each company to define the concept itself. Generally speaking, most definitions refer to CSR as being a voluntary engagement in an activity without necessary focus on economic profit. Even though the responsibility is voluntary, many corporations choose to take on concepts of CSR and communicate the fact that they are CSR-aware.[123] How CSR is organised in different corporations varies; sometimes the management is responsible, at times it is a matter for the human resources-department and recently and a growing number of corporations have chosen to establish a CSR-director.[124]

Are pharmaceutical companies multinational entities?[125] Many of these corporations have an economical turnover that could be compared to smaller countries' GDPs.[126] Based on the fact that their activities affect the foundations of society to a great degree they should be classified as MNEs. According to the Commentary on the Norms on the Responsibility of Transnational Corporations: *"transnational corporations and other business enterprises shall observe standards to promote the availability, accessibility, acceptability and quality of the right to health, for example as identified in article 12 of the International Covenant on Economic, Social and Cultural Rights, General Comment No. 14 on the right to highest attainable standard of health adopted by the Committee on Economic, Social and Cultural Rights and the relevant standards established by the World Health Organization"*.[127]

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[121] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 32, and McWilliams and Siegel, Corporate Social Responsibility: Firm Perspective, pages 117-127.
[122] Waddock and Graves, The Corporate Social Performance – Financial Performance Link, pages 303-319.
[123] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 43.
[124] Ibid, page 48.
[125] As stated in my delimitations under section 1.3, I use transnational corporations interchangeably with multinational enterprises.
[126] For example: Wal-Mart outdid Austria's GDP in 2002, according to Hestermeyer, Human Rights and the WTO: The Case of Patents and Access to Medicine, page 95.
[127] E/CN.4/Sub.2/2003/38/Rev.2 (2003), E. Respect for national sovereignty and human rights, paragraph 12 (a).

A transnational company is identified as "*an economic entity operating in more than one country or a cluster of economic entities operating in two or more countries – whatever their legal form, whether in their home country or a country of activity, and whether taken individually or collectively*".[128]

MNEs and their issues are addressed in two ways: to some limited extent in binding treaties, such as several conventions of the International Labour Organization (ILO), the Covenant on Civil and Political Rights (ICCPR) and the Covenant on Economical, Social and Cultural Rights (ICESCR). Soft law acts as a fill-out, which often directly addresses MNEs and examples of these includes the OECD Principles of Corporate Governance Principle III,[129] the OECD Guidelines for Multinational Enterprises 19[130] and the United Nations Millennium Declaration (UNMD) adopted in 2000. The OECD documents regulate how and under what circumstances MNEs should manufacture their products.[131] But as a matter of fact, these guidelines and principles have little strength and merely serve as guidance. The UNMD clearly recognizes the role of industry and multinational enterprises in eradicating poverty in less-developed countries, as well as making essential drugs available and affordable.[132] MNEs have a significant role to play in promoting sustainable development and alleviating global poverty, as they possess the potential, resources and the power to be heard.[133]

From being seen as a matter of philanthropy, where MNEs performed laudable and beneficial acts towards stakeholders, it has become a matter of necessity in order to adhere to a wider spectrum of people. Simply, CSR has become fashionable and enterprises use corporate social conducts to attract the best employees, clients, investors etc. For example, over the past fifteen years, *Merck* has donated $1 billion to curing river blindness, a disease that affects thirty million people every year in sub-Saharan Africa. The company has also donated $100 millions worth of vaccines against such diseases as hepatitis and has adopted a differential pricing strategy for certain drugs such as *Crixian*, an AIDS drug, which sells at 85% less in the poorest countries.[134]

The role of the media in these aspects is of great value, as their choice to bring light upon the fact that a company is engaging in socially responsible activities, results in free commercial and a good reputation.[135] Media attention may also result in making politicians aware, and as a consequence

[128] E/CN.4/Sub.2/2003/38/Rev.2 (2003), I. Definitions, paragraph 20.
[129] Organisation for Economic Co-Operation and Development (OECD) Doc. SG/CG(99)5 (1999), available at http://www.worldbank.org/html/fpd/privatesector/cg/docs/oecd-principles.pdf (last visited on November 6, 2008).
[130] OECD Doc. OECD/GD(97)40 (2000), available at http:// www.oecd.org/dataoecd/56/36/1922428.pdf (last visited on November 6, 2008).
[131] Bantekas, Corporate Social Responsibility in International Law, BUILJ, page 310.
[132] The United Nations Millennium Declaration, principle 20.
[133] Bantekas, Corporate Social Responsibility in International Law, BUILJ, page 345.
[134] Warner, The Acceptable Face of Capitalism? The Economist.
[135] Dyck and Zingales, The Corporate Governance Role of the Media, CEPR, pages 5-6.

introduce corporate law reforms.[136]

CSR is clearly a marketing approach to enhance the brand images or profiles of corporations. It has resulted in a market mechanism, which aims to maximise good brand images and is referred to as *cause-related marketing*[137], being *"a commercial activity by which businesses and charities or good causes form a partnership with each other to market an image, product or service for mutual benefit"*.[138]

According to Bantekas, there are four types of CSR sources. Firstly, there are public international CSR instruments, of which the most influential are the OECD guidelines, the UN Global Compact and the 1998 ILO Declaration on Fundamental Rights and Rights at Work. None of them are legally binding on MNEs, though OECD States have agreed to follow the guidelines and encourage their companies to observe them during their operations. These instruments often have various follow-up mechanisms and strict disclosure requirements to which many companies have taken notice of.[139] Secondly, there are guidelines on CSR given by various NGOs, which exist in hundreds. Corporate codes of conduct are identified as a third source of CSR. These codes of conduct may be incorporated into contracts between corporation and suppliers, buying agents or contractors, often in the aspect of demanding the contracting party to abide to the codes of the enterprise. On the other hand, such corporate conducts have limited legal enforceability, and may only gain support in domestic legislation, which is the fourth source of corporate social responsibility.[140]

