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Is there a legal barrier to medication?“

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Foreword

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Table of Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
CSR	Corporate Social Responsibiity
DSU	Dispute Settlement Understanding
FTA	Federal Trade Agreement
GATT	General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
Ibid	*Ibidem* (in the same place)
IP	Intellectual Property
LDC	Least-developed country
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Cooperation and Developement
PPP	Public Private Partnership
R&D	Reseach & Development
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UN	United Nations
US	United States
WTO	World Trade Organisation

1. Introduction

In 2000, the importance of an effective response to HIV/Aids was acknowledged in the 6th Millenium Development Goal (which says to combat HIV/Aids, malaria and other diseases) in the United Nations Millenium Declaration[1], adopted by the UN General Assembly, which should be achieved by 2015.[2] Since 2000, the annual number of new HIV infections has continued to decline and there are more people now receiving life-saving antiretroviral therapy, which do not only prevent AIDS-related illness and death, but also reduce the risk of HIV transmission and the spreading of tuberculosis.[3]

Anyway, with 35.3 million people living with HIV in 2012 and 66 per cent of those in clinical need of antriretroviral treatment not receiving such treatment, HIV/Aids remains an unresolved health crisis on an unprecedent scale, while tuberculosis still remains the leading cause of death among people living with HIV.[4]

The reasons for the lack of access to essential medicines are manifold. Concerning HIV/Aids, in many cases the high prices of life-prolonging drugs which combat and relieve the symptoms of HIV/Aids are a barrier to needed treatments as a result of strong intellectual property protection.[5]

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1 Resolution (General Assembly of United Nations) A/RES/55/2 of 18 September 2000 UN Millenium Declaration [2000] <http://www.un.org/millennium/declaration/ares552e.pdf> accessed 31 March 2014.

2 There were 189 UN Member States and 23 organisations that agreed to the Millenium Declaration. The Millenium Declaration complies 8 development goals whereas the deadline for achieving these goals ends in 2015. These goals include the eradication of extreme poverty and hunger, the achievement of universal primary education, the promotion of gender equality and the empowerment of women, the reduction of child mortality, the improvement of maternal health, the struggle against HIV/Aids, malaria and other diseases, the safeguard of environmental sustainability and the development of global partnerships. See more informations under <http://www.un.org/millenniumgoals/>.

3 UNAIDS, *2013 Report on the Global AIDS Epidemic* (2013) 2, 6 <http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf> accessed 03 April 2014.

4 Ibid 4.

5 S Joseph, 'Pharmaceutical Corporations and Access to Drugs: The fourth wave of corporate human rights scrutiny' (2003) 25 Human Rights Quarterly 425-452

The TRIPS Agreement which was signed in 1994 and came into effect in 1995, introduced the obligation on all WTO members to provide patents for pharmaceuticals. Under TRIPS, a patent-holder over a drug has monopolistic control over the sale of that drug with a minimum duration of 20 years from the original date of filing[6].

The minimum obligatory standards for the protection of intellectual property rights required by the TRIPS Agreement with respect to the patenting of medicines are generally more similar to the norms that already existed in the Unites States and the European Union than those that existed in developing countries.[7]

The TRIPS rules permit the producer to hold prices well above production costs, so there is a great leeway for uncompetitive and arguably unconscionable prices. The adoption of patent legislation, in particular the implentation of the TRIPS Agreement results therefore in higher prices, too costly for the vast majority of people in poor areas, such as South East Asia and the Asia Pacific, the Caribbean, Latin America, and Africa.[8] There are several studies saying that prices have even increased over around 200 percent with the introduction of product patention.[9]

In my thesis, I am going to describe and evaluate the conflict between patent law obligations under the TRIPS Agreement and the access to medicine as a human right.

<http://hmb.utoronto.ca/HMB303H/weekly_supp/week-08-09/Joseph_Drug_Patents.pdf> accessed 23 March 2014.

6 Anyway, it has to be noted that most patents are unlikely to have an effective patent term of 20 years due to the time-consuming nature of the patent examination process (Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) 7 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 23 March 2014.

7 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 1.

8 UNAIDS, *2011 Progress Report. Epidemic Update and health sector progress towards Universal Access* (2011) 23 ff <http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20111130_ua_report_en.pdf> accessed 23 March 2014.

9 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 8.

The underlying question of this research was to see firstly, what the problems and issues are that arise between these two different fields of law – the system of patent law on the one hand and that of human rights on the other hand- and secondly, if the existing international legal instruments are sufficient tools to solve this conflict in order to secure the access to medicine of low-income country-inhibitants.

The topic of my thesis has been widely discussed as part of the international human rights regime with the goal to grant more justice to those, who cannot afford the medicine they need. I have picked this topic because it combines two approaches of completely different legal regimes, that of human rights on the one hand, and that of patent rights as part of the intellectual property rights system. Therefore, I tried to consider both positions in my research without bias, that of developing and least-developed countries seeking to achieve an appropriate access to medicine on the one side, and that of pharmaceutical companies striving for realizing profits and recouping their research and development expenditures on the other side.

The focus of this work was directed to the inequalities of developing and least-developed member countries in contrast to members of developed countries. Therefore the perspective of my thesis lies on the effect, pharmaceutical corporations have on societies in economically weak countries. The underlying question was, how the raised problems can be solved, with a view to bring more justice to those, who can easily be exploited due to their weak economic position on the world market.

My personal background of this topic goes back to the time of my semester abroad in Finland in 2009, when I had already began to engage in this topic a little on the basis of a seminar with the title “Rights, power and communication“. After attending this seminar at the University of Turku, I wrote an essay about this topic. After finishing my studies and completing my examinations to become a lawyer, I started working on my doctoral thesis. However, as this topic excited me already

at the time of my semester abroad, and as this excitement has continued until now, I decided to proceed with my investigations and to expand my research interest in this topic.

The topic is of particular relevance by now because the last transitional arrangement developed by the WTO TRIPS Council in June 2013 allowed least-developed WTO members not to apply the provisions of the TRIPS Agreement for another eight years until 2021. That is why the next few years will be pathbreaking for the time after the transitional period has expired.

2. Research Interest

In my doctoral thesis I am going to describe and evaluate the conflict between patent law obligations under the TRIPS Agreement and the access to medicine as a human right. I will therefore divide the interest and handle it in three different parts:

The first part will be about the basic fundament of the relevant patent law rules. I will first illustrate dogmatic arguments and want to give a brief overview of the WTO, the most important Articles of the TRIPS Agreement and the rights conferred to a patent holder. This part of the analysis is especially intended to provide informational background.

I will examine in this context, how the way of implementation of TRIPS into the legislation of developing and least-developed countries can influence the possible achievement of public health goals in a positive way. I will therefore turn my attention in particular to the scope of patentability.

One main problem in implementing the TRIPS rules is the fact, that developing countries fail to have well-experienced legal drafters who could undertake the

implementation in a manner that is appropriate to their individual needs. In my doctoral thesis, I want to carve out the problems arising with the receiving of assistance by WIPO and the WHA.

One subchapter of my doctoral thesis will be devoted to generic drugs. I will emphasize in this chapter their importance of the decrease of prices through the occurence of competition under generic firms.

Alongside this, attention will be devoted to several theories with different basic approaches trying to justify the conflict between patent law and human rights law. I will discuss in detail the pro- and counter arguments in the overlapping of patent law and human rights. The main argument argument in favor of pharmaceutical patents might be that they promote research and development in the industry and therefore operate as an incentive for research. However, my doctoral thesis will make obvious that the "incentive theory" seems to represent only partial truths and that the incentive impact alone does not automatically ensure the fastest possible R&D progress as many surveys have shown that the amount reinvested into R&D by big pharmaceutical corporations is disproportionately small. Most pharmaceutical companies tend to spend even two times more on marketing than they do on R&D.[10]

The next section of my doctoral thesis is on the examination of possible measures to protect public health goals, the so-called TRIPS-flexibilities. I will then in a next step oppose the application of TRIPS-flexibilities to a so-called TRIPS-plus trend that can be observed in recent time. TRIPS-plus can be described as an effort of Western countries in putting pressure on developing and least-developed countries in order to achieve TRIPS-plus standards that go beyond the minimum requirements of TRIPS.[11]

10 Supplement to Earnings Release 3Q13 final <http://www.merck.com>.
11 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 9

For the added practical applicability of my doctoral thesis, I will study some court cases in the debate on access to drug and intellectual property to demonstrate the importance of clarification concerning the flexibilities of TRIPS required in order to make sure that developing and least-developed countries could use their provisions without the threat of political pressure or losing in litigation.[12]

The second part will be about the legal framework of the access to medicine as a human right. I will therefore in particular examine carefully the two relevant Universal Human Rights Covenants, the ICESCR and the ICCPR in respect of the right to health and the right to life. Anyway, it is argued from different sides that the right to health can only be fully realized when always bearing in mind the underlying different circumstances. It is therefore necessary to analyse the relationship between the right to health and other relevant human rights in order to achieve the best possible accessibility to medicine.

In this context I must also take a closer look at the possible addressees of human rights law. The main question relating to the possible addressees of human rights law will be: Is there a binding of human rights duties for pharmaceutical companies in relation to access to drugs. In this context, I will also focus on the recent developments in the debate on “corporate social responsibilty“ (CSR) and continue with a more detailed description and comparison of the different legal frameworks.

Another issue to examine in this context will be, if there are convincing arguments to reason that the WTO as an international organisation is bound by human rights treaties as well.

<http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument> accessed 03 April 2014.

12 E Hoen, ’TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond’ (2003) 3 Chicago Journal for International Law 44 <http://fieldresearch.msf.org/msf/bitstream/10144/28436/1/Access%20TRIPS%20%27t%20Hoen.pdf> accessed 23 March 2014.

The doctoral thesis will in its third part discuss the question about a hierarchy in international law and the distinction between a factual and a normative hierarchy. In this context my research will illustrate the necessity to consider that human rights are regarded to be higher in the framework of a normative hierarchy. However, according to the factual hierarchy system, states will- in case of a conflict- rather abide by the rules of regime with the strongest enforcement mechanism, which is the dispute settlement mechanism of the WTO[13].

Another potentially concerning issue will be the role of human rights within the WTO regime. The main question concerning the WTO panel jurisdiction will be, if the WTO dispute settlement body can actually be used to enforce human rights law, as it has only jurisdiction for violations of covered agreements: Can a WTO member rely on the right to access to drugs as a defence against a claim of violation of WTO law? In this context, it will be interesting to investigate, as to what extent WTO panels have jurisdiction in general. This question must sharply be distinguished from the second question, namely, which law the WTO panel is enabled to apply.[14]

In a second to last step, I will take a look at the previous WTO decisions, in particular the Doha Declaration, the Decision of 30 August 2003 and the corresponding Amendment. I will in the context of this short analysis turn my focus especially to the question, which advantages these newer WTO decisions implify for the developing and least-developed world.

As a very last point before the conclusion follows, I will study the possible solutions for solving the conflict between patent law under the TRIPS Agreement and the access to medicine as a human right. In order to improve the access to medicine for people in the developing world, it is necessary to look at the different future

13 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 191.
14 J Pauwelyn, *Conflict of Norms in Public International Law. How WTO Law relates to other rules of international law* (1st edn, Cambridge University Press 2003) 561 ff.

possibilities in order to give human rights a stronger status within the WTO system.

3. Patent Law

3.1. The WTO and the TRIPS Agreement in general

The World Trade Organization (WTO) is an international organisation, which was created in 1994 by the WTO Agreement and which replaced the provisional General Agreement on Tariffs and Trade (GATT).

The WTO came into being with the aim of providing predictability and stability in international trade, reducing existing barriers to trade and preventing new ones from developing, in order to raise standards of living and ensure full employment.

The WTO Agreement consists of over forty international treaties on trade in goods, trade in services, agriculture, textiles and clothing, intellectual property rights, subsidies, and investment measures which were agreed upon at the conclusion of the Urugay Round. One of these Agreements is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which establishes minimum standards of protection to creators of intellectual property, meaning that members can also introduce stricter, or additional forms of protection that are not included in the Agreement. The TRIPS minimum standards for intellectual property protection must also be adopted by developing and least developed countries, although there are several transitional periods, that I will discuss later in detail.

TRIPS covers amongst others copyright, trademarks, geographical indications, patents, and plant variety protection, and lays out the procedures and remedies

which should be available in member states to enforce intellectual property rights.[15]

Members of the WTO are under the clear obligation to make patents available when the conditions of patentability regulated in Articles 27 ff of the TRIPS Agreement are fulfilled.[16] This change represents a milestone in the development as prior to the TRIPS Agreement, national IPR protection varied from country to country, and it were domestic patent laws, which played a critical role in creating incentives for domestic invention. Prior to the TRIPS Agreement, every state was free to decide what level of protection it would provide in order to cover its technologies according to its relevant development status. It should be noted that many developed countries such as Germany, Japan, Switzerland, Italy and Norway have also excluded specific industries, such as pharmaceutical products, from patenting until the 20th century for fear of negative effects on public health.[17]

As developing and developed countries have naturally completely different interests, it is no surprise that the positions have originally differed widely and that it was anything but easy to strike an agreement.

I will therefore, in the following subchapter, outline the historical background and development of the TRIPS Agreement. In order to round the picture and to bring the overview on an updated level, I will present several different positions concerning TRIPS.

15 C Dommen, 'Raising Human Rights Concerns in the World Trade Organization: Actors, Processes and Possible Strategies' (2002) 24 Human Rights Quarterly 5 ff.
16 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 53 ff.
17 P Challu, 'The Consequences of Pharmaceutical Product Patenting' (1991) 15-2 World Competition 65, 75.

3.1.1. The historical background

In the nineteenth century, the lack of patent laws in many countries appears in general to have guided innovation especially toward industries where other mechanisms than patent laws protected intellectual property. Thus innovators in countries without patent laws concentrated on industries, such as scientific instruments and food processing, where other mechanisms in addition to patent grants were allowed. For instance, inventors in these industries were able to achieve similar conditions to patent monopolies by keeping innovations secret. That was also the reason, why countries without patent laws could still become technological leaders in those industries.

On the other hand, inventors in the patentless countries tended to avoid innovations in manufacturing and other machinery, which were strongly dependent on patent protection, and the patentless countries lost their early lead in manufacturing industries as machinery and mechanization became more important.[18]

It is in a next step fascinating to look into the different positions of TRIPS in order to gain insight regarding the question how TRIPS finally could become realized at all.

3.1.2. The different positions

The opinions concerning TRIPS differ widely: For instance, *Ellen Hoen*, former director of Médecins Sans Frontières, posits that TRIPS was designed “to offer comfort to the US and the Western pharmaceutical industry“ while offering only “little comfort for poor patients“.

18 P Moser, ’How do Patent Laws influence Innovation? Evidence from Nineteenth-Century World’s Fairs’ (2005) 95 The American Economic Review 1215 <http://www.colorado.edu/ibs/eb/alston/econ8534/SectionXI/Moser,_How_Do_Patent_Laws_Influence_Innovation_Evidence_from_Nineteenth-Century_World's_Fairs.pdf> accessed 24 March 2014.

By contrast, the former director of the WTO states that “the TRIPS Agreement is a historic agreement for the World Trade Organisation“ and that “it proves the organisation can handle humanitarian as well as trade concerns“.[19]

The International Federation of Pharmaceutical Manufacturers Associations even goes further and argues that the less developed countries stand to benefit from a stronger IP regime, because the regions concerned would be more attractive for foreign direct investment and technology transfer.[20]

These three opinions concerning TRIPS that serve – of course – only as demonstrative examples and do not even rudimentarily deliver an exhaustive overview, make at least obvious that the positions differ from each other to a great extent.

So based on these different positions, what is the truth concerning the entity and influences of TRIPS?

It is obvious that the TRIPS Agreement was a very difficult issue, pitting industrialised against developing countries.

The biggest patent-holding pharmaceutical companies are seated in a few industrialised countries, such as the United States, Great Britain, Germany, Japan and Switzerland, which take in high earnings from the exploitation of pharmaceutical patents. It is therefore not surprising that the initiation of negotiations for the TRIPS Agreement was definitively motivated by demands from industrialised countries in order to protect their exports and investments. It was clear from the beginning, that the TRIPS Agreement will automatically increase the economic strength of industrialised-country enterprises.

19 N Mathiason, ’Drugs deal “not viable“’ *The Observer* (31 August 2003).
20 HE Kettler and R Modi, ’Building Local Research and Development Capacity fort he Prevention and Cure of Negelcted Diseases: The Case of India’ (2001) 79 Bulletin of the WHO 744.

Thus, there was a general worry amongst developing countries that stronger IP protection would strenghten the monopoly power of multinational companies on the one hand, and would affect poor populations by raising the price of medicines on the other hand.

It has been argued that the implementation of a strong intellectual property protection and enforcement will enhance investments in and technology transfer to developing countries, leading to more economic development within these regions.[21] The main reason, why developing countries finally did accept the TRIPS Agreement, was not because the adoption of intellectual property protection was high on their list of priorities, but partly because they feared persuasion by the USA and the EU.

Besides, developing countries hoped to benefit in other areas of interest to them, such as textiles and agriculture, where they enjoy competitive advantage in form of a reduction of trade protectionism.[22]

Further, part of the bargain for developing countries during the negotiations of TRIPS was also the promise by developed countries to increase R&D in neglected diseases in exchange for a higher level of IP protection.[23]

Anyway, many of them feel that the commitments made by developed countries were not a quarter as serious as the burdens of the TRIPS Agreement, developing countries have to live with nowadays.[24]

21 B Stirner, 'News and Views, Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases' (2008) 15 European Journal of Health Law 398.
22 C Dommen, 'Raising Human Rights Concerns in the World Trade Organization: Actors, Processes and Possible Strategies' (2002) 24 Human Rights Quarterly 25 ff.
23 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 2 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

3.2. The TRIPS Agreement in detail

After giving an overview of the TRIPS Agreement and outlining the different positions concerning TRIPS, I now want to elaborate on the most essential Articles of the TRIPS Agreement.

The provisions of TRIPS most relevant to patent rights are Articles 27, 28, 30, 31, 32, 33, 34, 40, 65 and 70.

To provide a theoretical basis for the analysis afterwards, I will firstly draw a wider picture of the conditions of patentability under TRIPS. Then I will go on to describe the rights conferred to a patent holder and in a third subchapter, I will give a quick overview about the transitional arrangements.

3.2.1. Conditions of patentability

According to Article 27.1 of the TRIPS Agreement which regulates the above mentioned conditions of patentability "(...) 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 (...)."

Pharmaceutical products and processes are therefore explicitly within the scope of patentability, but might be excluded from patentability under one of the exceptions that the TRIPS Agreement contains, allowing members to exclude certain areas from patentability, which I want to discuss below.
First of all, I want to take a look at the single conditons of the term "patentable subject matter":

24 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 8 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

Patents only have to be made available for inventions[25], which have to be distinguished from not patentable discoveries that can be described as already existing in nature, such as ideas, laws of nature, and materials discovered in nature.[26]

In this context it is worth mentioning that it is up to the individual member state to exactly define the subject matter "invention". Depending on the concrete definition choosen by the individual member state, the scope of patentability can either be broader or narrower.[27] I will elaborate on the influence of national law through the implementation of TRIPS into the national legislation of developing countries in chapter 3.3. in more detail.

The extension of patents to all fields of technology by the TRIPS Agreement has been fought for intensively by the pharmaceutical industry lobby.[28] It is now generally accepted that patents have to be made available in the pharmaceutical field as well as in any other field.

One might argue that pharmaceuticals are covered by one of the exceptions that the TRIPS Agreement contains. Article 27.2 of the TRIPS Agreement allows the exemption of "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 (...)."

The provision clearly requires the prevention of the commercial exploitation of the invention, more precisely the marketing of the invention for profit.[29] But preventing the sale of pharmaceuticals for profit is not necessary to reach the intended public

25 *Canada-Term of Patent Protection*, WT/DS170/AB/R (2000) paras 65-66 <http://www.wto.org/english/tratop_e/dispu_e/1391da.pdf> accessed 24 March 2014.
26 CM Correa, *Intellectual Property Rights, the WTO and Developing Countries. The TRIPS Agreement and Policy Options* (Zed Books-Third World Network 2000) 52.
27 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 54.
28 J Straus, 'Bedeutung des TRIPS für das Patentrecht' (1996) Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 179, 188.
29 P Peter, *Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen* (Nomos 2002) 103, 136.

health goals and can thus not serve as an exemption from the general duty to make patents available in all fields.[30]

Article 27.3 (a) of the TRIPS Agreement gives members the possibility to exclude "diagnostic, therapeutic, and surgical methods for the treatment of humans or animals" from patentability, but here, too, it is undisputed that pharmaceuticals are not covered by the exception.[31]

Finally, a member country suffering from a grave pandemic could try to invoke the national security exception contained in Article 73 (b) of the TRIPS Agreement which states that a member should not be prevented by any part of the TRIPS Agreement "from taking any action which it considers necessary for the protection of its essential security interests". Although the term "security" has been used rather broadly, including such areas as diseases, it has to be considered that taking advantage of the expansive interpretation always involves a high risk of losing in a WTO dispute settlement.[32] It has to be noted, that WTO Panels have prefered a textual interpretation of the TRIPS Agreement, which in general favors the patent holder.[33]

The obligation of non-discrimination contained in Article 27.1, demands that "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". This includes the effect that discrimination against pharmaceuticals would constitute an impermissible discrimination as to the field of technology.[34]

30 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 57.
31 J Straus, 'Bedeutung des TRIPS für das Patentrecht' (1996) Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 179, 189 ff.
32 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 58 ff.
33 *Canada- Patent Protection of Pharmaceutical Products*, WT/DS114/R (2000) <http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm> accessed 24 March 2014.
34 DL Burk and MA Lemley, 'Is Patent Law Technology-Specific?' (2002) 17 Berkeley Tech Law Journal 1155 <http://www.law.berkeley.edu/journals/btlj/articles/vol17/Burk-Lemley.stripped.pdf> accessed 24 March 2014.

In Article 27.1 the TRIPS Agreement also covers the prerequisites of patentable subject matter which are novelty, inventive step and capability of industrial application.

Further, in return for granting a patent, according to Article 29.1 of the TRIPS Agreement, society requires that the patent applicant discloses the invention in a manner that enables others to put it into practice in order to make it available for further research.[35]

I will come back to the content of Article 27 and 29 of TRIPS in chapter 3.3. in detail when elaborating the influence of national law through the implementation of TRIPS into the national legislaton of developing countries.

3.2.2. Conferred rights

If the conditions for patentability are fulfilled, the national patent offices have to grant a patent. Patents do not grant a positive right but a negative right, namely the right to exclude others from certain actions.[36]

According to Article 28.1 (a) of the TRIPS Agreement the patentee has the exclusive right "to prevent third parties not having the owner's consent from the act of: making, using, offering for sale, selling, or importing for these purposes that product".

It is evident, that a company simply needs to obtain patents in all markets with the capacity to produce the drug, and then can use the patent to prevent others from manufacturing the drug without its consent.

35 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 12 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
36 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 68.

Even though this negative right is meant to give the patent holder the right to fully exploit the value of his/her invention, it does not automatically allow the patentee to give him/her control over a product after placing it on the market as the patent right has then been "exhausted". This doctrine has come to be known as the "doctrine of exhaustion" or "first sale doctrine", and has for a long time been a very controversial issue in intellectual property law, at least if it is not used in a national context and the patented product has been placed on a foreign market by the patent holder or with his/her content.[37] I will come back to that point in detail below.

3.2.3. Transitional arrangements

The TRIPS Agreement came into force on 1 January 1995. Industrialised WTO Members had time until 1 January 1996 and developing countries until 1 January 2000 to implement it.

During the negotiations and especially after the TRIPS Agreement entered into force, developing countries voiced public health concerns to argue for weaker or more flexible patent protection in the pharmaceutical field.[38]

They particulary emphasized the existence of their right to access to medicine which I want to elaborate on in more detail below. Furthermore, they argued that the adoption of patent legislation leads to investors' charging higher prices and thus rendering those pharmaceuticals unaffordable for parts of the population.

Anyway, it is evident that these were vast changes for many WTO members in direction of strong intellectual property rights.

37 HC Jehoram, 'International Exhaustion versus Importation Right: a Murky Area of Intellectual Property Law' (1996) 4 Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 280 ff.
38 Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, *Meeting of the Negotiating Group* (MTN.GNG/NG11/5, 1987) para 7 <http://www.wto.org/gatt_docs/English/SULPDF/92030176.pdf> accessed 24 March 2014.

Transitional arrangements were necessary to make sure that least developed and developing countries have enough time to comply with their obligations as well.[39]

The transitional periods, which depend on the extent of development of the individual country, are regulated in Article 65 and 66 of the TRIPS Agreement.

According to Article 65.4 of the TRIPS Agreement, developing countries,[40] such as Brazil and India, that did not grant pharmaceutical product patents at the date of the application of the TRIPS Agreement on 1st January 2000, were allowed under the transitional arrangement not to grant product patent protection for pharmaceuticals expired on 1 January 2005.

The extension includes in Article 65.5 of the TRIPS Agreement a so-called "no-rollback-clause", which has been effective from the entry into force of the TRIPS Agreement on 1 January 1995. This clause drew criticism on the overall decision and states, that a developing country "shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement".

The term "rollback" means giving developing countries, that have already implemented provisions of the TRIPS Agreement in national legislation to become TRIPS compliant, the possibility of reducing or withdrawing these existing IP protections in their own legislation.[41] Developing countries were forbidden to rollback according to Article 65.5 of the TRIPS Agreement.

For least-developed countries, there is another transitional period for the duration of 10 years until 1 January 2006 from the date of application according to Article

39 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 70 ff.
40 WTO law itself does not contain a definition of developing member countries. Anyway, Article XVIII:1 of the GATT points out two important factors for identifying a developing country: Firstly, a low standards of living and secondly, an early stage of development.
41 S Shashikant, 'TWN Info Service on WTO and Trade Issues' (*Third World Network*, 25 June 2013) <http://www.twnside.org.sg/title2/wto.info/2013/twninfo130611.htm> accessed 25 March 2014.

66.1 of the TRIPS Agreement.[42] Article 66.1 of the TRIPS Agreement permits least-developed countries not to apply TRIPS provisions "in view of the special needs and requirements of their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base". In contrast to Article 65.5 which only refers to developing countries, least-developed countries are completely free to roll back their actual level of IP protection.[43]

Thus, it was acknowledged according to Article 66.1 of the TRIPS Agreement, that the transition period until 1 January 2006 might not be sufficient for least-developed countries. That is why for pharmaceuticals, the 2001 Doha Ministerial Declaration on TRIPS and Public Health had instructed the TRIPS Council to extend the period for least-developed countries to comply with provisions on pharmaceuticals until 2016 upon request. The TRIPS Council formally adopted a decision implementing this in 2002.[44] With respect to most other TRIPS Agreement obligations, the TRIPS Council extended the period until 1 July 2013 in its decision of 29 November 2005. Again, this Decision of 29 November 2005 included a "no-rollback-clause" for least-developed countries.[45]

However, countries that made use of any transition period were according to Article 70.8 of the TRIPS Agreement under the obligation to implement a so-called "mailbox" provision in order to receive patent applications during the transition period and to preserve the filing and priority dates of these applications.[46] Under

42 The category of least-developed member countries is well defined: according to Article 11.2 of the WTO Agreement, the WTO recognizes the classification of the United States to designate countries as least-developed countries: To be added to the United Nations list of least-developed countries a country has to have a low per capita income, a low level of human resource development and a high degree of economic vulnerability. These indicators are being reviewed and updated every three years by the Committee for Development Policy of the UN Economic and Social Council.

43 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 72.

44 World Trade Organization, Decision of the Council of TRIPS of 27 June 2002 (IP/C/25) <http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm> accessed 24 March 2014.

45 World Trade Organization, Decision of the Council of TRIPS of 29 November 2005 (IP/C/40) <http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm> accessed 25 March 2014.

46 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 6

this mailbox-system, only those products for which patents were filed after 1995 can claim for a product patent.[47]

Just before the last deadline was set to expire on 1 July 2013, least-developed members of the WTO filed an application for an extension that would have enabled them to remain excluded from implementing most of the provisions of the TRIPS Agreement, also for pharmaceutical products, as long as they were classified as "least-developed". This would have enabled least-developed countries to determine the level of IP protection on their own according to their current level of economic, social and technological development, instead of adopting a specific date, regardless of the individual progress in becoming TRIPS compliant.

However, this proposal was not accepted by the United States and the EU.[48] They were under the impression that an unlimited extension would modify the nature of the original TRIPS Agreement from a transition into a total exemption from protecting IP[49], and therefore a compromise was developed by the WTO TRIPS Council on 11 June 2013: WTO members finally agreed to extend the flexibility of least-developed countries under Article 66.1 to not apply the provisions of the TRIPS Agreement except for Articles 3, 4 and 5, which concern national treatment and most favored nation treatment, for eight more years until 1 July 2021.[50]

<http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

47 J Hepburn, 'Implementing the Paragraph 6 Decision and Doha Declaration: Solving Practical Problems to Make the System Work' (2004) Quaker United Nations Office 6 <http://www.geneva.quno.info/pdf/DohaImplSeminar0504.pdf> accessed 03 April 2014.

48 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 12 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.

49 World Trade Organization, *The least developed get eight years more leeway on protecting intellectual property* (11 and 12 June 2013) <http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm> accessed 25 March 2014.

50 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 12 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.

There are huge disputes about the question, whether the extension implicates a so-called “no-rollback clause“ as it was adopted in the last extension from 2005. From what I understand, this issue is very important as it finally clarifies the question, if least-developed countries that have already implemented the TRIPS provisions are allowed to back-pedal and to finally make use of the transition period for their benefit.

Even the WTO itself avoids to clarify this uncertainty, when the chairperson simply says, that “the non-rollback commitment of 2005 has been replaced with more positive wording“ through the current extension decision.

Third World Network, a non-profit international network of organisations argues, that the new extension decision does not hamper least-developing countries from rolling back.

I agree with the Third World Network which justifies this proposition with the simple fact, that there is – compared to the decision of 2005 – no “no-rollback clause“ included in the wording of the current decision of the WTO TRIPS Council.[51] Instead, the new extension decision only states that “least developed countries express their determination to preserve and continue the progress towards implementation of the TRIPS Agreement“, but that “nothing in this decision shall prevent least-developed countries from making full use of the flexibilities provided by the Agreement to address their needs (...).“

Anyway, at least there is mutual consent concerning the circumstance, that the use of flexibilities allowed under the TRIPS Agreement does not fall under the category “roll back“.[52]

51 S Shashikant, ’TWN Info Service on WTO and Trade Issues’ (*Third World Network*, 25 June 2013) <http://www.twnside.org.sg/title2/wto.info/2013/twninfo130611.htm> accessed 25 March 2014.
52 World Trade Organization, Decision of the Council of TRIPS of 11 June 2013 (IP/C/64) <http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm#decision> accessed 25 March 2014.

