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Conflict or Flexibility?
Pharmaceutical Patents, Access
to Medicines and the Role of
Compulsory Licences

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Summary

International law related to patents, on the one side, and human rights, on the other, both constitute interesting areas of law on their own. From time-to-time the two distinct fields of international law intertwine. A tragic but highly relevant example is the ongoing HIV/AIDS epidemic. The core of law-related considerations of the HIV/AIDS epidemic consists of specific parts of the two fields, namely, pharmaceutical patents and access to medicines, as a part of the right to health. This thesis examines this specific relationship between the two areas of international law.

Although pharmaceutical patents are mainly related to economic justifications and access to medicines to social justifications, both form justified and desirable parts of international law. As a result, the idea has been presented that the relationship between these two fields amounts to a conflict of norms. Some contributors to the debate on the relationship tend to get stuck on a conflict-focused approach. This thesis attempts to consider the relationship from a flexibility approach. Fundamental to such an approach are the built-in flexibilities of the present international system for patent protection. One such flexibility is examined in detail, namely, compulsory licences.

Although the practice of compulsory licences has been rather limited up until now, it is suggested that it is a flexibility with great potential for easing the relationship between pharmaceutical patents and access to medicines. The use exercised so far suggests that developing countries taking an interest in it can be divided into an A-team and a B-team. A-team States are those who have domestic manufacturing capacity and B-team States those who have insufficient or no capacity. A-team States so far appear to be far better off as they can use the threat of compulsory licences when negotiating prices for patented medicines to get significant price reductions. In any case, several roadblocks appear to stand in the way of both A-team and B-team States trying to make use of the flexibility at present. These come in the form of both internal barriers such as lacking

‘health and intellectual property infrastructure’ and external barriers such as trade and diplomatic pressure from States with a strong interest in the pharmaceutical industry.

In conclusion, it is argued that the flexibility approach needs to be combined with an understanding of the necessity of political commitment. In other words, States need to start taking their international obligations seriously. This holds true both for obligations following from the patent framework, including the full realization of flexibilities such as compulsory licences, and the human rights framework, including access to medicines. A three-step agenda is presented as a suggestion on the direction that future development on the relationship should be heading. First, the importance of both patents and the related international instruments, on the one side, and access to medicines and its instruments, on the other, must be fully recognised by its Member States. Secondly, there is a need to promote and create awareness about the flexibilities to the TRIPS Agreement in general and compulsory licences in particular. Thirdly, international cooperation and assistance must be exercised on a much wider scale than what is seen today.

Preface

During the course of writing this thesis, several persons have been of great inspiration and assistance.

First, I would like to thank my fellow students from the Master's Programme at the Raoul Wallenberg Institute in Lund. It has been both fun and inspirational to be in an environment of such fascinating people. Also, Lena Olsson, librarian at the Institute, has been helpful in a number of ways and for that I am very grateful.

I would also like to express my appreciation to my supervisor, Prof. Mpazi Sinjela, for helping me complete this task.

Finally, as always, my biggest portion of gratitude is saved for those who mean the most to me. My family and Karin. Without your love, support and inspiration this would not be possible.

Björn Länsisyrjä,

Stockholm, 12 December 2007

Abbreviations

ARV	Antiretroviral (medicine for treating HIV/AIDS)
BIRPI	United International Bureaux for the Protection of Intellectual Property
CESCR	Committee on Economic, Social and Cultural Rights
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
Doha Declaration	2001 Declaration on the TRIPS Agreement and Public Health
ETS	European Treaty Series (Council of Europe)
GAOR	Official Records of the UN General Assembly
ICCPR	1966 Covenant on Civil and Political Rights
ICESCR	1966 Covenant on Economic, Social and Cultural Rights
I.L.M.	International Legal Materials
Implementation Decision	2003 Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health
OAS	Organization of American States
OAU	Organization for African Unity
Paris Convention	1883 Paris Convention for the Protection of Industrial Property
TRIPS Agreement	1994 Agreement on Trade-Related Aspects of Intellectual Property Rights
UDHR	1948 Universal Declaration on Human Rights
UN	United Nations
UNAIDS	The Joint UN Programme on HIV/AIDS
UNTS	United Nations Treaty Series
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Introduction

Patents are often seen as a necessary component in the domestic legislations of modern States with the potential to assist in the quest for the progress of society. The general idea of such a view is that the incentive offered by patent protection is invaluable to invention. With the adoption of the 1994 Agreement of Trade-Related Aspects of Intellectual Property (TRIPS Agreement), an increasing scope of patentability has been codified. Patents now stretch broadly across all fields of technology, particularly into the pharmaceutical sector, for every State that wants to be a Member of the World Trade Organization (WTO). Under the requirements of the TRIPS Agreement national authorities must provide patent protection for a minimum period of 20 years if the invention meets adequate patentability standards.

At the same time, patent protection does not occur in a vacuum. The granting of a patent and the monopoly privilege that results from it takes place in a societal context. Patents and the international legal framework related to their administration are just one of the colours on the much bigger palette that constitutes international law. Another colour on the same palette is provided by the human rights framework. Human rights, such as the right to health, are generally accepted as an integral part for the advancement of society and human well-being. Access to medicines, in one form or the other, is usually considered to constitute a fundamental part of the right to health. Unfortunately, for millions of people around the world, access to medicines is nothing but a 'golden dream. Reports on the overall access to essential medicines in some developing countries are often very disturbing to read.

It is not very difficult to think of situations where the two areas of international law, *i.e.* pharmaceutical patents and access to medicines, could possibly intertwine. A tragic example that has received a lot of attention in recent years is the worldwide HIV/AIDS epidemic. The monopoly privileges of patent protection allow pharmaceutical companies to put a

price on medicines, *e.g.* HIV/AIDS medicines, which can sometimes be beyond the reach of poor developing countries. It is precisely such situations that have seen the link between pharmaceutical patents and access to medicines turn into a hotly debated topic on the international arena. Some human rights advocates claim that the present international system of patent protection is hindering the right to health, including its cornerstone of access to medicines. In other words, they believe that there is a legal conflict at hand between the two separate areas of international law. Others, usually representatives of the pharmaceutical industry and States with a strong interest in the pharmaceutical industry, prefer to focus on patents as a fundamental incentive for inventions. They usually argue that the right to health is a beneficiary of patents as their existence in the long run guarantees newer and more efficient medicines.

Clearly, the two distinct areas of international law intertwine occasionally, and these meetings do not always run smoothly. However, it is necessary that these vital parts of international law function well together. For that to happen, it is essential to find a proper balance, where both sides will give each other due consideration. This balance will have to consider the economic motives usually linked to patents and the social motives usually linked to human rights and find a way of making it work. An approach that constantly points out situations where there may, or may not, be a legal conflict at hand does not appear to be the most constructive way forward. Therefore, the contribution of the built-in flexibilities to patent protection offered in the TRIPS Agreement are worthy of examination. The flexibilities, most notably compulsory licences, have great potential to work as a balancing tool in the relationship between pharmaceutical patents and access to medicines. Consequently, the role played by compulsory licences in the relationship up until now, including potential issues standing in the way of utilisation, appears to be both interesting and highly relevant. Compulsory licences could possibly be the tool required to blend two colours on the palette of international law, *i.e.* pharmaceutical patents and access to medicines, into the colour needed to fulfil the painting of societal progress and the highest attainable standard of health for everyone.

1.1 Purpose and Delimitation

The idea for the topic of this thesis comes from a paper written during a course in industrial property rights as part of the Master's Programme in Human Rights and Intellectual Property Rights Law at the Raoul Wallenberg Institute in Lund, Sweden. The title of the paper was 'Patents, the Right to Health, and the Problems Faced by Compulsory Licences'. Thanks to writing the paper, my interest in the relationship between pharmaceutical patents and access to medicines developed quite a bit. However, as a paper has its limitations in space, it was felt that the topic could be developed a lot more. A lot of stones were left unturned, and it is the purpose of this thesis to make sure that also those stones are turned.

The overall purpose of this thesis is to examine the relationship between patents and the right to health in international law. More specifically, certain parts of these distinct but interrelated areas of international law will be targeted, namely, pharmaceutical patents and access to medicines. To allow for a thorough understanding of the topic, it is necessary to include a rather large section on the international legal framework related to these two areas of international law. As these two areas of law are rarely explained next to each other, the aim of this thesis is to do just that and, thus, provide the reader with a useful tool for coming to grips with precisely what areas of international law are at stake. Furthermore, it is the aim of this thesis to contribute to the highly debated topic of the potential influence of pharmaceutical patents on access to medicines. It will do so by examining and pinpointing the main problem areas in this relationship. A necessary part of such an examination is to consider different options in approaching the relationship and examining current trends in both the scholarly and the institutional world.

Finally, the purpose of this thesis is also to highlight one particular flexibility in the present international patent system, namely, compulsory licences. The idea is to cover various aspects of this flexibility, such as its base in international law, its role as a tool for bridging potential gaps in the relationship between pharmaceutical patents and access to medicines, practice exercised on compulsory licences up until now and potential

roadblocks standing in the way of its use. In other words, the aim is to present the reader with an illustrative view of the role played by compulsory licences in international law today. Therefore, the following questions will be used as a foundation for this thesis:

- What are the main features of the relationship between pharmaceutical patents and access to medicines in international law, including the legal and institutional characteristics of the two distinct areas of international law?
- Is there any evident legal conflict between the two distinct areas of international law, or is it possible to approach the relationship in a different manner?
- How do the flexibilities of the present patent regime, especially compulsory licences, fit into the equation? Can the system of compulsory licences assist in bridging potential negative effects that pharmaceutical patents may have on access to medicines? What does the practice of compulsory licences up until now reveal – widespread use or limited use? If use has been limited, is it possible to deduce potential roadblocks standing in the way of more widespread use?

Access to medicines can probably be approached as a component of several internationally recognised human rights, such as the rights to health, life, and enjoyment of the benefits of scientific progress. For limitations of space and for presenting a more in-depth study of a specific human right, this thesis will be limited to consider access to medicines as a part of the right to health. Other human rights, such as those mentioned, will only be briefly touched upon. It is hoped that this delimitation will present the reader with useful information on how a specific human right functions with a specific part of the present international patent system.

There are various flexibilities to patents under the present international legal framework, such as differential pricing, parallel importing, and compulsory licences. This thesis will be limited to the latter of these. Other flexibilities will only briefly be mentioned to make the reader aware of the

variety. Partly this is due to limitations of space, but mostly because the aim of this thesis is to present an in-depth study of a particular topic. The regime of compulsory licences has been highly debated in recent years by everyone from international organizations with an interest in the topic, such as the UN and the WTO, to scholars. Therefore, it is believed that compulsory licences for pharmaceutical patents represent both an interesting and relevant focal point and, thus, a well-suited delimitation to make in this thesis.

1.2 Method and Terminology

In order to fulfil the aim of providing the reader with a useful tool to assist in the understanding of two intertwining areas of international law, *i.e.* pharmaceutical patents and access to medicines, large parts of the thesis consists of descriptive parts on existing international law on the topic. However, analytical parts are included throughout to present a more interesting text on the topic chosen. As it is not the aim of this thesis to give any recommendations on what future law in the field could or should look like, *i.e. de lege ferenda*, the perspective applied is exclusively that of *de lege lata*.

Though it is hoped that the language used in this thesis will appear clear and consistent to the reader, one particular issue could possibly seem inconsistent and should therefore be clarified. When discussing a national entity in the text, such as South Africa or the United States, the terms *country/countries* and *State/States* will be used interchangeably. The main reason for this is that much discussion is devoted to *developing countries*. Developing countries is a widely accepted term and the United Nations normally use the term interchangeably with States in their documents. Therefore, it is believed that a similar approach is well-suited for this thesis.

1.3 Material

A vast amount of material has been used to produce this thesis. Primary sources in the form of international instruments have formed a natural part of this thesis when presenting the international legal framework. However,

the materials most useful, and also most frequently used, to describe the topic chosen have been subsidiary sources. For instance judicial decisions, including dispute settlement procedures within the WTO and national cases, and various forms of legal academic works have been central to the completion of this thesis. Concerning the legal academic works, much of the material related to patent protection does not concern itself with the relationship to human rights. Similarly, a lot of the material describing the particular human right under scrutiny in this thesis, *i.e.* the right to health, does not reflect upon the relationship to patents. This can of course at times be frustrating when trying to bring the two together for scrutiny. Nevertheless, a fair amount of contributors have taken the step to contrast the two areas of international law. A trend within the material discussing the relationship and the potential effects of pharmaceutical patents on access to medicines is to limit the discussion to access to HIV/AIDS medicines. As a result of this, a lot of the discussion in this thesis will also be on access to such medicines.

A few contributors have proved invaluable for the completion of this thesis, either because of inspiration or due to the fact that they have been used extensively. One such contributor is Philippe Cullet and his article 'Patents and Medicines: the Relationship between the TRIPS Agreement and the Human Right to Health'. This article has been both inspiring in that it approaches the topic in an interesting way and very helpful, as evident from the fact that it has been used extensively as a reference throughout this thesis. Additionally, the multiple articles by Frederick M. Abbott on the relationship have been of great assistance in that they clarify complicated aspects in a helpful way. Among other things, his extensive clarifications of the Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health have proved very useful for the understanding of the full scope of that document. One author should also be mentioned for his extensive and very useful book on the TRIPS Agreement and the negotiations taking place before and after its adoption. Daniel Gervais' book 'The TRIPS Agreement: Drafting History and Analysis' has proved to be a fundamental component for the completion of the chapter on

the international legal framework related to patents. Finally, Cecilia Oh's article 'Compulsory Licences: Recent Experiences in Developing Countries' has offered necessary guidance on the practice of compulsory licences for pharmaceutical patents in recent years. Seeing as such material is very difficult to find, the information provided by this article has been very welcome for the broadening of this thesis.

1.4 Outline

Following this introductory chapter is the *second chapter* which contains a presentation of the international legal framework related to the right to health as a part of the larger human rights framework. In this chapter, it is established that access to medicines constitutes a fundamental part of the right to health. This chapter also includes a presentation of the international legal framework related to patents. The development of patent protection in international law, with the 1994 TRIPS Agreement as a cornerstone, is presented. Succeeding instruments and their focus on compulsory licences and the potential effects of pharmaceutical patents are also brought to the attention of the reader.

The *third chapter* is devoted to the relationship between pharmaceutical patents and access to medicines. This chapter takes off by briefly discussing the idea that patents themselves could amount to a human right. After that, the alarming HIV/AIDS epidemic is used as an illustrative example of a situation where pharmaceutical patents and access to medicines intertwine. Having established that the two areas of international law sometimes do intertwine, the next step is to consider if the relationship amounts to a legal conflict. Therefore, section 3.3 examines the relationship to consider whether it amounts to a legal conflict or if there is room to focus on available flexibilities. For clarification, a brief description of the flexibilities available under the international patent framework is provided. Following that is a part looking into the practice of one of the flexibilities, compulsory licences, in more detail. As it is discovered that there has only been limited use of compulsory licences up until now, the next part of the chapter suggests a few possible roadblocks standing in the way of greater use. To

conclude the chapter, a final part presenting some reflections on the relationship between pharmaceutical patents and access to medicines in general and compulsory licences in particular is provided.

The *fourth chapter* concludes the thesis by presenting some analytical observations on the results arrived upon during the course of examination.

2 International Legal Framework

When examining the relationship between pharmaceutical patents and access to medicines, a fundamental first step is to examine the international legal framework they are placed in. To get the full picture of the two concepts, one should keep in mind that they are part of two wider sets of rules, namely, human rights and intellectual property rights. Therefore, this chapter aims to present a general picture of the right to health, and its respective cornerstone of access to medicines, and pharmaceutical patents and the wider frameworks they are connected to. The two concepts and their corresponding regulations will be presented separately in the following. However, the perceptive reader will also find that some parts of the legal framework presented are concerned with the relationship between the two.

2.1 Human Rights

2.1.1 Historical Background

The atrocities of World War II provided for the immediate background and spark for the adoption of what has been called “the single most authoritative statement of human rights”¹, namely, the 1948 Universal Declaration on Human Rights² (UDHR).

However, the 20th century was not the first time in history that the idea surfaced that every human being should be bestowed with a number of rights because of her existence as an individual. At least in Western history the roots of the UDHR can be traced back well into antiquity, and maybe more prominently to latter parts of history with such instruments as the English Bill of Rights in 1689 and the American Declaration of

¹ A. R. Chapman, ‘The Human Rights Implications of Intellectual Property Protection’, 5(4) *Journal of International Economic Law* (2002) p. 862 [hereinafter Chapman 2002].

² The Universal Declaration of Human Rights, adopted 10 December 1948, GA Res 217A (III), 3 UN GAOR Resolutions, part 1, p. 71, UN Doc. A/810 (1948).

Independence in 1776.³ Nevertheless, the pre-war international system focused exclusively on State-State relations. Potential human rights violations that took place within the borders of a State were generally considered an ‘internal affair’. The human rights movement epitomised by the UDHR altered the scope of international law by piercing the veil of national sovereignty and elevating human rights as an issue of international concern.⁴

A comprehensive list of human rights granted to every human being is enumerated in the UDHR. The opening 21 Articles presents a series of civil and political rights, including, among many other, the rights to life, liberty and security of person; equality before the law and non-discrimination; and freedom of thought conscience and religion. Additionally, a number of economic, social and cultural rights are included in the enumeration. These include the rights to favourable conditions of work; to education; to a standard of living adequate for health and well-being; and to share in the benefits of scientific advancement.

As a Declaration concluded by the UN General Assembly, the UDHR is not a legally enforceable instrument as such. However, the provisions contained in the UDHR, or at least some of them, have subsequently assumed the status of customary international law.⁵ Therefore, the UDHR constitutes an authoritative source and a highly relevant instrument. Nevertheless, to turn the provisions of the UDHR into legally binding human rights obligations, the UN continued its work on the human rights framework by drafting a series of human rights instruments. These instruments developed and clarified the rights enumerated in the UDHR. Two central instruments are the 1966 International Covenant on Civil and

³ G. Alfredsson and A. Eide, ‘Introduction’ in G. Alfredsson and A. Eide (eds.), *The Universal Declaration of Human Rights – A Common Standard of Achievement* (Martinus Nijhoff, The Hague, 1999) pp. xxv-xxviii.

⁴ L. O. Gostin and Z. Lazzarini, *Human Rights and Public Health in the AIDS Pandemic* (Oxford University Press, Oxford, 1997) p. 2 [hereinafter Gostin and Lazzarini].

⁵ See, e.g., A. R. Chapman ‘A Human Rights Perspective on Intellectual Property, Scientific Progress, and Access to the Benefits of Science’ in *Intellectual Property and Human Rights* (WIPO Publication No. 762(E), 1999) p. 132; M. N. Shaw, *International Law, Fifth Edition* (Cambridge University Press, Cambridge, 2003) pp. 256-261 [hereinafter Shaw].

Political Rights⁶ (ICCPR) and the 1966 International Covenant on Economic, Social and Cultural Rights⁷ (ICESCR). Combined with the UDHR, they are usually referred to as the International Bill of Human Rights. States ratifying the ICCPR and ICESCR and other human rights instruments⁸ become legally bound by their requirements as States Parties. Nearly all UN Member States have ratified some of the human rights instruments, and a number of instruments have been ratified by an overwhelming majority of Member States.⁹ The instrument most relevant to the following discussion, the ICESCR, has some 157 States Parties.¹⁰

There is widespread acceptance that the legal obligations assumed by a State as a result of becoming a Party to a human rights instrument are threefold. First, they must *respect* the right by abstaining from taking legal or policy measures that would violate it. Secondly, they must take measures to *protect* the right from being violated by third parties. Finally, to *fulfil* the right, States Parties must implement positive measures that assist individuals to enjoy their right.¹¹ Seeing as human rights instruments are something that States and not individuals become Parties to, it is the State that assumes legal obligations. The legal obligation for each and every human right should be considered under this threefold approach.

Traditionally, it has been a common feature to equate human rights with civil and political rights. The development of the international human rights framework in the decades succeeding the adoption of the UDHR has,

⁶ International Covenant on Civil and Political Rights, adopted 16 December 1966, 999 UNTS 171 (entered into force 23 March 1976), GA Res 2200A (XXI), 21 UN GAOR, Supp. No. 16, p. 52, UN Doc. A/6316 (1966).

⁷ International Covenant on Economic, Social and Cultural Rights, adopted 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976), GA Res 2200A (XXI), 21 UN GAOR, Supp. No. 16, p. 49, UN Doc. A/6316 (1966).

⁸ See *infra* chapter 2.1.2 for a discussion on a few of these instruments in relation to the right to health.

⁹ Chapman 2002, *supra* note 1, p. 864.

¹⁰ As of 3 December 2007, UN Treaty Database, <<http://untreaty.un.org/ENGLISH/bible/englishinternetbible/partI/chapterIV/treaty5.asp>>, visited on 3 December 2007.

¹¹ The legal obligations of States have been developed by human rights monitoring bodies, such as the Committee on Economic, Social and Cultural Rights (CESCR), through General Comments (authoritative interpretations of the human rights instruments), see, e.g., General Comment No. 12 of the CESCR, dealing with the right to adequate food (Article 11), UN Doc. E/C.12/1999/5, para. 15; General Comment No. 14 of the CESCR, dealing with the right to the highest attainable standard of health (Article 12), UN Doc. E/C.12/2000/4, paras. 33-37, 50-52 [hereinafter General Comment No. 14 of the CESCR].

however, emphasised the equal importance of civil and political rights on the one side and economic, social and cultural rights on the other. In fact, nowadays States have committed themselves to the equal importance and universality of all human rights to an extent great enough for some commentators to hold it as an international consensus.¹² An illustrative and highly relevant example of this is the language used in the Vienna Declaration and Programme of Action of the 1993 World Conference on Human Rights, “All human rights are universal, indivisible and interdependent”.¹³ Consequently, to realise any one right, all other human rights must be protected and promoted at the same time.