Public health law may be regulated on three levels: national law, international law and through global governance. National law mainly deals with protection against public health threats through offering vaccinations and boarder control measures to prevent disease importation and exportation.[141] International law obliges States to identify, prevent and ameliorate risks to health in their populations.[142] The right to health can be found in several international legal documents.[143] Global governance differs from both national and international law as it includes non-state actors. Civil society groups and multinational corporations participate in the making, interpreting, monitoring, and enforcement of rules of international law. Non-governmental organisations and multinational corporations have considerable power to affect global public health, in for example the context of access to HIV/AIDS medicine. In that sense, these actors, jointly with States, should possess duties towards the global public health. Unfortunately, there is a global weakness in the existence of public health.

[136] Dyck and Zingales, The Corporate Governance Role of the Media, CEPR, page 4.
[137] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 49.
[138] Bantekas, Corporate Social Responsibility in International Law, BUILJ, page 340.
[139] Ibid, pages 317-321.
[140] Ibid, pages 323-325.
[141] Fidler, A Globalized Theory of Public Health Law, JLMEDETH, page 153-154.
[142] Gostin and Hodge, Global Health Law, Ethics, and Policy, JLMEDETH, page 519.
[143] For example the International Covenant to Economic, Social and Cultural Rights. See chapter three for further details.

This is evident from the fact that governments have failed to exercise their powers and duties in the response to protect their citizens from the HIV/AIDS threat.[144]

4.3 Corporate Social Responsibility in the Pharmaceutical Sector

Corporations are important economical cornerstones of the society today. They provide States with employment opportunities and contribute with goods and services. To what extent are these economical entities responsible towards the society were they are established and which they affect and is there a corporate social responsibility? As will be seen below under section 5.2, an increasing amount of corporations claim to adhere to the idea of having a social responsibility.

Undertaking active social responsibility may contribute to creating a positive image of the corporation, indicating awareness, stability and modern thinking. Companies, which do not recognize CSR, are often put under pressure from various NGOs and their reputation may be down-marked in polls and rankings due to the lack of engagement.[145] The pressure on corporations consists partly of making satisfactory profit versus making CSR-aware decisions, often resulting in less short-term profit, but contributing to a greater good. A good and strong reputation has both immediate and long-term positive effects for the company as it attracts investors and shareowners.

Financial indexes for corporate sustainability have been established, such as the Dow Jones Sustainability Indexes[146] and the FTSE4Good.[147] Maybe even more important are the voluntary rules of guidance towards sustainability: the Global Compact[148] and the Global Reporting Initiative (GRI).[149] These rules are completely voluntary and are just an example of many rules or systems of comparison, which aim to guide corporations in CSR. The Global Compact is a set of ten principles, presented by the UN in 1999, on how corporations *should* manage their corporate social responsibility, without any legal sanctions attached to potential breaches. These principles only define what the UN considers being a part of the social responsibility of corporations. The GRI is a set of guidelines on how to report adequately on activities undertaken aiming for sustainability, also merely being a voluntary set of rules. The advantage for companies in using these guidelines could be to enhance their goodwill towards interested parties. Also, it facilitates comparison between themselves with other

[144] Fidler, A Globalized Theory of Public Health Law, JLMEDETH, pages 157-159.
[145] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 111.
[146] http://www.sustainability-index.com (last visited on 4 December 2008).
[147] http://www.ftse.com/Indices/FTSE4Good_Index_Series/index.jsp (last visited on 4 December 2008).
[148] http://www.unglobalcompact.com/AboutTheGC/TheTenPrinciples/indez.html. (last visited on 5 December 2008).
[149] http://www.globalreporting.org/Home (last visited on 11 December 2008).

corporations in the same business, also using the GRI, which could be used in a marketing strategy.[150] It is simply easier to compare the level of devotion to CSR by using the same set of guidelines.

The newest contribution to this field is the ISO 26000, which has been worked on by a wide range of corporations, consultants, consumers, employees, employers and representatives for the financial sector.[151] It aims to become an international standard for social responsibility in corporations and organisations. A clear and coherent language is to be used for this set of voluntary standards in order to facilitate usage and understanding, even amongst non-experts. The ISO 26000 is estimated to be completed in 2010.[152]

Corporations in the pharmaceutical sector often make use of charity when aiming to incorporate social responsibility in their work of conduct.[153] It could be a matter of donating a batch of needed medicine to a specific State with the aim that it there will be distributed to those in need. Pure donations are often criticised as they are unexpected, unknown in time and amount and do in fact not solve the real problem behind the shortcomings of access to medicine, only soothe some aspects for a certain time.[154] Other engagements in CSR could take form in contributions to various research centres established and run in areas where knowledge and access to medicine is poor. The aim behind these centres is often to create awareness and to involve natives in the reasons behind the disease, as well as granting access to vaccines or pharmaceuticals.[155]

There is a need to analyse whether CSR is compatible with the economical responsibility of corporations. As discussed above, the traditional theory aims at maximising the economical profit in a corporation. Recent debates have circulated around the potential inclusion of both ethical and moral responsibilities, such as the responsibility of corporations in the society and towards citizens.[156] As multinational enterprises have meaningful economical power in the society where they are based, it is natural that questions arise due to their business ethics and other responsibilities. There are claims that corporations of such impact should take responsibility and act as well-mannered citizens. These arguments pressuring towards more CSR are often based on the vision that the goal of these companies much be transformed into comprehending more than mere profit as a success. Other ethical values should be vital and aimed for.[157] But how should these ethical

