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Pharmaceutical Patents, Right to Health and Access to Essential Medicines: A Human Rights Critique

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Summary

(Keywords: pharmaceutical patents, TRIPS, right to health, access to essential medicines, developing countries, neglected diseases, counterfeit drugs, compulsory licences, generic medicines, Health Impact Fund)

Until recently, the areas of patent law and human rights law were treated separately. The tensions between pharmaceutical patents and the human right to health could be felt already in the 1980s, when the HIV/AIDS pandemic broke out and the pharmaceutical company that discovered a drug which could be used to treat this disease decided to patent it and set the price so high, that it was impossible for most people living in poor countries, where the disease was most prevalent, to access them. The conflict intensified when 40 pharmaceutical companies decided to sue South Africa for enacting a law improving access to medicines of its citizens, claiming that this was in conflict with the TRIPS Agreement. The trial was a complete disaster for the pharmaceutical companies, which decided to withdraw the claim. However, from that moment on, the international community became aware of the conflict between pharmaceutical patents and the human right to health.

The TRIPS Agreement represents the biggest victory of pharmaceutical companies, since it obliges all Member States to provide patent protection for inventions belonging to all fields of technology, including pharmaceuticals, for a period of 20 years. Before TRIPS, States were free to choose whether they would provide patent protection for pharmaceutical products. However, TRIPS also provides for a few flexibilities that are of value for developing countries, such as compulsory licences and other exceptions to the exclusive rights conferred to the patent owner. The negotiations on the barriers to access to medicines caused by the Agreement resulted in the adoption of the Doha Declaration on TRIPS and Public Health and subsequent decisions on the so-called 'Paragraph 6' issue. However, apart from the price-setting of patented medicines, the pharmaceutical industry is in the position to impact people's enjoyment of the right to health through deciding on the direction of research and development of drugs. For those diseases that affect mostly the developing countries, the industry does not feel the need to develop new drugs, since it cannot recoup what it had invested into their development, nor gain profit from the sales of the medicines in these markets. This leads to the so-called '90/10 gap' and the existence of neglected diseases.

This thesis starts with introducing the reader to the law on patents, by addressing the general characteristics of patents, while simultaneously trying to set its focus on the peculiarities of pharmaceutical patents. It presents the relevant international and EU documents on this issue. It then continues with the introduction of the right to health and the right to access to essential medicines. It reflects on the existing legislation on the right to health and presents all its implications and obligations of States stemming from it. Moreover, it establishes the right to access to medicines as a human right, which could be viewed as both being an indispensable part of the right to health, or arguably, as an independent human right, which is paving its way to even becoming a part of customary international law.

The subsequent Chapters deal with the main subject of the thesis. Chapter 4 addresses the conflict itself and shows all the ways in which patents affect the human right to health and access to essential medicines. It presents the arguments of both the human rights proponents and those of the industry, in order to give an overall, objective picture of the conflict. It deals with the issues of neglected diseases, counterfeit drugs, and the particular situation in developing countries. The last Chapter gives an overview of existing and possible solutions to this conflict, including compulsory licences, other exceptions to the exclusive rights conferred to the patent owner, differential pricing schemes, generic competition and the Health Impact Fund. It also reflects upon the corporate social responsibility of pharmaceutical companies and good practices shown by numerous stakeholders.

Preface

During the final year of my Bachelor Studies at Union University Faculty of Law in Belgrade, I started thinking of applying for a Master Programme that would combine two areas of law that interest me the most, human rights and intellectual property. Lund University offered just what I was looking for. The topic of the conflict between pharmaceutical patents and the right to health and access to essential medicines have been my main focus from the beginning of the Programme, as it perfectly reflects the interdependence of intellectual property law and human rights. The thesis-writing journey has been very challenging, yet infinitely interesting to me, and I sincerely believe I managed to present this conflict in the appropriate way for the readers from all branches of law, as well as from other educational backgrounds. Knowing that this topic is of interest to many people and expecting further developments in this area would make me feel like I have achieved my goal.

First and foremost, I am very grateful to my supervisor, Peter Gottschalk, who guided me throughout the writing of the thesis and provided me with extremely valuable comments on my work. Without his input, this thesis would not be complete. I would also like to express my gratitude to the Swedish Institute for providing me with the full study SI Scholarship for Eastern Europe during these two years at Lund University. Without both financial, and the selfless support from its staff, especially Rita Wikander and Johanna Jeppsson, I would not be able to achieve this.

Furthermore, I would like to thank my professors from Union University Faculty of Law in Belgrade for helping me develop as an intellectual and professional and the one who seeks greatness in everything. A special thank you goes to the late professor dr. h.c. mult. Vojin Dimitrijević and professors Aleksandra Čavoški, Tatjana Papić and Marko Milanović, for being my role models and my true academic inspiration.

Last, but not least, I would like to thank my friends and family for their selfless support and patience. They have been there for me whenever I was in doubt of my writing and persuaded me to use all of my strength and energy in order to write this thesis. A special thank you goes to my mother, without whose support, love and belief in me, I would not be who I am today. Moreover, I would like to thank my partner, who has patiently waited two years for me to finish my Master Studies and with whose love, support and strength I managed to face and overcome many different challenges. Furthermore, I would like to thank my father, stepfather, stepmother and grandparents for their indispensable roles in my upbringing. And finally special thanks to all of my friends, especially Željko, Branko, Irma, Andrea, Jelena, Ana, Deana, Slavica, Amalia, Nazlı, Yasemin, Luis, Lloyd, Dimas and my classmates, who had made my life richer and the time spent in Lund a great one, either by being here or coming to visit me. Since it is not possible to thank everyone, I would like to extend my gratitude to all who supported me, in one way or the other, in the course of my studies at Lund University.

Abbreviations

AJIL	American Journal of International Law
AZT	Azidothymidine/zidovudine
BIRPI	Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle (United International Bureau for the Protection of Intellectual Property)
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CIPR	UK Commission on Intellectual Property Rights
CommHR	United Nations Commission on Human Rights
Cong. Rec.	Congressional Record
CPTech	Consumer Project on Technology
CSR	Corporate Social Responsibility
CUP	Cambridge University Press
DP	Differential Pricing
DSB	Dispute Settlement Body
ECJ	European Court of Justice
EIPR	European Intellectual Property Review
EJHL	European Journal of Health Law
Emory Int'l L. Rev	Emory International Law Review
EPC	European Patent Convention
EPO	European Patent Office
ESCR	Economic, Social and Cultural Right
EU	European Union
FTA	Free-Trade Agreement
GC	General Comment

GSK	GlaxoSmithKline
HAI	Health Action International
Health Care Manag. Sci.	Health Care Management Science
HEPL	Health Economics, Policy and Law
HIF	Health Impact Fund
HIV/AIDS	Human immunodeficiency virus infection/acquired immunodeficiency syndrome
HRQ	Human Rights Quarterly
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICTSD	International Centre for Trade and Sustainable Development
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IJHR	International Journal of Human Rights
ILM	International Legal Materials
IP	Intellectual Property
IPR	Intellectual Property Right
LDC	Least Developed Country
Liv. L. Rev.	Liverpool Law Review
MDG	Millennium Development Goals
Metaphil.	Metaphilosophy
Mich. L. Rev.	Michigan Law Review
Minn. J. Global Trade	Minnesota Journal of Global Trade
MSF	Médecins Sans Frontières
NGO	Non-Governmental Organization
Neth. Q. Hum. Rts.	Netherlands Quarterly of Human Rights
OHCHR	Office of the United Nations High Commissioner for Human Rights

OJ	Official Journal of European Union
OUP	Oxford University Press
PPP	Public-Private Partnership
R&D	Research and Development
SA	South Africa
Sub-CommHR	UN Sub-Commission on Human Rights
TAC	Treatment Action Campaign
TRIPS	Agreement on Trade Related Aspects of Intellectual Property Rights
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
UN	United Nations
UNGA	United Nations General Assembly
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNICEF	United Nations Children's Fund
UNTS	United Nations Treaty Series
US	United States
USAID	United States Agency for International Development
UST	United States Treaties and Other International Agreements
UDHR	Universal Declaration on Human Rights
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1. Introduction

1.1. Background of the topic

The conflict between pharmaceutical patents and access to essential medicines was in the beginning ignored by the public, but started to receive global attention in the late 1990s, in the midst of the trial between the South African (SA) Government and several multinational pharmaceutical companies regarding the newly enacted SA Medicines and Related Substances Control Amendment Act.¹ From this moment on, it became a very important international topic, addressed by numerous international organizations, non-governmental organizations (NGOs) as well as States and scholars.² Although all of these actors recognize the urgency and necessity of solving this conflict, there is still no consensus on how it should be resolved, and it unfortunately does not look like any solution will be achieved in the near future.

The background of the conflict is as follows. Patents for pharmaceutical products were not introduced in most countries until the second half of the 20th century³, mainly because of the fear of how they might affect public health.⁴ However, even before the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)⁵ came into force, patent protection for pharmaceuticals was introduced in the developed countries⁶ and TRIPS only strengthened this protection. The pharmaceutical industry was content with the provisions of this Agreement, unlike the developing countries and NGOs, which stressed the harmful effect it has on the protection of public health and access to essential medicines in the less developed parts of the world. These disparities in perceptions of the industry on one side, and developing countries and NGOs on the other, will be addressed throughout the thesis.

When the HIV/AIDS pandemic broke out in the 1980s, the world was faced with the devastating consequences caused by the lack of medicines for treatment of the then unknown disease. Everything was put into research and development (R&D) for finding a cure for this disease.⁷ When a compound that showed activity against the HIV virus was finally discovered and developed by researchers in the *Institute Pasteur* in 1985, a drug called AZT (azidothymidine or zidovudine) became the first, and for a long period of time, the only treatment for HIV/AIDS.⁸ This, of course, led Burroughs Wellcome (now GlaxoSmithKline (GSK)),⁹ a pharmaceutical company that discovered the compound, to file for patent protection of the medicine and subsequently set the price of one year's necessary dosage at \$10,000 per patient. This inevitably caused disapproval from NGOs and activists groups which called upon the patent holder to lower the price. Even though the price was cut by 20 percent in 1987, the company refused to lower it

¹ H. Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (2008) OUP, pp. 12-15; V. Muzaka, *The Politics of Intellectual Property Law and Access to Medicines* (2011) International Political Economy Series, Palgrave Macmillan, p. 76-7; *Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others* (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241 (25 February 2000) [PMA case].

² R. S. Park, 'The International Drug Industry: What the Future Holds for South Africa's HIV/AIDS Patients' (2002) 11 Minn. J. Global Trade Vol. 11 at 125, pp. 138-9; Hestermeyer (n1), p. 14.

³ Hestermeyer (n1), p. 29.

⁴ Ibid, p. 28.

⁵ WTO, Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 UNTS 299, 33 ILM 1197 (1994) [TRIPS Agreement].

⁶ Hestermeyer (n1), p. 29.

⁷ See Ibid, pp. 1-4.

⁸ Ibid, p. 4.

⁹ <http://www.gsk.com/about-us/our-history.html> (accessed 10 February 2013).

further, justifying the price by the costs of the R&D necessary for its development. The HIV/AIDS pandemic is not the only example of pharmaceutical patents clashing with the right to access to medicines, but it is the first and the most widespread one.¹⁰ Other such instances are addressed in Chapter 4. It should be noted, however, that today there exist three other anti-retroviral (ARV) drugs that are approved in the United States (US), and the World Health Organization (WHO) now recommends a combination of several drugs for the treatment of HIV/AIDS.¹¹ However, as noted by Hestermeyer, who significantly influenced the writing of this thesis, ‘the availability of treatment does not imply its accessibility’.¹²

Although one cannot, and should not, overlook the positive impact patents have on R&D for new medicines, the stringent patent protection of pharmaceuticals gives rise to several serious problems. The first of these is the effect it has on the pricing of these products and consequently their availability and accessibility. A further problem surrounds the issue of neglected diseases, which arises due to the lack of interest of companies to invest into R&D for drugs needed to treat these diseases. Moreover, access to essential medicines was recognized as the ‘indispensable part of the right to the highest attainable standard of health.’¹³ This makes the position of pharmaceutical industry, which is pushing for even stronger patent protection, a very difficult one to sustain. Consequently, the conflict between pharmaceutical patents and the right to health is a deep one, with both sides of the conflict having legitimate interests which they intend to pursue. The only way for this conflict to be resolved is through cooperation and mutual understanding between these two actors.

1.2. Purpose

It is said that ‘no other issue so clearly epitomizes the clash between human rights and intellectual property as access to patented medicines’, since ‘the idea of withholding lifesaving drugs from individuals suffering from fatal or debilitating diseases when the means exist to distribute those drugs cheaply and effectively is anathema to all notions of morality’.¹⁴ This is the reason why I chose this topic.

The purpose of the thesis is to give a human rights critique on the conflict between pharmaceutical patents, the right to health and the right to access to essential medicines. The goal is to analyse the existing law on pharmaceutical patents through the perspective of human rights, show how pharmaceutical patents affect the right to health and access to medicines, and provide the reader with a human rights approach to this subject. The main question is how the balance can be restored between these two areas of law. Moreover, there consequently arises the question as to whether a change in legislation is needed, and what it should entail, so that both the pharmaceutical innovation and access to medicines are maximized.¹⁵

This thesis attempts to show both sides of the pharmaceutical patents coin: namely to present the arguments of both the pharmaceutical industry and those in need of accessible essential medicines. It provides the reader with a critical assessment of the current state of patent legislation, as well as the human rights law, in order to point out the loopholes in both systems. Deriving from this analysis, it tries to provide a number of possible solutions to this problem. It

¹⁰ Hestermeyer (n1), p. 15.

¹¹ Ibid, p. 8.

¹² Ibid, p. 28.

¹³ P. Hunt and R. Khosla, ‘The Human Right to Medicines’ (2008) SUR– IJHR, Year 5, No. 8 at 99, p. 100.

¹⁴ L. R. Helfer and G. W. Austin, *Human rights and intellectual property: mapping the global interface* (2011) CUP, p. 90.

¹⁵ See Ibid, p. 91.

should be noted, however, that it is upon the States and international organizations to reach an understanding with the pharmaceutical industry and finally find the balance between the needs of all the stakeholders. Hopefully, we will not need to wait too long for this to happen.

1.3. Delimitation

Due to the breadth of the topic, which can include the assessment of numerous human rights as well as intellectual property rights (IPRs), it is very important to determine the limits of this thesis. Thus, the thesis will only concentrate on the human right to health and patent law, more specifically, the law on pharmaceutical patents, and the relation between these two areas of law. Consequently, it will not engage in the evaluation of the relation between patent law and the human right to life nor the right to benefit from the scientific progress and its applications. It should also be noted that I will not engage in the assessment of norm conflict in international law as such, since this is beyond the scope of the thesis. Moreover, this thesis will not deal with the bilateral trade agreements concerning pharmaceutical patents and the ‘TRIPS-plus’ free trade agreements (FTAs), nor the human rights obligations and responsibilities of pharmaceutical companies (although it may touch upon these topics as a matter of reference). Even though these areas are closely related to the subject of this thesis, much more time and further resources would be needed to cover all of them in a manner suitable for a master thesis. Furthermore, the barriers in relation to access to essential medicines will be presented from the perspective of developing and the least-developed countries (LDCs), meaning that the problems faced by certain groups of people in the developed countries will not be covered. Finally, since this topic represents a matter to which mostly universal norms apply, in contrast to regional ones, the regional instruments will only be referred to when they need to serve as an example of good practice or as a point of reference.

1.4. Methodology and material

This thesis combines the traditional legal method of interpretation with a sociological and human rights approach. It presents the patent law as it is today and examines its impact on the society and the human rights law and vice versa. It uses the so-called ‘human rights critique’ of the current patent legislation. This is because the human rights scholars and activist have, from its beginnings, taken an opposing approach towards the intellectual property (IP) protection of essential medicines, especially the extensive patent protection provided under the TRIPS, due to its negative impact on the right to health. The human rights approach and critique of the WTO rules and IP law has been said to be the most important when it comes to assessing the conflict between human rights law and trade rules.¹⁶ This is so because the human rights framework ‘shifts the focus’ of the analysis of the impact of IPRs over the human right to health, by reframing the ‘existing legal discourses that privilege legal rules protecting intellectual property over those protecting individual rights and social values’, by providing ‘a mechanism to hold governments accountable for providing at least minimal levels of health care’, and by emphasizing ‘the need to restructure incentives for medical research and innovation toward the treatment of neglected diseases and the health needs of the poor’.¹⁷ Through this method, therefore, I will show the reader how these two areas of law are intertwined and interrelated, and how one affects the other.

¹⁶ Hestermeyer (n1), p. 182.

¹⁷ Helfer and Austin (n14), p. 144.

Throughout the history of the human rights law, scholars have made a distinction between civil and political rights on one side, and economic, social and cultural rights (ESCRs) on the other, which resulted in the drafting of two separate Covenants, which each dealt with only one set of rights.¹⁸ Although the Vienna Declaration adopted in 1993 clearly stated that ‘[a]ll human rights are universal, indivisible and interdependent and interrelated’ and that ‘[t]he international community must treat human rights globally in a fair and equal manner, on the same footing, and with the same emphasis’,¹⁹ there has always been an evident difference in the treatment of these two sets of rights, in a way that ESCRs have until recently been neglected.²⁰ The most evident instances of the neglect of human rights in general can be seen in the ‘predominance of market discipline’ over human rights in a way that ‘human life [and other human rights] has value as far as it contributes to [profit]’.²¹ Evans calls this ‘the Dutch auction’ of human rights, meaning that less developed countries are willing to sacrifice the social and economic rights of their citizens in order to attract foreign investments.²² Moreover, this corporate pressure is evident in major international organizations such as the International Chamber of Commerce and the World Trade Organization (WTO), where human rights activists are considered as a ‘threat to the further expansion of corporate activities’ or simply exempt from major negotiations in these organizations.²³

For these reasons, this thesis will attempt to provide a human rights approach to the subject of patent law and the human right to health in order to overcome the attempts of the business world to marginalize human rights in their pursuit of profit. It is true that human rights vocabulary and aspirations may seem too utopian and unrealistic. However, this thesis will attempt to stay as realistic as possible, taking into account both the interests of the people in need of essential medicines and that of the pharmaceutical companies. In doing so, I will present and analyse the instruments dealing with patents as well as human rights, and the commentaries of relevant international bodies and distinguished scholars. This thesis is influenced by the works of some of the most prominent names in this area, such as Thomas Pogge, Herman Hestermeyer, Paul Hunt, Ellen 't Hoen and Frederic Abbott, as well as the reports and official documents of highly respected NGOs and international organizations, and it will try to build on their indispensable findings and comments.

Of course, the discourse in this thesis shall strive to avoid the unintentional victimization of people in developing countries or the portrayal of the pharmaceutical industry as the ‘villain’ solely responsible for the current situation regarding access to essential medicines. However, although there are other actors responsible, the biggest reason why people in developing countries lack access to essential medicines, in my opinion, is the fact that pharmaceutical companies are unwilling to consider lowering the prices of medicines in certain countries, or at least lowering the patent protection of the medicines in favour of companies manufacturing generic drugs and medicines so that they can produce the medicines at lower costs. Finding a balance is easier said than done, but a constructive critique cannot do any harm.

¹⁸ Hestermeyer (n1), pp. 81-3.

¹⁹ UNGA, ‘Vienna Declaration and Programme of Action’, World Conference on Human Rights, A/CONF.157/23, 12 July 1993, para. 5.

²⁰ Hestermeyer (n1), p. 83.

²¹ T. Evans, ‘International Human Rights Law as Power/Knowledge’ (2005) 27 HRQ at 1046-1068, p. 1057.

²² Ibid, p. 1059.

²³ Ibid, p. 1064.

1.5. Outline

This thesis has the following structure. The first Chapter deals with the law of patents as it exists today, concentrating primarily on the provisions relevant to pharmaceutical patents and the situation in developing countries. It presents the main characteristics of patents in general, peculiarities of pharmaceutical patents and the relevant international documents, while briefly touching upon regional ones as well. Finally, it analyses whether IPRs can be viewed as human rights in the context of Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)²⁴ and Article 27 of the Universal Declaration of Human Rights (UDHR).²⁵ This Chapter may appear overly technical, but in order to understand how pharmaceutical patents affect the human right to health, one needs to be aware of the law and rules surrounding patents in general, what pharmaceutical patents imply and what are the current discussions and issues surrounding them. Only then can one engage in constructive discussion as to their impact on the right to health, which is presented in the subsequent Chapter.

The third Chapter proceeds with the assessment of the right to health and the right to access to essential medicines, trying to establish its place in the area of international human rights law. In the course of doing this, it analyses the relevant human rights instruments, belonging to both the soft and hard baskets of law, as well as findings of esteemed scholars, in order to present the right to access to essential medicines as a human right. It also presents all the relevant aspects of the human right to health, the responsibilities of States in relation to this right, as well as the particular problems that developing countries are facing in relation to access to essential medicines. Together with the previous Chapter, it serves as a solid introduction for the main topic of the thesis, the conflict between these two areas of law.

Following this, the fourth Chapter deals with the impact pharmaceutical patents have on the right to health. It engages in the problem of compulsory licences in developing countries, neglected diseases and counterfeited drugs. It tries to present the arguments of the both sides to the conflict. The understanding of the needs of all stakeholders is necessary because it makes the path to finding a balance smoother.

The final Chapter presents a few existing and possible solutions that show some prospect of resolving this complicated conflict in order to find a balance between the interests of all actors involved. It reflects upon the corporate social responsibility (CSR) of pharmaceutical companies and gives an overview of good practices of both the industry and the NGO sector, as well as a few examples of public-private partnerships (PPPs). This Chapter is then followed by concluding remarks on the whole thesis.

²⁴ UN, International Covenant on Economic, Social and Cultural Rights, 16 December 1966, UNTS vol. 993, p. 3 [ICESCR], Art. 15(1) (c).

²⁵ UNGA, Universal Declaration of Human Rights, 217 A (III), 10 December 1948 [UDHR], Art. 27(2).

2. Pharmaceutical patents

In order to fully engage in the topic of this thesis one first needs to learn about the basic rules and characteristics of patent law and the peculiarities of pharmaceutical patents.

2.1 General characteristics of patents

A patent can be defined as ‘a limited monopoly that is granted in return for the disclosure of technical information’.²⁶ A more detailed definition would be that it is an ‘exclusive right awarded to an inventor to prevent others from making, selling, distributing, importing or using the invention, without licence or authorization’²⁷ for a period of 20 years after the registration of the patent. Three types of patents can be identified, namely, product patents (patents on the product itself), process patents (which protect the process used to produce a product) and the so-called ‘new use patents’ (which protect a particular use of a patent).²⁸

Patent law is a national law.²⁹ Throughout their long history, patents were granted as a ‘means to promote the industrial advancement of the nation’.³⁰ Today, the primary and most emphasized justification for patents is that they represent incentives for future production of new inventions and for the disclosure of useful information, which would have remained a secret without patent protection.³¹ In other words, ‘[t]he patent system is based on providing incentive to the inventor by granting restricted monopoly rights on one hand and by encouraging dissemination of knowledge on the other through the disclosure of the invention’.³² The proponents of patent protection claim that this form of protection is in fact a ‘bargain struck by society on the premise that, in its absence, there would be insufficient invention and innovation’.³³

2.1.1. Patentability requirements

In order to be granted a patent for an invention, the inventor needs to prove that his invention, belonging to any field of technology, is new, involves an inventive step and is susceptible of industrial application.³⁴ The assessment of these three conditions is necessary since an invention that fulfils them has to be differentiated from a mere discovery, a natural process or a minor modification of an already existing product. An additional element in the assessment of the patent application that may be said to exist is the disclosure of the invention. Article 29(1) of the TRIPS provides that the future patent holder should ‘disclose the invention in a manner

²⁶ L. Bentley and B. Sherman, *Intellectual Property Law* (3rd Edition, 2009), OUP, p. 335.

²⁷ CIPIH, ‘Public Health, Innovation and Intellectual Property Rights’ (2006) WHO, available at: <http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf> [CIPIH Report 2006], p. 194; *See also* Hestermeyer (n1), p. 19.

²⁸ Hestermeyer (n1), p. 64; TRIPS Agreement, Art. 27(1).

²⁹ Hestermeyer (n1), p. 19.

³⁰ *Ibid*, p. 21.

³¹ Bentley and Sherman (n26), pp. 339-40.

³² Carlos M. Correa (ed.), ‘A Guide to Pharmaceutical Patents, Vol. I’ (2008) available at: http://www.southcentre.org/index.php?option=com_content&task=view&id=678&Itemid=1 [Guide to Pharmaceutical Patents], p. 4.

³³ CIPR, Final Report of the Commission of Intellectual Property Rights: ‘Integrating Intellectual Property Rights and Development Policy’ (2002) CIPR [CIPR Report 2002], p. 14.

³⁴ TRIPS Agreement, Art. 27(1); *See also* Carlos M. Correa, ICTSD, WHO, UNCTAD ‘Guidelines for the examination of pharmaceutical patents: developing a public health perspective – A Working Paper’ (2006) available at: http://ictsd.net/downloads/2008/06/correa_patentability20guidelines.pdf [Guidelines 2006], pp. 3-4.

sufficiently clear and complete for the invention to be carried out by a person skilled in the art' and may be asked 'to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where the priority is claimed, at the priority date of application'.

This element is very important for the generic industry since it ensures that all the necessary information is disclosed so that they can reproduce the pharmaceutical product under a compulsory license or after the patent term has expired.³⁵ Hestermeyer argues that this requirement is one of the fundamental principles of patent law since 'patents can fulfill their social purpose only if Members ensure that the disclosure is really enabling and do not grant patents where this is not the case'.³⁶

What is very important in relation to developing countries' regulation of these requirements is the flexibility provided by the TRIPS, which stipulates that WTO Members are free to define the patentability criteria as referred to under the Agreement in accordance with their national priorities.³⁷ The way these criteria are assessed is relevant for public health purposes and access to medicines '[g]iven the substantial effects that patents can have on competition and, hence, prices of medicines'.³⁸

2.1.1.1 Novelty

The first patentability requirement, the requirement of novelty, forms 'an essential part of the patent system'.³⁹ For this requirement to be fulfilled, the invention has to be 'new before the date of filing of a patent application',⁴⁰ meaning that it has not been previously disclosed to the public in any form or in any other way available as state of the prior art.⁴¹ The state of the art comprises 'everything made available to the public by means of a written or oral description, by use or in any other way before the date of filing of the application',⁴² meaning that an invention will be considered as a state of the art if it is available to the public and can be analysed and reproduced by a person skilled in the art.⁴³ A person skilled in the art is defined as 'a skilled practitioner in the relevant field, who is possessed of average knowledge and ability and is aware of what was common general knowledge in the art at the relevant date'.⁴⁴

A distinction should be made in relation to the absolute notion of novelty, i.e. inventions that are universally new in the whole world, compared to the relative novelty, where the invention is new within a restricted area.⁴⁵ This distinction is significant for pharmaceutical patents from the perspective of public health and access to medicines, since if a State applies the relative concept of novelty, and not the absolute, it will not be in a position to decline patent

³⁵ Guidelines 2006 (n34), p. 4.

