

**A COMPARATIVE STUDY OF THE IMPLEMENTATION IN ZIMBABWE
AND SOUTH AFRICA OF THE INTERNATIONAL LAW RULES THAT
ALLOW COMPULSORY LICENSING AND PARALLEL IMPORTATION
FOR HIV/AIDS DRUGS**

**Dissertation submitted in partial fulfilment of the requirements of the degree
LLM in Human Rights and Democratisation in Africa**

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at the American University in Cairo,

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Declaration

I, Solomon Frank Sacco, declare that the work presented in this dissertation is original. It has never been presented to any other University or institution. Where other people's works have been used, references have been provided, and in some cases, quotations made. It is in this regard that I declare this work as originally mine. It is hereby presented in partial fulfilment of the requirements for the award of the LL.M Degree in Human Rights and Democratisation in Africa.

Signed.....

Date.....

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Signature.....

Date.....

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List of Abbreviations

International Covenant on Economic, Social and Cultural Rights:	ICESCR
Médecins sans Frontières:	MSF
Research and Development:	R&D
The agreement on the trade related aspects of intellectual property:	TRIPS
Trans-national Corporations:	TNCs
Treatment Action Campaign:	TAC
Universal Declaration of Human Rights:	UDHR
World Health Organisation:	WHO
World Trade Organisation:	WTO

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Chapter 1: Introduction

In 1995 the international community adopted the Agreement on the Trade Related Aspects of Intellectual Property (TRIPS) as part of the wider World Trade Organisation (WTO) agreement. Intellectual property had received international recognition from the 1880s. Indeed, the substantive provisions of TRIPS are restatements of the 1883 Paris Convention for the Protection of Industrial Property, the 1886 Berne Convention for the Protection of Literary and Artistic Works and the Washington Treaty on Intellectual Property on Integrated Circuits.¹ However, TRIPS changed two important things. It increased the protection mechanisms and strengthened the dispute resolution procedure for intellectual property,² and it removed the state's discretion under the Paris Convention to determine the extent of patent protection.³ For the protection of pharmaceuticals this change means that states that had traditionally not allowed patent protection for pharmaceuticals or had limited this protection to product patents had to amend their legislation to become "TRIPS compliant". Developing and least developed nations were allowed under TRIPS a limited period to ensure that their legislation was TRIPS compliant. Developing countries such as India (the supplier of much of the generic drugs sold in Africa) will have to amend their legislation by the end of this year, while least developed countries, such as Malawi (which generally have no manufacturing capacity) have until 2016.

The WTO agreement included "flexibilities" to allow member states to disregard or "bend" the rules in certain circumstances, such as (but not restricted to) national emergencies. These flexibilities were implicit in articles 7 (the objectives) and 8 (the principles) of TRIPS but were explicit as regards patents in articles 30 (which allows exceptions to the rights of patent holders) and 31 (which allows "other unauthorised" use of the patent).

This was the general international law on the protection of patents, and flexibilities therein for specific national interests, before the HIV/AIDS medicines controversy of the late 1990s. In the second half of the nineteen-nineties the HIV/AIDS pandemic put

¹ B Elangi "From the Paris Convention to the TRIPS Agreement: A one-hundred-and-twelve-year transitional period for the industrialised countries," *Journal of World Intellectual Property* (2004) 7 [1], 115.

² As above 123 – 124.

³ T Kongolo "Towards a more balanced co-existence of traditional knowledge and pharmaceuticals protection in Africa," *Kluwer Law International* (April 2001) 35 [2] 349.

increasing pressure on developing countries, especially in sub-Saharan Africa, to provide cheap or free anti-retroviral drugs to their citizens in accordance with their duties to protect and fulfil the right to health. Patents on pharmaceutical products and processes were seen as keeping the prices of medicines unreasonably high, making the medicines unaffordable in public hospitals in developing countries. As a result the WTO, meeting in Doha in 2001, declared that members of the WTO should interpret article 31 of TRIPS to allow the manufacture of generic drugs in countries facing national health crises. Article 6 of the Doha Declaration called on the Ministerial Conference to speedily achieve consensus on how countries without manufacturing capacity could benefit from the Doha declaration. Since the TRIPS agreement stipulates that generic manufacture, where allowed, should primarily be for the local market⁴, parallel importation of generic drugs from a country that has legally manufactured the drugs under a compulsory licence to a country with a health crisis (grey importation) would have been illegal under TRIPS. Thus on 30 September 2003 the WTO Council of Ministers agreed on a statement establishing procedures for grey importation setting out a stringent procedure that has to be followed both by the exporting and importing country.

The situation therefore is that, applying the Doha Declaration and the 30 September 2003 decision to Article 31 of TRIPS, a country facing a public health emergency (such as the HIV/AIDS crisis) may issue compulsory licences to local manufacturers to produce patent protected medicines. The country may alternatively choose to issue licences to companies to import medicines from countries that produce generic medicines. However, because the latter provisions mandated stringent procedures for grey importation this procedure has been the subject of much criticism.

1.1 Background context of the study

Zimbabwe and South Africa are facing an HIV/AIDS epidemic of such proportions that the populations of these countries will markedly decline in the next ten years despite the existence of effective drugs to treat the symptoms of AIDS and dramatically lower the communicability of the virus. These drugs are under patent protection by

⁴ TRIPS allows compulsory licences to primarily meet the local market, meaning that licences are issued by states to allow companies to produce enough for the local market and any exports should be incidental. This was the provision perceived as preventing grey importation as it limited compulsory licences to satisfying the local market.

companies in the developed world and the patents raise the prices above the level of affordability for HIV infected persons in South Africa and Zimbabwe. Zimbabwe has declared a national emergency on HIV/AIDS, apparently in conformance with TRIPS and has issued compulsory licenses to a local company that has started to manufacture and sell cheap anti-retroviral drugs. South Africa has not declared a national emergency and has not invoked the TRIPS flexibilities or utilized flexibilities inherent in its own legislation.

However, while thousands of people die every week in the two countries neither government has yet provided an effective HIV/AIDS policy. Extensive litigation and public pressure in South Africa has led the government to announce a policy of supplying free HIV drugs in public hospitals while the Zimbabwean government has announced the provision of the same drugs, also in public hospitals, apparently utilising the state of emergency. The TRIPS agreement under which the two governments undertook to protect international patents allows compulsory licensing under certain circumstances (not limited to a national emergency) and the Doha Declaration on TRIPS and Public Health, and subsequent agreements by the Ministerial Council of the WTO allow the manufacture and, in limited circumstances, the parallel importation of generic drugs. These provisions provide a theoretical mechanism for poor countries to ensure their citizens' rights of access to health (care).