[150] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, pages 94-95.
[151] Ibid, page 104.
[152] www.iso.org/sr and www.iso26000.se (both last visited on 7 December 2008).
[153] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 122.
[154] Example of a product donation programme is for example Bristol Myers-Squibb's *Secure the Future*, which can be found on http://www.securethefuture.com (last visited on 7 December 2008).
[155] AstraZeneca has for example established several research centres aiming to contribute knowledge of tuberculosis.
[156] Samuelsson, Liber Amicorum Fahlbeck, page 461.
[157] Samuelsson, Liber Amicorum Fahlbeck, pages 462-464.

values be chosen and in whose interest should the company work for? The board of members often gain the role of supervision and insight to how rewards or profits should be distributed. Normally, shareholders have the residual right to divide the profit, meaning the profit that remains after the economical claims and demands of the company are settled. Therefore a degree of risk is united with being a shareholder.[158] The board of members have a huge responsibility of making the right choices, keeping and attracting new shareholders to their company. Is it possible to change the goal from profit-maximisation to something else and still keep all interested parties content?

Taking decisions striving towards social sustainability are argued to affect the economical profit of corporations negatively. Others claim it might be a prerequisite in order to succeed amongst the vast number of existing corporations all trying to stand out on the global market. Today, the evidence on CSR having a positive correlation on the economical profit is weak.[159] There are studies indicating that there is no relationship between the two at all,[160] while others indicate the opposite.[161] The reason to the diversity in conclusions is due to how difficult it is to measure the effect of CSR, and that the results can be interpreted in various ways.[162] It is also difficult, if not impossible, to isolate merely the social responsibility from other factors, which can affect the level of performance and achievements of a company. In other words, other factors than CSR may be the reason to the positive, or negative, profit.

According to a workshop, where the findings later on where summarised in a report by the Department of Trade and Industry (DTI): *"A business with strong corporate social responsibility will often be more successful in generating Economic Value Added, for reasons rooted in business strategy".*[163] The report strongly emphasises that CSR is not necessarily a cost of doing business, but should rather be seen as a business competitiveness strategy. Findings also indicated that there is a clear linkage between reputation and CSR, whereas corporate reputation is in linkage with consumer satisfaction.

The concept of *triple bottom line* is often referred to, where corporations enlarge their responsibility into including sustainability.[164] Pharmaceutical enterprises want to be so-called good citizens and often act on a voluntary basis. It is highly uncertain whether it is possible to demand that corporations, due to their economical resources and expertise, should

[158] Ibid, pages 469-470.
[159] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 152.
[160] McWilliams and Siegel, Corporate Social Responsibility: Firm Perspective, pages 117-127.
[161] Waddock and Graves, The Corporate Social Performance – Financial Performance Link, pages 303-319.
[162] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 152.
[163] DTI, Sustainability and business competitiveness executive summary, Measuring the Benefit for Business Competitive Advantage from Social Responsibility and Sustainability.
[164] Samuelsson, Liber Amicorum Fahlbeck, page 472.

contribute to making the world better. It is also highly uncertain how the situation would appear if the board of members were given freedom to make economical decisions without taking notice to the profit-criterion. It is unsure whether individuals, placed in the board of members, share their ethical views on how to solve the question of access to medicine, with the majority of society.[165]

The voices speaking against CSR having a positive influence on economical profit, claim that taking on social responsibility correlates with higher costs and therefore affects the economical performance negatively.[166] Those arguing in favour of a positive correlation claim the investments in CSR have consequences, which result in economical profit. Through social responsibility, enhanced relationships with interested parties are established.[167] On the overall, it is possible to distinguish a few areas, where CSR may be understood as positive and consequently seen as a smart commercial basis. For example, the interest in consuming *ethical* goods and services has increased, e.g. goods that have been produced in good working-conditions, or are ecological. Companies being socially responsible may also attract employees and investors. The good will of the company may also be strengthened. In the same line of argument, a company that does not adapt corporate social responsibility in their work may create suspicion amongst interested parties.[168] Therefore, being socially responsible may simply be a mean to avoid negative criticism or a way of strengthening the company brand towards employees, consumers, clients, shareholders and other interested parties.

4.4 Concluding Comments

A compromise between both sides of arguments is probably the most prevalent solution amongst pharmaceutical corporations today. None of the major ones, which have been investigated in this thesis, ignore their corporate social responsibility completely, as will be seen below in chapter five.

Taking both sides into account pressures me towards establishing a personal view on this matter. What can we realistically demand from pharmaceutical corporations? The question to whether corporate social responsibility may provide access to medicine is complex. When trying to answer the question, the wall of ethical values makes it extremely difficult. The difference between what my desires are; that no man or woman should be denied their right to health, versus my sound understanding of the pharmaceutical companies as economical entities; provides for profit maximisation being the only reasonable code of conduct to opt for in this current time. To change this, other references are needed to transform the essence of

[165] Ibid, pages 482-483.
[166] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 154.
[167] Ibid, pages 154-155.
[168] Ibid, pages 155-158.

corporations, i.e. maximisation of economical profit. An incentive to accept the challenge must be introduced.

The media may, to a large degree, shape this set of references. The reputation of board members in large corporations may be affected if they fail to act according to what the society demands. When the media reports on the lack of positive response towards CSR in pharmaceutical corporations, a pressure is established upon the board members to act according to current societal norms. An important emphasise here is that the media has a selective coverage, and often chooses areas which sell, i.e. have a high consumer demand.