³⁶ Hestermeyer (n1), p. 67.

³⁷ Guidelines 2006 (n34), pp. vii-viii.

³⁸ Ibid, p. 1.

³⁹ Guide to Pharmaceutical Patents (n32), p. 1.

⁴⁰ Ibid, p. 2.

⁴¹ Ibid; EPO, 'Guidelines for Examination in the European Patent Office' (2010) available at: [http://documents.epo.org/projects/babylon/eponet.nsf/0/7ffc755ad943703dc12576f00054cacc/\\$FILE/guidelines_2010_complete_en.pdf](http://documents.epo.org/projects/babylon/eponet.nsf/0/7ffc755ad943703dc12576f00054cacc/$FILE/guidelines_2010_complete_en.pdf) [EPO Guidelines 2010], Part C-Chapter IV-27, 9.1.

⁴² Convention on the Grant of European Patents (European Patent Convention), 5 October 1973, available at: <http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ma1.html> [EPC 1973], Art. 54(2).

⁴³ Guide to Pharmaceutical Patents (n32), p. 8.

⁴⁴ EPO Guidelines 2010 (n41), Part C - Chapter IV-33, 11.3.

⁴⁵ Guide to Pharmaceutical Patents (n32), pp. 2-3; Guidelines 2006 (n34), p. 3.

applications for inventions that already exist in the public domain.⁴⁶ In applying the absolute standard, the developing countries are in a position to ‘consider all types of acts, whether in written form or not, that may destroy [the novelty of an invention]’.⁴⁷

2.1.1.2 Inventive step

The issue of novelty in patents is closely connected to the requirement of the ‘inventive step’, which is substantial in relation to pharmaceutical patents⁴⁸, and which is assessed only after the novelty requirement is fulfilled. This second requirement is attained if ‘having regard to the state of the art, [the invention] is not obvious to a person skilled in the art’.⁴⁹ It stems from this definition that the crucial aspect of the requirement is proving the non-obviousness of the invention. The TRIPS even goes so far as to equate these terms in a footnote to its Article 27(1). This term means that the invention should ‘go beyond the normal progress of technology’ and not merely follow ‘plainly or logically from the prior art’.⁵⁰

In the pharmaceutical industry, a high threshold for the inventive step is recommended, since it creates strong patents and precludes the competition from infringing them, but also prevents the inventor from making minor changes to the invention and thereby prolonging the patent duration (which leads to gaining profit from the so-called ‘evergreening’ patents).⁵¹ This approach requires the persons skilled in the art to be ‘particularly strict when examining the inventive step’ and to apply their specialized knowledge combined with a degree of imagination and intuition.⁵² However, developing countries are in an undesirable position, since both the low and the high threshold of the inventive step can lead to unwanted consequences. This is so for two reasons. Firstly, a high inventive step requirement would mean that the incremental innovations (modifications and improvements of existing drugs with slightly different chemical consistency)⁵³ will not be protected, and the pharmaceutical industry of developing countries relies mostly on these products.⁵⁴ On the other hand, if they opt for a low inventive step approach, the multinational pharmaceutical companies will obtain patents on both the existing drugs and their modifications, since they are in a better financial position.⁵⁵ Therefore, it was rightly pointed out by Shabalala that ‘[d]eveloping countries will need the flexibility to alter the standard to fit the changing needs of industrial and innovation policy and should choose legislation, regulations and guidelines that will institutionalize and operationalize that flexibility’.⁵⁶

⁴⁶ Guide to Pharmaceutical Patents (n32), p. 28; I. Lasic, ‘Pharmaceutical patents: A General Overview and Current Issues’ (2012) unpublished exam paper in the course JAMR29 Introduction to European Intellectual Property Law, Master Programme in International Human Rights Law at Lund University [Pharmaceutical Patents Paper], p. 6.

⁴⁷ Guide to Pharmaceutical Patents (n32), p. 38.

⁴⁸ Ibid, p. 28.

⁴⁹ EPC 1973, Art. 56; EPO Guidelines 2010 (n41), Part C- Chapter IV-33, 11.1; Guide to Pharmaceutical Patents (n32), p. 39.

⁵⁰ EPO Guidelines 2010 (n41), Part C- Chapter IV-33, 11.4.

⁵¹ Guide to Pharmaceutical Patents (n32), p. 46.

⁵² Guidelines 2006 (n34), p. 4.

⁵³ CIPIH Report 2006 (n27), p. 193.

⁵⁴ Guide to Pharmaceutical Patents (n32), pp. 46-7.

⁵⁵ Ibid, p. 47.

⁵⁶ Ibid.

2.1.1.3 Industrial applicability

The last patentability requirement is that of industrial applicability or usefulness of the invention. The rationale behind this requirement is that ‘patent protection should not be available for abstract ideas or purely intellectual creations that cannot be put to any use.’⁵⁷ The term ‘industrial’ is used in a wide sense, and its interpretation varies from one country to another.⁵⁸ Under Article 57 of the European Patent Convention (EPC), for example, ‘an invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry’. Moreover, the TRIPS Agreement, in the already mentioned footnote to Article 27(1) stipulates that the term ‘industrial applicability’ is tantamount to the term ‘useful’.

In the case of developing countries, it is recommended that they adopt a higher threshold of industrial applicability, since this will ensure that dubious inventions, i.e. those with no actual purpose, are not patented.⁵⁹

2.1.2 Peculiarities of pharmaceutical patents

As already stated, patent protection for pharmaceuticals was introduced only recently, in the second half of the 20th century. The pharmaceutical industry needs strong patent protection of its products, since the costs of R&D for their production are very high, and only through patent protection can they encourage inventors to develop new medicines from which the whole society has benefit.⁶⁰ Pharmaceutical patents slightly differ from other kinds of patents, since they need more time to be developed and granted protection.⁶¹ Before a drug can be placed on the market it needs to pass numerous tests in order to be proven safe and effective, and this can take up to 15 years.⁶² During that time, as well as after the patent is granted, if not protected properly, numerous forms of patent infringement can occur.⁶³ Three issues that are of importance for the purposes of the thesis, are the issues of data exclusivity and regulatory data protection, supplementary protection for patented pharmaceutical products and finally, compulsory licensing.

Regulatory data protection, which is also known under the heading ‘data exclusivity’, refers to the period of time during which pharmaceutical companies can deny generic competition to use their clinical data, since they enjoy exclusive proprietary rights over them. This data normally involves information on the safety and efficacy of the medicine, which is important in the process of applying for the authorization to place a generic version of a certain drug on the market.⁶⁴ The TRIPS, in its Article 39 obliges Member States to protect this undisclosed data, ‘the origination of which involves a considerable effort’, against unfair commercial use. Additionally, it provides that ‘Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use’.⁶⁵ Unlike the TRIPS, which does not prescribe the period of time

⁵⁷ Ibid, p. 81; Guidelines 2006 (n34), p. 4.

⁵⁸ Guide to Pharmaceutical Patents (n32), p. 81.

⁵⁹ Ibid, p. 108.

⁶⁰ Carlos M. Correa, ‘Ownership of knowledge- the role of patents in pharmaceutical R&D’ (2004) 82 Bulletin of the WHO at 784-790, p. 785.

⁶¹ Pharmaceutical Patents Paper (n46), p. 1.

⁶² J. Killick, A. Schulz and A. Dawes, The Stockholm Network Experts’ Series on Pharmaceutical Intellectual Property Rights: ‘The special regime of intellectual property for the pharmaceutical industry’ (2008) Stockholm Network, p. 3.

⁶³ Pharmaceutical Patents Paper (n46), p. 1.

⁶⁴ Killick et al. (n62), p. 9.

⁶⁵ TRIPS Agreement, Art. 39(3).

during which the data is to be protected, the European Union (EU) Legislation provides for a '8+2+1' data exclusivity period.⁶⁶ This means that the data will enjoy an eight year period of data exclusivity from the date of the first approval in the EU and an additional two years of market protection during which the data can be used, but the competing generic drug cannot be placed on the market.⁶⁷ These ten years can be extended for maximum of one more year if additional requirements are met.⁶⁸ The data exclusivity regime is crucial to the pharmaceutical companies since it gives them an additional period of protection and incentive for further research, as well as the exclusive sale of their products in the developing countries' market, which would not be possible if generic competition existed. However, this regime has arguably no advantages for the developing countries, since it does not promote R&D there.⁶⁹ These countries rely mostly on generic medicines for the supply of their markets. Therefore, it was suggested that 'developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS'.⁷⁰

The second instrument that is peculiar to pharmaceutical patents, and that is sometimes referred to as the 'special intellectual property right of the pharmaceutical industry',⁷¹ is the Supplementary Protection Certificate (SPC). Since pharmaceutical products can receive marketing approval only after they have undergone a number of tests and trials, pharmaceutical companies are not able to recoup all that they have invested in the R&D process from the sale of the product before the patent protection period expires.⁷² In 1998, a survey of more than 300 pharmaceuticals showed that the effective patent protection of these products in the EU lasts for eight years.⁷³ This is the reason why the industry needed an extension of the protection period, and this was achieved in the EU through the adoption of the SPC Regulation.⁷⁴ This Regulation provides for the grant of a SPC which has the same effect as a patent, but does not extend the duration of the patent term as such. It is a *sui generis* instrument which has the effect of a limited extension of protection.⁷⁵ The period of supplementary protection starts when the patent protection has expired and cannot exceed five years.⁷⁶ Through this instrument, pharmaceutical companies 'can get back' the time they have 'lost' between the lodging of the patent and the gaining of the marketing authorization. However, this system can be easily misused by pharmaceutical companies, as was the case with the AstraZeneca Group (AZ) in relation to an ulcer drug called *Losec*.⁷⁷ The company was brought before the General Court of the EU on two charges. The first charge was for misleading representations made before the patent offices in

⁶⁶ Killick et al. (n62), p. 9; Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency Regulation 726/2004 (OJ L 136/1, 30.04.2004), Art. 14(11); Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ L 136, 30.4.2004, pp. 34-57, amending Article 10 of Directive 2001/83), Art. 1.

⁶⁷ Killick et al. (n62), p. 9; *see also* CIPRH Report 2006 (n27), p. 125.

⁶⁸ Killick et al. (n62), pp. 9-10.

⁶⁹ CIPRH Report 2006 (n27), p. 125; Pharmaceutical Patents Paper (n46), p. 8.

⁷⁰ CIPRH Report 2006 (n27), p. 126.

⁷¹ Killick et al. (n62), p. 5.

⁷² *Ibid.*, pp. 3-5.

⁷³ G. Tritton et al., *Intellectual Property in Europe* (Second Edition, 2002) Sweet and Maxwell, p. 177.

⁷⁴ Council Regulation 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182/1, 02.07.1992).

⁷⁵ Tritton et al. (n73), p. 177.

⁷⁶ Council Regulation 1768/92 (n74), Art. 13.

⁷⁷ *Astra Zeneca v. Commission*, Case T-321/05, Judgement of the General Court, 1 July 2010, ECJ, paras. 1-2.

several European countries. The second charge was for the attempt to deregister the marketing authorisations for *Losec* capsules in Denmark, Norway and Sweden, and withdraw them from their markets, while launching *Losec* MUPS tablets instead.⁷⁸ The Court found that

[p]atent protection is central to the encouragement of innovation in economically viable conditions and it is therefore necessary to recognise a public policy imperative that undertakings should not be unduly deterred from registering patents in the pharmaceutical sector under the SPC scheme.⁷⁹

The Decision of the Court was to fine AZ a total of €60 million for misusing the patent system in order to unlawfully obtain a SPC which was done with the intention to block or delay market entry for generic competitors to *Losec* and keep the price of the drug artificially high.⁸⁰ One of the Commissioners stated that, although she fully supports strong patent protection for new innovative products in order to redeem the R&D investments, it is for the legislator to decide which period of protection is adequate. She also stressed that generic drugs ‘keep costs down’, which is beneficial for both health care systems and patients, and that ‘competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals’.⁸¹ The appeal of AZ before the Court of Justice of the EU was dismissed in December 2012, and the Court upheld the previous decision.⁸²

Thirdly and finally, compulsory licences are an instrument that allows for persons other than the patent owner to exploit the invention without the patent owner’s consent, when he is unable or unwilling to do so.⁸³ The Paris Convention for the Protection of Industrial Property (Paris Convention) first introduced compulsory licenses that could be issued ‘to prevent abuses which may result from the exercise of the exclusive rights conferred by the patent, for example, failure to work’.⁸⁴ The TRIPS also provides for the possibility of issuing these licenses under certain conditions.⁸⁵ They became an issue when they were placed under the scrutiny of the international community at the WTO discussions about access to essential medicines in developing countries,⁸⁶ and the subsequent conference in Doha contributed to further development in this area. This will be discussed in more detail in subsequent sections.

2.2 International and regional (EU) documents

2.2.1 Paris Convention for the Protection of Industrial Property

In its early stages, patent law was limited mostly to a small number of bilateral treaties.⁸⁷ This remained so until a conference held in Paris in 1878 and the adoption of the Paris Convention in 1883, which was last amended in 1979. This Convention was the first multilateral treaty which dealt with all aspects of industrial property.⁸⁸ It provides that industrial property

⁷⁸ Ibid, para. 8.

⁷⁹ Ibid, para. 313.

⁸⁰ Competition: Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs, IP/05/737, Brussels, 15.06.2005, p. 1.

⁸¹ Ibid.

⁸² *Astra Zeneca v. Commission*, Case C-457/10 P, Judgment of the Court (First Chamber), 6 December 2012, ECJ.

⁸³ Bentley and Sherman (n26), p. 578.

⁸⁴ Paris Convention for the Protection of Industrial Property, 21 UST 1583, 828 UNTS 305 [Paris Convention], Art. 5(A(2)).

⁸⁵ TRIPS Agreement, Art. 31.

⁸⁶ Bentley and Sherman (n26), p. 578.

⁸⁷ Hestermeyer (n1), p. 34.

⁸⁸ Paris Convention, Art. 1(2).

shall be understood in the broadest sense, thereby including ‘activities and products which would otherwise run the risk of not being assimilated to those industry proper’.⁸⁹ The Convention establishes the Paris Union for the protection of industrial property, composed of Countries to which the Paris Convention applies. The administrative tasks of the Union are today conducted by the World Intellectual Property Organization (WIPO).⁹⁰

The key principle of the Convention, included already in its original text from 1883, is the principle of national treatment.⁹¹ It provides that a State that is a Member of the Union has to offer the same protection of industrial property to nationals of other Members of the Union as it offers to its own nationals, without discrimination.⁹² The Convention, however, does not include a definition of a patent, and leaves it to each Member to define it in its national legislation.⁹³ With regard to pharmaceutical patents, the most relevant provisions of the Convention are the previously mentioned Article 5(A(2&4)), which deals with compulsory licenses, and Article 10*bis* which provides for the protection against unfair competition.

Article 5(A(2)) establishes that each country has the right to take legislative measures and grant compulsory licenses in order to prevent the patent owner from abusing his or her exclusive rights conferred by the patent, such as failure to work. These abuses include, *inter alia*, refusal of the patent owner to grant a license on reasonable terms, failure to supply the domestic market with sufficient amounts of the patented product or setting unreasonably high prices for the product in question.⁹⁴ It also stipulates that compulsory licenses are non-exclusive and non-transferable in order to prevent misuse of the compulsory license by the grantee of the license.⁹⁵

The original text of the Convention did not include a provision on repression of unfair competition and Article 10*bis* was inserted into the Convention at the Revision Conference held in 1900.⁹⁶ Under this Article, States Members of the Union are obliged to ensure that nationals of other Members are effectively protected against unfair competition. The Article defines unfair competition as ‘any act of competition contrary to honest practices in industrial or commercial matters’.⁹⁷ Paragraph 3 then lists acts which will be considered as unfair competition, and which constitute a minimum which needs to be prescribed in national laws, leaving room for the Members to include other acts which fall into this category.⁹⁸

Even though it was the first multilateral treaty that provided protection for patent rights, developed countries were very sceptical about it, mainly because developing countries did not want to sign the Convention and include the provisions on industrial property protection into their legislation, thereby opening doors for all sorts of patent infringement in their territories.⁹⁹ The other obstacles which developed states pointed out were: the lack of effective enforcement of the obligations incurred by states, the fact that there was no provision on national enforcement of patents, the lack of harmonized rules on the minimum patent term, compulsory licenses and areas

⁸⁹ Paris Convention, Art. 1(3); G. H. C. Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property as Revised in Stockholm in 1967* (1968) BIRPI, p. 25.

⁹⁰ Paris Convention, Art. 1(1); Hestermeyer (n1), p. 35.

⁹¹ Bodenhausen (n89), p. 27; Paris Convention, Art. 2.

⁹² Bentley and Sherman (n26), p. 5.

⁹³ Bodenhausen (n89), p. 21.

⁹⁴ *Ibid.*, p. 71.

⁹⁵ *Ibid.*, p. 73.

⁹⁶ *Ibid.*, p. 142.

⁹⁷ Paris Convention, Art. 10*bis* (1) (2).

⁹⁸ Bodenhausen (n89), pp. 145-6.

⁹⁹ Hestermeyer (n1), pp. 36 and 38.

that could be excluded from patentability.¹⁰⁰ The result of the last critique was that in 1988, 49 member states excluded pharmaceutical patents from patentability, while 10 states excluded pharmaceutical processes.¹⁰¹ These are the main reasons why developed states insisted on a higher patent protection and drafting of a better treaty which would fulfil their expectations. Some States resorted to unilateral pressures towards developing countries in order to achieve this aim.¹⁰² It was not until the end of the Uruguay Rounds in 1994 and the signing of the Final Act of the Uruguay Round¹⁰³ and the Marrakesh Agreement Establishing the WTO (the WTO Agreement)¹⁰⁴ which included a document on the protection of IPRs, that they finally achieved a stronger and harmonized IPR protection.

2.2.2 The TRIPS Agreement

The TRIPS is an annex to the WTO Agreement, which was signed in 1994, and it covers all of the main areas of IPRs¹⁰⁵ and represents ‘theoretically, one form of incentive for innovation in developed and developing countries’.¹⁰⁶ The Agreement provided for the first time a link between IP and trade issues,¹⁰⁷ as well as a multilateral mechanism for prevention and dispute settlement between States Parties. At the same time, it recognized ‘the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations’.¹⁰⁸ It provides for the minimum of IP protection standards that are to be implemented in the laws of the Member States.¹⁰⁹ The object and purpose of the Agreement is enclosed in Articles 7 and 8. Article 7 provides that both the interests of the rights holders and the users of technological knowledge should be taken into account ‘in a manner conducive to social and economic welfare’ and that rights and obligations should be in balance. Hestermeyer argues that ‘[a]ccessibility of medicine is one of the interests of society that have to be brought into balance with the TRIPS’¹¹⁰, and quotes Article 8 in support. Article 8 allows Members to adopt legislative measures for the protection of public health and promotion of socio-economic and technological development, since they may be needed to ‘prevent the abuse of intellectual property rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology’.

The adoption of the TRIPS was of great importance for pharmaceutical patents, mostly because it provided uniformity in legislation in this area. Before its adoption, patent protection for pharmaceuticals was not provided for in more than 50 countries, and the patent duration was much shorter than 20 years.¹¹¹ Some claim that the TRIPS represents ‘a victory for the

¹⁰⁰ Ibid, p. 37.

¹⁰¹ Ibid.

¹⁰² Ibid, pp. 39-40.

¹⁰³ WTO, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Apr. 15, 1994, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 2 (1999) 1867 UNTS 14, 33 ILM 1143 (1994).

¹⁰⁴ WTO Agreement: Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 4 (1999) 1867 UNTS 154, 33 ILM 1144 (1994).

¹⁰⁵ Bentley and Sherman (n26), p. 7.

¹⁰⁶ CIPIH Report 2006 (n27), p. 83.

¹⁰⁷ Guidelines 2006 (n34), p. vii.

¹⁰⁸ TRIPS Agreement, Preamble.

¹⁰⁹ TRIPS Agreement, Art. 1.

¹¹⁰ Hestermeyer (n1), p. 51.

¹¹¹ Guidelines 2006 (n34), p. vii; Hestermeyer (n1), p. 55.

pharmaceutical companies’¹¹², since all States Parties are now obliged to provide patent protection for pharmaceuticals.¹¹³ Article 27 provides that ‘patents shall be available for all inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application’ and Article 28 lists the exclusive rights conferred to the patent owner. Article 30, on the other hand, provides for limited exceptions to these exclusive rights. This Article will be addressed in more detail in the last Chapter.

However, apart from extensive patent protection, TRIPS also provides for some flexibilities, the most important (and most disputed) of which, in relation to public health and access to essential medicines, is compulsory licensing provided for in Article 31.¹¹⁴ This Article sets the rules for the ‘other use’ of a patent without the consent of the right holder, which pertains to compulsory licences. The requirements that need to be met in order for a compulsory licence to be issued are extensive. Firstly, every licence is to be authorized according to the merits of each individual case and it may be permitted only after reasonable effort has been unsuccessfully made to obtain the authorization of the patent owner, except in the case of national emergency or any other extreme urgency, when the right-holder should be notified as soon as possible.¹¹⁵ In each case, an adequate remuneration is to be paid to the right holder.¹¹⁶ Furthermore, the authorization of a licence is limited to the purposes for which it was issued and shall be terminated as soon as the circumstances under which it was granted cease to exist or are unlikely to recur.¹¹⁷ The licence is non-exclusive and non-assignable.¹¹⁸ The most disputed rule set by this Article is provided in Paragraph (f) which stipulates that the compulsory licenses are to be ‘authorised predominantly for the supply of the domestic market of the Member authorising such [licence]’. This paragraph has been the basis for subsequent declarations which tried to overcome this territorial barrier in order to ensure access to essential medicines in LDCs with undeveloped or non-existent pharmaceutical industries. These documents will be addressed shortly.

Transitional provisions of the Agreement provide for a ten-year period in which developing countries may delay the application of the IP protection for products in areas of technology, e.g. pharmaceutical products¹¹⁹, and instead provide for the so-called ‘mailbox’ provisions and exclusive marketing rights for these inventions.¹²⁰ This period expired only recently in 2005.¹²¹ Finally, Article 66 deals with LDCs and declares that these countries are not ‘required to apply for the provisions of the Agreement [...] for the period of ten years from the date of application’ and that developed countries need to encourage and promote technology transfer and technical and financial cooperation in relation to these countries.¹²² One of the successful examples of these provisions is India, which introduced legislation on protection of pharmaceuticals in 2005 and, since 2000, has shown a very rapid increase in pharmaceutical R&D. However, this development was probably achieved because of India’s size and the numerous possibilities pharmaceutical companies have for the progress of R&D in its territory.

¹¹² Guide to Pharmaceutical Patents (n32), p. xiii.

¹¹³ Hestermeyer (n1), p. 49.

¹¹⁴ Guide to pharmaceutical Patents (n32), p. 117.

¹¹⁵ TRIPS Agreement, Art. 31 (a) (b).

¹¹⁶ Ibid, Art. 31(h).

¹¹⁷ Ibid, Art. 31(c) (g).

¹¹⁸ Ibid, Art. 31(d) (e).

¹¹⁹ Ibid, Art. 65(4).

¹²⁰ Ibid, Art. 70(8) (9).

¹²¹ Hestermeyer (n1), p. 70.

¹²² See also TRIPS Agreement, Art. 67.

When it comes to smaller developing countries, however, there is no evidence of significant increase of R&D after the adoption of TRIPS.¹²³ In November 2005 this transition period for LDC Members was extended until 1 July 2013.¹²⁴

2.2.2.1 The Doha Declaration and subsequent ‘Paragraph 6’ decisions

As already mentioned, the territorial barrier for compulsory licenses caused heated debates in the WTO, mainly because of its effect on access to medicines in the LDCs which do not have manufacturing capacities for pharmaceuticals. This led to this topic being the central one at the WTO Ministerial Conference in Doha held in 2001. The Declaration on the TRIPS Agreement and Public Health (Doha Declaration)¹²⁵ was adopted on 14 November 2001. The Declaration represents an ‘important milestone in the debate on intellectual property rights and access to medicines’¹²⁶, mainly because it recognized the public health problems in the developing countries and stressed the need of the adjustment of the provisions of the TRIPS to these needs.¹²⁷ It recognized the importance of IP protection, and at the same time raised its concerns about its effects on prices and confirmed 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’.¹²⁸ The most important provision of the Declaration can be found in its Paragraph 6, which stipulates that:

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

This paragraph was the basis of the subsequent decision drafted in 2003. The Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2003 Decision)¹²⁹, also known as ‘the TRIPS waiver’¹³⁰ was adopted on 30 August 2003 and states that:

[t]he obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s).¹³¹

¹²³ CIPR Report 2002 (n33), pp.1-2; Pharmaceutical Patents Paper (n46), p. 4.

¹²⁴ WTO, Council for TRIPS, ‘Extension of the Transition Period under Article 66.1 for Least-Developed Country Members’ IP/C/40, 30 November 2005, para. 1; Hestermeyer (n1), p. 72.

¹²⁵ WTO, ‘Declaration on the TRIPS Agreement on Public Health’, WT/MIN(01)/DEC/2, 20 November 2001, [Doha Declaration].

¹²⁶ Guidelines 2006 (n34), p. vii.

¹²⁷ Doha Declaration, paras. 1 and 2.

¹²⁸ Ibid, paras. 3 and 4.