The research is aimed at identifying the extent of the effectiveness of the legal norms created by Articles 30 and 31 of TRIPS, the Doha Declaration and subsequent Council of Ministers' decisions, which together ostensibly provide a framework to allow provision of generic drugs. It is further aimed at investigating how the state of emergency in Zimbabwe has been utilised to provide cheap generic drugs to Zimbabweans and whether this would be an option for South Africa. A comparison of the legal provisions governing the provision of drugs in the two countries will also be undertaken to examine the extent to which international and national constitutional and legal provisions may be utilised to give effect to the right to health.

1.2 Problem Statement

The flexibilities in the TRIPS agreement, which allow the licensing of generic antiretroviral drugs, theoretically allow governments a mechanism to drastically cut the

cost of the drugs in their countries, both in the private and public sector. However, the procedures set out in the TRIPS agreement and subsequent WTO agreements have been impugned by commentators such as OXFAM as too onerous to allow governments to legalise the manufacture and importation of generic drugs. The flexibilities in these instruments will only be effective if governments make use of them and issue licenses to companies that manufacture or import cheap generic drugs. Since neither country seems to be fulfilling its duty to protect and fulfil the rights to health the question arises to what extent this is due to difficulties in applying the agreements that are inherent in the agreements themselves or for other reasons.

1.3 Assumptions

1. The compulsory licensing procedure under the World Trade Organisation's Agreement on the Trade Related Aspects of Intellectual Property is not sufficient to enable states to protect the rights of their citizens, but at the same time Zimbabwe and South Africa have failed to maximize the use of these flexibilities.

1.4 Research Questions

1. In what ways have Zimbabwe and South Africa utilized the flexibilities in TRIPS been utilised to effectively protect the right to health?
2. In what ways have Zimbabwe and South Africa not utilised the flexibilities in TRIPS to effectively protect the right to health?

1.5 Hypotheses

1. The governments of South Africa and Zimbabwe could increase provision of HIV/AIDS drugs by fully utilizing the flexibilities in the TRIPS agreement.
2. South Africa could improve its performance in the implementation of the right to access to health care by issuing compulsory licenses to local companies to manufacture cheap anti-retroviral drugs.

1.6 Relevance of Study

The HIV/AIDS pandemic is considered to be under control in the North, where effective use of anti-retroviral therapy allows patients to continue with a quality of life generally comparable to that of uninfected people. In the developing world HIV infection is often still a death-sentence. Governments have the duty to protect and fulfil the right to health as guaranteed under international agreements and this duty needs to be monitored. This paper seeks to provide a kind of evaluation to show how the governments have utilised the flexibilities in TRIPS to comply with their duty. The study will attempt to measure the flexibilities in TRIPS in achieving the expressed aim of allowing governments to fulfil and protect the right to health. Finally by comparing different attitudes towards compulsory licensing the study will provide insight as to how different governments facing the same crisis should proceed to protect the right to health.

1.7 Literature Review

1.7.1 Previous Research into the flexibilities in TRIPS

Musungu (2001) deals extensively with the right to health at international law and the relationship between this right and the intellectual property regime of the WTO. However he does not deal with the responses by the governments of Zimbabwe and South Africa to their obligations to protect their citizens' rights health and the opportunities available under the TRIPS agreement.

Mashelkar (2001) argues that the presence of generics on the market directly affects the price of pharmaceuticals and that therefore patents have the effect of increasing the prices of essential drugs.

Hunt (2004) sets out the international law on the right to health in relation to trade and argues that the right to health contains a minimum core obligation to 'ensure the satisfaction of, at very least, minimum essential levels of health care'. He argues that trade liberalization must be conducted in such a manner as to foster the progressive realisation of the right to health and that the state has an obligation to ensure *availability, accessibility and good quality* of drugs.

McCalman (2002) sets out the agreement reached at Doha regarding intellectual property and health and is of the opinion that the Declaration has the effect of allowing developing countries to circumvent international protection of intellectual property in national emergencies.

Mayne and Bailey (2002) argue that the Doha Declaration was insufficient in its protection of the rights of third world countries with no manufacturing capacities. They raise the dangers that will arise once countries such as India are forced, under article 31 (f) of TRIPS, to stop exports of generic drugs to other developing countries in early 2005.

1.7.2 Significance of the study

While much research has been done on the international law establishing the duties of states to protect and fulfil the right to health, and on the flexibilities in TRIPS and the subsequent agreements, there has been no research on how this has affected Zimbabwe and South Africa, two countries that have been especially hard hit by the HIV/AIDS pandemic. The paper attempts to place the duties of Zimbabwe and South Africa in perspective against the backdrop of the international law on patent protection and to assess their implementation of the flexibilities and the usefulness of these flexibilities in achieving their duties.

1.8 Methodology

The research is divided into two areas. First there will be a discussion of the international and national constitutional and legal provisions protecting human rights and intellectual property. Secondly, there will be an analysis of the application of TRIPS flexibilities in Zimbabwe and South Africa, and the enforcement of the human right to health in the two countries. Where documentation does not exist, this shall be done by analyzing empirical evidence regarding prices of essential medicines.

1.9 Limitations

The study shall be limited to rights of persons in the two countries to access drugs under patent protection at a cheaper price and shall not consider the conflict between

this right and the right of the owners of the intellectual property to protection, except insofar as these rights affect the way the relevant provisions of the TRIPS and related agreements have been formulated. The study further shall be limited to access to specific patented drugs for the symptomatic 'treatment' of HIV/AIDS, especially antiretroviral drugs, and shall not consider access to other essential drugs and the policies and norms regulating such drugs in the two countries. The study shall not attempt to determine the non-legal aspects of access to antiretroviral drugs, such as difficulties in dosage and ensuring compliance with required prescription regimes. The study shall not engage in quantitative analysis of the policies of the two governments in the provision of antiretroviral drugs.

1.10 Structure

Chapter One

Introduces the topic, the questions to be answered by the research, and the research methodology.

Chapter Two

An analysis of international and national norms on the right to health, establishing the extent of the duties of Zimbabwe and South Africa at international law regarding the protection and promotion of the right to health.

Chapter Three

An investigation of the international protection of the rights to Intellectual Property and the duties imposed on states under TRIPS and the flexibilities and procedures under the TRIPS agreements which allow governments to issue compulsory licences to companies to manufacture and import generic drugs from countries manufacturing generic drugs.

Chapter Four

This chapter analyses the legal regimes adopted by the two countries to implement the rights of their citizens for access to affordable essential anti-HIV drugs and whether the two countries have taken steps under the TRIPS agreement to facilitate the provision of generic antiretroviral drugs. An analysis is made of the situation in the

two countries regarding access to antiretroviral drugs and the relative cost/affordability of the drugs, and the availability of the drugs in the private and public sectors.