However, many humanitarian organisations, such as “Médecins sans frontières“ qualified this compromise as unsatisfactory as the exemption is – once again – still time-bound and only gains reprieve instead of finding a real solution in granting least-developed countries a longer and more complete extension.[53]

Naturally, the steps taken by countries in implementing TRIPS, differ widely. It is in my opinion imperative to realize that the speed of implementation has to respond to each country’s development in order to be effective. Therefore the only valuable way to find a suitable solution is to work on a possibility that determines several parameters and to abstain from this narrow-minded dependence on singular time-oriented terms for the implentation.

3.3. The design of patent systems & the influence of national law

In its wording, the TRIPS Agreement refers to a clear ideal, namely a maximum patentability and protection.

Anyway, it should be mentioned in that regard that members – although obliged to provide for product patent protection for drugs- enjoy considerable latitude as to how they draft their patent laws, in particular with more or less stringent requirements for patentability, which can help to promote public health goals.[54]

As already mentioned in chapter 3.2.1., every member state can decide by itself, how to exactly define the terms “novelty“ and “inventive step“ in implementing the relevant provisions of the TRIPS Agreement in its national legislation. Further, the member state is free to find a suitable definition of what constitutes a patentable

53 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 12 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.

54 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 53 ff.

"invention" as opposed to an unpatentable discovery, as none of these terms are defined under TRIPS and there is no obligation to follow the very low thresholds for patentability criteria in the United States.[55]

However, it is not that simple to determine the optimal degree of patent protection, as I will illustrate in the following subchapter:

3.3.1. Scope of patentability

First of all, developing and least-developed countries should especially pay attention to the scope of patentability in implementing the relevant TRIPS-clauses in their legislation, as we will see in more detail later on in chapter 3.5.

The mentioned point was also affirmed by the Commission on Intellectual Property Rights, when they finally described "the level of protection as a kind of compromise".[56]

The Economist has already seemed to take a similar view in 1851, noting that the privileges granted to investors by patent laws are in fact prohibitions on other men, except by the patentee.[57]

It is important to note that too broad patents might discourage further innovation by other researchers in the general field of the patent.

On the other hand, too narrow patents might encourage others to "work around" the patent, offering little restriction on related research by others.[58]

55 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 2.
56 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 14 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
57 Ibid 19.
58 Ibid 14.

This very last point, namely “restricting the ability of the patentee to prohibit others from building on or designing around patented inventions“ is seen as an essential factor in order to faciliate competition and to encourage follow-on innovation, such as diverse dosage forms of medicines.[59]

Thus, several scholars even consider this side effect of a narrow scope of a patent system, namely the pressure on competitors to design around existing patents instead of just imitating products, as important possibility to stimulate innovation and to develop other succesful drugs which can be patented too afterwards.[60]

Several generic pharmaceutical firms even make public that they frequently use disclosed patents as the basis on which to “design-around“ in order to develop generic versions of brand-name products.[61]

The downside of an innovation developed in a design-around process, is that it does not necessarily lead to a new drug. Often competitors have to work harder to get to the same result and there is no additional value achieved through the process of designing around. It is therefore indeed often a waste of ressources.[62]

However, based on these arguments above, it is critical to realize, that neither too broad nor too narrow patents can be recommended to a member country. The concrete level of protection is in fact a double-edged sword. Again, it is difficult if

59 Ibid 49, 119.
60 Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) Chapter 2, The role of competition and the patent system in spurring innovation 21 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 25 March 2014.
61 Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) Chapter 3, Business testimony: Current innovation landscape in selected industries 10 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 25 March 2014.
62 Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) Chapter 2, The role of competition and the patent system in spurring innovation 22 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 23 May 2014.

not impossible to find a universal solution that can be applied to all member countries to the same extent.

In my view, a recommendation concerning the scope of patentability depends first and foremost on the level of development of the individual country and the goals that are sought to achieve with the implementation of the TRIPS rules. Each member country can exert influence on the concrete definition of the terms. I therefore hold the view that this leeway should really be utilized to the full extent. If a decision has to be made between a rather narrow or rather broad scope of patentability, I would recommend to a country, be it a developing country or a least-developed one, that is interested in improving its access to medicine, to include a definition of patentability-scope into their legislation that is rather narrow. Only then, competition can be stimulated through competitors that seek to design around. And as a common business rule states, more competition leads to descreasing prices. The alternative, namely the definition of a broad scope of patentability, would mean the elimination of competition to a large part permitting the patent holder to determine prices quasi ad libitum.

3.3.2. Standards of patentability

There are several provisions that can be quite significant for developing and least-developed countries in exerting influence on the individual design of their patent system. An analsysis of these provisions seemed of particular importance to me. Therefore it is important to reduce the issue to the common denominator, namely to the question, how countries can make use of the provisions to their benefit. Herein lies the crux of the matter. I am convinced, that countries that really exploit all their possibilities to their advantage in implementing the TRIPS provisions can achieve a lot in improving the access of their inhabitants to affordable medicine.

3.3.2.1. Data protection

First of all, according to Article 39 of the TRIPS Agreement, which deals with the subject of data protection and exclusivity, members “shall protect undisclosed information (...) and data submitted to governments or governmental agencies in the course of ensuring effective protection against unfair competition“.

It is essential to realize that the act of implementation of “data protection“ into national law can be a harmful barrier to generic entry.

Therefore it is useful to pause at this point and ask whether it is really reasonable for a potential generic competitor to repeat costly tests which have already been executed in the past. This question has already been posed by the Commission on Intellectual Property Rights, when they illustrated the main argument from a public health point of view, which is, that such data should remain in the public domain because it contains critical medical information which is hardly available anywhere else.

As already illustrated above, TRIPS does not make the imposition of data exclusivity necessary, as Article 39.3. requires only protection against unfair commercial use.[63] It is therefore advisable for developing and least-developed countries to refrain from the implementation of a general provision of data exclusivity.

3.3.2.2. Disclosure requirement

Another imporant point in implementing the TRIPS provisions is the disclosure requirement in Article 29.1, as already mentioned above in chapter 3.2.1..

63 Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy* (2002) 50 f <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

The obligation to disclose a discovery can be described as a kind of trade-off for obtaining the negative right stemming from the patent.[64]

The Commission on Intellectual Property Rights defines this requirement as a contract between the patent holder and the society, whereas the extent of the necessary disclosure to satisfy the applicant's part of the contract can – again – be influenced by every single country.

It is useful for developing and least-developed countries to ensure that the patent holder does not keep critical information that can be useful for future research secret.[65] It is therefore necessary to note that the requirement of disclosure of a patented invention contributes to the advancement of further innovations[66] by enabling a person competent in the particular skill to learn from another's invention.[67]

In this context the example given by the Commission on Intellectual Property Rights is worth mentioning: Hereby the Commission exemplifies a company inventing a new compound for the treatment of headaches and extending the claims beyond the use of the compound itself over all its potential uses, for example in treating heart diseaeses.

The Commission on Intellectual Property Rights asks in this context the important question, if such broad claims can be really justified on the basis of limited disclosure.

64 Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) 10 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 23 March 2014.
65 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 117 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
66 Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) 6 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 23 March 2014.
67 Ibid 10.

As already mentioned, it is up to the single country to define the possible scope of protection. In doing that, the developing or least-developed country should be careful to provide that claims are limited to the uses which are effectively disclosed in order to encourage further research of any new uses of the same compound.[68]

3.3.2.3. Bolar exception

The so-called Bolar-exception is defined as “an exception to patent rights allowing a third party to undertake, without the authorisation of the patentee, acts in respect of a patented product necessary for the purpose of obtaining regulatory approval for a product“.[69]

Developing countries are adviced to include such a “Bolar exception“ for “early working“ in their legislation, in order to make it possible for a generic producer to import, manufacture and test a patented product prior to the expiry of the patent.[70] Through the implementation of such provision, one can ensure that cheaper generics can reach the market a lot earlier- again, a measure, that can be taken by any member country quite easily and that can have a huge influence on the prices of drugs and on the access to medicine at the same time. To me, it is more than obvious that often a small step is sufficient in reaching a big goal concerning the access problem.

3.3.3. Practical evidence

After having analysed the theoretical possibilities available to every member country implementing the TRIPS Agreement, I will now move on to give some

68 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 117 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
69 Ibid 173.
70 Ibid 50.

practical evidence. This part of the analysis will be rather short as it merely intended to provide some exemplary illustration.

First of all, the importance of the optimal degree of patent-scope was an essential issue in the decision of India's Supreme Court in April 2013, when the attack of the Swiss pharmaceutical company Novartis against India's patent law was finally rejected after a seven-year battle.

The background was the Amendment of the Indian Patents Act in 2005 which was adopted in order to become TRIPS-compliant. The result of the implementation-process was the adoption of a strict medicines patent law in 2005 in India, which formulated rather high criteria for patentability. It had the objective to restrict the number of granted patents and to award only significant innovation.[71] The Amendment Act should hamper "ever-greening", a term I will explain in detail in subchapter 3.5.4., in order to make the solely patentation of new forms of existing medicines impossible. The main goal of the Act was, however, to improve the access to affordable medicines through generics made in India.[72]

A similar process took place in India even before, when the 1970 India Patent Act implicated a degradation of IP protection concerning pharmaceuticals. This Act reduced the period of validity of process patents from 20 to 7 years and eliminated all product patent protection. Thus, it was possible to allow patented drugs to be reverse engineered under the only prerequisite that a different process is used in manufacturing.[73] In general this law was the reason for many Indian companies

71 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 57 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

72 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 8 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.

73 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 20 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

pursuing this reverse engineering strategy through imitating and producing own versions of new drugs that are patented in other countries. It further allowed the introduction of automatic licensing and price controls.[74] The provisions of the Act are considered to have been the relevant factor for the fast growth of India's pharmaceutical industry, as a supplier of low-cost medicines.[75]

In general, India can be described as a suitable example of a completely new and innovative way of making products affordable. It seems for me that India has been one of the few developing countries that has taken matters into its own hands by making use of legislation in order to design a patent system that is able to achieve certain public health goals, in particular to reduce drug prices.

The fact that such a big development can not be observed in many countries, will be illustrated in the next subchapter. I will analyse the difficulties and challenges that most developing countries have struggled with, when implementing the relevant TRIPS provisions. The fact, that there has been some assistance provided through several agencies does not automatically mean an accurate solution to the problem.

3.3.4. Assisting developing countries to implement TRIPS - Difficulties & Challenges

A critical, but unpleasant aspect is the fact, that in many developing countries, the institutional capacity is quite weak and that there is a general lack of well-experienced legal drafters[76], who could implement the provisions of the TRIPS Agreement in national law in a manner consistent with the individual needs of the countries. That's why there was a nameable dependence on assistance in the

74 HE Kettler and R Modi, 'Building Local Research and Development Capacity fort he Prevention and Cure of Negelcted Diseases: The Case of India' (2001) 79 Bulletin of the WHO 743.
75 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 20 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
76 Ibid 138.

form of expert advice on new draft legislation in the past, provided by UN specialised agencies, such as WIPO[77] and the WHA.[78]

The problem with the receivement of technical assistance by WIPO, one must keep in mind, might be, that it is an international institution which is responsible for the promotion of IP. Therefore the risk is high, that IP laws become quite strict in the particular countries and that the individual needs of developing countries are not enough considered.

The assumption, that through WIPO's assistance the TRIPS-flexibilities are not enough incorporated, has already shown evidence in the case of the Bangui Agreement[79], where India received legal advice from WIPO. The Bangui Agreement serves as a prime example for the recent trend "TRIPS plus", a term that I will discuss in detail below in chapter 3.6.

Similarly, the World Health Assembly (WHA) was asked by the WHO to assist developing and least developed countries in deactivating the negative effects of TRIPS when implementing the TRIPS provisions into their legislation. The main problem with the assistance on the part of the WHA is, that lots of its members are trade and intellectual property experts, so that even some developing countries annotate this fact by declaring "We are the World Health Assembly, not the World Intellectual Property Assembly".[80]

77 WIPO defines itself as a global forum for intellectual property services, policy, information and cooperation. WIPO was established in 1967 and is a self-funding agency of the United Nations with 186 member states <http://www.wipo.int/about-wipo/en>.

78 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 27 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

79 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 161 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

80 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 27 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

It is important to realize that developing and least-developed countries cannot rely completely on the assistance of several agencies when implementing the TRIPS provisions. Although it is certainly easier said than done, the main responsibility in finding the right way for defining the patent terms in their national legislation according to the appropriate development level, still lies in the hands of the countries themselves.

3.3.5. The intention of international patent harmonisation

It is interesting to note, that there have been made some efforts in the previous years within WIPO to harmonize the patent law systems of the individual member countries through international IP treaties. This chapter will be rather short as it primarily intends to give an impression of the existing treaties and of the possible problems that could arise from such a trend in the direction of harmonization.

3.3.5.1. Patent Law Treaty

In this context it is worth mentioning, firstly the Patent Law Treaty: This treaty was signed in 2000 and aimed to streamline formalities in respect of national and regional applications and patents, such as the requirements to obtain a filing date for a patent application, the form and content of a patent application, and representation,[81] all in all formal procedures, which the office of a contracting party should apply.[82]

81 *Wikipedia 2013*, headword 'Substantive Patent Law Treaty'.
82 World Intellectual Property Organisation, *Summary of the Patent Law Treaty* (2000) <http://www.wipo.int/treaties/en/ip/plt/summary_plt.html> accessed 26 March 2014.

3.3.5.2. Substantive Patent Law Treaty

Anyway, more fascinating to observe are the newer negotiations within the Standing Committee on the Law of Patents of WIPO to draft a substantive patent law treaty which aims to go far beyond formalities to harmonize substantive points of patent law with regards to content. This treaty would seek to determine substantive requirements, for example, what constitutes a patentable invention and how the requirements of novelty, inventive step and industrial application are to be defined.[83]

These efforts made within WIPO are in my opinion harmful for developing and least-developed countries, as to me the danger seems great, that WIPO harmonisation will lead to standards being geared too much towards the ones of developed countries and that do not consider enough the individual interests of developing and least-developed countries.

3.4. The importance of generic drugs

A generic drug is defined as “the chemical equivalent of a patented drug“.[84]

Generic drugs have so far been manufactured in countries where the medication is not protected by patents and which have the technological capacity to manufacture drugs. Above all India, but also Brazil, Argentina, Thailand, South Africa and Cuba.[85]

83 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 132 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
84 Ibid 173.
85 R Kampf, ’Patents versus Patients?’ (2002) 40 Archiv des Völkerrechts 90, 91.

The main advantage of a generic drug lies in the fact that it is on average around 31% lower than the originator price of a drug.[86] The following chapter is devoted to the question, how generic drugs can influence the determination of a drug-price.

The first step must be to identify the general factors that affect the price of a drug and to illustrate the differences between developing countries and developed countries in that respect. In a second step I will explain the changes that TRIPS has already implified or rather the problems that will occur after the transitional periods have expired. The main difficulty in the context of generic drugs is the fact, that there won't be any useable low-priced generic drugs available after the expiration of the transitional periods. In a last step, I will analyse the main factors that can affect the supply of generic drugs by pharmaceutical corporations. I will then go on to illustrate in short several possible measures that can be taken by health insurance systems in order to make the generic entry more attractive.

3.4.1. Evidence on prices

In contrast to developed states, where costs are in general met by the state or through insurance schemes, this is not the case in the developing world. Insurance schemes can be seen in general as an advantage as national authorities in developed countries have the possibility to negotiate significant discounts for branded products and to eliminate insurances that do not accept the pretented prerequisites.[87] Since the majority of developing countries are self-pay markets, they do not get the same discounts and have to pay for health care out of their

86 P Danzon, A Mulcahy and A Towse, 'Pharmaceutical pricing in emerging markets: Effects of income, competition and procurement' NBER Working Paper Series, Paper No 17174 (2011) 13 <http://www.nber.org/papers/w17174.pdf> accessed 26 March 2014.
87 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 50 ff.

own pockets. Moreover, the state provision is normally selective,[88] that is why the accessibility of drugs is heavily reduced.[89]

The first necessary realisation is that patents have a high impact on product prices because they hamper competition. Thus, the price of a drug is very much connected to the extent of competition among several drug-companies.[90] It is interesting to note, that at the time, when there was no product protection in India, it was the lowest priced market in the world.[91]

There is evidence that pharmaceutical product prices decrease when generic entry occurs following the expiration of the patents.[92] This arising competition among generic producers was significant in bringing down the prices of first and second generation antiretroviral drugs in the developing world, which are used when patients first begin AIDS treatment.[93] Several other studies emphasise more precisely that the first generic drug that enters the drug-market, represents around 70 to 80 percent of the price of the appropriate brand product and guarantee around two-thirds market share.[94]

88 World Health Organization, *Globalization, TRIPS and Access to Pharmaceuticals*, WHO Policy Perspectives on Medicines No. 3 (March 2001) 5 <http://apps.who.int/medicinedocs/pdf/s2240e/s2240e.pdf> accessed 23 March 2014.
89 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 18 ff.
90 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 5 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.
91 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 36 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
92 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 5.
93 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 7 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.
94 Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) 11 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 23 March 2014.

However, these first and second generation antiretroviral drugs were brought on to the market in the pre-TRIPS era[95] and the main problem is, that these drugs – although affordable thanks to the impact of generic competition in the past – are toxic and already lose their effectiveness because of increasing resistance and spreads.[96] More precisely in terms of HIV, the fact that the virus mutates easily has the consequence that the distribution of antiretroviral drugs without developing adequate infrastructure contributes to the occurence of drug resistance.[97] That is why new medicines are urgently needed.[98]

Anyway as most of the transition periods have already expired or respectively will expire in the following years, all members will have to provide for pharmaceutical product patents and generics will therefore be limited to older off-patent drugs. As these older off-patent drugs are mostly first and second antiretroviral drugs, they are useless for the majority of the population of developing and least-developed country-members. Manufacturers will then be able to obtain product patents for new medicines to address resistance to existing antiretroviral drugs. Thus, the manufacturing of low-priced generic versions will come to an end, at least for all members having the relevant production capacity for the duration of the patent term.[99]

95 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 7 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

96 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 2 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.

97 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 38 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

98 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 2 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.

99 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 75.

Hence all these new - already patented – antiretroviral drugs, used to treat patients for whom first and second generation rights are no longer effective, are unaffordable for the population of developing and least-developed countries.

3.4.2. Factors affecting the supply of generics

An essential point, that *Scherer* recognizes in context with the supply of generic substitutes in general, is the importance to create positive incentives for pharmaceutical corporations by health insurance systems to favor generic production.

As *Scherer* notes, generic entry depends on several factors: Firstly, generic entry is more likely to be undertaken, when the prospective market is large enough, and thus when sufficient sales can be expected to cover initial investments. Hereby the Waxman-Hatch Act of the United States adopted in 1984 can serve as an example, as it sharply reduced the front-end investment outlays and consequently raised the generic drugs' quantity share.[100]

The question how pharmaceutical companies can be enhanced to enter into the production of generic drugs will only be relevant as long as the transitional arrangements have not expired. After that time, every drug has to be patented and there will be no more space for the production of generic drugs. Thus, alternative measures will be needed to guarantee the access to medicine for the inhabitants of developing and least-developed countries through reducing the drug-prices significantly. I will come back to this issue in detail when analysing the TRIPS-flexibilities in chapter 3.6.

100 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 6.

3.5. Justification of the Interference?- Research incentive

There are several theories with different basic approaches trying to justify the conflict between patent law and human rights law in general and the high prices of drugs in particular.

A profound research of all these different theories serves no purpose and will therefore not be undertaken in the framework of my doctoral thesis, as it would go beyond the scope of my thesis . Instead, I want to especially focus on the so-called “incentive rationale“ which is not only the widely favored but in my opinion also the most convincing and reasonable theory, at least at first glance.

In the following chapter, I will firstly illustrate the main arguments of the “incentive theory“. I will then go on to emphasise the point of criticisms in order to give an overview of the whole picture. However, my analysis draws the conclusion that the theory is in general unsupportable and nothing but hot air. In my opinion, the theory is nothing but the pharmaceutical industries’ attempt of justifying their behaviour in public.

The main argument of the theory is the assumption, that patent systems are justified as main incentive to encourage private sector pharmaceutical R&D, because patents grant exclusive rights preventing rival companies from free riding on the discoveries of the innovating firm and allowing the inventor to charge monopoly prices above marginal costs and to recoup research and development expenditures. Thus, without patents, there would be no innovation at all.[101] *Professor Synder*, who was engaged with the research of this matter, specifies this

101 S Joseph, ’Pharmaceutical Corporations and Access to Drugs: The fourth wave of corporate human rights scrutiny’ (2003) 25 Human Rights Quarterly 431 <http://hmb.utoronto.ca/HMB303H/weekly_supp/week-08-09/Joseph_Drug_Patents.pdf> accessed 23 March 2014.

thesis arguing that without patents for pharmaceuticals, innovation would decrease by approximately 60 %.[102]

In other words, the “incentive theory“ justifies deviances from the access to medicine as a human right declaring it to be a necessary sacrifice for a better future.

Another argument in favor of pharmaceutical patents might be, that they are justified within international human rights law, because they encourage greater technology transfer between countries and accelerate the economic development of poor countries.[103]

Anyway, I do not agree with *Professor Synder* to the furthest extent as the exact opposite was shown in several studies. Fact is, that the amount reinvested by big pharmaceutical corporations into R&D is disproportionately small compared to the amount invested in marketing which is about two times higher than the amount invested on R&D.[104] Thus, patent rents do not primarily cover revenues on R&D, but a much larger portion of expenditures goes to administration, advertising and promotion.[105]

Another captivating aspect, many scholars argue with, is the fact, that pharmaceutical corporations in general overestimate their R&D costs.[106] The

102 Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) Chapter 3, Business Testimony: Current innovation landscape in selected industries 11 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 27 March 2014.

103 S Joseph, ’Pharmaceutical Corporations and Access to Drugs: The fourth wave of corporate human rights scrutiny’ (2003) 25 Human Rights Quarterly 432 <http://hmb.utoronto.ca/HMB303H/weekly_supp/week-08-09/Joseph_Drug_Patents.pdf> accessed 23 March 2014.

104 See for example figures quoted in the annual reports of Merck <http://www.merck.com>.

105 F Abbott, ’The WTO Medicines decision: World pharmaceutical Trade and the protection of public health’ (2005) 99 American Journal of International Law 325 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=763224> accessed 27 March 2014.

106 B Young, *Rx R&D Myths: ’The Case against the Drug Industry’s R&D ’Scare Card* (Public Citizien’s Congress Watch 2001) <http://www.citizen.org/publications/publicationredirect.cfm?ID=7065> accessed 27 March 2014.

pharmaceutical industry even fought a nine-year battle in the United States in order to prevent the disclosure of its R&D costs.

However, one must keep in mind, that the pharmaceutical industry has been for many decades an extraordinarily profitable sector.[107] It is therefore highly obvious, that most pharmaceutical industries could easily afford to cut their profits by lowering prices without sacrificing R&D outlays.[108]

To me, the counter-argument that the inflated prices primarily restrict the ability of poorer people to access drugs that they need, still seems to be stronger. The analysis in this chapter shows that there is in fact no substance to the main argument of the "incentive theory", namely that patents are necessary to encourage private sector pharmaceutical R&D. Therefore it follows that patents alone must not be seen as the motor for innovation and the high prices of drugs cannot be justified under the incentive rationale.

3.5.1. Innovation deficit in the pharmaceutical industry

The following chapter will demonstrate, that the "incentive theory" is not only plain wrong, but that in fact the opposite of this theory is reality. Before coming to that conclusion, it was necessary as a first step to analyse the interplay between the level of intellectual property rights on the one hand and the number of new inventions on the other hand. The analysis will demonstrate that the stronger IP-rights are, the lower the number of new inventions is. In a second step, I will emphasise the reasons for that conclusion.

107 A Marcia, 'The Pharmaceutical Industry: To whom is it accountable?' (2000) 342 The New England Journal of Medicine 342.
108 S Joseph, 'Pharmaceutical Corporations and Access to Drugs: The fourth wave of corporate human rights scrutiny' (2003) 25 Human Rights Quarterly 433 <http://hmb.utoronto.ca/HMB303H/weekly_supp/week-08-09/Joseph_Drug_Patents.pdf> accessed 23 March 2014.

As illustrated in the previous subchapter, the “incentive theory“ is not able to deliver a clear justification for the high price of a drug in context with a pharmaceutical patent. In spite of the fact that the TRIPS Agreement in general introduced the obligation on all WTO-Members to provide patents for pharmaceuticals, evidence shows that in the last decade an innovation deficit in the pharmaceutical industry could be observed.

For instance, the experience in Italy in the 12 years after the introduction of product patents for pharmaceuticals shows that neither R&D expenditure growth nor new product introductions increased.[109]

A similar econometric analysis focused on the question whether the expansion of patent scope in Japan through the patent law reforms in 1988, induces more innovative efforts by companies. This analysis used Japanese and U.S. patent data on 307 Japanese companies concluding that there is no evidence that the patent reform is responsible for spending more money on R&D nor for achieving more innovative output.[110]

This lack of innovation is even more extreme when it comes to drugs targeting neglected diseases. Several reports show that drug discovery and drug development targeting infectious and parasitic diseases in poor countries has virtually come to a standstill and that the expansion of pharmaceutical patent protection in the developing world has not resulted in any real increase in R&D expenditure. For instance, between 1975 and 2004, only 20 out of 1.556 new

109 FM Scherer and J Watal, ’Post-Trips Options for Access to Patented Medicines in Developing Countries’ CMH Working Paper Series, Paper No WG4:1 (2001) 11.

110 L Branstetter and M Sakakibara, ’Do stronger Patents induce more Innovation? Evidence from the 1988 Japanese Patent Law Reforms’ (2001) 7 Journal of International Economic Law 2-3 <http://repository.cmu.edu/cgi/viewcontent.cgi?article=1044&context=sds&seiredir=1&referer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3Ddo%2520stronger%2520patents%2520induce%2520more%2520innovation%26source%3Dweb%26cd%3D1%26ved%3D0CC0QFjAA%26url%3Dhttp%253A%252F%252Frepository.cmu.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D1044%2526context%253Dsds%26ei%3DYiIoU9WnCs3M0AWR44DQAQ%26usg%3DAFQjCNEki_s96AvuO2wq3pxoCXBofbE4nw%26sig2%3DhQDnXqBCHYkZkQoV19kc6A%26bvm%3Dbv.62922401%2Cd.d2k#search=%22do%20stronger%20patents%20induce%20more%20innovation%22> accessed 27 March 2014.

chemical entities globally developed, targeted neglected diseases. Thus evidence shows, that the argument making the lack of patent protection responsible for the lack of innovation concentrating on neglected diseases, is flat out wrong.[111]

Quite the contrary, there is evidence that strong intellectual property rights restrict the use of innovations and ideas and reduce the number of inventions.

But what are the reasons for that interplay?

James Thou Gathii mentions the threat of expensive patent litigation as the main reason for that interplay[112] meaning that pharmaceutical corporations feel rather reluctant about the innovation of new drugs simply for the reason that they are afraid of getting sued by other pharmaceutical corporations.

This assumption was also pointed out by the Commission on Intellectual Property Rights, when its members argue in their report, that more intellectual property rights may lead to fewer useful products. The reason for that assumption is, that companies may invest time and money just in order to determine how to do research without infringing other companies' patent rights, and to defend their own patent rights against other companies.[113]

111 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 83 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

112 JT Gathii, 'Construing Intellectual Property Rights and Competition Policy Consistency with Faciliating Access to Affordable AIDS Drugs to Low-End Consumers' (2001) 53 Florida Law Review 727 <http://ssrn.com/abstract=1624892> accessed 27 March 2014;
T Palmer, 'Are Patents and Copyrights morally justified? The philosophy of property rights and ideal objects' (1990) 13 Harvard Journal of Law & Public Policy 817, 849 <http://tomgpalmer.com/wp-content/uploads/papers/morallyjustified.pdf> accessed 27 March 2014.

113 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 4 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

Shapiro puts it in a nutshell saying "the vast number of patents currently being issued creates a very real danger that a single product or service will infringe on many patents".[114]

One must ask himself in this context, if it can really be considered useful, that companies are patenting for the sole reason of preventing others gaining access to areas of research, or to ensure that other companies cannot block their research. I would definitively say, it cannot.

It seems to me that some companies have already established a second main pillar when trying to patent things that other companies will unwittingly infringe upon and then just wait for those companies to bring those products on the market in order to make profits through litigating.

An executive from CISCO hit the bull's eye when he compared this process to a "lottery game" and explained, that "the companies who file these patents and extract license fees from successful businesses play the patent system like a lottery (...)."[115]

I agree with the Commission on Intellectual Property Rights, that these costs should not be the necessary price to pay for the incentives in the framework of the patent system, quite the opposite there are better ways of investing this money.[116]

114 C Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting', in A Jaffe, J Lerner and S Stern (eds), *Innovation Policy and the Economy* (MIT Press 2001) 3.
115 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 126 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
116 Ibid 4.

3.5.2. Profit motive in the pharmaceutical industry

Another, and in my opinion, probably the most convincing argument to discount the described justification of interference with the access to medicine as a human right, is the profit motive in the pharmaceutical R&D field, which must not be underestimated.

The intellectual property-based R&D model is inherently linked to the value of the final intellectual property market. The idea of this model is that larger potential profits stimulate greater R&D activity, whereas in case of low profit expectations, intellectual property rights provide little or no value to the pharmaceutical industry and therefore stimulate little R&D activity.[117]

Anyway, to me the exact idea of this model, namely to define patent monopolies as the motor for R&D, seems to be the main problem of the entire issue. Similarly, *Ellen Hoen* describes the problem of access on the one hand and the lack of R&D on the other hand as two sides of the same coin. In her opinion, the solution lies in changing the funding of R&D through the elimination of the linkage between R&D-costs and the prices of medicine products. I agree with *Hoen* who argues that only through such a de-linkage, it would be possible to hamper the funding of R&D through charging high prices.[118] A justification would then not be possible anymore.

In this context, *Hoen* mentions in this context non-exclusive licensing practices as one possible approach. It is undeniable, that not-for profit drug development through the inclusion of government or university, would be – of course - beneficial

117 B Stirner, 'News and Views, Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases' (2008) 15 European Journal of Health Law 398.
118 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 93 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

as the inventor is independent from sales of the invention to finance his product.[119] Though *Hoen* words are comprehensible to me, I miss concrete suggestions for the transformation of her ideas. It is of course easy to define a concept that sounds idealistic from a theoretical point of view. But there is no purpose in doing so if there is no practical applicability. To me, it is questionable whether the funding of R&D through the government alone by eliminating private sector investments completely, would be enforceable at all. Instead, the goal should be the establishment of a system that constitutes a balance between public and private sector fundings. This proposal sounds a lot more realistic and enforceable to me. I will come back to that issue in chapter 3.5.5.. Further, I will analyse the possible effects of compulsory licensing in detail in chapter 3.6.3.