Everything points to the fact that if pharmaceutical corporations are CSR-conscious, it appears not to be out of a philanthropic belief in the greater good, but rather due to a pressure existing in society. It seems a corporation, which is socially responsible, is a corporation to trust and believe in. Adhering to CSR-policies has become a clever business strategy. In that sense, it may be argued that non-binding ethical norms have emerged, which increasingly affects corporate conducts. Overall, the situation today appears to draw the line of limit for corporations on the boarder to economical profit. In order to extent the obligations of corporations a new viewing of CSR is needed. Governments need to get involved in establishing the obligations of corporations through national, European and international co-operations. A concept of public accountability and the creation of standardising norms might be a solution, where it would *de facto* create a framework for social sustainability with accounting, reporting and auditing. With time, maybe even the principle of global accountability will be a possibility, but that time is yet to come.

5 Investing For Life

Pharmaceutical companies and their relationship with corporate social responsibility may be difficult to see. Individuals living in developing countries most often encounter problems with either not having access to medicine or simply not affording it, even though it exists to buy. Access to medicine, which obviously also needs to be affordable, leads to sustainable development for both individuals and States.

The main source for this chapter is a report made by Oxfam International, which aimed to investigate how far pharmaceutical companies have taken upon corporate social responsibility practises when it comes to access to medicine. This was conducted through interviewing the top-thirteen pharmaceutical companies[169] on a various range of question. A draft was assembled and the participating corporations were thereafter given the opportunity to comment on the content. After these interactions, the final report was published and it is this version that the analysis in this chapter is based upon.

5.1 Meeting Poor People's Needs for Access to Medicine Through Responsible Business Practices

According to Oxfam International, there has been a drastic impact on poor people's access to medicine due to the global intellectual property regime created by the TRIPS Agreement. Diseases such as HIV/AIDS, tuberculosis and malaria have, due to their spread and high mortality rate in developing States, created huge challenges to the global health. More recent health threats such as the severe acute respiratory syndrome (SARS) and the avian flu, spreading in both developing and developed nations, have caused widespread fear as mortality is high. Infectious diseases are the main cause of death in Africa.[170] According to Oxfam's report, one million people, mostly pregnant women and children die of malaria each year. Tuberculosis claims around two million lives annually.[171] Exact number of deaths due to HIV/AIDS are pretty much unknown, as there is still a wide-spread shortcoming in access to testing, so people may never know they have AIDS.

Perhaps the goal towards establishing global health and access to medicine should be a responsibility of several actors on the global market. The United Nations' Special Rapporteur on Health clearly points out that States have

[169] Participating pharmaceutical corporations were: *Abbott Ltd., AstraZeneca, Bristol-Myers Squibb, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Merck, Novartis, Pfizer, Roche, Sanofi-Aventis,* and *Wyeth*. *Gilead* was also interviewed due to its portfolio on HIV/AIDS.
[170] Levin and Nilsson, Läkemedel & Immaterialrätt, page 77.
[171] Investing For Life, Oxfam Briefing Paper, page 6.

the primary responsibility to give their people access to essential medicines.[172] In order to fulfil the responsibility of universal access to medicine, pharmaceuticals need to be both accessible and affordable.[173] The responsibility of patent-holding pharmaceutical companies has craved attention from public pressure in media. Issues, such as high prices and inadequate focus on research and development of medicines against diseases, which primarily affect people living in developing countries, is claimed to have direct negative impact on poor people in need of medicine.[174]

5.1.1 Pricing

Affordability and availability of essential medicines are a prime problem for almost two billion people.[175] The cost of essential medicine is one of the largest obstacles in access to health. Many developing countries cannot offer health-insurance coverage to its individuals. Poor people are forced to either spend a large part of their income on medicine or to neglect treatment. If the choice is medicine, other essentials such as food or spending on basic needs is reduced. On the other hand, if treatment is neglected or not completed, this may lead to problems such as drug resistance.[176]

As high prices on medicine have direct effect on poor people's vulnerability, they depend on generic drugs to bring down the prices through market competition forces, which enhance affordability as well as access to essential drugs.[177] The Oxfam report is critical against the intellectual property regime established through the TRIPS Agreement, which it argues to be an obstacle against access to affordable new drugs. Long-term patent-protections, which are given on essential drugs, result in monopolies keeping the prices high.[178]

Furthermore, the report points out that pharmaceutical companies tend to lower prices on selected patented drugs only. For example, anti-retrovirals for HIV/AIDS have only experienced a price-drop for the first-line category. Almost no second-line anti-retrovirals have had their prices lowered, even though they are newer, less toxic and more efficient than the first-line.[179] In fact, the price may differ up to ten times more between the first and second-line categories.[180] Only one voluntary license has been issued for a second-

[172] A/63/263, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Section IV, paragraph 19.
[173] Investing For Life, Oxfam Briefing Paper, page 11.
[174] A/63/263, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Section IV, paragraph 23.
[175] A/63/263, Annex: Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines, preamble a.
[176] Investing For Life, Oxfam Briefing Paper, page 8.
[177] Levin and Nilsson, Läkemedel & Immaterialrätt, page 88.
[178] Investing For Life, Oxfam Briefing Paper, page 9.
[179] Ibid, page 9.
[180] Ibid.

line anti-retroviral, which is *Bristol-Myers Squibb* issuance to an Indian generics firm.[181]

Unfortunately, there are other reasons to why certain pharmaceuticals may be expensive in developing countries. Expensiveness may be due to taxes, add-on costs in the supply chain and mark-up by pharmacists and doctors.[182] Inefficiencies in the distribution chains may also result in higher prices and diminished access to medicine in some regions.[183] The WHO recommends governments to remove taxes on pharmaceuticals, where appropriate, to enhance the access to medicine. [184]

Pricing is probably the main area were companies can do the most in order to enhance access to medicine and help to diminish the ongoing health crisis. According to international non-governmental actors such as Oxfam, pharmaceutical companies should lower the prices on products, which are relevant for the need in current health-crisis areas. They even go as far as arguing for the need of a *systematic global approach to pricing, overseen by an international public-health body*.[185] Also, transparency, were price offers and tenders are official, may enhance the verification of prices not aimed for profit.[186]