Although States have committed themselves to the equal importance of all human rights, it should be noted that the drafters of the ICESCR anticipated the potential problems for some States of realising immediately the full provisions of all the rights in the Covenant. Therefore a provision on *progressive realization* was included in Article 2(1). It states that each State Party “undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights”. This is different from the ICCPR, which in Article 2(2) obliges each State Party to take legislative or other measures as may be necessary to give effect to the rights included in the Covenant. In other words, necessary measures must be taken to give immediate effect to the rights. However, it should be noted that the monitoring body for the ICESCR, the UN Committee on Economic, Social and Cultural Rights (CESCR), has interpreted the provisions of the ICESCR to mandate all States Parties to move quickly and effectively towards full realization of the rights. In other words, progressive realization does not remove obligations on the States Parties. Additionally, the CESCR has also clarified that the ICESCR entails some obligations which should have immediate effect, including core or key obligations related to each specific right enumerated

¹² See, e.g., Chapman 2002, *supra* note 1, p. 863.

¹³ World Conference on Human Rights, Vienna Declaration and Programme of Action, Vienna, 14-25 June 1993, UN Doc. A/CONF.157/23, para. 5.

in the Covenant.¹⁴ Core obligations will be returned to when discussing the right to health, including access to medicines, in more detail later.

Conclusively, the development of human rights during the 20th century was not a completely novel idea since thoughts on rights of individuals had surfaced prior to that. However, it cemented and developed the idea that every individual is entitled to a number of human rights and, importantly, created an international legal framework on human rights. In other words, to recognise these rights under international law was novel, as was holding States accountable for violations.¹⁵ Justification for this framework can be found both in the fact that the ideas had surfaced for quite some time and that the importance of human rights was and continues to be an integral part of the UN system.¹⁶ Seeing as almost every State in the world is a member of the UN¹⁷, and a great number of States are Parties to one or more of the international human rights instruments, human rights are evidently an important part of international law. We will now proceed by looking into one particular human right, the right to health, in more detail.

2.1.2 The Development of a Right to Health

The concept of a right to health has, much like the general human rights framework, been developed in recent parts of history. This is not to say that a sense of State or community responsibility for the health of the public did not exist in the past. In fact, there are indications that the authorities even in ancient civilisations took measures to improve the health of the public.¹⁸ However, such measures usually reflected a desire to promote the public good rather than concerns for individual welfare or greater access to health

¹⁴ See General Comment No. 3 of the CESCR, dealing with the nature of States parties obligations (Article 2(1)), UN Doc. E/1991/23, Annex III, pp. 83-87 [hereinafter General Comment No. 3 of the CESCR]; see also Chapman 2002, *supra* note 1, pp. 864-866.

¹⁵ Gostin and Lazzarini, *supra* note 4, p. 2.

¹⁶ Shaw, *supra* note 5, p. 261.

¹⁷ 191 States Parties as of 3 December 2007, UN Treaty Database, <<http://untreaty.un.org/ENGLISH/bible/englishinternetbible/partI/chapterI/treaty1.asp>>, visited on 3 December 2007.

¹⁸ See B. C. A. Toebes, *The Right to Health as a Human Right in International Law* (Intersentia, Antwerp, 1999) pp. 7-16 [hereinafter Toebes 1999], presenting a useful summary of the historical evolution of health as a human right.

care. References to a right to health in official documents were on the whole absent before the 20th century.¹⁹

The first organization to explicitly formulate a ‘right to health’ was the World Health Organization (WHO).²⁰ In the Preamble of its Constitution from 1946, it is stated that “The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being”.²¹ Furthermore, health is defined as “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”.²² It has been noted that the WHO approach is a problematic grounding for a human right as it implies that a Government must guarantee complete physical, mental and social well-being for all its citizens. Such an approach is not really feasible as “a right to health cannot be meaningfully interpreted as a right to be healthy”.²³ Seeing as the health status is not only the result of State obligations, but also actions of other individuals and the behaviour of the individual herself, it is difficult not to agree with this view.

Drafters of the human rights framework appear to have been a bit more cautious in their approach. The foundations for an international legal framework on a right to health were laid by the UDHR, adopted two years after the WHO Constitution.²⁴ Somewhat influenced by the WHO Constitution, but staying clear from a narrow definition, Article 25(1) enumerates “the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services”. Since then, the right to

¹⁹ *Ibid.*; A. R. Chapman, ‘Core Obligations Related to the Right to Health’ in A. R. Chapman and S. Russell (eds.), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (Intersentia, Antwerp, 2003) pp. 190-191 [hereinafter Chapman 2003].

²⁰ B. C. A. Toebes, ‘The Right to Health’ in A. Eide *et al* (eds.), *Economic, Social and Cultural Rights: a Textbook, Second Revised Edition* (Martinus Nijhoff, Dordrecht, 2001) p. 172 [hereinafter Toebes 2001].

²¹ Constitution of the World Health Organization, adopted by the International Health Conference held in New York from 19 June to 22 July 1946, 14 UNTS 185, 193 States Parties as of 3 December 2007, UN Treaty Database, <<http://untreaty.un.org/ENGLISH/bible/englishinternetbible/partI/chapterIX/treaty1.asp>>, visited on 3 December 2007.

²² *Ibid.*

²³ Chapman 2003, *supra* note 19, pp. 187-188.

²⁴ See Toebes 1999, *supra* note 18, pp. 27-88, for an extensive examination of the right to health in international instruments and related draft work.

health has been codified in numerous legally binding international and regional human rights instruments.

The ICESCR provides what has been called the “cornerstone protection”²⁵ and “the most authoritative delineation”²⁶ of the right to health in international law. In its Article 12(1), it defines the right as “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”. The ‘highest attainable standard of health’ had already been pinpointed as a fundamental right by the WHO Constitution 20 years earlier. However, with the ICESCR it was established in a legally binding instrument and, importantly, not combined with the unfeasible definition of its predecessor. In the second paragraph of the Article, a non-exhaustive list of States Parties’ obligations under the right to health is included:

- “(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
- (b) The improvement of all aspects of environmental and industrial hygiene;
- (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
- (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.”²⁷

Additional right to health protection for certain vulnerable groups can be found in group-specific instruments. For example, the 1989 Convention on the Rights of the Child²⁸ includes Article 24 which is fully focused on the child’s right to health, and adopts a similar definitional approach as that of the ICESCR. Emphasising non-discrimination in relation to the right to health, the 1965 International Convention on the Elimination of All Forms

²⁵ 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), 13 February 2003, UN Doc. E/CN.4/2003/58, para. 11 [hereinafter Special Rapporteur 2003].

²⁶ Chapman 2003, *supra* note 19, p. 191.

²⁷ Article 12(2) of the ICESCR, *see supra* note 7

²⁸ Convention on the Rights of the Child, adopted 20 November 1989, 1553 UNTS 3 (entered into force 2 September 1990), GA Res. 25 (XLIV), 44 UN GAOR, Supp. No. 49, p. 166, UN Doc. A/44/49 (1989).

of Racial Discrimination²⁹, in Article 5(e)(iv), and the 1979 Convention on the Elimination of All Forms of Discrimination against Women³⁰, in Article 12, proscribe race-based and gender-based discrimination in health services.³¹ Furthermore, the right to health has a clear link to other rights enumerated in the ICESCR, such as food, clothing and housing, listed in Article 11. Not least, this is evident from the fact that the UDHR in Article 25 enumerates these rights in the same Article as the right to health. One author, Brigit Toebe, explains these rights as “underlying preconditions for health”. As such, Toebe claims that they are both fundamental for realizing a right to health and at the same time a natural part of the specific right to health.³² In addition, the inherent right to life in Article 6 of the ICCPR could also be advocated as closely related to the right to health. In fact, the monitoring body for the ICCPR has explained that the role of the State in protecting the right to life includes measures to eliminate epidemics.³³

In addition to international standards, the right to health has also found its way into several regional human rights instruments. These include the 1961 European Social Charter³⁴ (Article 11); the 1981 African Charter on Human and Peoples’ Rights³⁵ (Article 16); the 1988 Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights³⁶ (Article 10); and the 1990 African Charter on the Rights and Welfare of the Child³⁷ (Article 14).

²⁹ International Convention on the Elimination of All Forms of Racial Discrimination, adopted 21 December 1965, 660 UNTS 195 (entered into force 4 January 1969), GA Res. 2106 (XX), 20 UN GAOR, Supp. No. 20, p. 47, UN Doc. A/6014 (1965).

³⁰ Convention on the Elimination of All Forms of Discrimination against Women, adopted 18 December 1979, 1249 UNTS 13 (entered into force 3 September 1981), GA Res. 34/180, 34 UN GAOR, Supp. No. 46, p. 193, UN Doc. A/34/46 (1980).

³¹ A. E. Yamin, ‘Not Just a Tragedy: Access to Medications as a Right under International Law’, 21 *Boston University International Law Journal* (2003), p. 338 [hereinafter Yamin].

³² Toebe 2001, *supra* note 20, pp. 174-175.

³³ General Comment No. 6 of the Human Rights Committee, dealing with the right to life (Article 6), UN Doc. HRI/GEN/1/Rev.6, p. 34.

³⁴ European Social Charter, adopted 18 October 1961, ETS No. 35; revised in 1996, ETS No. 163 (the revision did not bring any significant changes to the listed right to health).

³⁵ African Charter on Human and Peoples’ Rights, adopted 27 June 1981, OAU Doc. CAB/LEG/67/3 Rev.5, reprinted in 21 I.L.M. 58 (1982).

³⁶ Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights, adopted 17 November 1988, OAS Treaty Series, No. 69.

³⁷ African Charter on the Rights and Welfare of the Child, adopted July 1990, OAU Doc. CAB/LEG/24.9/49 (1990).

Furthermore, the right to health, or health-related rights, is also included in a number of national constitutions. According to the preliminary findings of a study on the topic, more than 60 constitutional provisions include the right to health, or the right to health care, and more than 40 constitutional provisions include health-related rights, such as a right to reproductive health care.³⁸ A combination of both can be found in the South African Constitution, stating that “[e]veryone has the right to have access to health care services, including reproductive health care”.³⁹

Apparently, there is widespread recognition of the right to health in international, regional and national instruments. However, without some form of accountability, the right runs the risk of becoming merely aspirational. Fortunately, the right to health has the evidence to prove that it is connected to judicial accountability. Numerous cases have been brought and tried by international, regional and national tribunals.⁴⁰ The practice of these tribunals can help in clarifying the meaning of the right to health and hopefully work to secure better health services for those in need. To name but one case, in the *Minister of Health v. Treatment Action Campaign*, the South African Constitutional Court held that the Government was not doing all it reasonably could in providing for health services to pregnant women in risk of infecting their children with HIV.⁴¹

Before moving on to identify the core content and corresponding obligations on States, it should be noted that there has been much confusion over what the most suitable term for the right is. Several terms have occurred in law literature. However, ‘the right to health’, ‘the right to health care’ and ‘the right to health protection’ are probably the most common

³⁸ Special Rapporteur 2003, *supra* note 25, para. 20.

³⁹ Constitution of the Republic of South Africa, Chapter 2, para. 27(1)(a), <<http://www.info.gov.za/documents/constitution/1996/96cons2.htm>>, visited on 3 December 2007.

⁴⁰ See 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), 17 January 2007, UN Doc. A/HRC/4/28, paras. 55-89, for a useful summary of cases.

⁴¹ *Minister of Health v. Treatment Action Campaign*, 5 July 2002, Constitutional Court of South Africa, CCT 8/02, <http://www.law-lib.utoronto.ca/Diana/TAC_case_study/MinisterofhealthvTACconst.court.pdf>, visited on 3 December 2007; see also M. Heywood, ‘Shaping, Making and Breaking the Law in the Campaign for a National HIV/AIDS Treatment Plan’ in P. Jones and K. Stokke (eds.), *Democratizing Development: the Politics of Socio-Economic Rights in South Africa* (Martinus Nijhoff, Leiden, 2005) pp. 181-212.

ones. Though the various terms have their respective advocates, it is believed that the 'right to health' is the most suitable one, both in general and for the purpose of this thesis. Brigit Toebes has presented a convincing argument for applying the term 'the right to health'. Her approach is three-fold in justification. First, it is the term best in line with the character of provisions in international human rights instruments. Secondly, it is the term most commonly used at the international level when discussing health issues. Finally, it allows for recognising a number of underlying preconditions for health within the specific right, such as access to safe drinking water and environmental health.⁴²

With more than half a century of legal progression in a variety of international, regional and national instruments, the confusion over what term to use coincides with confusion and controversy about the specific content of the right to health and the corresponding obligations of States Parties. Fortunately, the CESCR and several scholars have pronounced themselves on precisely this, and can surely be used as an indication of what the right entails. Alicia E. Yamin has even argued that the right to health "has undergone remarkable normative development and clarification in recent years".⁴³

Rather than trying to point out every possible component of the content of the right, it could be useful to focus on the core content of the right. As the provision on the right to health in the ICESCR is normally considered to be the cornerstone provision, it is only natural for it to form the basis of an examination of the core content. First, it is necessary to keep in mind that the rights enumerated in the ICESCR are normally to be realized under the standard of *progressive realization*.⁴⁴ Without any restriction on progressive realization, it could potentially leave an escape clause wide enough to render large parts of the ICESCR practically nullified. To prevent this, a number of

⁴² Toebes 1999, *supra* note 18, pp. 16-20.

⁴³ Yamin, *supra* note 31, p. 336.

⁴⁴ See *supra* chapter 2.1.1.

restrictions have been imposed on the standard, both in the language of the ICESCR itself and by interpretations of it.⁴⁵

Firstly, the language of the ICESCR in Articles 2(2) and 3 clearly indicates that States Parties have an immediate obligation to guarantee that the rights in the Covenant are not exercised discriminatorily. In other words, the obligation to ensure non-discrimination is not subject to progressive realization. This has been confirmed by the CESCR on a number of times⁴⁶, and the UN Special Rapporteur on the right to health has reiterated this view⁴⁷.

Secondly, when it comes to interpretations of the ICESCR, there has been a trend since the 1980s among scholars and relevant UN institutions towards establishing the core of the right to health.⁴⁸ Brigit Toebes describes this so-called *core content*⁴⁹ as “a set of elements States must guarantee under any circumstances, irrespective of their available resources”.⁵⁰ The concept of core content for economic, social and cultural rights in general, and for the right to health in particular has been given a lot of attention by the CESCR. In its General Comment No. 3, the Committee declared that the concept of core content was to ensure the satisfaction of, at least, minimum essential levels of each of the rights in the ICESCR in every State Party. Without such a concept, the ICESCR would be largely deprived of its *raison d'être*.⁵¹ In its General Comment No. 14, it clarified the concept in relation to the right to health. Inspired by the 1978 WHO Alma-Ata

⁴⁵ A. R. Chapman and S. Russell, ‘Introduction’ ‘Core Obligations Related to the Right to Health’ in A. R. Chapman and S. Russell (eds.), *Core Obligations: Building a Framework for Economic, Social and Cultural Rights* (Intersentia, Antwerp, 2003) pp. 4-5.

⁴⁶ See, e.g., General Comment No. 3 of the CESCR, *supra* note 14, para. 1; General Comment No. 16 of the CESCR, dealing with the equal right of men and women to the enjoyment of all economic, social and cultural rights (Article 3), UN Doc. E/C.12/2005/4, paras. 16-17.

⁴⁷ See, e.g., Special Rapporteur 2003, *supra* note 25, para. 27; 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), Mission to the World Trade Organization, 1 March 2004, UN Doc. E/CN.4/2004/49/Add.1, paras. 21-22 [hereinafter Special Rapporteur 2004].

⁴⁸ Toebes 2001, *supra* note 20, pp. 175-177.

⁴⁹ In literature and UN documents it has been variously referred to as minimum core content, core content, essential elements, core entitlements, core obligations, minimum State obligations and various other forms. The term *core content* is chosen for this thesis as it is felt it is a neutral term well-suited for shifting the focus to the actual content rather than the terminology. In addition, it is widely used in literature on the topic.

⁵⁰ Toebes 2001, *supra* note 20, p. 176.

⁵¹ General Comment No. 3 of the CESCR, *supra* note 14, para. 10.

Declaration⁵², the Committee presented a, not necessarily exhaustive, list of elements constituting the core content. Presented in the form of duties upon States, the list includes, among others, the duties to:

- ensure the right of access to health facilities, goods and services on a non-discriminatory basis, especially for vulnerable or marginalised groups;
- provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs⁵³;
- ensure equitable distribution of all health facilities, goods and services;
- adopt and implement a national public health strategy and plan of action...;
- provide immunisation against the major infectious diseases occurring in the community;
- take measures to prevent, treat and control epidemic and endemic diseases.⁵⁴

The Committee then went on to clarify that resource constraints “cannot, under any circumstances whatsoever, justify its (*i.e.* the State Party) non-compliance with the core obligations...which are non-derogable”.⁵⁵ The Special Rapporteur on the right to health adheres to the view of core content as something that is of immediate effect.⁵⁶

When discussing the feasibility of a core content-approach, the Committee touches upon something that is of utmost importance for the fulfilment of the rights in the ICESCR in general and the core content of those rights in particular. The General Comment states that “it is particularly incumbent on States Parties and other actors in a position to assist, to provide international assistance and cooperation, especially economic and

⁵² Alma-Ata Declaration, Report of the International Conference on Primary Health Care, Alma-Ata, 6-12 September 1978, in World Health Organization, *Health for All Series*, No. 1 (Geneva, WHO, 1978).

⁵³ See *infra* chapter 2.1.2.1 for a more detailed discussion on access to medicines as a part of the right to health.

⁵⁴ General Comment No. 14 of the CESCR, *supra* note 11, paras. 43-44.

⁵⁵ *Ibid.*, para. 47 (my parenthesis).

⁵⁶ See, *e.g.*, Special Rapporteur 2004, *supra* note 47, paras. 21-22.

technical”.⁵⁷ International assistance and cooperation is stipulated in Article 2(1) of the ICESCR and is of fundamental importance for States with lesser resources to be able to fulfil their obligations. The need for international assistance and cooperation has also been targeted by the Commission on Human Rights, the predecessor to the present Human Rights Council.⁵⁸ Evidently, international assistance and cooperation forms a fundamental part of the right to health.

The application of the concept of core content to the right to health, however, needs to be exercised with some caution. To single out certain elements that form the core content brings the risk of interpreting the remaining elements of the right as unimportant. In a ‘worst case scenario’, this could lead to States denying these important elements of the right. Therefore, it is necessary at all times to keep in mind there is a clear obligation on States to take steps towards the full enjoyment of the right.⁵⁹

Conclusively, the right to health should not be understood as right to be healthy, but rather a requirement on States to provide “a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health”.⁶⁰ As has been demonstrated, this includes the notion that some elements of the right should be realized immediately, without affecting the importance of the other elements. One element that should be fulfilled immediately, notwithstanding available resources, is the core content of the right to health. We will now proceed by examining a fundamental part of this core content in more detail, namely, access to medicines.

2.1.2.1 Access to medicines

A perceptive reader will quickly realize that there is no ‘right of access to medicines’ in existing human rights instruments. However, such an obligation, although not defined as a specific human right, is firmly rooted

⁵⁷ General Comment No. 14 of the CESCR, *supra* note 11, para. 45.

⁵⁸ Commission on Human Rights Res. 2002/31, The right of everyone to the enjoyment of the highest attainable standard of physical and mental health, UN Doc. E/CN.4/RES/2002/31.

⁵⁹ Toebes 2001, *supra* note 20, p. 176.

⁶⁰ General Comment No. 14 of the CESCR, *supra* note 11, para. 8.

in the implications of existing provisions on human rights, especially the right to health. All the instruments and respective provisions enumerated in the previous chapter form the general legal basis also when it comes to access to medicines. Therefore, instead of repeating the material base, this chapter will focus more directly on discussions within both relevant UN institutions and the scholarly world on the interpretation of the right to health as to include access to medicines. Furthermore, it will try to clarify what access to medicines constitutes for the purpose of its role within the right to health, including the resulting obligations on States.

Access to medicines and its role within the human rights framework has been a highly debated topic within both relevant UN institutions and the scholarly world in recent years. A strong case for access to medicines as being part of the right to health is presented by the CESCR. In its General Comment No. 14, it lists, among other elements, the need to provide essential medicines, to provide immunisation against major infectious diseases and to take measures to prevent, treat and control epidemic and endemic diseases as being part of the core content of the right to health. It then goes on to state that these obligations are a non-derogable part of the right.⁶¹ Though the Committee's interpretations are not legally binding, they "may be said to have considerable legal weight".⁶²

Other UN institutions and mechanisms have articulated similar views. First, the Commission on Human Rights has adopted numerous resolutions on the topic of "access to medication in the context of pandemics such as HIV/AIDS". In one of the resolutions, from 2002, the Commission "[r]ecognizes that access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving...the right of everyone to...the highest attainable standard of...health". It then goes on to call upon States to promote availability and accessibility on an international level.⁶³ In

⁶¹ See *supra* chapter 2.1.2.

⁶² L. Ferreira, 'Access to Affordable HIV/AIDS Drugs: the Human Rights Obligations of Multinational Pharmaceutical Corporations', 71 *Fordham Law Review* (2002), p. 1163 [hereinafter Ferreira].