¹²⁹ WTO, Decision of the General Council on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 1 September 2003 [2003 Decision].

¹³⁰ I. Lasic, ‘*De lege lata* – Article 31(f) of the TRIPS Agreement and subsequent WTO Declarations regarding Compulsory Licences’ (2012) unpublished paper in the course JAMR 16 Legal Writing and Research, Master Programme in International Human Rights Law at Lund University, p. 2.

¹³¹ 2003 Decision, para. 2.

This decision sets out the rules and conditions for both the importing and exporting members in order for them to use the compulsory licensing system provided by the waiver,¹³² as well as the rules on the assessment of manufacturing capacities in the pharmaceutical sector.¹³³ Moreover, in order to ensure that the pharmaceuticals produced under the compulsory licence are not exported and sold in other countries under lower prices, the Decision provides that importing Members need to take ‘reasonable measures’ and ‘ensure the availability of effective legal means’ to prevent this kind of misuse of the system.¹³⁴ Pursuant to the Decision an ‘eligible importing member’ is any LDC Member and any other Member that notified the Council for TRIPS that it intends to use the system, and an ‘eligible exporting member’ is any country Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.¹³⁵ The Decision sets out the rules on a complicated procedure that needs to be followed in order to grant a compulsory licence,¹³⁶ which will be discussed in Chapter 5. However, it allows the LDCs to extend the period for the grant of pharmaceutical patents until 2016.¹³⁷

The process of amending the TRIPS was continued in Cancun in September 2003, where the 5th WTO Ministerial Conference was held, but these negotiations ‘ended in a deadlock.’¹³⁸ It was not until 2005 that the WTO General Council decided to permanently incorporate the 2003 Decision into the TRIPS Agreement. The Decision on the Amendment of the TRIPS Agreement (2005 Amendment) was signed in December 2005, and it had very similar content to that of the 2003 Decision.¹³⁹ The Decision suggested a ‘Protocol Amending the TRIPS Agreement’, which stipulated that the Agreement would be changed through Article 31*bis* following Article 31, and an Annex to the TRIPS following Article 73.¹⁴⁰ Although this Decision seemed like a viable solution to the problem, the amendment of the TRIPS has not yet been achieved, since, until today, only 45 countries and the EU Members States have supported the TRIPS waiver.¹⁴¹ This is only 25 more than in 2009.¹⁴² Therefore, the period for acceptances of the Amendment by the WTO Members was extended for the third time in 2011, until 31 December 2013.¹⁴³ The only time the system was used was in 2007, in relation to a HIV/AIDS drug *TriAvir*. Rwanda notified the Council for TRIPS in July 2007 of its intentions to import the drug manufactured in Canada by a generic pharmaceutical company Apotex Inc.¹⁴⁴ After many difficulties¹⁴⁵, Canada granted

¹³² Ibid, paras. 1-3.

¹³³ Ibid, Annex.

¹³⁴ Ibid, paras. 4 and 5.

¹³⁵ Ibid, para. 1.

¹³⁶ Helfer and Austin (n14), p. 123.

¹³⁷ Doha Declaration, para. 7; Helfer and Austin (n14), p. 123.

¹³⁸ Bentley and Sherman (n26), p. 354.

¹³⁹ WTO, ‘Amendment of the TRIPS Agreement’, WT/L/641, 8 December 2005 [2005 Amendment].

¹⁴⁰ Ibid, Attachment, para. 1.

¹⁴¹ WTO, Members accepting amendment of the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed on 15 May 2013).

¹⁴² T. Pogge, M. Rimmer and K. Rubenstein (eds.), *Incentives for Global Health: Patent Law and Access to Essential Medicines* (2010) CUP, p. 12.

¹⁴³ WTO, ‘Amendment of the TRIPS agreement – third extension of the period for the acceptance by Members of the protocol amending the trips agreement’, Decision of 30 November 2011, WT/L/829, 5 December 2011.

¹⁴⁴ Council for TRIPS, ‘Notification Under Paragraph 2(A) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Rwanda’, WTO Doc. IP/N/9/RWA/1/2007, 19 July 2007.

¹⁴⁵ Helfer and Austin (n14), pp. 133-4.

the compulsory licence in October 2007.¹⁴⁶ No other member has to date notified Council for TRIPS under the 2003 Decision, and only a few members have implemented legislation to enable them to issue compulsory licenses in accordance with the waiver.¹⁴⁷ The 2003 Decision will be discussed in more detail in later Chapters due to its significance for the developing countries.

2.2.3 EU Law

As already stated in the introduction, the law that is of relevance for this thesis is mostly the international law which is universally applicable. However, due to its progressiveness and influence, the law of the EU will be briefly discussed in this sub-section.

The most important instrument on the EU level is the EPC establishing the European Patent Office (EPO), adopted in 1973¹⁴⁸ and last revised in 2000.¹⁴⁹ It establishes a system of law for the grant of European patents for inventions, and its membership extends beyond the membership in the EU.¹⁵⁰ The main benefit which this Convention provides for the inventors is that they can apply for the protection of their invention in a number of countries through a single application and a single grant of national patents in the States members of the Convention for a period of 20 years, through the EPO. However, under the provisions of the 1973 Convention, these patents remained national patents, and it is therefore upon the national institutions to decide on matters concerning them, i.e. infringement and enforcement.¹⁵¹ With the amendment in 2000, the procedure for the grant of the patent was simplified and a central court system for the enforcement of European patents was introduced.¹⁵² This document sets the rules on the patentability requirements that need to be fulfilled prior to the registration of the patent.¹⁵³ What is also relevant for the area of pharmaceutical patents is that it excludes methods of treatment and diagnosis from patentability.¹⁵⁴ Finally, as already mentioned in the section concerning the patentability requirement of industrial applicability, under the EPC, the term ‘industry’ is referred to in a wide sense, thus extending to the pharmaceutical industry.¹⁵⁵

Apart from the EPC, for the purposes of this thesis, the most important documents are the Council Regulation No. 953/2003 to avoid trade diversion into the European Union of certain key medicines¹⁵⁶ and the Regulation No. 816/2006 on compulsory licensing.¹⁵⁷ They provide a good example on how to balance the needs of all the stakeholders and incorporate the flexibilities provided by the TRIPS and subsequent documents mentioned above. On the other hand, the Council Regulation 1383/2003 concerning customs action against goods suspected of infringing

¹⁴⁶ Council for TRIPS, ‘Notification Under Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Canada’, WTO Doc. IP/N/10/CAN/1, 8 October 2007.

¹⁴⁷ Pogge et al. (eds.) (n141), pp. 69-70.

¹⁴⁸ EPC 1973.

¹⁴⁹ Convention on the Grant of European Patents (European Patent Convention), as revised on 29 November 2000, Munich, available at: <http://www.epo.org/law-practice/legal-texts/html/epec/2010/e/ma1.html> [EPC 2000].

¹⁵⁰ Bentley and Sherman (n26), p. 341.

¹⁵¹ Ibid, p. 342.

¹⁵² EPC 2000, Art. 149 (a) (1); Bentley and Sherman (n26), p. 344.

¹⁵³ EPC 2000, Arts. 52-4.

¹⁵⁴ Ibid, Art. 53.

¹⁵⁵ Ibid, Art. 57.

¹⁵⁶ Council Regulation (EC) No. 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines (OJ L 135/5, 30.04.2004) [Tiered Pricing Regulation].

¹⁵⁷ Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157/1, 9.06.2006) [Compulsory Licensing Regulation].

certain IPRs¹⁵⁸ is an example of a document that created tensions between the EU and a number of countries due to the seizures of generic medicines by EU customs officials.¹⁵⁹

After the adoption of the Doha Declaration in 2001 and the subsequent decisions, the EU has tried to balance the patent rights of pharmaceutical companies and the right to access to medicines of those living in developing countries facing public health crises.¹⁶⁰ The first regulation that dealt with this issue was the Regulation No. 953/2003 on tiered pricing of medicines and their re-exportation into the EU. In 2001, the Commission adopted a document which proposed the establishment of a 'global tiered pricing system for key pharmaceuticals for the prevention, diagnosis and treatment of HIV/AIDS, TB [tuberculosis] and malaria and related diseases for the poorest developing countries' and to 'prevent product diversion of these products to other markets by ensuring that effective safeguards were in place'.¹⁶¹ A 'tiered priced product' is defined as any pharmaceutical product used in the prevention, diagnosis and treatment of the aforementioned diseases, which is priced in accordance with one of the optional price calculations set in the Regulation¹⁶² and afterwards exported to developing countries listed in Annex II of the Regulation. The goal of the Regulation is to enable European pharmaceutical companies to export cheaper medicines to developing countries without the fear of these medicines being imported back to the developed countries under heavily discounted prices.¹⁶³

Furthermore, in order to comply with the proposed 2003 Decision, the EU decided to implement the decision into its own legislation. In 2006, the European Parliament and Council adopted the Regulation No. 816/2006 on compulsory licensing of pharmaceuticals for export to countries facing public health crises, with the purpose of being 'part of wider European and international action to address public health problems faced by least developed countries and other developing countries' and 'improve access to affordable medicines which are safe and effective ... and whose quality is guaranteed'.¹⁶⁴ Similar to the previous Regulation, it stresses the importance of medicines manufactured under a compulsory license to reach only those in need and not to be diverted from them.¹⁶⁵ The countries eligible for the import of the medicines are the LDCs that are listed as such in the UN list¹⁶⁶, any WTO Member, other than those that renounced their rights to use the system, that has made a notification to the Council for TRIPS of its intention to use the system, or any non-WTO Member State that appears on the Organization for Economic Co-operation and Development (OECD) Development Assistance Committee's list of low-income countries 'with a gross national product per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer'.¹⁶⁷ This

¹⁵⁸ Council Regulation (EC) No. 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such right (OJ L 196/7, 02.08.2003).

¹⁵⁹ WTO, European Union and a Member State-Seizure of Generic Drugs in Transit, Request for Consultations by India, G/L/921, IP/D/28, WT/DS408/1; full list of documents available at: https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=%28@Symbol=%20wt/ds408/*%29&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true# (accessed on 13 May 2013).

¹⁶⁰ <http://ec.europa.eu/trade/wider-agenda/health/access-to-medicines/> (accessed on 15 February 2013).

¹⁶¹ Tiered Pricing Regulation, para. 1.

¹⁶² Ibid, Art. 1(2) (a).

¹⁶³ <http://ec.europa.eu/trade/wider-agenda/health/access-to-medicines/> (accessed on 15 February 2013).

¹⁶⁴ Compulsory Licensing Regulation, para. 5, Arts. 10(4) and 13.

¹⁶⁵ Ibid, para. 8.

¹⁶⁶ <http://unctad.org/en/Pages/ALDC/Least%20Developed%20Countries/UN-list-of-Least-Developed-Countries.aspx> (accessed on 29 April 2013).

¹⁶⁷ Compulsory Licensing Regulation, Art. 4.

Regulation sets out detailed rules on the issuing procedure, conditions of the compulsory license, termination of the license, appeals, review and safety and efficacy of medicinal products.

Finally, a document that sheds an entirely different light to the EU commitments towards improving access to medicines is the Council Regulation 1383/2003 concerning customs action against goods suspected of infringing certain IPRs, which allows for the ‘detention’ and ‘suspension release’ of products that are suspected of violating IPRs.¹⁶⁸ Since late 2008, the EU customs authorities have detained, on numerous occasions, shipments of generic drugs from India that were intended for export to other developing countries, because they suspected they were counterfeit products.¹⁶⁹ India, which was later joined by other countries where generic drug manufacturing is widespread,¹⁷⁰ has challenged these seizures before the TRIPS Council on the grounds that they violate the TRIPS Articles 41 and 51, and on other grounds.¹⁷¹ They have a strong standing, since ‘seizing lawfully manufactured generic drugs not intended for “release into free circulation” in the EU creates “barriers to legitimate trade” in generic medicines in contravention of TRIPS’.¹⁷² This case is still ‘in consultation’ stage since 11 May 2010.¹⁷³

2.3 Can patent rights be considered as human rights?

The answer to this often asked question is no. The confusion may be caused by Articles 27(2) and 15(1(c)) of the UDHR and ICESCR respectively, which provide, in short, that the authors of literary, scientific or artistic work have a human right to the protection of the moral and material interests resulting from it. The scopes of these provisions are, however, different from the scope of modern-day IP law.¹⁷⁴ These provisions provide protection of human rights, but they do not protect patents as such.¹⁷⁵ The Committee on Economic, Social and Cultural Rights (CESCR), in its General Comment (GC) No. 17, made a clear distinction between human rights on one side and IP rights on the other. The GC provides that human rights are fundamental since they are

inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole.¹⁷⁶

Moreover, unlike IP rights, which are temporary in nature, transferable, revocable or licensable, human rights are ‘timeless expressions of fundamental entitlements of the human person’.¹⁷⁷ Therefore, what these Articles protect is the personal link between the author of a

¹⁶⁸ Council Regulation (EC) No. 1383/2003, Art. 4.

¹⁶⁹ Helfer and Austin (n14), p. 138.

¹⁷⁰ https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=%28@Symbol=%20wt/ds408/*%29&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true# (accessed on 13 May 2013).

¹⁷¹ Helfer and Austin (n14), pp. 130-40.

¹⁷² Ibid, p. 140.

¹⁷³ http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm (accessed on 13 May 2013).

¹⁷⁴ Hestermeyer (n1), p. 153; CESCR, General Comment No. 17: ‘The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author’ (2005) (article 15, paragraph 1 (c) of the ICESCR), E/C.12/GC/17, 12 January 2006 [CESCR GC No. 17], para. 3.

¹⁷⁵ Hestermeyer (n1), p. 154.

¹⁷⁶ CESCR GC No. 17, para. 1.

¹⁷⁷ Ibid, para. 6.

scientific production and ‘their basic material interests which are necessary to enable authors to enjoy an adequate standard of living’, and not their IPRs which extend beyond these moral and material interests.¹⁷⁸ Furthermore, these provisions are protecting the rights of the inventors as individuals, or as group of individuals, and not the entitlements of pharmaceutical companies or other businesses which are usually the holders of IP rights and major investors to the R&D of the inventions.¹⁷⁹ Therefore, as pointed out by Hestermeyer, ‘the ICESCR [or the UDHR] does not elevate modern day intellectual property lock, stock and barrel to a human right’.¹⁸⁰

Finally, it should be noted that some regional instruments may serve as a basis for the claim that IP rights are in fact human rights¹⁸¹ since they protect IPRs as property rights. However, due to the breadth of this topic and the fact that when it comes to access to essential medicines, universal human rights instruments are of higher relevance,¹⁸² the assessment of regional instruments on this particular issue is beyond the scope of this thesis.

¹⁷⁸ Ibid, para. 2.

¹⁷⁹ Hestermeyer (n1), pp. 155 and 157.

¹⁸⁰ Ibid, p. 154.

¹⁸¹ E.g. Charter of Fundamental Rights of the EU (OJ C 364/3, 18.12.2000), Art. 17(2).

¹⁸² Hestermeyer (n1), p. 158.

3. The right to health and access to essential medicines

3.1 Introduction to the right to health

Human rights are inherent to all human beings and are indispensable for living a life in dignity. One human right that is of the utmost importance for a dignified life is the right to health, since it ensures the full enjoyment of all other human rights and freedoms.¹⁸³ In other words, without the right to health being ensured, all other rights become trivial. The rights that are closely related to the right to health are, *inter alia*, the right to life, food, housing, equality and non-discrimination, privacy, work and education.¹⁸⁴ Since all human rights are indivisible, interrelated and interdependent,¹⁸⁵ all of these rights ‘address integral components of the right to health’.¹⁸⁶ Most countries in the world have ratified at least one international or regional human rights document providing for the protection of the human right to health.¹⁸⁷ However, not all of them are investing enough effort in respecting their obligations under these instruments.

US President Franklin Roosevelt mentioned the right to health in his ‘four freedoms’ speech from 1941. In his speech, he included ‘a healthy peacetime life for [the] inhabitants’ of every nation as being a part of the ‘freedom from want’.¹⁸⁸ Three years after this famous speech, he urged for a document that would include ‘the right to adequate medical care and the opportunity to achieve and enjoy good health’.¹⁸⁹ Although a reference to the right to health already existed in the United Nations (UN) Charter,¹⁹⁰ the right to health was explicitly defined for the first time in the WHO Constitution as a ‘state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’.¹⁹¹ Moreover, the Constitution in its Preamble stressed that ‘[t]he enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being’ without any distinction whatsoever. Although the Preamble of an instrument is not binding upon the States that ratify it, it does serve as a ‘purpose’ of the treaty and expresses the motives and goals of the drafters.¹⁹² Notwithstanding the legality of the Preamble, the definition provided in the WHO Constitution was relied upon by the World Health Assembly (WHA), the principal organ of the WHO,¹⁹³ as well as the academia. Moreover,

¹⁸³ CESCR, General Comment No. 14: ‘The Right to the Highest Attainable Standard of Health’ (2000) (Art. 12 of the ICESCR) E/C.12/2000/4, 11 August 2000 [CESCR GC No. 14], para 1; E. Riedel, ‘The Human Right to Health: Conceptual Foundations’, in A. Clapham et al (eds.), *Realizing the Right to Health* (2009) Swiss Human Rights Book Vol. 3, Rüffer&rub at 21-39, p. 21.

¹⁸⁴ CESCR GC No. 14, para. 2; B. Wilson, ‘Social Determinants of health from a Rights-Based Approach’, in A. Clapham et al (eds.) (n183) at 60-79, p. 60; Helfer and Austin (n14), p. 99.

¹⁸⁵ Vienna Declaration and Programme of Action (n19), para. 5.

¹⁸⁶ CESCR GC No. 14, para 2.

¹⁸⁷ H. V. Hogerzeil, and Z. Mirza, ‘The World Medicines Situation 2011: Access to Essential Medicines as Part of the Right to Health’ (3rd Edition, 2011) WHO, p. 6.

¹⁸⁸ F. D. Roosevelt, ‘The Four Freedoms Address’ (1941), quoted in Helfer and Austin (n14), p. 105.

¹⁸⁹ F. D. Roosevelt, ‘State of the Union Address to Congress (1944), quoted in Helfer and Austin (n14), p. 105.

¹⁹⁰ UN, Charter of the United Nations, 24 October 1945, 1 UNTS XVI, Arts. 55, 57 and 62.

¹⁹¹ WHO, Constitution of the World Health Organization, adopted by the International Health Conference, New York, 19 June-22 July 1946, available at: <http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf>, Preamble.

¹⁹² Hestermeyer (n1), p. 113.

¹⁹³ See e.g. WHA, Resolution WHA 55.14: ‘Ensuring accessibility of essential medicines’, 18 May 2002; WHO, Health-related Millennium Development Goals: A Report by the Secretariat A64/11, 64th World Health Assembly, Provisional Agenda 13.3, 7 April 2011.

since the adoption of the Constitution, the right to health has been confirmed in numerous international and regional instruments, as well as national constitutions.¹⁹⁴

The first document after the Constitution that had a provision on the right to health was the 1948 UDHR, which provided that ‘everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including... medical care’.¹⁹⁵ However, just as the Preamble is not legally binding, neither is this Declaration since it is a resolution of the UN General Assembly, and as such, serves as merely a ‘recommendation’ to States.¹⁹⁶ Yet, most members of the human rights academia agree that this document has a certain legal effect, and even that it has the status of customary international law - forming a part of the ‘International Bill of Rights’.¹⁹⁷ I agree with this articulation concerning the legality of the UDHR.

The first ‘truly’ legally binding instrument that provides for the enjoyment of the highest attainable standard of health is the 1966 ICESCR. In its Article 12, it stipulates that the States Parties ‘recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’. The drafters of the Covenant decided to narrow down the definition of health contained in the WHO Constitution, and instead opted for the notion of the ‘highest attainable standard of health’, which pertains not only to the right to health care, but also to ‘a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health’.¹⁹⁸ However, it should be noted that it does not grant to an individual the ‘right to be healthy’,¹⁹⁹ but merely the right to the ‘highest attainable *standard* of health’.²⁰⁰ The rationale behind this is obvious, since a State cannot provide protection from all causes of illnesses, nor can it ensure good health for all of its citizens. Therefore, the right to health under the ICESCR should be understood as ‘a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health’.²⁰¹

After the adoption of the Covenant, the right to health has been reiterated in numerous instruments, one of the first being the Alma-Ata Declaration on Primary Health Care of 1978, which strongly reaffirmed that

health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.²⁰²

The most influential document that followed the adoption of the ICESCR was the GC No. 14 from 2000,²⁰³ drafted by the CESCR, which is referred to on numerous occasions in this thesis. Moreover, a very important development regarding the right to health is the appointment

¹⁹⁴ For a detailed list see OHCHR, WHO, ‘The Right to Health, Fact Sheet No. 31’ (2008) available at: http://www.who.int/hhr/activities/Right_to_Health_factsheet31.pdf, pp. 9-10.

¹⁹⁵ UDHR, Art. 25 (1).

¹⁹⁶ Hestermeyer (n1), p. 120.

¹⁹⁷ Ibid.

¹⁹⁸ CESCR GC No. 14, para. 4.

¹⁹⁹ Ibid, para. 5.

²⁰⁰ Hestermeyer (n1), p. 103 (*emphasis in the original*).

²⁰¹ CESCR GC No. 14, para 9.

²⁰² Declaration of Alma-Ata, International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978, Geneva: WHO, para. 1.

²⁰³ CESCR GC No. 14.

of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (Special Rapporteur). Mr. Paul Hunt was appointed to this position by a Resolution of the UN Commission on Human Rights in 2002, as an independent expert with the mandate to, *inter alia*, report on the conditions and status of the realization of the right to health worldwide and to make recommendations on appropriate measures for the realization of the right.²⁰⁴ He has drafted numerous reports on all components of the right to health, including essential medicines, neglected diseases as well as the responsibilities of pharmaceutical companies, and has drafted the Human Rights Guidelines for Pharmaceutical Companies in relation to access to medicines.²⁰⁵ His successor, Mr. Anand Grover, who took up this position in 2008,²⁰⁶ continued this successful and fruitful practice.

3.2 Essential components and implications stemming from the right to health

Although the protection of the right to health is provided for in numerous international as well as national instruments, in practice, it still lacks global recognition which allows it to be neglected and systematically violated in ‘too many parts of the world’, especially in developing countries.²⁰⁷ This is the case with most of the ESCRs, since they are usually considered as not justiciable,²⁰⁸ and therefore ‘less important’ than the civil and political rights. Namely, Article 2(1) of the ICESCR provides that the State Parties are required ‘to take steps, individually and through international assistance and co-operation’, ‘to the maximum of [their] available resources, with a view to achieving progressively the full realization of the rights’ recognized in the Covenant. Moreover, in relation to the developing States, the Covenant provides that they may ‘determine to what extent they would guarantee the economic rights recognized in the present Covenant to non-nationals’, ‘with due regard to human rights and their national economy’.²⁰⁹ This provision is used as a basis for the claims that the ESCRs are not justiciable, since there is no certain threshold of the appropriate means and measures that need to be implemented in order for a State to fulfil its obligations under the Covenant.²¹⁰ Moreover, some authors stressed that this standard of progressive realization creates ‘a loophole large enough in practical terms to nullify the Covenant’s guarantees: the possibility that States will claim lack of resources as the reason they have not met their obligations’.²¹¹ Hestermeyer rightly pointed out that this ‘debate is fraught with misunderstandings stemming from the vagueness of the concept of “justiciability” and from inappropriate analogies to national law’.²¹² Therefore, these claims have been rebutted, especially in the light of the Vienna Declaration from 1993 and numerous

²⁰⁴ UN CommHR, Resolution 2002/31: ‘The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health’, E/CN.4/RES/2002/31, 22 April 2002, para. 4; See also <http://unsrhealth.org/> (accessed on 7 March 2013).

²⁰⁵ *The complete list of documents* available at: http://ap.ohchr.org/documents/dpage_e.aspx?m=100 (accessed 7 March 2013).

²⁰⁶ UN HRC, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover, A/HRC/11/12, 31 March 2009, p. 2.

²⁰⁷ A. Clapham et al (eds.) (n183), p. 17.

²⁰⁸ Hestermeyer (n1), p. 86.

²⁰⁹ ICESCR, Art. 2 (3).

²¹⁰ Helfer and Austin (n14), p. 106.

²¹¹ A. Chapman and S. Russel (eds.), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (2002) Intersentia, p. 5.

²¹² Hestermeyer (n1), p. 86.

other instruments establishing the indivisibility and interdependence of all human rights.²¹³ It is certain now that the ESCRs are of the same value as the civil and political rights, and therefore, States can no longer escape their obligations stemming from them, basing their failure to comply on financial constraints. The reason why the drafters of the Covenant included the provision on the progressive realization of the rights is because, as pointed out by Paul Hunt, a ‘comprehensive, integrated health system’ cannot be constructed overnight,²¹⁴ and they knew they could not impose impossible requirements on States Parties. Thus, Article 12(2) of the ICESCR provides that the States Parties need to take steps to achieve the full realization of the right to health.

However, the progressive realization imposes some immediate core obligations upon the States, which represent the minimum requirements, as well as the obligations to protect, respect and fulfil the right to the highest attainable standard of health. The first immediate obligation imposed by the Covenant is the obligation to take concrete, deliberate and targeted steps towards the progressive realization of the right to health.²¹⁵ This obligation also pertains to the obligation of the State to ensure the satisfaction of the minimum essential levels of health care and determinants of health.²¹⁶ The Special Rapporteur calls these obligations the ‘minimum “basket” of health-related services and facilities’,²¹⁷ others call it the ‘bottom floor from which States should endeavour to go up’,²¹⁸ or a ‘survival kit’ necessary for the existence and dignifying life of every person.²¹⁹ Whichever the appropriate name may be, they all include, *inter alia*, access to health facilities, goods and services, minimum essential food and medicines as well as equitable distribution to all.²²⁰

The second obligation is that of non-discrimination, meaning that the steps taken should be available to all, without discrimination of any kind,²²¹ with the extension that even ‘an unintended discriminatory effect may be in breach of international human rights law’.²²² These obligations have to be fulfilled ‘notwithstanding the financial resources constraints and progressive realization’, because ‘otherwise pursuit of the right to health might be constantly postponed, emptying the right of any meaning’.²²³ It is also firmly established that retrogressive measures in relation to an already established level of protection of the right to health are not allowed, with the exception of extraordinary circumstances, meaning that the State cannot

²¹³ Ibid, p. 90; Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, Maastricht, 22-26 January 1997, available at: http://www1.umn.edu/humanrts/instree/Maastrichtguidelines_.html, para. 4.