3.5.3. Life-style drugs versus Neglected diseases

In the following subchapter, I will first circumscribe the terms “life-style drugs“ and “neglected diseases“ and the differences in motivation of pharmaceutical companies to put R&D in. In a second step, I will analyse the reasons for the lack of R&D put into “neglected diseases“. The analysis will demonstrate that most of R&D is put into so-called “life-style drugs“ and that in this context pharmaceutical corporations are even ready to define new “illnesses“ or rather “unwanted health conditions“ just in order to sell the appropriate drug to the public. Again, the question taking center stage and running like a common thread through the whole chapter, will be, if patents can really be considered a sufficient incentive for the whole pharmaceutical industry to do R&D.

It is necessary to realize, that lots of R&D is put into drugs which deal with chronic, ongoing conditions, like heart diseases or high cholesterol[120] whereas little research is conducted into so-called “neglected diseases“.

119 Ibid 94.
120 AM Tabor, ’Recent Development: AIDS Crisis’ (2001) 38 Harvard Journal on Legislation 514, 525.

The term “neglected diseases“ is used in various ways in the international debate. The definition of the WHO classifies neglected diseases as “diseases affecting almost exclusively poor and powerless people living in rural parts and urban slums of low-income countries“.

The designation as “neglected“ reflects the lack of attention given to the diseases by affluent countries and global health agendas until recent years.

Firstly, the term “neglected diseases“ includes illnesses like HIV/Aids. Aids is an acronym for “acquired immune deficiency syndrome“ and can further be described as “impairment of the body’s ability to fight disease“. Evidence shows, that HIV-positive persons are enabled to live productive lives for many years as the appropriate medications interrupt the cycle of HIV infection, allowing an infected person’s immune system to rebuild itself at the same time. Thus, Aids is a treatable illness in contrast to the majority view that it is a guarantor for a certain death.[121]

Further, malaria and tuberculosis are also classified as “neglected diseases“, although they have similarly to HIV/Aids – more than other diseases – already received more attention and financial resources in the international context. Other “neglected diseases“ which have attracted less international attention and funding are for instance parasitic diseases transmitted by insects such as Chagas disease. Some are bacterial infections like trachoma, others however are spread by contaminated water and soil infected with eggs of worms like for example lymphatic filariasis alias elephantitis.[122]

121 JT Gathii, ’Construing Intellectual Property Rights and Competition Policy Consistency with Faciliating Access to Affordable AIDS Drugs to Low-End Consumers’ (2001) 53 Florida Law Review 733-734 <http://ssrn.com/abstract=1624892> accessed 27 March 2014.
122 B Stirner, ’News and Views, Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases’ (2008) 15 European Journal of Health Law 392.

Quite to the contrary, disproportionate research is put into so-called "life-style drugs", drugs that can be marketed to a large share of the population[123] in order to combat lucrative problems like obesity, cellulite, and impotence. This fact is understandable as these symptoms create stable markets. Anyway, this includes in general the fact, that the majority of these new drugs had a low overall health-value to developing country patients,[124] due to high prices or lack of suitability for developing country settings.[125]

There are different authors who studied the classification or rather differentiation of illnesses on the one hand and unwanted health conditions on the other hand. They brought up the question how pharmaceutical companies take advantage of the vague line concerning these terms.

Moynihan says it best when declaring the question what counts as an illness as an important issue.[126] It has to be considered that the line between an unwanted health condition on the one hand and a real illness on the other hand is not precise at all and remains rather vague. That is why for instance obesity can be seen as both.

Similarly, *Lane* examined the different approaches concerning shyness and illustrated the development of the definition in a very descriptive way in a case study. In the 1980s shyness was seen as an illness, primarily caused by a

123 European Generic Medicines Association, 'Tangled Patent Linkages Reduce Pharmaceutical Innovation. 6,730 patents for 27 pharmaceutical inventions' EGA Press Release (2004) <http://198.170.119.137/pr-2004-07-01.htm> accessed 28 March 2014.
124 M Moran and J Guzman, 'Neglected diseases – Doctors can make a difference', 335 British Medical Association 269 (2007) 8 ff.
125 It has to be mentioned, that in the last years the fight against chronic diseases, such as cardiovascular disease and cancer, has also become an important issue for developing countries as the deaths from such diseases already occur in low and middle-income countries by nearly 80 percent. In high-income countries, for instance the drug-treatment has reduced average blood pressure and thus has enormously decreased deaths from heart disease. Anyway, in lower-income countries in Africa, more than 40 percent of adults are estimated to have high blood pressure, a situation that could easily be rectified through the appropriate medication (K Kelland, 'Chronic Diseases growing in developing nations: WHO' (*Huffpost Healthy Living* 2012).
126 R Moynihan, I Heath and H David, 'Selling sickness: the medicine industry and disease mongering' (2002) 324 British Medical Journal 886-891 <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1122833> accessed 30 March 2014.

chemical imbalance or faulty neurotransmitter in the brain while nowadays it is rather defined as a common, socially tolerable personality trait.[127]

It was *Meislik* who in this context suggested that pharmaceutical companies have exploited this definition-vagueness to treat unwanted health conditions as illnesses just in order to sell the correspondent drug to the public.[128]

As in any industry, the pharmaceutical industry does research where money can be made with a sufficient probability. Large pharmaceutical companies are unwilling to spend money in R&D, unless the potential outcome is a "blockbuster" drug, which can be described as a product with annual sales of 1 billion US dollars.[129]

Patents in developed countries may therefore be necessary as an incentive for research whereas patents in developing countries' markets do not contribute in an economically significant manner to research costs on global diseases and are not a sufficient incentive for research on diseases prevalent in the developing world.[130]

The global pharmaceuticals market is worth 300 billion US dollars a year.[131] Most major drug companies achieve over 80 per cent of their sales in the United States, Canada, the European Union, and Japan alone[132]while especially Africa is particularly neglible as a market- it represents just 1.1 per cent of the global

127 C Lane, *Shyness- How Normal Behaviour became Sickness* (1st edn, Yale University Press 2008) 194-195.
128 A Meislik, 'Weighing in the Scales of Justice: The Obesity Epidemic and Litigation Against the Food Industry' (2004) 46 Arizona Law Review 781-813 <http://www.arizonalawreview.org/pdf/46-4/46arizlrev781.pdf> accessed 03 March 2014.
129 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 32 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
130 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 161 ff.
131 World Health Organisation, 'Trade, foreign policy, diplomacy and health- Pharmaceutical industry' <http://www.who.int/trade/glossary/story073/en> accessed 30 March 2014.
132 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 161 ff.

market.[133] For this reason, it is very unlikely that the profits in least-developed countries or in developing countries are necessary to sustain research and development expenditure.[134]

To sum it up, I would like to say that patents are not a sufficient incentive for the local, developing world industry. The conducted analysis has shown that the local pharmaceutical industry lacks the capacity to do research at all[135] and where it does, it won't target developing markets, but prefers, similarly to the industry in the developed world, to do research on diseases that also concern developed countries. The main reason lies in the larger economic opportunities those markets offer.[136] There is some evidence of this behaviour in the past from firms in countries such as India.[137]

3.5.4. No new developments - Me-too drugs and Ever-greening

In the following subchapter, I am going to describe the recent trends concerning the drug-invention-sector. Therefore I will describe the two terms "me-too-drugs" and "evergreening" that are imperative in this context to describe the whole situation. In a next step, I will analyse the advantages for the pharmaceutical sector on the one hand and the disadvantages for developing and least-developed countries on the other hand that are combined with the two phenomens "me-too-

133 A Attaran, 'The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law' (2002) 12 Fordham Intellectual Property Media & Entertainment Law Journal 859-885 <http://ssrn.com/abstract=333363> or <http://dx.doi.org/10.2139/ssrn.333363> accessed 30 March 2014;
A Attaran Amir and L Gillespie-White, 'Do Patents for Antriretroviral Drugs Constrain Access to AIDS Treatment in Africa?' (2001) 286 Journal of American Medical Association 1886-1892 <http://ssrn.com/abstract=350080> accessed 30 March 2014.
134 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 161 ff.
135I bid 163.
136 HE Kettler and R Modi, 'Building Local Research and Development Capacity fort he Prevention and Cure of Negelcted Diseases: The Case of India' (2001) 79 Bulletin of the WHO 742, 745.
137 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 33 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

drugs“ and “ever-greening“. I will then examine the possibilities that are provided to developing and least-developed countries in order to influence their legislation in that regard when implementing the TRIPS provisions.

Evidence reveals that in the last decades, only minor (but patentable) improvements on already existing drugs mainly by the private sector without public involvement were made in order to ensure safe investments and profits.[138]

Consequently, the difference between the number of patents awarded for new uses of a drug, process, formulations and other forms of the same molecule, and the factual number of new drugs which are actually developed as new chemical entities, is therefore quite large.

These forms of broad patents for drugs are so called “me-too-drugs“, which are just different enough to fulfill the prerequisite of novelty in order to gain patent protection, but in reality have nearly the same effects as priorly patented drugs.[139] It is an interesting fact that only 15 per cent of the new drug applications authorized from 1989 to 2000 by the US Food and Drug Administration were identified as real improvements in relation to products that are already established on the drug-market.[140]

Similarly, “ever-greening“ can be desribed as s process where minor innovations to already patented innovations become patented for the sole purpose of extending the life of the patent beyond the 20 year TRIPS minimum term.[141]

138 European Generic Medicines Association, ’Tangled Patent Linkages Reduce Pharmaceutical Innovation. 6,730 patents for 27 pharmaceutical inventions’ EGA Press Release (2004) <http://198.170.119.137/pr-2004-07-01.htm> accessed 28 March 2014.
139 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 12 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.
140 R Malpani, M Kamal-Yanni, *Patents versus Patients- Five years after the Doha Declaration*, (Oxfam International 2006) 20.
141 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human*

The main advantage of these patent-forms for pharmaceutical companies is the reduction of the risk of investing lots of money in the unpredictable search of new drugs.

The main disadvantage for the population of developing member countries is – however – that “me-too-drugs“ and the process of “ever-greening“ in general only provide minimal therapeutic progress and are therefore useless to the poor population.

The member states are given leeway at this point as it is up to the member states to establish the relevant criterias for the terms “new“ and “inventive“ in their legislation[142], as already analysed above in chapter 3.2. and 3.3..

Developing countries, which have not yet implemented the relevant TRIPS provisions in their national legislation and can now make use of the extension periods, are adjured to think carefully when applying the appropriate standard to their national patent regimes.

The Commission on Intellectual Property Rights was right, when it adviced developing countries to overcome the temptation to apply a higher standard of IP protection as necessary, already in 2002, when the situation was similar, because of the granted extension period for least developed countries agreed upon in the Doha Declaration.

According to the Commission on Intellectual Property Rights, the objective of any standard should be to ensure that minimal creative input should in general not be patentable.[143]

Rights. Report of the High Commissioner, U.N Doc. E/CN4/Sub2/2001/13 (2001) 13 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.

142 World Health Organization*, Globalization, TRIPS and Access to Pharmaceuticals*, WHO Policy Perspectives on Medicines No. 3 (March 2001) 2 <http://apps.who.int/medicinedocs/pdf/s2240e/s2240e.pdf> accessed 23 March 2014.

Therefore, India serves as a good model as ever-greening is not permitted under the Indian legislation and the scope of patentability is defined quite narrowly.[144]

It is obvious that these kinds of broad patents run completely counter to the original objective of patent systems, which is promoting innovation and not focusing on private commercial interests through blocking future medical research as consequence of the overly patent-broadness. [145]

In my opinion, an important step in the right direction for developing and least-developed member states would be to categorize medicine patents in national legislation solely according to their therapeutic impact and novelty element. For developing and least-developed member countries this would lead to the beneficial outcome that neither “me-too drugs“ nor drugs developed by a process of “ever-greening“ could become patented. Through such measure the motivation of pharmaceutical companies to invent more drugs with higher therapeutic gain could be increased.

However, *Banerjee* in this context warns against a potentially new corruption factor.[146] I suppose that the main disadavantage could be the increase in supervising bureaucracy, a factor which should be put up with in favor of a better access to necessary medicine.

143 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 116 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
144 J Hepburn, ’Implementing the Paragraph 6 Decision and Doha Declaration: Solving Practical Problems to Make the System Work’ (2004) Quaker United Nations Office 7 <http://www.geneva.quno.info/pdf/DohaImplSeminar0504.pdf> accessed 03 April 2014.
145 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 19 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.
146 A Banerjee, A Holli and T Pogge, ’The Health Impact Fund: incentives for the improving access to medicines’ (2010) 375 Lancet 166-169 <http://www.academia.edu/1019643/The_Health_Impact_Fund_incentives_for_improving_access_to_medicines> accessed 30 March 2014.

3.5.5. Public sector research versus Private sector research

This subchapter is dedicated to the differentiation between the effects of private and public sector research. In particular, I will analyse in particular the advantages of the involvement of public sector investment for developing and least-developed country-members, but will in a second step also discuss the dangers public sector research can bring along. I will then turn my attention especially to the instrument of public-private partnerships.

Firstly, it is critical to note, that in general, the quality of health services is largely determined by the availability of monetary ressources to improve health in each country. We have to bear in mind, that only few companies are in a position to self finance R&D and that in the past approximately 70 per cent of drugs with therapeutic gain were produced with government involvement where research is hardly driven by a pervasive profit motive.[147]

But yet the overall proportion of public sector spending on neglected diseases is still not high enough, and one possibility might be to increase the aid resources devoted to such R&D. If government were more involved in R&D projects, new developed products would be more likely to target diseases affecting impoverished countries.[148]

There are several authors, however, who especially turn their attention to the point of science-autonomy arguing that independent of whether funds enabling R&D are stemming from the state or private budgets, the autonomy of science should

147 UNDP, *Human Development Report 1999* (1999) 69 <http://hdr.undp.org/en/media/HDR_1999_EN.pdf> accessed 30 March 2014.
148 S Joseph, 'Pharmaceutical Corporations and Access to Drugs: The fourth wave of corporate human rights scrutiny' (2003) 25 Human Rights Quarterly 441 <http://hmb.utoronto.ca/HMB303H/weekly_supp/week-08-09/Joseph_Drug_Patents.pdf> accessed 23 March 2014.

always be kept. This implies the ability of pharmaceutical firms to define the agenda of science programs on their own.[149]

It seems obvious to me, that the danger of science programs being influenced can become relevant in the case of public sector investments. In that case, this exercise of influence is necessary as otherwise, public investments would probably not be used for R&D to target “neglected diseases“. If there are no ways of influencing or rather controlling the concrete use of investments through the public sector, pharmaceutical companies would rather be inveigled to use fundings in order to develop “life-style drugs“ which would completely run counter the original goal of public sector investments.

In general, the keyword in this context is “public-private partnerships“ (PPPs) which are defined by the WHO as an “informal or formal arrangement between one or more public sector entities and one ore more private sector entities created in order to achieve a public health objective or to produce a health-related product or service for the public good“.[150]

By bringing together all essential stakeholders involved in a PPP, namely pharmaceutical companies, academic institutions, science and regulatory agencies, biotechnology firms, patient advocacy associations and representatives of private and public payers, it is made possible to share data, expertise and resources.[151]

149 C Sherry, *Who owns Academic Work?- Battling for control of intellectual property* (Harvard University Press 2001) 2.
150 JK Lazdins-Helds, ’Drug development through public private partnerships’ (Symposium on Public Sector IP Management in the Life Sciences, December 2008) <http://www.wipo.int/edocs/mdocs/tk/en/wipo_ip_lss3_08/wipo_ip_lss3_08_www_114643.pdf> accessed 30 March 2014.
151 M Goldman, ’Public-private partnerships as driving forces in the quest for innovative medicines’ (2013) 2:2 Clinical and Transnational Medicine <http://www.clintransmed.com/content/2/1/2> accessed 30 March 2014.

In recent years, the WHO has already recognized that the sector-wide approach through establishing PPPs offers an effective method in achieving long-term public health goals.[152]

According to *Lazdins-Helds*, PPPs have become popular by "recognizing the gap in innovative products addressing neglected and most neglected diseases" and after "recognizing that the private pharma alone cannot address this gap".

As *Janis K. Lazdins-Helds* points out in his symposium on public sector IP Management in the Life Sciences, PPPs are not at all a new concept.[153] It is intriguing to note, that a PPP surprisingly includes the same components as a private company, namely a management team, a board of directors, a scientific advisory committee and a stakeholder council.[154]

Anyway, among authors there are some very critical voices in the context of PPPs. For instance, *Sarah Joseph* argues that it is unlikely to garner much political support in an age of increasing faith in "the efficiency" of market solutions and the private sector, and consequent public sector rollback.[155]

In my opinion, however, this mixture of public capital with private experience through establishing PPPs, could guarantee the best balance and has at least a positive impact on the drug development process as public funds can be used in exceptional ways in order to engage private and public researchers in the development of new drugs against neglected diseases.[156]

152 JK Lazdins-Helds, 'Drug development through public private partnerships' (Symposium on Public Sector IP Management in the Life Sciences, December 2008) <http://www.wipo.int/edocs/mdocs/tk/en/wipo_ip_lss3_08/wipo_ip_lss3_08_www_114643.pdf> accessed 30 March 2014.
153 Ibid 5.
154 Ibid 13.
155 S Joseph, 'Pharmaceutical Corporations and Access to Drugs: The fourth wave of corporate human rights scrutiny' (2003) 25 Human Rights Quarterly 441 <http://hmb.utoronto.ca/HMB303H/weekly_supp/week-08-09/Joseph_Drug_Patents.pdf> accessed 23 March 2014.
156 JK Lazdins-Helds, 'Drug development through public private partnerships' (Symposium on Public Sector IP Management in the Life Sciences, December 2008)

3.5.6. Incentives to perform R&D in Neglected Diseases

It appears that the main question in this context is, how the interest of multinational pharmaceutical companies can be attracted in order to perform pharmaceutical R&D for neglected diseases. There are several proposals which I will present in short in the following:

Some schemes suggest a patent term extension for a commercial drug of choice to be awarded to a company that developed a drug for a neglected disease. This assumes of course, that the extension period is long enough to increase the returns on R&D. This model, though, is uncommon and has been widely refused .

Another model allows for prize funds, which implicates that government and private and public donors can provide a significant sum to reward the innovator of a new drug for a neglected disease. An example is the “U.S. Medical Innovation Price Act of 2007“ introduced to the U.S. Congress. The uniqueness of this model is that it is not reliant on high prices on drugs as a consequence of the monopolistic control of the patent-holder. Instead the innovative company is able to compensate R&D expenses only by means of the financial reward.

Yet another system is the so-called “Advanced Purchase Commitment“, which also intends to motivate pharmaceutical companies to focus on R&D targeting neglected diseases. This system demands government and private or public donors to obligate themselves to purchase a neglected disease drug when it has been completed. The developed drug should then be made available to developing countries for no or a very low co-payment. The important element of this purchase commitment is a contract or binding agreement of the sponsors to buy any new drug if specific prerequisites are fulfilled.

<http://www.wipo.int/edocs/mdocs/tk/en/wipo_ip_lss3_08/wipo_ip_lss3_08_www_114643.pdf> accessed 30 March 2014.

There are plenty more theories with different approaches most of which are at this stage only discussed and not yet implented. In addition, they only serve as additional options to the current patent based incentive system for pharmaceutical R&D for neglected diseases.[157]

To sum up this chapter to the question if the conflict between patent law obligations under TRIPS and the access to medicine as a human right can be justified, I can say that pharmaceutical patents in the developing world are an impediment to the access to medicine without causing any adequate benefit.

It was the WHO Director-General *Margaret Chan*, who hit the bull's eye, when she defined the only important incentive as to consider the prevention of large numbers of needless deaths and suffering.[158]

In reality, there is no clear justification for the interference with access to medicine and thus, from my point of view, pharmaceutical patents clearly violate the right of access to medicine.

3.6. TRIPS- Flexibilities versus TRIPS-plus

In the following part of my doctoral thesis, I will examine the possible measures that limit the rights of patent holders, the so-called TRIPS-flexibilities. In this venue it firstly is necessary to take a look at the TRIPS-Agreement itself in order to find out how the TRIPS-flexibilities can be interpreted. It will become evident that the influence of every individual member country on the concrete implementation of the TRIPS provisions into their national legislation, is a very large one. It is therefore really advisable for developing and least-developed member countries to

157 B Stirner, 'News and Views, Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases' (2008) 15 European Journal of Health Law 399 f.
158 International Centre for Trade and Sustainable Development, 11 *Bridges Weekly Trade News Digest* (23 May 2007) <http://ictsd.org/downloads/bridgesweekly/bridgesweekly11-18.pdf> accessed 31 March 2014.

establish a sophisticated system of TRIPS-flexibilities in the framework of their national patent law system. Further in this chapter, I will give attention to a so-called TRIPS-plus trend that can be observed in recent time. By doing that, I will also examine the question, if a TRIPS-plus procedure can in general be justified inside the framework of TRIPS.

First of all, it is essential to recognize that in spite of the fact that members in principle have to grant patent protection for pharmaceuticals, the TRIPS Agreement also provides flexibilities that I will present in the following subchapters.

The interpretation of the TRIPS Agreement has to take into account the access to medicine as a public health concern, mentioned as an object and purpose of the agreement which can be found in its praemble and in its Articles 7 and 8.

The praemble lists a number of goals, such as that members should take into account both the need "to promote effective and adequate protection of intellectual property rights" and the need to prevent that protection from itself becoming a "barrier to legitimate trade". Thus, the praemble makes clear that the purpose of TRIPS was not the protection of any private interests of companies, but that it serves particulary the wider goals of trade and economic development. [159]

One might argue that access to medicine serves as an argument for a broad interpretation of the flexibilities. For instance, from the United Nations General assembly's point of view, "TRIPS does not and should not prevent members from taking measures now and in the future to protect public health".[160]

159 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 50.
160 Resolution (General Assembly of United Nations) A/RES/60/262 of 15 June 2006 Political Declaration on HIV/Aids [2006] para 43 <http://data.unaids.org/pub/report/2006/20060615_hlm_politicaldeclaration_ares60262_en.pdf> accessed 31 March 2014.

However, access to medicine suffers from the fundamental weakness that the right to access to medicine is only one argument amongst several in the interpretation of the flexibilities[161]and that it is not necessarily dispositive.

Anyhow, the WHO supports its member states in the use of TRIPS-related safeguards, for example in setting standards for patentability which reflects public health concerns. Hereby the WHO gives the clear instruction to every developing state to be cautious about enacting TRIPS plus-legislation,[162] a term that I will later discuss in detail.

Further, the Commission on Intellectual Property Rights recommends developing countries should not feel obliged to adopt developed country standards for IPR regimes until the expiration term expires. Instead developing member countries should really be ready to make demands on the TRIPS-flexibilities and to ensure that their legislation provides for appropriate standards and practices.[163]

Pascal Lamy, the former WTO Director-General affirmed the importance of TRIPS-related safeguards in noting that "safeguards can make an important difference in saving life and ensuring more people can afford medical treatment".[164]

The establishing of such a system of TRIPS-flexibilities has worked well in Brazil and India, which have built crucial safeguards into their national patent systems in order to enhance the affordability of important HIV medicines. In India, for instance, a provision was implemented, that allows for the automatic compulsory licensing for generic drugs during the mailbox period between 1995 and 2005.

161 E Ghanotakis, 'How the U.S. Interpretation of Flexibilities Inherent in TRIPS Affects Access to Medicines for Developing Countries' (2004) 7 Journal of World Intellectual Property 563.
162 World Health Organization*, Globalization, TRIPS and Access to Pharmaceuticals*, WHO Policy Perspectives on Medicines No. 3 (March 2001) 5 <http://apps.who.int/medicinedocs/pdf/s2240e/s2240e.pdf> accessed 23 March 2014.
163 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 12 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.
164 R Malpani, M Kamal-Yanni, *Patents versus Patients- Five years after the Doha Declaration*, (Oxfam International 2006) 9.

Further, India has a very simple provision for the production and the export of generics under compulsory license in developing countries that do not have the manufacturing capacity.[165]

Anyway, in other countries' patent law systems, like that of South Africa's, TRIPS-flexibilities still remain under-utilized as a strategy to lower antiretroviral drug prices as there are no measures such as compulsory licences used.[166]

On top of that, developing member countries in general are not sheltered from pressure by Western governments and the pharmaceutical industry to implement patent legislation that goes beyond the minimum requirements of TRIPS in order to speed up the process to become TRIPS-compliant. Therefore, bilateral or regional Free Trade Agreements (FTAs) between developed and developing countries have been arranged, including commitments of developed countries to increase the levels of IP protection in their own regimes, based on developed-countries-standards.[167]

The FTAs contain different TRIPS-plus rules, for instance the expansion of the scope of pharmaceutical patents to new formulations and indications or the limitation of the grounds for issuing compulsory licences to emergencies.[168]

165 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 86 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

166 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 12 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.

167 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 5 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

168 R Malpani, M Kamal-Yanni, *Patents versus Patients- Five years after the Doha Declaration*, (Oxfam International 2006) 14.

Several African countries, for example, have committed to provide higher patent protection than the one mandated by the TRIPs Agreement by ratifying the Bangui Agreement.[169]

Further, the EU and India are negotiating since 2007 in an effort to complete the EU-India Free Trade Agreement, which should include measures that could seriously restrict the production of generic medicines in India.[170]

Furthermore, particularly the US has achieved an increase in IP requirements through the adoption of several FTAs. Thereby the USA strives for a worldwide harmonisation of intellectual property rules on a level that is at least in accordance with US law, and stricter than the requirements under TRIPS.[171]

To reach this goal, the US government orders a survey once in a year, that is known as the "Special 301" report in order to find out whether standards of intellectual property protection in other countries are in accordance with the level of protection that is preferred by the US. If the US standards are not observed by a particular country, this country can be placed on the "Priority Watch List" meaning that the US is ready to send warnings including threats of trade sanctions to this country.[172]

Today, new member countries of the WTO are often pressured by their accession treaties to implement provisions stricter than under the TRIPS-Agreement. For instance, Jordan was charged in 2000 during the negotiations with the WTO not to make demands on the transition periods. The final Jordan-US Free Trade Agreement included a serial of provisions that go beyond the minimum

169 C Dommen, 'Raising Human Rights Concerns in the World Trade Organization: Actors, Processes and Possible Strategies' (2002) 24 Human Rights Quarterly 28 ff.
170 Médecins sans frontières, *Untangling the web of Antiretroviral Price Reductions. Aids-Report* (2013) 10 <http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf> accessed 25 March 2014.
171 R Malpani, M Kamal-Yanni, *Patents versus Patients- Five years after the Doha Declaration*, (Oxfam International 2006) 13.
172 Ibid 14.

requirements under TRIPS and it was also the first Agreement that became a Guideline for following Free Trade Agreements with other member countries.[173]

These occurences are often referred to as “TRIPS plus“, meaning that more stringent requirements are necessary than the ones agreed upon under the TRIPS Agreement.

The WHO describes “TRIPS plus“ as “efforts to extend patent life beyond the twenty-year TRIPS minimum, to tighten patent protection, to limit compulsory licensing in ways not required by TRIPS, or to limit exceptions which faciliate prompt introduction of generics“.[174] However, the term “TRIPS plus“ also refers to situations where countries implement TRIPS-consistent legislation although they are not yet obliged to do so.[175]

The main reason why these FTAs have not attracted a lot of attention until recently is, that they are mostly negotiated in secret and that there are not any public draft texts available.

Another interesting, but harmful aspect pointed out by *Ellen Hoen*, is that the negotiations of the Agreements are not conducted by health ministers, but by trade ministers, who of course do not turn their attention in particular to the possible health-consequences of an Agreement.[176]

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173 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 70 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

174 World Health Organization*, Globalization, TRIPS and Access to Pharmaceuticals*, WHO Policy Perspectives on Medicines No. 3 (March 2001) <http://apps.who.int/medicinedocs/pdf/s2240e/s2240e.pdf> accessed 23 March 2014.

175 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 9 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument> accessed 03 April 2014.

176 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 70

There fortunately has been some backpedalling on part of the US Congress in recent years concerning the TRIPS-plus phenomen. In particular, the agreement the US Congress and the White House reached in 2007, on easing the TRIPS-plus restrictions in FTAs – although certainly a step into the right direction – do not go far enough as most scholars describe.[177]

In this context it is worth taking a look at Article 1.1. of the TRIPS Agreement, which defines the nature and scope of the TRIPS-obligations. Article 1.1. of the TRIPS Agreement states that "members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice".

When reading Article 1.1. of the TRIPS Agreement, I get the impression that it is primarily a definition of required minimum standards, which does not automatically forbid the adoption of a TRIPS-plus provision.

Some scholars, for instance *Correa*, argue that Article 1.1. of TRIPS provides protection against demands for higher standards than TRIPS requires.

The UNCTAD was even adopting a much wider approach when stating that a country demanding TRIPS-plus provisions from a trade partner would be acting in bad faith in regard to its TRIPS obligations.[178]

In my opinion, the main problem is that TRIPS sets out minimum standards but denies to set out maximum standards at the same time. I think that the establishment of maximum standards would help extensively to prevent developed

<http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.
177 Ibid 72-73.
178 Ibid 13-14.

countries from putting pressure on developing and least-developed countries in order to adopt TRIPS-plus provisions.

3.6.1. Parallel Imports

One of the TRIPS-flexibilities are parallel imports. In the following subchapter, I will firstly explain the term "parallel import". As a second step I will discuss the question of national versus international exhaustion and will therefore examine the relevant legal framework as well. The main question will be if parallel imports can be justified inside the framework of TRIPS, firstly in a national context but also in an international connection.

Further, I will analyse another system which is called "differential pricing" in context with its underlying theory, the "*Ramsey* pricing theory". This second system can be considered as a counter piece to parallel importation. The analysis will compare both systems in particular under the aspect of possible difficulties and challenges. The focus of the analysis in this chapter lies on the following question: Which system brings more advantages for the population of developing and least-developed countries concerning better access to medicine? That of parallel importation or that of differential pricing?

In connection with the rights conferred through a patent, I have already described the first sale-doctrine which is highly contested in an international context.[179] The proposed question is whether the TRIPS Agreement provides that a patent holder can prevent the importation of a product where the product has been placed on a foreign market by the patent holder itself or with his/her consent.[180]

179 L Rubini, 'Is the Siege of Fortress Europe Really Over? The Exhaustion of Trademarks in the EC, Competition and International Trade' (2001) 29 Legal Issues of Economic Integration 205 ff <http://www.aspenpublishers.com/PDF/15666573.pdf> accessed 01 April 2014.
180 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 231.