⁶³ Commission on Human Rights Res. 2002/32, Access to Medication in the Context of Pandemics such as HIV/AIDS, UN Doc. E/CN.4/RES/2002/32 [hereinafter CHR Res. 2002/32].

addition, the Special Rapporteur on health has on a number of occasions pointed out that access to medicines forms an indispensable part of the right to health.⁶⁴

Deliberation within the UN system has run parallel to an extensive debate in the scholarly world. Several contributors consider access to medicines to be an important part of the right to health. The general view is that this is the result of several factors. These factors include: a well-established human right to health open for interpretation; the development within relevant UN institutions to consider it to be the case; and special needs created by the current health status in the world. In academic works on the topic, access to medicines has been advocated as an “essential”⁶⁵ and “fundamental”⁶⁶ part of the right to health. Alicia E. Yamin presents a strong argument for access to medicines as being a necessary part of the right to health by looking at the text of Article 12 in the ICESCR. In her opinion, “[a]ccess to medications is a critical component of the right to health both as treatment for epidemic and endemic diseases and as part of medical attention in the event of any kind of sickness”.⁶⁷ A majority among human rights scholars appear to support the idea of access to medicines as constituting a fundamental part of the right to health. However, not everyone is as optimistic about the possibility of clarifying the content of the right. David P. Fidler simply puts it that “the right is so broad that it lacks coherent meaning”.⁶⁸

To obtain a thorough understanding of what access to medicines consists of, it may be useful to consider some of the clarifications that have been brought forward within the UN system. First, in the already frequently mentioned General Comment No. 14, the CESCR offers an analytical framework to provide for a better understanding of the right to health. This

⁶⁴ See, e.g., 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), 13 September 2006, UN Doc. A/61/338, paras. 40, 56 [hereinafter Special Rapporteur 2006].

⁶⁵ N. Nanda and R. Lodha, ‘Making Essential Medicines Affordable to the Poor’, 20 *Wisconsin International Law Journal* (2002), p. 581.

⁶⁶ P. Cullet, ‘Patents and Medicines: the Relationship Between TRIPS and the Human Right to Health’, 79 *International Affairs* (2003), p. 142 [hereinafter Cullet].

⁶⁷ Yamin, *supra* note 31, p. 336.

⁶⁸ D. P. Fidler, *International Law and Infectious Diseases* (Oxford University Press, Oxford, 1999) p. 197.

analytical framework is also well-suited for deducing the elements of access to medicines. One part of the framework, especially relevant to policy analysis, declares that all components of the right to health should be available, accessible, culturally acceptable and of good quality.⁶⁹ Applying this to access to medicines, means that States must do all they reasonably can to make medicines available. At the same time, medicines should not be available only in the urban centres, but not in the rural areas; only to some ethnic groups, but not to others; only to the rich, but not to those living in poverty; and so on. Such a situation is not acceptable as it would mean that medicines are not accessible. In addition, access should be combined with awareness of cultural traditions within certain groups and assure good quality medicines, for instance by the establishment of a regulatory system to check medicine safety and quality.⁷⁰

A second, or complementary, part of the analytical framework is the well-established concept that States Parties to a human rights instrument have duties to respect, protect and fulfil the enumerated rights. This part of the framework may be more directly suited for legal analysis. The *duty to respect* obliges a State to refrain from interfering, directly or indirectly, with access to medicines. For instance, a State should not market unsafe medicines and it should have a medicines policy that does not discriminate against any certain disadvantaged group. *The duty to protect* requires States to ensure that third parties do not obstruct the access. For instance, it should make sure that a privatised health sector enhances access to medicines for all, including those living in poverty. *The duty to fulfil* obliges a State to adopt appropriate legislative, administrative, budgetary, judicial and other measures of which access to medicines would benefit. This includes providing essential medicines to those living in poverty if they would otherwise be unable to access them.⁷¹

This policy and legal analysis of access to medicines should be combined with a general distinction between medicines. Namely, the

⁶⁹ General Comment No. 14 of the CESCR, *supra* note 11, para. 12.

⁷⁰ *Ibid.*; Special Rapporteur 2006, *supra* note 64, paras. 59-60.

⁷¹ Special Rapporteur 2004, *supra* note 47, paras. 39-40; Special Rapporteur 2006, *supra* note 64, paras. 47-51.

distinction between *essential medicines* and *non-essential medicines*. As explained above, the right to health, and thus access to medicines, is subject to progressive realization.⁷² However, access to certain types of medicines has been declared by the CESCR to be a part of the core content of the right to health.⁷³ These medicines are usually referred to as essential medicines. General Comment No. 14 indicates that States are supposed to be guided by the WHO Model List of Essential Medicines to prepare a national essential medicines list.⁷⁴ If a State fails to prepare its own national essential medicines list, the WHO list will apply, subject to contextual revisions.⁷⁵ The WHO list includes a long list of essential medicines that needs to be made available, *e.g.* several antiretrovirals (ARVs) for the treatment of HIV/AIDS.⁷⁶ Apparently, exactly which medicines are regarded as essential remains a national responsibility, but the WHO list is of great importance, both as guidance and for filling potential gaps. Medicines neither on national lists nor on the WHO list, usually given the rather unfortunate term non-essential medicines, can of course be of significant importance to public health. The lists are merely supposed to clarify the minimum need of each State. However, it does mean that these latter medicines are not linked to an immediate obligation of the State. Therefore, States have an immediate obligation to make essential medicines available and accessible throughout its jurisdiction. For non-essential medicines, this obligation should be realized progressively.⁷⁷

It may be difficult to set a certain number of percent of the population that should have access to essential medicines for a State to be in compliance with its obligation of access to medicines. One of the main reasons for this is the difficulty in collecting accurate data to evaluate progress. The problem usually arises because of a lack of vital registration systems. Unfortunately, this is especially prevalent in many of the States

⁷² See *supra* chapter 2.1.2.

⁷³ General Comment No. 14 of the CESCR, *supra* note 11, paras. 43-44.

⁷⁴ *Ibid.*, paras. 12, 43.

⁷⁵ Special Rapporteur 2006, *supra* note 64, para. 57.

⁷⁶ WHO Model List of Essential Medicines, 15th List, March 2007, <<http://www.who.int/medicines/publications/EML15.pdf>>, visited on 3 December 2007.

⁷⁷ Special Rapporteur 2006, *supra* note 64, para. 58.

most in need of essential medicines. A more useful approach instead of focusing on obligations of result could be to focus on obligations of conduct. Inspired by the approach in General Comment No. 14, Audrey R. Chapman is a strong advocate of this approach.⁷⁸ Whatever approach applied, the most important thing to note is that, there seems to be a general idea that States need to direct their policies towards trying to provide for access to medicines.

To further cement the idea that access to medicines, especially access to essential medicines, is a fundamental part of the right to health, it should be noted that several successful court cases indicates its justiciable character. A recent study identified and analysed 71 court cases from 12 States in which access to medicines was claimed with reference to the right to health. In 59 cases, access to essential medicines as part of the fulfilment of the right to health could be enforced through the courts. It is interesting to note that skilful litigation can help ensure that States fulfil their obligation of access to medicines. However, it should also be noted that the authors firmly emphasise the importance of redressing to litigation only as a last resort. In their opinion, policymakers should ensure that human rights standards guide their health policies and programmes from the outset.⁷⁹

In conclusion, human rights appear to be a justified and well-established part of international law. Within this framework, the right to health has developed into a widely accepted right. Even though it may not always be entirely clear what the right encompasses, there is clear evidence both among UN institutions and mechanisms and in the scholarly world that access to medicines is a fundamental part of the right to health. As such, it is an element of the right to health that States should do their utmost to realize. When it comes to essential medicines, it is an immediate obligation that should be pursued at all times despite of potential obstacles standing in the way of its realization. Patents, especially pharmaceutical patents, are often put forward as a possible obstacle to the realization of access to medicines.

⁷⁸ Chapman 2003, *supra* note 19, pp. 201-203.

⁷⁹ H. Hogerzeil et al., 'Is Access to Essential Medicines as Part of the Fulfilment of the Right to Health Enforceable Through the Courts?', 368 *Lancet* (2006), pp. 305-311; *see also supra* note 41, for the *Treatment Action Campaign*-case.

Therefore, we will proceed by considering their place in international law in more detail in the next chapter.

2.2 Patents

2.2.1 Historical Background

Intellectual property is the generic term used for various forms of subjective rights that various legal orders grant to the creators of immaterial assets of intellectual origin. Those immaterial assets may be of two kinds, either literary and artistic creations or distinctive signs and inventions. The afforded form of protection varies depending on what kind the immaterial asset belongs to. Therefore, legal literature has divided intellectual property into two subfields, namely; (1) copyright, which protects literary and artistic work; and (2) industrial property, which protects industrial creations.⁸⁰ It is the latter form of protection that will be presented in this chapter, more precisely a specific part of it, namely, patents. In short, a patent is a legal title given to an inventor so she may exclude others from using the invention. It works as a deal between the inventor and the public authorities. Public authorities offer protection provided that the inventor discloses the information linked to the invention.

Ideas of intellectual property protection, and subsequently patent protection, have a long history. Some commentators date the origins of intellectual property protection as far back as the fourth century B.C. to Aristotle.⁸¹ However, more modern ideas of patent protection at an international level can be divided into three periods. The first period, known as the territorial period, included instruments such as the 1474 Venetian Decree, usually considered the first true patent law, and the 1623 English

⁸⁰ S. Salazar, *Intellectual Property and the Right to Health*, paper prepared for Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights (Geneva, November 9, 1998), pp. 4-5, <<http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/salazar.pdf>>, visited on 3 December 2007.

⁸¹ A. R. Chapman, 'Approaching Intellectual Property as a Human Right: Obligations Related to Article 15(1)(c)', 35(3) *Copyright Bulletin* (2001), p. 7 [hereinafter Chapman 2001].

Statute of Monopolies. In the following centuries, the principle of patents in the English Statute of Monopolies spread to several States, including the United States 1790 Patent Act and the French Law of 1791, recognising inventors' rights. A fundamental aspect of this period was the principle of territoriality. In short, this meant that protection did not go beyond the borders of a State offering protection. Thus, international protection was basically non-existent. The second period, identified as the international period, is signified by a growing interest in international cooperation in patent protection among States. This eventually resulted in the creation of the 1883 Paris Convention for the Protection of Industrial Property⁸² (Paris Convention). The 20th century saw an explosion in international intellectual property regimes with several multilateral instruments concluded. Additionally, the Paris Convention underwent several revisions and was accompanied by the creation of an international organization in the field of intellectual property. After the merging of two separate Bureaus, the United International Bureaus for the Protection of Intellectual Property (BIRPI) was created in 1893. BIRPI was then superseded by the World Intellectual Property Organization (WIPO), established in 1967 and a Specialized Agency of the UN since 1974.

The third period, the global period, originates in the linkage that States such as the United States made between trade and intellectual property in the 1980s.⁸³ At the multilateral level, this culminated in the form of the 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights⁸⁴ (TRIPS Agreement). States from the developing world were generally very reluctant to move patent protection into the trading regime, but in the end

⁸² Paris Convention for the Protection of Industrial Property, 20 March 1883.

⁸³ P. Drahos, *The Universality of Intellectual Property Rights: Origins and Development*, paper prepared for Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights (Geneva, November 9, 1998), pp. 3-10, <<http://www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/drahos.pdf>>, visited on 3 December 2007.

⁸⁴ The Agreement on Trade-Related Aspects of Intellectual Property Rights, included as Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

more than 100 States signed the Final Act.⁸⁵ Binding on all Members of the WTO, the TRIPS Agreement is at present binding on 151 States.⁸⁶ The TRIPS Agreement has been followed by a couple of declarations and decisions concerned with certain flexibilities related to the Agreement. These will be returned to later, when discussing patents, and the flexibilities offered by compulsory licences, in more detail.

The development of patents has been combined with several views of justifications advocated for its existence. A commonly presented view is that the patent system was developed with a main objective of creating an incentive for inventors to disclose their inventions to the public instead of keeping it secret. The basic idea is that inventors should be rewarded for their effort and risk of capital by the grant of a limited, though strong, monopoly. As a result, society will benefit as the system stimulates investment and employment and because detailed information of the invention is put into the realm of public knowledge.⁸⁷ Such an argument clearly bears a practical and utilitarian flavour to it. In fact, an influential utilitarian like English philosopher Jeremy Bentham (1748-1832) argued along these lines when advocating that exclusive use of the invention should be asserted by law for the inventor in exchange for all the effort and money put into the invention. Thereafter, the invention itself could be used for the general increase of knowledge and wealth.⁸⁸ Other views include those justifying patents as following from natural rights, consisting of a right to property of their mental labour, and justice arguments, claiming that justice demands an inventor's contribution to be recognised by a reward.⁸⁹

Nowadays, patent protection is usually justified as a necessary incentive for the private sector in areas in which they are granted.

⁸⁵ F. M. Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO', 5 *Journal of International Economic Law* (2002), p. 470 [hereinafter Abbott 2002].

⁸⁶ WTO Membership status, <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm>, visited on 3 December 2007.

⁸⁷ D. I. Bainbridge, *Intellectual Property, Fourth Edition* (Financial Times Pitman, London 1999) pp. 321-326 [hereinafter Bainbridge]; L. Bently and B. Sherman, *Intellectual Property Law, Second Edition* (Oxford University Press, Oxford, 2004) pp. 327-329 [hereinafter Bently and Sherman].

⁸⁸ Bainbridge, *supra* note 87, p. 321.

⁸⁹ Bently and Sherman, *supra* note 87, pp. 327-329.

Representatives of the pharmaceutical industry frequently point out that their industry spends enormous amounts on research and development. This combined with the fact that an existing medicine is relatively cheap and easy to copy, translates, in their opinion, into patents being indispensable for the development of new medicines and therefore justified. In fact, it has even been argued that industries such as the pharmaceutical industry “would become stagnant without patent protection through the lack of investment”.⁹⁰ Not everyone agrees that patents are the only way of providing an incentive for innovation and the corresponding research and development.⁹¹ Keith E. Maskus, on the other hand, takes another view. While considering several models, he arrives at the conclusion that patents may have its imperfections, but that it is still probably the most effective way of promoting innovation.⁹²

Whatever view applied to justify patents, its existence in present international law is a matter of fact. The majority of States in the world are bound by the TRIPS Agreement. The general idea put forward appears to be that patents promote innovation. Some authors adhere to this view and some question it. Without necessarily saying something on its functionality, it is sufficient to settle for patents as a tool intended to promote innovation and development. We will now proceed by taking a deeper look at the development of patents in international law.

2.2.2 Patents in International Law

The 1883 Paris Convention was the first genuine step in trying to harmonise patent legislation at the international level. It contains provisions on patents, such as the right to priority⁹³, territoriality⁹⁴ and compulsory licences.⁹⁵ However, the Paris Convention does not impose obligations on a Member

⁹⁰ Bainbridge, *supra* note 87, p. 325.

⁹¹ See, e.g., Cullet, *supra* note 66, pp. 141-142; Z. Lazzarini, ‘Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil’, 6 *Yale Human Right and Development Law Journal* (2003), pp. 111-112 [hereinafter Lazzarini].

⁹² K. E. Maskus, *Intellectual Property Rights in the Global Economy* (Institute of International Economics, Washington D.C., 2000) pp. 42-44.

⁹³ Article 4.

⁹⁴ Article 4*bis*, stipulating the independence of patent rights.

⁹⁵ Article 5A.

State to protect the right of foreigners if the State does not afford protection to its own nationals. Consequently, the requirements of the Paris Convention could easily be sidestepped by withholding patent protection for everyone. International harmonisation and protection of patents was therefore difficult to achieve under the Paris Convention.⁹⁶ Despite the conclusion of WIPO treaties, such as the Patent Cooperation Treaty⁹⁷ that simplified the filing for patents in more than one Member State, States maintained independent patent regimes. These various regimes used a wide variety of approaches, ranging from restrictive patents of relatively long duration to no patent protection at all for certain products, such as pharmaceuticals.⁹⁸

During the Uruguay Round of discussions (1986-1994) undertaken within the GATT-system⁹⁹, pressure was mounting to incorporate intellectual property, including patent protection, into the world trade regime. The primary advocates of this idea were States having a lot to gain from enforcement of patent law on the international level. The United States probably constituted the main driving force, voicing concerns over the unsatisfactory system of independent regimes and promoting greater harmonisation.¹⁰⁰ Some commentators have pointed out the influence of multinational companies in forming the position of the United States during the discussion over a new trade regime. In fact, lobbyists from a number of companies drafted several of the documents which later formed the position

⁹⁶ N. A. Bass, 'Implications of the TRIPS Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century', 34 *George Washington International Law Review* (2002), p. 194 [hereinafter Bass].

⁹⁷ Patent Cooperation Treaty, 19 June 1970 (in force 1 April 2002).

⁹⁸ Lazzarini, *supra* note 91, pp. 108-109; S. Bartelt, 'Compulsory Licences Pursuant to Trips Article 31 in the Light of the Doha Declaration on the Trips Agreement and Public Health', 6(2) *The Journal of World Intellectual Property* (2002), pp. 284-285 [hereinafter Bartelt].

⁹⁹ The General Agreement on Tariffs and Trade (GATT) was originally created by the Bretton Woods Conference as part of a larger plan for economic recovery after World War II. GATT never materialized as an international organization, which had been the idea from the beginning, so it remained simply as an agreement. The establishment of the World Trade Organization (WTO) included the Organization taking over the functions of GATT. However, GATT still exists as the WTO's umbrella treaty for trade in goods, updated as a result of the Uruguay Round negotiations.

¹⁰⁰ J. Braithwaite and P. Drahos, *Global Business Regulation* (Cambridge University Press, Cambridge, 2000) pp. 79-83.

of the United States during negotiations.¹⁰¹ The advocates for including patent protection succeeded and the Final Act, signed in 1994, worked as a cover note, with several other instruments attached to it. Those included the Agreement Establishing the WTO and the TRIPS Agreement. With the TRIPS Agreement in place, intellectual property, including patents, cemented its place in the multilateral trading system and in the WTO it had found the necessary institution for enforcement.

The TRIPS Agreement incorporates parts of the Paris Convention in Article 2 but nevertheless goes on to include a number of provisions dealing specifically with patents. Article 27(1) provides that Members shall make patents available for all inventions, whether products or processes, in all fields of technology, clearly including patents in the pharmaceutical industry. Patents are subject to normal tests of novelty, inventiveness and industrial applicability.¹⁰² A perceptive reader will note that the description in Article 27 is consistent with the definition of patentable subject matter in United States patent laws.¹⁰³ Some may interpret this as an indication of the influence that the United States exercised on the negotiations and the conclusion of the TRIPS Agreement. Additionally, the same Article allows States to exclude certain inventions from patentability. The condition for excluding inventions is that it is necessary for the protection of *ordre public* or morality, including protection of human health or serious environmental damage.

Article 28 deals with the exclusive rights conferred to the patent holder. For product patents this includes making, using, offering for sale, selling, and importing for these purposes. Process patents give rights not only over the use of the process but also for products resulting from it. Furthermore, patent holders have the right to assign, transfer by succession and conclude licensing contracts related to the patent. The duration of protection was a

¹⁰¹ See, e.g., D. Halbert and C. May, 'AIDS, Pharmaceutical Patents and the African State: Reorienting the Global Governance of Intellectual Property' in A. S. Patterson (ed.), *The African State and the AIDS Crisis* (Ashgate, Burlington, 2005) pp. 197-198 [hereinafter Halbert and May].

¹⁰² See, e.g., Bently and Sherman, *supra* note 87, pp. 384-487, for a detailed description on the conditions for granting patents.

¹⁰³ Bass, *supra* note 96, p. 197.

complicated subject during the negotiations leading up to the TRIPS Agreement. Prior to the TRIPS Agreement States applied a variety of standards, both as to the number of years to offer protection and to the starting date of the calculation. Article 33 applies a single standard, stipulating a minimum of 20 years of protection from the filing date. During negotiations, some States pushed for an extended protection for certain products, notably pharmaceuticals. However, no such provision made into the final version of the text.¹⁰⁴

Member States are enabled to limit the exclusive rights conferred in case some qualifications are met. Article 30 provides that some limited exceptions can be applied provided that they 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. The text in Article 30 is rather vague, making it difficult to deduce exactly what these ‘limited exceptions’ can be. However, in the *Canada – Patent Protection of Pharmaceutical Products*-case¹⁰⁵, the WTO Panel had to interpret the scope of exceptions in Article 30. Offering some guidance on the scope of exceptions, the Panel established that the term ‘limited exception’ indicated that an exception had to be narrow in scope, *i.e.* it should “make only a small diminution of the right in question”.¹⁰⁶ Furthermore, an Article 30-exception was not deemed ‘limited’ simply because restricted to a certain area of technology, but had to be evaluated on a case-by-case basis.¹⁰⁷ Apparently, unlike the exceptions in Article 27, a State cannot under Article 30 reject the patentability of a particular invention but only regulate its use.

It should be noted that during the negotiations of the TRIPS Agreement, it was evident that potential Member States were not merely concerned with protecting and enforcing intellectual property rights, including patents, as such. There were also calls for balancing the right of

¹⁰⁴ D. Gervais, *The TRIPS Agreement: Drafting History and Analysis, Second Edition*, (Sweet & Maxwell, London, 2003) pp. 255-256 [hereinafter Gervais].

¹⁰⁵ *Canada – Patent Protection of Pharmaceutical Products*, 17 March 2000, WTO doc. WT/DS114R [hereinafter *Canada*-case].

¹⁰⁶ *Ibid.*, para. 7.30.