²¹⁴ UN HRC, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, A/HRC/7/11, 31 January 2008 [UN Special Rapporteur Report 2008], para. 46; *See also* Helfer and Austin (n14), p. 103.

²¹⁵ ICESCR Art 2(1); CESCR GC No. 14, para. 30.

²¹⁶ CESCR, General Comment No. 3: ‘The Nature of States Parties’ Obligations’ (1990) (Art. 2, Para. 1, of the ICESCR) E/1991/23, 14 December 1990 [CESCR GC No. 3], para. 10; UN Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, ‘The right of everyone to the enjoyment of the highest attainable standard of physical and mental health’, Addendum, Mission to the World Trade Organization, E/CN.4/2004/49/Add.1, 1 March 2004 [UN Special Rapporteur Report 2004], para. 22.

²¹⁷ UN Special Rapporteur Report 2008 (n214), para. 52.

²¹⁸ Chapman and Russel (eds.) (n211), p. 16.

²¹⁹ Riedel (n183), p. 32.

²²⁰ CESCR GC No. 14, para. 44.

²²¹ ICESCR, Art. 2 (2).

²²² UN Special Rapporteur Report 2004 (n216), para. 25.

²²³ Ibid, paras. 21-2; Maastricht Guidelines (n213), para. 9; *see also* CESCR GC No. 3, para. 9.

deteriorate the level of its citizens' right to health it has already achieved.²²⁴ Any such measure requires 'the most careful consideration and would need to be fully justified by reference to the totality of the rights provided for in the Covenant and in the context of the full use of the maximum available resources'.²²⁵

Like all human rights, the right to health imposes upon States the responsibilities to respect, protect and fulfil the right to health of their citizens.²²⁶ The obligation to respect requires from the States not to interfere with the right to health of their citizens, while the obligation to protect entails the implementation and undertaking of measures to prevent third parties from interfering and violating the right to health. Finally, the obligation to fulfil includes the obligations to facilitate, provide and promote, which requires the States to adopt appropriate measures in order to enable the full realization of this right.²²⁷ The right to health contains four essential elements: the availability, accessibility, acceptability and quality of health facilities, services and goods (also known as the 'AAAQ standard').²²⁸ A detailed analysis of these components will be provided in the next section in relation to essential medicines. Furthermore, in order to decide whether a violation of the right to health has occurred, one should primarily distinguish between the inability of the State to comply with its obligations on one side, and its unwillingness to adhere to the treaty rules on the other.²²⁹

Additionally, the CESCR and other bodies²³⁰ have constantly stressed the importance of international cooperation in fulfilling the obligations stemming from the ESCRs. This entails both financial and technological assistance, as well as joint efforts in eliminating poverty and realizing the full enjoyment of the highest attainable standard of health.²³¹ This requires action of all relevant actors in the international forum, including NGOs, local communities and private businesses, as well as all of the Members of the WTO which undertook this commitment through the adoption of the TRIPS and Doha Declaration.²³² However, although the ICESCR is today the most widely adopted convention on ESCRs with as much as 160 States Parties,²³³ a persistent problem is that more than 30 countries have not ratified it yet, while over 60 countries do not provide for the constitutional protection of the right to health to their citizens.²³⁴ This unequal protection of a fundamental human right indispensable for the enjoyment of all other rights and a dignifying life needs to be dealt with the utmost urgency.

3.3 The right to access to essential medicines: a human right

Unlike in early medical science, medicines today play an essential role in preventing and curing diseases.²³⁵ Almost all diseases and illnesses are now preventable or curable through the

²²⁴ CESCR GC No. 14, para. 32; Hogerzeil and Mirza (n187), p. 3.

²²⁵ CESCR GC No. 3, para. 9.

²²⁶ CESCR GC No. 14, para. 33.

²²⁷ Ibid.

²²⁸ Ibid, para. 12.

²²⁹ Maastricht Guidelines (n213), para. 13.

²³⁰ See e.g. UN Special Rapporteur Report 2004 (n216), para 28.

²³¹ Ibid.

²³² Ibid, paras. 29 and 30.

²³³ *For the full list of countries see:*

http://treaties.un.org/pages/ShowMTDSGDetails.aspx?src=UNTSOnline&tabid=1&mtdsg_no=IV-3&chapter=4&lang=en#Participants (accessed 9 March 2013).

²³⁴ Hogerzeil and Mirza (n187), p. 1.

²³⁵ Hestermeyer (n1), p. 104.

appropriate combinations of existing medicines.²³⁶ Therefore, access to these medicines is a necessary component in the course of the full realization of the right to health. Essential medicines are defined as ‘those that satisfy the priority health-care needs of the population’, which are ‘intended to be available at all times in adequate amounts, in appropriate dosage forms, with assured quality, and at a price the individual and the community can afford’.²³⁷ ‘Access’ in the context of essential medicines was defined by the UN Millennium Development Goals (MDGs) Task Force as ‘having medicines continuously available and affordable at public or private health facilities or medicine outlets that are within one hour’s walk from the homes of the population’.²³⁸ Although it is not explicitly mentioned as an independent human right, the right to access to medicines is derived from the human right to health.

The first indications of recognition of the right to access to essential medicines as a part of the right to health were manifested in the second half of the 20th century. The ICESCR implied this, in Article 12(2), by stipulating that the steps necessary for the realization of the right to health shall include, *inter alia*, the prevention, treatment and control of diseases and ‘the creation of conditions which would assure to all medical service and medical attention in the event of sickness’. However, the first document which clearly included access to medicines as a part of the right to health was the Alma-Ata Declaration which stated that primary health care includes ‘at least [...] a provision of essential drugs’.²³⁹ A year before that, the WHO issued the first Model List of Essential Medicines, and today has issued 17 Model Lists for Adults, and 3 for children.²⁴⁰ All doubts on this topic were removed in the CESC’s GC No. 14, which expressly accepted access to essential medicines as an indispensable part of the right to health.²⁴¹ Since then, this has been reiterated in numerous international documents²⁴², and stressed by the Special Rapporteur on many occasions.²⁴³

The right to access to essential medicines was also established as forming a part of the right to health in a number of national cases. The WHO has conducted a systematic search on case-law regarding access to medicines in low- and middle-income countries, and the results were that out of 71 court cases from 12 countries, in 59 it was found that access to essential medicines, as a part of the right to health, is enforceable through the courts.²⁴⁴ One of the most famous cases is the SA case regarding access to ARV drugs. In *Minister of Health v. Treatment Action Campaign*, the Constitutional Court of SA decided that the government has to make an

²³⁶ UN Millennium Project, ‘Prescription for Healthy Development: Increasing Access to Medicines’ (2005) Report of the Task Force on HIV/AIDS, Malaria, TB, and Access to Essential Medicines, Working Group on Access to Essential Medicines Sterling, Va.: Earthscan [UN Millennium Project 2005], p. 1; Hestermeyer (n1), p. 104.

²³⁷ http://www.who.int/topics/essential_medicines/en/ (accessed on 9 March 2013).

²³⁸ MDG Gap Task Force Report, Millennium Development Goal 8: ‘Delivering on the Global Partnership for Achieving the Millennium Development Goals’ (2008) UN publication, available at: <http://www.un.org/millenniumgoals/pdf/MDG%20Gap%20Task%20Force%20Report%202008.pdf> [MDG Report 2008], p. 35.

²³⁹ Alma-Ata Declaration (n202), Art. VII (3) at p. 4 and para. 14 at p. 28.

²⁴⁰ <http://www.who.int/medicines/publications/essentialmedicines/en/> (accessed 9 March 2013).

²⁴¹ CESC GC No. 14, paras. 12(a) and 43.

²⁴² See e.g. UNGA, UN Millennium Declaration, Resolution A/RES/55/2, 18 September 2000, para. 5; WHA, Resolution WHA 54.11: ‘WHO medicines strategy’, 21 May 2001; WHA 55.14 (n193); UN HRC, Resolution 6/29: Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, A/HRC/6/29, 14 December 2007, para. 4; UN CommHR, Resolution 2003/29: Access to Medication in the Context of Pandemics Such as HIV/AIDS, Tuberculosis and Malaria, E/CN.4/RES/2003/29, 22 April 2003, paras. 1 and 4.

²⁴³ E.g. UN Special Rapporteur Report 2004 (n216), paras. 1 and 4; UN Special Rapporteur Report 2008 (n206), paras. 54, 68 and 70.

²⁴⁴ Hestermeyer (n1), Box 1.3, p. 6.

ARV drug called *Nevirapine* more available and accessible, in order to prevent mother-to-child transmission of HIV.²⁴⁵ The case was brought against the Minister of Health of SA by a number of associations of civil society, because of a programme devised by the Government which imposed restrictions to access and availability of the drug in question to the public health sector. The second issue in the case was whether the Government is obliged to draft and implement a national programme to prevent mother-to-child transmission of HIV.²⁴⁶ The Court held that the Government must devise and implement a programme aimed to ‘realize progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child transmission of HIV’, and this included counselling, testing, treatment and available and accessible drugs to combat this disease.²⁴⁷ Thus, the Court ordered the Government to remove all the barriers that denied access to *Nevirapine* in the public sector, and make it more widely available to all.²⁴⁸ This is not the only instance where a national court held that access to medicines is a necessary condition in realizing the right to health. For example, in *Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social*, the Venezuelan Supreme Court ordered the Government to provide access to ARV drugs to all its citizens infected with HIV.²⁴⁹ Also, in *Edgar Carpio Castro Jofre Mendoza y otros v. Ministry of Health*, the Constitutional Court of Ecuador found that the decision of the Ministry of Health to stop the supply of ARV treatment for people living with HIV/AIDS represents a violation of the right health.²⁵⁰ Therefore, all of the above cases clearly establish the right to essential medicines as a human right belonging to a wider concept of the right to health.²⁵¹

There has also been a discussion on whether the right to access to essential medicines could be viewed as being a part of customary international law, either as a component of the right to health, or as a part of the right to life.²⁵² The reason for this is the fact that it can be argued that there is enough evidence of both the widespread state practice, as well as the *opinio juris*, which entails the belief of States that they are ‘conforming to what amounts to a legal obligation’²⁵³, to make this claim a viable one. When the right to health and access to medicines is in question, I agree with Koskeniemi’s argument that:

[s]ome norms seem so basic, so important, that it is more than slightly artificial to argue that states are legally bound to comply with them simply because there exists an agreement between them to that effect, rather than because (...) noncompliance

²⁴⁵ *Minister of Health et al v Treatment Action Campaign et al* 2002 (5) SA 721 (CC); 2002 (10) BCLR 1033 (CC), Judgment of 5 July 2002, p. 34, para. 45.

²⁴⁶ *Ibid*, pp. 2-3, paras. 3-5.

²⁴⁷ *Ibid*, p. 34, para. 45 (2).

²⁴⁸ *Ibid*, p. 35, para. 45 (3).

²⁴⁹ Tribunal Supremo de Justicia de Venezuela, *Cruz Bermúdez v. Ministerio de Sanidad y Asistencia Social*, Case No 15.789, Decision No 916 (1999); Hestermeyer (n1), pp. 104-5.

²⁵⁰ See P. Hunt, ‘Neglected diseases: a human rights analysis’ (2007) Special topics in social, economic and behavioural research report series, no. 6, TDR/SDR/SEB/ST/07.2, WHO on behalf of the Special Programme for Research and Training in Tropical Diseases, Box 13, p. 34; *Edgar Carpio Castro Jofre Mendoza y otros v. Ministry of Health*, Case No. 749-2003-RA (2004) Constitutional Court of Ecuador.

²⁵¹ See also http://www.who.int/medicines/areas/human_rights/en/index.html (accessed on 14 March 2013).

²⁵² Hestermeyer (n1), pp. 122-36.

²⁵³ *North Sea Continental Shelf* case (Federal Republic of Germany v. Denmark; Federal Republic of Germany v. Netherlands), Judgment, International Court of Justice, ICJ Reports 1969, 3, para. 77.

would shock ... the conscience of mankind and be contrary to elementary considerations of humanity.²⁵⁴

Apart from the fact that both the right to health and right to life are contained in most of the international and national human rights instruments, while the right to life is already recognized as forming international customary law²⁵⁵, it could be inferred from the documents listed above, as well as constant reminders at the international conferences on the right to health, that access to essential itself is paving its path to becoming a part of customary international law, if it is not already accepted as belonging to it.

3.3.1 Essential elements of the right to access to essential medicines

Before turning to the components of the right to access to life-saving drugs, it should be noted that as a human right, access to medicines only pertains to essential medicines within the meaning of WHO Action Programme on Essential Drugs,²⁵⁶ thereby excluding from human rights protection the so-called 'life-style drugs'. Which medicines will be included in the list of essential medicines is a matter of the national policy of each country,²⁵⁷ and the selection depends on the particular diseases affecting it as well as the quality, safety, efficacy and costs of the medicines.²⁵⁸ However, all States need to bear in mind the WHO Model List of Essential Medicines, which is updated every two years,²⁵⁹ and tailor their national lists accordingly.

The right to access to essential medicines requires from States to respect the aforementioned 'AAAQ standard' regarding essential medicines.²⁶⁰ Availability of essential medicines entails that the essential medicines are available in sufficient quantity to everyone within the State. Accessibility means that the medicines need to be accessible to everyone without discrimination of any kind. It includes physical accessibility, meaning that medicines need to be within safe physical reach for everyone, including the part of the population living in rural areas, as well as persons with disabilities. Moreover, accessibility encompasses economic accessibility or affordability, which means that medicines need to be affordable to all, including socially disadvantaged parts of the population, based on equity, which implies that 'poorer households should not be disproportionately burdened with health expenses as compared to richer households.' Finally, accessibility comprises accessibility of information, meaning that everyone should have equal access to information relating to health issues. However, this accessibility of information should not result in an infringement of the confidentiality of personal health records. The third element of the right to access to medicines is their acceptability or appropriateness. This element requires that all medicines need to be ethically and culturally appropriate as well as 'designed to respect confidentiality and improve the health status of those concerned'. Finally, essential medicines need to be of good quality and 'scientifically and medically appropriate'.²⁶¹ Hestermeyer points out that these four elements might sometimes conflict each other, since, for example, medicine quality may take precedence against the availability or affordability of it.²⁶²

²⁵⁴ M. Koskenniemi, 'The Pull of the Mainstream' (1989–1990) 88 Mich. L. Rev. at 1946–47, in Hestermeyer (n1), p. 124.

²⁵⁵ Hestermeyer (n1), pp. 127-33.

²⁵⁶ CESC GC No. 14, para. 12 (a).

²⁵⁷ Hestermeyer (n1), p. 106.

²⁵⁸ http://www.who.int/topics/essential_medicines/en/ (accessed on 14 March 2013).

²⁵⁹ <http://www.who.int/medicines/publications/essentialmedicines/en/> (accessed on 14 March 2013).

²⁶⁰ CESC GC No. 14, para. 12; Hestermeyer (n1), p. 105.

²⁶¹ CESC GC No. 14, para 12 (a-d).

²⁶² Hestermeyer (n1), p. 105.

However, as noted above, since drugs need to pass numerous trial phases, this usually leads to the pharmaceutical industry setting higher prices on essential medicines, thereby hampering the availability and accessibility of medicines. Notwithstanding this, these trials are incontestably required for ensuring of the quality of medicines. The impact of patents and prices set by the pharmaceutical industry will be dealt with in the next chapters. Additionally, the WHA has identified another four components of access to essential medicines in its Resolution 54.11, namely, the rational selection and use of medicines, reliable health and supply systems, sustainable financing and affordable prices, and stressed the ‘price sensitivity’ of access to medicines.²⁶³

The Working Group of the MDGs has identified six barriers to access to medicines.²⁶⁴ The first one is the inadequate commitment of States to make healthcare a priority, which usually stems from the lack of political will, corruption and the inadequacy of donor programmes and international loans. The second obstacle to access to existing medicines is the inadequacy of human resources for health, due to inappropriate education, training and access to information provided for those working in the health sector. Furthermore, the Working Group stresses that the international community has not fulfilled its promises to developing countries in relation to improving access to medicines, nor has it provided adequate financing to achieve this. The fourth barrier is the fact that ‘persistent lack of coordination of international aid reduces access to medicines’. There is a need for transparent and coordinated donor funding at both national and international level. The last two barriers are related to the development of new affordable medicines necessary for combating widespread epidemics. The Working Group emphasized that the TRIPS ‘may block access to affordable new medicines and vaccines’, since after 2005, generic production in countries with necessary manufacturing capacities has been subject to the provisions of this Agreement, and the subsequent declarations on compulsory licensing are ‘too cumbersome for developing countries to exploit’. Finally, the Group also pointed out that ‘the current incentive structure is inadequate to promote research and development of medicines and vaccines to address priority health problems of developing countries’, especially in relation to neglected diseases.²⁶⁵ All of these barriers are a real and dangerous threat to people in need of affordable and accessible essential medicines, and States, as well as the international community, need to make their overcoming an urgent priority. Moreover, the Working Group, in defining accessibility of essential medicines qualified it by stipulating that it applies ‘only to products that are effective and of consistently good quality, that have no financial obstacle to a patient receiving it, and that have available the knowledge and guidance needed to use them properly’.²⁶⁶

As for the obligations of States to respect, protect and fulfil the right to access to medicines, they receive their full meaning in this domain.²⁶⁷ The responsibility to respect entails that the State has to refrain from denying equal access to medicines to everyone, as well as from any conduct which would prevent people from accessing life-saving drugs,²⁶⁸ such as preventing a group of people from accessing the medicines, while at the same time allowing others to have access. This could be done by allowing the private sector to administer a certain essential drug to patients, while prohibiting the prescription of the same medicine in the public sector. The

²⁶³ WHA Resolution 54.11 (n242), Preamble.

²⁶⁴ UN Millennium Project 2005 (n236), pp. 4-7.

²⁶⁵ Ibid.

²⁶⁶ Ibid, p. 27.

²⁶⁷ T. Pogge, ‘Montreal Statement on the Human Right to Essential Medicines’ (2007) Cambridge Quarterly of Healthcare Ethics, Vol. 16, Issue 1 at 97-108, pp. 104-5, para. 4.

²⁶⁸ Hestermeyer (n1), p. 109.

obligation to protect requires from the State to prevent others interfering with the right to access to medicines through the adoption of laws or other measures in order to ensure access to health care and products. This obligation is of great importance in the domain of access to medicines, since it is the private pharmaceutical sector that sets the prices and markets the medicines.²⁶⁹ It is the duty of the State to make sure that all of its citizens have equal access to affordable medicines and, consequently, to ensure a certain amount of essential medicines will always be available (physically and economically) to everyone on equal basis, whether through adoption of insurance policies or through any other effective measure. Finally, the obligation to fulfil, in relation to access to medicines, imposes upon the State the requirement to adopt legislative, budgetary and administrative policies regarding essential medicines and to provide the necessary information to patients on the existing treatment of diseases.²⁷⁰

Access to essential medicines has been accepted by the UN, as well as the WHO, as one of the primary indicators in assessing the level of the progressive realization of the right to health.²⁷¹ This right depends on numerous conditions, including production, distribution, pricing, effective health care system, infrastructure, as well as on the incentives for R&D of medicines.²⁷² Although it is nowadays uncontested that access to essential medicines forms an indispensable part of the right to health,²⁷³ only five States expressly recognize this in their legislation.²⁷⁴ This lack of legal as well as factual possibilities of access to essential medicines ‘stands as a direct contradiction to the fundamental principle of health as a human right’.²⁷⁵ However, as rightly pointed out by Hogerzeil,

[w]hile constitutional recognition of the right to access to essential medicines is an important sign of national values and commitment, it is neither a guarantee nor an essential step. This is shown by the many countries with failing health systems despite good constitutional language, and by those countries with good access to essential medicines without it.²⁷⁶

The next section will present the current obstacles and inequalities that developing countries are facing in relation to access to life-saving medicines.

3.4 Constraints faced by developing countries in relation to access to essential medicines

The right to access to essential medicines has not been realized to the full extent even in developed countries. However, it is the developing countries that feel the worst consequences stemming from the inequality in access and distribution of life-saving drugs. At least two billion people worldwide do not have adequate access to essential medicines,²⁷⁷ and it is even more shocking to know that at least forty thousand people die every day, and ten million children every

²⁶⁹ Ibid.

²⁷⁰ Hestermeyer (n1), p. 110; Pogge (n267), p. 105, para. 7.

²⁷¹ Hogerzeil and Mirza (n187), pp. 1 and 6; WHO, WHO Medicines Strategy 2008-2013, Draft 8, 13 June 2008, available at: http://www.who.int/medicines/publications/Medicines_Strategy_draft08-13.pdf, p. 10.

²⁷² S. P. Marks, ‘Access to Essential Medicines as a Component of the Right to Health’ (2009) in A. Clapham et al. (eds.) (n183) at 80-99, p. 80.

²⁷³ WHO Medicines Strategy 2008-2013 (n271), p. 4.

²⁷⁴ Wilson (n184), p. 82; MDG Report 2008 (n238), p. 42.

²⁷⁵ Wilson (n184), p. 82.

²⁷⁶ Hogerzeil and Mirza (n187), p. 7.

²⁷⁷ See e.g. Pogge (n267), p. 104, para. 1; WHO, ‘Drug Information Vol. 13, No. 4’ (1999), available at: <http://apps.who.int/medicinedocs/pdf/h1461e/h1461e.pdf>, p. 217; CESCR GC No. 14, para. 5.

year, as a result of this lack of access, mostly from diseases that are easily prevented and cured, such as diarrhoea, respiratory diseases and malnutrition.²⁷⁸ The UN Millennium Declaration recognized that developing countries ‘face special difficulties’ in responding to challenges of unevenly distributed costs and benefits of globalization.²⁷⁹ This is mostly the result of lack of financial resources of both the State and the individuals.²⁸⁰

The WHO identified three factors critical for securing access to essential medicines: sustainable financing, affordable prices, and reliable supply systems, which also implies that drugs need to be of good quality, rationally selected and appropriately used.²⁸¹ The Special Rapporteur stressed the great importance of ensuring the good quality of medicines, which extends from the State to health workers, since it is important that the medicines are correctly prescribed and administered.²⁸² Moreover, it is a common case that medicines rejected in the developed part of the world (either because they are unsafe or because their expiry date has passed) somehow find their way to the developing countries. This ‘recycling’ of medicines is unacceptable. The States have the duty to make sure that these medicines, as well as counterfeited ones, do not reach patients, by establishing an effective health system.²⁸³ Another major problem in developing countries is that because of the lack of insurance policies or bad health care systems, the majority of essential medicines are paid ‘out of pocket’, which represents the biggest financial burden households in these countries need to bear.²⁸⁴

One of the MDG Targets, namely Target 8, is to ‘in cooperation with pharmaceutical companies, provide access to affordable medicines’. The MDG Working Group found that in those countries that do provide information on their health systems, the discrepancies between public and private sectors are enormous, with availability of essential medicines in the public sector being as low as one third, in relation to two thirds in the private sector.²⁸⁵ Moreover, the prices for generically manufactured drugs are up to 6.5 times larger than the international reference prices.²⁸⁶ It also warned that people who cannot access essential medicines in the public sector, will be forced to buy them for much higher prices in the private sector, or decide not to treat the illness at all. This is the reason why it urged pharmaceutical companies to start working towards improving access to essential medicines through partnerships with governments or specially designed programmes intended for the developing part of the world. It presented the case of Kenya, which signed an agreement with Novartis on differential pricing, whereby Novartis agreed to provide the medicines at lower prices for the public sector in developing countries.²⁸⁷ More of these successful arrangements will be presented in the last Chapter.

Here, one should make a note of the national case-law derived from constitutional provisions on access to medicines and the right to health. The case that received the most attention is the SA *Pharmaceutical Manufacturer’s Association (PMA) case*, already mentioned in the introduction. The SA President issued a proclamation that was to change the existing legislation, making it easier to access essential medicines. Both the US and the pharmaceutical

²⁷⁸ Pogge (n267), p. 104, para. 1; UN Millennium Project 2005 (n236), p. 1.

²⁷⁹ UN Millennium Declaration (n242), para. 5.

²⁸⁰ Wilson (n184), p. 61.

²⁸¹ WHO Drug Information (n277), p. 217; *See also* WHA Res. 54.11 (n242), Preamble.

²⁸² UN Special Rapporteur Report 2008 (n214), para. 54.

²⁸³ *Ibid.*

²⁸⁴ WHO Drug Information (n277), p. 218; UN Millennium Project 2005 (n236), p. 2.

²⁸⁵ MDG Report 2008 (n238) p. 35; *see also* WHO Report A64/11 (n193), para. 13.

²⁸⁶ MDG Report 2008 (n238), p. 35.

²⁸⁷ *Ibid.*, p. 36.

industry opposed this decision, and tried to change it through trade pressures and threats of litigation.²⁸⁸ The US decided to cease these trade pressure tactics in 2000, after the public embarrassment of Al Gore by HIV/AIDS advocates during his presidential campaign.²⁸⁹ However, in 2001, 40 pharmaceutical companies (PMA) lodged a case against the Government, under the argument that this law breaches SA obligations under the TRIPS.²⁹⁰ After the public and the media attention reached worldwide proportions, and they supported the Government's case that the right to health has precedence over private IPRs, the pharmaceutical industry withdrew the lawsuit and committed itself to working together with the Republic of SA to further the health of its population.²⁹¹ Another case was against the government of Brazil before of the WTO Dispute Settlement Body (DSB), lodged by the US, who tried to challenge the Brazilian law on compulsory licensing, ensuring better access to HIV/AIDS drugs, which, according to the US, violated Articles 27 and 28 of the TRIPS.²⁹² On 5 July 2001, the parties notified to the DSB a mutually satisfactory solution on the matter, and the case was withdrawn. One of the reasons of these withdrawals was the fact that the cases, and the potential judgments, posed a risk of irreparable reputational damage to the pharmaceutical companies. Even world known magazines such as Washington Post and Time have questioned the IP protection of pharmaceuticals in developing countries.²⁹³ These events turned the attention of the international community to the problem of access to essential medicines in developing countries, and a few other cases, already mentioned in the previous section, made sure this issue remained on the international agenda.²⁹⁴

Although there are many barriers to access to essential medicines that need to be overcome by the developing countries, the main obstacle, in my opinion, is the one regarding pharmaceutical patents and their effect on prices and availability of life-saving drugs, as well as lack of incentives for R&D for drugs for neglected diseases. The United Kingdom (UK) Government has called this a 'mismatch between pharmaceutical needs in developing countries and the current nature of the global pharmaceutical market'.²⁹⁵ This will be addressed in the subsequent Chapter. Moreover, the drafters of the Montreal Statement on Human Right to Essential Medicines stressed the importance of international cooperation and assistance, emphasizing that providing better access to medicines is in the hands of more affluent countries, which 'must, therefore, ensure fairer trade and investment, eliminate crippling debt, and contribute equitably to international assistance aimed at facilitating the full realization of the right to essential medicines'.²⁹⁶ On the other hand, all the developing and less affluent countries have the shared burden of eliminating poverty and need to implement effective policies in this regard.²⁹⁷

²⁸⁸ Helfer and Austin (n14), p. 146.