Parallel import can be defined as an importation, without necessarily having the consent of the patent holder, for a product from another country where the product has been lawfully placed on the market by the IPR owner or with the owner's consent.[181]

Scherer defines parallel trade as a "form of arbitrage, tending to reduce differences in prices across diverse markets". Further, the incentive for parallel trade was illustrated by *Scherer* as a "sufficient difference in prices between the price paid by the first purchaser and prices charged in Nation B to cover shipping and other transaction costs and still offer gains to both the shipper and the Nation B buyer".[182] Consequently, where a patented drug is marketed at a cheaper price in one country, another country can benefit from that cheaper price through importing them rather than paying the more expensive price to the patent holder.

3.6.1.1. National versus International Exhaustion

This procedure is possible, if the importing country's patent regime stipulates that the patent holder's right has been – in TRIPS terminology – "exhausted", e.g. that the patent holder's rights to control the import and the export of drugs are "exhausted" once they have been placed on the market.[183]

In this context, it is important to strictly distinguish between national exhaustion and international exhaustion.

181 C Dommen, 'Raising Human Rights Concerns in the World Trade Organization: Actors, Processes and Possible Strategies' (2002) 24 Human Rights Quarterly 24 ff.
182 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 30.
183 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 15 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.

Since the Doha Declaration, which I will discuss later, the WTO's standpoint is clear, namely that each member is free to establish its own system of international exhaustion.

Prior to Doha, controversy emerged in particular concerning the rights of a patent holder to limit parallel trade of its products across national borders, while a system of national exhaustion in jurisdictions was – generally speaking – acknowledged.[184]

The European Union, however, authorized parallel trade within the EU, meaning that the patent holder exhausts his patent right once he places the product on the market anywhere in the EU.[185]

Anyway, arguing that Article 28.1 of the TRIPS Agreement grants patent holders the exclusive right to prevent third parties from importing the product even if they placed the product on the foreign market themselves, some authors considered the adoption of a system of international exhaustion as prohibited by the TRIPS Agreement.[186]

Although there are also some commentators regarding a regime of international exhaustion as mandatory,[187] most commentators have seen parallel importation always as a matter of national discretion leaving the choice, whether to follow the principle of international exhaustion or not, to members at the individual nation level.[188] This interpretation was confirmed in the Doha Declaration.

184 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 31.
185 P Danzon, 'Differential Pricing for Pharmaceuticals: Reconciling Access, R & D and Patents' CMH Working Paper Series, Paper No WG2:9 (2001) 10.
186 J Straus, 'Implications of the TRIPS Agreement in the Field of Patent Law' in FK Beier and G Schricker (eds), *From GATT to TRIPs- The Agreement on Trade-Related Aspects of Intellectual Property Rights* (VCH Publishing 1997) 160, 191 ff.
187 C Herrmann, 'TRIPS, Patentschutz für Medikamente und staatliche Gesundheitspolitik: Hinreichende Flexibilität?' (2002) Europäische Zeitschrift für Wirtschaftsrecht 41.
188 R Kampf, 'Patents versus Patients?' (2002) 40 Archiv des Völkerrechts 90.

This very last approach is also supported by the right to access to medicine, because it allows developing member countries to opt for international exhaustion and developed member countries to only apply national exhaustion.

Further, Article 6 of the TRIPS Agreement states that this matter cannot be challenged under the WTO dispute settlement system and is therefore a matter of national discretion.[189] As a result, widely diversifying national policies exist between the different intellectual property regimes within countries.[190]

3.6.1.2. Differential pricing as a counter piece

If one argues, that parallel imports can be banned as a result of the exclusive rights of a patent, the patent holder could consequently establish strictly seperated markets.

This system is called “discriminatory pricing“ and can be seen as a counter piece to the instrument of parallel importation- the patent holder can sell products at low prices where the market would not pay for high ones and at high prices where the market allows for such prices, instead of charging a uniform global price.[191]

3.6.1.2.1. Ramsey pricing as the underlying theory

The underlying theory of the system of “differential pricing“, the so-called “*Ramsey* pricing theory“, attributable to *Frank Ramsey*, helps to understand why prices are set at varying levels in different national markets instead of charging a uniform price and what the consequences of such price discrimination are.

189 World Trade Organisation, *TRIPS and pharmaceutical patents: Fact sheet* (2006) 1 <http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm> accessed 01 April 2014.
190 FM Scherer and J Watal, ’Post-Trips Options for Access to Patented Medicines in Developing Countries’ CMH Working Paper Series, Paper No WG4:1 (2001) 32.
191 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 146.

Scherer and *Watal* focus on explaining the entire theory by means of several figures arguing that prices are related to price sensitivity and demand elasticity: They assume two nations A and B, whereas nation A is assumed to have high average per capita income and nation B to have low income per capita. This "income effect" leads to different demand curves on the figures with the demand curve for nation A being higher than the demand curve for nation B. Further, in nation B as the more price-sensitive, cheaper prices should be charged as otherwise consumption would be reduced, if faced with the same prices. The Ramsey pricing principle argues against a uniform price in every national market with the justification that the drug producer could sell nothing in low-income nation B at the price maximizing profits in nation A. *Scherer* and *Watal* explain in a very plausible way that the price in Nation A would have to be reduced in order to sell anything at all in nation B under a uniform price policy, but that the general sacrifice is larger than the zero profit the firm could make. The consequence is, that the firm would not sell anything in nation B, if it is forced to charge a uniform price. Thus, the price differentials would be in the self-interest of every single corporation.[192]

Danzon distinguishes two differential pricing systems, firstly that for drugs in demand in high income countries and secondly that of drugs, that target diseases that exist in least-developed and developing countries: The standpoint taken by *Danzon* in her study due to the first system, is that through differential pricing the adoption of incentives for R&D as well as the affordability in least-developed countries can be guaranteed. Thus, the solution must be, that prices in high income countries exceed the marginal costs of production by enough to cover also the joint costs of R&D, while prices in least-developed countries cover only marginal costs.

In contrast, for drugs, that target diseases existing in least-developed and developing countries, the prices which can be afforded by patients in least-

192 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 36.

developed countries can not be at the same time high enough to cover joint costs of R&D and establishing incentives for R&D.

As *Danzon* states, patents might hypothetically be useful instruments in that case, but are of no value, because patients cannot pay for the high prices charged by the patent holder.[193]

3.6.1.2.2. Arguments in favor of discriminatory pricing

The adoption of a rule of "discriminatory pricing" is mainly seen as the most beneficial policy: First of all for developing and least-developed countries, but also for the company itself, at least from a theoretical point of view, as companies should be able to make more profits by charging low prices in low income markets and high prices in high income markets.

In the words of *Danzon*, differential pricing is even seen as the "key to resolving the potential conflict between patents (...) and affordability of drugs".[194]

Although in the past, there was remarkably little correlation between the price of the same drug and a country's per capita income, this situation has changed in the last decade, when companies have radically decreased their prices in response to international pressure, especially from NGOs, and potential competition from generic manufacturers.[195]

193 P Danzon, 'Differential Pricing for Pharmaceuticals: Reconciling Access, R & D and Patents' CMH Working Paper Series, Paper No WG2:9 (2001) 10.
194 Ibid 10.
195 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 37 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

3.6.1.2.3. Difficulties & Challenges of discriminatory pricing

However, one of the main problems concerning differential pricing is the possibility of cheap drugs spilling over to wealthy markets due to parallel trade or external referencing. These price weakages across countries are the reason why incentives for differential pricing are being undermined.

In the words of *Danzon*, external referencing can be defined as phenomen, which occurs, when "governments or other purchasers use low foreign drug prices as a benchmark for regulating their domestic prices" and which is equivalent to "fully importing a foreign price".[196]

As regards parallel trade, it is argued that the price of one national market would "leak" into another and importers would make use of such price discrimination through buying the product in low-price markets to resell them in high price-markets.

It has to be noted, that in both cases – parallel trade and external referencing – the drug producer will then – of course – rethink his pricing decision and will not be willing to offer lower prices in least-developed countries anymore.[197] Consequently, the patent holder might limit the supply for the market with the lower price[198] or raise the price in the low-income countries just in order to prevent this price leakage. Moreover, if the low income market is smaller than the high income market, it is obvious, that the drug price in the low income market will be geared to the conditions of the high income market price.[199] Hence, a uniform

196 P Danzon, 'Differential Pricing for Pharmaceuticals: Reconciling Access, R & D and Patents' CMH Working Paper Series, Paper No WG2:9 (2001) 11.
197 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 36.
198 Case T-41/96 *Bayer AG v Commission of the European Communities* [2001] CR 735 ECJ <http://curia.europa.eu/juris/showPdf.jsf;jsessionid=9ea7d2dc30db390d147fbc8a4339b962bbec5ca9ac6f.e34KaxiLc3qMb40Rch0SaxuKbxb0?text=&docid=103820&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=995078> accessed 01 April 2014.
199 P Danzon, 'Differential Pricing for Pharmaceuticals: Reconciling Access, R & D and Patents' CMH Working Paper Series, Paper No WG2:9 (2001) 11.

price much higher for low-income countries than one charged if markets had been seperate, would be the consequence.[200]

Thus, as *Danzon* points out, it is often not the patent, but this potential phenomen of price leakage that is responsible for setting prices at unaffordable levels in least-developed countries.[201]

This can only be hampered through establishing some form of enforceable market segmentation to maintain higher prices in wealthy countries and to hinder cheap drugs entering wealthier markets.[202]

Some authors argue that there should be an international agreement to bar parallel imports from low-income countries into high-income countries, while allowing the contrary way from high-income countries into low-income countries. This requires controlling exports and imports of relevant products. Such an agreement would enable low-income countries to determine on their own, when parallel imports are allowed and when they are prohibited according to the individual situation.[203]

Consequently the critical question arises, whether people and insurance companies in wealthy countries are really noble enough to pay high prices for drugs while lower prices are systematically being offered elsewhere.[204]

200 Ibid 12.
201 Ibid 1.
202 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 15 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.
203 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1 (2001) 62.
204 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 15 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.

I completely support the farsightedness of *Danzon* when declaring, that consumers in high-income countries will in the long run also benefit from this system of "differential pricing". This idea of *Danzon* might not seem understandable at first glance, because high-income countries might appear to benefit from importing low priced drugs in the short run. It does become reasonable when considering the circumstance, that high-income member countries would be worse off under a uniform pricing regime than under differential pricing. This results from the fact, that there would be less money left over for R&D. Further, under a uniform pricing system, fewer innovative new drugs would be developed than under one of differential pricing.[205]

After considering all the aspects concerning the system of "differential pricing", I can say that it is the more preferable system for everybody.

The only question remains, if developed countries already share this farsightedness of *Danzon* and are ready to accept the responsibility to pay higher prices. To be frank, I doubt, that high income countries would accept to pay a higher price for the same medicine on a voluntary basis. In my opinion, an international agreement between developed and developing countries, which I mentioned above, is therefore not very likely. More promising seems the proposal of *Danzon*, arguing the necessity to establish several policies that can hold price markets separately: One of that could be permitting the patent holder to ban parallel trade which would imply deciding against a system of international exhaustion. Anyway, price leakages through external pricing could not be hampered through this measure.

Another concept, proposed by *Danzon*, is to establish a system of confidential rebates, negotiated between the manufacturer, namely the individual company and the final purchaser, rather than by selling to wholesalers at the lower price. Through that system it is possible to allocate the rebates to the intended

205 P Danzon, 'Differential Pricing for Pharmaceuticals: Reconciling Access, R & D and Patents' CMH Working Paper Series, Paper No WG2:9 (2001) 4.

beneficiaries and to prevent price spillovers due to parallel trade and external referencing. The prerequisite for that system to work is, that the rebate negotiations between the company and the final purchaser remain really confidential and that the discount prices are not known instead of being regulated by a supranational body and thus becoming a public information, as otherwise external referencing would occur in the high-income country and the company would become reluctant to grant low prices in low-income countries.[206]

3.6.2. Limited exceptions

The second form of TRIPS-flexibilities are so-called limited exceptions. As they are in contrast to parallel imports and compulsory licenses not very prevalent, I will reduce the explanations in that chapter to the most important facts.

The provision of limited exceptions is regulated in Article 30 of the TRIPS Agreement which states that “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“.

Thus, Article 30 allows for exceptions to the rights of a granted patent and again, access to medicine mitigates in favor of a broad interpretation.[207] In particular, access to medicine has to be taken into account in defining “normal“ exploitation and “legitimate interests“ and Article 30 must be read as an exception to the rule of

206 Ibid 13-15.
207 ICTSD and UNCTAD, *Resource Book on TRIPS and Development- An authoritative and practical guide to the TRIPS Agreement* (2002) 25, 94 <http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm> accessed 01 April 2014.

non-discrimination in Article 27 of the TRIPS Agreement putting the members in a position to react to arising problems.[208]

3.6.3. Compulsory licenses

Compulsory licenses are the third form of TRIPS-flexibilities, regulated in Article 31 of the TRIPS Agreement. In the following subchapters, I will firstly give an explanation concerning the term “compulsory license“ and will then proceed to analyse, how the different stakeholders interpret Article 31 in order to define the concrete application-field of compulsory licenses. One subchapter will be devoted to the question, if there are any limitations on the grounds on which a compulsory licence can be granted. In a next step, I will examine the procedure of the grant and give thought to the question of the appropriate amount of “adequate remuneration“. Again, the possibilities of developing and least-developed countries to exert influence on particular points, through the concrete implementation of the TRIPS provisions into their own national legislation, runs like a common thread through the whole chapter. I will then continue to explain the principle of territoriality which originally formed the basis for granting a compulsory license. I will in this context also take a closer look at the problems that have arised in connection with the principle of territoriality. This principle does not exist in its original form anymore since the decision of 30 August 2003 which I will discuss in detail later on.

Compulsory licenses are regulated in Article 31 of the TRIPS Agreement and are granted by the government upon request, or for example as a result of a court decision, regardless of the will of the rightholder, permitting someone else, mostly a third party or a government agency (government use) to produce the patented

208 K Stegemann and B Pazderka, ’The TRIPS Agreement as an Alliance for Knowledge Production. The Funding of Pharmaceutical Innovation’ (2003) 6 Journal of World Intellectual Property 529, 541 <http://onlinelibrary.wiley.com/store/10.1111/j.1747-1796.2003.tb00228.x/asset/j.1747-1796.2003.tb00228.x.pdf?v=1&t=hth7q4o8&s=48c9abbd30e626bad077ca6686311a1fb5a42852> accessed 01 April 2014.

product and to ensure the availability of needed medicines or to use the process and thus create competition and lower prices.[209]

The main field of application of compulsory licenses nowadays is the purchase of antiretroviral drugs for the AIDS programmes of developing countries and least-developed countries.[210]

While developing countries were in favor of giving broad powers to grant compulsory licences, developed countries took a restrictive application of Article 31.[211] This is a very fascinating point considering that in the past, countries such as Canada, the UK and the US have broadly used compulsory licenses themselves in order to obtain medicine products for the public sector and the military. A decline of drug-prices due to a stimulated competition was the pleasant consequence. The striking success of these experiences in high-income countries should render as a model for developing and least-developed countries as well to make use of compulsory licensing.[212]

Until 2010, there were sixteen low and middle-income developing countries that had issued compulsory licenses or government use licenses to gain access to generic ARVs. Further, twenty-eight out of thirty-three least developed country WTO members had opted to import generic ARVs according to Paragraph 7 of the Doha declaration, which enables them to delay granting patents until 2016.[213]

209 P Rott, *Patentrecht und Sozialpolitik unter dem TRIPS-Abkommen* (Nomos 2002) 103, 13.
210 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 39 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.
211 FK Beier, 'Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law' (1999) 30 International Review of Industrial Property and Copyright Law 260.
212 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 88 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.
213 E Hoen (UNITAID) speech at AIDS 2010 IAS Conference: 'A proposal for change: Managing patents to ensure access to AIDS medicines for all'.

The serious threat, to pharma industry interests, however, is not the low-income countries granting compulsory licenses basically without or only against a minor remuneration, but the rich industrialized countries, where the profitable markets are located, doing the same thing.

Compulsory licenses are an important tool for safeguarding access to medicine as the patent holder will be more willing to supply a market with the product or to reduce the price of it, the more he fears government to grant a compulsory licence.[214] Ideally the chance of having a compulsory licence granted should be enough to encourage the patent holder to change his behaviour. In order to create – in the words of the Commission on Intellectual Property Rights - a "credible threat",[215] it is necessary to have a potential licensee up one's sleeve, who is really able to supply the patented product at a lower price than the patent holder, otherwise I assume, that the "threat" would appear ridiculous.

3.6.3.1. Grounds for compulsory licences

The TRIPS Agreement does not contain any explicit limitations for the grounds on which a compulsory licence may be granted, so that compulsory licences for pharmaceutical patents could be granted for a number of reasons.[216]

However, some authors argue, that compulsory licences can only be given out in cases of abuse, particulary when the patent owner fails to fulfil its obligation to work the patented invention.

214 FK Beier, 'Exclusive Rights, Statutory Licenses and Compulsory Licenses in Patent and Utility Model Law' (1999) 30 International Review of Industrial Property and Copyright Law 260.
215 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 120 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
216 T Cottier T, 'TRIPS, the Doha Declaration and Public Health' (2003) 6 Journal of World Intellectual Property 385.

A so-called “local working requirement“ requires the patent holder to manufacture the patented good in the country of the patent grant rather than to merely import it and is therefore of particular interest to developing countries.

However, such a “local working requirement“ contradicts the application of the non-discrimination rule of Article 27 of the Agreement which states that patent rights shall be enjoyable without discrimination as to whether products are imported or locally produced so that any working requirement can be fulfilled entirely by imports.[217]

The situation was not that clear before the Doha Declaration. Since the adoption of the Doha Declaration in 2001, though, it should be clear to everybody that the grounds for issuing a compulsory license are unlimited as Paragraph 5 (b) of the Doha Declaration expressly declares, that “each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted“.

Anyway, several states, developing and developed, have implemented in their own national patent laws provisions permitting compulsory licensing of patents only under specific conditions, whereat non-working of the patented invention with the patent-granting nation is the most common statutory ground.[218]

3.6.3.2. Procedure of the Grant

Before a compulsory licence can be granted according to Article 31 (b) of the TRIPS-Agreement, efforts have to be made, namely prior negotiations with the right holder, to obtain his/her authorization. However, a member can waive the

217 J Straus, ’Bedeutung des TRIPS für das Patentrecht’ (1996) Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 179, 189-19.
218 FM Scherer and J Watal, ’Post-Trips Options for Access to Patented Medicines in Developing Countries’ CMH Working Paper Series, Paper No WG4:1 (2001) 15.

requirement of prior negotiations in cases which require rapid action, such as national emergency or extreme urgency.[219]

Further, according to Article 31 (h) of the TRIPS-Agreement, the right holder has to be paid “adequate remuneration“ where a compulsory licence is granted.
The question to each national decision-maker at this point is, how much compensation is appropriate.

Firstly, it has to be noted, that the right to access to medicine and the economic value of the authorization are essential considerations in the determination of this payment. Thus, a developing country reacting to a public health crisis can determine a relatively low, in special cases even symbolic rate of remuneration.[220]

In general, developing countries are advised to set royalty rates not too high. *Scherer* reveals that “a reasonable royalty is one that is higher than zero, but much less than the royalty, that would compensate a patent holder fully for the loss of whatever monopoly position it might enjoy by virtue of the patent“.[221]

Even in the United States, the highest royalty rate paid by the U.S. government was 10 percent and rates of 6 percent were said to be applied as a general rule.[222]

In this context it has to be noted, that the extent to which price-reducing competition can arise through compulsory licensing, amongst other criterias, depends upon the dimension of the compensation paid.[223] Thus, evidence suggests that low royalty rates can provide the basis for competitive drug supplies on the one hand and compensating patent holders to at least some extent for their research and development efforts on the other hand. By contrast, high royalty

219 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 245-246.
220 C Ridder, *Die Bedeutung von Zwangslizenzen im Rahmen des TRIPS- Abkommens* (1st edn, Recht und Wirtschaft 2004) 54 ff.
221 FM Scherer and J Watal, ’Post-Trips Options for Access to Patented Medicines in Developing Countries’ CMH Working Paper Series, Paper No WG4:1 (2001) 61.
222 Ibid 24.
223 Ibid 21.

rates, as for example in Britain, may hamper the availability to low-income member countries.[224]

Anyway, in the past developing countries often did not make use of their right to establish a system of compulsory license and even when they made it available statutorily, they often did not invoke it.[225]

One reason for that was that they were under intense pressure on part of developed countries not to do so and had feared trade sanctions as well. Secondly, establishing a system of compulsory license requires the implementation of workable national laws and procedures. Therefore, a massive legal and administrative infrastructure is necessary to put it into effect, which is for the most part unavailable in developing countries. Further, the potential licensee must have the know-how to reverse engineer and to produce the drug without the cooperation of the patent owner, which can be quite challenging when the production technologies are difficult to replicate. Thus, the licensee has to forecast a fair enough market to cover the costs of investment and manufacture as well as an adequate remuneration to the patentee.[226] It is easy to see that essential drugs for poor patients will not attract many applicants as compulsory licensees are only attracted to large enough markets.[227] Only in case of these requirements being fulfilled, the threat of a compulsory license is really credible.

3.6.3.3. Principle of territoriality

The original of Article 31 (f) of the TRIPS Agreement states that “any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use“.

224 Ibid 28.
225 Ibid 15.
226 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 42 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
227 FM Scherer and J Watal, ’Post-Trips Options for Access to Patented Medicines in Developing Countries’ CMH Working Paper Series, Paper No WG4:1 (2001) 30.

Thus, pursuant to this principle of territoriality the effect of a compulsory licence has originally been limited to the territory in which it was granted.[228]

This could pose a problem for country-members who lack pharmaceutical manufacturing capacities. If the beneficiary of a compulsory licence does not set up manufacturing capacities in such country-members, the licence can only be worked by importing drugs from third members.[229] In order to be able to import cheap generics, the beneficiary has to find a market where the drug is produced and not under patent.[230]

With the expiration of the transition periods, developing and least developed countries can no longer simply import new generic medicines from other developing member countries as all WTO member countries with manufacturing capacities have to provide patent protection.[231] Members without manufacturing capacities now have to rely on compulsory licences by exporting members to obtain generic medicines. This option can result in some problems as it puts the importing member at the mercy of the exporting one. In addition, the exporting member might have to adapt its patent rules to allow the grant of a compulsory licence in such cases.

I will describe the complex of problems regarding countries without manufacturing capacities below. In this context, I will have a closer look at the decision of 30 August 2003 in chapter 5.3.2.

228 R Kampf, 'Patents versus Patients?' (2002) 40 Archiv des Völkerrechts 108.
229 Ibid 107.
230 S Bartelt, 'Compulsory Licenses Pursuant to TRIPS Article 31 in the Light of the Doha Declaration on the TRIPS Agreement and Public Health' (2003) 6 Journal of World Intellectual Property 295.
231 DG McNeil, 'India Alters Law on Drug Patents' *New York Times* (24 March 2005) <http://www.nytimes.com/2005/03/24/international/asia/24aids.html?_r=0> accessed 01 April 2014.

3.6.4. Revocation of Patents

The revocation of patents is the fourth form of TRIPS-flexibilities. As the revocation of patents takes more of a back seat in comparison to parallel imports and compulsory licenses, I will only mention them at this point for the sake of completeness.

The complete revocation of patents under Article 32 of the Agreement is a much harsher measure and should therefore – considering the principle of "access to medicine" in its interpretation- only be available in case of abuse of the patent where this abuse cannot be remedied by a compulsory licence.

However, some members consider the revocation of patents to be permissible only where the invention is not patentable or patent office fees are not paid.[232]

3.7. Major developments in the discussion about access to drugs and IP

For the added practical applicability of my thesis, I will study two court cases about the debate on access to drugs and intellectual property in the following chapter. These two cases will demonstrate the importance of clarification concerning the flexibilities of TRIPS required in order to make sure that developing and least-developed countries countries can use their provisions without the threat of political pressure or losing in litigation.[233]

232 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 252.
233 E Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) 3 Chicago Journal for International Law 44 <http://fieldresearch.msf.org/msf/bitstream/10144/28436/1/Access%20TRIPS%20%27t%20Hoen.pdf> accessed 23 March 2014.

3.7.1. Big Pharma vs. South Africa

In 1998, the South African Pharmaceutical Manufacturers Association, a coalition of the world's thirty-nine biggest drug companies[234] brought a suit against the government of South Africa, alleging that the Medicines and Related Substances Control Amendment Act violated TRIPS and the South African constitution.[235]

The Act was designed to bring in three important measures to increase the availability of affordable medicines in South Africa. First, it enables the parallel importation of patented medicines. Second, it compels pharmacists to distribute cheaper generic versions of off-patented medicines and finally, the Act establishes a pricing committee to faciliate the development of a transparent pricing system for all medicines.[236]

At the beginning of the litigation, the United States and the European Commission had placed immense pressure on South Africa by withholding trade benefits and threatening further trade sanctions, aiming to force the South African government to repeal the Amendment Act in order to suit US and European interests.[237] However, as a result of increasing public protest that the suit had provoked, the possibility of failure and the fear of a court order forcing disclosure of their real R&D costs[238], the Big Pharma dropped the suit in 2001.

234 R Loewenson, 'Essential Drugs in Southern Africa Need Protection from Public Health Safeguards under TRIPs', *Bridges Comment* (2000) 4.
235 Case No 4183/98 *Pharmaceutical Manufacturers' Association of South Africa v President of the Republic of South Africa* (February 1998) <http://www.cptech.org/ip/health/sa/pharmasuit.html> accessed 01 April 2014.
236 Health Care and Intellectual Property, 'Parallel Imports' <http://www.cptech.org/ip/fsd/health-pi.html> accessed 01 April 2014.
237 S Barber, 'US Withholds Benefits over Zuma's Bill' (15 July 1998) Business Day 13.
238 N Mathiason, 'The Pretoria Court Case: Drugs: Round One to Africa' *The Observer* (22 April 2001).

The South African court case illustrates descriptively, how the implementation of TRIPS into the legislation of developing countries can influence the possible achievement of public health goals in a positive way.[239]

3.7.2. United States vs. Brazil

Since the mid-1990s, Brazil has successfully supplied universal free antiretroviral treatments to all who need them.[240] The ability to produce medicines locally was at the core of the success of Brazil's AIDS programme. Brazil has been successful at negotiating deep price discounts for patented drugs by using the threat of production under a compulsory license.[241] Big pharmaceutical companies agreed to reduce drug-prices because they were afraid of otherwise losing the entire market. That is why the total price Brazil is paying per patient per year for providing the free HIV/AIDS programme has remained at quite a low level in comparison to price levels in comparable countries.[242]

The reason why newer drugs are urgently needed, is the growing drug resistance and the fact that nearly all of them are patent-protected nowadays. This has been the reason for the re-increase in drug-prices over the last few years.

239 E Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) 3 Chicago Journal for International Law 44 <http://fieldresearch.msf.org/msf/bitstream/10144/28436/1/Access%20TRIPS%20%27t%20Hoen.pdf> accessed 23 March 2014.

240 T Rosenberg, 'Look at Brazil' *New York Times* (28 January 2001) 26 <http://www.nytimes.com/2001/01/28/magazine/look-at-brazil.html> accessed 01 April 2014.

241 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 51-58 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument> accessed 03 April 2014.

242 A Nunn, E Fonseca, F Bastos, S Gruskin and J Salomon, 'Evolution of Antiretroviral Drug Costs in Brazil in the Context of Free and Universal Access to AIDS Treatment' (2007) 4 PLoS MEDICINE 305 <http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040305#pmed-0040305-g006> accessed 01 April 2014.

In my opinion, a very interesting point is, that Brazil has only actually issued its first compulsory license allowing the importation and production of generic versions of efavirenz in 2007. This may come rather unexpected for many as the negotiations between Brazil and several pharmaceutical companies were often publicized in the international media, which was probably also the reason for the wrong impression that Brazil had used the system of compulsory license quite often even before 2007. In reality, though, the threat of issuing a compulsory license through the Brazilian government has been sufficient to negotiate low enough drug-prices.[243]

Brazilian serves as a good example showing how a state can observe its obligations to guarantee access to medicine without having the financial resources.

Further, Brazil supported developing countries in manufacturing capacity by transfering technology and know-how and as a result of this program, the death rate from HIV/AIDS has reportedly been reduced by 50 percent.

Big Pharma, however, made a number of claims to discourage the use of generics arguing for example that the quality control of generic drugs could not be guaranteed.[244]

The United States brought a complaint against Brazil at the WTO Dispute Settlement Body over Article 68 of the Brazilian intellectual property law for alleged breach of TRIPS in 2001. Under that provision, Brazil requires holders of Brazilian patents to fulfill the so-called “local working“ requirement, namely to manufacture

243 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 46 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

244 S Jacobzone, ’Pharmaceutical Policies in OECD Countries: ’Reconciling Social and Industrial Goals’ (2000) 40 OECD Labour Market and Social Policy Occasional Papers 4, 9, 94 <http://www.oecd-ilibrary.org/docserver/download/5lgsjhvj7s0x.pdf?expires=1396444950&id=id&accname=guest&checksum=1B61D95F3C29FB3ED8688A9F9A89ECBB> accessed 01 April 2014.

the product within Brazil. The United States argued that the Brazilian law discriminated against United States owners of Brazilian patents and thus violated Article 27.1 and Article 28.1 of TRIPS.[245]

However, similar to the latter case, in 2001 the United States announced in a joint statement with Brazil that it would withdraw the WTO panel against Brazil. This second outside court settlement was caused primarily by Brazil's growing economic power and also the United States' intention to hamper another conflict that would have had – once again - negative effect on their public image.[246]

4. Access to Medicine as a Human Right

4.1. Universal Human Rights Instruments

This part of my thesis is intended to provide informational background from a human rights' point of view. The chapter will concentrate on the legal framework of the access to medicine as a human right. I will therefore examine in a general way the eligible Universal Human Rights Instruments, which mention the right to access to medicine. Then as a second step, I will analyse in detail the two major Universal Human Rights Covenants, the ICESCR and the ICCPR in respect of the right to health and the right to life. As a last step, I will also take a look at the WHO Constitution in that respect and will analyse the meaning of the right to life-saving medicines as part of general international law. In the very end of the chapter, I will focus on the question if there are other human rights that can be associated with the right to health in general. It is especially the right to culture and the right to developement that should be looked at more closely in this context. In order to answer the question above and precisely analyse the relationship between the

245 World Trade Organization, *Request for the Establishment of a Panel by the United States, Brazil Measures Affecting Patent Protection*, WT/DS1999/3 (2001), <http://www.cptech.org/ip/health/c/brazil/Req4EstabPanel.html> accessed 01 April 2014.
246 H Cooper, 'U.S. Drops WTO Complaint: Against Brazilian Patent Law', *Wall Street Journal Europe* (26 June 2001).

right to health and these two human rights, it is again necessary to examine the relevant documents, in particular the ICESCR and the Declaration on the Right to Development, adopted by the UN General Assembly.