¹⁰⁷ *Ibid.*, para. 7.92.

patent holders in relation to societal interests, such as public policy objectives of public health. For achieving this aim, Articles 7 and 8 were included, applicable to the TRIPS Agreement as a whole. Thus, they function as a means of interpretation for other parts of the Agreement, *e.g.* applicable when Members take measures to meet health objectives.¹⁰⁸

Article 7 provides that intellectual property protection should foster both technological innovation and transfer of technology to the mutual advantage of producers and users in a manner conducive to social and economic welfare, and to a balance of rights and obligations. A general principle is established in Article 8(1) allowing Members to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development”. A restriction is included stating that the measures must be consistent with the provisions of the TRIPS Agreement, indicating that non-compliance based on Article 8 is not an option.

In the *Canada – Patent Protection of Pharmaceutical Products*-case, Canada invoked Articles 7 and 8 in order to justify an exception to the patent protection provided by the TRIPS Agreement. Canada suggested that an Article 30-exception should be interpreted in the light of Articles 7 and 8, allowing for broader exceptions to patent protection because of public policy considerations. However, the WTO Panel opted for a more strict textual approach and did not uphold the Canadian position.¹⁰⁹ In the light of this, Daniel Gervais suggests that the principles included in Article 8 are primarily a policy statement more than anything else. As such, it would explain the rationale for the inclusion of specific provisions on exceptions to patent protection in Articles 30 and 31.¹¹⁰ Article 31 is concerned with compulsory licences of products under patent protection and will be returned to in great detail later.¹¹¹

Taking account of the potential problems faced by developing countries in implementing the TRIPS Agreement, a set of transitional provisions was

¹⁰⁸ Bartelt, *supra* note 98, pp. 285-286.

¹⁰⁹ *Canada*-case, *supra* note 105, paras. 7.23-7.26; *see also* Bartelt, *supra* note 98, pp. 286-287.

¹¹⁰ Gervais, *supra* note 104, pp. 120-122.

¹¹¹ *See infra* chapter 2.2.3.

included in Articles 65 and 66. Developing countries and countries in the process of transformation from central planning were given until 1 January 2000 to implement TRIPS. Article 65(4) provides for a special regime for pharmaceutical products. For such products, the deadline may be extended by five years if patent protection was unavailable for that particular category when the TRIPS Agreement came into force. States considered to belong to the least-developed countries were under Article 66 given until 1 January 2006 to implement. As a result of subsequent development within the WTO, the deadline for least-developed countries in protecting pharmaceutical patents has been extended to expire 1 January 2016.¹¹²

During the transitional period, States eligible to use such a period had to allow inventors to file for patents already from 1 January 1995 according to Article 70(8). This provision is usually referred to as the ‘mailbox provision’, because the filing of the application is what counts in order to assess whether the application meets the criteria for patenting, especially as regards to that of novelty. The actual assessment will take place after the transitional period has expired. Furthermore, if the Government allows the product to be marketed during the transitional period, Article 70(9) provides that the patent applicant should be afforded exclusive marketing rights for a period of five years.¹¹³

Finally, it is important to note that the framework established by the TRIPS Agreement is merely a set of minimum standards. Article 1(1) provides that “Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement”. In a commentary to the TRIPS Agreement, Daniel Gervais explains that this indicates that “the Agreement did not achieve all that some countries wished”.¹¹⁴ Philippe Cullet simply concludes that the minimum level of protection established by the TRIPS Agreement is equal to the consensus position that developed countries felt that they could settle on.¹¹⁵ It appears to be that the States from the developed world came out on top from the

¹¹² See *infra* chapter 2.2.3.2.

¹¹³ Bartelt, *supra* note 98, pp. 289-290.

¹¹⁴ Gervais, *supra* note 104, p. 86.

¹¹⁵ Cullet, *supra* note 66, p. 144.

negotiations leading up to the adoption of the TRIPS Agreement. A global system for the protection of patents is now in place. The system is intended to harmonise an area of law which had been very diverging from State to State prior to its conception. Much of this has been to the benefit of strong economical interests in the developed countries. Nevertheless, the TRIPS Agreement saw the inclusion of a number of flexibilities allowing for consideration from a social perspective. We will now turn to an integral flexibility included in the TRIPS Agreement, namely, compulsory licences.

2.2.3 Compulsory Licences

The regime of compulsory licences offers an interesting flexibility in a sphere that is normally within the exclusive right of the patent holder. In short, the system of compulsory licences, under certain circumstances, gives Governments the right to authorise a third party, whether a private company or a Government agency, to exploit a patent without the patent holder's consent. This chapter examines how this flexibility has developed from the Paris Convention to the TRIPS Agreement and related Declarations and Decisions.

2.2.3.1 The TRIPS Agreement and its Predecessors

The Paris Convention includes compulsory licences in Article 5(A). In fact, Article 5(A)(3) recognises compulsory licensing as the primary means to ensure that a patent was actually being worked by declaring that forfeiture of the patent would only appear if compulsory licensing proved insufficient. For a compulsory licence to be issued, a period of four years without working the patent had to take place. Additionally, the licences were to be non-exclusive and non-transferable. Interestingly, few other restrictions were included, for instance, nothing is said about the need to compensate the patent holder economically. Inspired by the Paris Convention, several

States included provisions on compulsory licences during the 20th century on grounds such as anti-competitive behaviour and public interest.¹¹⁶

Although the TRIPS Agreement does not mention the term ‘compulsory licences’ explicitly, it is evident that Article 31 deals with exactly such kinds of exceptions along with government use when it is talking about ‘other use’. This provision supplements the general exceptions provided in Articles 27 and 30 and does not specifically list the reasons that may be claimed to justify its application. However, for it to be permissible a strict and comprehensive set of conditions must be fulfilled.

First, such a licence should be granted taking into consideration “its individual merits”, Article 31(a). This means that decisions need to be taken for each individual application and that a compulsory licence therefore cannot be given to an entire product category, such as pharmaceuticals. Article 31(b) provides that the proposed user should first try to get the authorisation of the patent holder for the use, *i.e.* a voluntary licence. Without clarifying exactly what it means the Article states that such efforts must be made on reasonable terms and for a reasonable period of time. One author has noted that the technological development in the State where a compulsory licence is contemplated could have an influence on how to decide what is reasonable.¹¹⁷ However, in cases of national emergency, other extreme emergencies and anti-competitive practices, the condition to first seek a voluntary licence does not have to be fulfilled. Again, the TRIPS Agreement fails to explain what is meant by national emergencies and who is to decide on whether or not a national emergency is at hand. As will be shown later, this has been somewhat corrected by subsequent work on the topic within WTO.

Concerning the duration of a licence, Article 31(g) stipulates that it should be liable to be revoked as soon as the purposes for which it was granted cease to exist and are unlikely to recur, for instance, the end of a national emergency. Additionally, the scope of the licence should be

¹¹⁶ G. Curci and M. Vittori, ‘Improving Access to Life-Saving Patented Drugs – Between Compulsory Licensing and Differential Pricing’, 7(5) *The Journal of World Intellectual Property* (2004), p. 744 [hereinafter Curci and Vittori].

¹¹⁷ Gervais, *supra* note 104, pp. 250-251.

proportional, or in the terms of Article 31(c), “limited to the purpose for which it was authorized”. Therefore, a compulsory licence could be limited to certain claims of a patent. Similarly, proportionality also applies to the duration period.¹¹⁸ Furthermore, Articles 31(d) and (e) provides that the licence should be both non-exclusive and non-assignable. Among other things, this means that more than one compulsory licence can be granted for a given patent

Carlos Correa has noted that the TRIPS Agreement does not limit the purpose for which a compulsory licence can be granted. To put it differently, a compulsory licence could work either to import or to domestically produce the patented product.¹¹⁹ However, a possible roadblock for using compulsory licences for import is Article 31(f) stipulating that a licence should “be authorized predominantly for the supply of the domestic market of the Member authorizing such use”. This means that compulsory licences issued to mainly serve the needs of another State, *e.g.* in need of affordable medicines, are not allowed. Consequently, States without domestic manufacturing capacity may find it difficult to find available exporters catering for their needs. As of 1 January 2005, potential suppliers have become even harder to find. This is due to the fact that the transitional period offered to developing countries under Article 65(4) has expired; meaning patent protection now extends to all areas in those States. Unfortunately, this means that potential providers, such as Brazil, China and India, all boasting high levels of manufacturing capacity, will not be able to export the much needed cheap generic versions of a number of patented medicines.¹²⁰

Finally, under Article 31(h), the patent holder should always “be paid adequate remuneration” for the use. This holds true also for the cases where

¹¹⁸ *Ibid.*, p. 251.

¹¹⁹ C. M. Correa, ‘The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection’, 16 *European Intellectual Property Review* (1994) in P. Goldstein, *International Intellectual Property Law: Cases and Materials* (Foundation Press, New York, 2001) p. 383.

¹²⁰ D. Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: a Solution to the Access to Essential Medicines Problem?’, 7(1) *Journal of International Economic Law* (2004), pp. 77-78 [hereinafter Matthews]; *see also infra* chapter 3.5.

a voluntary licence does not have to be sought. Similar to a lot of the wording in Article 31, no guidance is given on roughly what could constitute adequate remuneration. One author understands the condition as the need for the licensee to pay what such a licence would normally cost if available from the patent holder.¹²¹ Not everyone agrees with this view. Philippe Cullet looks to the context of Article 31 and states that it “implies that this remuneration is necessarily below the cost of a normal licence, since there would be no need for compulsion otherwise”.¹²² Clearly, the question of the size of the remuneration will vary depending on what side of the non-voluntary contract one belongs to, the patent holder or the licensee. However, it is believed that the argument brought forward by Cullet has a strong sense of logic speaking to its advantage. In any case, in the event of potential clashes over remuneration size, it is for the WTO system to decide. A precedent on the topic would certainly be useful.

Consequently, the TRIPS Agreement offers the flexibility of compulsory licences for a number of circumstances. These situations include situations of national emergency or extreme urgency and cases of public non-commercial use, also known as government use. Compared to the Paris Convention, the TRIPS Agreement goes a lot further when it comes to regulating compulsory licences. Unlike the TRIPS Agreement, the former only offered compulsory licences for failure to work a patent. The condition in Article 31 that has caused most controversy is probably the requirement to limit the licence to predominantly supply the domestic market. The Paris Convention contained no such provision. The controversy created by that condition and the rather vague language contained in Article 31 in general has resulted in the adoption of a couple of subsequent documents and decisions dealing with compulsory licences.

2.2.3.2 The Doha Declaration

The compulsory licensing framework established by the TRIPS Agreement offered the possibility for developing countries to control some of the

¹²¹ Gervais, *supra* note 104, p. 252.

¹²² Cullet, *supra* note 66, p. 147.

impacts of the introduction of patents and for the extended patentability provided by Article 27. Nevertheless, Article 31 and compulsory licensing in relation to public health issues has been at the centre of debate following the adoption of the TRIPS Agreement.

Concerns, predominantly from developing countries, over the impact of the TRIPS Agreement on access to medicines evolved over a period of years following the adoption of the TRIPS Agreement. These concerns were expressed in several fora, such as NGOs and the European Commission. However, it was not until the request of Zimbabwe, on behalf of the Africa Group, at a TRIPS Council meeting in April 2001 that the question was firmly established on the agenda of the TRIPS Council. The Council decided to convene a Special Session for the discussion of access to medicines to take place in June the same year.¹²³ The initial discussions at the Special Session focused on two main issues, namely, a clarification of the flexibilities in the TRIPS Agreement and the relationship between the TRIPS Agreement and affordable access to medicines.¹²⁴ As a result of the initiative by the African group of States, a separate Declaration was adopted on the issue at a WTO Ministerial Conference in Doha, Qatar in 2001 (Doha Declaration).¹²⁵

It is not difficult to guess why developing countries raised their concerns over TRIPS-impact on access to medicines. With an extended obligation to provide patents for medicines, it is only natural to be concerned about the potential effects on access. Surely, concerned States also took into account the apparent reluctance of foreign patent holders to actually work a patent held in the developing world. In fact, a study has revealed that less than five percent of foreign owned product patents in the developing world were actually used to protect production processes in those States. Vandana Shiva interprets this as an intention by companies to

¹²³ Abbott 2002, *supra* note 85, pp. 480-481; T. Kongolo, 'TRIPS the Doha Declaration and Public Health', 6(2) *The Journal of World Intellectual Property* (2003), pp. 373-374.

¹²⁴ Gervais, *supra* note 104, p. 52.

¹²⁵ Declaration on the TRIPS Agreement and Public Health, Ministerial Conference, Fourth Session, WTO Doc. WT/MIN(01)/DEC/2, 14 November 2001; *see* Abbott 2002, *supra* note 85, pp. 480-504, for an extensive examination of the discussion leading up to the Doha Declaration and a paragraph-by-paragraph commentary.

merely prevent others from using the innovation, and, thus, possibly limiting access.¹²⁶

Returning to the Doha Declaration, paragraph 4 stipulates that the TRIPS Agreement should not prevent Members from taking measures to protect public health. The TRIPS Agreement should be interpreted and implemented so that Members' right to protect public health, in particular to promote access of medicines to all, is supported. The paragraph also reminds WTO Members of their right to use the flexibility of the provisions in the TRIPS Agreement to achieve this aim. Frederick M. Abbott highlights the importance of this paragraph. In his opinion, it strongly indicates the weight that should be given by the WTO to public health considerations, such as promoting access to medicines, when interpreting whether or not a State is in compliance with its obligations under the TRIPS Agreement.¹²⁷

Paragraph 5 explains the flexibilities available to States to include "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted". This clearly indicates that the grounds listed in the TRIPS Agreement for issuing a compulsory licence should not be understood as exhaustive. Consequently, States should be able to implement additional grounds, such as the failure to work a patent or environmental protection.¹²⁸ Furthermore, each Member has the right to determine what constitutes national or other extreme emergency for the purposes of compulsory licences. In the paragraph, it is explicitly stipulated that a public health crisis, such as HIV/AIDS, can represent such a state. Though the clarification on who actually determines when a national emergency is at hand is most welcome, Daniel Gervais does not believe that it brings anything new. According to him, even without the clarification it would be unlikely that a WTO dispute settlement panel would override such a decision made in good faith by a Member State.¹²⁹

¹²⁶ V. Shiva, *Protect or Plunder? Understanding Intellectual Property Rights* (Zed, London, 2001) pp. 108-109.

¹²⁷ Abbott 2002, *supra* note 85, pp. 491-493.

¹²⁸ Bartelt, *supra* note 98, p. 295; K. M. Gopakumar, 'TRIPS Implementation and Public Health Safeguards' in *South Asian Yearbook of Trade and Development - Mainstreaming Development in Trade Negotiations: Run Up to Hong Kong 2005* (Centre for Trade and Development, New Delhi, 2005) p. 246 [hereinafter Gopakumar].

¹²⁹ Gervais, *supra* note 104, p. 251.

In paragraph 6, the Declaration takes special notice of WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector. It is recognised that these States face particular difficulties in making effective use of compulsory licences under the TRIPS Agreement. Though it is not explicitly spelt out in the paragraph, it is evident that potential problems caused by Article 31(f), *i.e.* the restriction to produce predominantly for the domestic market, are what the Declaration is considering. In order to try and conquer the problem, the TRIPS Council is instructed to find an expeditious solution and report back to the General Council before the end of 2002. Finally, in paragraph 7, the Declaration extends the transitional period for least-developed countries until 1 January 2016 as regards to providing patent protection for pharmaceutical products. The TRIPS Council is instructed to take the necessary action to give effect to the extended period. This was achieved by the Council in a Decision of 27 June 2002.¹³⁰

The Doha Declaration is not a formal interpretation under the procedural requirements of the WTO Agreement definitively interpreting the TRIPS Agreement. Only the Ministerial Conference or the General Council have the authority to render such formal interpretations. However, one author argues that in case of disputes arising over measures taken by Member States on public health grounds, the Doha Declaration should be used to interpret the TRIPS Agreement in a manner supportive of such measures. The reason for this being that the Doha Declaration can be seen as “subsequent practice in application of the treaty” as stated in Article 31(3)(b) the 1969 Vienna Convention on the Law of Treaties.¹³¹ Other authors, on the other hand, offer some words of caution by pointing out that the legal status of the Doha Declaration is still uncertain.¹³²

¹³⁰ Decision on Extension of the Transition Period under Article 66(1) of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, WTO Doc. IP/C/25, 27 June 2002.

¹³¹ Bartelt, *supra* note 98, pp. 302-303; Vienna Convention on the Law of Treaties, adopted 23 May 1969, 1155 UNTS 331 (entered into force 27 January 1980), UN Doc. A/Conf.39/27 (1969).

¹³² See, e.g., Matthews, *supra* note 120, pp. 82-83.

No matter what legal status one ascribes to the Doha Declaration, its value of principle should not be underestimated. Unlike the TRIPS Agreement, the Doha Declaration explicitly talks about compulsory licences as an important flexibility. This semantic shift from ‘other use’ in Article 31 of the TRIPS Agreement to ‘compulsory licences’ in the Doha Declaration may work in favour of generating greater public awareness of its existence and importance. Another important feature is the mere fact that an entire declaration is devoted to the issue of the relationship between patents and public health consideration. One author goes as far as saying that the Doha Declaration was the first time the WTO “openly acknowledged that the public health problems in many countries were in part a result of the intellectual property regime under the TRIPS Agreement”.¹³³ Not everyone is as enthusiastic about the value of the Doha Declaration. One view offered is that it merely restated in more lengthy terms the principles that were already included in Article 8 of the TRIPS Agreement.¹³⁴

In conclusion, opinions may vary on the extent to which the Doha Declaration has brought any novel ideas into the regime of compulsory licences. Nevertheless, it is difficult to question the fact that it has brought some welcome clarifications to an area of the TRIPS Agreement that was flawed with uncertainty. It may not have opened up new avenues within the TRIPS Agreement, but it confirms the legitimacy of pursuing the already built-in flexibilities.

2.2.3.3 The Implementation Decision

Attempting to resolve the issue presented by paragraph 6 of the Doha Declaration, *i.e.* the difficulties of States with insufficient or no manufacturing capacity to make use of compulsory licences, WTO Members began discussions within the TRIPS Council at its first meeting in 2002. Negotiations continued in both formal and informal meetings throughout the year and into the next one.¹³⁵ During the course of

¹³³ A. Gupta, ‘Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?’, 2 *Buffalo Intellectual Property Law Journal* (2004), p. 146.

¹³⁴ Halbert and May, *supra* note 101, p. 204.

¹³⁵ Gervais, *supra* note 104, pp. 48-54.

negotiations a number of proposals were brought forward on how to resolve the issue. The various proposals can be summarised into four overall options:

- Moratorium on dispute settlement cases in relation to Article 31(f) of the TRIPS Agreement;
- Waiver of Article 31(f) in line with the requirements under the WTO Agreement;
- Amendment of Article 31(f) to allow exports of products produced under compulsory licence; and
- Extensive interpretation of the 'limited exceptions' clause of Article 30 of the TRIPS Agreement.¹³⁶

Negotiations lingered on beyond the stipulated deadline of the end of 2002 without States being able to reach a compromise. Each option had its advocates. A breakthrough was finally achieved when a small group of WTO Members met in mid-2003 to negotiate a solution. The compromise solution arrived at by the group was based on the option of a waiver of Article 31(f) of the TRIPS Agreement (option 2 above), until Article 31 is amended. This group, consisting of the United States, Kenya, Brazil, South Africa and India, succeeded in delivering a Draft proposal, followed by a revised Draft, in August 2003. The TRIPS Council approved the revised Draft on 28 August 2003 and presented it to the WTO General Council.¹³⁷ The General Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health on 30 August 2003 (Implementation Decision).¹³⁸

Paragraph 2 of the Implementation Decision waives the condition in Article 31(f) of the TRIPS Agreement for exporting Members when producing pharmaceuticals for export to States with insufficient or no

¹³⁶ See Matthews, *supra* note 120, pp. 83-92, for a very useful examination of the four options and their respective positive and negative attributes.

¹³⁷ *Ibid.*, p. 95.

¹³⁸ Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WTO Doc. WT/L/540 and Corr.1, 30 August 2003.

manufacturing capacity. Consequently, a novelty is introduced in that compulsory licences can be authorised for the export of pharmaceuticals without the need to worry about predominantly satisfying the domestic market of the exporting Member. According to Paragraph 3, the exporting Member is required to pay adequate remuneration in line with Article 31(h) of the TRIPS Agreement. The importing Member is exempted from this to the extent remuneration is paid in the exporting Member.¹³⁹

It should be noted that for compulsory licences to be issued under this new regime a number of conditions still need to be met. The importing Member must still first seek a voluntary licence from the patent holder on reasonable terms for a reasonable period of time. If this is not viable, the next step for the importing Member is to assess its domestic generic industry's capacity to produce the medicine. If capacity is deemed insufficient, it should then notify the WTO with a detailed justification of its decision. Furthermore, the importing Member must then notify a potential exporting Member, which must in turn first seek a voluntary licence. Failing that, the exporting Member needs to seek a compulsory licence on a single-State basis from its own Government, including the requirement to reasonably remunerate the patent holder in the importing Member. Additional requirements include certain provisions on packaging, labelling and the shape of the medicine and to post information of quantities on the WTO website.¹⁴⁰

It may well be that the solution to one of the major concerns raised in the Doha Declaration has resulted in a regime that is too complex to be practically available. Not least, the requirement of issuing two compulsory licences for the same situation, one in the importing and one in the exporting Member could turn out to be procedurally cumbersome. At least

¹³⁹ See F. M. Abbott, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health', 99 *American Journal of International Law* (2005), pp. 317-358 [hereinafter Abbott 2005], for an extensive coverage of the Implementation Decision and the negotiations leading up to it.