The report acknowledges that some progress has been made in the field of pricing since 2002. Several pharmaceutical companies now offer differentiated prices on their patented pharmaceuticals, aiming to help developing nations. *GlaxoSmithKline* has introduced tiered pricing for some antibiotics as well as diabetes treatments.[187] Corporations such as *Novartis* and *Johnson & Johnson* base their pricing on a model segmenting nations into two markets; one for people with middle-income and above, and one for poor people.[188] The latter market is given drugs at prices claimed to be set without contributing any profit to the company, through philanthropic programmes normally based on donations.[189] On the other hand, *GlaxoSmithKline* uses an approach called *Tearing Down the Barriers Strategy,*[190] which includes tiered-priced models.[191]

The main criticism against these efforts is that only selected diseases during an unknown length of time are being targeted. The report emphasises that not enough effort is being made. The discounted prices are still above

[181] Ibid, page 21.
[182] Ibid, page 10.
[183] Ibid, page 14.
[184] WHO, Report of the Commission on the Intellectual Property Rights, Innovation and Public Health, page 180 under paragraph 4.12.
[185] Investing For Life, Oxfam Briefing Paper, page 13.
[186] Ibid, page 15.
[187] Ibid, page 13.
[188] Ibid, page 14.
[189] Ibid.
[190] GSK's Corporate Social Responsibility Report found on: http://www.gsk.com/responsibility/cr-review-2007/downloads/access-to-medicines.pdf (last visited on 4 December 2008), page 42.
[191] Investing For Life, Oxfam Briefing Paper, page 14.

people's mean incomes,[192] and the selected drugs given at lower prices are mostly for specific high-profile diseases, which currently crave attention in media. Diseases such as HIV/AIDS or malaria have therefore been benefited by having prices cut on their pharmaceuticals, while other forgotten or region-based diseases, that mainly affect people in developing countries are dismissed.[193] Some companies, such as, *AstraZeneca, Johnson & Johnson*, *Pfizer* and *Novartis*, even believe that the price on pharmaceuticals is not the key barrier to access, but instead other factors are involved.[194]

Most companies engage some efforts into variously focused donation programmes to reduce prices.[195] This shows that pharmaceutical corporations are guided by the publicity surrounding a country or a disease when adopting their specific pricing policies, which indicates instability and uncertainty for the future of the access to medicine.[196] Also, with an emphasis on donations, only relatively small groups of people are targeted and limited contribution towards a sustainable national health service is made.[197] Oxfam's report also argues that donated medicine often is unsuitable, near expiration date, comes in various quantities on an irregular basis, and may be unfamiliar to local prescribing doctors.[198] If free medicine is given through donations, generics will never be able to compete on the market, as donated drugs are for free, which undermines the market competition.[199]

5.1.2 Research and Development

There is a lack of medicines against diseases prevalent in developing countries lacking purchasing power. Pharmaceutical companies may simply not desire to invest, when the return is not sufficient.[200] At the same time, pharmaceutical companies argue that without the current intellectual property legislation there will be no innovation, as incentives to invest in research for new medicines would be non-existent.[201]

According to Oxfam's report, there has been a lot of progress in the transparency concerning research and development (R&D) since 2002. Today, all twelve pharmaceutical companies taking part in the Oxfam report publish their total R&D expenditure as percentage of sales in their annual reports.[202] Especially involvement in infectious diseases prevalent in developing countries has increased, mainly through global public-private

[192] Ibid, page 13.
[193] Ibid.
[194] Ibid, page 38.
[195] Investing For Life, Oxfam Briefing Paper, page 39-40.
[196] Ibid, page 13.
[197] Ibid, page 22-23.
[198] Ibid, page 23.
[199] Ibid.
[200] Levin and Nilsson, Läkemedel & Immaterialrätt, page 89.
[201] Investing For Life, Oxfam Briefing Paper, page 11.
[202] Ibid, page 16.

initiatives.[203] For example, *Johnson & Johnson* and *Pfizer* address R&D into new medicines against HIV.[204] *AstraZeneca* conducts research into tuberculosis at its own research centre in Bangalore, India.[205] *GlaxoSmithKline* conducts R&D into eleven diseases relevant to developing countries, such as HIV/AIDS, tuberculosis, malaria and development of vaccines, while *Novartis* focuses their research on diseases prevalent in the developing world, such as tuberculosis, the dengue fever and malaria.[206] All companies interviewed pointed on areas of R&D investments, but in spite of these efforts, the Oxfam report criticises the pharmaceutical industry of having primary focus on a handful of infectious diseases such as HIV/AIDS, malaria and tuberculosis. Oxfam argues that there is *a critical need for companies to have more diverse and strengthened R&D portfolio that better reflects the chronic lack of innovation for diseases predominantly affecting poor people in the developing world.*[207]

Medicine that is suitable for the climate and conditions often prevalent in developing countries, i.e. access to refrigerators may not be prevalent everywhere etc., should be a concern for pharmaceutical companies to invest R&D into. Particular groups of people, such as children and pregnant or breast-feeding women may require special formulations of existing medicine. Unfortunately, the pharmaceutical industry currently shows little interest into investing time and money to develop new formulations, even though capabilities exist according to Oxfam.[208]

5.1.3 Patents

> *"Claims that patents are a barrier to access to medicines are unfounded and inaccurate."*[209]

According to the pharmaceutical companies interviewed for the report, none of them considers the current intellectual property regime as a serious barrier to ensuring access to medicine for poor people. In fact, all of them argue in favour of stricter intellectual property frameworks and believe that this is needed to stimulate R&D.[210] The WHO dismisses this idea and instead argues that in markets with limited purchasing power, as in developing countries where millions of poor people are affected by diseases, R&D is not stimulated by patents.[211]

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[203] Ibid.
[204] Ibid, page 36.
[205] Ibid.
[206] Ibid.
[207] Investing For Life, Oxfam Briefing Paper, page 16-17.
[208] Ibid, page 17.
[209] The website of the International Federation of Pharmaceutical Manufacturers & Associations on http://www.ifpma.org/issues/index.php?id=418 (last visited on 24 November 2008).
[210] Investing For Life, Oxfam Briefing Paper, page 17.
[211] WHO, Report of the Commission on the Intellectual Property Rights, Innovation and Public Health, page 22.