The right to access to medicine is mentioned first, in the founding document of the UN, the United Nation Charter of 1945, that all member states formally ratified. Further the right to access to medicine is referred to in the Universal Declaration of Human Rights, a resolution passed by the UN General Assembly in 1948 and at the same time the first UN Document that provides a list of human rights.[247]

The Universal Declaration of Human Rights is as the name says a declaration, not a treaty, and as such, it was originally not intended to establish legally binding obligations.[248] Still, it remains one of the most respected and authoritative human rights documents[249] as states have accepted that it has become – at least in parts of it - legally binding as customary international law.

The Universal Declaration of Human Rights states that "everyone has the right to a standard of living adequate for the health of himself and his family, including food, clothing housing and medical care (...)."

Of course, the right to access to medicine is further mentioned in several other conventions. Anyway, I do not aim to present a complete list of human rights sources on which the right to access to medicine is based on, but prefer to limit my research on the most essential ones.

247 E Riedel, 'The Human Right to Health: Conceptual Foundations' Health' in A Clapham and M Robinson (eds), *Realizing the Right to Health the Right to Health* (Rüffer & Rub Zurich 2009) 21-39.
248 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 59 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
249 Ibid 74.

After adopting the Universal Declaration of Human Rights, the member states of the UN started with the task of drafting international human rights covenants.[250]

There are two major universal human rights treaties with two categories of rights, one protecting civil and political rights (ICCPR) and one economic, social and cultural rights (ICESCR). Both were adopted in 1966 and have been ratified by approximately 85 per cent of the WTO members.

While the first category provides negative rights, also known as “first generation rights“ which protect the individual from undue interference from the state, the second category alias “second generation rights“ provides positive rights and therefore demands action from the state[251] and committal of financial resources.

Whereas the content of the first category is fixed and can be implemented immediately, the content of the other varies according to a state’s financial resources and thus requires a choice of what parts to implement first.[252]

One might argue, that for this very reason the obligations by the ICESCR are mere relative rights and too vague to be justiciable in court. It is captivating to note that the degree to which states accept and define the second group of rights, varies significantly. For instance, the United States has never recognized the legitimate existence of ICESCR or similar instruments. However, the ICESCR is a legally binding document and its rights must therefore be justiciable.[253]

Now I want to turn to the issue of protection of access to medicine under the single human rights conventions:

250 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 21 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
251 This distinction is advanced by TC Van Boven, ’Les Criteres de Distinction des Droits de l’Homme’ in K Vasak (ed), *Les Dimensions Internationales des Droits de l’Hobeyondmme* (1978) 790.
252 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 89.
253 Ibid 159.

4.1.1. ICESCR

First of all, access to medicine is protected by Article 12 ICESCR as part of the right to health.

Although the right to health is set out in many different treaties, I would like to concentrate on the provision in the ICESCR, which implies the core provision on the right to health in international human rights law.

Article 12.1 of the Covenant recognizes the "right of everyone to the enjoyment of the highest attainable standard of physical and mental health".

Article 12.2 illustrates a number of steps to be taken by states to achieve the full realization of this right, such as ensuring "prevention, treatment and control of epidemic, endemic, occupational and other diseases" and "the creation of conditions which would assure to all medical service and medical attention in the event of sickness".[254]

According to the General Comment No. 14 on Article 12 of the Committee on Economics, Social and Cultural Rights,[255] the right to health is not to be understood as right to be healthy, but rather as the right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the achievement of the highest attainable standard of health.[256]

254 B Stirner, 'News and Views, Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases' (2008) 15 European Journal of Health Law 395.
255 The Committee on Economics, Social and Cultural Rights as a treaty-monitoring body, issued General Comments intending to support states in fulfilling their obligations. These General Comments can be described as authoritative interpretations concerning the particular provisions (AE Yamin, 'Not just a Tragedy: Access to Medications as a Right under International Law' (2003) 21 Boston University International Law Journal 337 <http://www.bu.edu/law/central/jd/organizations/journals/international/volume21n2/325-372.pdf.pdf> accessed 01 April 2014.
256 Committee on Economic, Social and Cultural Rights, *General Comment No. 14* (2000) para 9.

The ESCR Committee describes the four components of the right to health as (1) the availability of medicine in sufficient quantity, (2) the accessibility of that medication without discrimination to everybody, (3) the acceptability of the treatment with respect to the culture and ethics of the individual and (4) an appropriate quality of the medicine.[257]

The second component, which is accessibility, includes three different aspects, namely (1) physical accessibility meaning that "health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/Aids", (2) economic accessibility meaning that "health facilities, goods and services must be affordable for all" and (3) information accessibility meaning that "accessibility includes the right to seek, receive and impart information and ideas concerning health issues".[258]

This also means that member states are required to provide technical and economic international cooperation, to support developing countries to fulfill their obligations unter the Covenant, although these diseases are not even prevalent within their regions.[259]

It would be unrealistic to require a state to realize the full extent of the right to health immediately.[260] States have to achieve the right progressively, but are under an immediate obligation to take steps to the maximum of their available

257 AE Yamin, 'Not just a Tragedy: Access to Medications as a Right under International Law' (2003) 21 Boston University International Law Journal 358 <http://www.bu.edu/law/central/jd/organizations/journals/international/volume21n2/325-372.pdf.pdf> accessed 01 April 2014.
258 Committee on Economic, Social and Cultural Rights, *General Comment No. 14* (2000) para 12.
259 P Hunt, 'Neglected Diseases, social justice amd human rights: some preliminary observations', Health and Human Rights working paper Series No. 4 (2003) 11.
260 R Ago, *Second Report on State Responsibility*, Extract from the Yearbook of the International Law Commission, II (1970) 3, 8 ff.

resources to respect, protect and fulfill the right.[261] This tripartite framework is nowadays widely accepted also throughout the United Nations system, as all human rights in general impose these three different types of obligations.[262]

In General Comment No. 14, the ESCR Committee clarifies that the obligation to respect requires states to refrain from interfering directly or indirectly with the enjoyment of the right to health. Thus, a violation of the obligation to respect the right to health occurs when a state "repeals or suspends legislation necessary for the continued enjoyment of the right or when it adopts legislation or policies that are manifestly incompatible with pre-existing domestic or international legal obligations relating to the right to health".[263]

The ESCR Committee notes in this context that a violation of the duty to respect the right to health can also be fulfilled through "the failure of the state to take into account its legal obligations regarding the right to health when entering into bilateral or multilateral agreements with other states, international organisations and other entities, such as multinational corporations".[264]

Secondly, the obligation to protect requires states to take measures that prevent third parties from interfering with Article 12 guarantees. According to the General Comment No 14, Article 12 of the International Covenant on Economics, Social and Cultural Rights, the obligation to protect includes "ensuring that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services, controlling the marketing of medical equipment and medicines by third parties and states

261 G Behrman, *The Invisible People, How the U.S. Has Slept through the Global AIDS Pandemic, the Greatest Humanitarian Catastrophe of Our Time* (Free Press 2004) 44-45.
262 AE Yamin, 'Not just a Tragedy: Access to Medications as a Right under International Law' (2003) 21 Boston University International Law Journal 352 <http://www.bu.edu/law/central/jd/organizations/journals/international/volume21n2/325-372.pdf.pdf> accessed 01 April 2014.
263 Committee on Economic, Social and Cultural Rights, *General Comment No. 14* (2000) para 48.
264 Ibid para 50.

ensuring that third parties do not limit people's access to health-related information and services".[265]

Finally, the obligation to fulfill can be reached through the state by establishing a health care system and funding the medication for their citizens. In general, this very last obligation requires states to adopt appropriate legislative, administrative, budgetary, judicial, promotional and other measures towards the full realization of the right to health".[266]

Non-compliance with access to medicine as a minimum core obligation is a prima facie violation of the ICESCR. According to the ESCR Committee, the access to essential drugs as defined by the WHO are part of the minimum core obligation of the right to health under the ICESCR.[267] However, to justify its non-compliance the state must "demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations".

Holger Hestermeyer pointed out that the obligations of the state do not require state resources at all and thus can be fullfilled by developing countries and least-developed countries in the same way.[268] Developing countries which are often financially unable to provide medicine for their population, have to prevent private parties from pricing drugs excessively. They can do so by strictly enforcing their competition laws or by changing their patent legislation,[269] both of which do not require significant state resources.

265 Ibid para 35.
266 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 11 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.
267 Committee on Economic, Social and Cultural Rights, *General Comment No. 14* (2000) para 10.
268 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 112.
269 Ibid 110-112.

4.1.2. ICCPR

Article 6 of the ICCPR protects access to life-saving medicine as part of the right to life, which is the most basic of all rights.

Article 6 of the ICCPR states that “every human being has the inherent right to life. This right shall be protected by law. No one shall arbitrarily deprived of his life“.

According to Article 2 of the Covenant, states have an immediate duty to respect and to ensure the right, which includes a duty to protect individuals against violations of the right by the state and by private parties.[270]

The Human Rights Committee of the United Nations, which monitors the implementation of the ICCPR, has explicitly expressed, that the wording “inherent right to life“ should not be understood in a restricitive way, but should be seen to require states to adopt positive measures.[271]

Thus, states have to make sure that pharmaceutical manufacturers do not limit the economic accessibility of essential drugs.

4.1.3. Other approaches- The WHO & General international law

The right to health is also regulated in the WHO Constitution. It even was the first international legal document to mention the right to health, but does not create any

270 E Klein, ’The Duty to Protect and to Ensure Human Rights Under the International Covenant on Civil and Political Rights’ in E Klein (ed), *The Duty to Protect and to Ensure Human Rights. Colloquium. Potsdam,1-3 July 1999 (*2000) 296-297.

271 AE Yamin, ’Not just a Tragedy: Access to Medications as a Right under International Law’ (2003) 21 Boston University International Law Journal 331 <http://www.bu.edu/law/central/jd/organizations/journals/international/volume21n2/325-372.pdf.pdf> accessed 01 April 2014.

legal commitment as it is just mentioned in the praemble as the object and purpose of the treaty.[272]

Access to life-saving medicines in the face of national health emergencies, particularly pandemics, is also protected as part of general international law.[273]

This includes customary international law, which is based on the practice of states and has developed over time. It does not necessarily have to be found in a written agreement between states.[274] It is as a general principle binding for all states, especially for those states that are not ratified to the treaty. According to *Joost Pauwelyn*, each new state and each new treaty automatically has the status of general international law, which therefore fills the gaps left by treaties.[275] This principle is valid with the exception of "persistent objectors".[276]

4.2. Addressees of Human Rights Law

In the following chapter, I must have a closer look at the possible addressees of human rights law. It will become clear very quickly that states have always been

272 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 113.
273 T Meron, *Human Rights and Humanitarian Norms as Customary Law* (Clarendon Press 1991) 79.
274 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 5 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
275 J Pauwelyn, 'The role of Public International Law in the WTO: How far can we go?' (2001) 95 The American Journal of International Law 536 <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1065&context=faculty_scholarship&seiredir=1&referer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3D%25E2%2580%2599the%2520role%2520of%2520public%2520international%2520law%2520in%2520the%2520wto%253Ahow%2520far%2520can%2520we%2520go%253F%26source%3Dweb%26cd%3D1%26ved%3D0CC8QFjAA%26url%3Dhttp%253A%252F%252Fscholarship.law.duke.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D1065%2526context%253Dfaculty_scholarship%26ei%3DPW6xUqTGI4SKhQeu94HoBw%26usg%3DAFQjCNHKmciKOktYAjUPqIqiazWdap8FKg%26sig2%3D5VTrEKD4f8_pRSf9s1gEFw%26bvm%3Dbv.58187178%2Cd.ZG4#search=%22'the%20role%20public%20international%20law%20wto%3Ahow%20far%20can%20go%3F%22> accessed 01 April 2014.
276 T Meron, *Human Rights and Humanitarian Norms as Customary Law* (Clarendon Press 1991) 79 ff.

the typical duty-bearer in international human rights law. However, I will also analyse the exceptions to that general rule in the following chapter. One question will be, whether the WTO as an international organisation can be subject of international law. The main question relating to the possible addressees of human rights law, however, will be, if pharmaceutical companies, who determine the prices of drugs, can be held responsible to human rights duties. Therefore it is necessary to strictly distinguish between the systems of direct responsibility and that of indirect responsibility of multinational corporations. In this context, I will also focus on the recent developments in the debate about "corporate social responsibilty" (CSR) and will examine the two different underlying concepts, that of "codes of conduct" on the one hand and that of "Guidelines & Initiatives" on the other hand. Concerning the latter, I will then continue with a more detailed description and comparison of the different legal frameworks.

4.2.1. The state as ordinary duty-bearer

The ordinary duty-bearer in international human rights law is the state rather than private entities like pharmaceutical companies. International human rights law is therefore binding for states, while multinational corporations in principle cannot be held legally accountable under the international human rights framework.[277]

How the regulation came to be, was that international human rights were developed after the Second World War as a response to the growing power of states, in order to protect the individual from abuse by the state. The main focus at this time was on states, because states were identified to have the most influence on the lives of people. Thus, through the establishment of minimum rights for individual people and corresponding obligations for states after the Second World

277 For the US Constitution see JE Nowak and RD Rotunda, *Constitutional Law* (5th edn, Hornbook Series 1995) 343-344; For Germany see A Bleckmann, *Staatsrecht 2-Die Grundrechte* (4th edn, Carl Heymanns 1997) 219 ff.

War, the state's monopoly of power should have been limited to hamper war crimes and crimes against humanity for the future.[278]

That is why under traditional approaches of human rights, corporations as non-state actors can not be considered parties to the relevant human rights treaties, so they are only bound to the extent that governments can apply obligations accepted by states.[279]

4.2.2. Exceptions to that approach

However, there are exceptions to this state-based paradigm as the recent International Criminal Court jurisdiction reveals holding individuals criminally responsible for grave human rights crimes, such as genocide, war crimes and crimes against humanity.[280]

The praembles of the ICCPR and the ICESCR seem to extend the binding effect of the Covenants to private parties, too, when stating that "the individual, having duties to other individuals and to the community to which he belongs, is under a responsibility to strive for the promotion and observance of the rights recognized in the present Covenant". Nevertheless, it is important to bear in mind, that praembles do not create legal obligations by themselves as their legal value is limited to aiding in the interpretation of the Agreement.[281] Anyway, a praemble is used to understand the rest of the document, and the latter should be read with this understanding.

278 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 9 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
279 B Lindner and A Steinkellner, 'Corporate Responsibility for Human Rights' in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 578.
280 S Joseph, 'Pharmaceutical Corporations and Access to Drugs: The fourth wave of corporate human rights scrutiny' (2003) 25 Human Rights Quarterly 437 <http://hmb.utoronto.ca/HMB303H/weekly_supp/week-08-09/Joseph_Drug_Patents.pdf> accessed 23 March 2014.
281 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 96.

In relation to access to drugs, I would like to start out by saying that at first glance, it is difficult to find convincing arguments that support a direct binding of human rights duties for pharmaceutical companies. In the abscence of relevant binding treaty norms, customary international law may only impose direct private liability- as already mentioned- for the gravest war crimes, enslavement, and genocide.[282]

However, the fact that private parties are not directly bound by international human rights law does not imply that international human rights have no effect whatsoever on the private sphere, as I will illustrate in the following.

4.2.3. The WTO as duty-bearer?

Before I focus my attention on multinational corporations as possible duty-bearers inside the international legal framework, I will first take a look at the WTO as an international organisation. The first question to examine is therefore, whether the WTO itself is bound by international human rights law, in particular by the right to access to medicine.

In order to answer this question, one must first of all consider, that the WTO as an international organisation is subject of international law with its own rights and obligations and can thus sign its own treaties and conventions.[283]

As a non-signatory the WTO is not bound by human rights treaties.[284] However, it is bound by human rights that are part of general international law to the extent that WTO law is not contradicting them, implicitly contradicting out of them.[285] I will

282 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 73-76 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
283 K Ipsen , *Völkerrecht* (4th edn, C.H. Beck 1999) 71 ff.
284 HG Schermers,'The Legal Basis of international Organization Action' in Dupuy RJ (ed), *A Handbook on International Organizations* (2nd edn, Dordrecht 1998) 401, 403.
285 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 101.

research the question, which role human rights play within the WTO regime, in chapter 5.2. in detail.

4.2.4. Multinational corporations as duty-bearers?

The main question, which runs like a common thread through my doctoral thesis and which I want to elaborate on in detail, is, if pharmaceutical companies, who determine high prices, are bound by international law.

An argument or rather a justification for identifying direct human rights duties for private corporations might be, that corporate power has grown in recent years as states tend to privatize many of the obligations that used to be considered among their traditional domestic functions, for example in the provision of basic services.[286] For instance, postal, transport and telecommunications services as state institutions were originally obliged to respect human rights. The main argument, however, is, that a state should not be in the position to get rid of its human rights obligations simply by privatizing its functions.[287] Some authors argue that such a right must exist in order to prevent this grown corporate power from being abused to violate the rights of individuals, which might affect the lives of millions of people around the world.[288]

4.2.4.1. The legal framework

As already mentioned above, states are in the context of second-generation rights under a duty to protect individuals from violations of their rights by private parties.

286 Ibid 94.
287 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 53 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
288 M Monshipouri, CE Welch and ET Kennedy, 'Multinational Corporations and the Ethics of Global Responsibility: Problems and Possibilities' (2003) 25 Human Rights Quarterly 965-966, 971.

The protection of the second-generation rights have increased reference to nonstate individuals, multinational corporations included.[289]

Thus, if a multinational corporation violates the human right of access to medicine through pricing drugs excessively, it is the government behind that has to be held responsible for breaching human rights duties, while the multinational corporation would only be guilty for indirectly complying with these human rights violations. This point represents exactly the weakness of the system, as that action and enforcement are left to national governments and thus rules are only enforceable through particular action taken by governments.[290] In case, states are unwilling to take effective action against firms, it raises the question of direct accountability.

This "indirect responsibility" of multinational corporations has to be distinguished from the "direct corporate responsibility", a process which is still in its infancy. "Direct corporate responsibility" means that a corporation can be held legally accountable for its own behaviour, namely for ascertaining exorbitant price-drugs, while state involvement is not a prerequisite for that. To date, there only exists some form of "soft law mechanism" concerning the latter form of corporate responsibility[291] to address the corporations directly. In general there are two different legal instruments to distinguish, that of codes of conduct on the one hand

289 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 99.
290 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 3 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
291 It is worth to mention the distinction between „hard" and „soft" rules of international law at this point. „Hard" rules are found in agreements, referred to as treaties, conventions or covenants and create binding legal obligations, while „soft" rules can be found in declarations, principles, resolutions or standards adopted by international organisations and have merely the nature of guidelines setting out how states are expected to act concerning different human rights issues.
See International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 5 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.

and that of Guidelines and Initiatives on the other hand. The expression “soft law“ does not mean to have no legal significance, as I will describe below.[292]

4.2.4.2. Corporate social responsibility

In the following, I will pay attention to the term “corporate social responsibility“ (CSR), which has become extremely popular over the last few decades.

The term “corporate social responsibility“ is an ethic business concept, which aims to give companies operating in society, rules and guidance how to conduct business without interfering with the livelihood of human beings.

Based on the content and objectives of CSR, it is clear that this concept is closely interconnected with the framework of human rights. *Angelika Watzl* highlights the overlaps between the two systems, pointing out that CSR consists – at least to a certain extent – of human rights’ norms, namely labour standards, social rights and human rights related to environmental aspects.[293]

However, *Watzl* puts it in a nutshell when arguing in her master-thesis, that the term CSR is not clearly defined at all. She hits the core of the problem declaring, that the reason for the lack of clarity is the involvement of different stakeholders, each of them interpreting the term in a different way according to the way, they would like it to be understood. Thus, the views about CSR differ to a great extent, especially concerning the exact scope of the term.[294]

However, a very accurate description of CSR is offered by *Barbara Lindner* and *Astrid Steinkellner*, when defining the term as a “voluntary means of corporate

292 B Lindner and A Steinkellner, ’Corporate Responsibility for Human Rights’ in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 578.
293 A Watzl, ’The OECD Complaint Mechanism: An Analysis of the OECD Complaint Mechanism’s Case Law with regard to Human Rights violations in developing countries’ (Master thesis, University of Vienna 2014) 25.
294 Ibid 14-15.

self-regulation with regard to the economic, social and environmental impacts of a company's operations".[295]

A broader definition is provided by the European Commission, that defines CSR as "the responsibilty of enterprises for their impacts on society".[296]

Over the last decades several companies have started to get involved with CSR actions. Their involvement covers the access to different international networks, like the UN Global Compact, but also the establishment of individual codes of conduct.[297]

The European Commission makes it clear, that the complexness of becoming CSR depends on several factors, which determines the scale and nature of the necessary CSR process. Especially the size of the corporation is a critical parameter as it will influence the kinds of approaches taken to meet that responsibilty. It is noticeable at this point, that the CSR-process of smaller corporations will be more informal.[298]

4.2.4.2.1. Codes of conduct

NGOs have played an important role in promoting CSR by getting companies to respect human rights in their core business through exerting increasing pressure on them to accept several internationally recognized codes of conduct within their

295 B Lindner and A Steinkellner, 'Corporate Responsibility for Human Rights' in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 578-579.
296 European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions' (2011) COM 681 final 6.
297 B Lindner and A Steinkellner, 'Corporate Responsibility for Human Rights' in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 579.
298 European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions' (2011) COM 681 final 6.

companies and in assuming the monitoring function through rectifying their human rights abuses as well.[299]

An interesting fact is that most voluntary codes use phrases like “seek, strive or try to minimise“ in order to define rather certain goals than particular obligations. Simillarly, other codes establish rather broad values of a company, like “openness or conducting business responsibility“.[300]

Although companies have – of course – accepted at least responsibility through these codes and this process is without a doubt a step in the right direction, there still is a lack of international agencies with the enforcement power needed.[301]

Medea Benjamin, an important political activist and co-founder of Global Exchange, who visited many US factories around the world that have adopted codes of conduct, points out that “most companies have not been very serious about translating the codes into reality on the ground“. Further, *Benjamin* warns against the illusion of self-regulation through companies, when stating that “it is untenable to expect companies to enforce their codes voluntarily“.[302]

One of the main reasons for multinational corporations making modifications and observing global standards at all is the influence by public denunciation, especially the pressure from private actions and lawsuits based on civil law. It is suggested that such activities would jeopardize the corporations’ brand name and profit

299 M Monshipouri, CE Welch and ET Kennedy, ’Multinational Corporations and the Ethics of Global Responsibility: Problems and Possibilities’ (2003) 25 Human Rights Quarterly 987.
300 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 70 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
301 M Monshipouri, CE Welch and ET Kennedy, ’Multinational Corporations and the Ethics of Global Responsibility: Problems and Possibilities’ (2003) 25 Human Rights Quarterly 979-980.
302 Human Rights Dialogue, Interview with Medea Benjamin, Founding Director of Global Exchange (6 October 2000) <https://www.carnegiecouncil.org/publications/archive/dialogue/2_04/articles/892.html> accessed 01 April 2014.

margin. That is actually the main reason for more and more companies being prepared to adopt voluntary codes of conduct.[303]

Another imperative point of criticism and risk in general is that the organ, what functions as a protector of human rights, namely the NGO, may get too close, and therefore compromising too much, when negotiating a compact or code of conduct with a multinational company. In other words there is always the risk of this organ, which originally has it at its main task to defend human rights, to "jump into bed with some of the most notorious companies in the world".[304]

Frankly, I can understand the widespread cynicism of several authors about the jungle of international codes of multinational corporations as they all remain voluntary and can therefore not be seen as a mandatory set of resolutions. The only reason for pharmaceutical corporations to agree to these international codes, is that they are non-binding and apply only to those corporations, that choose to apply them.

4.2.4.2.2. Guidelines & Initiatives

The second rail of "direct corporate resonsibility" besides codes of conduct has led to a number of Guidelines and Initiatives that are – again - non-binding on corporations and which serve in fact only as public relations, such as the OECD Guidelines for Multinational Enterprises,[305] the UN Global Compact[306] and the United Nations Guiding Principles on Business and Human Rights.

303 M Monshipouri, CE Welch and ET Kennedy, 'Multinational Corporations and the Ethics of Global Responsibility: Problems and Possibilities' (2003) 25 Human Rights Quarterly 968, 987.
304 Ibid 980-981.
305 Organization for Economic Co-operation and Development, *The OECD Guidelines for Multinational Enterprises. Revision 2000* (2000) 19 <http://www.oecd.org/dataoecd/56/36/1922428.pdf> accessed 01 April 2014.
306 K Annan, 'Secretary-General Proposes Global Compact on Human Rights, Labour, Environment' UN Press Release SG/SM/6881 (1 February 1999) <http://www.un.org/News/Press/docs/1999/19990201.sgsm6881.html> accessed 01 April 2014

As an excursion into the content of every single CSR instrument would go beyond the scope of my thesis, I only quote the relevant passages of the instruments and will elsewise reduce the matter to the general question of to what extent human rights in general (meaning the right of health as a concrete one) must play a role for corporations.

As the UN Guiding Principles on Business and Human Rights are not only the youngest accomplishment of CSR but also have the most far-reaching impacts concerning direct accountability of multinational corporations, I will turn my attention to this Guideline while only giving an overview of the other Guidelines. In this context, I would further like to analyze the so-called “Hunt-Guidelines“, the Human Rights Guidelines for Pharmaceutical Companies in relation to access to medicines in order to identify the impacts on the pharmaceutical industry.

Before looking into the subject of every single Guideline, it is worth to mention that a first approach in the regard of corporate responsibility can be already found in the Universal Declaration of Human Rights.

The praemble of the Universal Declaration of Human Rights namely states, that “(...) every organ of society (...) shall strive by teaching and education to promote respect for these rights and freedoms (...) to secure their universal and effective recognition and observance (...).“

Nowadays it is widely accepted that the Universal Declaration encompasses private enterprises as an “organ of society“. Although the phrase is found in the praemble and is therefore not legally binding, at least it sets out the purpose and the object of the whole document.[307] For pharmaceutical corporations, this means to set drug-prices, that are affordable for the population of developing and least-developed countries in order to guarantee the human right of access to medicine.

307 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 61 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.

4.2.4.2.2.1. OECD Guidelines

First of all, the OECD Guidelines for Multinational Enterprises, adopted in 1976 and latest updated in 2011, are non-binding recommendations addressed by OECD governments to multinational enterprises operating in or from the territories of the adhering countries concerning responsible business conduct in order to protect the rights of investors.[308]

Thus, the Guidelines can not be applied to companies as such, as they require a transformation of the regulations through the governments. It is, however important to note that governments are not bound by these Guidelines to implement certain standards. They are still free to decide in what way to implement them exactly.[309]

In comparison to the version prior to the up-date in 2011, the new version includes a new human rights chapter, which was influenced by the UN Guiding Principles on Business and Human Rights and by the "Protect, Respect and Remedy" framework.

Thus according to chapter IV. of the OECD Guidelines, states have the duty to protect human rights, while enterprises should among others

(1) respect human rights, which means they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved,

(2) within the context of their own activities, avoid causing or contributing to adverse human rights impacts and address such impacts when they occur and

308 B Lindner and A Steinkellner, 'Corporate Responsibility for Human Rights' in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 580-581.
309 A Watzl, 'The OECD Complaint Mechanism: An Analysis of the OECD Complaint Mechanism's Case Law with regard to Human Rights violations in developing countries' (Master thesis, University of Vienna 2014) 32.

(3) seek ways to prevent or mitigate adverse human rights impacts that are directly linked to their business operations, products or services by a business relationship, even if they do not contribute to those impacts.

The commentary on the human rights chapter of the OECD Guidelines states that "enterprises can have an impact on virtually the entire spectrum of internationally recognized human rights" while admitting in the same breath that "some human rights may be at greater risk than others in particular industries, and therefore will be the focus of heightened attention".[310] Adjusted to the topic of my doctoral thesis, the human right in danger by the conduct of pharmaceutical corporations might be the right to health respectively the access to medicine resulting from the high drug prices, ascertained by pharmaceutical companies.

The OECD Guidelines take up a special position among the other international CSR instruments as they are the only ones that provide a complaint mechanism in case of a breach of its regulations. Therefore the adhering governments are obliged to implement the Guidelines and to establish so-called National Contact Points in order to ensure the observance of the Guidelines and to handle complaints on companies' breaches of the Guidelines through mediation.[311]

There is still a lot of criticism pertained especially to the inefficiency and lack of transparency of the National Contact Points.[312] The fact, that governments have flexibility in organising their national contact points, results in their structure and functioning varying from country to country.[313]

310 Organization for Economic Co-operation and Development, *The OECD Guidelines for Multinational Enterprises. Revision 2011* <http://www.oecd.org/daf/inv/mne/48004323.pdf> accessed 01 April 2014.
311 M Theuws and M Huijstee, 'Corporate Responsibility Instruments- A comparison of the OECD Guidelines, ISO 26000 & the UN Global Compact' (*Somo*, 2013) <http://somo.nl/dossiers-en/csr/corporate-responsibility-instruments> accessed 01 April 2014.
312 B Lindner and A Steinkellner, 'Corporate Responsibility for Human Rights' in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 581.
313 A Watzl, 'The OECD Complaint Mechanism: An Analysis of the OECD Complaint Mechanism's Case Law with regard to Human Rights violations in developing countries' (Master thesis, University of Vienna 2014) 95.

Another critical point, that one should always remember, is that the OECD is an international organisation that unites 34 of the most economically potent countries in the world, a fact that suggests that their main aim still remains to achieve economic instead of human rights goals. Thus, the risk remains high that the access to medicine as a human right will not be respected to the same extent as economic goals.

4.2.4.2.2.2. UN Global Compact

The United Nations Global Compact, adopted in 2000 by the *former UN Secretary General Kofi Annan*, is in contrast to the OECD Guidelines a quite different instrument, although it is – similar to the OECD Guidelines – defined as "part of the core set of internationally recognised principles and Guidelines regarding corporate social responsibility" by the European Commission.[314]

The relevant principles in the context of human rights in general respectively with the right to health in particular are the first two of the Compact: According to Principle 1 of the UN Global Compact, businesses "should support and respect the protection of internationally proclaimed human rights" and should according to Principle 2 "make sure that they are not complicit in human rights abuses".[315]

It has to be noted that the Global Compact is the most popular corporate responsibility programme with around 7.000,00 corporate participants.

Anyway, the UN Global Compact has no government backing, which results in it not being a legally binding but a purely voluntary instrument.