¹⁴⁰ Curci and Vittori, *supra* note 116, pp. 746-747; C. M. Correa, *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (WHO, Geneva, 2004) pp. 15-26, <http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf>, visited on 3 December 2007.

one author believes that the procedural requirements make the whole Implementation Decision impractical to practise.¹⁴¹ Other authors prefer to focus on the positive aspects of the Implementation Decision. Curci and Vittori points out that a Decision devoted entirely to allowing States with insufficient or no manufacturing capacity to make full use of compulsory licences is evidence that things are moving in the right direction.¹⁴²

At present, a Protocol of Amendment of the TRIPS Agreement¹⁴³ is open for Members to accept, including the regime set out in the Implementation Decision. In line with Article X of the WTO Agreement, it is required that two thirds of the Members of the WTO accept the Amendment for it to enter into force. The Protocol of Amendment was first open for acceptance until 1 December 2007. As States appeared reluctant to accept the Protocol, the deadline was extended to 31 December 2009. Until present, only 13 Members have accepted the Protocol of Amendment.¹⁴⁴

To sum up the legal framework on compulsory licences, three texts, the TRIPS Agreement, the Doha Declaration and the Implementation Decision, now collectively regulate the use. The inclusion of compulsory licences, and other flexibilities, already from the beginning in the TRIPS Agreement appears to indicate that there must have been some awareness of the potential effects that patents can have on issues related to public health. It does not seem far-fetched to believe that the idea of a human right to health, including the fundamental part of access to medicines, might have been in the minds of those negotiating the Agreement. This awareness is what has generated succeeding documents on the topic such as the Doha Declaration and the Implementation Decision. It is true that the procedural mechanism of applying compulsory licences is burdensome. However, one should not only focus on the problematic side. It appears to be more constructive to

¹⁴¹ Gopakumar, *supra* note 128, p. 247.

¹⁴² Curci and Vittori, *supra* note 116, pp. 751-752.

¹⁴³ Decision on Amendment of the TRIPS Agreement, WTO Doc. WT/L/641, 6 December 2005.

¹⁴⁴ The Members that have accepted the Amendment as of 3 December 2007 in order of acceptance date are the United States, Switzerland, El Salvador, the Republic of Korea, Norway, India, the Philippines, Israel, Japan, Australia, Singapore, Hong Kong and China, <http://www.wto.org/English/tratop_e/trips_e/amendment_e.htm>, visited on 3 December 2007.

focus on the fact that some much needed clarification on the rules on compulsory licences has now been offered. Furthermore, it now appears to be that the WTO considers the flexibility of compulsory licences to be an important alternative for overcoming potential problems raised by pharmaceutical patents on access to medicines.

3 Relationship between Pharmaceutical Patents and Access to Medicines

After the rather extensive examination of the separate legal frameworks surrounding pharmaceutical patents and access to medicines, this chapter will proceed to consider the relationship between the two in more detail. Some voices have been raised that the relationship is quite simple in that patents themselves actually constitute a human right. Though this idea is by no means extensively raised in the literature, it will be examined in the first subchapter below.

The discussion exercised so far in this thesis has clearly indicated that the two areas of international law from time-to-time intertwine. To illustrate this, a brief part of this chapter will be devoted to the presentation of the worldwide HIV/AIDS epidemic. As both areas of international law appear to be both justified and well-established, a fundamental feature of this chapter will be to consider the character of the relationship. Does it necessarily amount to a legal conflict or is it possible to consider it under an alternative approach? To explore a possible alternative approach, the flexibilities to the present patent system will be investigated. More specifically, a particular flexibility will be examined at length, namely, compulsory licences. Since the international legal framework related to compulsory licences has been covered above, this chapter will focus on practice until present and potential roadblocks standing in the way of its use. To conclude the chapter, some thoughts on the relationship and the role of compulsory licences will be provided.

3.1 Patents as Human Rights

As pointed out by Audrey R. Chapman, not much attention has been paid to the interpretation of intellectual property, such as patents, as a human

right.¹⁴⁵ Nevertheless, drafters of human rights instruments have at least taken enough consideration of it to include a few provisions that are closely linked to the idea of affording intellectual property protection, including patents, to inventors. Among these is Article 27(2) of the UDHR that proclaims “the right to protection of the moral and material interest resulting from any scientific, literary or artistic production of which he is the author”. A similar provision was included in Article 15(1)(c) of the ICESCR, which unlike UDHR is of a legally binding nature.

The inclusion of these provisions in prominent human rights instruments has led to some calls of patents as amounting to a human right. The conceptualisation of patents as a human right will clearly have some features distinct from its role as an economic interest under intellectual property law. The balancing of interests between inventors and the wider society included in the patent framework is given a much broader approach in the field of human rights. For human rights, the prevailing goal is to improve human welfare and not to maximise economic profits. Or in other terms, from a human rights perspective, the protection of patents should be understood from its role as a social product bearing a social function and not principally as an economic relationship.¹⁴⁶ Furthermore, and more concretely, the human right status ensures that patents must make sure that all other internationally recognised human rights are respected and promoted. This follows from the generally accepted view that all human rights are of equal status and interdependent.¹⁴⁷

However, the drafters of the mentioned human rights instruments did not intend to recognise the inventor’s interest as a fundamental human right of its own. Article 15 of the ICESCR also deals with obligations on States Parties to provide cultural rights, Article 15(1)(a), and the right of everyone to enjoy the benefits of scientific progress and its applications, Article 15(1)(b). The right included for inventors is just a part of a bigger right. It bears a subsidiary status and was included with the intention to try and

¹⁴⁵ Chapman 2001, *supra* note 81, p. 13.

¹⁴⁶ Chapman 2002, *supra* note 1, p. 867.

¹⁴⁷ As established by the 1993 Vienna Declaration and Programme Action, *see supra* note 13.

balance the societal interests with those of the private inventor. In fact, the inclusion of a right to protect inventors' interests was highly debated during the negotiations leading to the adoption of the ICESCR. Some believed that such protection could possibly work as an obstacle to the possibility for others to enjoy the benefits of scientific progress.¹⁴⁸ The CESCR, has produced an authoritative interpretation of the rights connected to Article 15(1)(c) of the ICESCR in its General Comment No. 17. In it, the Committee establishes that the right of inventors to protection of interests is in fact a human right.¹⁴⁹ However, and this is crucial, this does not mean that patents provided under the present international intellectual property framework should be mistaken for the human right recognised in Article 15(1)(c).¹⁵⁰

Consequently, a more appropriate way of approaching the issue could be to consider the right to protection of inventors' interests included in the human rights instruments as something separate from patents provided under the international patent framework established by the TRIPS Agreement. What we are dealing with are two different sets of protecting inventors' moral and material interest. The Committee further explained that the protection required under Article 15(1)(c) need not necessarily reflect the level of protection provided by the present international patent framework. In fact, States are free to enter into international instruments with a higher level of protection as long as they do not unjustifiably limit the full enjoyment by others of any of the human rights under the ICESCR.¹⁵¹ Clearly, whether exercised as a right under Article 15(1)(c) of the ICESCR or under the international patent system, provisions on patents should always consider its potential implications on human rights. Protection of patents cannot completely disregard human rights provisions

¹⁴⁸ A. Eide, 'Cultural Rights as Individual Human Rights' in A. Eide *et al* (eds.), *Economic, Social and Cultural Rights: a Textbook, Second Revised Edition* (Martinus Nijhoff, Dordrecht, 2001) pp. 296-298.

¹⁴⁹ General Comment No. 17 of the CESCR, dealing with 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 (Article 15(1)(c)), UN Doc. E/C.12/GC/17, para. 1.

¹⁵⁰ *Ibid.*, paras. 2-3.

¹⁵¹ *Ibid.*, paras. 10-11.

but needs to find a balance for compliance with the international human rights framework.

3.2 HIV/AIDS

An illustrative and highly tragic example of an area where pharmaceutical patents and access to medicines, and the corresponding areas of international law, intertwine is the ongoing HIV/AIDS epidemic. Since 1981, 65 million people have been infected with HIV and 25 million have died of AIDS-related illnesses. In 2006, 4.3 million new infections were recorded, as were 2.9 million AIDS-related deaths – more than in any previous year. Today, 39.5 million people are living with HIV.¹⁵²

HIV is a type of virus called a retrovirus, and the medicines developed to disrupt the action of HIV are called antiretrovirals or ARVs. The AIDS virus mutates rapidly and often develops resistance to various medicines. To minimise the risk, a person with AIDS is usually treated with a cocktail of ARVs. Today, there are various forms of ARVs available on the market to combat HIV/AIDS. ARVs have proved effective at treating people with AIDS. However, they are not a cure. If treatment is suspended the virus becomes active again, so a person on ARVs must take them for life.¹⁵³

The life-saving medicines in the form of ARVs are generally developed by major pharmaceutical companies carrying a patent for the product. This holds especially true for newer and more effective versions. This does not necessarily mean that a patent is applied for in all possible cases in all States of a developing region. In fact, a recent study in 53 African States concluded that patents on ARVs had only been applied for in 172 of 795 possible cases. This had allowed importation of the generic versions in the remaining 623 cases.¹⁵⁴ However, it has been pointed out that South Africa,

¹⁵² 2006 Annual Report: Making the Money Work, UNAIDS (UNAIDS, Geneva, 2007); AIDS Epidemic Update: Special Report on HIV/AIDS: December 2006, UNAIDS and WHO (UNAIDS/WHO, Geneva, 2006), both at <<http://www.unaids.org/en/Publications/default.asp>>, visited on 3 December 2007.

¹⁵³ Description of HIV/AIDS and ARVs on UNAIDS website, <http://www.unaids.org/en/Issues/Prevention_treatment/antiretroviral_therapy.asp>, visited on 3 December 2007.

¹⁵⁴ A. Attaran and L. Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain

the region's richest State and with the highest number of people living with HIV, had most patents in force. This appears to indicate that patents are pursued and applied for where there is a potential market.

Furthermore, patents on a particular medicine in other States often blocked use of the 'cocktail therapy' that is key to treatment. Consequently, even without applying patents to its fullest extent, access to the necessary combination of ARVs could easily be affected.¹⁵⁵ As will be shown by the discussion on the practice of compulsory licences later¹⁵⁶, this can lead to that patented ARVs become too expensive for some States to provide them in sufficient amounts. These States are exclusively found in the developing world. Not surprisingly, developing countries also have the highest number of people living with HIV. In fact, 95 percent of the people infected with HIV live in developing countries.¹⁵⁷

To add to the economic burden of these States, it has been noted that the widespread occurrence of HIV/AIDS significantly reduces the productivity of affected populations. To give but one example, economic studies have suggested that the South African gross domestic product (GDP) will be 17 percent lower in 2010 than it would be without the disease. To put it in other terms, US\$ 22 billion in output is removed from the economy leaving even less money to spend on life-saving medicines.¹⁵⁸

The high cost of ARVs has made them a natural target for the generic pharmaceutical industry. Research and development of a new ARV is usually quite a costly endeavour. However, to merely copy the product and make a generic version of it is not very difficult and therefore clearly not as expensive as the process of developing the original. As a result of generic ARVs, a number of developing countries have managed to provide life-

Access to AIDS Treatment in Africa?', 286 *Journal of the American Medical Association* (2001), pp. 1886–1892.

¹⁵⁵ M. Foreman, 'Patents, Pills and Public Health: Can TRIPS Deliver?' (Panos Institute, London, 2002) p. 12 [hereinafter Foreman], <http://www.panos.org.uk/PDF/reports/TRIPS_low_res.pdf>, visited on 3 December 2007.

¹⁵⁶ See *infra* chapter 3.4.

¹⁵⁷ Lazzarini, *supra* note 91, p. 106.

¹⁵⁸ M. Ganslandt, K. E. Maskus and E. V. Wong, 'Developing and Distributing Essential Medicines' in C. Fink and K. E. Maskus (eds.), *Intellectual Property and Development: Lessons from Recent Economic Research* (World Bank, Washington D.C., 2005) pp. 211–212.

saving medicines to a greater number of people. To put it differently, developing countries have been able to fulfil their obligation to provide access to essential medicines to a greater degree. The adoption of the TRIPS Agreement and the continued harmonisation of patented legislation, *i.e.* transitional periods coming to end, could potentially hamper this development.¹⁵⁹ In a recent report, The Joint UN Programme on HIV/AIDS (UNAIDS) mentions the potential problems of pharmaceutical patents and the continued harmonisation. In their opinion, there is an uncertainty over future sources of generic medicines which could make it difficult to generate access to ARVs on a sufficient level.¹⁶⁰

Some positive developments on the worldwide struggle against HIV/AIDS should be noted. Political commitment and leadership appears to be evolving, at least within the UN system. In 2001, States signed a Declaration on Commitment on HIV/AIDS, adopted as a resolution of the UN General Assembly.¹⁶¹ States agreed to look upon HIV/AIDS as one of the major challenges to human life and dignity and called for a global commitment to coordinate its struggles. Five years later, a follow-up Political Declaration on HIV/AIDS was adopted in which States are requested to intensify their efforts against what is seen as an unprecedented human catastrophe.¹⁶² Combined with this political commitment, funding levels to tackle HIV/AIDS have increased from some US\$ 300 million in 1996 to US\$ 8.9 billion in 2006. However, the funding available today may be just one-third of what will be required to respond to the growing epidemic in a few years. The epidemic is growing at a rate which makes it extremely important that States take their apparent political commitment seriously and provide the necessary funds to start reversing the epidemic. UNAIDS estimates that US\$ 18.1 billion is needed in 2007 and US\$ 22.1 billion in 2008.¹⁶³

¹⁵⁹ See *infra* chapter 3.5.

¹⁶⁰ 2006 Report on the Global AIDS Epidemic, UNAIDS (UNAIDS, Geneva, 2007) p. 165 [hereinafter 2006 Report], <http://www.unaids.org/en/HIV_data/2006GlobalReport/default.asp>, visited on 3 December 2007.

¹⁶¹ Declaration of Commitment on HIV/AIDS, 2 August 2001, UN Doc. A/RES/S-26/2.

¹⁶² Political Declaration on HIV/AIDS, 15 June 2006, UN Doc. A/RES/60/262.

¹⁶³ 2006 Report, *supra* note 160, pp. 224-252.

3.3 Conflict or Flexibility?

As is evident from the discussion presented so far, the relationship between pharmaceutical patents and access to medicines is by no means straightforward. Situations exist where the two areas intertwine. In such situations, different institutions may call for distinct solutions on how to handle the situation at hand. In the following section, an examination will be presented on whether such situations translate the relationship between pharmaceutical patents and access to medicines into a legal conflict or if alternative approaches are possible. Flexibilities to patent protection, particularly in the form of compulsory licences, will form an integral part of the examination.

3.3.1 Generally

From the discussion concluded so far, it seems fair to state that both patents and access to medicines are well-established parts of international law. Belonging to bigger frameworks of intellectual property and human rights respectively, the two distinct areas of international law are connected to different justifications and different international institutions. Patents are commonly justified as a necessary incentive for invention under the auspices of the WTO, where trade and economic perspectives form the focal point. Human rights, on the other hand, find its main sponsor in the UN and are commonly promoted from a social perspective of human well-being. If one takes as a starting point that both areas of international law are justified, the next step would be to consider their relationship. As evident from the illustrative example of the HIV/AIDS epidemic presented above, there are situations where the two areas of international law intertwine. It is not far-fetched to imagine that different institutions with different perspectives may have varying opinions and rules on how intertwining situations should be handled. Does this mean that the international law related to patents, on the one hand, and access to medicines, on the other, form a legal conflict? Or, is there enough flexibility and potential in the present system for them to be exercised side-by-side?

A useful method for examining the relationship is to apply a human rights perspective to present patent legislation and its flexibilities. Nowhere in the TRIPS Agreement are the terms ‘human rights’ or ‘right to health’ used, though ‘public health’ is used in Article 8(1) as a ground for taking certain measures. Discussions succeeding the adoption of the TRIPS Agreement focused on the general notion of public health, to the exclusion of individual human rights. The rather vague term of public health allows for a number of possible interpretations. One might only speculate if the term has been selected to avoid overt recognition of human rights, such as the right to health and its cornerstone of access to medicines. At least one author believes this to be the case.¹⁶⁴ An NGO, the American Institute of Medicine, has produced a thoughtful definition of public health:

“Public health is what we, as a society, do collectively to assure the conditions for people to be healthy. This requires that continuing and emerging threats to the health of the public be successfully countered. These threats include immediate crises, such as the AIDS epidemic; enduring problems, such as injuries and chronic illness; and growing challenges, such as the aging of our population and the toxic by-products of modern economy, transmitted through air, water, soil, or food. These and many other problems raise in common the need to protect the nation’s health through effective, organized, and sustained efforts led by the public sector.”¹⁶⁵

It seems likely that the obligations assumed by States as a result of the existing human right to health would fit in well under such a definition. In any case, no matter what definition is applied to the notion of public health, the TRIPS Agreement has significant impact beyond trade and intellectual property. Such impact also stretches into the sphere of human rights in general, and access to medicines in particular.¹⁶⁶

Despite the apparent lack within the WTO-system of discussing in terms of individual human rights in relation to patents, latter years have seen a growing tendency to consider the potential effect of pharmaceutical

¹⁶⁴ M. McClellan, “‘Tools for Success’: The TRIPS Agreement and the Human Right to Essential Medicines”, 12 *Washington and Lee Journal of Civil Rights and Social Justice* (2005), p. 160.

¹⁶⁵ Gostin and Lazzarini, *supra* note 4, p. 29.

¹⁶⁶ Cullet, *supra* note 66, p. 144.

patents on access to medicines. Not least this is evident from the extensive debate taking place over compulsory licences and public health issues, which lead to the adoption of the Doha Declaration and the Implementation Decision. If nothing else, this development indicates awareness within the WTO-system about the value of human rights in general and access to medicines in particular.

However, this growing tendency is not enough for some human rights advocates. As an example, the UN Sub-Commission has adopted a resolution focusing on what they believe to be the malfunctioning relationship between intellectual property and human rights. In it, the Sub-Commission expressed its concerns about the impact of intellectual property developments, including patents, on human rights. Considering such development in the light of the TRIPS Agreement, the resolution declares that “since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights...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”.¹⁶⁷ The UN Special Rapporteur on the right to health is equally concerned about the impact of the TRIPS Agreement. Though welcoming the clarifications of the Doha Declaration and the Implementation Decision, he still points out conflicting obligations and that patent protection may hinder accessibility of essential medicines.¹⁶⁸

It is not only within the UN-system that the idea of a conflict of norms has surfaced. Several contributors in the academic world have raised similar concerns. Lissett Ferreira admits that patents may be important for the development of new and more effective medicines. Nevertheless, her conclusion is that pharmaceutical patents and access to medicines do sometimes clash and when this happens patents should not trump the human right that is access to medicines.¹⁶⁹ Another author adheres to the same view of considering the situation as a conflict of norms and firmly believes in the

¹⁶⁷ Sub-Commission on the Promotion and Protection of Human Rights Res. 2000/7, Intellectual Property and Human Rights, UN Doc. E/CN.4/2001/2, p. 28.

¹⁶⁸ Special Rapporteur 2004, *supra* note 47, para. 43.

¹⁶⁹ Ferreira, *supra* note 62, p. 1179.

primacy of human rights over trade obligations.¹⁷⁰ Joost Pauwelyn has produced extensive work on the relationship of WTO rules and other rules of international law. With a strong focus on potential conflicts, without necessarily talking about the situation of patents and access to medicines in specific, he believes that human rights obligations can modify WTO law and that the opposite is not possible. In other words, in case of a conflict of norms, Pauwelyn believes that the existing order prescribes that human rights should prevail.¹⁷¹

Additionally, promoters of an order where human rights always prevail frequently point to the international character of human rights. General Comment No. 14 of the CESCR demands Member States to respect the enjoyment of health in other Members and to prevent third parties under their authority to violate the right to health in other Members.¹⁷² In one author's opinion, this requires a State to prevent third parties, from using patent rights in a manner that would hinder access to treatment for their citizens.¹⁷³ In other words, in case of a conflict between patents and access to medicines, the latter should prevail and its international character should work to strengthen this.

Another way of approaching the relationship between pharmaceutical patents and access to medicines is to try and move away from the conflict perspective. Prabhash Ranjan somewhat tries to do this and has produced some interesting thoughts. Though admitting that rules on patents and rules on access to medicines to some extent impose conflicting obligations, he points out that neither of the two are mutually exclusive concepts. In his opinion the two areas of international law can work side-by-side without one of them always prevailing. For this to happen, it is fundamental that

¹⁷⁰ L. Forman, 'Trade Rules, Intellectual Property, and the Right to Health', 21(3) *Ethics and International Affairs* (2007), pp. 346-348 [hereinafter Forman].

¹⁷¹ J. Pauwelyn, *Conflict of Norms in International Law: How WTO Law Relates to other Rules of International Law* (Cambridge University Press, Cambridge, 2003) pp. 5-492.

¹⁷² General Comment No. 14 of the CESCR, *supra* note 11, para. 39.

¹⁷³ J. Crook, 'Balancing Intellectual Property Protection with the Human Right to Health', 23 *Berkeley Journal of International Law* (2005), p. 536 [hereinafter Crook].

rules are implemented in an honest way.¹⁷⁴ It seems fair to believe that such honest implementation would include the full implementation of the flexibilities offered in the TRIPS Agreement and clarified by succeeding documents. The ideas of a non-conflict approach have been further developed by Jakob Cornides. He believes that patents, besides protecting the interest of inventors, serves the purpose of promoting progress and development. If international law on patents corresponds to this purpose, there can be no true conflict between patents and policy objectives such as public health, including access to medicines. Patents are subordinated to such policy objectives and should not be seen as end themselves but a tool to realize these higher objectives.¹⁷⁵ With this line of reasoning, the flexibilities offered in the TRIPS Agreement, such as compulsory licences, would appear to have an important role to play. Without them, the quest to achieve policy objectives of public health could prove more difficult.