Some pharmaceutical companies, such as *Abbott* and *Novartis* have taken on to this idea and have it as a policy not to file for patents in developing countries.[212] Other corporations, such as *AstraZeneca*, will apply patent protection for all its products and *Pfizer* claims to have zero tolerance when it comes to defending their patents.[213]

Willingness to issue compulsory licenses to the patented pharmaceuticals has also proven to be rather reluctant. Even though compulsory licensing is a good way to ensure affordability, as argued and concluded above under chapter two of this thesis, the pharmaceutical industry is still sceptical. *Abbott* simply does not believe in voluntary licensing,[214] while others apply it very restrictively. Most corporations support the flexibilities in TRIPS as reaffirmed in the Doha Declaration, where compulsory licenses only can be issued in emergencies or urgent situations.[215]

Finally, there are arguments that voluntary licensing is not the prime choice in contributing to price reductions of medicines. Instead, generic competition has proven to be the most effective method.[216] Unfortunately, not much indicates that pharmaceutical companies have stepped up to the level of acceptance and acknowledging generics to their patented medicines. Instead it appears that voluntary license may be the method to be used within the nearest future. If that is the case, it is important that the voluntary license is transparent and non-exclusive, allows for distribution by both the private and public sectors and does not include any price controls or limitations.[217]

As a conclusion, there is strong criticism against the pharmaceutical industry for being persistently inflexible with their intellectual property protection and even in some cases desiring stricter patent rules, which prevents poor people from accessing essential medicines in cheaper generic forms.

5.2 The Opinions of the Pharmaceutical Companies

The larger extent of corporations chooses to communicate their viewpoints and engagement in CSR-related questions via their websites.[218] The chart below serves as an overlook that what their opinions on CSR are. It is a compilation of how pharmaceutical corporations define and work with CSR and whether or not it is understood to be a vital concept in their business strategy.

[212] Investing For Life, Oxfam Briefing Paper, page 43-44.
[213] Ibid, page 43.
[214] Investing For Life, Oxfam Briefing Paper, page 43.
[215] Ibid, page 21.
[216] Ibid, page 21-22.
[217] Ibid, page 22.
[218] Grafström, Göthberg, Windell, CSR: Företagsansvar i förändring, page 139.

	CONCEPT	DEFINITION	PRACTICE	ORGANIZATION	MOTIVES
ABBOTT[219]	*Global Citizenship*	Improving access to affordable health care.	No patents on HIV Medicines in Africa.	Humanitarian programmes, policy advocacy, workplace policies and product availability.	Abbott recognizes the serious social, economical and health impact of HIV/AIDS globally in the developing world.
ASTRA ZENECA[220]	*Responsibility*	The challenge is to balance the associated downward pressure on the prices of our medicines with the cost of continued pharmaceutical innovation.	Pricing set with consideration to its full value to patients, recognition of the flexibilities in the TRIPS amendment.	Research facilities, engaged in *Stop TB Partnership for Europe*[221] and *New Medicines for TB.*[222]	Main focus on TB, believe real progress in improving healthcare is through involvement of all related stakeholders, patents are important incentives for continued innovation.
BRISTOL-MYERS SQUIBB[223]	*Corporate Responsibility and Corporate Philanthropy.*	Acknowledges its obligations to the world at large not only in the products it offers but also in its commitments to act as a responsible corporate citizen for today and tomorrow.	Product donations, care and support for women and children with HIV/AIDS in Africa through Secure the Future.[224]	*The Bristol-Myers Squibb Foundation*[225] aims at reducing health disparities by strengthening health workers capacity, integrating medical care and mobilising communities in the fight against diseases.	Mission is to extend and enhance human life by providing the highest-quality biopharmaceutical products.

[219] http://www.abbott.com (last visited on 7 December 2008).
[220] http://www.astrazeneca.com (last visited on 7 December 2008).
[221] http://www.stoptb.org (last visited on 7 December 2008).
[222] http://www.nm4tb.org (last visited on 7 December 2008).
[223] http://www.bms.com (last visited on 7 December 2008).
[224] http://www.securethefuture.com (last visited on 7 December 2008).
[225] http://www.bms.com/sr/foundation/content/data/about_foundation.html (last visited on 7 December 2008).

	CONCEPT	DEFINITION	PRACTICE	ORGANIZATION	MOTIVES
GLAXOSMITH KLINE[226]	*Corporate Responsibility*	Contribution to the global health and the needs of society.	Conducts R & D in ten diseases of particular relevance to the developing world, not-for-profit prices for the least-developed States, but no donations of HIV/AIDS drugs.	Publishes a *Corporate Social Responsibility Report* each year.[227]	GSK does not believe that donations offer a solution to the AIDS pandemic. This is a widespread crisis, which requires a long-term commitment to treatment. This commitment cannot be sustained through donations.
GILEAD[228]	*Corporate Responsibility*	Our commitment to being an exemplary corporate citizen, contributing to the well being of the communities to which we belong.	Healthcare grants and supporting patient access.	*Gilead's Business Conduct Manual*[229] and the *Gilead Foundation.*[230]	Mission is to discover, develop and commercialise therapies that will improve the lives of patients with life-threatening illnesses around the world.
JOHNSON & JOHNSON[231]	*Access2wellness*[232]	Help creating a world where people across all economic and social circumstances have access to treatments needed to keep healthy and improve their lives.	Community work in Africa and local community responsibility.	*The Contributions Report* publishes each year[233] and the credo values.	The desire to make people healthier and safer is at the heart of our Company's giving.