²⁸⁹ Ibid.

²⁹⁰ S. Joseph, 'Trade and the Right to Health', in Clapham et al. (eds.) (n183) at 359-368, p. 361; Helfer and Austin (n14), pp. 146-8; Hestermeyer (n1), p. 14.

²⁹¹ Hestermeyer (n1), p. 14; Helfer and Austin (n14), p. 147.

²⁹² *Brazil-Measures Affecting Patent Protection*, WT/DS199/4, G/L/454, IP/D/23/Add.1, (01-3506) (2001) available at: http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds199_e.htm.

²⁹³ Helfer and Austin (n14), p. 157; Hestermeyer (n1), p. 14.

²⁹⁴ *Cruz del Valle Bermúdez case* (n249); *Edgar Carpio Castro Jofre Mendoza y otros v. Ministry of Health* (n250); *Jorge Odir Miranda Cortez et al v. El Salvador* (2000), Case 12.249, Report No. 29/01, Inter-American Commission on Human Rights; *Minister of Health v. TAC* (n245).

²⁹⁵ UN Millennium Project 2005 (n236), p. 4; Pogge (n267), p. 104, para. 2.

²⁹⁶ Pogge (n267), p. 106, para. 9.

²⁹⁷ Ibid, para. 12.

Notwithstanding the difficulties developing countries face, they also have another, completely different role in relation to improving access to medicines. Namely, developing countries have played an indispensable role in promoting awareness of the needs of their population in both the WHO and WTO.²⁹⁸ This influence can be seen throughout the WTO Doha Ministerial Rounds, and the adoption of the Doha Declaration and subsequent decisions, as well as numerous WHO declarations and resolutions dealing with the right to health and access to medicines, making this issue one of the most pressing today.

3.5 Conclusion

This Chapter attempted to provide a clear picture on the right to access to essential medicines and to ascertain its place in the area of human rights law, as well as to present the particular situation in developing countries. Although this is not an easy task, it looks like ‘the tide has shifted’ in favour of the human right to essential medicines.²⁹⁹ Many civil society movements and NGOs, such as Médecins Sans Frontières (MSF), the Health Action International (HAI), the Third World Network and OXFAM, have raised global awareness of the importance of adequate access to essential medicines. They have also warned the international community about the possible negative implications of international trade agreements on the prices of new essential medicines, as well as the lack of incentives for the development of new ones.³⁰⁰ The Alma-Ata Declaration stipulated that

An acceptable level of health for all the people of the world by the year 2000 can be attained through a fuller and better use of the world’s resources, a considerable part of which is now spent on armaments and military conflicts. A genuine policy of independence, peace, detente and disarmament could and should release additional resources that could well be devoted to peaceful means and in particular to the acceleration of social and economic development of which primary health care, as an essential part, should be allotted its proper share.³⁰¹

It is now year 2013, and this goal has not yet been reached. However, there are considerable efforts made by both the international organizations and NGOs to make this a reality. The next suggested timeframe to ‘close the gap between “haves” and “have-nots”’³⁰² and achieve better access to essential medicines is now set to the year of 2015.³⁰³

²⁹⁸ S. F. Musungu, ‘Developing Countries and the Promotion of the Right to Health in Multilateral Institutions: A Review of Development in Trade and Health Institutions’ (2009) in Clapham et al. (eds.) (n183) at 368-79, p. 371.

²⁹⁹ Marks (n272), p. 86.

³⁰⁰ Hoyerzeil and Mirza (n187), p. 5.

³⁰¹ Alma-Ata Declaration (n202), Art. X.

³⁰² Ibid, para. 14

³⁰³ Marks (n272), p. 81; <http://www.un.org/millenniumgoals/> (accessed on 16 May 2013).

4. The impact pharmaceutical patents have on the right to health

The areas of IP law and human rights have been addressed separately for a long period of time.³⁰⁴ International documents regulating IP law did not have reference to human rights norms, and vice-versa.³⁰⁵ This was so until the adoption of the UDHR and the ICESCR which both refer to the moral and material interests of the authors.³⁰⁶ After the human rights community noted the interplay between the TRIPS and human rights,³⁰⁷ subsequent declarations on the TRIPS, as well as numerous declarations on the interdependence of these two areas of law further developed the relationship between them. As Helfer eloquently put it, ‘human rights and intellectual property, two bodies of law that were once strangers are now becoming increasingly intimate bedfellows’.³⁰⁸

Helfer also points out two approaches to the relationship between these areas of law, the first one being the view that these two are in a ‘fundamental conflict’ and the second one seeing them as compatible, both dealing with the same fundamental concern of balancing the monopolies that give inventors incentives for further work, with the need of the public’s access to the inventions, often conflicting with where this balance should be struck.³⁰⁹ On my part, I agree with the second approach, but sometimes lean towards the first, especially when it comes to neglected diseases. It is my contention that while it is true that patents are needed for future incentives for R&D in the pharmaceutical sector, high prices of drugs as well as the direction of investment into R&D is in serious conflict with the right to access to medicines in developing countries. The reality is that the international patent system has ‘created wealth for as many as it has sparked outrage in others’.³¹⁰ The purpose of this Chapter is to present both sides’ arguments and to point to the direction in which the future negotiations should go. The subsequent Chapter then presents some concrete solutions.

4.1 The background and main developments concerning the conflict between access to medicines and pharmaceutical patents

The topic of the conflict between pharmaceutical patents and access to essential medicines, as stated before, emerged after the breakthrough discovery of HIV/AIDS medicines and their subsequent patent protection. It later intensified after the adoption of the TRIPS. Prior to the year 1995, when TRIPS entered into force, national authorities had a certain margin of appreciation when it came to adjusting their national IP norms to the socio-economic situation in their countries. By providing for the ‘minimal standards’ for IP protection, TRIPS turned the previously solely national rules ‘upside down’³¹¹ and transferred them to a global level, posing

³⁰⁴ L. Helfer, ‘Human Rights and Intellectual Property: Conflict or co-existence?’ (2004) 22 Neth. Q. Hum. Rts. at 167, pp. 169-70.

³⁰⁵ Ibid, p. 170.

³⁰⁶ UDHR, Art. 27(2); ICESCR, Art. 15(1).

³⁰⁷ Ibid, p. 171.

³⁰⁸ Ibid, p. 167.

³⁰⁹ Ibid, p. 168.

³¹⁰ E. Siew-Kuan NG, ‘Global health and development: Patents and Public Interest’, in Pogge et al. (eds.) (n142) at 101-32, p. 101.

³¹¹ Muzaka (n1), p. 60.

strict rules that need to be obeyed by States in relation to IP regulation, under the threat of enforcement and dispute settlement before the WTO bodies. This has, arguably, taken some autonomy from the Member States, because the TRIPS provides for the patent protection of all forms of technology, thereby not allowing the States to exclude something from patentability, like pharmaceuticals for example, which would, in their opinion, improve their development prospects.³¹²

The beginnings of the conflict between access to medicines and pharmaceutical patents have been described in the introductory chapter. Hence, I will now only reiterate the main points. After the discovery and subsequent patent protection of AZT (a drug that showed effectiveness in treating HIV/AIDS) in the 1980s, the NGOs and the public were dissatisfied with the high price for the treatment set by the pharmaceutical company owning the patent on the drug. Another significant development in the treatment of HIV/AIDS in 1996, namely the discovery of triple-drug combination therapy that was effective in suppressing HIV/AIDS, known as HAART (Highly Active Antiretroviral Therapy), brought this issue back into focus of the international community. It was stressed that where patients had access to this treatment there was a reduction in mortality, while the opposite was the case with those that had no access to the HAART regime.³¹³ It was the NGOs such as Oxfam, MSF, Treatment Action Campaign (TAC), HAI and Consumer Project on Technology (CPTech) that first made a connection between pharmaceutical patents and access to essential medicines and that warned the international community about the drawbacks this conflict will cause, especially in the developing countries.³¹⁴ 1997 was the year when the debate started to reach global perspectives. It is the year when the already mentioned SA Medicines Act was enacted, which provided that the Minister of health has the power to prescribe conditions for the supply of affordable essential medicines in order to protect public health, including compulsory licences and parallel imports.³¹⁵ In 1998, 40 pharmaceutical companies decided to sue SA for the alleged violation of the TRIPS and the SA Constitution.³¹⁶ This lawsuit turned out to be an ‘unmitigated disaster for the pharmaceutical industry.’³¹⁷ The media coverage was enormous, and the public outrage even bigger, with 300,000 people signing a petition for the withdrawal of the lawsuit. Again, NGOs played a crucial role, with TAC joining as *amicus curiae* in the case. Soon everyone was discussing the issue of access to medicines and pharmaceutical patents. In the end, due to the unbearable pressure and threat to their reputation, the industry decided to withdraw the lawsuit and to work with the Government of SA on the joint struggle to improve access to medicines in this country.³¹⁸

The HIV/AIDS pandemic may be the biggest, but certainly not the sole example of the conflict between pharmaceutical patents and access to medicines. Certain other medicines have also caused heated debate on this subject, such as Novartis’ cancer medicine *Glivec*, Gilead’s patented medicine against avian influenza called *Tamiflu*, and in my opinion, the most controversial case of the drug called *Cipro* patented by Bayer. The reason why I find this particular case so disturbing is the sudden shift in approach of the US regarding the price of

³¹² Report of the High Commissioner for Human Rights: The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights, E/CN.4/Sub.2/2001/13, 27 June 2001, para. 24.

³¹³ D. Matthews, ‘Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements’ (2011) Edward Edgar Publishing Limited, p. 26.

³¹⁴ Ibid; Hestermeyer (n1), pp. 5-6; Muzaka (n1), p. 76.

³¹⁵ See Hestermeyer (n1), p. 12.

³¹⁶ *PMA case* (n1).

³¹⁷ Hestermeyer (n1), p. 14.

³¹⁸ Helfer and Austin (n14), p. 157; Hestermeyer (n1), p. 14.

medicines and generic manufacturing. Namely, on 18 September 2001, the US was once again under a terrorist attack, and this time biological ‘weapons’ were used. Letters containing a deadly poison, Anthrax, were sent to a number of prominent persons in the US, and resulted in five deaths.³¹⁹ *Cipro*, a drug on which Bayer still had patent protection in the US, was the only existing treatment available. After heated negotiations with Bayer, and the threat of purchasing the generic version produced by the Indian generic company Cipla, Bayer agreed to drop the price from \$1.83 to \$0.95 per tablet.³²⁰ The sudden change of heart on the side of the US, one of the main proponents of stringent patent protection, is more than hypocritical. My question is: what is the difference between the five people who died in the US, and hundreds of millions of people dying every year in the developing world because they lack access to essential medicines?

Be that as it may, we should move on to the subsequent important developments for this topic. Apart from their enrolment in the SA trial, NGOs have constantly stressed the urgency of the problem of access to medicines. According to Muzaka, there were three routes used by the NGOs to warn the international community of the grave impact the TRIPS had on the right to access to medicines.³²¹ Initially, a line of networking went through the WHO and its Revised Drug Strategy of 1998, where they made sure that access to medicine was viewed as more important than trade.³²² This led to the WHA adopting the Resolution 52.19 in 1999, in which it noted that ‘that there are trade issues which require a public health perspective’ and urged Member States to ‘reaffirm their commitment of developing, implementing and monitoring national drug policies and to take all necessary concrete measures in order to ensure equitable access to essential drugs’, as well as to ‘ensure that public health interests are paramount in pharmaceutical and health policies’.³²³

The second route NGOs took was through the WTO and the Seattle Ministerial in 1999, which subsequently led to the adoption of the Doha Declaration. This Declaration was viewed as a victory for developing countries and NGOs fighting for the prevalence of human rights over trade concerns.³²⁴ Due to the fact that the TRIPS did not mention the right to health directly, although the connection could be inferred from two of its Articles,³²⁵ the NGOs tried to reach the WTO and put the issue of access to medicines and patents on the Seattle Ministerial Agenda through the Amsterdam Statement to WTO Member States on Access to Medicines.³²⁶ This Statement was adopted at a conference organized by HAI, MSF and CPTEch held in November 1999. The Statement pointed out that the market had failed to provide equitably priced medicines and ensure R&D for infectious diseases which are the main cause of 90 per cent of deaths in the developing world. Moreover, it stressed that a political action is necessary to address this issue and urged for the WTO to address the relation of health and IPRs at the WTO Seattle negotiations that were to take place just after this Conference. The WTO was also advised to establish a Standing Working Group on Access to Medicines, which would have a task of examining

³¹⁹ <http://www.fbi.gov/about-us/history/famous-cases/anthrax-amerithrax/amerithrax-investigation> (accessed on 17 May 2013).

³²⁰ Hestermeyer (n1), pp. 16-17.

³²¹ Muzaka (n1), p. 77.

³²² Ibid, p. 78.

³²³ WHA, Resolution WHA 52.19: ‘Revised Drug Strategy’, 24 May 1999.

³²⁴ P. Drahos, ‘Four Lessons for developing countries from the trade negotiations over access to medicines’ (2007) 28 *Liv. L. Rev.* at 11-39, Springer, p. 11.

³²⁵ TRIPS Agreement, Arts. 7 and 8.

³²⁶ HAI, MSF, and CPTEch, ‘The Amsterdam Statement to WTO Member States on Access to Medicines’ (1999) developed at the Increasing Access to Essential Drugs in a Globalised Economy Working Towards Solutions conference, 25-26 November 1999, available at: <http://www.cptech.org/ip/health/amsterdamstatement.html>.

important issues in relation to TRIPS, such as compulsory licensing of patents, exceptions to patent rights for the production of medicines intended for export to a country granted a compulsory license, assessing the impact of inadequate reviews of patentability standards on access to medicines and assessing practical burdens imposed on poor countries when administering patent systems. The drafters of the Statement also urged national governments to develop new and innovative approaches to stimulate R&D for neglected diseases.³²⁷ As already stated, the Seattle negotiations failed and the debate was resumed in Doha, where the final Declaration was drafted. Notwithstanding this victory, the subsequent negotiations leading to the 2003 Decision and 2005 Amendment were mostly led by the developed countries which watered down the wording of the Doha Declaration,³²⁸ and adopted a solution that is not quite right for the developing countries. This was perhaps down to the so-called ‘negotiation fatigue’ the developing countries were feeling,³²⁹ or the lack of a mutual goal all the developing states agreed upon, or possibly something else entirely. The concrete critique on these documents will be provided in the next Chapter.

Finally, the third road taken by the NGOs, as stated by Muzaka, was through human rights resolutions and reports adopted from 2000 until today.³³⁰ Most were already mentioned in Chapter 2, but for the sake of clarity, the most important may be the UN Millennium Development Goals, WHA Resolutions 54.11 and 55.14, Human Rights Council Resolution 6/29 on the Right of everyone to the enjoyment of the highest attainable standard of physical and mental health, Commission on Human Rights’ Resolution 2003/29 on Access to medication in the context of pandemics such as HIV/AIDS, tuberculosis and malaria and the numerous reports of the Special Rapporteur. However, the most important progress in this area was made through the Resolution 2000/7 on Intellectual Property and Human Rights in which it was noted that ‘there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other’.³³¹

4.2 Two sides of the argument: pharmaceutical industry vs. human rights activists

Throughout most of the events described above, the pharmaceutical industry and the human rights activists have had entirely opposing views on what the issue was in relation to the problem of access to essential medicines in developing countries. This section serves to present the main points of discord and contestations of both sides of the dispute. The views of the industry are mainly taken from the submissions of officials present at the negotiations surrounding the Doha Declaration and subsequent decisions, but they will also be taken from the views of some authors that support these arguments.

The main argument of the industry is that patents in no way present an obstacle for developing countries to ensure access to medicines to its citizens. Their view is that health care problems existed even before the IP protection on pharmaceutical products was introduced in the developing countries.³³² Therefore, the promotion of pharmaceutical innovation in the developing

³²⁷ Ibid.

³²⁸ Drahos (n324), p. 14.

³²⁹ Ibid, p. 26.

³³⁰ Muzaka (n1), p. 77.

³³¹ UN Sub-CommHR, Resolution 2000/7 ‘Intellectual Property and Human Rights’, 17 August 2000, para. 2.

³³² F. Rozanski, ‘Developing Countries and Pharmaceutical Intellectual Property Rights: Myths and Reality’ (2007) Stockholm Network, p. 4.

world cannot be achieved by undermining the IP system, since most of the problems in access to medicines in these countries are unrelated to patents.³³³ The real obstacle for access to medicines according to them is poverty,³³⁴ the origin of which are communities where hospitals usually do not even exist, where clinics are hours of walk away, and where millions die from diseases which are easily treatable, 'a world of child labour, child mortality and child soldiers, of a massive population explosion', where majority of the people do not have access to health care or cannot afford it.³³⁵ In the midst of the negotiations following the adoption of the Doha Declaration, a number of people from the industry circulated two studies in which they claimed that the real barriers for access to medicines in Africa are poverty and limited spending on health care, not patents.³³⁶ Furthermore, they allege that it is because of the 'fragility of the health systems',³³⁷ underdeveloped infrastructure, incorrect assignment of resources and corruption which results in poor funding, that people living in developing countries lack access to medicines.³³⁸ In order to establish a clearer understanding of the industry's view, I will quote a representative of the pharmaceutical industry's response to the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property's report, where it defined the barriers to access to medicines:

We do not believe that the main problem in barring medicines to the poor is patent protection, nor do we accept that individual company pricing practices are fundamental to explaining why one-third of the world's poor lack access to basic, low-cost essential medicines. An inaccurate and subjective link is forged between rights, 'monopoly' pricing, and global inequalities in access to medicines... We also believe that our private sector research model is worthy of preserving rather than abandoning on the risky premise that more public investment will by itself yield miracle cures against the complex scientific challenge of fighting resistant strains of infectious disease.³³⁹

No one denies the fact that poverty is one of the biggest problems in the developing world. But poverty does not erase the impact of patents on access to medicines. On the contrary, patents actually exacerbate the already unbearable situation of people living in developing countries. As pointed out in the third Chapter, people in these countries usually have to pay for the expensive patented medicines out of their own pockets, either because there is no generic version of the drug or it is unavailable, thereby requiring persons to expend money which would otherwise be used on food, housing and education.³⁴⁰ This leads to malnutrition and inadequate living conditions, which then leads back to illness. It is a vicious circle. On a legal note, in 2000, the already mentioned Resolution on Intellectual Property Rights and Human Rights was adopted. The drafters of the resolution took a critical approach to the TRIPS and pointed out that 'actual or potential conflicts exist between the implementation of the TRIPS Agreement and the realisation of economic, social and cultural rights'.³⁴¹ Also, the IP standards provided in the TRIPS are 'not necessarily appropriate for countries struggling to meet health and development

³³³ Ibid, p. 6; Pharmaceutical Patents Paper (n46), p. 11.

³³⁴ A. Attaran, 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?' (2004) *Health Affairs*, Volume 2i, Number 3, p. 156.

³³⁵ WHO Drug Information (n277), p. 221.

³³⁶ Muzaka (n1), p. 82.

³³⁷ Rozanski (n332), p. 7.

³³⁸ Ibid, p. 6.

³³⁹ MDG Report 2008 (n238) p. 136; Marks (n272), p. 83.

³⁴⁰ CIPR Report 2002 (n33), p. 36.

³⁴¹ Resolution 2000/7 (n331), Preamble and para. 2; *see also* Guidelines 2006 (n34), p. vii.

needs'.³⁴² This is due to their complexity and built-in barriers for export of essential medicines through compulsory licensing to countries with no manufacturing capacities.³⁴³ The Doha Declaration and subsequent decisions did have a positive outcome, but this is still not adequate enough to solve the problem of access to medicines caused by pharmaceutical patents.

The second argument of the pharmaceutical industry is that patent protection on existing medicines is of the utmost necessity for future incentives for R&D for new drugs. Only patent protection can enable the inventors to recoup their investment into the development of the medicines.³⁴⁴ From the trade law perspective, 'the issues of access to medicines is a clear cut matter of patenting of a new chemical product and the process for its use, as well as the protection of the patents involved in the markets where the producers intend to sell them'.³⁴⁵ Patent owners are protected against piracy or any illegal copying of their invention under the TRIPS, which provides them with the possibility of taking anyone in breach of the patents before the WTO DSB.

Patents are, without doubt, necessary for the pharmaceutical industry to recoup its investment and invest it back into the R&D of other drugs. However, patents are 'a means, not an end'.³⁴⁶ The problem with patents is that they, first and foremost, restrict competition, notwithstanding the anti-competition clauses provided in the IP legislation.³⁴⁷ This exclusion of generic companies serves the industry as a tool to increase prices of medicines, which then excludes poor segments of population from having access to them.³⁴⁸ The need for generic competition was stressed in the aforementioned *Astra Zeneca case* from 2005³⁴⁹, where, although the European Court did agree on the importance of strong IP protection so the industry can regain their investments, it also stated that 'competition from generic products after a patent has expired itself encourages innovation in pharmaceuticals'.³⁵⁰ The second problem with the stringent patent protection sought by the industry is that patents artificially inflate prices of medicines for a period of 20 years to allow the industry to maximize their revenues, which could be viewed as acceptable for the developed part of the world, where insurance regimes work, and public has, in general, access to essential medicines.³⁵¹ The situation in developing countries is entirely different. Here, prices do matter.³⁵² Pogge claims that 'allowing firms to make up for the costs of research' has the 'morally perverse effect on raising the prices of pharmaceuticals to a level where they become unaffordable to the poor'.³⁵³ Muzaka stresses the philosophical, economic and moral unjustifiableness of the situation where a selected few individuals are granted the 'privilege of harnessing most or all of the market value' for an invention, 'without guaranteeing that society at large has access to it on reasonable and affordable terms'.³⁵⁴ People living in poverty cannot afford high priced medicines, so most of the diseases effectively amount to a

³⁴² Guidelines 2006 (n34), p. vii.

³⁴³ TRIPS Agreement, Art. 31(f).

³⁴⁴ Muzaka (n1), p. 23.

³⁴⁵ Marks (n272), p. 83.

³⁴⁶ CIPIH Report 2006 (n27), p. x.

³⁴⁷ Joseph (n290), p. 360.

³⁴⁸ UN Special Rapporteur Report 2004 (n216), para. 43.

³⁴⁹ *Astra Zeneca case* (n77), Recital 116 of the Decision; Killick et al. (n62), p. 8.

³⁵⁰ Killick et al. (n62), p. 9; See Press Release IP/05/737 of 15 June 2005 (n80).

³⁵¹ Joseph (n290), p. 360; E. F. M. 't Hoen, 'TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond' (2003) available at: <http://www.who.int/intellectualproperty/topics/ip/tHoen.pdf>, p. 42.

³⁵² UN Millennium Project 2005 (n236), p. 17.

³⁵³ T. Pogge, 'Could Globalization be Good for World Health?' (2007) *Global Justice: Theory practice Rhetoric*, p. 1.

³⁵⁴ Muzaka (n1), p. 23.

‘death sentence’ for them, despite the fact that effective treatments do exist.³⁵⁵ People suffering from these diseases then often risk their economic security by buying these expensive drugs, and they mostly buy them instead of food, housing and education.³⁵⁶ Therefore, the WHO contends that Member States need to use the flexibilities provided in the TRIPS and ensure equitable access to medicines for all without discrimination of any kind.³⁵⁷

To this argument of the human rights proponents, the industry and those supporting its claim stipulate that, again, patents cannot be a barrier to access to medicines or to the generic competition, since only an insignificant number of medicines from the WHO Model List are in fact patentable.³⁵⁸ David Earnshaw from SmithKline Beecham phrased his views like this:

It is [also] claimed that relaxing patent law through a TRIPS review will miraculously promote equitable access to health care. It is difficult to understand why patents are seen as being such a problem. In reality, about ten of the 300 or so medicines on the WHO Model List of Essential Drugs are still under patent and, of these, all but one will be off patent within the next three years. If TRIPS is such a problem, and patents the root — or even sole — cause of the access problem, people in developing countries should today have unlimited and unhindered access to almost all the generic drugs on the WHO Model List. In practice, patents can be seen as creating a burden-sharing mechanism between rich and poor. Funding for research and development comes from current revenue derived principally from patented products. In reality, institutions and companies in the rich countries of the northern hemisphere carry the burden of paying for pharmaceutical innovation with the USA and Europe paying for probably 80% of innovation. I do not think anyone would seriously want that to change.³⁵⁹

The industry further claims that it has invested into the R&D at least three times more than telecommunications industry, four times more than the defence and all other industries, that without the productions of the research-based pharmaceutical companies there would be no medicines for HIV/AIDS, nor the improvements on existing medicines for which there has grown a resistance.³⁶⁰

Be that as it may, what about the R&D priority setting in the pharmaceutical industry? Here it should be stressed that, although pharmaceutical patents do stimulate R&D and discovery of new drugs, most of these incentives are directed towards diseases that are profitable for the industry. This neglect for the ‘unprofitable diseases’ mostly affecting the poor, together with the fact that most drugs are priced beyond the financial abilities of people living in developing countries, creates the so-called ‘global drug gap’.³⁶¹ The WHO has expressed its ‘increasing concern’ for the fact that R&D in the pharmaceutical industry ‘follows industrialized countries’ market demands’, and that tropical diseases and diseases affecting mostly the developing part of the world are neglected.³⁶² The crux of this problem, according to the industry, lies elsewhere. Most of the diseases that affect the poor can be treated with already available resources, if they

³⁵⁵ Joseph (n290), pp. 360-361.