Consequently, there appears to be two main schools of thought on how to tackle the relationship between patents and access to medicines. The first argues that human rights, including access to medicines, and the international legal framework on patents are in fundamental conflict. Its advocates hold that strong protection of patents is incompatible to the obligations under the right to health. The second school promotes the idea that patents and human rights have the same goal, which is to define their private scope of monopoly power in protecting the rights of inventors and insuring that the public have adequate access to the inventions. According to this view, patents and the right to health, with its fundamental component of access to medicines, are compatible and should coexist. An important part of this latter approach is the inclusion of flexibilities in the present international patent system.

The relationship between pharmaceutical patents and access to medicines may be a conflict of norms and it may not be. To some extent this is a question of how one defines a conflict of norms. In any case, too strong

¹⁷⁴ P. Ranjan, 'International Trade and Human Rights: Conflicting Obligations', in T. Cottier *et al* (eds.), *Human Rights and International Trade* (Oxford University Press, Oxford, 2005) pp. 311, 318-321.

¹⁷⁵ J. Cornides, 'Human Rights and Intellectual Property – Conflict of Convergence?', 7(2) *The Journal of World Intellectual Property* (2004), pp. 158-159.

of a focus on the potential conflict of norms will naturally result in the need to answer the question of how to solve the conflict. This would include examining if there is an order on how to solve such conflicts at all. The conflict-focused school of thought presented above would need to deal with this question. Furthermore, it would probably have to promote a major reconstruction of WTO legislation on patents or at least new ways to interpret the documents in question. The relationship does not have to be that difficult and a solution does not necessarily have to come from the drafting of new rules or reinterpretation to always give one set of rules priority. Those types of solutions appear to be extremely difficult to achieve and neglect the fact that present legislation with its flexibilities is the result of extensive efforts to put it in place.

Another more viable approach is to put the flexibilities offered by present patent legislation at the forefront. This type of ‘flexibility approach’ is also the approach chosen for this thesis. Such an approach includes an examination of whether or not the flexibilities provide for a sufficient amount of human rights consideration. If they can offer this, it may be more useful to promote the flexibilities than to dwell on a possible conflict of norms and how such a conflict could be resolved. Flexibilities such as compulsory licences were included for a reason and should therefore be explored. As it is the idea of this thesis to scrutinise the existing patent system from a human rights perspective, *i.e.* the idea is not to produce any form of suggestions on what a possible future system could look like, this approach seems valid. Therefore, in the following a brief presentation, or repetition, of the existing flexibilities will be given followed by the consideration of the practice of one flexibility in more detail, namely, compulsory licences.

3.3.2 Flexibilities

The TRIPS Agreement and succeeding documents opened up for various flexibilities by allowing for exceptions to patent protection under certain circumstances and by offering transitional periods for developing countries. The flexibilities have been presented in some detail above when discussing

the international legal framework.¹⁷⁶ Therefore, only a brief overview will be given here. The overview is presented well-aware of the fact that flexibilities are not the only way for States in need to get a hold of the medicines they require. There is of course the contribution offered by aid and donor financing in various forms, including development aid from States in the developed world, NGOs contributing, wealthy individuals offering aid assistance, pharmaceutical companies donating medicines *etc.*¹⁷⁷

Among the flexibilities, there is one that is not explicitly mentioned in the TRIPS Agreement but follows from the general character of international trade, namely, *differential pricing*. In short, differential pricing occurs when a patent holder sets different prices for its patented medicines according to the purchaser's ability to pay. Differential pricing therefore has the potential of benefiting both the consumer, if prices are reduced to an affordable level, and the patent holder, who can maintain or even increase market share. Critics of this model has pointed out that differential pricing offers depend on the manufacturers' decision and will rather than patient need.¹⁷⁸ It has also been noted that in some cases where differential pricing exists, medicines have turned out to be more expensive in developing countries than in the rest of the world.¹⁷⁹

The system of differential pricing is also inherently linked to another flexibility offered under the TRIPS Agreement, namely, *parallel importation*. This flexibility is based on the doctrine of exhaustion whereby the patent holder loses or 'exhausts' the right after the first sale of the product. As a result, this flexibility allows for the import of a patented product without the authorisation of the patent holder.¹⁸⁰ If a worldwide market exists for the patented medicine and prices differ from State to State, *e.g.* because of differential pricing, it may be of great interest for a State to

¹⁷⁶ See *supra* chapters 2.2.2 and 2.2.3.

¹⁷⁷ See, *e.g.*, S. J. Haakonsson and L. A. Richey, 'TRIPS and Public Health: the Doha Declaration and Africa', 25(1) *Development Policy Review* 25 (2007), pp. 81-82, 86-88 [hereinafter Haakonsson and Richey]; Foreman, *supra* note 155, pp. 32-33.

¹⁷⁸ Foreman, *supra* note 155, pp. 30-32.

¹⁷⁹ K. H. Manion, 'A Global Perspective on Intellectual Property Rights: a Social Work View', 48(1) *International Social Work* (2005), p. 82.

¹⁸⁰ Gopakumar, *supra* note 128, pp. 252-253.

import the medicine from another State with lower prices. It has been noted that Article 6 of the TRIPS Agreement indicates that the question of parallel imports is not dealt with by the Agreement because it leaves the question of exhaustion outside the Agreement. Therefore, it is for the individual State to decide on whether they want to take advantage of existing price differences around the world. A problematic feature of this flexibility is that the United States have strongly advocated against its permission under the TRIPS Agreement.¹⁸¹

Finally, there is the flexibility offered under various forms of licences. The granting of a licence for a patented medicine means that a producer is given the right to produce a medicine under patent by another producer. Such licences are granted on certain preconditions, including the requirement to compensate the patent holder economically. If the patent holder agrees to such a licence, a *voluntary licence* is established between the patent holder and a producer or a Government. Some, usually major actors in the pharmaceutical industry, argue voluntary licences to be a fair and efficient tool for increasing access to medicines and, therefore, a useful flexibility.¹⁸² However, voluntary licences are dependant on the arbitrary will of the patent holder to grant such licences on a regular basis. As such, they do not really amount to a genuine flexibility available for States in need of medicines to foster greater access.

The most efficient aspect of voluntary licences may instead be the role it plays in the process of another important flexibility, namely, *compulsory licences*. Patent holders tend to be more cooperative on granting voluntary licences under reasonable terms when faced with the threat of a State granting a compulsory licence. Compulsory licences have been advocated as an important and interesting flexibility throughout this thesis. To get the full picture of the concept, we will now turn to look at the practice of compulsory licences that has taken place up until now.

¹⁸¹ F. M. Abbott, 'The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference', 5(2) *The Journal of World Intellectual Property* (2002), pp. 30-34.

¹⁸² Foreman, *supra* note 155, p. 29.

3.4 The Use (or Non-Use) of Compulsory Licences

Compulsory licences have frequently been targeted as the one flexibility that offers a necessary balancing tool between pharmaceutical patents and access to medicines. This chapter will examine a number of situations where compulsory licences have been on the agenda. The situations chosen for consideration are exclusively from developing countries. Though the practice of compulsory licences also occurs in developed countries, it is believed that developing countries are of greater interest for the purpose of this thesis. States in the developing world usually face greater difficulties in trying to provide sufficient access to medicines. Furthermore, the Doha Declaration and the Implementation Decision specifically target these States.

Information on the use of compulsory licences in the developing countries is quite difficult to come by. Apart from a few high-profile situations, Government authorities do not generally make public their intentions of making use of the flexibilities to the TRIPS Agreement. Reasons for not doing so vary from concerns about losing foreign direct investment to wanting to avoid external political pressure.¹⁸³ Therefore, the task of trying to survey compulsory licences in developing countries is a somewhat difficult one. Nevertheless, a few examples have been located by scholars and NGOs and will be presented in the following.

In 1998, 42 pharmaceuticals companies joined forces to bring a case before the High Court of *South Africa* against the Government of South Africa.¹⁸⁴ In the lawsuit, the constitutionality of parts of the Medicines Amendment Act of 1997 was challenged.¹⁸⁵ The South African Constitution

¹⁸³ C. Oh, 'Compulsory Licences: Recent Experiences in Developing Countries', 1(1-2) *International Journal of Intellectual Property Management* (2006), p. 31 [hereinafter Oh].

¹⁸⁴ See T. Kongolo, 'Public Interest versus the Pharmaceutical Industry's Monopoly in South Africa', 4(5) *The Journal of World Intellectual Property* 4 (2001), pp. 610-621 [hereinafter Kongolo 2001], for a useful overview of the contested legal framework and the lawsuit in general.

¹⁸⁵ Medicines and Related Substances Control Amendment, Act 90 of 1997, South Africa, <<http://www.info.gov.za/gazette/acts/1997/a90-97.pdf>>, visited on 3 December 2007.

guarantees South Africans the right to health care,¹⁸⁶ and to meet this goal the Government had adopted a national policy of promoting access to essential medicines.¹⁸⁷ The 1997 Medicines Amendment Act was passed to further that policy, all occurring in a State with an alarming HIV/AIDS-problem. Section 15C of the Act granted broad powers to the Minister of Health to ensure access to essential medicines, for example via allowing parallel importation. Opinions differ on whether the Act also mandated the Minister of Health to issue compulsory licences to generate greater access to medicines. Some claim this to be the case as a result of the 1997 Act overriding previous law.¹⁸⁸ Others point out that the 1997 Act is directed towards parallel importation and did not change anything on compulsory licences as this was already allowed under the 1978 Patents Act.¹⁸⁹

No matter how one interprets the 1997 Act, it is clear that the actions of the pharmaceutical industry were the result of fear over the use of flexibilities in relation to patent protection. The pharmaceutical industry feared that the amended legislation granted the Government enough discretion to implement measures such as compulsory licences.¹⁹⁰ Thus, the lawsuit became a question of whether the Minister of Health could take health based decisions under the Act that would override the exclusive right given to patent holders by the South African Patent Act. Parallel to this, the United States presented threats of trade sanctions.¹⁹¹

The lawsuit turned out to be a hot topic in worldwide media and NGOs and civil society made sure to make their protests heard. The pharmaceutical companies held their ground for quite some time, but finally in 2001, they realized that a prolongation of the lawsuit was impossible because of the inflicted public relations damage. Therefore, the lawsuit was withdrawn to minimise further damage. An out-of-court settlement was reached were the

¹⁸⁶ Constitution of the Republic of South Africa, Chapter 2, para. 27, <<http://www.info.gov.za/documents/constitution/1996/96cons2.htm#27>>, visited on 3 December 2007.

¹⁸⁷ Ferreira, *supra* note 62, p. 1149.

¹⁸⁸ See, e.g., Kongolo 2001, *supra* note 184, pp. 612, 620; Bass, *supra* note 96, pp. 210-211.

¹⁸⁹ See, e.g., S. Joseph, 'Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny', 25 *Human Rights Quarterly* (2003), p. 442 [hereinafter Joseph].

¹⁹⁰ *Ibid.*, pp. 442-443.

¹⁹¹ Kongolo 2001, *supra* note 184, p. 609.

pharmaceutical companies agreed to cooperate with South Africa in trying to generate greater access to medicines and South Africa promised to respect the TRIPS Agreement and consult with the pharmaceutical industry on the proposed amendment.¹⁹²

Though no compulsory licence was issued based on the 1997 Act, it still generated some positive impacts on access to medicines. As a result of the publicity and the fear of compulsory licences, several pharmaceutical companies began to offer medicines at discounted prices in South Africa and to give donations of medicines to both South Africa and other developing countries. In addition, GlaxoSmithKline decided to grant a voluntary licence to a South African producer to produce and market generic versions of three of its HIV/AIDS medicines.¹⁹³ This action by the pharmaceutical companies can to some extent be explained by fear of damaged public relations. However, it also indicates the role flexibilities like compulsory licences can play as a bargaining tool. The awareness among patent holders that they risk facing a compulsory licence gives Governments a better bargaining position when negotiating about the price of patented medicines.

Finally, it should be noted that the South African case is not necessarily directly concerned with the TRIPS Agreement, as South Africa had until 2005 to implement TRIPS-compliant legislation. Nevertheless, the case is usually seen as a symbol of how the protection of private companies' patent rights could affect national Governments' room to manoeuvre.

In addition to South Africa, a number of other Sub-Saharan African States have also showed an interest in compulsory licences. In 2002, the Minister of Justice, Legal and Parliamentary Affairs in *Zimbabwe* issued a notice declaring a period of national emergency because of the rapid increase of HIV/AIDS in the State. The Emergency Declaration enabled government use of patented medicines, *i.e.* a form of compulsory licences, and importation of generic versions of ARVs.¹⁹⁴ The Declaration was made

¹⁹² Ferreira, *supra* note 62, pp. 1156-1157.

¹⁹³ *Ibid.*, p. 1154; Bass, *supra* note 96, p. 213.

¹⁹⁴ S. U. Musungu and C. Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines?*, Study 4C of the Commission on Intellectual

pursuant to Section 34 of the Patents Act in Zimbabwe, empowering the Minister to authorise the use of patented inventions for the service of the State. Section 35 clarifies that an authorisation by the Minister under Section 34 during a period of emergency includes the right to make use of the invention for any purpose which the Minister finds necessary or expedient.¹⁹⁵ The Declaration was also in line with the then newly adopted Doha Declaration, emphasising the importance of compulsory licences and the right for every individual State to decide what constitutes a national emergency.¹⁹⁶ Initially, the declared period of emergency was only for six months. It has been noted that the rather short term was most likely due to the fact that the Ministry of Health feared that the Declaration would be challenged by the pharmaceutical industry. When no such challenge materialised, the Declaration was extended to a period of five years ending in December 2008.¹⁹⁷

In April 2003, Varichem Pharmaceuticals [Pvt] Ltd, a Zimbabwean registered company, was granted a licence to make use or exercise any invention under patent protection for the purpose of achieving the objectives of the Emergency Declaration. Under the terms of the authorisation, Varichem agreed to produce ARVs or HIV/AIDS-related medicines and supply three-quarters of its produced medicines to State-owned health institutions at fixed prices under control of the Minister. It has been reported that the company agreed to supply a specific ARV, Combivir, to the Government at a significantly reduced price. According to information provided by Varichem, the company introduced its first ARV to the Zimbabwean market in October 2003, and now has seven generic versions of ARVs on the market.¹⁹⁸ Reports also reveal that two other companies,

Property Rights, Innovation and Public Health (CIPIH), August 2005, p. 22 [hereinafter Musungu and Oh], <<http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>>, visited on 3 December 2007.

¹⁹⁵ The Patents Act Chapter 26:03, Zimbabwe, Sections 34 and 35,

<<http://www.cptech.org/ip/health/c/zimbabwe/patentsact.html>>, visited on 3 December 2007; see also Oh, *supra* note 183, pp. 25-26.

¹⁹⁶ See *supra* chapter 2.2.3.2.

¹⁹⁷ Oh, *supra* note 183, p. 26.

¹⁹⁸ Musungu and Oh, *supra* note 194, p. 23.

Datlabs and Omahn have been authorised to acquire ARVs under the Declaration by importing generic ARVs from India.¹⁹⁹

It may be difficult to assess the full impact of compulsory licences for Zimbabwe in terms of increased access to medicines just yet. This will require further information in terms of prices of medicines and their distribution to patients in need of treatment. Nevertheless, first indications show that the prices of patented ARVs have not increased or in some cases dropped significantly. Furthermore, it is interesting to note that the Declaration opens up for multiple licences. Hopefully, multiple licensees will help to ensure competition in the pricing of generic versions.²⁰⁰

Following the practice of Zimbabwe, in 2004, both *Mozambique* and *Zambia* granted compulsory licences to enable domestic production of ARVs. The licences issued are very similar, possibly due to the fact that the licensee is understood to be the same company in both cases. In Mozambique, Pharco Mozambique Lda. was authorised to commence production, and in Zambia the domestically-incorporated company Pharco Ltd. was granted a licence. The main difference is that while the licence in Zambia is limited to a five year period of national emergency to combat HIV/AIDS, the one in Mozambique is valid until the emergency created by HIV/AIDS comes to an end without setting a specific end date. As there is no valid information available on the progress of domestic production by Pharco in the respective States, the value of compulsory licences for the States is difficult to assess. However, the monitoring of the situation should continue so that the effectiveness of compulsory licences in generating greater access to medicines can finally be evaluated.²⁰¹

Another situation that has received a lot of publicity is Brazil's national HIV/AIDS programme. Since 1997, *Brazil* has been able to supply ARVs for free to all who need them under a declared national policy to combat HIV/AIDS by free access to ARVs. To be able to fulfil its national policy the Government realized that the price of ARVs had to be reduced and decided to apply a twofold strategy. First, domestic manufacturing capacity

¹⁹⁹ Oh, *supra* note 183, p. 26.

²⁰⁰ *Ibid.*, p. 27; Musungu and Oh, *supra* note 194, p. 24.

²⁰¹ Oh, *supra* note 183, pp. 28-30.

and production of generic ARVs was to be increased with the help of compulsory licences. Secondly, the Government would try to get greater discounts on patented ARVs, with the possibility to threaten with compulsory licences in case discounts were not big enough.²⁰²

With the ambition both to fulfil its national policy and to comply with international obligations under the TRIPS Agreement, Brazil enacted the 1996 Industrial Property Law.²⁰³ Before becoming a Party to and implementing the TRIPS Agreement, Brazil did not recognise or enforce pharmaceutical patents. The 1996 Industrial Property Law provided for patent protection of pharmaceuticals, but included the condition that at least some of the production had to take place in Brazil. Article 68 provides that in case a foreign manufacturer fails to satisfy this domestic working requirement, Brazil may subject the patent to compulsory licensing, allowing Brazilian manufacturers to produce generic versions. In line with the national policy, the Government decided to regulate, or clarify, the provision a couple of years later. The Government authorised relevant authorities to issue compulsory licences if, after three years, the patent holder did not begin to manufacture the medicine domestically. It has been noted that the aim of this legislation was quite clear, namely, to increase the Government's bargaining power in negotiations with suppliers of patented medicines.²⁰⁴

This step by Brazil triggered a strong response by the United States. After several months of fruitless negotiations, the United States launched a WTO dispute settlement proceeding against Brazil in the beginning of 2001. The United States challenged the Brazilian legislation on patents for violating the TRIPS Agreement.²⁰⁵ It was claimed that Article 68 of the 1996 Industrial Property Law was incompatible with the principle of non-discrimination set out in Article 27(1) of the TRIPS Agreement. The position of the United States was met with a firm response by Brazil, holding on to its national policy, including the right to issue compulsory

²⁰² Joseph, *supra* note 189, p. 444; Foreman, *supra* note 155, p. 35.

²⁰³ 1996 Industrial Property Law, Law No. 9.279 of 14 May 1996, Brazil, <http://www.wipo.int/clea/docs_new/en/br/br003en.html>, visited on 3 December 2007.

²⁰⁴ Foreman, *supra* note 155, p. 36.

²⁰⁵ *Ibid.*

licences under the conditions provided in domestic law. Following a storm of criticism from the international community, the United States withdrew its complaint to avoid another international relations disaster. In connection to the withdrawal, Brazil agreed to hold prior talks with the United States, in case Brazil considered granting a compulsory licence on a patent held by a company from the United States.²⁰⁶

The Brazilian HIV/AIDS programme has often been described as a success story. Unquestionably, the combination of domestic manufacturing capacity and the tool of compulsory licences have proved successful for Brazil in generating greater access to medicines. In 2006, it was estimated that around 140 000 people had access to free ARVs provided through government financing in the form of both domestically produced generics and imported patented versions.²⁰⁷ An important part of the programme is played by patented ARVs at reduced prices. In recent years, both Merck & Co and Roche have had to reduce the price on patented ARVs at the risk of facing compulsory licences.²⁰⁸

The flexibility of compulsory licences has also been explored by a few States on the Asian continent. For instance, in 2004, a Decree of the President of the Republic of *Indonesia* was produced to try and control the HIV/AIDS epidemic spreading quickly in the State. The Presidential Decree provided for the possibility to use compulsory licences in the form of government use for a couple of ARVs. The text does not specifically refer to domestic production or importation, suggesting that the government use authorisation may be for either. Since issuing the Presidential Decree, the Indonesian Government has been in discussions with domestic producers to undertake domestic production of ARVs.²⁰⁹ Only time will tell if the Indonesian approach to the flexibility offered by compulsory licences turns out to be successful in providing greater access to medicines.

²⁰⁶ Matthews, *supra* note 120, p. 80.

²⁰⁷ *Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health* (WHO, Geneva, 2006) p. 110,

<<http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>>, visited on 3 December 2007.

²⁰⁸ Bass, *supra* note 96, pp. 209-210.

²⁰⁹ Oh, *supra* note 183, pp. 30-31.

Similarly to several of the situations presented above, *Malaysia* developed a strong interest in compulsory licences in connection to governmental plans to speed up HIV/AIDS treatment. First, the Government decided to request price discounts on a number of ARVs to be able to increase HIV/AIDS treatment. When such negotiations failed to generate the reductions desired, the Government decided to start considering other options. Inspired by the Doha Declaration, compulsory licences presented itself as an interesting option. Because of overlapping mandates, a number of Ministries spent a few years discussing the issue before anything concrete could be presented. However, in 2003, the Minister of Domestic Trade and Consumer Affairs issued a letter authorising a domestic distributing agent for an Indian manufacturer to import generic HIV/AIDS medicines. Further discussions followed within and between the Ministries, but in February 2004 the contract for the importation of generic ARVs was finally issued by the Ministry of Health.²¹⁰

The Malaysian use of compulsory licences is interesting for several reasons. Unlike many of the other situations mentioned, a compulsory licence was issued with the main purpose of importing ARVs, rather than producing them domestically. Furthermore, it strengthens the idea that compulsory licences, and the threat thereof, could also play the role of a bargaining tool for States. In fact, in the wake of the 2003 letter proposing the authorisation to import generic ARVs, several major pharmaceutical companies moved quickly to offer significant discounts to try and discourage the authorisation. GlaxoSmithKline dropped prices on a number of ARVs by 53-80 percent, whilst Bristol-Meyers reductions varied from 49-82 percent.²¹¹ The Cabinet of Government Ministers appears to have been unfazed with the price reductions as they allowed the Ministry of Health to proceed and issue the contract in February 2004. By doing so they allowed for the ‘best of two worlds’, in that both cheaper patented ARVs and imported generic versions would be available on the market. It has been noted that with the introduction of generic ARVs, the monthly cost of

²¹⁰ Musungu and Oh, *supra* note 194, pp. 24-26.