Chapter Five

An analysis is made of other factors that affect the supply of antiretroviral drugs in South Africa and Zimbabwe, including lack of resources and political will, and an analysis of the efforts of multi-national companies to block the utilisation of the flexibilities inherent in TRIPS.

Chapter 6: Conclusion and recommendations

The study concludes by looking at manners in which the two countries are meeting their obligations under international law to protect the right to health and makes recommendations on manners in which the countries may improve on this delivery.

Chapter 2: the right to health

The right to health contains both freedoms and entitlements ... the entitlements include the right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.⁵

In the second half of the twentieth century international law developed a system of human rights protection, which system includes the protection of so-called economic, social and cultural rights. One of the rights that have been developed in international and national law has been the right to health (both to health care and to the determinants of health such as clean water, food and shelter). The Ecuadorean Constitutional Court has confirmed that the rights to health and life are interrelated and the HIV/AIDS pandemic in the developing world is clear evidence of the interrelation.⁶

The Committee on Economic, Social and Cultural Rights (the Committee) has confirmed that state parties to the International Convention on Economic, Social and Cultural Rights (ICESCR) have obligations to take progressive steps towards implementation of the rights as well as a minimum core of obligations that have to be fulfilled immediately. In national law the South African Constitution and constitutional cases such as the *Minister of Health and others v Treatment Action Campaign and others* (the TAC case) have demonstrated that governments may be held accountable for failures to provide health care in certain circumstances.⁷ In Ecuador the Constitutional Court has held that the right to health in the Ecuadorian Constitution, as interpreted with reference to international norms such as article XI of the American declaration of the Rights of Man and article X of the Protocol of San Salvador,

entitles citizens not only to take legal action for the adoption of policies, plans and programmes related to the general protection of health (for example in the case of disease or epidemic) but also demand that appropriate laws be enacted, that the government undertake the necessary research, that it develop public policies in the area of health care, and that it provides the

⁵ United Nations Committee on Economic Social and Cultural Rights (the Committee), "The right to the highest attainable standard of health: 11/08/2000; Substantive issues arising in the implementation of the International Covenant on Economic, Social and Cultural Rights," *E/C.12/2000/4 (General Comments), General Comment No. 14 (2000)*, (General Comment 14).

⁶ C Fairstein "The right to health - an Ecuadorian perspective," in *Housing and ESC Quarterly* 1 [1]. The case referred to is *Edgar Carpio Castro Jofre Mendoza & Ors v Ministry of Public Health and the Director of the HIV-AIDS National Programme (amparo writ)* Resolucion No. 0749-2003-RA, 28 Jan. 2004.

⁷ 2002 (5) SA 703 (CC). In the TAC case it was the failure to implement a reasonable policy to prevent mother to child transmission of HIV/AIDS that was found unconstitutional.

necessary entities to ensure that the general public benefits from such policies, plans and programmes.⁸

While the right to health is broad and includes many factors,⁹ these factors, such as food and nutrition, are conceptually easier to deal with as separate rights while remembering that all rights are inter-related and interdependent.

The right to health is protected in numerous international and regional declarations and treaties. At the international level the Universal Declaration of Human Rights (UDHR) and the ICESCR lay the foundation. References to health as a human right are found in several other United Nations Human Rights treaties such as the Convention on the Rights of the Child, the Convention on the Elimination of all forms of Racial Discrimination, and the Convention on the Elimination of All Forms of Discrimination against Women. Regional treaties that recognise the right include the European Social Charter, the Declaration of Alma Ata, the African Charter on Human and People's Rights (the African Charter), and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights.

2.1 The right to health in international law

The first expression of the right to health was in the preamble of the World Health Organisation (WHO) Constitution of 1946:

The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions.

This was two years before the UDHR of 1948. In the UDHR the United Nations declared that “[e]veryone has the right to a standard of living adequate to the health of

⁸ Fairstein (note 6 above).

⁹ The Committee stated, in General Comment 14 (note 5 above) that “(i)n drafting article 12 of the Covenant, the Third Committee of the United Nations General Assembly did not adopt the definition of health contained in the preamble to the Constitution of WHO, which conceptualizes health as ‘a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’. However, the reference in article 12.1 of the Covenant to ‘the highest attainable standard of physical and mental health’ is not confined to the right to health care. On the contrary, the drafting history and the express wording of article 12.2 acknowledge that the right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead a healthy life, and extends to the underlying determinants of health, such as food and nutrition, housing, access to safe and potable water and adequate sanitation, safe and healthy working conditions, and a healthy environment.” This statement indicates both the extent to which the right to health may be taken; the World Health Organisation’s definition, and the range of factors that the committee is prepared to consider, even on the more limited definition in the ICESCR.

himself and of his family, including food, clothing, housing and **medical care** and necessary social services (emphasis added).”

While the UDHR is important because of its general acceptance by all states, the right to health is more definitively explained in the ICESCR.¹⁰ Article 12 (1) of the ICESCR protects “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.” At the core of the right to health as protected by article 12 of the ICESCR is the “enjoyment of a variety of essential facilities, goods, services and conditions necessary for the realisation of the highest attainable standard of health.”¹¹

2.1.1 General Comment 14

The Committee is a body of independent experts in charge of interpreting and monitoring the application of the ICESCR. In May 2000 the Committee issued General Comment number 14 on the substantive issues arising from the application of the right to the highest attainable standard of health. General Comment 14 provides the most detailed explanation of the scope of States’ responsibility under the United Nations system with regards to the right to health, and is thus definitive of the rights and obligations arising from the ICESCR.

The Committee noted that states could not be expected to guarantee good health for the individual and noted that the right would therefore have to be measured by the criteria of whether the state had provided certain goods and services.¹² The Committee outlined the essential elements of the right to health, which are availability, accessibility, acceptability and quality.¹³ The Committee stated that health facilities, goods and services must be available “in sufficient quantity within the State party.” The Committee recognized that the precise nature of these facilities, goods and services will vary in accordance with the State party’s developmental level but insisted that the underlying determinants of health must be made available. Among other things the Committee outlined the requirement of economic accessibility. The Committee stated

¹⁰ See F Musungu “The right to health in the global economy, reading human rights obligations into the patent regime of the WTO-TRIPS agreement,” *International yearbook of regional human rights masters programmes* (2001) 194–203, “While article 12 of the ICESCR is modelled on the Universal Declaration provisions, it provides a more comprehensive definition and is more specific.”

¹¹ As above 204.

¹² General Comment 14 (note 5 above) para 7.