³⁵⁶ UN Millennium Project 2005 (n236), p. 17.

³⁵⁷ WHO Drug Information (n277), p. 218.

³⁵⁸ Attaran (n334), p. 155-7.

³⁵⁹ WHO Drug Information (n277), p. 220.

³⁶⁰ UN Millennium Project 2005 (n236), p. 137; ‘t Hoen (n351), p. 55; F. M. Abbott, ‘The WTO Medicines Decision: World Pharmaceutical Trade and Protection of Public Health’ (2005) 99 AJIL at 317, p. 325.

³⁶¹ Helfer and Austin (n14), p. 92.

³⁶² WHO Drug Information (n277), p. 219.

are combined properly, and the only barrier is the allocation and division of the medicines to people who need them.³⁶³ Yet this does not explain the phenomenon of neglected diseases for which there is no treatment available, not even a combination of already existing drugs. Also, there is now a high prevalence of Multi-Drug Resistant (MDR) Tuberculosis, which is rapidly spreading through Eastern-Europe³⁶⁴, already having spread through Africa and other developing parts of the world, and it is just a matter of time as to when it will reach the Western-European states³⁶⁵, as was the case with Severe Acute Respiratory Syndrome (SARS) outbreak in 2003, which in a very short time spread from the Southern China to the rest of the world.³⁶⁶

The already available treatment for MDR-Tuberculosis does not work, because, as the name says, it has become resistant to the existing medicines. Also, it should be mentioned that the pharmaceutical industry has a widespread practice of patenting the so-called ‘me too’ drugs, also known as copycat drugs, which are basically a new drug, but very similar to one or more already existing drugs.³⁶⁷ They are new in a way that they differ from the previous version of the medicine just enough to be considered novel for the purposes of patent protection.³⁶⁸ They do not bring additional clinical benefits and ‘they lack innovation compared with existing therapeutic options’.³⁶⁹ They are usually used to extend patent protection for those drugs that are nearing the end of the 20 years protection. ‘Me too’ drugs need to pass all the stages of the R&D as the previous version of the drug, so the industry needs to invest a great amount of money into its development, thereby ‘divert[ing] R&D investment away from diseases with higher unmet needs’.³⁷⁰ They are usually priced the same or at a higher price as the drug that is already available on the market.³⁷¹ Muzaka also criticizes the fact that apart from their investments into the costly R&D process, the companies also spend considerable amounts on legal disputes over these drug modifications that are very frequent nowadays.³⁷² This money could be invested into research for new medicines for neglected diseases, but the ‘me-too’ drugs are apparently more profitable for the industry.

Finally, as for the flexibilities provided in the TRIPS, particularly the compulsory licensing, none of the actors in this dispute agree that they are a perfect solution to the problem. The industry claims that the new regime provided by the 2003 Decision goes beyond the scope of the TRIPS, and against the interest of the companies, which is unacceptable.³⁷³ On the other side, the human rights activists claim it is too burdensome and inapplicable in real life.³⁷⁴ The industry is mostly concerned about the generic competition coming from India and other developing countries with developed generic industry, since, according to them, the paragraph 6 system makes it too easy for these countries to export the generic drugs, thereby lowering the profit of

³⁶³ UN Millennium Project 2005 (n236), p. 138.

³⁶⁴ Ibid, p. 25-6.

³⁶⁵ http://www.who.int/tb/challenges/mdr/MDR_TB_FactSheet.pdf (accessed on 21 April 2013).

³⁶⁶ T. Pogge, ‘Human rights and global health: a research program’ (2005) 36 *Metaphil.* (1/2) at 182-209, p. 193.

³⁶⁷ Y. Zhang, *Encyclopaedia of Global Health* (2008) SAGE Publications, Inc., definition available at: <http://knowledge.sagepub.com.ludwig.lub.lu.se/view/globalhealth/n749.xml>.

³⁶⁸ Report of the High Commissioner for Human Rights (n312), para. 39.

³⁶⁹ S. Régnier, ‘What is the value of ‘me-too’ drugs?’ (2013) *Health Care Manag. Sci.*, available at: <http://link.springer.com.ludwig.lub.lu.se/content/pdf/10.1007%2Fs10729-013-9225-3.pdf>, pp. 1-3.

³⁷⁰ Ibid, p. 2; Muzaka (n1), p. 30.

³⁷¹ Muzaka (n1), p. 29.

³⁷² Ibid, p. 30.

³⁷³ Attaran (n334), p. 162.

³⁷⁴ Abbott (n360), p. 317.

the industry.³⁷⁵ Moreover, the International Federation of Pharmaceutical Manufacturers and Associations' (IFPMA) position on compulsory licensing is that '[c]ompulsory licensing is a threat to good public health by denying patients around the world the future benefits of R&D capabilities of the research-based industry from which new therapies come'.³⁷⁶ Their flaws aside, the rules on compulsory licensing as provided by the Doha Declaration and subsequent decisions are necessary for ensuring access to essential medicines. TRIPS had many obstacles in its compulsory licences regime, which most harshly affected the developing countries without manufacturing capacities. Something had to be changed, and the 2003 Decision provided this change. As rightly noted by 't Hoen, '[t]he very fact that public health and access to medicines have been singled out as major issues needing special attention in TRIPS implementation indicates that health care and health care products need to be treated differently from other products'.³⁷⁷ Another attempt by the industry to prevent the adoption of 2003 Decision was the claim that developing countries with manufacturing capacities, such as India and Brazil, would use the system to promote the export of 'lifestyle' drugs. However, it can be inferred from the texts of both the Doha Declaration and the 2003 Decision that these drugs are not covered by these documents, since they do not fall under the 'essential medicines' category, nor can hair loss or impotence be considered as 'public health crises'.³⁷⁸ During the negotiations, the developing countries suggested the inclusion of a negative provision ensuring that these drugs do not fall under the system, but the proposal was not adopted.³⁷⁹ More on compulsory licenses will be written in the subsequent chapter.

As can be seen from this section, this is a never-ending battle of arguments, they all have standing, but this standing can be easily lost. It is a matter of perspective. In the developed part of the world, patents are indispensable; they are of the utmost necessity for the discovery and production of new medicines, without which fighting diseases would be impossible. However, the situation in developing countries is completely different. The UN, the WHO and many other organizations have expressed their concerns about the TRIPS' 'one size fits all' approach to IP protection.³⁸⁰ This could be bypassed with the appropriate use of TRIPS flexibilities (which are not the perfect solution, but are still a solution). However, many developed countries simply do not allow others to use these flexibilities in their full extent, mostly through the 'TRIPS-plus' FTAs and through numerous judicial disputes whenever a country wants to implement these into its legislation. The situation in developing countries needs special attention from the international community. The next section will explain why.

4.3 The specific problems faced by the developing countries in relation to access to essential medicines

The population of developing countries reached 4.8 billion in 2008, which represents 80% of the world's population, and is rapidly growing each year.³⁸¹ Out of these 4.8 billion people,

³⁷⁵ Drahos (n324), p. 20.

³⁷⁶ 't Hoen (n351), p. 55.

³⁷⁷ Ibid, p. 61.

³⁷⁸ See e.g. Doha Declaration, paras. 1 and 5 (c); 2003 Decision, 1 (a).

³⁷⁹ Abbott (n360), p. 328.

³⁸⁰ UN Millennium Project 2005 (n236), p. 69.

³⁸¹ WHA, Resolution WHA 61.21: 'Global strategy and plan of action on public health, innovation and intellectual property', 24 May 2008 [WHA Res. 61.21], Annex, para. 2.

almost 2 billion do not have access to essential medicines.³⁸² More than 10 million people die each year from infectious diseases, and 90 per cent of these deaths occur in the developing countries. The high prices of medicines generated by stringent patent protection, along with the pressures exerted by industrialized countries and pharmaceutical companies on those developing countries that try to improve access to medicines for their populations, provide no help in alleviating these sufferings.³⁸³ This pressure is usually manifested through legal disputes concerning legislation that is designed to improve access to medicines, as was the case with the SA and Brazilian disputes already mentioned, and FTAs, which usually include the 'TRIPS-plus' provisions that strengthen IP protection even more.³⁸⁴ To make things worse, although the burden of the diseases in developing countries rises up to 90 per cent, only 10 per cent of global R&D is invested into the diseases that affect the poor. This is called the 90/10 gap.³⁸⁵ Barriers to access to medicines in developing countries are numerous, from underdeveloped health care systems, through corruption and poverty in general, as shown in the previous section, but high prices of medicines generated by patents and the course in which the R&D for new drugs is directed remain the biggest ones.

The TRIPS, by imposing the minimum standards of IP protection, has worsened the situation in developing countries, which, before the adoption of the Agreement, have not provided for patent protection of pharmaceuticals. The territorial limitation for compulsory licensing provided by the TRIPS made it impossible for countries without manufacturing capacities to import cheap versions of medicines through this flexibility. Concerns were raised about the 'one size fits all' approach of the TRIPS, since it 'leads to unjust and burdensome outcomes for countries that are struggling to meet the most basic needs of their citizens'.³⁸⁶ In this regard, the Doha Declaration and subsequent decisions present a crucial development for the developing countries. Although the system has been used only once so far (in 2007 by Rwanda and Canada), the fact that the territorial barrier was overcome and the goal of providing a possibility for accessing cheaper medicines has been reached, at least on paper, shows the readiness of the international community to tackle the problems developing world is facing.³⁸⁷ The Geneva Declaration on the Future of WIPO from 2004 stressed that '[d]eveloping countries must have the tools to implement the WTO Doha Declaration on TRIPS and Public Health, and "use, to the full" the flexibilities in the TRIPS to "promote access to medicines for all"'.³⁸⁸ However, in 2005, India, the biggest generic producer of medicines, had to introduce patents on pharmaceuticals, which has resulted in the unavailability of cheap generic versions of newly discovered medicines necessary for the treatment of most infectious diseases affecting developing countries.³⁸⁹ Recently, at the opening session of the UN Economic and Social Council in 2007, the UN Secretary-General, Mr. Ban Ki-moon, stated that '[t]he rules of intellectual property

³⁸² UN Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, 'Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines', A/63/263, Annex, 11 August 2008, Preamble(a), p. 15 [Guidelines for Pharmaceutical Companies]; Pogge (n267), p. 2.

³⁸³ 't Hoen (n351), p. 40; Matthews (n313), p. 25.

³⁸⁴ Helfer and Austin (n14), pp. 40, 124-5.

³⁸⁵ Pogge et al. (eds.) (n142), p. 4.

³⁸⁶ Geneva Declaration on the Future of WIPO (2004) available at: <http://www.cptech.org/ip/wipo/futureofwipodeclaration.pdf>, p. 2; Siew-Kuan NG (n310), p. 107; Helfer and Austin (n14), p. 40.

³⁸⁷ See Abbott (n360), p. 343.

³⁸⁸ Geneva Declaration on the Future of WIPO 2004 (n386), p. 3.

³⁸⁹ Abbott (n360), p. 321; Pogge et al. (eds.) (n142), p. 6; Pogge (n267), p. 3.

rights need to be reformed, so as to strengthen technological progress and to ensure that the poor have better access to new technologies and products.³⁹⁰ The Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) stated that:

[i]n the developing world, where the market has very limited purchasing power, as is the case for diseases affecting millions of poor people in developing countries, patents are not a relevant factor or effective in stimulating R&D and bringing new products to market. Moreover, because most poor people in developing countries have to meet the cost of treatments from their own very limited disposable income, in contrast to people in most developed countries where governments and private or government insurance schemes play a major role, any impact that patents or indeed other policies may have on prices paid need to be carefully considered.³⁹¹

The HIV/AIDS pandemic represents one of the greatest challenges for the developing countries. In 2011, 34 million people were living with HIV/AIDS, and 1.7 million people, both adults and children, died from it. Most of these people live in the developing world.³⁹² HIV/AIDS not only takes lives, but it also affects all aspects of development. Households with members affected with this disease suffer from a decrease in income, children are being brought up without parental support, without the possibility to pursue education due to the high costs of the treatment, and it is said that this disease might ‘push additional 6 million households into poverty by 2015’ unless something is done to address the problem.³⁹³ Moreover, all public sectors, such as agriculture, business and education, are affected due to the lack of workers and lower productivity.³⁹⁴ All the while, the prices of the medicines necessary for the treatment of this disease serve to make them unavailable and unaffordable for most of those affected.³⁹⁵ In recent years, the awareness of the international community of the sufferings of people living with HIV/AIDS has grown considerably, and there now exist numerous international organizations and NGOs that are addressing this issue. The most important organizations that are helping fight this disease on a global level are the Joint United Nations Programme on HIV/AIDS (UNAIDS), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the WHO, which has a Department on HIV/AIDS.³⁹⁶ Alongside regional and national NGOs that are fighting for the same cause, they have invested considerable effort and funding into helping get the problem solved and improving the lives of those living with HIV/AIDS. We can now say that, although at the beginning HIV/AIDS was considered as a neglected disease, today it has attracted numerous investments for R&D of medicines³⁹⁷ and there now exists a necessary treatment for this deadly disease. However, as already pointed out in this thesis, the fact that the medicines are available does not necessarily mean that they are accessible to everyone. Although the number of people affected with HIV/AIDS in developing countries is constantly rising, most of these people are not

³⁹⁰ UNCTAD, ‘The Least Developed Countries Report 2007’, UN Doc. UNCTAD/LDC/2007, available at: http://unctad.org/en/docs/ldc2007_en.pdf, p. 100.

³⁹¹ CIPRH Report 2006 (n27), p. 22.

³⁹² <http://www.unaids.org/en/dataanalysis/datatools/aidsinfo/> (accessed on 21 April 2013); *See also* Helfer and Austin (n14), p. 94.

³⁹³ Austin and Helfer (n14), p. 93.

³⁹⁴ Report of the High Commissioner for Human Rights (n312), para. 45.

³⁹⁵ *Ibid*, para. 44.

³⁹⁶ *See* Helfer and Austin (n14), pp. 96-7.

³⁹⁷ *Ibid*, p. 93.

receiving adequate treatment.³⁹⁸ It is both due to patent protection and consequent high prices of these medicines, together with their bad disposition, that they remain unavailable for the poor.

Two more issues are particularly affecting the developing countries, namely the problem with neglected diseases and counterfeit drugs. The next sections will address these problems.

4.3.1 Neglected diseases

A major problem in the developing countries is the issue of neglected diseases. Here, the impact of pharmaceutical patents monopolies, or more precisely, the direction of R&D for new drugs, is the most visible. Unlike the 'usual' lack of essential medicines, in the case of neglected diseases, there are no drugs that are to be accessed.³⁹⁹ The reason for this is that only 10 per cent of pharmaceutical R&D is focused on developing drugs for diseases that affect 90 per cent of the global burden of disease, the so-called '10/90 gap'.⁴⁰⁰ Medicines for these diseases are simply of very little interest for the industry, since it cannot gain enough profit from their sales, or recoup the investments made into their discovery and development. It is so because the market for these medicines is either too small or too poor.⁴⁰¹ The updated statistics show that out of 1556 new drugs developed from 1974 to 2004, only around 1% (10 drugs) was specifically indicated for neglected diseases.⁴⁰²

Neglected diseases can be defined as those diseases for which there are no adequate, effective or any means at all to prevent, diagnose or cure them.⁴⁰³ Also known as tropical or poverty-related diseases, they affect mostly the poor, living in low-income countries, especially in rural areas.⁴⁰⁴ They belong to the Type II (neglected) diseases which are 'incident in both rich and poor countries, but with a substantial proportion of the cases in poor countries' and Type III (very neglected) diseases, which are 'overwhelmingly or exclusively incident in developing countries'⁴⁰⁵, and include, *inter alia*, Chagas disease, leprosy, leishmaniasis, onchocerciasis (river blindness), African trypanosomiasis (sleeping sickness) and dengue.⁴⁰⁶ The WHO has drafted a non-exhaustive list of about 14 diseases that fall within this group in 2007⁴⁰⁷, and today this list includes a total of 17 diseases.⁴⁰⁸ Until recently, HIV/AIDS, malaria and tuberculosis have also been included as Type II diseases. However, since they now attract considerable attention and investments from various actors, they are not considered as neglected as other tropical diseases,

³⁹⁸ Ibid, p. 94.

³⁹⁹ I. Lasic, 'Pharmaceutical Patents and Access to Essential Medicines: The conflict' (2012), unpublished exam paper in the course JAMR26 Human Rights Perspectives on Intellectual Property Law, Master Programme in International Human Rights Law at Lund University [Pharmaceutical Patents and Access to Medicines Paper], p. 18.

⁴⁰⁰ Pogge et al. (eds.) (n142), p. 4.

⁴⁰¹ UN Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt, 'Neglected Diseases, Social Justice and Human Rights: Some Preliminary Observations' (2003) Health and Human Rights Working Paper Series No. 4 [Neglected Diseases Report], p. 7; Hunt (n250), p. 38.

⁴⁰² B. Stirner, 'Stimulating Research and Development of Pharmaceutical Products for Neglected Diseases' (2008) 15 EJHL at 391-409, p. 394; *See also* Hunt (n250), p. 38.

⁴⁰³ CIPR Report 2006 (n27), p. 194.

⁴⁰⁴ Neglected Diseases Report (n401), p. 5; Hunt (n250), p. 1; *see also* Pogge et al. (eds.) (n142), pp. 4-5.

⁴⁰⁵ CIPR Report 2006 (n27), p. 13; *See also* Helfer and Austin (n14), p. 141.

⁴⁰⁶ Hunt (n250), p. 3.

⁴⁰⁷ WHO, 'Global Plan to Combat Neglected Tropical Diseases, 2008-2015' (2007) WHO/CDS/NTD/2007.3, available at: http://whqlibdoc.who.int/hq/2007/who_cds_ntd_2007.3_eng.pdf, p. 2; *See also* Stirner (n402), p. 393.

⁴⁰⁸ http://www.who.int/neglected_diseases/diseases/en/ (accessed on 22 April 2013).

although a certain degree of effort is still needed in developing countries to enable access to medicines for these diseases as well.⁴⁰⁹

Neglected diseases share seven common features according to the WHO: they are a ‘proxy for poverty and disadvantage’; they ‘affect populations with low visibility and little political voice’; they do not spread to the high-income countries since they are climate bound; they cause stigma and discrimination, especially among the most vulnerable members of the society; they have an important impact on morbidity and mortality; and are relatively neglected by research.⁴¹⁰ From a human rights standpoint, these diseases are both the cause and the consequence of human rights violations.⁴¹¹ Looking at them from the consequence perspective, we can see that they mostly appear in countries where human rights are systemically violated, where people are usually denied their basic human rights to health, housing, water, education and participation.⁴¹² From the cause perspective, people living with these diseases are subjected to discrimination in the everyday aspects of life such as work, privacy, education and enjoyment of the benefits of scientific progress, apart from the obvious violations of the rights to life and health.⁴¹³ In developing countries, some neglected diseases such as leishmaniasis and leprosy are ‘a source of fears, stereotypes and prejudices’, mostly because these diseases cause severe changes in physical appearance as well as disabilities.⁴¹⁴ The special needs of vulnerable and high-risk groups were addressed at the Alma-Ata Conference, where it was recommended that high priority in health care should be given to people belonging to these groups.⁴¹⁵

As noted above, the direction which pharmaceutical innovation is taking is towards the development of medicines for diseases that are ‘profitable’ and thus are a secure investment for the industry. The pharmaceutical industry directs its investments ‘where money can be made with sufficient probability’ and what is really attractive and profitable are the so-called ‘life-style drugs’ for impotence, hair loss, obesity and other non-communicable and non-life-threatening diseases.⁴¹⁶ Sometimes, even when medicines for neglected diseases are developed or are at the final stage of development, they may not go to the stage of production if they are not considered profitable.⁴¹⁷ The major pharmaceutical companies are situated in the US, Germany, Japan and Switzerland and they derive 80 per cent of their profits from sales in these countries. Linked to this, these countries earn considerable amounts of money from rents paid by the manufacturers for the exploitation of pharmaceutical patents. The money earned by both of these actors can be used to cover the existing R&D costs as well as promotion of future R&D for medicines for neglected diseases.⁴¹⁸ This was also affirmed by the Special Rapporteur, who stressed that ‘[i]n the field of essential medicines, states have a responsibility to ensure that patent protections of pharmaceutical products do not make these medicines inaccessible, on account of high prices charged by pharmaceutical companies’ and recommended that they could fund and provide

⁴⁰⁹ Guidelines for Pharmaceutical Companies (n382), Preamble (r); Stirner (n402), p. 392, footnote 4.

⁴¹⁰ WHO, ‘Global Plan to Combat Neglected Tropical Diseases, 2008-2015’ (n407), p. 5; *See also* Hunt (n401), p. 4; Stirner (n402), pp. 393-4; Pharmaceutical Patents and Access to Medicines Paper (n399), p. 16.

⁴¹¹ Hunt (n250), p. 3.

⁴¹² *Ibid*, pp. 1 and 3.

⁴¹³ *Ibid*, p. 3; Pharmaceutical Patents and Access to Medicines Paper (n399), p. 17.

⁴¹⁴ Hunt (n250), pp. 23-4.

⁴¹⁵ Alma-Ata Declaration (n202), Recommendation 8.

⁴¹⁶ Hestermeyer (n1), pp. 160 and 162; J. Drews, ‘Drug Research: Between Ethical Demands and Economic Constraints’, in M. A. Santoro and T. M. Gorrie (eds.), *Ethics and the Pharmaceutical Industry* (2005) CUP at 21, p. 28.

⁴¹⁷ UN Millennium Project 2005 (n236), p. 61.

⁴¹⁸ Abbott (n360), p. 324; Hestermeyer (n1), pp. 161-2.

incentives for R&D for both the public and private sector through tax credits, patents, subventions and grants.⁴¹⁹ As for the pharmaceutical industry, in his Human Rights Guidelines for Pharmaceutical Companies, he advised the companies to ‘make a public commitment’ to contribute to R&D for neglected diseases and to either provide ‘in-house’ R&D for these diseases, or support ‘external’ R&D for them, or both.⁴²⁰ Furthermore, he noted that they should consult with the WHO, the WHA and other leading international organizations and initiatives in order to improve their contribution to R&D, which should be publicly disclosed.⁴²¹

The Special Rapporteur finally noted that ‘[t]here is no “universal checklist” of who is vulnerable in a given society’⁴²², and Pogge stressed the special status of pharmaceutical patents and their relation with neglected diseases by saying that:

[i]t may be acceptable that no one is developing software demanded only by a few and that no one is producing music valued only by the very poor. But it is morally problematic that few treatments are developed for rare diseases, and it is extremely problematic, morally, that so few treatments are developed for medical conditions that cause most of the premature deaths and suffering in the world today.⁴²³

Today, even though they are climate-bound, the diseases that only affect the poor can be easily transmitted to the developed part of the world and because of the neglect of the needs of people affected by these diseases, the developed world will be caught unprepared for tackling them.⁴²⁴ As we have seen from the Anthrax scare in the US, the developed world quickly changes its position when its own populations are at stake. Perhaps the fact that their own populations may one day require medicines for combating tropical diseases could engender a change in perspective and make them invest more into the R&D for tropical diseases. When all the stages of R&D are complete, and the medicines are available, the matter of their accessibility in developing countries could be tackled with fewer difficulties.

4.3.2 Counterfeit Drugs

Although there exist numerous definitions of counterfeit drugs, the WHO defines them as those that are ‘deliberately and fraudulently mislabelled with respect to identity and/or source’.⁴²⁵ Counterfeit drugs ‘may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging’.⁴²⁶

Apart from neglected diseases, the issue of counterfeit drugs presents one of the biggest problems the developing countries are facing. Poverty, lack of essential medicines and their high prices are the main reasons why the production of counterfeit drugs has proliferated in developing countries, and why the availability of these drugs has ‘reached a disturbing proportion’.⁴²⁷ As previously stated, in addition to being made readily available, affordable and accessible, essential medicines must be of good quality and safe for the patient.⁴²⁸ Counterfeit

⁴¹⁹ Hunt (n250), pp. 12 and 38.

⁴²⁰ Guidelines for Pharmaceutical Companies (n382), para. 23.

⁴²¹ Ibid, paras. 23-5; Pharmaceutical Patents and Access to Medicines Paper (n399), p. 19.

⁴²² Hunt (n250), p. 16.

⁴²³ Pogge (n353), pp. 6-7.

⁴²⁴ Ibid, p. 9.

⁴²⁵ <http://www.who.int/medicines/services/counterfeit/overview/en/index.html> (accessed on 22 April 2013).

⁴²⁶ Ibid.

⁴²⁷ CIPIH Report 2006 (n27), p. 105.

⁴²⁸ CESCR GC No. 14, para. 12.

drugs do not meet any of those conditions. These drugs present an immense threat to the lives and health of those who purchase and use them.

Apart from these dangers, the use of poor quality medicines may result in loss of work and income because of death of a family member, disability or extended duration of the disease.⁴²⁹ Moreover, these drugs also contribute to the development of resistance to anti-infectives and waste the already scarce resources of people living in developing countries.⁴³⁰ The WHO Medicines Strategy 2008-2013 stressed that, although it is impossible to give exact information on the extent of the problem with counterfeit drugs, the number of cases where counterfeit drugs were involved in 2007 has increased to over 1500, which is more than four cases each day.⁴³¹ However, the true prevalence of the problem is still unknown, because, according to the WHO, no global action has been conducted yet.⁴³²

The reasons why counterfeit drugs find their way into the markets of both developed and developing countries are numerous, extending from the unwillingness of states to investigate and punish those who commit this crime, corruption, absence of or weak drug regulation, to lack of appropriate drug legislation.⁴³³ However, the WHO has identified one more reason which is of importance for this thesis. Namely, it has identified high drug prices as one of the factors that encourage drug counterfeiting.⁴³⁴ Because drug prices are high, people, in developing countries especially, will seek for a cheaper variant if it is available on the market, without thinking of the consequences. Due to the sheer scale of the problem, the WHO has decided to launch the International Medical Products Anti-Counterfeiting Task Force (IMPACT) in 2006, comprised of all the major actors concerned, including NGOs and associations representing pharmaceutical manufacturers, with the aim of putting an end to counterfeiting medical products around the world.⁴³⁵

Besides the devastating impact on the right to life and health of people, counterfeit drugs also have an impact on the pharmaceutical industry. Because of the similarities in packaging and labelling, these drugs are usually associated with the real manufacturer and that puts the industry's reputation at risk. Not only will patients lose the confidence in the original medicines from the manufacturer whose drugs have been counterfeited, but the industry may also face litigation where it has to prove it had nothing to do with the counterfeiting. Therefore, the industry needs to work with the states to combat the problem of counterfeit drugs, for its own sake and for the sake of people using their products.