²¹¹ Oh, *supra* note 183, p. 28.

HIV/AIDS for a patient in Malaysia has dropped to one third of its previous price.²¹²

Additionally, NGOs and civil society have been active on pressing for the use of compulsory licences in the region. One example of this is *Thailand* where an NGO and two AIDS patients took the initiative to, first, have the Thai Government grant a compulsory licence over a specific ARV, and, second, request partial revocation of the corresponding patent. Because of peculiarities of Thai patent law, the compulsory licence claim looked very promising, but ultimately failed. However, the request for invalidation for parts of the patent, sponsored by a public campaign, turned out to be successful.²¹³ This is yet another indication of the importance NGOs and civil society can have on creating awareness about the relationship between pharmaceutical patents and access to medicines and the corresponding flexibilities. Sometimes the efforts by NGOs and civil society can result in Governments considering the flexibilities in more detail or re-examining the effects of a specific patents, as in the case of Thailand.

It appears to be that the practice of compulsory licences in the first few years after the adoption of the TRIPS Agreement has been rather limited. The condition in the TRIPS Agreement requiring predominant domestic sales appears to have directed the practice of compulsory licences to mainly focus on generating greater domestic production. The result of this has been that the use has practically been restricted to a few developing countries with a strong pharmaceutical industry and a large population, such as Brazil. States with insufficient or no manufacturing capacity have found it very difficult to make use of the compulsory licences regime, even if a specific licence is actually granted for domestic production. The necessary pharmaceutical infrastructure and technical knowledge is just not in place.

The Implementation Decision specifically targets States with insufficient or no manufacturing capacity looking to import under a compulsory licence and tries to ease their position. Domestic production via compulsory licences is not really affected by it. Both the importing and the

²¹² *Ibid.*, pp. 27-28.

²¹³ J. Kuanpoth, 'Patents and Access to Medicines in Thailand – The DDI Case and Beyond', 2 *Intellectual Property Quarterly* (2006), pp. 149-158.

exporting State planning to make use of the compulsory licence regime have to notify its intention on the website of the TRIPS Council, explaining the details of the proposed compulsory licence. Until recently, no such notification had been made. However, in July 2007 *Rwanda* notified its intention to import ARVs from the Canadian producer Apotex Inc.²¹⁴ Three months later *Canada* notified the TRIPS Council that Apotex Inc. had been granted a compulsory licence to go ahead with the export of ARVs to Rwanda.²¹⁵

It is clearly too early to pronounce anything on what the outcome of this pilot attempt to make use of the extended flexibility offered by the Implementation Decision will result in. Such an evaluation will require more data on prices and distribution to patients in need before it can be determined if the endeavour has generated greater access to medicines. Only then will it be possible to get any hints on whether the waiver of the requirement to predominantly supply the domestic market will actually assist in creating greater access to medicines. Such an evaluation will of course also be limited to this specific situation and succeeding attempts will be necessary to get a general picture of the value of the Implementation Decision. Nevertheless, it is interesting to see that things are starting to move. The question of compulsory licences in the light of the Implementation Decision has been brought to the front with this pilot case. However, it should be remembered that the Implementation Decision also brings one problematic feature with it. While the Decision removes one burdensome requirement, *i.e.* the predominant domestic sales, it adds another, namely, an intricate procedural process.²¹⁶ Only time will tell if

²¹⁴ 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, <http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm>, visited on 3 December 2007.

²¹⁵ 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, <http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm>, visited on 3 December 2007.

²¹⁶ See *supra* chapter 2.2.3.3.

States looking to make use of the flexibility in the same way as Rwanda and Canada will master the process.

As evident from the presentation above, the flexibility offered by compulsory licences also brings with it an interesting side effect, namely, the role it plays as a bargaining tool. Several States have been able to use this feature of compulsory licences to get significant reductions on patented medicines. The feature appears to be more useful to States with domestic manufacturing capacity as the pharmaceutical industry knows that these States can follow up threats with actual production. The Implementation Decision, targeting States with insufficient or no domestic capacity, does not really appear to have changed this. However, this could change if the export/import-regime of compulsory licences were to be applied more frequently in the future. Willing exporters could result in a growing role for compulsory licences as a bargaining tool for States with insufficient or no manufacturing capacity. If pharmaceutical companies know that there is a State ready to export under a compulsory licence as soon as the import licence is in place the pressure on the companies will increase. In fact, as the potential exporter will probably be a State with a well-established pharmaceutical industry, *i.e.* guaranteeing delivery of generics, it may well turn out to be more threatening than a potential licence for domestic production.

Finally, compulsory licences have so far mainly been restricted to licences granted for domestic production. To the extent that such licences have assisted in providing for greater access to medicines, most notably in Brazil, the purpose of compulsory licences has been fulfilled. However, examples of compulsory licences and figures indicating greater access to medicines in the developing world are few and far between. The waiver of the requirement to predominantly supply the domestic market brought by the Implementation Decision does not appear to have changed much just yet. The intention of the Decision was to offer an opening to States with insufficient or no manufacturing capacity. Until now, very few have taken up that option. With a first pilot case in place, it could be that both potential exporting and importing States will await the outcome of that endeavour

before moving towards the same direction. As the States with insufficient or no manufacturing capacity are normally the States most in need of medicines, the situation at present is very unfortunate. The fact that compulsory licences are mostly granted for domestic production; the apparent awaiting attitude of potential exporters; and the procedurally burdensome process, all suggest that these States have the biggest hurdles to climb in making proper use of compulsory licences. The next step of this thesis will be to consider some of the potential hurdles standing in the way of the use of compulsory licences.

3.5 Compulsory Licence Roadblocks

A number of suggestions have been put forward as to what constitutes the roadblocks standing in the way of a fully operational system of compulsory licences in developing countries. A few of these suggestions will be briefly examined in this chapter. The examination will not be concerned with the argument often raised by representatives of the pharmaceutical industry that the question of access to medicines is about “poverty, not patents”.²¹⁷ Such an approach tend to focus on poverty as the sole culprit without even considering the potential of compulsory licences, and is therefore not a very constructive approach. This is not to say that poverty does not influence access to medicines or that it does not stand in the way of an extended use of compulsory licence. On the contrary, it probably does to a significant extent. Nevertheless, it is believed that a broader approach examining suggestions on concrete obstacles will suit this thesis better.

A first problem appears to be the apparent ‘lack of infrastructure’ in some developing countries that could potentially benefit from a fully functioning system of compulsory licences. This can be divided into two aspects. The first is the lack of ‘health infrastructure’. For some States this tends so stretch over the entire health spectra, including health institutions, national policy, and legal and technical expertise. Several of these areas can be lacking in that they are not effective enough or even non-existing. It

²¹⁷ See, e.g., Crook, *supra* note 173, pp. 528-530.

should be noted that this does not mean that administration of HIV/AIDS medicines is impossible for developing countries at present. Some seem to argue that generic medicines tend to be hazardous for developing countries because it would not be combined with a necessary consumption regime. However, studies have shown that ARV therapies in Kenya and Senegal have had success rates similar to those in the West.²¹⁸ Patented medicines normally constitute only a minority of the medicines consumed, but almost always tend to represent a significant percentage of the healthcare budget in developing countries.²¹⁹ Without a health infrastructure in place where a strong health institution formulates national policy to try and procure more affordable medicines, generating greater access to medicines will probably continue to prove difficult. However, with a health infrastructure in place, compulsory licences will probably present themselves as an interesting option.

Secondly, the lacking health infrastructure frequently corresponds with a lacking 'intellectual property infrastructure'. This usually means that a State lacks effective patent offices and the legal and technical expertise connected to it. One may think that this could benefit the States in need of medicines as an unclear patent situation will allow them to procure medicines without having to consider potential patents. However, the lack of access to accurate and up-to-date information on the patent status of certain medicines usually works the other way around for these States. This is because the uncertainty surrounding the situation in several cases delays decision-making, or even worse, prevents decisions on the procurement of medicines.²²⁰

A second roadblock, which both relates to and further deepens the problem of a lacking infrastructure is the fact that the granting of compulsory licences is a procedurally burdensome task. This holds especially true for the system of double compulsory licences developed by the Implementation Decision.²²¹ As the States with a lacking infrastructure

²¹⁸ Joseph, *supra* note 189, pp. 444-445.

²¹⁹ Foreman, *supra* note 155, p. 39.

²²⁰ Oh, *supra* note 183, p. 33.

²²¹ See *supra* chapter 2.2.3.3.

are usually the same States as those targeted by the Implementation Decision, *i.e.* those with insufficient or no domestic manufacturing capacity, the problem appears to be highly relevant. These States' experience in implementing the TRIPS Agreement is limited. Such a process requires the effective cooperation between different Government agencies and departments, including trade, health and industry. A similar approach is necessary when it comes to try and make use of the flexibility offered by compulsory licences. Without the experience in coordinating to develop a common policy this could prove a very difficult task.²²²

Furthermore, the lack of technical and legal expertise means that the necessary procedural steps may be beyond the reach of these States as the knowledge on how to execute them is not in place. In fact, in the pending pilot case of Rwanda/Canada presented above, the Canadian exporting company pointed out the difficulties in overcoming the procedural process. In their opinion, the process is “unnecessarily complex and does not adequately represent the interests of those who require treatment”.²²³ One should of course remember that the company has an economic interest in exporting their medicines. Nevertheless, the burdensome procedure is most likely one of the reasons that we have seen so few attempts to make use of the extended possibilities offered by the Implementation Decision. If experts from developed countries find the process burdensome, it is not unlikely that less skilled personnel in developing countries will find it even more difficult to master.

Another roadblock is added by the fact that even if the procedural process of compulsory licences is mastered, it could prove difficult to find a generic producer that is willing or able to export. Previous importation to developing countries has to a large extent been in the form of off-patented generics. However, the sources of supply for such generics are quickly drying out. As a result of ending transitional periods, a number of developing countries with the capacity to produce off-patent generic

²²² Musungu and Oh, *supra* note 194, p. 68.

²²³ *Life Saving AIDS Drug for Africa Gets Final Clearance*, Press release by the Apotex Group on 20 September 2007, <<http://www.apotex.com/PressReleases/20070920-01.asp>>, visited on 3 December 2007.

medicines for export, such as India, were required to implement TRIPS-regulations on patents on 1 January 2005. Subsequently, newly developed medicines, *i.e.* post-1 January 2005, are now subjected to patenting in these States. Furthermore, applications collected under the 'mailbox' provision since 1 January 1995 will be processed and possibly granted with patent protection.²²⁴ Therefore, the low-priced generic versions that other developing countries are in need of may not be available for these medicines unless States such as India issue compulsory licences. However, the national legislation implemented as a result of TRIPS-compliance in these States, may not necessarily allow for compulsory licences of these newer patented medicines. Seeing as a compulsory licence needs to be issued also in the exporting State for a transaction to be possible, TRIPS-compliance in India and other States may lead to that the sources of cheap generic medicines dry out.²²⁵ Seeing as about 80 percent of developing countries can be categorised as having insufficient or no domestic manufacturing capacity,²²⁶ this problem crystallises itself as one of fundamental concern to the developing world.

A fairly practical hindrance to achieving a fully functioning compulsory licence system could be the fact that there may not be any useful medicines to issue a compulsory licence for. The interest of pharmaceutical companies to direct research and development towards diseases prevalent mainly in developing countries, so called tropical diseases, is at best very sparse. In fact, of the 1223 new chemical entities developed between 1975 and 1996, only 11 were for treatment of tropical diseases. HIV/AIDS medicines do not really fit into this category since it is a problem also in developed countries.²²⁷ Continuing focus on more 'profitable' diseases in markets where the return is likely to be higher could result in a situation where a State is in dire need of medicines, but where this medicine simply does not exist and evidently a compulsory licence is

²²⁴ See *supra* chapter 2.2.2.

²²⁵ Abbott 2005, *supra* note 139, pp. 320-323.

²²⁶ O. Aginam, 'Between Life and Profit: Global Governance and the Trilogy of Human Rights, Public Health and Pharmaceutical Patents', 31 *North Carolina Journal of International Law and Commercial Regulation* (2006), p. 913.

²²⁷ Cullet, *supra* note 66, p. 142.

out of the question.²²⁸ Additionally, extensive use of compulsory licences may not be well-received by pharmaceutical companies. There is a risk that the companies decide not to make future technology available in developing countries. An overly excessive use may also make it more unlikely that future research and development is reoriented towards diseases prevalent in these States. Gionathan Curci and Massimo Vittori describe this as the “double-edged sword” character of compulsory licences.²²⁹

The problem of finding generic exporters and lack of research and development are not the only external barriers. Developing countries considering putting compulsory licences to use will also inevitably feel threatened by the possibility of trade sanctions from other WTO Members with extensive interests in the pharmaceutical industry. In the cases of South Africa and Brazil discussed in the previous chapter, the United States threatened to impose trade sanctions for making efforts to pursue the flexibilities offered under the TRIPS Agreement.²³⁰ Smaller States and States with weaker economies cannot afford to lose a major trading partner like the United States. Similarly, parallel to threats of trade sanctions in South Africa, the United States went as far as threatening to withhold foreign aid.²³¹ Just like pondering the potential loss of a major trading partner, the potential loss of foreign aid may be something that drives developing countries to think twice about granting a compulsory licence. It has been pointed out that this stance by the United States is somewhat hypocritical, since several of its domestic laws allow compulsory licensing. Critics usually raise the example of the anthrax scare following the 9/11 terrorist bombings. At the time, the United States Government considered granting a compulsory licence for Cipro, an anthrax antibiotic. In the end, the United States did not issue a compulsory licence for the medicine. However, it did use the threat of a compulsory licence to negotiate very favourable terms from Bayer, the patent holder of Cipro.²³²

²²⁸ Chapman 2002, *supra* note 1, pp. 877-878.

²²⁹ Curci and Vittori, *supra* note 116, p. 754.

²³⁰ Crook, *supra* note 173, pp. 532-533; *see also supra* chapter 3.4.

²³¹ Ferreira, *supra* note 62, p. 1155.

²³² *Ibid.*, p. 1147.

An even greater barrier than trade and diplomatic pressure may be some developed countries' pursuit of certain bilateral and regional free trade agreements. Many of these free trade agreements include numerous provisions affecting patent protection and the possible flexibilities to it. Common standards include: broad definitions of patents; an extended patent period beyond 20 years; and severe restrictions on flexibilities such as compulsory licences.²³³ Because the objective of these agreements normally is to extend patent protection beyond the terms under the TRIPS Agreement, they are usually referred to as 'TRIPS-plus' agreements. The United States has concluded bilateral and regional free trade agreements containing TRIPS-plus standards with over 60 States, many of which are developing countries with high disease burdens, including HIV/AIDS.²³⁴ A strong driving force behind the conclusion of such agreements by the United States has been the domestic pharmaceutical industry.²³⁵

The concept of TRIPS-plus agreements has been attacked from several fronts. Fredrick M. Abbott suggests that agreements affecting intellectual property rights be subject "objective prior impact assessment". In his opinion, such evaluations would assist all stakeholders in weighing the trade-offs involved in these agreements.²³⁶ Abbott appears to indicate that some States signing these agreements, especially developing countries, are not fully aware of the impact it might have on issues such as access to medicines. Abbott's ideas appear to have received some recognition as Peru recently conducted an assessment of the potential impact of a free-trade agreement being negotiated with the United States. The outcome was that the agreement would limit access to medicines for approximately 700,000 people, and the Government accordingly recommended implementing a fund from benefiting industries to supplement this shortfall.²³⁷

²³³ Abbott 2005, *supra* note 139, pp. 349-351.

²³⁴ Forman, *supra* note 170, p. 342.

²³⁵ Abbott 2005, *supra* note 139, p. 350.

²³⁶ F. M. Abbott, 'Toward a New Era of Objective Impact Assessment in the Field of TRIPS and Variable Geometry for the Preservation of Multilateralism', 8 *Journal of International Economic Law* (2005), pp. 88-97.

²³⁷ Forman, *supra* note 170, p. 343.

A contributing factor to the Peruvian assessment was also the advocacy of another critic of TRIPS-plus agreements, namely, Paul Hunt, the UN Special Rapporteur on Health. Besides his involvement in the Peruvian experience he has on a number of occasions questioned the legitimacy of TRIPS-plus agreements. In a panel discussion at the WTO's failed ministerial meeting in Cancún, Mexico, in 2003, Hunt stated that "[R]ich states should not discourage a developing country from using the TRIPS flexibilities. On the contrary, they should actively facilitate the use of the flexibilities. They should help the [less developed country] deliver the essential drug to all at affordable prices".²³⁸ In subsequent work, the Special Rapporteur has developed these thoughts to relate directly to TRIPS-plus agreements. He believes that "States should not encourage a developing country to accept "TRIPS-plus" standards in any bilateral or multilateral trade agreement. They should help developing countries establish effective, integrated, inclusive health systems that include reliable medicine supply systems delivering quality affordable medicines for all".²³⁹

To sum it up, domestic legislation opening up for the use of compulsory licences appear to be in place in a number of developing countries. This indicates the importance these States place on compulsory licences as a tool in assuring access to medicines and other socio-economic purposes in general. However, the potential of a fully functioning system of compulsory licences have not yet been realized. Both internal and external roadblocks at present appear to stand in the way of such realization. The lack of infrastructure translates into uncertainty about the options available under the flexibilities to the TRIPS Agreement. Without the necessary technical and legal expertise, flexibilities such as compulsory licences fail to turn into an important part of national health policy. External barriers such as the problem of finding willing and able generic exporter and the pressure from influential States, threatening with trade sanctions and demanding TRIPS-plus agreements, makes one wonder if a fully functioning system is really feasible.

²³⁸ *Quote in Yamin, supra* note 31, p. 364.

²³⁹ Special Rapporteur 2006, *supra* note 64, para. 64.

3.6 Some Thoughts

The main theme presented in the discussion above has been that the legal frameworks related to pharmaceutical patents and access to medicines from time-to-time intertwine. In the following, some thoughts on the future of the relationship between pharmaceutical patents and access to medicines, in particular the role played by compulsory licences, will be presented. The idea is to try and pinpoint what aspects of the relationship that needs to be in focus for ensuring that the future role of compulsory licences continues to take desirable steps forward.

It has been argued that States must use TRIPS flexibilities, such as compulsory licences, to fulfil their duties under the right to health, in particular the part of the right that is access to medicines. It is seen as necessary to “curb the abuse of patent monopoly”, or in other words, to try and bridge the conflict between pharmaceutical patents and access to medicines.²⁴⁰ As has been advocated throughout this thesis, it is easy to agree with the idea that compulsory licences could very well have an important role to play in the relationship between pharmaceutical patents and access to medicines. However, it is more difficult to agree with the idea of attacking patents or the TRIPS Agreement in general as something abusive. The benefits of constantly focusing on a conflicting relationship, as several authors appear to do, are difficult to deduce. It is difficult to see how such an approach could benefit the bigger cause of fostering access to medicines.

It is believed that a different approach to the relationship better serves this purpose. A more feasible way forward could be to consider the relationship from a ‘flexibility approach’. Instead of a conflict-focus, a focus on the flexibilities to the present system has a better chance of contributing to the overall aim of fostering greater access to medicines. A ‘conflict-focused approach’ is usually combined with an idea that large parts of the present international legal framework on patents needs to be revised. Such a

²⁴⁰ ‘Executive Summary’ in *South Asian Yearbook of Trade and Development - Mainstreaming Development in Trade Negotiations: Run Up to Hong Kong 2005* (Centre for Trade and Development, New Delhi, 2005) pp. 6-7.

process is both an extremely time-consuming and highly unlikely event. The TRIPS Agreement is the result of extensive negotiations, and, more importantly, so are the included flexibilities. An approach focusing on these flexibilities would take notice of and respect the extensive work exercised by developing countries to get them in place. Furthermore, such an approach offers the possibility of taking immediate steps in trying to generate greater access to medicines while at the same time keeping the present patent system intact. A continuing focus on flexibilities will broaden the understanding of the possibilities that the flexibilities have to offer. Hopefully, an increased understanding could lead to new and improved ways of implementing and, in the end, utilising the flexibilities to the benefit of those in need of medicines.

The approach of focusing on flexibilities, rather than conflicts, needs to be combined with strong support for the potential inherent in the system of compulsory licences. Its inclusion in the TRIPS Agreement is a result of concern from the developing world about the possible effects of patents on the well-being of their inhabitants. The legal framework in place for compulsory licences combined with the will that generated its inclusion in the TRIPS Agreement and development in subsequent documents truly has the potential of turning it into a functioning system.