¹³ This paper concentrates on the issue of availability and accessibility.

that

health facilities, goods and services must be affordable for all. Payment for health-care services ... has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households.¹⁴

The Committee said that state parties have an obligation to create a “system of urgent medical care in cases of accidents, epidemics and similar health hazards, and the provision of disaster relief and humanitarian assistance,” and that the right to health facilities, goods and services, “includes appropriate treatment of prevalent diseases [...], preferably at community level; [and] the provision of essential drugs.”¹⁵

2.1.2 The obligations of the state

State obligations relating to economic, social and cultural rights are limited by the concept of progressive realisation within a state’s available resources. Thus a state may argue that its duties in relation to health are only to be judged in terms of whether the state has a policy to progressively realise its obligations, taking into consideration its available resources. In South Africa the Constitutional Court, while interpreting the South African Constitution which refers to “progressive realisation,” has held that the government was required to have a “reasonable” policy to deal with emergency situations in the housing crisis (implementing the right to housing under the South African Constitution), see *Government of the Republic of South Africa and Others v Grootboom and Others*,¹⁶ and a similar approach was applied in *Soobramoney v Minister of Health, KwaZulu-Natal*.¹⁷ The result is that the South African courts are entitled to review the policies of governments and determine whether the policies are reasonable in their implementation of the government’s obligations. While this was a test developed within the constitutional framework of South Africa it is equally applicable to the enforcement of international obligations. Whether reference is made to progressive realisation or to a reasonable policy the duty of the state is to ensure that it takes concrete steps towards the realisation of the right and it cannot simply fail to meet its obligations under the pretext that it has no available resources – the state

¹⁴ General Comment 14 (note 5 above) para 9.

¹⁵ As above para 16.

¹⁶ 2001 (1) SA 46 (CC).

¹⁷ 1998 (1) SA 765 (CC), see also the *TAC* case (note 7 above).

is obliged to do as much as it can.

The right to health, like all other rights, imposes on state parties the obligations to promote, respect, protect and fulfil. For the purposes of this paper the second two duties are most important. The State has an obligation under the ICESCR to take measures to prevent third parties from interfering with the elements of the right to health. The obligation includes controlling the production, supply and sale of medicines by third parties.¹⁸ This duty includes not only ensuring the quality of the medicines sold but also that medicines of acceptable quality are sold at prices affordable by the poor and other vulnerable sectors of society. This protection can take several forms including enacting legislation regulating the prices of drugs.¹⁹

The duty to fulfil is traditionally seen as implying expenditure by the state, for example by providing free or cheap medicines to the sector of society that cannot afford to buy the medicines. However, the duty to fulfil may include more facilitative roles, such as ensuring provision of cheaper medicines by third parties through legislative and policy regimes. Thus, with respect to the right to health the duty was defined as requiring that

states must ensure provision of health care ... and ensure equal access for all to the underlying determinants of health ..., the provision of a sufficient number of hospitals, clinics and other health-related facilities ... Further obligations include the provision of a public, private or mixed health insurance system which is affordable for all.²⁰

In the context of the right to health under the ICESCR states have an obligation to ensure the availability and accessibility of essential medicines to the individual. These obligations may be satisfied by the provision of free or cheap medicines by the government or by way of the adoption of a legislative/normative framework to ensure provision of cheap medicines by third parties.

2.1.3 Core Obligations

[T]he Committee is of the view that a minimum core obligation to ensure the satisfaction of, at the very least, minimum essential levels of each of the rights is incumbent upon every State

¹⁸ General Comment 14 (note 5 above) para. 35. See also para. 51, "Violations of the obligation to protect follow from the failure of a State to take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties. This category includes such omissions as the failure to regulate the activities of individuals, groups or corporations so as to prevent them from violating the right to health of others; the failure to protect consumers and workers from practices detrimental to health, e.g. by employers and manufacturers of medicines or food..."

¹⁹ This approach has, for example, been utilised in Egypt.

party. Thus, for example, a State party in which any significant number of individuals is deprived of essential foodstuffs, of **essential primary health care** ... is, prima facie, failing to discharge its obligations under the Covenant (emphasis added).²¹

While the ICESCR generally provides for progressive realization of rights (acknowledging the limits of available resources), State parties have an immediate obligation to take steps towards the full realization of the rights of the Covenant. With respect to health the Committee held that the minimum core obligations with regard to the right to health include, at a minimum, the obligation

(d) To provide essential drugs, as from time to time defined under the WHO Action Programme on Essential Drugs;

(e) To ensure equitable distribution of all health facilities, goods and services.²²

General Comment 14 is therefore authority for the contention that all state parties have an immediate obligation to provide either free or affordable essential medicines to the market and if a significant proportion of the population does not have access to such medicines the state has violated its obligations. This duty may be implemented by the state providing free or cheap medicines or may be implemented through the regulation of pricing by third parties (or by facilitating the provision of generic anti-retroviral drugs).

2.2 Regional protection of the right to health: the African Human Rights System

The African Charter on Human and Peoples' Rights (the Charter) enshrines and protects economic, social and economic rights on the same basis as civil-political rights. Article 16 protects the right of the individual to the highest attainable standard of health and article 16(2) sets out the duties of the state to ensure health care. There is no general clause in the Charter limiting the enforcement of economic, social and cultural rights to progressive realisation within available resources. Thus it can be argued that the obligations arising from the Charter are immediate, regardless of the nature of the rights concerned,

Unlike the ICESCR, the African Charter avoids the incremental language of progressive realisation in guaranteeing these economic, social and cultural rights, except in article 16(1)

²⁰ General Comment 14 (note 5 above) para 36.

²¹ The United Nations Committee on Economic Social and Cultural Rights, *The nature of States parties obligations (Art. 2, par.1)* 14/12/90. CESCR General comment 3. (General Comments) Contained in document E/1991/23.

²² General Comment 14 (note 5 above) para 43.

which guarantees the best attainable state of physical and mental health. Instead, the obligations that state parties assume with respect to these rights are clearly stated as being of immediate application.²³

It is Odinkalu's opinion therefore that all economic, social and cultural rights in the Charter, except the right to health, imply immediate obligations on the state. The exception on health is based on a misunderstanding of the phrase, "best attainable," which should be read, in the context of the African Charter, to refer to the personal circumstances of the individual.²⁴ Article 16(2) of the Charter, which sets out the obligations of the state with respect to the right to health, does not make any reference to the progressive realisation or available resources, and thus it is arguable that the right to health and the obligation of states to provide, or make available, health care, and therefore essential medicines, is immediate under the African system.