[226] http://www.gsk.com (last visited on 7 December 2008).
[227] http://www.gsk.com/responsibility/cr-review-2007/downloads/CR-Report-2007.pdf (last visited on 7 December 2008).
[228] http://www.gilead.com (last visited on 7 December 2008).
[229] http://www.gilead.com/pdf/Conduct_Pocket_Guide.pdf (last visited on 7 December 2008).
[230] http://www.gilead.com/Gilead_Foundation (last visited on 7 December 2008).
[231] http://www.jnj.com (last visited on 7 December 2008).
[232] http://www.access2wellness.com/a2w/index.html (last visited on 7 December 2008).
[233] http://www.jnj.com/connect/caring/corporate-giving (last visited on 7 December 2008).

	CONCEPT	DEFINITION	PRACTICE	ORGANIZATION	MOTIVES
MERCK[234]	*Corporate Responsibility*	Listening, responding and working toward a healthier future.	*Merck Vaccine Network* and the *African Comprehensive HIV and AIDS Partnerships.*	Yearly *Corporate Social Responsibility Report.*[235]	We have a responsibility to take positive steps to support the right to health. These steps include policies and actions around product registration, pricing, patenting and partnerships.
NOVARTIS[236]	*Corporate Citizenship*	Our commitment rests on four pillars; patients, business conduct, people and communities and environmental care.	Access-to-medicines programmes, produce both patented drugs and generics, *and Novartis Vaccines Institute for Global Health.*	Have published their position on access to medicine in a report.[237]	Novartis strongly supports the TRIPS Agreement, believing it is a fair balance of providing IP protection to pharmaceutical companies, while allowing countries the flexibility to provide treatment to poor people in national emergencies.
PFIZER[238]	*Corporate Responsibility*	Dedicated to developing new, safe medicines to prevent and treat the world's most serious diseases. We are making them available to the people who need them most.	Partnering with health care providers, community organizations, to help make health care more accessible.	*Pfizer Corporate Responsibility Report.*[239]	As a member of today's rapidly changing global community, we are striving to adapt to the evolving needs of society and contribute to the overall health and wellness of our world.

[234] http://www.merck.com (last visited on 7 December 2008).
[235] http://www.merck.com/corporate-responsibility/docs/cr2006-2007.pdf (last visited on 7 December 2008).
[236] http://www.novartis.com (last visited on 7 December 2008).
[237] http://www.corporatecitizenship.novartis.com/downloads/patients/access-medicines/klaus_access.pdf (last visited on 7 December 2008).
[238] http://www.pfizer.com (last visited on 7 December 2008).
[239] http://media.pfizer.com/files/corporate_citizenship/cr_report_2007.pdf (last visited on 7 December 2008).

As can be seen from the chart, all of the major pharmaceutical companies do acknowledge corporate social responsibility on their respective websites in different wording. *Corporate responsibility* is most commonly used,[240] but wordings such as *global citizenship,*[241] *corporate philanthropy*[242] and *access2wellness*[243] are also used. Their respective definitions of what CSR includes vary. Some claim to have a great responsibility due to them being global actors, and wordings with reference to their obligation in making the world healthier is used.[244] These bold statements are of great interest as they create a curiosity whether the corporation truly are contributing to facilitating access to medicine.

Abbott for example claims to not file for patent on their HIV/AIDS medication in African States, where at-cost pricing is applied.[245] *Novartis* engages in access-to-medicine programmes, which are aimed at improving the distribution chain of medicine so that they are accessible to more people. Various programmes such as vaccine networks, community work, research centres etc. have been established in States where the need is great. Contributions have been made.

The most prevalent criticism pharmaceutical companies receive relates to the understanding that pricing is the obstacle in access to medicine. It is true that medicines and vaccines for many poor people are unaffordable, but this is due to poverty and not the price of pharmaceuticals.[246] No institution, public or private, can be obliged to resolve this problem, according to the opinion of the pharmaceutical sector. It is a responsibility for governments, NGOs and economical entities together. The pharmaceutical industry is only one stakeholder. Sustained access to medicine cannot be assured by one single sector.[247]

The Oxfam report is highly critical against donation programmes, as they are not considered to solve the problem of access to medicine, merely soothe the ache for some time. According to for example *Merck*, donations are an interim step, and they are not of the opinion that such programmes are a sustainable response to the existing need.[248] *Pfizer* argues that donation programmes are one of the many roads to public health

[240] Used by Bristol-Myers Squibb, GlaxoSmithKline, Gilead, Merck, Novartis and Pfizer.
[241] Used by Abbott.
[242] Used by Bristol-Myers Squibb together with corporate responsibility.
[243] Used by Johnson & Johnson.
[244] Used by amongst others Bristol-Myers Squibb and Johnon & Johnson.
[245] Abbott's response to Oxfam's report "Investing for Life", found on: http://www.business-humanrights.org/Documents/Oxfamresponses (last visited on 14 December 2008).
[246] Pfizer's response to Oxfam's report "Investing for Life", found on: http://www.business-humanrights.org/Documents/Oxfamresponses (last visited on 14 December 2008).
[247] AstraZeneca's response to Oxfam's report "Investing for Life", found on: http://www.business-humanrights.org/Documents/Oxfamresponses (last visited on 14 December 2008).
[248] Merck's response to Oxfam's report "Investing for Life", found on: http://www.business-humanrights.org/Documents/Merck-response-to-Oxfam-11-Dec-2007.pdf (last visited on 14 December 2008).