The CIPIH Report has noted that there is 'growing awareness of the problem posed by counterfeit medicines, although the full extent is not well understood because of a lack of data'.⁴³⁶ The WHO has identified a number of routes that need to be taken to combat counterfeit medicines, both on the national and international levels. They mainly consist of enactment of appropriate drug legislations, training personnel for national drug control, making judicial action more effective in processing cases of counterfeit drugs and spreading awareness of the problem

⁴²⁹ CIPIH Report 2006 (n27), p. 105.

⁴³⁰ UN Millennium Project 2005 (n236), p. 13.

⁴³¹ WHO Medicines Strategy 2008-2013 (n271), p. 12.

⁴³² <http://www.who.int/medicines/services/counterfeit/overview/en/index.html> (accessed on 22 April 2013).

⁴³³ Ibid.

⁴³⁴ Ibid.

⁴³⁵ WHO Medicines Strategy 2008-2013 (n271), p. 13.

⁴³⁶ CIPIH Report 2006 (n27), p. 106; *see also* WHO General information on counterfeit medicines, available at: <http://www.who.int/medicines/services/counterfeit/overview/en/index.html> (accessed on 22 April 2013).

to the general public.⁴³⁷ Finally, the WHO has adopted Guidelines for the development of measures to combat counterfeit drugs in 1999, which are to be referred to in order to effectively combat counterfeiting of medicines.⁴³⁸

4.4 Conclusion

As can be seen from this Chapter, there are many obstacles to access to medicines in the developing countries other than patents⁴³⁹, and although most of the medicines needed to cure diseases in the LDCs are not under patent protection⁴⁴⁰, patents remain the biggest reasons why prices of medicines are artificially inflated and the main barrier to access to medicines. Moreover, these countries are not affected only by the ‘diseases of the poor’, but also by cancer, diabetes, cardiovascular diseases, asthma which also cause unbearable suffering and deaths, and ‘newer, more effective treatments for these conditions are often patented and will be patented in the future’.⁴⁴¹ As Bill Gates said to the WHA in 2005:

Political systems in rich countries work well to fuel research and fund health care delivery, but only for their own citizens. The market works well in driving the private sector to conduct research and deliver interventions, but only for people who can pay. Unfortunately, the political and market conditions that drive high quality health care in the developed world are almost entirely absent in the rest of the world. We have to make these forces work better for the world’s poorest people.⁴⁴²

The world needs a coordinated action from all the relevant actors in order to improve access to safe and affordable essential medicines for all.

⁴³⁷ <http://www.who.int/medicines/services/counterfeit/overview/en/index1.html> (accessed on 22 April 2013).

⁴³⁸ WHO Guidelines for the development of measures to combat counterfeit drugs (1999) WHO/EDM/QSM/99.1, available at: http://whqlibdoc.who.int/hq/1999/WHO_EDM_QSM_99.1.pdf.

⁴³⁹ ‘t Hoen (n351), p. 42; UN Special Rapporteur Report 2008 (n214), para. 43; Marks (n272), p. 82.

⁴⁴⁰ Abbott (n360), pp. 322-3.

⁴⁴¹ Ibid, p. 323.

⁴⁴² CIPHI Report 2006 (n27), p. 172.

5. Finding balance and possible solutions

One might ask whether a balance between the right to health and pharmaceutical patents should be sought at all. If the right to health is a fundamental human right necessary for the enjoyment of all other human rights, do we really need to balance it against other ‘trivial’ and less important trade norms? The answer is yes. Although the right to health is of the utmost importance, it still has to make some way for the innovators to protect their viable interests in the form of patented medicines and through them, their livelihood. Of course, this balance has to be carefully assessed. The pharmaceutical industry, with a few exceptions, has so far been, in my opinion, too greedy in trying to make the patent protection even more stringent, no matter the costs. This is in contradiction with the TRIPS, which they consider their most powerful weapon in pursuing their profit-driven interests. Namely, as already stated, even the TRIPS in its Article 7 stresses the need of balancing the needs of producers and users of technological knowledge, ‘in a manner conducive to social and economic welfare’, while Article 8 allows Member States to ‘adopt measures necessary to protect public health and nutrition’.⁴⁴³

However, this never-ending battle is far from lost. Apart from the existing solutions to the problem, some of course better than others (some proposed by the WTO itself), we can see the emergence of possible solutions proposed by distinguished scholars who have invested their time, effort and knowledge into conceptualizing them. Moreover, there already exist some examples of ‘good practices’ conducted by large pharmaceutical companies in collaboration with NGOs and PPPs, which are doing a great job in enabling better access to medicines. Whether these proposed solutions will get the chance to be materialized and become a reality for those who desperately need a long-term solution remains to be decided by the international community. I will now present some of the solutions that are most likely to succeed, while at the same time providing some critique on the existing ones.

5.1 Existing solutions

This section provides an insight into some existing solutions for the resolution of the pharmaceutical patents-access to medicines conflict. Some of these are praised as great solutions, while others are unfairly set aside because they do not support the interests of the high-profile players, although they are of same quality, if not better. I will start with the solution that acquired the most attention from the international community, namely the TRIPS flexibilities in the form of compulsory licenses and the Article 30 solution (which was neither upheld nor declined). Then I will proceed with the generic industry alternative, which is not acceptable for the industry, at least not during the term of patent protection.

5.1.1 Article 30 solution and compulsory licensing- the TRIPS flexibilities

The TRIPS, as already noted, provides for the minimum standard of IP protection that is obligatory for all Member States. Although in a couple of Articles it does take into account certain aspects that could be viewed as reference to human rights⁴⁴⁴, it cannot be said that it ‘takes a human right approach to intellectual property protection’, but that it is trying to strike a balance between these sets of rights.⁴⁴⁵ If it succeeded then it would become another issue

⁴⁴³ See Report of the High Commissioner (n394), paras. 16-19.

⁴⁴⁴ TRIPS Agreement, Arts. 7 and 8.

⁴⁴⁵ See Report of the High Commissioner (n394), para. 21.

altogether. Even though it provides for certain flexibilities in its implementation, one cannot overlook the fact that it only speaks of IP *rights*, and in very much detail, but only ‘alludes’ to the responsibilities of the right bearers.⁴⁴⁶

Notwithstanding this criticism, the TRIPS, together with the subsequent declarations on compulsory licensing does provide for flexibilities that can and should be used by developing countries. I will here present two such flexibilities, namely the ones provided in Articles 30 and 31 of the Agreement, along with a few remarks on the actual prospect of their implementation in practice.

5.1.1.1 Article 30 Solution

Article 30 of the TRIPS provides for exceptions to the rights conferred upon the patent holder, and stipulates 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.

There is no official interpretation of what these limited exceptions may be, but many propositions have been given during the negotiations leading to the 2003 Decision. A number of NGOs have campaigned for an Article 30 solution to the ‘Paragraph 6’ problem. Their view of this solution was that it was administratively simple, workable and economically viable.⁴⁴⁷ This was also upheld by the WHO and many developing countries because it would be much easier for the exporting country not to go through the burdensome compulsory licence procedure if the medicines were not patented in the importing country. However, if the patent existed in the country of destination, then the compulsory licensing system would apply.⁴⁴⁸

Article 30 provides for limited exceptions which apply without the authorization of the patent holder, which is deducted from the title of Article 31.⁴⁴⁹ This Article provides for at least two kinds of exemptions: the ‘research exemption’, which allows researchers to use the patented invention for further research, and the ‘regulatory exception’, which allows generic manufacturers to use the patented invention to obtain the necessary marketing approval without the permission of the patent holder, before the patent protection expires.⁴⁵⁰ This solution would, therefore, authorize generic companies to produce and export patented medicines to the LDCs affected by a public health crisis, thereby circumventing the patent protection of the medicines in the exporting country.⁴⁵¹ The use of Article 30 exceptions was addressed in the *Canada-Patent Protection of Pharmaceutical Products* dispute⁴⁵², where the DSU Panel adopted a very narrow definition of ‘limited exceptions’.⁴⁵³ This was criticized by Hestermeyer who said that the Panel

⁴⁴⁶ Ibid, para. 23.

⁴⁴⁷ t Hoen (n351), p. 59.

⁴⁴⁸ Abbott (n360), p. 339.

⁴⁴⁹ Hestermeyer (n1), p. 234; TRIPS Agreement, Art. 31 (*‘Other Use Without Authorization of the Right Holder’*).

⁴⁵⁰ K. Paas, ‘Compulsory licensing under the TRIPS Agreement - a cruel taunt for developing countries?’ (2009) 31(12) EIPR at 609-13, p. 3.

⁴⁵¹ Ibid, p. 3; I. Lasic, ‘*De lege ferenda* – Article 31(f) of the TRIPS Agreement and subsequent WTO Declarations regarding Compulsory Licences’ (2013) unpublished exam paper in the course JAMR 16 Legal Writing and Research, Master Programme in International Human Rights Law at Lund University [De Lege Ferenda Paper], p. 3.

⁴⁵² *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (2000) WTO, available at: http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf.

⁴⁵³ Ibid, para. 7.27 ff; Hestermeyer (n1), p. 235.

should not have used the ‘dictionary definition of “limited” as “confined within limits”’, but ‘taking account of both Articles 7, 8 of the TRIPS Agreement and the right to access to medicine, [should have] allowed exceptions that are narrowly tailored to achieve the purposes laid down in Articles 7 and 8’.⁴⁵⁴ Be that as it may, due to the vague wording of the Article and the interpretation of the Panel, this solution was not upheld at the negotiations. From the perspective of the patent holders, this solution was simply not acceptable as it did not provide ‘adequate procedural safeguards or respect for the patent holder interests’.⁴⁵⁵ This was maintained by the developed countries where most of the industry is based, so that, in the end, an Article 31 approach was adopted, while at the same time, nothing was said about relinquishing the use of Article 30 flexibilities if needed, for exports to the non-WTO Members, which were not covered in the final Decision.⁴⁵⁶

5.1.1.2 Compulsory licensing

Another flexibility provided by the TRIPS is the possibility of compulsory licensing stipulated in Article 31. As already mentioned, due to a territorial barrier in paragraph F of the Article, negotiations were held in 2001, which resulted in the adoption of the Doha Declaration. The Declaration recognized in paragraph 6 that the members with no manufacturing capacities could face difficulties in using the flexibility provided in Article 31, and called for the Council for TRIPS to find an expeditious solution to the problem no later than the end of 2002. The result proved to be not ‘expeditious’ at all⁴⁵⁷ and only partly a solution.⁴⁵⁸

The Council for TRIPS did break the time frame provided in the Doha Declaration, but a ‘paragraph 6’ decision was adopted in 2003. Unlike the Doha Declaration, which was praised as a victory of the developing countries, the 2003 Decision was a watered down solution that benefited the needs of the industry.⁴⁵⁹ At first glance, the Decision seems like a legitimate solution to the problem posed by the paragraph F. But if one examines in more detail the provisions of the Decision, he will encounter quite a few obstacles and difficulties which Member states will face when trying to implement this system in practice.⁴⁶⁰

First and foremost, the procedure for granting the license is too burdensome and complicated for both the exporting and importing countries.⁴⁶¹ The exporting country needs to issue a compulsory license in order to export the medicines to the importing country facing a public health crisis. If, however, the drug is patented in the importing country as well, the importing member has to issue a second compulsory licence.⁴⁶² The requirements that need to be met by both the importing and exporting country are enumerated in paragraph 2 of the 2003 Decision, which is attached to the thesis. However, one problem appears to be the most burdensome, and that is the fact that the whole system is based on a ‘drug-by-drug, country-by-

⁴⁵⁴ Hestermeyer (n1), p. 236.

⁴⁵⁵ Abbott (n360), p. 339; Paas (n450), p. 3.

⁴⁵⁶ Abbott (n360), p. 340.

⁴⁵⁷ Paas (n450), p. 5.

⁴⁵⁸ De Lege Ferenda Paper (n451), p. 6; *See also* MSF, ‘Neither Expeditious, Nor a Solution: The WTO August 30th Decision is Unworkable’ (2006), available at: http://www.msffaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_NeitherExpeditiousNorSolution_WTO_ENG_2006.pdf.

⁴⁵⁹ Drahos (n324), p. 14.

⁴⁶⁰ De Lege Ferenda Paper (n451), p. 6.

⁴⁶¹ UN Millennium Project 2005 (n236), p. 6.

⁴⁶² Paas (n450), p. 4; De Lege Ferenda Paper (n451), p. 6.

country and case-by-case decision-making'⁴⁶³, and the Decision does not take into account the uncertainty of most of the health crises. It is overly complicated for both the importing and exporting country to repeat the whole process again, when, for example, the designated amount of medicines produced under the licence, proves to be insufficient.⁴⁶⁴

Furthermore, some States and NGOs have expressed their concerns about the 'scope of the diseases' covered by both the Declaration and the 2003 Decision, because it states that it recognizes '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*'.⁴⁶⁵ Abbott pointed out this problem, saying that this may be seen as limiting the 'scope of the disease' covered by the documents and that there was no reason for the drafters to distinguish these epidemics and other 'common diseases' such as cancer and asthma because they affect people in developing countries as well as the infectious diseases, and the need for the medicine is the same.⁴⁶⁶ There is also a problem with the vagueness in the wording of paragraphs 4 and 5 of the Decision, dealing with the prohibition of re-exportation of cheaper medicines back to the developed countries, and the assessment of manufacturing capacities in the pharmaceutical sector provided in the Annex of the Decision. Concrete interpretation on the part of the WTO is needed in order to make the rules more clear.⁴⁶⁷ Finally, I would like to point out two more problems that arise from both the 2003 Decision and 2005 Amendment. First, these instruments only pertain to WTO Member States, thereby excluding some of the LDCs in the world such as Somalia, Eritrea and South Sudan, which have no means to import the generic drugs without violating the IP rights owned by the pharmaceutical companies.⁴⁶⁸ Second, the TRIPS is to be amended when two thirds of the WTO Members have ratified the Article 31 waiver.⁴⁶⁹ The first deadline for this was 1 December 2007, but it is currently extended for the third time until 2013.⁴⁷⁰ Until the conclusion of this thesis, only 45 States (including the EU) have accepted the Amendment, the last acceptance dating 31 July 2012.⁴⁷¹ This cannot be seen as an expeditious solution to the problems identified in the Doha Declaration.

In conclusion, putting aside all of the criticism, compulsory licenses, if used in non-discriminative ways, and if some changes and clarifications are made, may promote access to medicines. As noted by Hestermeyer, they may be used not only as a remedy for the unwillingness of the patent holder to supply a market with his invention, but also as a sort of a threat used by governments when they need the industry to lower the prices of medicines, as was the case with the US Government and Bayer during the Anthrax scare.⁴⁷² They were also used in this manner by Brazil and Thailand, in order to get discounted prices on patented medicines, which resulted in their population having affordable medicines.⁴⁷³ When the Brazilian President was asked to justify these actions, he claimed that 'he was not willing to sacrifice the health of his country's citizens for the sake of world trade'.⁴⁷⁴ This is a good example of the value of

⁴⁶³ Paas (n450), p. 4.

⁴⁶⁴ De Lege Ferenda Paper (n451), p. 7; Pogge et al. (eds.) (n142), p. 70.

⁴⁶⁵ Doha Declaration, para. 1 (*emphasis added*); 2003 Decision, para. 1.

⁴⁶⁶ See Abbott (n360), p. 328.

⁴⁶⁷ De Lege Ferenda Paper (n451), p. 7.

⁴⁶⁸ Ibid, p. 8.

⁴⁶⁹ WTO, Members accepting amendment of the TRIPS Agreement (n141).

⁴⁷⁰ WTO, Third Extension WT/L/829, 5 December 2011 (n143).

⁴⁷¹ http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed on 15 May 2013).

⁴⁷² Hestermeyer (n1), pp. 240-1.

⁴⁷³ See Helfer and Austin (n14), pp. 127-34.

⁴⁷⁴ Ibid, p. 132.

compulsory licences, since Brazil managed to improve the enjoyment of the right to health of its citizens through the enactment of compulsory licensing legislation, even without issuing a single licence.⁴⁷⁵ As already stated, the 2003 system was used only once by Rwanda and Canada, since the developing countries are not enthusiastic about using it as they fear that they might ‘scare off’ future investments that could be made by the industry.⁴⁷⁶ However, they are a valuable tool. Although the Brazilian legislation was adopted before the 2003 system came into force, and although the 2003 Decision was implemented in only a few other countries, it does not mean that it will not bring improvement to access to medicines in the future. Until that happens, I believe that Article 30 solution should be revisited, if only as an alternative to the compulsory licensing.

5.1.3 Generic Competition alternative

Generic pharmaceutical competition has from its inception helped to bring down the prices of overly expensive patented medicines.⁴⁷⁷ A generic drug is defined by the WHO as ‘a pharmaceutical product, usually intended to be interchangeable with an innovator product, that is manufactured without a licence from the innovator company and marketed after the expiry date of the patent or other exclusive rights’.⁴⁷⁸ They are usually of the same effect as the patented medicines, but are provided at a significantly lower cost.

Until 2005, the supply of the developing countries’ markets with essential medicines was mainly done with the help of generic companies from India and other countries with generic manufacturing capacities. However, since 2005 this is no longer a possibility as these countries are under an obligation to provide for the patent protection of pharmaceuticals.⁴⁷⁹ Today the supply of the markets of developing countries with generics is mainly, although very rarely, done through compulsory licensing. Developed countries, most notably the US, have invested all of their efforts into preventing countries like SA and Brazil in improving access to medicines for their citizens through legislation that allows generic manufacturing and compulsory licensing through disputes before the WTO DSU. Although most of these disputes were resolved through settlement, they have undoubtedly slowed down the process of implementation of the contested legislation, while at the same time served as a sort of warning to other countries that may desire to improve their generic manufacturing capacities, that they should proceed with such policies only with great caution.

It has been acknowledged that most of the essential medicines are now off patent and are available for generic production. Thus, the developing countries have been encouraged to produce the generic versions of these drugs in large quantities in order to ensure a better supply of their markets.⁴⁸⁰ Generic versions of drugs have been proven to lower prices of medicines whose patent terms have expired.⁴⁸¹ But this is applicable only to off-patent drugs. The problem today is achieving a breakthrough concerning drugs for newly discovered diseases that are spreading very fast. There is no generic competition for these medicines, and therefore the prices of patented medicines are rapidly rising.⁴⁸² This is the reason why generic companies need to invest into their own R&D structures. As for the already patented drugs and those that will be

⁴⁷⁵ Report of the High Commissioner (n312), paras. 55-7.

⁴⁷⁶ Joseph (n290), p. 362.

⁴⁷⁷ Siew-Kuan NG (n310), p. 117.

⁴⁷⁸ <http://www.who.int/trade/glossary/story034/en/> (accessed on 23 April 2013).

⁴⁷⁹ Abbott (n360), p. 321; Pogge et al. (eds.) (n142), p. 6; Pogge (n267), p. 3.

⁴⁸⁰ Siew-Kuan NG (n310), p. 115.

⁴⁸¹ CIPIH Report 2006 (n27), p. 112.

⁴⁸² Siew-Kuan NG (n310), p. 117.

patented in the future, the WHO is in favour of “early workings” of patented drugs by generic manufacturers to encourage competition as a way of improving these products and providing early access to generic essential drugs’.⁴⁸³ The UN Millennium Project also expressed the need for the identification and adoption of strategies permitting ‘continued production and supply of low-cost generic medicines for poor populations after January 2005’ and encouraged exporting countries to adopt policies which should favour international competition in the pharmaceutical field.⁴⁸⁴ The fast introduction of generic medicines is also allowed by the TRIPS through the ‘Bolar clause’, which could be subsumed under the Article 30 solution mentioned above. The Bolar clause, or the Bolar exemption, allows for the introduction of a generic drug immediately after the patent term has expired, by allowing ‘technical preparation for registration of the same medicine from an alternative source before the patent has expired’.⁴⁸⁵ This solution was upheld by the High Commissioner, who encouraged States to implement legislation allowing early testing and approval of generic drugs before patent expiry.⁴⁸⁶ Finally, the pharmaceutical companies could consider allowing generic manufacturing of the new essential medicines only for the developing countries’ markets. This could be done through special agreements with the generic industry that would serve to safeguard the generic medicines leaking into developed countries’ markets, as an alternative to differential pricing schemes that will be discussed below. This may be a long shot, but it is worth a try.

5.2 Possible solutions

The previous section has introduced the already existing solutions to the problem of access to medicines in developing countries. As well framed as they are, these solutions have not provided any significant improvements in this area. This is the reason why many organizations and scholars have invested a lot of effort into discovering alternative solutions that could be acceptable for both sides. I will first present the solution of price reductions for the developing countries - which has been highly contested by the industry - which could provide significant improvement in access to medicines, if applied correctly. Afterwards, I will present a potentially excellent solution developed by a team of distinguished professors, which includes, amongst others, Professors Thomas Pogge, Michael Abramowicz and James Love. This is followed by the proposal for the industry to work on their CSR schemes in order to improve their compliance with human rights law.

5.2.1 Price reductions (differential pricing schemes) for poor countries vs. parallel imports

Differential or preferential pricing schemes (DP), where pharmaceutical companies agree to sell their products for lower prices in developing countries⁴⁸⁷, have been proposed on many occasions as a solution to the conflict between access to medicines and pharmaceutical patents. It was stated by the WHO that preferential pricing is ‘essential for lower income countries and must be actively pursued’.⁴⁸⁸ Since prices are the greatest impediment to access to medicines, if the drugs were to be offered at a lower price, this problem would be greatly alleviated. This concept

⁴⁸³ MDG Report 2008 (n238), p. 219.

⁴⁸⁴ UN Millennium Project 2005 (n236), p. 18.

⁴⁸⁵ Ibid, p. 69.

⁴⁸⁶ Report of the High Commissioner (n312), paras. 48 and 57.

⁴⁸⁷ Ibid, para. 47.

⁴⁸⁸ WHO Drug Information (n277), p. 219.

has its roots in the concept of equity pricing introduced by the WHO in the late 1990s, which was based on the premise that ‘developing countries should not be asked to pay for medicine development cost, marketing, and shareholders return’, and was a much broader concept than DP.⁴⁸⁹ DP is the result of 30 years of successful practice of the concept of equity pricing.⁴⁹⁰ It means that the pharmaceutical industry should offer the medicines at production cost- ‘no profit to loss’ - to the low-income countries, and pursue this system in middle-income countries, with prices there not at marginal costs, but slightly higher.⁴⁹¹ Examples of DF strategies were given by the CIPIH and they include, *inter alia*, discounts for certain categories of customers, setting the prices of patented medicines according to the generic equivalents, issuing voluntary licenses to generic manufacturers in developing countries for the production of medicines, drug donation programmes etc.⁴⁹²

However, DP opens up the door to the anti-competition practice of parallel imports⁴⁹³, viewed by the pharmaceutical industry as breaching their IPRs. They contest that, if they were to offer medicines under lower prices in developing countries, these cheaper medicines might appear in the markets of developed countries, thereby undermining their companies’ interests.⁴⁹⁴ Pogge argues that DP solution is ‘generally unworkable unless the different categories of buyers can be prevented from knowing about, or from trading with, one another’.⁴⁹⁵

In order to get to the bottom of the issue of parallel imports, we need to address the doctrine of exhaustion, or the ‘first sale doctrine’.⁴⁹⁶ This doctrine provides that ‘where a patented product is placed on the market by the patent holder or with its consent, the patent holder has exhausted its patent rights and the buyer of the product is free to resell the product as it wishes’.⁴⁹⁷ Hereby, both the interests of the patent holder and the buyer are satisfied. There is no problem with this doctrine when it comes to national exhaustion, meaning when the patent owner has exhausted its rights and the product is available on the national market.⁴⁹⁸ However, there is great controversy when it comes to international exhaustion.⁴⁹⁹ The issue with international exhaustion is whether the TRIPS ‘provide[s] 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 its consent (parallel import)?’.⁵⁰⁰ The WTO decided that it is upon each Member to decide whether it will apply the national or the international doctrine of exhaustion.⁵⁰¹ The TRIPS itself is ambiguous on this, stating that nothing in the Agreement ‘shall be used to address the issue of the exhaustion of intellectual property rights’⁵⁰² and consequently leaving the option of which doctrine to use to the Members of the WTO, subject to the most-favoured nation clause and the national treatment provision.⁵⁰³ According to the UK Commission on Intellectual Property Rights

⁴⁸⁹ UN Millennium Project 2005 (n236), p. 67.

⁴⁹⁰ Ibid, pp. 67-8.

⁴⁹¹ Ibid, p. 68.

⁴⁹² CIPR Report 2002 (n33), pp. 121-3.

⁴⁹³ Siew-Kuan NG (n310), p. 118.

⁴⁹⁴ Pogge (n353), p. 4.

⁴⁹⁵ Pogge (n366), p. 187.

⁴⁹⁶ Hestermeyer (n1), p. 68.

⁴⁹⁷ Ibid, p. 229.

⁴⁹⁸ Helfer and Austin (n14), p. 121.

⁴⁹⁹ Hestermeyer (n1), p. 68; Helfer and Austin (n14), p. 121.

⁵⁰⁰ Hestermeyer (n1), pp. 230-1.

⁵⁰¹ Doha Declaration, para. 5(d); Helfer and Austin (n14), p. 122.

⁵⁰² TRIPS Agreement, Art. 6.

⁵⁰³ Siew-Kuan NG (n310), p. 118; Doha Declaration, para. 5(d).