However, in the *Purohit and Moore v Gambia* case the African Commission implied the limitation of available resources to the right to health under the African Charter.²⁵ Commenting on the decision it has been noted that this was based on recognition by the Commission

that millions of Africans are denied the maximal enjoyment of the right to health due to the prevailing poverty that renders African countries incapable of providing the necessary amenities, infrastructure and resources to facilitate enjoyment of the right.²⁶

A strong argument may be made, through the application of articles 60 and 61 of the African Charter which allow the African Commission to apply international law to the interpretation of the African Charter, that the African Commission was correct and that the concept of progressive realisation is applicable to the African Charter. The African Commission, however, did not go into detail in its argument on the applicability of the concept and this question must be considered still to be open.

²³ O Odinkalu "Implementing economic, social and cultural rights" in Murray and Evans (eds) *The African Charter on Human and Peoples' Rights* (Cambridge, 2002) 178 196. See also the Presentation of the Third Activity Report by the Chairman of the Commission, U Umzorike to the 26th session of the Assembly of Heads of State and Government of the Organisation of African Unity, 9-11 July 1990 (1990)(*Documents of the African Commission* 201) cited by Odinkalu.

²⁴ Thus the UN Committee has noted that, "there are a number of aspects which cannot be addressed solely within the relationship between States and individuals; in particular, good health cannot be ensured by a State, nor can States provide protection against every possible cause of human ill health. Thus, genetic factors, individual susceptibility to ill health and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual's health."

²⁵ Communication 241/200, decided at 33rd Ordinary Session of the African Commission (15-29 May 2003).

²⁶ A Mawuse "The right to health for mental health patients: African Commission," in *Housing and ESC Rights Law Quarterly* 1 [1].

African states have obligations under the African Charter to respect, protect, promote and fulfil economic, social and cultural rights at least to the same extent that these rights exist under the ICESCR.²⁷ In addition, these rights arguably give rise to immediate obligations under the African Charter. Further, the African Charter allows individuals to complain to the African Commission without requiring ratification of an optional protocol by the state concerned.²⁸ It is this avenue of complaint that makes the African system important for socio-economic rights and specifically for the enforcement of the right to health.

2.3 The right to essential medicines and anti-retrovirals

One of the elements of the right to health is the right to access essential medicines. In General Comment 14 the Committee stated that ensuring access to essential medicines for the large majority of the population is one of the minimum core obligations of the state. In 2002, a WHO expert committee prepared the 12th Model List of Essential Drugs. The new list contained 325 individual drugs, including 12 antiretroviral medicines for the prevention and treatment of HIV/AIDS.²⁹ Applying General Comment 14 to the WHO concept of essential medicines the states owe a duty to develop a policy that will incrementally ensure the provision of essential medicines to all individuals within the state.

In addition to the obligation to incrementally ensure the enjoyment of the right access to essential medicines through a reasonable policy the state has an immediate responsibility, as a core minimum, to ensure that the majority (or a large proportion of the population) is not denied access to essential medicines, or to use the Committee's, negative, phraseology, to ensure that no significant proportion of society is denied access.

2.7 The duties of Zimbabwe and South Africa

²⁷ See *SERAC V Nigeria*, 155/96, ACHPR/COMM/A044/1 and articles 60 and 61 of the African Charter.

²⁸ Articles 55 and 56 of the African Charter.

²⁹ The current list can be found at <http://mednet3.who.int/eml/diseases_disease_group_order.asp>, accessed on 4 September 2004.

The Zimbabwean Constitution does not protect the right to health and the protection of the right to life is restricted to the prohibition of the arbitrary deprivation of life.³⁰ However, Zimbabwe has ratified the ICESCR and the African Charter on Human and Peoples' Rights and is thus bound at international law to respect and implement this right. South Africa has protected the right to access to health care services under section 27(1) (a) and has put the duty on the state under article 27(2) to take progressive steps, within its available resources, to achieve the right. Section 28 (1) (c) of the South African Constitution gives children an apparently less restricted, i.e. immediate right to "basic health care services." However, South Africa is not a party to the ICESCR and the South African Constitutional Court has held that it is not bound by the concept of minimum core obligations.³¹ South Africa is a party to the African Charter on Human and Peoples' Rights and is thus bound by section 16 of the Charter. Article 16 may be interpreted to give rise to immediate obligations by the South African government, under article 16(2), which does not refer to progressive realisation, or may be interpreted, as in the *Purohit* case,³² with reference to articles 61 and 62 to include international law and thus to include the concept of minimum core obligations. Thus, at a minimum, both the governments of South Africa and Zimbabwe are obliged to take progressive steps towards the realisation of the right to health and are obliged to immediately realise a minimum core of obligations, including ensuring that there is no significant proportion of the society that does not have access to essential medicines, which include anti-retrovirals.

³⁰ Section 12 (1) of the Zimbabwean Constitution reads, "No person shall be deprived of his life intentionally save in execution of the sentence of a court in respect of a criminal offence of which he has been convicted."

³¹ The *TAC* case (note 7 above).

³² Note 25 above.

Chapter 3: The effect of intellectual property on the protection of the right to health

Intellectual property has been recognised, in various forms and with different levels of protection, since the eighth century AD in China and the sixteenth century in Europe.³³ However, prior to the deadline given to most developing countries of January 2005 many developing countries did not provide patent protection, or provided only limited protection, for pharmaceutical products. This meant that much of the medicines in the developing world were generic medicines manufactured by a process of reverse engineering in countries such as India or Brazil.³⁴ For countries that have relied on this supply of essential drugs the implementation of the TRIPS agreement will have a retrogressive effect on the delivery of essential drugs and even for countries that have generally relied on voluntary licences, such as South Africa, the implementation of TRIPS limits the options available to a state facing a health crisis.

3.1 The justification for patent protection

It is argued that patent protection is an incentive to inventors to invent and to disclose their inventions to the public. This is also expressed as a societal contract between the inventor and the rest of society allowing the inventor certain, limited, rights to a monopoly over the commercial exploitation of the patented product or process.³⁵ It is also argued that patent protection encourages research and development of pharmaceuticals (R&D) because the money raised from patents is necessary for carrying out costly research and development of the pharmaceuticals industry.³⁶ It is also arguable that “pharmaceutical patents are justifiable within international human rights law, as they promote R&D which is essential for the future enhancement of rights to life and health.”³⁷ Since it is the pharmaceutical companies that determine where to absorb revenue losses, undermining patent protection may threaten R&D as pharmaceutical companies may decide not to allocate funds to R&D.³⁸

³³ Musungu (note 10 above) 208 – 209.

³⁴ P Drahos “Access to medicines: after Doha,” *Trade hot topics commonwealth* No. 20.

³⁵ Musungu (note 10 above) 211.

³⁶ S Joseph “Pharmaceutical Companies and Access to Drugs: the “Fourth Wave” of Corporate Human Rights Scrutiny,” *25 Human Rights Quarterly* 425 (2003) 428 431.

³⁷ As above 432.