However, not everyone is convinced about the benefits of the system. As a representative of the pharmaceutical industry, Harvey E. Bale has questioned its potential by using Canada as an example. In his opinion, the price differences between generics and patented medicines are not very great.²⁴¹ In agreeing with several other authors, it is difficult to find much reason to share this negative view on compulsory licences. To give an example on how Canada has or, as in this case, has not benefited from compulsory licences does not necessarily give answers to whether or not it could work to generate greater access to medicines in developing countries. Others take a much more positive stance towards the potential of compulsory licences. Naomi A. Bass goes as far as saying that “compulsory

²⁴¹ H. E. Bale, *TRIPS, Pharmaceuticals, and Developing Countries: Implications for Health Care Access, Drug Quality and Drug Development* (IFPMA, Geneva, 2000) pp. 7-9.

licensing will prove instrumental as a device for maintaining affordable medicine in poor communities in the future”.²⁴² Similarly, the potential compulsory licences have as a bargaining tool should no be forgotten. It has already proved to come in handy for a few States negotiating prices for patented medicines,²⁴³ and has the potential to do so to an even bigger extent. However, that does not mean that the promotion of actual use of compulsory licences need not be done. In fact, once a State has issued a compulsory licence at least once, patent holders tend to be even more cooperative when it comes to negotiating prices

The full potential of compulsory licences is of course impossible to grasp before we have a fully functioning system in place. Nevertheless, it is believed that compulsory licences appear to have the potential of playing an important role in bridging the relationship between pharmaceutical patents and access to medicines. However, to move from something that has potential on paper to something that demonstrates its potential in practice is not necessarily an easy step. Unfortunately, this has been clearly illustrated by the practice of compulsory licences up until now. A more flexibility-focused approach, where those involved understand the potential of compulsory licences, requires a few necessary steps to take place. These steps require a large degree of political commitment both within the UN- and the WTO-systems and, maybe more importantly, within the Member States attached to the Organizations.

A first necessary step to take is to try and assure that the importance of both patents and the related international instruments, on the one side, and access to medicines and the related international instruments, on the other, are fully recognised by its Member States. Both the TRIPS Agreement and several international human rights instruments, such as the ICESCR, are widely ratified and there needs to be a political commitment to respect these instruments on a whole. Such political commitment needs to admit the importance of the right to health and its cornerstone of access to medicines. Similarly, it needs to accept an international and harmonised system for

²⁴² Bass, *supra* note 96, p. 220.

²⁴³ See *supra* chapter 3.4.

patent protection, including flexibilities such as compulsory licences. It is not satisfactory to go just half way and accept that there is a right to health but not dedicate enough effort to provide access to medicines. Neither is it up to standard to accept an international patent system but provide insufficient protection to patent holders, or not fully implement the provisions on compulsory licences.

Half way-solutions will most likely result in uncertainty about the obligations and the options available under the respective parts of international law. In combination to separately recognising the full scope of patents, on the one side, and access to medicines, on the other, there is also a need for companies, States and international organizations involved with one side of the international law to respect the other at all times. Mutual respect for the respective parts of international law will allow for greater clarity in situations where the two intertwine. With greater clarity the flexibility offered by compulsory licences will stand a greater chance to develop its full potential.

For this step to take place, genuine political commitment on a large scale on the international level is required. Such political commitment is by no means an easy thing to produce. However, some encouraging indications can be deduced from efforts that have taken place up until now. While recognising the importance of access to medicines, the UN Commission on Human Rights, in the same resolution made sure to recognise that “intellectual property protection is important for the development of new medicines”.²⁴⁴ Similarly the growing trend within the WTO concerning public health considerations such as access to medicines, symbolised by the Doha Declaration and the Implementation Decision, indicates awareness about the importance of ‘the other side’. Such encouraging efforts need to continue. This would enable a shift away from the dominating conflict-focus and open up for more of a flexibility approach to the relationship between pharmaceutical patents and access to medicines.

A second step to take is to promote and create awareness about the flexibilities to the TRIPS Agreement in general and compulsory licences in

²⁴⁴ CHR Res. 2002/32, *supra* note 63, para. 7(c).

particular. At present, the rather limited use of compulsory licences is to a certain extent due to the fact that States that could potentially benefit from it are not fully aware of what its options has to offer. Promoting the use on an international level, naturally with the assistance of global organizations such as the UN, will help raise awareness.

Furthermore, the promotion needs to be combined with a recommendation to developing countries to implement the flexibilities to the fullest and clearest extent in domestic legislation. The flexibilities offered under the TRIPS Agreement and developed by subsequent documents are not self-executing and can only be utilised if they are incorporated into a State's domestic legislation. Therefore, enabling legislation is a fundamental step in any attempt to use compulsory licences to generate greater access to medicines.²⁴⁵ Though most States provide for compulsory licences for varying reasons in their domestic legislations, it is important that the recommendation is implementation of the flexibilities precisely to the fullest extent. Developing countries need to make use of the permitting wording of the Doha Declaration and the Implementation Decision. Such wide-ranging implementation will provide the full range of options available under the flexibilities and hopefully make their application somewhat easier. Furthermore, and importantly, it will also strengthen the role of compulsory licences as a bargaining tool for the implementing State.

In addition, the promotion of compulsory licences should also be combined with an attempt to create awareness in developing countries about the potential effects of entering into TRIPS-plus agreements. As touched upon previously, these States are not always fully aware of the effects these agreements can have on public health issues such as access to medicines. It seems reasonable to adhere to the view of the Special Rapporteur on health, by recommending that developing countries should not be encouraged by other States to enter into such agreements,²⁴⁶ or at least that such agreements should never include provisions making it even more difficult to make use of compulsory licences.

²⁴⁵ Oh, *supra* note 183, pp. 31-32.

²⁴⁶ Special Rapporteur 2006, *supra* note 64, para. 64.

It should be noted that not only international organizations, such as the UN, have an important role to make sure that the step is taken to promote and create awareness about compulsory licences. The South African case presented above indicates the importance of civil society and NGOs when it comes to creating awareness about the relationship between pharmaceutical patents and access to medicines.²⁴⁷ Their combined voice is equally important when it comes to pressing for greater use of the flexibilities that the TRIPS Agreement has to offer. Furthermore, an active civil society has the potential of strengthening the political commitment of a Government. Awareness within the Government that strong voices in the community support them to pursue compulsory licences can hopefully assist in making them realize that they have the mandate to do so. Finally, the promotion and awareness creating efforts concerning TRIPS flexibilities will also mean that States honour the spirit of the Doha Declaration and the Implementation Decision and the will with which these documents were concluded.

Thirdly, there is a need to start taking steps to take the much needed international cooperation and assistance seriously. Both the patent framework and the human rights framework, including access to medicines, are fundamentally international in character. With full respect of the sovereignty of every State, their international character should be embraced. A vital part of the international character is the obligation to make international efforts in the form of cooperation and assistance to help other States fulfil their obligations. Both patent related and human rights related instruments indisputably establish this obligation. For patents, Article 67 of the TRIPS Agreement stipulates that developed country Members should provide technical and financial cooperation in favour of developing countries. The idea is that the cooperation should assist developing countries in the implementation of the TRIPS provisions, including the flexibilities. Concerning access to medicines, Article 2(1) of the ICESCR provides that steps must be taken to fully realize the rights in the Covenant, including access to medicines as a part of the right to health. Such steps should be

²⁴⁷ See *supra* chapter 3.4; see also 2006 Report, *supra* note 160, pp. 201-222, discussing the essential role of civil society.

taken both “individually and through international assistance and co-operation, especially economic and technical”.

The international obligations on States resulting from the ICESCR have been clarified by the CESCR in General Comment No. 14. In it, the CESCR states that Member States must recognise the essential role of international cooperation and show commitment towards it. This commitment includes respecting the enjoyment of the right to health in other States, and to prevent third parties from violating the right, if able to do so legally or politically. Furthermore, the CESCR believes that Member States are obliged to give due recognition to the right to health in other international agreements and protect it as Members of other international organizations.²⁴⁸ An important part of fulfilling these international obligations from both a patent and human rights perspective appears to be cooperation and assistance when it comes to flexibilities such as compulsory licences. Such cooperation and assistance would help assure both that important provisions of the TRIPS Agreement are implemented properly and that the political commitment required from a human rights perspective is in place.

Unfortunately, at present, States do not appear to take their international obligations seriously. The technical assistance provided by institutions such as WIPO to developing countries has historically not really focused on flexibilities such as compulsory licences. Instead, the assistance appears to have been devoted to making sure that a system of patent protection is in place, without necessarily developing its flexibilities.²⁴⁹

More of the international cooperation and assistance needs to be devoted to how developing countries could possibly develop the flexibilities of the patent system. Such efforts need to be guided by the idea of providing a tool allowing the developing countries to fulfil the human rights obligation of access to medicines while at the same time keeping within the boundaries of the international patent framework. Furthermore, it is fundamental that the cooperation and assistance is neutral in the way it provides advice on

²⁴⁸ General Comment No. 14 of the CESCR, *supra* note 11, paras. 38-39.

²⁴⁹ B. K. Baker, *Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilise TRIPS Flexibilities in Non-Producing Countries* (DFID Health Systems Resource Centre, London, 2004) p. 47, <<http://www.dfid.gov.uk/pubs/files/dfidbrookbakertrips.pdf>>, visited on 3 December 2007.

how the developing countries can use the patent system to their advantage. One idea would be to promote assistance from more pro-health sources such as the WHO, which is mandated to provide assistance. As with the other necessary steps advocated above, the most important factor in achieving a step forward when it comes to international cooperation and assistance is the required political commitment. States need to start taking their international obligations of cooperation and assistance seriously and move from something that they have agreed to on paper to make it happen in practice.

It is not likely that all States will require the same process for trying to fulfil the potential of compulsory licences. For some, the major problem might be actual implementation of the TRIPS flexibilities, a lack of necessary institutions or a dire need for international cooperation and assistance. For others, all of the aspects might appear troublesome. Each and every State will have their particular concerns and prerequisites. In any case, the three-step approach advocated above could prove to be a good starting point for moving forward. If applied, such an approach would create awareness about the system of compulsory licences. In other words, it would prove to be a good platform for trying to fulfil the potential of compulsory licences by crystallising it into a fully functioning system.

While advocating steps that need to be taken, one should also take notice of the progress that is actually occurring regarding access to medicines. As presented above, a first pilot case of the compulsory licence system clarified by the Implementation Decision is now pending with Rwanda and Canada as the pioneers.²⁵⁰ Furthermore, the last few years has seen a growing trend of States without domestic manufacturing capacity trying to establish such capacity. The flexibility offered by compulsory licences might very well have worked as an incentive for the initiatives in these States. As an example, during the last few years a number of States on the African continent have taken steps towards establishing domestic manufacturing capacity. The base for production varies between voluntary licences from patent holders and compulsory licences. Interestingly, a lot of the work has been with the collaboration of companies from otherwise

²⁵⁰ See *supra* chapter 3.4.

potential exporting States, such as Brazil and India.²⁵¹ In a world where potential exporters of generic medicines are quickly disappearing because of TRIPS compliant patent legislation, it is encouraging to see that some States previously able to export are now involved in these initiatives. The efforts to establish manufacturing capacity in developing countries should continue to be endorsed on a broad level. Hopefully, such efforts will also assist in building the infrastructure that these States need. Ideally, the efforts could also increase the interest in tropical diseases by major pharmaceutical companies to redirect some of their research towards these diseases.

An important feature of the Doha Declaration and the Implementation Decision is the actual debate it has triggered on the relationship between pharmaceutical patents and access to medicines and the role of compulsory licences. A key achievement of the debate may be that it has to some extent refocused attention to the severity of the problems faced by the developing countries. It is hoped that this could work as a stimulus for wider initiatives to tackle alarming problems such as the HIV/AIDS epidemic. Such initiatives should of course include awareness, promotion and extended use of TRIPS flexibilities such as compulsory licences. However, it is important not to stop there but to also consider parallel initiatives, such as building domestic manufacturing capacity.

In conclusion, the problem of providing sufficient access to medicines does not necessarily lie in the present international legal framework on patents. The relationship between pharmaceutical patents and access to medicines does not necessarily amount to a legal conflict. In fact, the TRIPS Agreement considered in the light of the Doha Declaration and the Implementation Decision provides for a substantial amount of flexibilities, opening up for human rights considerations. Compulsory licences form an integral part of the flexibilities. The real problem appears to be the application, or non-application, of the flexibilities. In practice, States do not give the flexibilities enough consideration to allow them to assure that due consideration is given to human rights such as access to medicines. Largely due to the very limited use up until now, the present system of compulsory

²⁵¹ Haakonsson and Richey, *supra* note 177, p. 80.

licences can at best be described as dysfunctional. Before a fully functional system of compulsory licences is in place, it will be impossible to fully evaluate its possible benefits and downfalls. Throughout this thesis it has been advocated that a fully functioning system can be exercised with full respect of international law related to both patents and access to medicines at the same time. Consequently, until the system gets the chance to fulfil its potential, the international community of States needs to show a strong political commitment to give it the chance to do so.

4 Concluding Remarks

At the outset of this thesis, the purpose of it and a few principal questions of interest were given. This chapter tries to conclude the work performed by presenting and reflecting upon the conclusions arrived at in what is hoped to be a clarifying manner.

The first couple of questions were concerned with the features of the relationship between pharmaceutical patents and access to medicines, including their separate areas of international law, and whether the relationship constitutes a legal conflict or not.

The review of international law has indicated that both pharmaceutical patents, as a part of the larger intellectual property framework, and access to medicines, as a part of the larger human rights framework, are justified and desirable parts of international law. Different justifications and different international institutions are linked to the respective areas of international law. Patents are usually justified as a necessary incentive for invention and receive backing by the WTO, where economic perspectives form the focal point. Human rights, on the other hand, has a powerful friend in the UN and are commonly promoted from a social perspective of human well-being. The examination conducted has showed that the two areas of law from time-to-time intertwine. Not least, this is evident from the disturbing example of the HIV/AIDS epidemic. It is precisely such situations that lift the question if the relationship between pharmaceutical patents and access to medicines amounts to a legal conflict or if other approaches are possible. Different justifications and institutions with different perspectives mean that the proponents of each side may have different opinions and rules on how intertwining situations should be handled.

An important conclusion on the relationship in this thesis is that the problem of providing sufficient access to medicines does not necessarily lie in the present international legal framework on patents. Consequently, the relationship between pharmaceutical patents and access to medicines does not necessarily amount to a legal conflict. In fact, the TRIPS Agreement

considered in the light of the Doha Declaration and the Implementation Decision provides for a substantial amount of flexibilities, opening up for human rights considerations. Too much attention in both the scholarly and the institutional worlds is focused on the potential legal conflict. The conflict-focused approach is usually combined with a solution where one of the frameworks, *e.g.* human rights, always prevails. Such an approach is not very helpful for several reasons.

First, it is not only highly unlikely, as it would never be generally accepted, but it is also undesirable. One could easily imagine the effects if the reward for innovation would be too modest – there would simply be less innovation. Applying this to the pharmaceutical industry means that the speed of developing new medicines to tackle epidemics, such as HIV/AIDS, would slow down. Certainly, there may be economic factors blocking such development today, but existing cures to HIV/AIDS would probably not have been developed without the incentive of patents. Of course, overly generous awarding of patents could also cause deteriorating effects on access to medicines. Therefore, it appears to be a question of finding the right balance, *e.g.* with the assistance of flexibilities to patent protection. Secondly, such an approach fails to acknowledge the efforts of developing countries to get the international patent system with a certain amount of flexibilities in place. The real problem instead appears to be the application, or non-application, of the flexibilities. In practice, States do not give the flexibilities enough consideration to allow them to assure that due consideration is given to human rights such as access to medicines.

People dying because of lacking access to or innovation in pharmaceutical products is surely not the goal of the patent system. Therefore, it must be of interest to proponents of both pharmaceutical patents and access to medicines to strike a balance between the two that stays within the boundaries of the present international legal framework. The growing trend in the WTO to consider issues of public health in relation to patents, evident from the discussions producing the Doha Declaration and the Implementation Decision, indicates that steps are taken in the right direction. In order to come up with a proper level, a particular flexibility

with the potential to function as a balancing tool may be necessary to explore to a larger extent. Compulsory licences were included as flexibility from the beginning in the TRIPS Agreement and its role has continued to be highly debated after its adoption.

A third set of questions presented at the outset of this thesis were directed towards a more detailed examination of the role compulsory licences plays in the relationship between pharmaceutical patents and access to medicines.

The right to health, including the cornerstone of access to medicines, is combined with an obligation to take necessary steps for its full realization. That would appear to include the requirement to pursue options that has the potential of generating greater access to more affordable medicines. The flexibilities offered by compulsory licences have been advocated as such an option throughout this thesis. It has been suggested that a fully operational system of compulsory licences has great potential to generate affordable medicines on a wide scale. Consequently, a fully operational use of compulsory licences and the promotion thereof appears to be a useful tool for some States in trying to fulfil its human rights obligation of access to medicines. Compulsory licences allow States to use a built-in tool of the international patent system to try and procure more affordable medicines. Being a built-in tool, it has the advantage of conformity with patent protection, allowing States to pursue it without having to enter into tricky discussions of conflicting norms, *i.e.* pharmaceutical patents *vs.* access to medicines. It is difficult to see why States in dire need of medicines should not pursue this option. Therefore, the promotion and future application of a functional system of compulsory licences is desirable.

The practice of compulsory licences for pharmaceutical patents up until now indicates a difference between developing countries with domestic manufacturing capacity and those with insufficient or no domestic manufacturing capacity. Although use up until now has been rather limited, for States that have manufacturing capacity, compulsory licences have proved useful in a couple of ways. First, there have been a few cases where compulsory licences have been issued allowing the State to produce generic

versions of the patented medicines within their own borders. Secondly, the most important feature of compulsory licences for these States so far has been its role as a bargaining tool when negotiating prices for patented medicines. For States with insufficient or no manufacturing capacity, the situation looks a bit different. These States rely on other States to produce the desired generics and must therefore issue a compulsory licence opening up for such production. Therefore, these States inescapably become more dependent on a global will to make use of compulsory licences. To put it differently, these States have to rely on a global will to fulfil the obligation of access to medicines on an international level.

One could argue that this division between States has left us with an 'A-team' and a 'B-team' when it comes to utilising the flexibilities that are compulsory licences. States with manufacturing capacity are in a better position to achieve the goal of getting access to medicines at a reasonable price and therefore form the A-team States. Pharmaceutical companies are aware of the flexibilities in present patent law and understand that if they develop to stern of an attitude in price negotiations they may very well end up facing a compulsory licence. Consequently, compulsory licences have and will continue to benefit these States, both as an actually issued licence and the threat thereof.

The B-team States, those with insufficient or no manufacturing capacity, on the other hand, could just as well bring up the threat of a compulsory licence in price negotiations. However, pharmaceutical companies will probably not feel as intimidated by this set of States as they rely on production outside their own borders. With the transitional period having expired for previous big exporters of generics, such as India, the sources of exporters are drying out. Furthermore, under the system set up by the Implementation Decision, a compulsory licence will not only have to be issued in the importing State but also in the exporting State. So far, very few States have indicated their intention to export under the extended flexibility brought by the Implementation Decision. The Implementation Decision also requires a procedurally burdensome process that may be difficult for the potential importers to overcome. Additionally, States with insufficient or no

manufacturing capacity also tend to be more vulnerable to other roadblocks such as the lack of health and intellectual property infrastructure, trade and diplomatic pressure, and TRIPS-plus agreements. Therefore, it appears to be that the States most in need of medicines, despite the added opportunities under the Doha Declaration and the Implementation Decision, are still the ones facing most difficulty in making use of the flexibilities offered by compulsory licences.

A positive aspect of the fairly intense discussions on the relationship between pharmaceutical patents and access to medicines over the last few years is that the issue is now clearly on the international political agenda. Everyone from international organizations, such as the UN and the WTO, to scholars and civil society now appear to show an interest. The fact that an actual discussion is taking place indicates awareness of problematic features in the relationship and, more practically, has resulted in the adoption of documents such as the Doha Declaration and the Implementation Decision. To some extent, this indicates that the patent framework needs to be, and is, concerned with possible social implications of its exercise. The fact that there is a living discussion is encouraging and hopefully it will lead to more developments on how to make international regulations on pharmaceutical patents and access to medicines function well together. It is hoped that the role of compulsory licences will continue to form an integral part of such development.

In conclusion, the examination on the relationship between pharmaceutical patents and access to medicines has proved to be an interesting task. The present international patent regime offers flexibilities in several forms, notably in the form of compulsory licences which have been at the front of this study. The character of compulsory licences is that of a tool with the potential to assist States in their efforts to try and satisfy human rights obligations, such as access to medicines. Unfortunately, the system of compulsory licences has not yet been able to truly fulfil its potential. For that to happen, it is vital that all States involved start taking their international commitment to patent protection, including flexibilities to it, and to the right to health, including access to medicines, seriously. There

is a need to create awareness about the options available under compulsory licences and promote the idea of getting a fully operational system in place. Another necessary step would be to provide for compulsory licences by taking the appropriate implementation decisions, both in possible exporting and importing States, including full implementation of the flexibilities. Furthermore, extended international cooperation and technical assistance is fundamental both to get the necessary legal framework in place and to get the system fully operational. Only time will tell if States are willing to take the next step and thereby declare their commitment on a worldwide level.

It should of course be remembered that compulsory licences merely constitutes one helpful piece of a much larger health puzzle. Patents are not the only potential obstacle for access to medicines in developing countries. Millions and millions of people around the world lack access to essential medicines, several of those living in States not yet protecting pharmaceuticals under patents. Poverty is normally a troublesome and fundamental feature in these States. Furthermore, compulsory licences are not the only way to tackle possible adverse effects that patents may have on access to medicines. Tools such as differential pricing and parallel imports also have roles to play. Nevertheless, recognising the importance of compulsory licences as a balancing tool and making use of it on a regular basis will foster societal progress and the strife for the highest attainable standard of health for all. This would be a constructive step towards making the marriage between pharmaceutical patents and the access to medicines into a pleasant one.

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