(CIPR), in order for the DP system to succeed, the markets of developed and developing countries need to be segmented ‘to prevent low priced products undermining high priced markets’ and recommended that

[d]eveloped countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries. However, to secure the segmentation of markets, it would also be desirable for developing countries to act to prevent exports to developed countries of drugs that are part of a donation or differential pricing scheme. It is especially important to avoid product diversion from those patients for whom the medicine is intended. But, recognising limitations in their capacity for enforcement, the primary burden of segmentation between developed and developing countries will realistically need to rest with developed countries.⁵⁰⁴

As for the developing countries, CIPR concluded that they ‘should not eliminate potential sources of low cost imports from other developing or developed countries’ and that ‘[s]ince TRIPS allows countries to design their own exhaustion of rights regimes (a point restated at Doha), developing countries should aim to facilitate parallel imports in their legislation.’⁵⁰⁵ The use of the doctrine of international exhaustion was also upheld by the High Commissioner.⁵⁰⁶ I believe this solution is a good one, but needs to be approached with caution and with a sensible and practicable plan on how to prevent smuggling the cheap drugs into the developed countries.

5.2.2 The Health Impact Fund

The Health Impact Fund (HIF) is a project which was devised by Professor Michael Abramowicz in 2003 and later developed through contributions of many distinguished professors, including Thomas Pogge, James Love, Tim Hubbard and Aidan Hollis.⁵⁰⁷ Concerned with the situation in the developing countries, where people live in hazardous environmental conditions which lead to the poor bearing a ‘hugely disproportionate burden of disease ... and a hugely disproportionate share of premature deaths’⁵⁰⁸, these distinguished professors decided to come up with a solution which would ensure access to medicines and better pharmaceutical innovation at much lower cost.

According to Pogge, who has written extensively on this subject⁵⁰⁹, pharmaceutical patents are necessary for the industry to protect itself from competition and illegal copying and a way for it to recoup its investments into R&D for the drugs, but ‘not everyone is either affluent enough to buy advanced medicines at very high prices or fortunate enough to need them only after patent expiration’.⁵¹⁰ He identified the ‘main drawbacks of the newly globalized patent regime’ as high prices of medicines, neglect of R&D for diseases affecting the poor, bias towards maintenance drugs (the drugs that improve the lives and functioning of the patient without

⁵⁰⁴ CIPR Report 2002 (n33), pp. 41-2.

⁵⁰⁵ Ibid, p. 42.

⁵⁰⁶ Report of the High Commissioner (n394), para. 66.

⁵⁰⁷ <http://healthimpactfund.com/origin/> (accessed on 24 April 2013).

⁵⁰⁸ T. Pogge, ‘The Health Impact Fund: better pharmaceutical innovations at much lower prices’, in Pogge et al. (eds.) (n142) at 135-54, p. 135.

⁵⁰⁹ E.g. A. Hollis and T. Pogge. ‘The Health Impact Fund: Making New Medicines Accessible for All’ (2008) Oslo and New Haven: Incentives for Global Health; T. Pogge, ‘The Health Impact Fund: More justice and efficiency in global health’ (2011) Crawford School of Economic and Government, Discussion Paper 7; T. Pogge (n366); Pogge (n267), pp. 8-10.

⁵¹⁰ Pogge (n508), p. 137.

removing the disease), wasting money on expensive litigation and patent filing in numerous jurisdictions, counterfeiting, excessive marketing and weak infrastructure in the developing countries.⁵¹¹ These impediments to access to medicines should be viewed and dealt with as a whole.

Pogge also reminds that, notwithstanding their moral appeal, compulsory licenses may be counterproductive, since they are ‘energetically resented’ by the industry, and governments do not want to use them so lightly, because they might ignite this resentment and be censured and sued by the companies and the developed countries opposing the system.⁵¹²

Therefore, a system where affordable medicines are available for both the developing and developed part of the world, and where R&D costs are funded by the government, needed to be constructed.⁵¹³ There are two ways of enabling public funds, and they are known as ‘push’ and ‘pull’ mechanisms. Unlike the push mechanism, where money is given by the government to an institution, usually universities, which is to discover and develop a new medicine, pull mechanisms are based on a sort of a competition, where a number of inventors engage in the R&D of a drug, and the one that comes with the best invention first is granted public financing.⁵¹⁴ According to Pogge, the latter is much better, since it is not based solely on trust for one particular institution, and if this institution fails to produce the medicine, all the financing is wasted.⁵¹⁵ However, even the pull mechanisms have drawbacks, including the highly politicized process of deciding which diseases should be researched, and the possibility that they will fail in addressing the fourth drawback of the patent regime- the weak infrastructure in the developing countries, also known as ‘the last mile problem’.⁵¹⁶

Therefore, a number of experts sat down, and designed a system that would overcome all of these barriers mentioned above- the Health Impact Fund. HIF is conceived of as a system that is to be financed by governments, which offers patent holders the possibility to opt for a reward, instead of monopoly pricing, based on the global impact the newly discovered medicine has on health. The medicine would be registered at the Fund and sold at marginal costs globally. According to the success the medicine in alleviating suffering and addressing public needs in both developed and developing countries, the Fund would distribute money allocated for this proportionately. The fund would have at its disposition a large sum of money, which would reach as much as \$6 billion annually.⁵¹⁷ It would reward ‘any successful medicine in proportion to its success’, while this success will be defined ‘simply in terms of human health’.⁵¹⁸ The most important aspect of the system is that HIF is designed to be optional for the industry, which can opt for the traditional patent system if it wishes.⁵¹⁹ The system has its benefits for patients in both rich and poor countries, since it ‘directs research toward the medicines that can do the most good’.⁵²⁰ From the perspective of pharmaceutical companies, by using the HIF, they will avoid the reduction of profits connected to the increased access to medicines in developing countries.

⁵¹¹ Ibid, pp. 139-42.

⁵¹² Ibid, pp. 142-3.

⁵¹³ Ibid, p. 146.

⁵¹⁴ F. Mueller-Langer, ‘Neglected infectious diseases: Are push and pull incentive mechanisms suitable for promoting drug development research?’ (2013) HEPL Volume 8, Issue 02 at 185-208, pp. 188 and 191.

⁵¹⁵ Pogge (n508), pp. 146-7; See also Marks (n272), p. 92.

⁵¹⁶ Pogge (n508), pp. 147-8.

⁵¹⁷ The Health Impact Fund: A cost-effective, feasible plan for improving human health worldwide, available at: <http://healthimpactfund.com/wp-content/uploads/2012/11/HIFshort.pdf>, p. 1.

⁵¹⁸ Pogge (n508), p. 149 (*emphasis in the original*).

⁵¹⁹ Ibid, p. 151.

⁵²⁰ The Health Impact Fund: A cost-effective, feasible plan for improving human health worldwide (n517), p. 1.

Instead, they will have the possibility to even gain additional profits by developing new drugs for neglected diseases. They will also improve their reputation, since they will not have to defend their monopoly status, or be forced to donate to charity. They will simply ‘do well by doing good’.⁵²¹ In the end, since the funds for the HIF are to be allocated through government support, which is usually done through taxes, the taxpayers will benefit from the system, as they will have access to low-cost medicines developed through it.⁵²² Other obstacles to access to medicines would be overcome too, such as counterfeiting, since it will not be profitable anymore to those who engage in these activities, as cheap medicines will already be available, while the industry will also stop spending so much money on expensive litigation and patent registrations.⁵²³

Finally, this system could be used not only to promote inventions in the pharmaceutical field, but also for other inventive ways to lower the burden of the disease in the developing countries, like water-cleaning systems which would enable access to safe drinking water, adequate sanitation and nutrition possibilities, providing mosquito nets and other physical protections against animal-transmitted diseases, and many others.⁵²⁴ Although some scholars have criticized this solution⁵²⁵, I believe it is a viable one, and the most likely to succeed in improving access to affordable essential medicines in developing countries. Therefore, all efforts should be invested into making this system work as it is designed, because none of the already existing ones have been so thoroughly researched and conceptualized. The drafters of the system have already established the next steps that need to be taken and how that should be done.⁵²⁶

5.2.3 Good corporate citizenship- Implementation of CSR policies to improve access to medicines

The implementation of CSR policies into business operations of pharmaceutical companies is not a solution to the problem of access to medicines *per se*, but merely a good start, since it shows that the company has committed itself to respecting human rights. Today, it is not possible to ‘operate a business globally while remaining totally aloof from social issues around it’.⁵²⁷ Although CSR is not enforceable, it is a proof that companies do care about human rights and are aware of their social responsibilities to both shareholders and stakeholders. Apart from that, it is great for the reputation of the company, since, by implementing CSR policies into their business, they will escape condemnation of the public, which can harm the reputation of the company severely. In this section, I will not address the issue of responsibility of businesses for respecting human rights in general, because that topic would entail a thesis of its own, but will only present the general framework of CSR, implemented in pharmaceutical industry.

The former Special Rapporteur, Paul Hunt, has issued numerous reports and recommendations on how pharmaceutical companies should conduct their business in a manner supportive of the human right to health. In 2008, he visited the headquarters of GSK and issued a report reflecting on this visit.⁵²⁸ In the report he reminded that the Special Representative of the

⁵²¹ Ibid, p. 2.

⁵²² Ibid.

⁵²³ Pogge (n508), p. 152.

⁵²⁴ Ibid, p. 153.

⁵²⁵ E.g. Kathleen Liddell, ‘The Health Impact Fund: a critique, in Pogge et al. (eds.) (n142) at 155-80.

⁵²⁶ <http://healthimpactfund.com/next-steps/> (accessed on 24 April 2013).

⁵²⁷ Siew-Kuan NG (n310), p. 125.

⁵²⁸ UN HRC, Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Paul Hunt: Annex: mission to GlaxoSmithKline, A/HRC/11/12/Add.2, 18 May 2009 [GSK Report 2009].

Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie, observed that '[c]ompanies need to adopt a human rights policy' and that '[b]road aspirational language may be used to describe respect for human rights, but more detailed guidance in specific functional areas is necessary to give those commitments meaning'.⁵²⁹

In his report, Hunt commended the GSK's Corporate Responsibility Report from 2007, but raised concern about the fact that the subsequent Report from 2008 did not include the same commitment in the form of an approach called 'Tearing down the barriers' which concerned marketing medicines in middle-income countries.⁵³⁰ This approach was evaluated as 'a promising initiative with the potential of enhancing access to medicines for many people'.⁵³¹ He also said that GSK 'deserves credit for significantly reducing some of its prices ... and enhancing access to medicines', but again raised concerns about the prices of a few medicines that 'remain beyond the reach of many millions of people for whom the medicine is literally a matter of life and death', like *Cervarix*, a drug for the treatment of cervical cancer, whose price remains at \$300, which is too high for people in developing countries.⁵³² GSK was also praised for using of commercial and non-commercial voluntary licences and its recent announcement on patent pooling, but was instructed to improve its use of voluntary licensing.⁵³³ Finally, the Special Rapporteur concluded that:

The status of innovator companies would be immeasurably enhanced if they did not see, and treat, patents as their "crown jewels". Companies must grasp, and publicly recognize, their critically important social function and right-to-health responsibilities. They must demonstrably do everything possible, within a viable business model, to fulfil their social function and human rights responsibilities. Presently, this is not happening. If it were to happen, it would not only greatly enhance companies' status but also pressurize States, generic manufacturers and others to provide the environment that companies need if they are to enter into arrangements, such as commercial voluntary licences, that enhance access to medicines for all.⁵³⁴

Not long after the Special Rapporteur conducted the interviews and his mission in GSK, the company announced a number of important improvements to its access to medicines strategy, including significant price reductions in the LDCs, and in April 2009, in association with Pfizer announced their intention to jointly create a new company for the discovery and delivery of treatments for HIV.⁵³⁵ This is just one example on how CSR policies can improve the reputation of a pharmaceutical company, whose predecessors, not long before the Report was drafted, were amongst the 40 companies that jointly sued SA for trying to improve access to medicines of its people.⁵³⁶

⁵²⁹ Ibid, para. 7; UN HRC, 'Protect, respect and remedy: a framework for business and human rights', Report of the Special Representative of the Secretary-General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie, A/HRC/8/5, 7 April 2008, para. 60.

⁵³⁰ GSK Report (n528), para. 61.

⁵³¹ Ibid, para. 64.

⁵³² Ibid, paras. 65-6.

⁵³³ Ibid, paras. 78-9.

⁵³⁴ Ibid, para. 108.

⁵³⁵ Ibid, para. 44.

⁵³⁶ Ibid, para. 54.

5.3 Good Practices

GSK is not a lonely example of good corporate governance in the pharmaceutical industry. The IFPMA has highlighted the significant contributions of ten largest pharmaceutical companies to health-related programmes in LDCs.⁵³⁷ Moreover, in 2008 and 2010, the Access to Medicine Index compared the efforts of 20 large drug companies in relation to access to medicines, and ranked them according to the assessment of their public policy influence and advocacy, pricing, patents and licensing, and donation programmes.⁵³⁸ In 2008, GSK was ranked first and was followed by NovoNordisk, Merck & Co., and Novartis. The ones that were ranked the lowest were: Pfizer, Wyeth, Teva Pharmaceutical, and Schering-Plough. In 2010, Gilead Sciences replaced NovoNordisk in the top four, and Merck KGaA, Takeda Pharmaceutical, Astellas Pharma, and Daiichi Sankyo Co were the bottom-ranked companies.⁵³⁹

However, it is not the companies that invest the most effort into ensuring access to medicines. NGOs, PPPs and numerous initiatives on neglected diseases are those that should be thanked for the improvement of the situation in developing countries. The numerous NGOs were already mentioned throughout the thesis, but I will briefly mention them again. MSF, HAI, CPTech, Oxfam, as well as numerous national and regional organizations have put all of their efforts into improving access of people in developing countries to affordable essential medicines and joined developing countries in their fights against pharmaceutical companies and stringent patent protection. The efforts of numerous international organizations should also not be disregarded. The WHO, WTO, UNAIDS, the Global Fund to Fight AIDS, Tuberculosis, and Malaria and many others, have significantly contributed to the fight for better access to medicines.⁵⁴⁰ I will use this section to introduce a few bilateral donors, PPPs and initiatives that ensured that the problem of access to medicines and pharmaceutical patents came to light and stayed in the spotlight for years.

Donor programmes have always been an indispensable source when it came to funding of health sectors in developing countries and enabling better access to essential medicines. Numerous developed countries' institutions have formed donor programmes in order to help improve health care in developing countries. Some of the most successful ones are the Swedish International Development Cooperation Agency (Sida), the Danish International Development Agency (Danida), the UK Department for International Development (DFID) and the US Agency for International Development (USAID).⁵⁴¹ Private donors that have had an outstanding impact on access to medicines are the Bill and Melinda Gates Foundation, the William J. Clinton Foundation, the Rockefeller Foundation, and many others.⁵⁴² Together with the public donors they have formed numerous PPPs that help supply the markets of developing countries with essential medicines and in general, improve the health situation in these countries. The WHO has praised the PPPs for their 'innovative service delivery strategies and positive consequences for national public health programmes'.⁵⁴³ One example of a good PPP is that of DHL and the UN

⁵³⁷ Siew-Kuan NG (n310), p. 126;

⁵³⁸ P. Hunt and R. Khosla, 'Are Drug Companies Living Up to Their Human Rights Responsibilities? The Perspective of the Former United Nations Special Rapporteur (2002-2008)' (2010) PLoS Medicine Vol. 7, Issue 9, p. 2.

⁵³⁹ Ibid.

⁵⁴⁰ See UN Millennium Project 2005 (n236), pp. 42-5.

⁵⁴¹ Ibid, pp. 45-6.

⁵⁴² Ibid, pp. 46-7.

⁵⁴³ WHO, 'Public-Private Partnerships: Managing contracting arrangements to strengthen the Reproductive and Child Health Programme in India: Lessons and implications from three case studies' (2007) WHO/RHR/07.15,

Children's Fund (UNICEF), which partnered up 'to reduce childhood mortality in Kenya' by providing logistics expertise, transportation of bed nets and vaccines.⁵⁴⁴

In the area of neglected diseases, there exist numerous initiatives and programmes that deal with the problem of neglect of pharmaceutical R&D for tropical diseases, such as the Special Programme for Research and Training in Tropical Diseases, which focuses on 'neglected infectious diseases that disproportionately affect poor and marginalized populations'.⁵⁴⁵ Moreover, the Institute for One World Health is currently developing new, affordable medicines for these diseases.⁵⁴⁶ There is also the Drugs for Neglected Diseases Initiative (DNDi) that concentrates mainly on sleeping sickness, leishmaniasis, malaria and Chagas disease. The goal of DNDi, as is that of almost all the initiatives, is to 'mobilize the public sector in developing countries to conduct R&D on neglected diseases'.⁵⁴⁷

As can be seen from this brief overview of good practices conducted by all the stakeholders in the access to medicines-pharmaceutical patents debate, there exists public awareness of the severity of the problem, and many are organizing themselves to address it the best way that they can. We can only hope that these collaborations and efforts will not remain a dead letter, but will develop into productive schemes that will help millions of people enjoy their human right to health in its full extent.

5.4 Conclusion and some recommendations

This Chapter has presented the existing and possible solutions to the problem of access to medicines in developing countries, and it can be deducted from it that there is prospect of improving this access on various levels. Health is a universal public good, and the enjoyment of the right to the highest attainable standard of health can only be ensured through international cooperation and transfer of technology. The TRIPS itself stipulates the importance of cooperation between developed and developing countries and encourages the developed part of the world to provide technical and financial assistance to the developing countries and LDCs.⁵⁴⁸

On a national level, the countries need to draft a national health plan, which would be used to improve the health care systems in these countries and include the needs of all levels of the population, the diseases that are the most pressing and distribution of essential medicines.⁵⁴⁹ The most important principle that developing countries need to have in mind is the principle of non-retrogression, meaning that the already achieved levels of access to medicines and enjoyment of the right to health cannot be diminished.⁵⁵⁰

The WHO summarised the problem of access to medicines the following way:

Too often, manufacturers who should be working to reduce prices are busy blaming unreliable supply systems; policy-makers in a position to influence drug financing

available at: http://whqlibdoc.who.int/hq/2007/WHO_RHR_07.15_eng.pdf, p. 1; UN Millennium Project 2005 (n236), p. 59.

⁵⁴⁴ K. Hayford, L. Privor-Dumm and O. Levine, 'Improving Access to Essential Medicines Through Public-Private Partnerships' (2011) International Vaccine Access Center (IVAC), p. 10-11; *see also* USAID Deliver Project at <http://deliver.jsi.com/dhome> (accessed on 25 April 2013).

⁵⁴⁵ CIPIH Report 2006 (n27), p. 71, Box 3.1; <http://www.who.int/tdr/en/> (accessed on 25 April 2013).

⁵⁴⁶ CIPIH Report 2006 (n27), p. 72, Box 3.2; <http://www.oneworldhealth.org/> (accessed on 25 April 2013).

⁵⁴⁷ CIPIH Report 2006 (n27), p. 76, Box 3.5; <http://www.dndi.org/> (accessed on 25 April 2013).

⁵⁴⁸ TRIPS Agreement, Arts. 66 and 67.

⁵⁴⁹ Alma-Ata Declaration (n202); CESC GC No. 14, para. 63; Clapham et al (eds.) (n183), pp. 45, 52; *Minister of Health v. TAC* (n245), para. 68 et al.; UN Special Rapporteur Report 2004 (n216), para. 53 et al.

⁵⁵⁰ CESC GC No. 14, para. 32.

are busy blaming high prices; and health care managers who could improve supply systems are busy blaming inadequate financing. Instead, all parties should work toward a common solution.⁵⁵¹

The former Special Rapporteur, Paul Hunt stressed that enhancing access to medicines is a shared responsibility, and that MDGs recognized that pharmaceutical companies are one of those who bear this responsibility.⁵⁵²

⁵⁵¹ WHO Drug Information (n277), p. 218.

⁵⁵² GSK Report (n528), para. 5; *see* MDG Report 2008 (n238).

6. Concluding remarks

Notwithstanding the extensive literature and recommendations on this issue which currently circulate in the international forum, there is still no concrete solution which has been deemed acceptable for all the stakeholders. Many have engaged their effort and knowledge into finding such a solution, but it is upon the States, especially Members of the WTO, as well as international organizations and the pharmaceutical industry to decide which solution, if any, to uphold in practice.

The TRIPS, while bringing immense progress in the IP protection for developed countries and the pharmaceutical industry, has in fact, considerably downgraded the process of development for developing countries. By imposing upon all Members the obligation to provide IP protection for all forms technologies, it has prevented developing states from deciding upon a strategy which would benefit their development, by for example excluding pharmaceutical patents from patentability, at least until the situation concerning the right to health of their citizens has improved. In an ideal world everyone would be rich enough to buy medicines at the price set by the industry or lucky enough to need them only after patent protection expired, as stated by Pogge. Then patents would not just be acceptable, but would benefit everyone, everywhere. However, the reality is far from this ideal. Too many people around the world cannot even afford to feed themselves, let alone buy expensive medicines, and are already infected by a disease for which either only patented medicines exist, or there is no medicine whatsoever.

The right to the highest attainable standard of health is indispensable for the enjoyment of all other rights, both civil and political and socio-economic. Without health, no other spheres of life can be realized in their full extent. The right to access to medicines forms an important part of the right to health, and could become a human right of its own, or at least a part of customary international law. People around the world, regardless of their country of residence or financial status, have the right to access affordable essential medicines, which are of good quality and to realize their right to health. The States have a duty to make this possible. The first step that needs to be taken is to ensure availability and affordability of essential medicines.

In the meantime, while pharmaceutical companies weigh their profit against the decisions where to direct their R&D investments, millions of people die in both the developing and developed parts of the world. A sentence from Oscar Wilde illustrates the present situation perfectly: 'Nowadays people know the price of everything and the value of nothing'.⁵⁵³ As was mentioned before, it is just a matter of time before certain diseases affecting only the developing countries spread to the developed part of the world. In order to prevent this from happening, pharmaceutical companies need to consider whether the medicines developed today are being utilised to serve their initial purpose, which is saving people's lives, or are they simply a source of income for these companies' shareholders.

As we have seen, although the HIV/AIDS pandemic has had devastating effects worldwide, because of the pressures from NGOs and the commitment of the public sector, there now exist necessary treatments for this disease, and it is constantly being invested into R&D for drugs that would improve the quality of life for people living with it. In the beginnings of the pandemic, no one probably hoped that HIV/AIDS medicines will be accessible in the near future,

⁵⁵³ O. Wilde, *The picture of Dorian Gray* (1890) e-book available at: <http://www.gutenberg.org/files/174/174-h/174-h.htm>, Chapter 4.

and a few those who did were considered to be naïve and unrealistic.⁵⁵⁴ However, in 2007 there was a 45% increase in people receiving the necessary treatment in developing countries.⁵⁵⁵ This shows that if there is enough incentives and willingness from all the stakeholders involved, a lot can be done to improve access to necessary medicines, for whatever disease, in whichever part of the world.

The example of the HIV/AIDS pandemic and the way the international community dealt with it and keeps doing so, can serve as a great example for what should be done in order to improve access to essential medicines for all, without discrimination of any kind, especially the one stemming from the place of origin, financial and social status. Until this is done, the international community has numerous ways to improve access to medicines. I am of the opinion that the proposal of the fund which would reward the company whose medicines show positive impact for the treatment of a disease, is the one of the best proposals so far. It is a thought through, stable mechanism which could improve, and maybe even erase, the global drug gap.

Both the pharmaceutical industry and human rights activists need to make compromises that will not be, by definition, ideal for either side. As long as there exist fundamental differences in approaches on both parts, there will not be a way to resolve this issue. A consensual approach to the conflict between pharmaceutical patents and access to medicines will help them pave the way to, on one side, people enjoying their human rights in entirety, while on the other side inventors enjoying the fruits of their hard work. Of course, ‘removing the patent barrier will not miraculously produce access to medicines’⁵⁵⁶, since there will still remain the need for better funding for the medicines in both public and private health care facilities, for effective health care systems that are free from corruption, wise selections of drugs and better social security schemes, but as soon as the prices are lowered and as soon as more people can afford and access the necessary medicines, these other tasks will be much easier. We have passed the first two stages needed for the emergence of a new norm concernig the effect of pharmaceutical patents on the right to access to essential medicines, namely the persuasion of norm enterprenours of the conflict between these two areas of law and it could be argued that the critical mass accepted it as existing.⁵⁵⁷ Now we need to take this norm out of the public debate and into a binding international treaty.

⁵⁵⁴ Helfer and Austin (n14), p. 145.

⁵⁵⁵ Ibid, p. 96.

⁵⁵⁶ Sean Flynn, ‘Legal Strategies for Expanding Access to Medicines’ (2003) 17 Emory Int’l L. Rev. at 535, p. 539.

⁵⁵⁷ Helfer and Austin (n14), p. 149.

7. Supplement A- The 2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

**WORLD TRADE
ORGANIZATION**

WT/L/540
2 September 2003
(03-4582)

IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Decision of 30 August 2003⁵⁵⁸

The General Council,

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

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

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

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

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

Decides as follows:

⁵⁵⁸ This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

1. For the purposes of this Decision:
 - (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included⁵⁵⁹;
 - (b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification⁵⁶⁰ to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members⁵⁶¹ and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;
 - (c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

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

- (a) the eligible importing Member(s)⁵⁶² has made a notification² to the Council for TRIPS, that:
 - (i) specifies the names and expected quantities of the product(s) needed⁵⁶³;
 - (ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

⁵⁵⁹ This subparagraph is without prejudice to subparagraph 1(b).

⁵⁶⁰ It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

⁵⁶¹ Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

⁵⁶² Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

⁵⁶³ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

- (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision⁵⁶⁴;
- (b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:
 - (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
 - (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/ shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
 - (iii) before shipment begins, the licensee shall post on a website⁵⁶⁵ the following information:
 - the quantities being supplied to each destination as referred to in indent (i) above; and
 - the distinguishing features of the product(s) referred to in indent (ii) above;
- (c) the exporting Member shall notify⁵⁶⁶ the Council for TRIPS of the grant of the licence, including the conditions attached to it.⁵⁶⁷ The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

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

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing

⁵⁶⁴ This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

⁵⁶⁵ The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

⁵⁶⁶ It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

⁵⁶⁷ The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

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

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

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

- (i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;
- (ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

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

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

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

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

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

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

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

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

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