314 European Commission, 'Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions' (2011) COM 681 final 6-7.
315 United Nations Global Compact, *The Ten Principles* <http://www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/index.html> accessed 01 April 2014.

Further, the Global Compact's complaint procedure is very weak, as it it aims to promote a dialogue between the complainant and the company concerned instead of achieving some remediation.[316] Even on the website of the United Nations Global Compact, its core tasks are only described as "stimulating change, promoting good corporate citizenship and encouraging innovative solutions and partnerships".[317]

Some authors argue, that there is a high risk of some companies becoming only members of the Global Compact in order to improve their public corporate image instead of really aiming to improve social matters.[318]

This is actually a point which runs like a common thread through the complex of soft law instruments, as the reputation of companies is an important element of their economic performance and thus companies are more likely to respond voluntarily to public pressure.[319]

4.2.4.2.2.3. UN Guiding Principles on Business and Human Rights

It is obvious to me, that the UN Guiding Principles on Business and Human Rights, established in 2011, represent the biggest achievement towards direct accountability of multinational corporations.

316 M Theuws and M Huijstee, 'Corporate Responsibility Instruments- A comparison of the OECD Guidelines, ISO 26000 & the UN Global Compact' (*Somo*, 2013) <http://somo.nl/dossiers-en/csr/corporate-responsibility-instruments> accessed 01 April 2014.
317 United Nations Global Compact, *About us- Frequently asked questions* <http://www.unglobalcompact.org/AboutTheGC/faq.html> accessed 01 April 2014.
318 M Theuws and M Huijstee, 'Corporate Responsibility Instruments- A comparison of the OECD Guidelines, ISO 26000 & the UN Global Compact' (*Somo*, 2013) <http://somo.nl/dossiers-en/csr/corporate-responsibility-instruments> accessed 01 April 2014.
319 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 18 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.

The Principles are based on *Professor John Ruggie's* six-year reseach. He was appointed to Special Representative[320] of the United Nations Secretary-General from 2005 until 2011.

In 2008, after a first phase of "identifying and clarifying existing standards and practices",[321] *John Ruggie* presented his "Protect, Respect and Remedy" framework to the United Nations, which consists of three pillars: (1) the state duty to protect human rights, (2) the corporate responsibility to respect human rights and (3) the need for greater access to remedy for victims of business-related abuse.[322]

In the second phase of his mandate, *John Ruggie* developed the UN Guiding Principles on Business and Human Rights which were intended to guide implementation of the "Protect, Respect and Remedy" framework and which finally were endorsed by the United Nations Human Rights Council.

They comprise thirty-one principles and reflect internationally recognized law obligations, but they propose no new ideas. They only aim to create a better understanding concerning the scope of responsibility of corporations. In the words of *Mark B. Taylor*, "the principles are just a reaffirmation of the hierarchy in law, in which the state is the legitimate source of authority and a company operates within that authority". [323]

320 A Special Representative is an independent expert appointed to monitor, examine and report on either a particular human rights issue or the human rights situation in a particular country or territory. See R Khosla and P Hunt, 'Human Rights Guidelines for pharmaceutical companies in relation to access to medicines- The Sexual and reproductive Health Context' (2007) Human Rights Center 3.

321 J Ruggie, *General on the Issue of human rights and transnational corporations and other business enterprises. Report of the Special Representative of the Secretary* A/HRC/17/31 (21 March 2011) 3 <http://www.business-humanrights.org/media/documents/ruggie/ruggie-guiding-principles-21-mar-2011.pdf> accessed 01 April 2014.

322 United Nations Human Rights, *The Corporate responsibility to respect human rights* (2012) 1 <http://www.ohchr.org/Documents/Publications/HR.PUB.12.2_En.pdf > accessed 01 April 2014.

323 M Taylor, 'Business, Human Rights Due Diligence and the role of the state' (*Biz,* 17 June 2013) <http://www.lawsofrule.net/2013/06/17/business-human-rights-due-diligence-and-the-role-of-the-state > accessed 01 April 2014.

Thus, a central principle of the new framework is the assumption that the obligations of states on the one hand and businesses on the other hand are not the same and have to be distinguished from each other. While reaffirming that states have the primary responsibility to respect, protect and fulfill human rights, *Ruggie* has emphasized that "companies have unique responsibilities". He further argued that "if those responsibilities are entangled with state obligations, it makes it difficult if not impossible to tell who is responsible for what in practice (...)."

Further, *Ruggie* identifies the main responsibility of companies to be "to respect" meaning not to infringe on the rights of others or in other words to do no harm. It is indisputable that this main responsibility has essential implications for the responsibilities of pharmaceutical corporations as they are according to this principle not allowed to infringe on the right of health of developing and least-developed member countries through pricing drugs excessively. According to *Ruggie*, this so-called "baseline-expectation" has to be distinguished from additional responsibilities which are only secondary.[324]

Anyway, the important point is connected to the second and third pillar of the framework, the concept of respect and corresponding remedy, meaning that business enterprises should establish a system of due diligence in order to prevent or to respond to an abuse by a private actor. Such a due diligence test comprises an ongoing management process as corporations have to fulfill several requirements, namely preparing a human rights policy statement, estimating human rights effects for their activities and arranging an internal control, legal proceedings and a reporting system concerning their human rights performance to meet their responsibility to respect human rights.[325]

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324 S Moon, 'Respecting the right to access to medicines: Implications of the UN Guiding Principles on business and human rights for the pharmaceutical industry' (2013) Health and Human Rights Journal 35 <http://www.hhrjournal.org/2013/10/03/respecting-the-right-to-access-to-medicines-implications-of-the-un-guiding-principles-on-business-and-human-rights-for-the-pharmaceutical-industry> accessed 01 April 2014.

325 B Lindner and A Steinkellner, 'Corporate Responsibility for Human Rights' in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 581.

In this context it is critical to note, that the UN Guiding Principles do not only address the impact on human rights through their own activities, but also those that arise as a result of their business relationships with other parties, including their value chains.[326]

The idea is explained by *Mark B. Taylor*, who argues "that a business is (...) – independent of what states do or not do - responsible for the effects, which arise from its actions, and that it should therefore take the necessary steps, namely establishing a system of due diligence, in order to ensure that its actions do not have harmful impacts on human rights".[327]

The system was well received by different key stakeholders and even some multinational corporations and governments have already referred to the UN Guiding Principles and have made some efforts to establish human rights due diligence prerequisites. Since then, elements of the UN Guiding Principles have been integrated into the latest revision of the OECD Guidelines for multinational enterprises, evident when comparing the wording (see above) to the new CSR policy of the EU Commission.

What becomes clear to me, is that the biggest shortcoming still remains the absence of a legal enforcement system. That is why it still has to be considered an instrument of non-binding soft law only, instead of enforceable direct legal accountability.[328]

When *John Ruggie* presented the Guiding Principles to the Human Rights Council, he finished his presentation with the following words: "I am under no illusion that

326 M Theuws and M Huijstee, 'Corporate Responsibility Instruments- A comparison of the OECD Guidelines, ISO 26000 & the UN Global Compact' (*Somo*, 2013) <http://somo.nl/dossiers-en/csr/corporate-responsibility-instruments> accessed 01 April 2014.
327 M Taylor, 'Business, Human Rights Due Diligence and the role of the state' (*Biz,* 17 June 2013) <http://www.lawsofrule.net/2013/06/17/business-human-rights-due-diligence-and-the-role-of-the-state > accessed 01 April 2014.
328 B Lindner and A Steinkellner, 'Corporate Responsibility for Human Rights' in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 581.

the conclusion of my mandate will bring all business and human rights challenges to an end. But Council endorsement of the Guiding Principles will mark the end of the beginning".[329]

In similar words, a group of several countries, namely the African Group, Pakistan, Sri Lanka, Kyrgyzstan, Cuba, Nicaragua, Bolivia, Venezuela, Peru and Ecuador described the UN Principles in a statement adressed to the president as a "first step", which will "without a legally binding instrument, remain only as such: a first step without further consequence".[330]

In my opinion, it is therefore highly important to build on this foundation established by the UN Guiding Principles and to immediately take the next step.

I subscribe to the view of these countries, which means establishing an international legally binding instrument within the UN system, which would not only "clarify the obligations of transnational corporations in the field of human rights" and of "corporations in relations to states", but would also "provide for the establishment of effective remedies for victims in cases where domestic jurisdiction is clearly unable to prosecute effectively those companies".[331]

Only then, pharmaceutical companies could effectively be hindered from pricing drugs excessively so that the population of developing and least-developed countries would finally be able to afford the medicine that they urgently need.

329 J Ruggie, 'A UN Business and Human Rights Treaty? An Issues Brief by John G. Ruggie' (Harvard Kennedy School, 28 January 2014) 2-5 <http://business-humanrights.org/media/documents/ruggie-on-un-business-human-rights-treaty-jan-2014.pdf> accessed 01 April 2014.
330 Statement on behalf of a group of countries at the 24rd session of the human rights council, 'Transnational Corporations and Human Rights', General Debate- Item 3 (September 2013) <http://business-humanrights.org/media/documents/statement-unhrc-legally-binding.pdf> accessed 01 April 2014.
331 Ibid.

4.2.4.2.2.4. Hunt Guidelines

Paul Hunt was mandated by the Human Rights Council from 2002 until 2008 as the first UN Special Rapporteur on the right to health. His main task was the clarification of human rights responsibilities of pharmaceutical companies in relation to the right to health and respectively the access to medicines.

At the end of his mandate in 2008, *Hunt* finalized the Human Rights Guidelines for Pharmaceutical Companies in relation to access to medicines.[332]

Hunt's try to persuade several pharmaceutical companies to engage in his project remained without result. This also becomes indisputable when reading for instance the afterwards-comment of Merck stating that they "feel the approach to define Guidelines specific to the pharmaceutical industry is misguided and will not result in any meaningful improvements".[333]

Similarly to the Ruggie Principles, the "Hunt Guidelines" place primary responsibility on states,[334] but define the ensurement of access to medicine as a shared responsibility between public and private actors.[335] *Hunt* describes the role of pharmaceutical companies in this context as an indispensable one.[336]

332 S Moon, 'Respecting the right to access to medicines: Implications of the UN Guiding Principles on business and human rights for the pharmaceutical industry' (2013) Health and Human Rights Journal 36 <http://www.hhrjournal.org/2013/10/03/respecting-the-right-to-access-to-medicines-implications-of-the-un-guiding-principles-on-business-and-human-rights-for-the-pharmaceutical-industry> accessed 01 April 2014.
333 JL Sturchio, 'Response from Merck & Co, Inc.' (2008).
334 S Moon, 'Respecting the right to access to medicines: Implications of the UN Guiding Principles on business and human rights for the pharmaceutical industry' (2013) Health and Human Rights Journal 37 <http://www.hhrjournal.org/2013/10/03/respecting-the-right-to-access-to-medicines-implications-of-the-un-guiding-principles-on-business-and-human-rights-for-the-pharmaceutical-industry> accessed 01 April 2014.
335 Ibid 36.
336 P Hunt, Economic, Social and Cultural Rights. *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Report of the Special Rapporteur; P Hunt, Submitted in Accordance with Commission Resolution 2002/31, E/CN.4/2003/58 (13 February 2003) 7* <http://www.populationmedicine.org/sites/default/files/Hunt-2008-UN%20GA-Draft%20Guidelines%20Pharmaceutical%20Companies_0.pdf> accessed 01 April 2014.

Further, *Hunt* emphasizes the necessity to interpret the Guidelines in accordance with the Ruggie Principles of "Protect, Respect and Remedy"[337] and stresses the risk of confusing the role of states, who have the main responsibility to "protect", with the one of pharmaceutical companies, that have the responsibility to "respect".

Although over half of the Guidelines clearly fell under the responsibility to "respect", concerning the rest this is not that clear as some Guidelines constitute a gray area where both responsibilities- that of states to protect and of pharmaceutical companies to respect – fall together. [338] *Sueri Moon* delivers a descriptive example when analysing the Guidelines 17-19 with the headline "public policy influence, advocacy and lobbying":

Guideline 17 states that "the company should disclose all current advocacy and lobbying positions and related activities, at the regional, national and international levels, that impact or may impact upon access to medicines".

Futher Guideline 18 says that "the company should annually disclose its financial and other support to key opinion leaders, patient associations, political parties and candidates, trade associations, academic departments, research centers and others, through which it seeks to influence public policy and national, regional and international law and practice. The disclosure should extent to amounts, beneficiaries and channels by which the support is provided".

Both Guidelines comprise a responsibility for pharmaceutical firms to "respect" when stating that "the company should disclose (...)." I agree with *Moon* who argues that it is rather unrealistic to expect pharmaceutical companies to abide by these Guidelines without the existence of a binding state regulation. Therefore a

337 S Moon, 'Respecting the right to access to medicines: Implications of the UN Guiding Principles on business and human rights for the pharmaceutical industry' (2013) Health and Human Rights Journal 37 <http://www.hhrjournal.org/2013/10/03/respecting-the-right-to-access-to-medicines-implications-of-the-un-guiding-principles-on-business-and-human-rights-for-the-pharmaceutical-industry> accessed 01 April 2014.
338 Ibid 38-39.

connected responsibility of states will be necessary, namely “to protect“ in order to establish binding state regulations which firms have to adhere then.[339]

In my opinion, it is noticeable that in order to achieve the goal of full disclosure, more than trust in voluntary behaviour of pharmaceutical companies without any action by the state, is needed.

In regards to content, the Guidelines begin with a praemble and are then grouped by theme, such as transparency, management, monitoring and accountability, pricing and ethical marketing, whereas each theme is followed by a brief commentary.[340]

Concerning the legal status of the “Hunt Guidelines“, it is evident when reading the Guidelines that most of them are not intended to be obligatory at all as even *Hunt* admits that “the Guidelines do not use the word “must“, but the more modest language “should“.[341] It seems to me that the Guidelines do not even deal with the question as to what extent pharmaceutical companies should be bound by international human rights law. Even *Hunt* himself states that “the central objective of the Guidelines is to provide practical, constructive and specific guidance to pharmaceutical companies (...).“[342]

Anand Grower, the Special Rapporteur on the right to health following *Hunt*, analyses the “Hunt Guidelines“ arguing that as non-binding legal framework, they are insufficient to ensure the responsibility of pharmaceutical companies to

339 Ibid 39.
340 P Hunt, Economic, Social and Cultural Rights. *The right of everyone to the enjoyment of the highest attainable standard of physical and mental health. Report of the Special Rapporteur; P Hunt, Submitted in Accordance with Commission Resolution 2002/31, E/CN.4/2003/58 (13 February 2003) 10* <http://www.populationmedicine.org/sites/default/files/Hunt-2008-UN%20GA-Draft%20Guidelines%20Pharmaceutical%20Companies_0.pdf> accessed 01 April 2014.
341 S Moon, ’Respecting the right to access to medicines: Implications of the UN Guiding Principles on business and human rights for the pharmaceutical industry’ (2013) Health and Human Rights Journal 36 <http://www.hhrjournal.org/2013/10/03/respecting-the-right-to-access-to-medicines-implications-of-the-un-guiding-principles-on-business-and-human-rights-for-the-pharmaceutical-industry> accessed 01 April 2014.
342 Ibid 36.

respect, because these private firms have an obligation to their shareholders to maximize market power and the connected earnings.[343] This argumentation is plausible.

Hunt and *Khosla* have defined the absence of an independent accountability mechanism as a key weakness of the "Hunt Guidelines" and have asked for greater attention to institutions for remedy in general.[344]

4.2.4.2.2.5. UN Draft Norms

By contrast, the UN Draft Norms, more precisely the "Norms on the Responsibilities of Transnational Corporations and Other Business Enterprises with Regard to Human Rights", worked out in 2003 by the UN Sub-Commission on the Promotion and Protection of Human Rights, go beyond this previous category of "soft law".

The ideas developed by the UN Sub-Commission originally showed great promise and covered many needed aspects as it provided for example an independent monitoring system by external bodies such as the UN and legally enforceable sanctions. It was actually a try to hold corporations in a direct, but second way accountable for several human rights, such as labour rights and non-discrimination, while states were still intended to act as the primary bearers of responsibility.

This try, however, remained unsuccessful as the Draft Norms were not supported by enough governments and have never been endorsed by the Human Rights

343 Ibid 39.
344 Ibid 41.

Commission.[345] Several scholars consider the broad scope of the Norms to be the main reason for the rejection on part of the international community.[346]

Another conceptual shortcoming of the UN Draft Norms identified by *Ruggie* is, that they make both states and businesses responsible in a very general way for the protection and fulfillment of rights without distinguishing clearly between the different obligations.

That is why the Human Rights Commission finally began a new process in 2005 by mandating *Ruggie* as Special Representative of the Secretary General in order to develop a new legal framework, as already illustrated in chapter 4.2.4.2.2.3.[347]

4.2.4.3. Deficits of the CSR process

In contrast to the UN Guiding Principles on Business and Human Rights with its new system of due diligence, what the other soft law Guidelines have in common, is that there is a great need for a monitoring system, which should be separated from the corporation itself.

In the past, some multinational corporations have chosen external firms like Pricewaterhouse Coopers to control their operations.

Monshipouri draws an accurate comparison in context with this phenomen when noting that “having a corporation pay a firm of its choosing to oversee its

345 Ibid 35.
346 B Lindner and A Steinkellner, ’Corporate Responsibility for Human Rights’ in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 580.
347 S Moon, ’Respecting the right to access to medicines: Implications of the UN Guiding Principles on business and human rights for the pharmaceutical industry’ (2013) Health and Human Rights Journal 34-35 <http://www.hhrjournal.org/2013/10/03/respecting-the-right-to-access-to-medicines-implications-of-the-un-guiding-principles-on-business-and-human-rights-for-the-pharmaceutical-industry> accessed 01 April 2014.

operations is like holding an election in which only members of one party can vote- the results are basically pre-determined".[348]

I completely agree, that the possibility of choosing an external firm like Pricewaterhouse Coopers can be equalized with allowing corporations to create the outcomes that suit them best. However, there are other companies as well, which have involved several stakeholder groups to elaborate on and implement their CSR processes, for example employees' representatives or NGOs[349]

Kenneth Roth, Executive Director of Human Rights Watch reduces the issue to a common denominator in a highly accurate way when defining the three deficits in connection with the UN Global Compact as "the lack of legally enforceable standards, the lack of monitoring and enforcement mechanism, and the lack of clarity about the meaning of the standards themselves".[350]

The important question for the future should therefore be how control over multinational corporations concerning the pricing of drugs can be established in the form of a monitoring system.

This question can be answered in different ways. *Baushik Basu*r, for example suggests to completely restructure international organisations, such as the WTO, the IMF and the World Bank, so that they can fulfill the task of monitoring multinational corporations.[351]

There are other opinions as well, for example that of *Prakash Sethi*, who prefers a voluntary access for multinational corporations, because it "minimizes the need for

348 M Monshipouri, CE Welch and ET Kennedy, 'Multinational Corporations and the Ethics of Global Responsibility: Problems and Possibilities' (2003) 25 Human Rights Quarterly 983-984.
349 B Lindner and A Steinkellner, 'Corporate Responsibility for Human Rights' in M Nowak, K Januszewski and T Hofstätter (eds), *All Human Rights for All- Vienna Manual on Human Rights* (NWV 2012) 579.
350 R Kenneth, 'Corporate Social Responsibility' (*Human Rights Watch,* 28 July 2000) <http://www.hrw.org/news/2000/07/27/corporate-social-responsibility> accessed 01 April 2014.
351 M Monshipouri, CE Welch and ET Kennedy, 'Multinational Corporations and the Ethics of Global Responsibility: Problems and Possibilities' (2003) 25 Human Rights Quarterly 984.

further governmental regulation“, which is in his opinion more expensive and less efficient“.[352] Some authors even take a wider and more general approach arguing that a legally binding instrument would and could not even be the appropriate means to regulate a problem of such dimension.[353]

The arguments behind this reasoning are manifold. Some scholars argue that legal norms are rather abstract and therefore in practice difficult to apply to different business practices, while on the other hand voluntary codes are quite flexible in application and can thus easily be adapted to the different circumstances of businesses.[354]

And yet others argue that the drafting of binding international rules would be premature because the new instruments of voluntary Initiatives first need time to spread. It has to be noted, however, that the drafting of a new treaty, would really need several years of negotiations in the prefield.[355]

I agree with the reasoning of the International Council on Human Rights Policy when arguing that both legal and voluntary norms are needed and neither of them can substitute the other.[356]

Anyway, to me it is unimaginable that codes of conduct and other voluntary Initiatives by companies alone, can be a more or at least equally effective tool for changing company behaviour in comparison to legal regulation. Further, companies that have voluntarily and seriously agreed to respect particular rights should have nothing to fear from the establishment of an enforceable legal system.

352 S Sethi, 'Corporate Codes of Conduct and the Success of Globalization' (2002) 16 Ethics and International Affairs 106.
353 W Abbott and D Snidal, 'Hard and Soft Law in International Governance' (2000) 54 International Organization 421-456 <http://web.efzg.hr/dok/pra/hhorak/Hard%20and%20soft%20law%20in%20international%20governance.pdf> accessed 01 April 2014.
354 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 9 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 01 April 2014.
355 Ibid 8.
356 Ibid 9.

In my opinion, pharmaceutical corporations can only be hampered from pricing drugs excessively when there are correspondent binding international rules.

4.3. The relationship between the right to health other human rights

Besides the human right of access to medicine itself, some authors emphasize the importance of a strong correlation with the cultural and political circumstances in order to be able to reach the best possible accessibility to and acceptability of health care. There is the argumentation that the full realisation of the right to health can only be achieved by implementing the cultural and political parameters that are essential for health, at the very same time.[357]

It is argued from different sides that the right to health must not be viewed in a narrow sense but that this human right can only be fully realized when thinking in a much broader context and always bearing in mind the diverse underlying circumstances.

It is therefore important to take a closer look at the cultural and political determinants that are relevant to health. For instance, *Johanna Gibson* specifies the right to culture as "ancillary to the right to health".[358] She even goes further and describes health as a "condition of social status".[359]

In this context, It is worth analysing Article 15 of the ICESCR, which regulates the right to culture as such. According to Article 15 of the ICESCR,

1. The State Parties to the present Covenant recognize the right of everyone:

357 J Gibson 'Access to Medicines and the Right to (Cultural) Life' in Yorke J (ed), *The Right to Life and the Value of Life: Orientations in Law Politics and Ethics* (Ashgate 2010) 2-3 <http://ssrn.com/abstract=1460825> accessed 06 July 2014.
358 Ibid 5.
359 Ibid 4.

(a) To take part in cultural life;
(b) To enjoy the benefits of scientific progress and its applications;
(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields.

From Articles 15. 1 (a) and (b), it is *Gibson* who draws the conclusion that everybody – independent of individual life chances – has the right to "access the benefits of medical research and development, including medicines".[360]

In similar words, the International Commission of Jurists tried to establish a connection between the right to cultural life and other human rights when declaring the rights to "adequate house, food, water and health" as significant components of cultural life.[361]

When analysing Article 15 (1) c, the necessity to achieve appropriate protection for the corresponding knowledge-holders, becomes undeniable. *Gibson* mentions in particular the knowledge concerning traditional medicine as a necessary main object of protection.

360 J Gibson 'Access to Medicines and the Right to (Cultural) Life' in Yorke J (ed), *The Right to Life and the Value of Life: Orientations in Law Politics and Ethics* (Ashgate 2010) 5 <http://ssrn.com/abstract=1460825> accessed 06 July 2014.
361 Ibid 7.

Besides the right to cultural life, it is the right to development that interacts with the right to health in a quite similar way. Again, it is the right to health that can be described as one imperative determinant for fulfilling the right to development.[362]

The relevant document which must be analysed in context of the right to development, is the Declaration on the Right to Development adopted by the UN General Assembly, by Resolution 41/128, in particular Article 8.

Article 8.1. of the Declaration on the Right to Development says that "states should undertake, at the national level, all necessary measures for the realization of the right to development and shall ensure, inter alia, equality of opportunity for all in their access to basic resources, education, health services, food, housing, employment, and the fair distribution of income".[363]

But it is not only the Declaration on the Right to Development itself that refers to the right to development. There can also be observed a strong connection between the right to development and the Millenium Development Goals, adopted by the UN General Assembly in 2000,[364] which I mentioned in the very beginning of my paper. It is the Millenium Development Goal Number 8 that provides for the "development of a global partnership for development". This includes the goal to guarantee access to affordable medicines for developing and least-developed countries through the establishment of cooperations with pharmaceutical companies.[365] Again, for me, the close relationship between the right to health and the right to development as a whole becomes more than evident.

362 Ibid 8-9.
363 Resolution (General Assembly of United Nations) A/RES/41/128 of 4 December 1986 Declaration on the Right to Development [1986] para 8.1 <http://www.un.org/documents/ga/res/41/a41r128.htm> accessed 31 March 2014.
364 Resolution (General Assembly of United Nations) A/RES/55/2 of 18 September 2000 UN Millenium Declaration [2000] <http://www.un.org/millennium/declaration/ares552e.pdf> accessed 31 March 2014.
365 J Gibson 'Access to Medicines and the Right to (Cultural) Life' in Yorke J (ed), *The Right to Life and the Value of Life: Orientations in Law Politics and Ethics* (Ashgate 2010) 14 <http://ssrn.com/abstract=1460825> accessed 06 July 2014.

In context of the right to cultural life, it is advisable to rethink in particular the TRIPS-flexibility of compulsory licenses that I illuminated in chapter 3.6. The connection between the right to cultural life and the instrument of compulsory licenses becomes evident when defining the invention as a "public good": If the inventor fails to fulfill his duty to provide the invention as a public good, the legal interest defined by the patent takes a back seat and thus, a compulsory license can be granted. Therefore the flexibility of compulsory licensing establishes a form of compensation between the legal interests of the patent holder and the beneficial interests of the public.[366]

When thinking this idea through, the entire health system as well as the R&D resources which are put into this health system in general and into the development of necessary drugs in particular, must be seen as a public good. *Gibson* developed a concept defining the access to this public good as an important part of the right to cultural life and to the right to health in a larger sense.[367]

After finishing my research on this topic, I have arrived at the conclusion that only if this relationship between the right to health and several other human rights is respected and understood, it is possible at all to fulfilling the right to health to the highest standard.

5. Conflict between Patents & Access to Medicine

5.1. Factual & Normative Hierarchy

In order to solve the described regime conflict between patent law and international human rights law, the question about a hierarchy in international law arises.

[366] Ibid 16-17.
[367] Ibid 18.

It is *Holger Hestermeyer* who distinguishes between a factual and a normative hierarchy.

5.1.1. Factual hierarchy

Concerning the first hierarchy system, it must be said that states will - in case of a conflict - rather abide by the rules of the regime with the strongest enforcement mechanism. The enforcement mechanism of international human rights law is weak and not very effective whereas the WTO dispute settlement is second to none in the factual hierarchy due to its effective enforcement mechanism.[368]

The dispute settlement mechanism of the WTO is even widely considered to be one of the most effective international judicial bodies, as it provides a binding dispute settlement procedure: Disputes arise in general, when countries differ in their interpretation of the WTO Agreement. A member can bring a dispute to the WTO when it believes that another member is violating trade rules set out by the WTO Agreement. The disputing members must then first hold consultations, and a panel is only set up in case that these consultations fail.[369] Thus, these panels have to be established ad hoc for each case by the WTO Dispute Settlement Body. It has to be noted that a WTO panel is therefore not a standing body but an ad hoc tribunal that is created according to a particular procedere in the DSU.[370]

368 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines*, (Oxford 2005) 199.

369 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 5 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.

370 J Pauwelyn, 'The role of Public International Law in the WTO: How far can we go?' (2001) 95 The American Journal of International Law 553 <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1065&context=faculty_scholarship&seiredir=1&referer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3D%25E2%2580%2599the%2520role%2520of%2520public%2520international%2520law%2520in%2520the%2520wto%253Ahow%2520far%2520can%2520we%2520go%253F%26source%3Dweb%26cd%3D1%26ved%3D0CC8QFjAA%26url%3Dhttp%253A%252F%252Fscholarship.law.duke.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D1065%2526context%253Dfaculty_scholarship%26ei%3DPW6xUqTGI4SKhQeu94HoBw%26usg%3DAFQjCNHKmciKOktYAjUPqIqiazWdap8FK

This panel of three or exceptionally five specially appointed trade experts[371] interprets the provisions of the Agreement and issues a report.[372] As an additional step, every party is allowed to appeal a panel decision at the WTO's appelate body, if the party rejects the Panel's legal analysis. As a particular consequence within the mechanism, a WTO member is allowed to impose trade sanctions proportional to the suffered harm against a member state who has failed to comply with the decision made until the member state does comply.[373] This is a considerable enforcement mechanism.

However, the practical effectiveness of the dispute settlement mechanism is also the reason, why the WTO proceeding's outcome will be determinative in case of a clash with human rights law, namely with the right to access to medicine.[374]

5.1.2. Normative hierarchy

On the other hand, human rights law is regarded to be higher than WTO law in what could be called the moral appeal.

In this context, it is especially important to distinguish between the differing characteristics of intellectual property rights on the one hand, and human rights on the other. Intellectual property rights are granted by the State according to well-defined criteria, which are defined by national legislation. The United Nations give

g%26sig2%3D5VTrEKD4f8_pRSf9s1gEFw%26bvm%3Dbv.58187178%2Cd.ZG4#search=%22'the%20role%20public%20international%20law%20wto%3Ahow%20far%20can%20go%3F%22> accessed 01 April 2014.

371 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 112 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 03 April 2014.

372 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 5 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument> accessed 03 April 2014.

373 C Dommen, 'Raising Human Rights Concerns in the World Trade Organization: Actors, Processes and Possible Strategies' (2002) 24 Human Rights Quarterly 10 ff.

374 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines*, (Oxford 2005) 199.

a graphic description of the differences, when they describe intellectual property rights as the kind of rights, that can be licensed, assigned to someone else, revoked or which can expire, while human rights are inalienable and universal. According to the United Nations, intellectual property rights are generally treated as economic and commercial rights and are held by companies or individual investors, human rights are not – they are just recognized.[375]

However, the existence of a normative hierarchy in international law is hotly debated. The idea of human rights norms, pre-existing in nature, and therefore claiming precedence over other norms, is underdeveloped in international law.[376]

This second route, namely to categorize human rights law as superior to other international law and granting them the status of erga omnes obligations, binding on the international community as a whole, would be categorize it as ius cogens. This approach is not correct at all as only very few norms fall into this category. That is why most human rights norms still remain on the same legal level as other international norms.[377]

In my opinion, the reasoning of such a normative hierarchy in order to favor the right to access to medicine over IP rights sound – of course- tempting from a human rights' perspective. Anyway, there are in fact no convincing arguments which could support the existence of a normative hierarchy in a sufficient manner.