³⁸ As above 439.

3.2 Criticism of patent protection

Patent protection leads to a rise in drug prices keeping drugs out of reach of people in developing countries.³⁹ Generic drugs are less expensive than the patented, brand-name types. This means that a wider market for generics will give access to more people – especially in developing countries – to essential medicines.⁴⁰ The strict application of patent rights will have an adverse impact on access to essential medicines as it will limit the possibility of purchasing affordable non-patented drugs.⁴¹ Moreover, “enforcement of WTO rules will have a negative effect on local manufacturing capacity and will remove a source of generic, innovative, quality drugs on which developing countries depend.”⁴² The inflated drug prices will prevent poorer people especially in developing countries from accessing essential drugs threatening – and in some instances violating – their right to health.⁴³

3.3 Patents and the right to health

Because of the industrialised nature of modern society the implementation of many rights protected at international and national law imply the provision of patented products and products manufactured by a patented process.⁴⁴ The health of the individual may depend on the provision of certain medicines or drugs which are protected by a patent and the manufacture of which are legally monopolised by the patent holder. It is the potential conflict between the rights of the person to receive food or medicine and the right of the patent holder to receive a monopoly over the patented product/process that defines the extent of the competing rights. The conflicting duties of the state – to protect the rights of the patent holder and the rights

³⁹ Médecins sans Frontières (MSF) “Surmounting challenges: procurement of antiretroviral medicines in low- and middle-income countries; the experience of Médecins sans Frontières,” (2003) available from the MSF website, on the effect of generics on medicine prices. See also MSF, “Doha derailed: a progress report on TRIPS and access to medicines,” *Médecins sans Frontières briefing for the 5th WTO Ministerial Conference, Cancun 2003*, “At the end of the day, the supply of affordable versions of new medicines would slow to a trickle, with developing countries having few alternatives to the high prices and long-term monopolies of originator companies ... The experience with antiretrovirals (ARV) and other drugs has amply shown that as competition rises, prices fall.”

⁴⁰ P Wjahn “A Conflict of rights: intellectual property under TRIPS, the right to health, and AIDS drugs,” 6 *UCLA Journal of International Law & Foreign Affairs* 463 (Fall 2001/Winter 2002) 465.

⁴¹ E Hoen “Public Health and International Law: TRIPS, pharmaceutical patents and access to essential medicines: a long way from Seattle to Doha,” 3 *Chicago Journal of International Law* 27 (Spring 2002) 29.

⁴² As above.

⁴³ Joseph (note 36 above) at 432.

⁴⁴ Musungu (note 10 above) 211.

of the patient – define the obligations of states under international law. These conflicting duties gave rise to the “flexibilities” within the original TRIPS agreement as it was seen that individual states would have to determine for themselves in what ways the conflict between the different rights were determined.

3.4 TRIPS

3.4.1 Introduction

TRIPS was one of the agreements reached after the Uruguay round of the General Agreement on Trade and Tariffs and was signed, as part of the Final Act, by 125 governments.⁴⁵ Provisions of the TRIPS reflect the strong US influence in the negotiation rounds and are a reflection of American patent laws, in particular Article 27 which applies to new technologies that had not previously been included such as pharmaceuticals.⁴⁶

Many experts from developing countries criticized these provisions, arguing that the impact of IPR [intellectual property rights] protection will vary significantly from country to country.⁴⁷

Trans-national companies (TNCs) pressurized developing countries, through the governments of developed countries in favour of strict intellectual property rules.⁴⁸ Subsequently pressure has been placed on members of TRIPS to accept obligations beyond those enshrined in the TRIPS. The pharmaceutical industry is dominated by a small number of large firms, a problem which has been intensified by a recent wave of mergers of pharmaceutical companies.⁴⁹

3.4.2 List of definitions

When discussing TRIPS there are a number of concepts and terms that need defining, and the following are the meanings used in this paper,

- Compulsory licensing is the grant by a government of permission to a third party to exploit a patented invention,
- Parallel importation is the importation of patented products from a third country where the products are cheaper,

⁴⁵ As above 213.

⁴⁶ Wojahn (note 40 above) 479.

⁴⁷ As above 479.

⁴⁸ Musungu (note 10 above) 215.

- Grey importation is the parallel importation of patented products from a third country where they are manufactured without the permission of the patent holder,
- TRIPS flexibilities are articles of the agreement that allow governments latitude in the enforcement of the agreement to allow for national concerns such as, but not limited to, health emergencies,
- TRIPS plus are agreements, usually in trade agreements with the United States of America, that impose obligations on states that go further than TRIPS,
- Doha Declaration was a declaration of the WTO member states on TRIPS and public health, reiterating flexibilities in TRIPS with regard to health,
- Article 6 of the Doha declaration called on member states to expeditiously find a solution for states that have no manufacturing capacity,
- The Ministerial Decision of 30 August 2003 was a decision by the Ministerial Council of the WTO that allows grey importation of medicines under very restricted circumstances.

3.4.3 Enforcement

The major effect of the TRIPS agreement was to introduce a dispute settlement forum for intellectual property that was parallel to the one enforced by the World Intellectual Property Organisation, which developed countries considered ineffective.⁵⁰ It requires states to introduce legislation to create enforcement procedures and introduces an international dispute resolution mechanism (international enforcement procedures).⁵¹

The dispute resolution system is the international enforcement system for the TRIPS agreement and allows governments to enforce the TRIPS agreement against other

⁴⁹ Joseph (note 36 above) 428.

⁵⁰ The importance of the WTO dispute resolution procedure and its place in international law is demonstrated by the comment that it was “was the most important change in the jurisprudence of the global economy in the second half of the twentieth century,” according to P Nicholls “GATT doctrine,” 2 *Virginia Journal of International Law* (1996) 380 quoted by D Shanker “The Vienna convention on the law of treaties, the dispute settlement system of the WTO and the Doha declaration on the TRIPS agreement,” *Journal of World Trade* 36(4) (2002) 721 723.

⁵¹ The WTO “A more detailed overview of the TRIPS agreement,” at <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm>, accessed on 22 August 2004.

states.⁵²The dispute resolution procedure under the WTO is potentially very serious; the Dispute Settlement Body may decide that sanctions can be levelled against a state,

If (after the completion of the complaint and negotiations between the parties), no satisfactory compensation is agreed, the complaining side may ask the Dispute Settlement Body for permission to impose limited trade sanctions (“suspend concessions or obligations”) against the other side. The Dispute Settlement Body must grant this authorization within 30 days ... unless there is a consensus against the request.⁵³

The wording of this clause, insisting on consensus for sanctions *not* to be applied, means that once the matter has been through the Dispute Resolution Body and the parties have failed to agree on compensation the complaining party will be entitled to impose sanctions. This is very serious for developing countries where sanctions may be disastrous to the national economy.⁵⁴

However the problem has more to do with the substantive aspects of the TRIPS agreement, especially regarding health. Developing and least developed countries were put under pressure to accept the TRIPS agreement and the procedure did not receive input from public health experts although the developed world’s pharmaceutical lobby was very active during the negotiation of TRIPS.⁵⁵

3.5 TRIPS Flexibilities

3.5.1 Introduction

There are a number of flexibilities in the TRIPS agreement relating to the working of patent protected products. Article 7 states that the protection and enforcement of

⁵² The WTO “Dispute settlement,” at <http://www.wto.org/english/tratop_e/dispu_e/dispu_e.htm>, accessed on 22 August 2004.