improvement, and that many governments, healthcare professionals and patients welcome them.[249]

5.3 Concluding Comments

5.3.1 What is the Situation Today?

The lack of essential medicine in combination with the increasing number of sick people requires a shift in management for a long-term survival. The vital question here is whether it is fair to oblige the pharmaceutical sector to address these challenges. It is true, as stated before, that States are primarily responsible making sure that the right to health is fulfilled as a human right, but this obligation may also be understood to include pharmaceutical companies to some extent. The UN Special Rapporteur on the Right to Health emphasises that the right to the highest attainable standard of health is the main responsibility of states, but the pharmaceutical sectors also has a profound impact.[250]

5.3.2 Addressing the Challenges

As a growing number of developing countries are beginning to seriously commit towards fulfilling human rights to a higher extent, aspects such as access to medicine and the right to health are becoming important. It will be difficult for these governments to meet their goals and obligations, if the problem with patented drugs is not solved first. People living in poverty are extremely restricted in their economy and high prices on essential medicine create a barrier to access for them. Access to medicine is characterised by profound global inequality, as 15% of the world's population consumes over 90% of the world's pharmaceuticals. At the same time, human resources in developing States are very limited. Even though governments are primarily responsible for fulfilling their human rights obligations, the corporate social responsibility trend is growing stronger and stronger. A responsibility upon companies has been created in the form of a challenge. The pharmaceutical industry is experiencing a growing pressure to respond to the challenge by implementing differential price-strategies based on peoples' incomes or by being flexible with their patent protections on the markets where poverty prevails. These strategies should aim at creating desirable low prices to meet the existing need.[251] Oxfam's argument that there is a need for a systematic global approach to pricing, overseen by an international public-health body, is probably demanding too much. It must be up to the pharmaceutical companies to set their own price levels, as they are in fact economical entities and have no official human rights obligations.

[249] Pfizer's response to Oxfam's report "Investing for Life", found on: http://www.business-humanrights.org/Documents/Oxfamresponses (last visited on 14 December 2008).
[250] A/63/263, Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Section IV, paragraph 23.
[251] Investing For Life, Oxfam Briefing Paper, page 31.

As the global human health constantly is changing due to new diseases, a wider range of medicines is required. New pharmaceuticals are needed, and companies must therefore engage in research to a greater extent addressing these issues.[252] To motivate corporations to making these investments, incentives are needed, and the patent system is therefore of vital importance. Development of formulations that are adapted to the climate in developing countries is also sought for. The importance of adapting medicine to make it suitable for groups that are in an especially vulnerable position, such as children and pregnant or breast-feeding women is also a part of corporate social responsibility.

The problem of developing States not having access to essential medicine cannot be blamed on the fact that the worldwide pharmaceutical industry works towards economical profit. Tax reduction may be a mean to enhance access to medicine. The United States has tax reductions on research projects on HIV/AIDS, tuberculosis and malaria.[253] But tax reductions are not the solution if the market does not have the possibility to pay for the pharmaceuticals, no matter what the price. The situation consists of a market where the demand for pharmaceuticals exists, but the people in need are too poor to pay for the products. Over two billion people do not have access even to a few essential drugs as they do not have the purchasing power.[254] Several of the pharmaceutical companies, which were investigated in this thesis, had various donation programmes, as it gives corporations good will. These programmes are uncertain in time and extensiveness. Furthermore, the infrastructure in several developing States makes it difficult to reach out to all people in need of the drugs, which delimits the purpose of the donations.

The amendments made to the TRIPS Agreement were intended to be a solution, but the results have so far been meagre. Not many countries have incorporated the amendment into their national legislation yet as it still needs more signatories to come into force. It appears that the amendment is not enough to make a difference. Another path must be taken in order to enhance access to medicine.

Even though many still comprehend corporate social responsibility as a blurry concept, several corporations are actively starting to acknowledge its importance. CSR may be compared to the social contract, where companies should meet demands from the civil society with new business models aiming at the existing needs within the global health. A long-term vision, strong leadership, with a flexible mind on a wide range of stakeholders is needed.[255] As pharmaceutical companies have great access to a global market due to the widespread request for their products, they have a powerful position. By having this position, should they take CSR aspects

[252] Investing For Life, Oxfam Briefing Paper, page 31.
[253] Levin and Nilsson, Läkemedel & Immaterialrätt, page 91.
[254] Drahos and Mayne, Global Intellectual Property Rights; Knowledge, Access and Development, page 102.
[255] Investing For Life, Oxfam Briefing Paper, page 32.

into their consideration? Is it reasonable to ask private and economical entities of these fulfilments? I believe there is a boundary of what may be asked for. Developing medicine, which is necessary, usable and distributed at reasonable prices on markets where the need exists, in a reliable and sustainable manner, should be considered as part of their responsibility towards improving the global health. Corporate social responsibility does not aim to save the world. The concept merely indicates that corporations should look over their business and make sure that *they* do not contribute to making it worse.

Supplement A: The TRIPS Agreement

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS[256]

PART II STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[257] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

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

3. Members may also exclude from patentability:

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

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants

[256] http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm (last visited 10 December 2008).

[257] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

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

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[258] for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

[258] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[259] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

[259] "Other use" refers to use other than that allowed under Article 30.

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32

Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[260]

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

[260] It is understood that those Members, which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

Supplement B: The Doha Declaration

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH[261]

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

[261] http://www.who.int/medicines/areas/policy/tripshealth.pdf (visited on 10 December 2008.)

Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

Supplement C: The TRIPS Amendment

Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health[262]

Decision of the General Council of 30 August 2003

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

(a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1

[262] http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (visited on 10 December 2008).

of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed;

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision;

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling

or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be

reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a

compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration.

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

OR

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply.

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