375 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 6 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.
376 FJ Garcia, 'The Global Market and Human Rights: Trading away the Human Rights Principle' (1999) 25 Brooklyn Journal of International Law 51-97.
377 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines*, (Oxford 2005) 205.

5.2. The role of human rights within the WTO regime

Because of the superior factual hierarchy of the WTO regime, the role of the human rights within the WTO regime and further the enforcement of human rights law by WTO dispute settlement is a critical issue.

Joost Pauwelyn puts it in a nutshell when posing the relevant question, "if a trade dispute before the WTO should be examined only in the light of WTO rules or if there is such a thing as general international law that binds all states?"[378]

The WTO appellate body has acknowledged that the WTO dispute settlement body must not interpret international law in "clinical isolation", so that the dispute settlement body has to take international human rights law definitively into account.[379]

Anyway, the question we have to examine, is to what extent the WTO dispute settlement body can apply the human rights norm of access to medicine because of its status as non-WTO law. There are different intensities discussed by scholars as to how human rights law can be applied to the WTO dispute settlement.[380]

378 J Pauwelyn, *Conflict of Norms in Public International Law. How WTO Law relates to other rules of international law* (1st edn, Cambridge University Press 2003) 2.
379 C Dommen, 'Raising Human Rights Concerns in the World Trade Organization: Actors, Processes and Possible Strategies' (2002) 24 Human Rights Quarterly 49 ff.
380 J Pauwelyn, 'The role of Public International Law in the WTO: How far can we go?' (2001) 95 The American Journal of International Law 535 ff <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1065&context=faculty_scholarship&seiredir=1&referer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3D%25E2%2580%2599the%2520role%2520of%2520public%2520international%2520law%2520in%2520the%2520wto%253Ahow%2520far%2520can%2520we%2520go%253F%26source%3Dweb%26cd%3D1%26ved%3D0CC8QFjAA%26url%3Dhttp%253A%252F%252Fscholarship.law.duke.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D1065%2526context%253Dfaculty_scholarship%26ei%3DPW6xUqTGI4SKhQeu94HoBw%26usg%3DAFQjCNHKmciKOktYAjUPqIqiazWdap8FKg%26sig2%3D5VTrEKD4f8_pRSf9s1gEFw%26bvm%3Dbv.58187178%2Cd.ZG4#search=%22'the%20role%20public%20international%20law%20wto%3Ahow%20far%20can%20go%3F%22> accessed 01 April 2014.

There are two different questions which one must distinguish from another. First, whether a WTO panel has the jurisdiction to decide the case[381] and secondly, which law the WTO panel has to apply.

5.2.1. Jurisdiction

Artcile 3.2 of the Dispute Settlement Understanding (DSU) confirms that the jurisdiction of WTO panels is limited to claims under WTO covered Agreements. Anyway, the Appelate Body confirmed, that the WTO panels themselves have "la compétence de la compétence" meaning that the WTO panels have the implied jurisdiction to decide firstly, whether, and secondly, as to what extent, they have jurisdiction over a given dispute.[382]

Thus, the only claims that can be brought before a WTO panel, are set out in the WTO covered Agreements. There is only one exception, namely when the parties of the dispute, by mutual consent, grant the WTO panel explicitly the jurisdiction to also include other claims of violation of non-WTO rules, for instance based on environmental or human rights conventions.[383]

As a WTO panel has only jurisdiction for violations of covered agreements, WTO dispute settlement cannot be used to enforce human rights law. Thus, a WTO

381 BA Garner, *Black's Law Dictionary* (7th edn, West Publishing 2000).
382 J Pauwelyn, 'The role of Public International Law in the WTO: How far can we go?' (2001) 95 The American Journal of International Law 556 <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1065&context=faculty_scholarship&seiredir=1&referer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3D%25E2%2580%2599the%2520role%2520of%2520public%2520international%2520law%2520in%2520the%2520wto%253Ahow%2520far%2520can%2520we%2520go%253F%26source%3Dweb%26cd%3D1%26ved%3D0CC8QFjAA%26url%3Dhttp%253A%252F%252Fscholarship.law.duke.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D1065%2526context%253Dfaculty_scholarship%26ei%3DPW6xUqTGI4SKhQeu94HoBw%26usg%3DAFQjCNHKmciKOktYAjUPqIqiazWdap8FKg%26sig2%3D5VTrEKD4f8_pRSf9s1gEFw%26bvm%3Dbv.58187178%2Cd.ZG4#search=%22'the%20role%20public%20international%20law%20wto%3Ahow%20far%20can%20go%3F%22> accessed 01 April 2014.
383 Ibid 554.

panel would need expanded jurisdiction in order to be able to enforce other rules of international law.[384]

De lege ferenda, it can be argued that WTO panels should have jurisdiction to rule on human rights, which includes the threat of trade sanctions, since such an extension of WTO panel jurisdiction would allow the use of a strong WTO mechanism in order to enforce human rights.

Therefore, major changes to the dispute resolution process would be required and many matters would have to be reconsidered, in particular the implementation of the possibility of trade sanctions for the benefit of human rights law.

A fascinating point is that the Appellate Body already considers WTO provisions in the context of other international agreements, which can be seen as a first step for giving human rights a stronger role in the future.[385] However, a complete change of WTO Agreements is unlikely to happen, given that states have consistently refused to strenghten enforcement mechanisms of international human rights law.[386]

The other – in my opinion more likely option – would be to bring several major member states to realize the importance of human rights in the interpretation of national law following that human rights will enter through the backdoor when implementing WTO law.

384 Ibid 566.
385 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 113 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 03 April 2014.
386 P Alston and G Quinn, 'The nature and scope of state parties' obligations under the International Covenant on Economic, Social and Cultural Rights' (1987) 9 Human Rights Quarterly 833-834.

5.2.2. Applicable law

Once a WTO panel has accepted a case, it has to decide which law it is empowered to apply.

It is essential to note, that the fact that the jurisdiction is limited to claims under WTO covered Agreements has to be distinguished from the question if the applicable law is limited to WTO covered Agreements. The question of jurisdiction cannot be equated with the question of applicable law as the DSU only limits the jurisdiction of WTO panels, but does not limit the applicable law in WTO dispute settlement to the covered agreements.[387]

Article 3.2. DSU prescribes that WTO law has to be interpreted "in accordance with customary rules of interpretation of public international law".[388] That is the reason why human rights law plays a role in the interpretation of the covered agreements. *Pauwelyn* depicts the issue when declaring that the WTO treaty must not be seen as "an island created and existing outside the sphere of international law".[389]

According to *Joost Pauwelyn*, there was no need for Article 3.2. DSU to confirm customary rules of interpretation of public international law,[390] as there is no

387 J Pauwelyn, *Conflict of Norms in Public International Law. How WTO Law relates to other rules of international law* (1st edn, Cambridge University Press 2003) 561-562.
388 Canal-Forgues E, 'Sur l'Interpretation Dans le Droit de l'OMC' (2001) Revue General de Droit International Public 5, 7 ff.
389 J Pauwelyn, 'The role of Public International Law in the WTO: How far can we go?' (2001) 95 The American Journal of International Law 567 <http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1065&context=faculty_scholarship&seiredir=1&referer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3D%25E2%2580%2599the%2520role%2520of%2520public%2520international%2520law%2520in%2520the%2520wto%253Ahow%2520far%2520can%2520we%2520go%253F%26source%3Dweb%26cd%3D1%26ved%3D0CC8QFjAA%26url%3Dhttp%253A%252F%252Fscholarship.law.duke.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D1065%2526context%253Dfaculty_scholarship%26ei%3DPW6xUqTGI4SKhQeu94HoBw%26usg%3DAFQjCNHKmciKOktYAjUPqIqiazWdap8FKg%26sig2%3D5VTrEKD4f8_pRSf9s1gEFw%26bvm%3Dbv.58187178%2Cd.ZG4#search=%22'the%20role%20public%20international%20law%20wto%3Ahow%20far%20can%20go%3F%22> accessed 01 April 2014.
390 Ibid 542.

hierarchy between general international law on the one hand and treaties on the other hand. *Pauwelyn*'s main argument is that all international law derives from the same source, namely state consent, and must therefore have the same value and be applied to the same extent.[391] *Pauwelyn* even goes further arguing that a court of international law is not even in the position to exclude the remark of international law different from WTO-rules.[392]

Pauwelyn continues arguing that the confirmation of some preexisting rules of general international law does not automatically mean to exclude all others. From this, *Pauwelyn* follows that the DSU had to exclude those rules that not applied.[393] It is questionable, however, if such a provision saying that WTO-law prevail over all other law, would have an all-embracing effect.[394] Anyway, as such a provision is not at all to be found in the DSU, the answer to this question does not have to be examined more closely.

Further, Articles 31 and 32 of the Vienna Convention on the Law of Treaties, which are universally acknowledged as customary rules of interpretation of public international law, are essential to note.[395] Hence, according to Article 31.3 (c) of the Vienna Convention, "any relevant rules of international law applicable in the relations between the parties" must be taken into account together with the context for interpreting the covered agreements.[396] Thus, human rights in general and the right to access to medicine in particular, under the non-WTO treaties ICESCR and ICCPR as well as under general international law should be taken into account in the interpretation of the TRIPS Agreement, but are not part of the applicable law. However, the right under general international law, which binds both the WTO and

391 Ibid 536.
392 Ibid 564.
393 Ibid 541.
394 Ibid 565.
395 G Marceau, 'A Call for Coherence in International Law. Praises for the Prohibition against 'clinical isolation' in WTO Dispute Settlement' (1999) 33 Journal of World Trade 124-125.
396 World Trade Organization Panel, *European Communities-Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R (2006) para 7.67 <http://www.wto.org/english/tratop_e/dispu_e/291r_3_e.pdf> accessed 03 April 2014.

its members, is more persuasive for the panel than the the right under the ICCPR or the ICESCR.[397]

Further Article 7 of the TRIPS Agreement, which sets out the objectives of the TRIPS Agreement, states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

According to the Economic and Social Council of the United Nations, these objectives acknowledge a need to balance between rights and obligations of technology holders on the one hand, and between the interests of producers and users of technological knowledge on the other hand, which should be considered in interpreting TRIPS.[398]

To sum it up, it can be said that a WTO member cannot rely on the right to access to medicine as a defence against a claim of violation of WTO law. The situation is only different where a human right has attained the status of ius cogens. Ius cogens norms are said to be so fundamental that any agreement between states that conflicts with them will be invalid.[399] These norms are said to have a "constitutional character" or the "character of supreme law". The International Court of Justice even goes beyond that explanation describing these norms as stemming from "the principles and rules concerning the basic rights of the human person" or as "elementary considerations of humanity".[400] According to Article 53

397 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines*, (Oxford 2005) 222.
398 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 6 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.
399 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 62 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 03 April 2014.
400 Ibid 63.

and 64 of the Vienna Convention on the Law of Treaties, provisions of ius cogens prevail over all treaty norms, those from the past as well as those of the future.

Although it is hard not to feel empathy with the proposition that access to medicine has to prevail over economic interests, it must be considered that the doctrine of ius cogens is a relatively young one, and only several principles are cited as examples of the doctrine, such as for instance the prohibition of genocide,[401] systematic racial, religious discrimination, slavery and crimes against humanity.[402]

Anyway, as WTO law has to be interpreted in accordance with customary rules of interpretation of public international law,[403] human rights definitively have to play a role in the interpretation of the covered agreements.

5.3. WTO Decisions to remedy insufficiencies

The WTO has issued three decisions on TRIPS and public health to remedy the deficiencies of the TRIPS Agreement in the area of access to medicine. In this chapter, I will examine the previous WTO decisions, namely the Doha Declaration, the Decision of 30 August 2003 and the corresponding Amendment. I will in the context of this analysis especially turn my attention to the question, which advantages these newer WTO decisions implicate for the developing and least-developed world.

401 P Cullet, 'Patents and Medicines: The Relationship between TRIPS and the Human Right to Health' (2003) 79 International Affairs 158-159 <http://www.ielrc.org/content/a0301.pdf> accessed 30 March 2014.
402 International Council on Human Rights Policy, *Beyond Voluntarism: Human Rights and Developing International Legal Obligations of Companies* (2002) 62 <http://www.ichrp.org/files/reports/7/107_report_en.pdf> accessed 03 April 2014.
403 Canal-Forgues E, 'Sur l'Interpretation Dans le Droit de l'OMC' (2001) Revue General de Droit International Public 5, 7 ff.

5.3.1. Doha Declaration

The first one, the Doha Declaration, has its seed in an Afican Group's request, supported by other developing countries, who presented a draft text in a meeting.[404] This origin of Doha is also the reason for some authors describing it as a "landmark decision", because it was actually the first time that developing countries had succeeded in pushing back on IP requirements.[405]

The first question that one asks himself is therefore, how it was possible at all to pass such a Declaration like Doha: It has been argued, that one of the main factors for the negotiation-success of developing countries was the fact, that they were very well-prepared and were working always hand in hand with each other.[406]

A second important factor was the weak position of developed countries that was caused by the anthrax crisis and the scare of a possible reduction of the only common treatment, ciprofloxacin. *Ellen Hoen* describes the relevant question, member countries should ask themselves in context with the anthrax threat as "how much of a prisoner they wanted to be of their own patent systems".[407]

A third reason for the adoption of the Doha Declaration was the strong role of NGOs during the negotiation process. *Drahos* even describes NGOs as a "third force in the global politics of intellectual property rights besides states and business".[408]

404 CM Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health' WHO Health Economics and Drugs, EDM Series No 12 (2002) 3 <http://apps.who.int/medicinedocs/en/d/Js2301e> accessed 04 March 2014.
405 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 2 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.
406 Ibid 29.
407 Ibid 29-30.
408 Ibid 30-31.

The Doha Declaration, adopted by the Ministerial Conference in 2001, mostly reiterates the state of the law, namely that the right to access to medicine has to be taken into account when interpreting the TRIPS Agreement.[409]

The Doha Declaration is divided into seven Paragraphs, which shall each be summed up briefly in the following:

The decision includes in its Paragraph 1 to 4 preambular provisions, whereas the problems addressed by the Doha Declaration are defined in its Paragraph 1.

Paragraph 1 states, “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“.

This Paragraph 1 shows, that the Declaration covers any “public health problems“ and that it is not limited to specific diseases as the enumeration of “HIV/Aids, tuberculosis, malaria“ is only to exemplify.[410]

Paragraph 2 of the Doha Declaration reads, “We stress the need for the TRIPS Agreement to be part of the wider national and international action to address these problems“.

Paragraph 2 was included particular due to the pressure of the United States. It should make clear that IP was one, but not the only factor that affected access problems.[411]

409 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines*, (Oxford 2005) 258.
410 CM Correa, ’Implications of the Doha Declaration on the TRIPS Agreement and Public Health’ WHO Health Economics and Drugs, EDM Series No 12 (2002) 5 <http://apps.who.int/medicinedocs/en/d/Js2301e> accessed 04 March 2014.
411 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 32 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

However, in Paragraph 3, the Declaration acknowledges the high prices of medicines caused by patent protection as the main problem that concern developing and least-developed countries.

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

Correa, who was a member of the Commission on Intellectual Property Rights, even considers this recognition as one of the “major political achievements of the developing countries in the Doha Declaration“,[412] because a connection between patents and the problems which occured in context with the high medicine-prices was acknowledged by the wording of the Paragraph for the first time.

In addition, Paragraph 4 shows that it assigns priority to public health matters[413] and says, “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“.

Further, the Doha Declaration clarifies some of the uncertainity involved in the interpretation of the flexibilities and aims to clarify the relationship between the TRIPS Agreement and public health policies of member countries in general.

412 CM Correa, ’Implications of the Doha Declaration on the TRIPS Agreement and Public Health’ WHO Health Economics and Drugs, EDM Series No 12 (2002) 7 <http://apps.who.int/medicinedocs/en/d/Js2301e> accessed 04 March 2014

413 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 33 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

The substantive text of the Doha Declaration starts with Paragraph 5. It is the same Paragraph, that pays attention to the TRIPS-flexibilities.

Firstly, the Declaration clarifies in its Paragraph 5 (b), that the grounds for issuing a compulsory license are unlimited and in no way confined to cases of emergency or urgency. This means that although Article 31 of the TRIPS Agreement mentions some of the possible grounds, such as emergency and anti-competitive practices for granting compulsory licences, it leaves it up to the members to determine other grounds, such as non-working, public health or public interest.[414]
Secondly, the Declaration explicates in its Paragraph 5 (c), that "public health crises" can represent "a national emergency or other circumstances of extreme urgency" Consequently, an "emergency" does not have to be a short-term problem, but can also be a long-lasting situation.

Further, the Declaration states in its Paragraph 5 (d), that "the effect of the provisions in the TRIPS Agreement (...) is to leave each member free to establish its own regime for such exhaustion without challenge", which in fact authorizes parallel imports without any doubt.

Anyway, it is critical to notice that the Doha Declaration is not self-executing and that all the advantages granted by the Doha Declaration do not redound automatically to the countries' advantage, but that they must be put into effect by implementing the provisions into national law. [415]

I will come back to Paragraph 6 below as it cannot be explained in one sentence at this point.

The Declaration also created new rights for least-developed countries as it permits them in its Paragraph 7 to opt for an extra ten-year extension, until 2016 under

414 CM Correa, 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health' WHO Health Economics and Drugs, EDM Series No 12 (2002) 16 <http://apps.who.int/medicinedocs/en/d/Js2301e> accessed 04 March 2014.
415 Ibid 18, 48.

Article 66.1 of the TRIPS Agreement in relation to pharmaceutical patents.[416] As some least-developed countries have already implemented the TRIPS provisions in their national legislation just after the conclusion of TRIPS, it was necessary for these countries to amend their legislation once again in order to remove protection on pharmaceuticals and take advantage of the Doha-extension.[417]

In detail, Paragraph 7 says, "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".

According to *Ellen Hoen*, the Doha Declaration is "one of the most significant developments of the last decade in trade and health".[418]

Similarly, *Drahos* describes the Doha Declaration as a "concrete success to which developing countries and NGOs can point". Anyway, the question if "Doha represents a significant shift in the power of developing countries to influence the

416 Third World Network, 'Update on Ministerial Declaration on TRIPS and Public Health' (*Third World Network Info Service on WTO Issues*, 26 October 2001) <www.twnside.org.sg/title/info3.htm> accessed 03 April 2014.
417 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 51 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.
418 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) Executive Summary XVI <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

standard-setting process in intellectual property within WTO remains a matter of conjecture“ for *Drahos*.[419]

What also seemsof importance to me is the question concerning the legal status of the Doha Declaration. According to *Correa*, a “Declaration has no specific legal status in the legal framework of WTO law, but has the same effects as an authoritative interpretetaion“. Apart from the legal status of the Doha Declaration, I agree with the view of the European Commission that points out, that the Doha Declaration is part of the context of the TRIPS Agreement and has to be taken into account when interpreting the Agreement.[420]

Nevertheless, the Doha Declaration did not solve all of the problems associated with intellectual property protection and public health as it does not fully clarify the role of access to medicine within the WTO system.[421]

The main problem, namely finding a way for members lacking manufacturing capacity for pharmaceutical products to make use of compulsory licensing, was not being addressed in the Doha Declaration but was postponed to a later date. Paragraph 6 of the Doha Declaration only instructs the governing body of the TRIPS, the TRIPS-Council “to find an expeditous solution to this problem and to report to the General Council before the end of 2002“. It took the TRIPS Council nearly two years to reach an Agreement to allow the export of drugs that are produced under a compulsory license. Thus, this matter was finally solved through the amendment of the second decision, the Decision of 30 August 2003:[422]

419 P Drahos, ’Developing Countries and International Intellectual Property Standard-Setting’ UK Commission on Intellectual Property Rights Study Paper 8 (2002) 26.
420 CM Correa, ’Implications of the Doha Declaration on the TRIPS Agreement and Public Health’ WHO Health Economics and Drugs, EDM Series No 12 (2002) 44 <http://apps.who.int/medicinedocs/en/d/Js2301e> accessed 04 March 2014.
421 R Kampf, ’Patents versus Patients?’ (2002) 40 Archiv des Völkerrechts 90.
422 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines*, (Oxford 2005) 262.

5.3.2. Decision of 30 August 2003

The original of Article 31 (f) of the TRIPS Agreement limited compulsory licensing to uses which are “predominantly for the supply of the domestic market“, meaning that according to Article 31 (f) of the TRIPS Agreement and prior to the Decision, a country with manufacturing capacity for a pharmaceutical product could firstly issue a license for its local manufacture and supply all of the country’s individual needs, and secondy could issue a license for the import of a product to meet all of its domestic needs. Thirdly, the country could allow export, but only for a “non-predominant“ part of the production.[423]

Thus, country-members with large markets, such as India, could easily grant compulsory licences, while it was nearly impossible for members with relatively small markets, like South-Africa, to make use of Article 31, if the product was on patent in the potential exporting country.[424]

That is why Article 31 (f) of the TRIPS Agreement was later amended through Paragraph 2 of the Decision of 30 August 2003, in order to allow compulsory licences in cases where it was not “predominantly for the domestic market“, but also for the manufacturing of a pharmaceutical product for export to members lacking pharmaceutical capacities.[425]

To benefit from the waiver, several conditions have to be fulfilled in order to prevent price leakages of cheaply priced products to markets where original patents are fully protected. Meaning for instance, special labelling or colouring, in order to prevent trade diversions or the abuse of the system. One option is to

423 F Abbott, ’The WTO Medicines decision: World pharmaceutical Trade and the protection of public health’ (2005) 99 American Journal of International Law 319 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=763224> accessed 27 March 2014.
424 CM Correa, ’Implications of the Doha Declaration on the TRIPS Agreement and Public Health’ WHO Health Economics and Drugs, EDM Series No 12 (2002) 26 <http://apps.who.int/medicinedocs/en/d/Js2301e> accessed 04 March 2014
425 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 262.

determine a different brand name from the originator drug or to diversify packaging.[426] This provision makes the re-export of the finished products from the importing member much more difficult as the products can be identified as having been produced under that mechanism.[427]

The Declaration applies to all "public health problems" in developing and least-developed countries. Anyway, the United States and some other developed countries attempted in the prefield of the Decision of 30 August 2003 to limit the solution to a fixed set of diseases, because this approach would have implified to also limit the number of patented technologies, subject to compulsory licensing for export. Anyway, the proposal of the United States was rejected by developing countries, who maintained a unified front, and thus, the intentions of the United States were not realized. It has to be noted, that several NGOs also played key roles in pointing out the extent of public health problems.[428]

The decision gives least-developed WTO members special treatment as they are automatically determined as "eligible importing members" according to Paragraph 1 (b) of the Decision.[429] The situation is more complicated for importing countries in other stages of development, namely developing countries, that have insufficient or no pharmaceutical manufacturing capacities as they have to submit a notification in advance to the TRIPS Council in order to use the mechanism.[430] It is indisputable, that this notification system puts intense political pressure on developing countries by developed countries and thus constitutes another disincentive to use the mechanism.[431]

426 J Hepburn, 'Implementing the Paragraph 6 Decision and Doha Declaration: Solving Practical Problems to Make the System Work' (2004) Quaker United Nations Office 9 <http://www.geneva.quno.info/pdf/DohaImplSeminar0504.pdf> accessed 03 April 2014.
427 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 266-267.
428 F Abbott, 'The WTO Medicines decision: World pharmaceutical Trade and the protection of public health' (2005) 99 American Journal of International Law 328 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=763224> accessed 27 March 2014.
429 Ibid 335.
430 Ibid 336.
431 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB

Due to the pressure of the United States and the European Union, several developed countries have already opted out of using the solution as importing countries, or have explained that they will use the system only in cases of national emergency or circumstances of extreme urgency. Thus, the low-priced drug imports are prevented from entering these markets.[432]

It has to be noted, that the Decision only explicitly mentions WTO members as qualified importers under the compulsory license system. Some member countries argue that the WTO Decision should be interpreted in a way that is not limiting to WTO member states as importing countries. The Netherlands, for instance, are arguing that when implementing the legislation.[433]

It is obvious, that the whole mechanism of the Declaration relies on exporting members' granting compulsory licences for production for export. The mechanism does not work automatically. There rather is a need to grant case-by-case, drug-by-drug and country-by-country compulsory licences in both the importing and the exporting country.[434] It is noticeable, that the need for two compulsory licenses for a single supply situation is administratively burdensome.[435] Thus, it is unlikely that this system provides sufficient economic incentive to keep the generic medicines sector alive.[436]

2009) 37 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

432 F Abbott, 'The WTO Medicines decision: World pharmaceutical Trade and the protection of public health' (2005) 99 American Journal of International Law 337 <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=763224> accessed 27 March 2014.

433 E Kohler and C, 'Finding flaws: The limitations of compulsory licensing for improving access to medicines – an international comparison' (2008) 16 Health Law Journal 170.

434 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 36 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

435 Commission on Intellectual Property Rights, Innovation and Public Health, *Integrating Intellectual Property Rights and Development Policy (2002)* 47 <http://www.iprcommission.org/papers/pdfs/final_report/ciprfullfinal.pdf> accessed 24 March 2014.

436 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) Executive Summary XVII

In order to make the system work, it is necessary to consider the time-factor that is needed for the government of a country to issue a compulsory license and to import the medicine needed.[437]

According to Paragraph 1 (c) of the Decision, any member may become an exporting member[438] under the prerequisite that the member country is ready to amend its legislation to provide for such licences.[439]

Thus, before exporting members can actually grant compulsory licences for production for export at the request of importing members, they are required to amend their legislation to provide for such licences.[440] Although some states as for example China[441] and the European Communities[442] have already passed the relevant amendments, the Decision is unlikely able to keep up the advantages of the situation before 2005 for members without manufacturing capacity.

Before 2005, large generic manufacturers in India – because of its market – started operations for many drugs, and importing members could then simply approach these manufacturers and buy the generic drugs from them. Now, manufacturers often have to decide whether to start manufacturing the product merely on the basis of the request of a small, poor, importing member.[443] This is

<http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

437 J Hepburn, 'Implementing the Paragraph 6 Decision and Doha Declaration: Solving Practical Problems to Make the System Work' (2004) Quaker United Nations Office 9 <http://www.geneva.quno.info/pdf/DohaImplSeminar0504.pdf> accessed 03 April 2014.

438 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 265.

439 J Hepburn, 'Implementing the Paragraph 6 Decision and Doha Declaration: Solving Practical Problems to Make the System Work' (2004) Quaker United Nations Office 12 <http://www.geneva.quno.info/pdf/DohaImplSeminar0504.pdf> accessed 03 April 2014.

440 Ibid 12 ff.

441 China State Intellectual Property Office Order No 37, *Measures to Implement Public Health-Related Compulsory Licensing* <http://www.cptech.org/ip/health/cl/china-order37.html> accessed 03 April 2014.

442 Council Regulation (EC) 816/2006 of 17 May 2006 the European Parliament on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems [2006] Official Journal of the European Union L 157/1 <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R0816:EN:NOT> accessed 03 April 2014.

443 N Mathiason, 'Drugs deal "not viable"' *The Observer* (31 August 2003).

also the reason, why more and more Indian generic producer companies are concentrating their businesses on the export of off-patent generics to high-income markets instead of developing new medicines for the developing world.[444]

It is undeniable that firms are rather reluctant to use this system producing generic medicines, firstly because the market is small in comparison to the normal market and secondly, because they cannot expect economies of scale.[445]

This deviation from the business market principles and the ignorance concerning this economic reality are probably also the reasons why to date only several compulsory licence based drugs have been exported to a member state without the manufacture capability according to the Decision of 30 August 2003.[446]

Ellen Hoen reduces the issue to a common denominator when describing the Decision of 30 August 2003 as a "textbook example of a WTO compromise with little practical use". I agree with the author when declaring that the objective apparently "was to reach an Agreement – any Agreement – at the end of the day without regard to the effectiveness of the compromise".[447]

In this context, it also raises the question if local production of pharmaceuticals in developing and least-developed countries would be an appropriate alternative to foster the access to the needed medicines. This idea seems logical to me at least

444 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 37 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

445 Kohler and C, 'Finding flaws: The limitations of compulsory licensing for improving access to medicines – an international comparison' (2008) 16 Health Law Journal 171.

446 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 37 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

447 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 38 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

to the extent that production-costs in general are expected to be lower in developing and least-developed countries than in developed countries.

However, *Kaplan* and *Laing* have examined that question in a study and found out that in many parts of the world, the domestic production of medicines makes little economic sense. This results from a loss of economies of scale due to a plus of production facilities in many more countries.[448] Further, many countries would have to import technical know-how and raw materials with the result that the savings are quite small at the end. The message of the study of *Kaplan* and *Laing* is to me, that there are better ways for improving the existing health care systems in developing and least-developed countries than to local manufacturing of pharmaceuticals.[449]

To sum it up, the main deficiency of the system is the huge administrative effort that makes the granting of two compulsory licenses in two different member countries necessary. It is evident to me that a new system is urgently needed in order to make sure that the whole procedure of granting compulsory licenses works more smoothly and also more time-efficient. The grantings of compulsory licenses must work automatically instead of case-by-case and drug-by-drug.

There is an intriguing approach proposed by *Ellen Hoen* arguing for so-called "patent pools"[450] as a counterpart to cumbersome case-by-case licenses that I described above. Although the instrument of patent pools is not a new business system, it seems to me in the framework of my research, that it has already been forgotten about. Anyway, my research indicates that patent pooling can be adopted as a very essential instrument for promoting generic competition, in

448 W Kaplan and R Laing, *Local production of pharmaceuticals: Industrial Policy and access to medicines An overview of key concepts, Issues and Opportunities for Future Research* (Health Nutrition and Population 2005) iii.
449 Ibid 34.
450 A patent pool can be described as a coalition of several enterprises accepting to cross-license patents with the main goal of hampering patent infringement and patent litigation. See J Gibson 'Access to Medicines and the Right to (Cultural) Life' in Yorke J (ed), *The Right to Life and the Value of Life: Orientations in Law Politics and Ethics* (Ashgate 2010) 14 <http://ssrn.com/abstract=1460825> accessed 06 July 2014.

particular for drugs relevant in developing and least-developed countries, for the following reasons:

Ellen Hoen designates patent pools as “one stop shop“ describing them as “a number of patent rights, held by different owners, for instance companies, universities, government institutions that are brought together, and that are made available on a non-exclusive basis to manufacturers and distributors of medicines against the payment of royalties“.

According to *Hoen* patent pools could offer various advantages: Firstly, the technology transfer could be improved through patent pools. Further, licensing transaction costs would decrease due to the fact that a potential generic company would have to obtain only one license instead of concluding several Agreements with every single patent holder of a fixed-dose combination that consists of several drugs.[451]

In my opinion, the main advantage of *Hoen*’s proposal would be the opportunity for both, the patent holder and the generic company, to simplify the whole case-by-case licensing procedere. Besides the benefit of simplifying the legal requirements for achieving access to medicine, it is in particular the pooling of “expertise“ that forms a big advantage of this instrument.