⁵³ The WTO “Understanding the WTO – A unique contribution,” at <http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm>, accessed on 22 August 2004.

⁵⁴ Musungu (note 10 above) at 215 and cited therein, Abbott, F “The TRIPS Agreement, access to medicines and the WTO Doha Ministerial Conference,” (2001) *Occasional Paper 7* Geneva: Quaker United Nations Office and Elliot, R “WTO needs reminding we all deserve health care” *Toronto Star* 11 November 2001.

⁵⁵ See Musungu (note 10 above) at 214 and quoted therein, R Howse and M Mutua “Trading in human rights: the human rights obligations of the WTO,” ICHRRD (April 2000), G Velasquez and P Boulet *Globalisation and access to drugs: Perspectives on the WTO/TRIPS agreement* (1999), accessed at <<http://www.eldis.org/static/DOC11519.htm>> on 10 September 2004.

intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, and should be to the mutual advantage of producers and users of technological knowledge. Article 7 refers to a balance of rights and obligations, allowing states to balance their obligations to patent holders with their obligations under human rights treaties. Article 8 recognizes the rights of Members to adopt measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights.⁵⁶ These guidelines and principles should underlie any interpretation of the TRIPS agreement, especially the flexibilities contained in Articles 30 and 31 of the agreement.

3.5.2 Article 30

Under article 30 member states are allowed to provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably prejudice the interests of the patent owner. While a literal interpretation of Article 30 would allow it to be applied to compulsory licensing and parallel importation, developed countries have resisted this interpretation because of the lack of controls in Article 30. Arguments can be made for either interpretation – Article 30 is similar to Article 9(2) of the Berne Convention which is relied on for parallel importation, supporting a broad interpretation of the article but the presence of a more detailed article under article 31 can be interpreted as limiting the extent of the exceptions under article 30. Much of the debate around the solution to article 6 of the Doha Declaration was based on whether to apply article 30 (which would have allowed a more flexible system) or article 31 (which is more limiting on the powers of the governments).⁵⁷

⁵⁶ The WTO “A More Detailed Overview of the TRIPS Agreement,” at http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm, accessed on 22 August 2004.

⁵⁷ See Shanker (note 50 above); T Haag “TRIPS since Doha: how far will the WTO go toward modifying the terms for compulsory licensing?” 84 *Journal of the Patent & Trademark Office Society* (2002) 945. See also A Blakett “Whither social clause? Human rights, trade theory and treaty interpretation,” 31 *Columbia Human Rights Law Review* (1999) 11, and Drahos (note 34 above) 3, who states that, “basically all developing countries were more favourably disposed to an Article 30 approach than either the US or the EU.” For a view that Article 30 is inapplicable to public health situations see the EU submissions to the WTO in the *Canada – Patent protection of pharmaceutical products (Canada – Patent Protection)*, WTO doc. WT/DS114R (6 March 2000), Report of the panel, where the EU stated that, “Article 30 of the TRIPS agreement was not a clause aimed at solving the public health problems of the entire world.” In this case the panel accepted the EU argument that object and purpose was irrelevant in interpreting the substantive articles of the TRIPS agreement. For a contrary interpretation of the TRIPS agreement see B Elangi “Potential and substantial benefits of the TRIPS agreement to the Member countries of the African Intellectual Property Organisation in the patent field,” *The Journal of world intellectual property* 4[1] (2001) 91 and especially at 95, “In fact, the TRIPS agreement

Article 30 of TRIPS has been interpreted mainly to allow early working – the *Bolar* exception to patent protection.⁵⁸ This allows a potential competitor to use a patented invention while it is still protected but only for research and registration of the generic (crucial in the case of generic medicines). This fits the criteria set out by article 30 as, "generic producers are not allowed to commercially exploit the invention before the expiration of the patent term and there is no prejudice to the legitimate interests of the patent owner."⁵⁹

3.5.3 Article 31

Article 31 of the agreement applies to compulsory licensing, parallel (including grey) importation, and government use⁶⁰ but makes these procedures subject to conditions aimed at protecting the interests of the right holder. Compulsory licensing has been accepted in international law since the Paris Convention of 1883.⁶¹ Compulsory licensing and government use, which is a variant of compulsory licensing in which the government licences itself to produce the medicines, are permissible under TRIPS, including for (but not limited to) public health emergencies.⁶²

However, Article 31 of TRIPS sets out a number of restrictions on the exercise of the state's right to issue a compulsory licence, including the restriction that goods produced under a compulsory licence should be for "predominantly" local use, the requirement to pay compensation and the need for evidence of an attempt to receive a voluntary licence at commercial terms.⁶³ While one of the requirements for a compulsory licence is reasonable compensation for the patent holder, this is subject to the rider adequate "in the circumstances of the case." Compensation under compulsory licences is often less than under voluntary licences and generic medicines made under compulsory licences are markedly cheaper than brand name medicines.

disapproves of too strict a protection of private rights. Exclusivity of the rights are granted on the one hand, but on the other hand they strive to maintain a fair competition and an open market."

⁵⁸ See Shanker (note 50 above) 737 – 738.

⁵⁹ Musungu (note 10 above) 222.

⁶⁰ Government use is specifically allowed under article 44(2) of TRIPS.

⁶¹ Musungu (note 10 above) 219. See also article 5 (A) (2) of the Paris Convention.

⁶² Musungu (note 10 above) and Article 31 of TRIPS as read with Article 5(A) (2) of the Paris Convention.