5.3.3. Amendment to the TRIPS Agreement

As already mentioned, WTO members passed an Amendment to the TRIPS Agreement in December 2005 altering the rights and obligations of members. It transforms the entire decision of 30 August 2003 into a permanent amendment,

451 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 90 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

following the wording of the Decision. As the content of the amendment is identical to that of the Decision of 30 August 2003, the amendment has not brought any further benefits besides the permanency of the mechanism, primarily it does not solve the patent-related problems of access to medicines for members without manufacturing capacity.[452]

5.4. Possible Solutions for Solving the Conflict

As *Scherer* already recognized, the interpretation and implementation of the TRIPS Agreement may have important life or death consequences for the citizens of less-developed countries.[453]

Thus, a solution to the conflict between the TRIPS Agreement and access to medicine can only be achieved by giving human rights law a stronger status within the WTO system.

First of all, the WTO Agreements could be amended to accommodate human rights whereas such an amendment could take the form of a WTO human rights treaty or it could include the ICCPR and the ICESCR by reference. Some authors argue, that the rewording of some of the WTO Agreement's provisions could therefore be an important step in making them more responsive to developing countries' needs.[454]

In the words of the Economic and Social Council of the United Nations, the drawback of this conflict still remains, that the language in which human rights are written, is generally using terms of permitted exceptions, that are subordinated to

452 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 275-276.
453 FM Scherer and J Watal, 'Post-Trips Options for Access to Patented Medicines in Developing Countries' CMH Working Paper Series, Paper No WG4:1(2001) 1.
454 C Dommen, 'Raising Human Rights Concerns in the World Trade Organization: Actors, Processes and Possible Strategies' (2002) 24 Human Rights Quarterly 30 ff.

the rest of the Agreement. The proposal is therefore to place the promotion and protection of human rights "at the heart of the Agreement".[455]

A second option would be the creation of a widespread exception allowing members to break TRIPS obligations to protect human rights.

Another possible solution is to provide stronger cooperation between the WTO and human rights related bodies and organisations, which would allow mutual influences between the two regimes.[456] However, hopes of a treaty amendment are not very realistic given the political opposition to such suggestions.

The most likely route for the importation of human rights law into WTO law is a change in the WTO jurisprudence. Thus, TRIPS exceptions have to be read in a new way, so that they include general international law into the interpretation of WTO Agreements.[457]

It is critical to interpret the TRIPS-flexibilities inside the WTO system more extensively in favor of human rights conventions as I illustrated in chapter 3.6. Thus, intellectual property regimes, in particular the TRIPS Agreement, should be interpreted in light of international human rights, including the right to health.

455 United Nations High Commissioner for Human Rights, *Economic Social and Cultural Rights. The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights. Report of the High Commissioner*, U.N Doc. E/CN4/Sub2/2001/13 (2001) 7 <http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En?Opendocument > accessed 03 April 2014.
456 N Matz, *Wege zur Koordinierung völkerrechtlicher Verträge. Völkerrechtliche und institutionelle Ansätze* (Springer 2005) 365 ff.
457 H Hestermeyer, *Human Rights and the WTO, The Case of Patents and Access to Medicines* (Oxford 2005) 288-289.

6. Conclusion

In my thesis, I described and evaluated the conflict between patent law obligations under the TRIPS Agreement and the access to medicine as a human right.

As illustrated in the very beginning of my doctoral thesis, according to Article 28 of the TRIPS Agreement, patents grant a negative right, namely the right "to prevent third parties not having the owner's consent from the act of: making, using, offering for sale, selling, or importing for these purposes that product".

As I tried to point out in my analysis, the consequences of this single Article are far reaching:

The Federal Trade Commission argues, that patent systems stimulate the competition to innovate, because they "increase the potential rewards to successful innovators by limiting the competition that may arise from the innovation". This in general means, that competition would stimulate the creation of patents, and patents would protect aspects that companies use in the competition process.[458]

This is, however, a view that I do not subscribe to, at all: My analysis shows that – due to the lack of competition – a patent implicates, that pharmaceutical products generally are more expensive than they would be if there was free competition. Or expressed the other way around, it means that an increase in IP protection as provided by TRIPS, automatically implicates a reduction in competition. What follows is, that a pharmaceutical industry based on competition, would in the longer run lead to a decrease in drug prices. Further, patents in

458 Federal Trade Commission, *To promote innovation: The proper balance of competition and Patent Law and Policy* (2003) 8 <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> accessed 03 March 2014.

general hinder others from building on the patented invention and therefore prevent important follow-on innovation.[459]

It was a captivating task to analyse the different approaches in respect to a solution to the conflict between patent law obligations under the TRIPS Agreement and the access to medicine as a human right. It has turned out in the framework of my analysis, that the way low-income countries implement the TRIPS clauses into their legislation can have a massive influence.

In my view, it is especially important for developing countries to define the appropriate scope of patentability when implementing the TRIPS provisions. As *John Sulston*, Nobel Prize Winner for Physiology and Medicine in 2002 expresses it, “intellectual property in the forms of patents should be thought of as a very usefool tool with a relatively narrow applicability rather than as a means for owning even larger swathes of human knowledge (...).“

As my doctoral thesis shows, neither a too broad nor a too narrow scope of patentability can be recommended to developing and least-developed countries when implementing the relevant TRIPS provisions. Instead, low-income countries must strike a balance between these two extremes as through skillfull implementation, a lot can be achieved in order to improve the access to needed medicines.

The pharmaceutical industry tries to justify this conflict between the patent right under the TRIPS Agreement, and the access to medicine as a human right, with the so-called “incentive theory“, arguing that innovation without patents in the pharmaceutical field might lead to a standstill. As my doctoral thesis indicates, there is no evidence, that in practice the implementation of the TRIPS Agreement

459 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 79 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.

in developing countries has encouraged R&D, dedicated to the needs of the poor. That the reality looks completely different in comparison to the ideal of the incentive model and that it is not rudimentary in Agreement with the main argument of the incentive rationale, is a circumstance which I have highlighted in my doctoral thesis as well.

It is undeniable that the era of big breakthroughs or so-called “blockbusters“ is definitively over as I illustrated in chapter 3.5.4. It is not surprising when business analysts more and more often advice pharmaceutical companies to focus their businesses on less risky, smaller step progresses because the present “ever-greening“ and “me-too“ trend will continue.

However, this also means that it is urgently necessary to counteract and question what the reasons behind this trend are. I agree with the argument that the interests of the shareholders of pharmaceutical companies are an substantial argument in this context. It is evident that the interests of shareholders can be defended in a better way when investing in safer pharmaceutical research instead of concentrating on uncertain and therefore riskier projects, especially when the rewards are the same. This very last subordinate clause is also the crux of the matter, as several authors exemplify: The reward for the implementation of a new development must be variabel according to the value of the product. This makes some significant patent law changes necessary, for instance by adopting mutable patent terms according to the usefulness of an innovation. This would for instance implicate a shorter patent term for a “me-too drug“.[460] Only then pharmaceutical corporations will be encouraged to re-invest in pharmaceutical research concentrating on drugs with therapeutic gain.[461]

460 E Hoen, *The global politics of pharmaceutical monopoly power- Drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and Public Health* (AMB 2009) 82 <http://www.msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_book_GlobalPolitics_tHoen_ENG_2009.pdf> accessed 24 March 2014.
461 Ibid 82-83.

In my opinion, the possibilities of R&D are not dead, as the entire issue is not one of suddenly lost talent of invention, but one of only concentrating on profits. The drawback needed, is therefore a determination of the different organisation-levels to work within society in order to re-establish the optimum degree of R&D and to develop new blockbusters once again. It is indisputable that this makes an adaption of the whole frame necessary, a process, which realistically can only happen with the support of public investments.

To me, it is obvious that the main responsibility definitively lies with the governments. That means, governments have to take control over pharmaceutical corporations' behaviour, in order to modify the present medicine patent system. This should be done in order to recover the original goal of the incentive rational which is to put that kind of investment at the center of attention which intends to help those human beings most in need. The goal should be to amend the existing patent system in order to find methods encouraging R&D in clinical research at a tremendous therapeutical progress instead of investing in the marketing departments of pharmaceutical corporations and in the fees of IP-lawyers.

The enhancement of PPPs pooling public capital with private experience in order to target neglected diseases, can therefore be an essential step.

The Doha Declaration intended to change the way of thinking about patents in the context of medicines and it provided indeed political backing to least developing countries, that needed to make use of the TRIPS-flexibilities. Although the Doha Declaration is seen by some authors, for instance by *Drahos*, as the only real win for developing countries in the history of the WTO,[462] full implementation however, is still far from a reality and many questions have remained unanswered.

However, evidence shows that from the last years onwards, developing countries have increasingly managed to make use of compulsory licensing and of the

462 Ibid 85.

TRIPS-flexibilities in general. Hereby the assistance of international organisations in implementing the TRIPS provisions have played a key role.

As my doctoral thesis tries to illustrate, TRIPS-plus provisions constitute a very serious danger to the effective use of patent law safeguards.[463] The US in particular, has sought to achieve high levels of intellectual property protection in deveoping countries through negotiating several bilateral and regional Free Trade Agreements. Thus, developing countries should find a way to withstand the pressure on the part of developed countries when trying to achieve stricter IP requirements through the implementation of TRIPS-plus provisions. This for instance, is the case in India, which has not signed any TRIPS-plus trade Agreements yet and was therefore only obliged to implement the regular TRIPS standards of intellectual property protection.[464] As my doctoral thesis shows, India serves as a model beyond that in many areas.

It is especially critical to note, that investment in HIV treatment services is not only cost-effective, but may also result in important cost savings. Several economic analysis even show that investment in antiretroviral therapy generates economic returns up to three times the investement costs, as a result of increased employment and productivity. Thus, future expenses for medical treatment and overall health care costs would get reduced, because the need for doctor and hospital visits and surgery would decline.[465] This is a fact, which many stakeholders forget, when thinking about the conflict between the patent law obligations under the TRIPS Agreement and the access to medicine as a human right.

Evidence shows, that a reevaluation has already taken place in the ideologies of

463 Ibid 71.
464 R Malpani Rohit, M Kamal-Yanni, *Patents versus Patients- Five years after the Doha Declaration* (Oxfam International 2006) 2.
465 UNAIDS, *2013 Report on the Global AIDS Epidemic* (2013) 48 <http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/UNAIDS_Global_Report_2013_en.pdf> accessed 03 April 2014.

some pharmaceutical companies. For instance, Merck & Co and GlaxoSmithKline have established several projects in 2013 intending to cut the prices of their cancer vaccines for several developing countries, such as Kenya, Niger, Ghana and Tanzania. Thus, the pharmaceutical companies sold their vaccines to eligible low-income countries for about 4.50 US dollars a dose, a more than 95 percent discount from the prices charged in the United States.[466] I suppose, that these pharmaceutical companies have finally realized the benefit of primarily putting their energy into the major markets of developed countries in order to maintain the strict TRIPS-rules, while at the same time not sticking to the narrow interpretations of TRIPS exceptions on the low-income markets.

It seems to me that it has been widely accepted for several years, that besides states, there are other actors as well, namely corporations, that participate in the international legal system. For instance, several of the largest pharmaceutical corporations – although primarily in response to public pressure, but still – have already recognized the importance of the issue and have therefore voluntarily adopted so-called "access policies" to their business philosophy. These policies include for instance drug-donations, the licensing of other pharmaceutical corporations in order to produce lower-cost generic versions of patented drugs, the reduction of drug-prices in lower-income markets and the investment of R&D into diseases that predominantly affect poorer people. Further, a study by the International Federation of Pharmaceutical Manufacturers' Associations in 2012 identified 220 health partnerships, 36 % of which focused on increasing the availability of treatments in developing countries.[467]

466 S Pettypiece, 'Merck, Glaxo Reduce HPV Vaccine Prices in Poorest Regions' (*Bloomberg*, 9 May 2013) <http://www.bloomberg.com/news/2013-05-09/merck-glaxo-reduce-hpv-vaccine-prices-in-poorest-regions.html> accessed 03 April 2014.

467 S Moon, 'Respecting the right to access to medicines: Implications of the UN Guiding Principles on business and human rights for the pharmaceutical industry' (2013) Health and Human Rights Journal 34 <http://www.hhrjournal.org/2013/10/03/respecting-the-right-to-access-to-medicines-implications-of-the-un-guiding-principles-on-business-and-human-rights-for-the-pharmaceutical-industry> accessed 01 April 2014.

It is evident, that this trend of more corporate social responsibility within the multinational pharmaceutical industry is without a doubt a step in the right direction. The main problem though, is that the reason for this trend does not stem from an obligation for multinational corporations, but originates from public expectations, that pharmaceutical corporations fear. In my opinion, it is more than questionable whether it is sufficient to just count on a cooperative behaviour of pharmaceutical corporations in order to guarantee an access to medicine.

My thesis makes obvious, that pharmaceutical innovation primarily depends on sufficient public investments. As the present system for funding R&D in the area of diseases has not been efficient enough, the development of additional international mechanisms is required in order to address health needs in developing countries. A shift in the way health R&D for drugs for neglected diseases is financed would be the right first step.

In my opinion, the two proposals mentioned by *Ellen Hoen* in this context, firstly the financing of health R&D based on a burden-sharing between countries and secondly the obligation for companies to complete essential medical research[468] are plausible examples to encourage essential health R&D for the benefit of all.

In my view, the most important step in solving the conflict between access to medicines and intellectual property is, as my study explains, to give human rights law a larger role in the WTO system in order to achieve a lasting balance between the two conflicting regimes. Therefore it is important to always take the AIDS pandemic into account when conducting and formulating government policy.

468 E Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) 3 Chicago Journal for International Law 62 <http://fieldresearch.msf.org/msf/bitstream/10144/28436/1/Access%20TRIPS%20%27t%20Hoen.pdf> accessed 23 March 2014.

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eiredir=1&referer=http%3A%2F%2Fwww.google.com%2Furl%3Fsa%3Dt%26rct%3Dj%26q%3Ddo%2520stronger%2520patents%2520induce%2520more%2520innovation%26source%3Dweb%26cd%3D1%26ved%3D0CC0QFjAA%26url%3Dhttp%253A%252F%252Frepository.cmu.edu%252Fcgi%252Fviewcontent.cgi%253Farticle%253D1044%2526context%253Dsds%26ei%3DYiIoU9WnCs3M0AWR44DQAQ%26usg%3DAFQjCNEki_s96AvuO2wq3pxoCXBofbE4nw%26sig2%3DhQDnXqBCHYkZkQoV19kc6A%26bvm%3Dbv.62922401%2Cd.d2k#search=%22do%20stronger%20patents%20induce%20more%20innovation%22> accessed 27 March 2014

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8. Abstract – English

This thesis deals with the conflict between patent law obligations under the TRIPS Agreement, which was signed by the WTO in 1994, and the access to medicine as a human right.

The TRIPS Agreement established the obligation on all WTO members to provide patents for pharmaceuticals. According to Article 28.1 (a) of the TRIPS Agreement the patentee has the exclusive right “to prevent third parties not having the owner’s consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product“.

The focus of the analysis lies on the consequences that are connected with this single article for the pharmaceutical industry on the one hand and for the population of developing and least-developed countries on the other hand. It should be noted, that due to a lack of competition, a patent implicates, that pharmaceutical products are in general more expensive than they would be if there was free competition. These higher prices for drugs are in general too costly for the vast majority of people in poor countries who are suffering from malaria, tuberculosis and HIV/Aids.

The topic of my thesis is of particular relevance at this time because the last transitional arrangement developed by the WTO TRIPS Council allowed least-developed WTO members not to apply the provisions of the TRIPS Agreement until 2021. That is why the next few years will be pathbreaking for the time after the transitional period has expired.

In summary, this thesis deals with the problems that result from the concurrence of two different fields of law, that of patent law and that of human rights.

The first part of the thesis outlines the relevant patent law rules and gives a brief overview of the WTO as an institution. Subsequently, the next part is dedicated to the analysis, how the way of implementation of TRIPS into the legislation of developing and least-developed countries can influence the possible achievement of public health goals in a positive way. It is essential to note in this context, that members enjoy considerable latitude as to how they draft their patent laws.

According to the thematic sequence, the thesis thereafter analyses several theories developed by the pharmaceutical industry with different basic approaches trying to justify the conflict between patent law and human rights law. The most popular theory is the so-called “Incentive theory“. According to that theory, patents are important because they promote research and development in the industry and therefore operate as an incentive for research. My thesis makes evident that the “Incentive theory“ seems to represent only partial truths and that the incentive impact alone does not automatically ensure the fastest possible R&D progress. Many surveys have shown that the amount reinvested into R&D by big pharmaceutical corporations is disproporionately small and that most pharmaceutical companies for instance tend to spend even two times more on marketing than they do on R&D. In this context the thesis critically analyses thereafter the trends of the last years. It is indisputable that the era of “blockbusters“ is definitively over. Even business analysts advice pharmaceutical companies to focus their businesses on less risky, smaller step progresses in order to foster the interests of their shareholders. The analysis focuses on the question, how pharmaceutical companies can be influenced into refocusing their businesses on the development of drugs with therapeutic gain and to start a new era of “blockbusters“.

A separate chapter is dedicated to the examination of possible measures to protect public health goals, the so-called TRIPS-flexibilities. In the following part, the application of TRIPS-flexibilities and the so-called “TRIPS-plus trend“, that can be observed in recent time, are being contrasted with each other. TRIPS-plus can be described as an effort by Western countries to put pressure on developing and

least-developed countries in order to achieve standards that go beyond the minimum requirements of TRIPS. It is important to note, that developing countries must be cautious about enacting TRIPS-plus legislation and are advised instead to establish a sophisticated system of TRIPS-flexibilities within the framework of their national patent law systems. Finally the thesis applies the obtained postulates to two specific judicial decisions (Big Pharma vs. South Africa; United States vs. Brazil).

Based on an outline of the legal framework of access to medicine as a human right in the second part of my thesis, it is also necessary to take a close look at the possible addressees of human rights law. The focus of the analysis lies on the question, whether human rights duties are only binding for states or also for the WTO and for pharmaceutical companies in relation to access to drugs.

The following part deals with the recent developments in the debate on “Corporate social responsibility“ and continues with a more detailed description of and comparison between the different legal frameworks. It should be noted, that there still are several deficits when it comes to the process of implementing “Corporate social responsibility“. For instance, it is problematic that at this juncture the whole system of “Corporate social responsibility“ only provides for voluntary conductings instead of legally enforceable obligations for pharmaceutical corporations. Relating to the topic of my thesis, this means that pharmaceutical companies must be influenced into reducing drug-prices voluntarily in terms of a corporate social responsible behaviour in order to guarantee access to medicine for the population of developing and least-developed countries. In terms of the motives of pharmaceutical corporations adopting voluntarily “Corporate social responsibility“, it is further problematic, that they do so primarily because of the influence of public denunciation and public expectations.

The third part of my thesis is dedicated to a detailed discussion about the conflict between patent law obligations under the TRIPS-Agreement and the acess to medicine as a human right. In this context, the thesis also analyses the question

regarding a hierarchy in international law and the distinction between a factual and a normative hierarchy. According to the thematic sequence, the thesis then analyses the role of human rights within the WTO regime. In this context, it is imperative to note that the question about jurisdiction must be sharply distinguished from the question about the applicable law. In a second to last step, the thesis takes a closer look at the previous WTO decisions and focuses in particular on the question, which consequences these newer WTO decisions implicate for the developing and least-developed world. As a very last point, the thesis analyses the possible solutions for solving the conflict between patent law obligations under the TRIPS Agreement and the access to medicine as a human right. It is noticeable that all solutions have a common goal, namely to give human rights a stronger status within the WTO system.

9. Abstract - German

Die vorliegende Dissertation beschäftigt sich mit dem Konflikt zwischen patentrechtlichen Obligationen unter dem von der WTO im Jahre 1994 unterzeichneten TRIPS-Abkommen und dem Zugang zum Gesundheitssystem als Menschenrecht.

Das TRIPS-Abkommen sieht die Verpflichtung für alle WTO-Mitgliedstaaten vor, Patente für pharmazeutische Produkte zu vergeben. Gemäß Artikel 28.1 (a) des TRIPS-Abkommens gewährt ein Patent seinem Inhaber das Recht, es Dritten zu verbieten, ohne die Zustimmung des Inhabers das Erzeugnis herzustellen, zu gebrauchen, zum Verkauf anzubieten, zu verkaufen oder zu diesen Zwecken einzuführen.

Im Fokus dieser Arbeit stehen die mit Artikel 28 des TRIPS-Abkommens verbundenen Konsequenzen für die Pharmaindustrie und für die Bevölkerung in ärmeren Entwicklungsländern. Festzuhalten ist, dass aufgrund des kompletten Wettbewerbsausschlusses während der Patentdauer die Preise für Medikamente viel höher sind, als sie dies bei Vorhandensein eines freien Wettbewerbs wären. Die hohen Medikamentenpreise führen gleichzeitig dazu, dass der Bevölkerung in ärmeren Ländern, die im Allgemeinen am meisten betroffen sind von Krankheiten wie Malaria, Tuberkulose und HIV/Aids, der Zugang zu den für sie lebensnotwendigen Medikamente verwehrt bleibt.

Das Thema meiner Dissertation hat momentan besondere Aktualität, zumal die letzte Übergangsfrist, die den am wenigsten entwickelten Ländern zur Umsetzung der relevanten TRIPS-Bestimmungen eingeräumt wurde, im Jahr 2021 abläuft. Darin begründet liegt auch der Umstand, dass die Entwicklung in den nächsten Jahren wegweisend für die Zeit nach Ablauf dieser Übergangsperiode sein wird.

Die vorliegende Dissertation untersucht die Probleme, die sich aus dem Zusammentreffen zweier komplett unterschiedlicher Rechtsgebiete ergeben – dem System der Patentrechte auf der einen Seite und jenem der Menschenrechte auf der anderen Seite.

Im ersten Teil der Arbeit wird zunächst ein informativer Überblick über die relevanten patentrechtlichen Bestimmungen des TRIPS-Abkommens sowie über die Institution der WTO geboten. Daran anschließend widme ich mich der Aufgabe, die unterschiedlichen Ansätze für eine Umsetzung der relevanten TRIPS-Bestimmungen in nationales Recht aufzuzeigen und zu analysieren. Die Analyse zeigt insbesondere, dass die Art und Weise der Umsetzung der relevanten TRIPS-Bestimmungen durch die einzelnen Mitgliedstaaten in nationales Recht eine besonders wichtige Rolle einnehmen, und gerade die Entwicklungsländer in diesem Punkt große Gestaltungsmöglichkeiten zu ihren Gunsten ausüben können.

Weitere Thematische Abfolge der Dissertation ist sodann die Darstellung und kritische Erörterung der unterschiedlichen Theorien, die die Pharmaindustrie entwickelt hat, um die hohen Medikamentenpreise zu rechtfertigen. Hauptaugenmerk liegt dabei auf der sogenannten “Incentive theory“ (zu deutsch “Anreiz-Theorie“), die davon ausgeht, dass Patente der Pharmaindustrie einen wichtigen Anreiz bieten, in Forschung und Entwicklung zu investieren, und dass ohne entsprechenden Anreiz für Investitionen durch die Pharmaindustrie keine neuen Medikamente entwickelt werden könnten. Meine Dissertation zeigt, dass diese Theorie nur ansatzweise korrekt ist und keinesfalls die ganze Wahrheit wiederspiegelt, zumal viele pharmazeutische Unternehmen beispielsweise mehr als zwei Mal so viel in Marketing als im Vergleich dazu in R&D investieren. In diesem Zusammenhang werden auch die Trends der letzten Jahre kritisch analysiert, wobei auffällt, dass die Ära der großen “Blockbuster“- Erfindungen, insbesondere Medikamente mit therapeutischem Nutzen für Entwicklungsländer, definitiv vorbei ist. Selbst Wirtschaftsanalyten raten pharmazeutischen Unternehmen dazu, nur noch kleine Schritte bei der Entwicklung von “neuen“

Medikamenten durch geringfügige Änderungen bereits bestehender Medikamente zu nehmen, zumal damit auch ein viel geringeres Risiko für die beteiligten Aktionäre verbunden ist. Im Fokus dieser Arbeit steht die Frage, wie pharmazeutische Unternehmen dazu gebracht werden können, wieder eine neue Ära von “Blockbuster“-Medikamenten einzuleiten, die für die Bevölkerung von Entwicklungsländern so wichtig wäre.

Ein eigenes Kapitel wird den TRIPS-flexibilities gewidmet, welche die umfassenden Rechte der Patentinhaber in gewissen Aspekten zu Gunsten der Bedürfnisse in Entwicklungsländern limitieren. Den TRIPS-flexibilities wird sodann der jüngste und für Entwicklungsländer überaus gefährliche TRIPS-Plus-Trend gegenübergestellt, der in den letzten Jahren beobachtet werden konnte. Darunter versteht man die vermehrte Ausübung von Druck seitens westlicher Mitgliedstaaten auf Entwicklungsländer, bei der Umsetzung von TRIPS-Bestimmungen in nationales Recht Standards anzusetzen, die über die notwendigen TRIPS-Minimumvoraussetzungen hinausgehen. Es stellt nach wie vor für viele Entwicklungsländer eine große Herausforderung dar, diesem Druck standzuhalten und stattdessen an der so wichtigen Aufnahme entsprechender TRIPS-flexibilities Bestimmungen in nationales Recht festzuhalten. Im Anschluss daran werden anhand von zwei ausgewählten Case-studies (Big Pharma vs. South Africa; United States vs. Brazil) die vorher gewonnenen Erkenntnisse praktisch angewendet.

Basierend auf dem im zweiten Teil dieser Arbeit bereiteten Überblick über das rechtliche Rahmenwerk des Zugangs zur Medizin als Menschenrecht, beschäftigt sich die vorliegende Dissertation auch mit der Frage, wer als Adressat von Menschenrechten überhaupt in Betracht kommt. In diesem Zusammenhang wird insbesondere auch der Frage nachgegegangen, inwiefern Menschenrechte im Allgemeinen und das Menschenrecht des Zugangs zur Medizin im Speziellen neben Staaten auch für die WTO und für pharmazeutische Unternehmen bindend sind. Hauptaugenmerk liegt dabei auf dem Aspekt der “Corporate social responsibility“ (zu deutsch: Unternehmerische Gesellschaftsverantwortung), der in

den letzten Jahren immer mehr an Bedeutung gewann. Im Rahmen dieses Kapitels werden auch die einzelnen Umsetzungskonzepte kritisch analysiert. Zusammenfassend kann festgehalten werden, dass das Konzept der unternehmerischen Gesellschaftsverantwortung noch nicht ausgereift ist und zum gegenwärtigen Zeitpunkt noch zahlreiche Defizite zu beobachten sind. Insbesondere basiert das gegenwärtige Modell ausschließlich auf dem freiwilligen Beitrag des einzelnen Unternehmens zu einer nachhaltigeren Entwicklung. Bezogen auf das Thema meiner Dissertation müssten demnach pharmazeutische Unternehmen dazu gebracht werden, freiwillig die Preise ihrer Medikamente im Sinne eines unternehmerischen verantwortlichen Handelns zu senken, um den Zugang zu Medikamenten zu gewährleisten. Im Zusammenhang mit den Unternehmensmotiven ist auch problematisch, dass viele Unternehmen nach wie vor “Corporate Social Responsibility“ nur aus ökonomischen Gründen betreiben und dabei überwiegend daran interessiert sind, ihr eigenes Image nach außen hin zu verbessern.

Im dritten Teil meiner Arbeit beschäftige ich mich ausführlich mit dem Konflikt zwischen patentrechtlichen Obligationen unter dem TRIPS-Abkommen und dem Zugang zum Gesundheitssystem als Menschenrecht. In diesem Zusammenhang setze ich mich auch mit der Frage nach einer Hierarchie im internationalen Recht auseinander, wobei hierbei zwischen einer normativen und einer faktischen Hierarchie strikt unterschieden werden muss. Thematische Abfolge ist sodann die Auseinandersetzung mit der Rolle der Menschenrechte innerhalb des WTO-Regimes, wobei die Differenzierung zwischen dem Zuständigkeitsbereich der WTO auf der einen Seite und dem anwendbaren Recht auf der anderen Seite eine wesentliche Rolle spielt. Anschließend werden die jüngsten Entwicklungen der WTO in den vergangenen Jahren samt entsprechendem Einfluss auf den Zugang zur Medizin als Menschenrecht analysiert. Das letzte Kapitel wird den unterschiedlichen Ansätzen zur Lösung dieses Konflikts gewidmet, wobei im Mittelpunkt sämtlicher Lösungskonzepte immer die Notwendigkeit steht, den Menschenrechten einen höheren Status innerhalb des WTO-Systems einzuräumen.

10. Curriculum vitae

Name:	Mag. Carina Steindl
Day of Birth:	11.01.1986
Citizenship:	Austrian

Bar exam and Employment in the law office:

11 and 12/2013	Passing the bar exam with „Sehr Gut“
04/2011 – today	Employment at the law firm Wess Kux Kispert, 1010 Wien; Fields of activity: Law of damages and warranty rights, family law, traffic law, criminal law
02/2011 – 03/2011	Part-time work at the law firm Wess Kux Kispert, 1010 Wien

Court-year:

12/2010 – 03/2011	Landesgericht für Zivilrechtssachen, civil law
10/2010 – 11/2010	Bezirksgericht Fünfhaus, civil law
07/2010 – 9/2010	Bezirksgericht Fünfhaus, criminal law

Employment history and internships:

03/2010 – 06/2010	Study nurse at the University of Vienna
07/2009 – 08/2009	Internship at the law firm Brandl & Talos Rechtsanwälte GmbH
07/2008 – 08/2008 & 10/2008-02/2009	Internship and afterwards part-time work at the law firm Dorda Brugger Jordis
07/2007 – 08/2007	WienXtra, summer internship, tasks: Eventorganisation Wiener Ferienspiel
09/2005 – 08/2008	Peek & Cloppenburg KG, part-time work, tasks: sales in the menswear department

Studies

12/2010 - today	Enrollment doctorate studies, University of Vienna
04/2010	Master of Law, University of Vienna
01/2009 – 06/2009	Semester abroad in Finland, Turku
06/2008	Meritscholarship University of Vienna aus den Mitteln der Stiftungen und Sondervermögen
02/2008	Merit scholarship University of Vienna nach dem StudFG
03/2005	Enrollment for studies of Law, University of Vienna
10/2004 – 02/2005	1 semester medical studies

Additional skills

Computer literacy	MS-Word, MS-Excel, Power Point
Language skills	German (mother tongue), English (very good), French (good)