3.6 The Doha Declaration⁶⁴

The Doha declaration affirmed what TRIPS already permitted, namely the right of states to issue compulsory licences.⁶⁵

The Doha Ministerial Declaration on the TRIPS and Public Health unambiguously states that HIV/AIDS, malaria, tuberculosis and other epidemics are continuing public emergencies in developing countries allowing exceptions to patents.⁶⁶ The Doha Declaration reaffirmed the right of each state to grant compulsory licensing and determine the conditions of these licenses.⁶⁷

The Doha declaration was important because the WTO specifically said that governments could issue compulsory licences for the manufacture of generic medicines. The declaration is essentially a clarification or interpretation of the TRIPS agreement and was the basis for the declaration of a state of emergency in Zimbabwe and the undertaking to issue compulsory licences in that country. The declaration thus assured developing countries that the granting of compulsory licences would not lead to litigation before the WTO dispute settlement bodies.⁶⁸ The Doha declaration also extended the deadline for least developed countries from 1 January 2006 to 1 January 2016.⁶⁹ However, least developed countries are unlikely to have any manufacturing capacity and thus the extension to 2016 may be an empty gesture.

⁶³ Although in public emergencies some of these requirements are relaxed, for example the requirement to prove attempts to receive a licence on commercial terms is not applicable in cases of public emergencies – article 31 (b).

⁶⁴ “Declaration on the TRIPS agreement and public health, Ministerial Conference, fourth Session, Doha 9-14 November 2001,” *WT/MIN (01)/DEC/W/2* 14 November 2001 (the Doha Declaration).

⁶⁵ Drahos (note 34 above).

⁶⁶ Doha Declaration, para. 5.

⁶⁷ As above, para. 5.

⁶⁸ Before the Doha Declaration many developed states had taken the position that societal interests were irrelevant in interpreting the TRIPS agreement and this interpretation would have restricted the possible interpretative options of developing nations. Thus the EU stated that, “... the TRIPS negotiating parties had taken societal interests into consideration when agreeing on the balance of interests which were enshrined in the TRIPS agreement. Consequently individual WTO members couldn’t now rebalance these interests unilaterally by modifying the level of protection provided for in the Agreement,” in *Canada – Patent protection* (note 57 above). The importance of the Doha Declaration in emphasising the rights of individual states to interpret the flexibilities in their interest must not be ignored, and by thus redefining the TRIPS agreement the Doha Declaration gave effect to the flexibilities, which otherwise would have been ineffective. The Doha Declaration essentially confirms the opinion that, “... countries are endowed by the TRIPS agreement with the right to adopt measures necessary to protect, for instance, public health and nutrition, and to promote the public interest in sectors of vital interest to their socio-economic and technological development in order to prevent the abuse of intellectual property by right holders.” See Elangi (note 59 above) 95.

3.7 Parallel importation and the Ministerial Decision of 30 August 2003

Parallel importation is a process whereby a product is imported into a country where it is patent protected from another country on the grounds that the patent holder was paid the first time it was sold.⁷⁰ Parallel importation is a suitable solution for countries that do not have infrastructure to manufacture generics through compulsory licensing. It is theoretically permissible for these countries to grant compulsory licenses for importing drugs. However, the trap is that TRIPS does not allow parallel importation of generics (grey importation), which shuts the door for a cheap source of medicines.⁷¹

While TRIPS allows states to legislate to allow parallel importation from states where the goods are produced by the patent holder, or under a voluntary licence, the provisions of article 31 (f) of TRIPS restricts compulsory licences predominantly to local use, limiting the scope of parallel importation.⁷² This means that parallel importation of medicines manufactured under a compulsory licence would *prima facie* breach the TRIPS agreement. It was this situation that gave rise to article 6 of the Doha Declaration and the Ministerial Statement of 30 August 2003.⁷³

Article 6 of Doha called on states to create a system to allow developing and least developed states to import medicines from other states manufacturing generic drugs to allow states without manufacturing capacity to benefit from the TRIPS agreement. The Decision of 30 August purports to be an answer to this instruction and sets up a procedure for the parallel importation of generic medicines, but this system has been criticised as excessively restrictive and unworkable.⁷⁴ Rights groups criticized this accord on the basis that it gives impractical solutions to developing countries,

⁶⁹ See Drahos (note 34 above) 2 for a comment on this flexibility.

⁷⁰ Musungu (note 10 above) 220.

⁷¹ Joseph (note 36 above) 450.

⁷² Drahos (note 34 above) 2.

⁷³ As above 3; K Gopakumar "The WTO deal on cheap drugs, a critique," *Journal of world intellectual property* 7(1) (2004) 99 100 and James, J "Drug patents and developing countries: problems remain," *AIDS Treatment News* Issue 385 November 2002. The Ministerial decision is *WT/L/540*, 2 September 2003.

⁷⁴ Gopakumar (note 73 above) 99, "A careful reading of the Decision and its accompanying General Council Chairperson's Statement shows that once again the developing countries have become victims of arm twisting by the West," and at 106, "(t)hus the decision has opted for a cumbersome route, ignoring a simple solution under Article 30 of TRIPS ...," and at 112, "(t)he procedural, legal, and institutional requirements to implement the Decision make it an ineffective as well as an impractical solution for such an implementation."

furthering the advantages of pharmaceutical companies.⁷⁵ The decision waives the obligations of members of the WTO under sub articles 31(f) and 31(h) (the conditions that the products be predominantly for the local market and the requirement to pay compensation respectively) but subject to certain conditions. These conditions are onerous and include a strict notification procedure and the issuance of compulsory licences by both the exporting and importing countries.⁷⁶

3.8 Effect of compulsory licensing on availability of medicines

The power to grant a compulsory licence does not necessarily entail the granting of licences and sometimes the mere threat can be enough to bring down prices. An example of the use of the threat of the use of compulsory licences in price negotiations was the anthrax scare in the USA and Canada. The United States of America and Canada exerted pressure on Bayer to sell them its patented anti-anthrax drug 'Cipro' at a discounted price in 2001 or they would – in response – allow the production of generics. The anthrax scare in North America led the US and Canada to violate the intellectual property rules they always advocated and pressurized developing countries – facing real public health threats – to accept.⁷⁷

The amounts spent on R&D by pharmaceutical companies, the main reason given by pharmaceutical companies to push for stricter patents, are disproportionately small compared to amounts spent on other sectors, especially marketing.⁷⁸ Much of R&D in the field is done in public laboratories by governmental funding.⁷⁹ Some big pharmaceutical companies spend most of its R&D budget on 'safe' research of formulas already known to be profitable and lucrative rather than life-threatening cases (e.g. obesity rather than heart diseases).⁸⁰ This means that these companies can cut down their profits, reducing patented-drugs prices, without cutting R&D expenditure.⁸¹ Thus, although an argument is made that compulsory licensing and the use of grey

⁷⁵ Al-Hayat newspaper, "Munazamat al Tijara Tubih lil duwal al faqira astirad adwiya badila qalilat al kulfa," [WTO allows poor countries to import cheap medicines] (2004), available at <<http://www.newsstand.com>>.

⁷⁶ Gopakumar (note 73 above) 105.

⁷⁷ Joseph (note 36 above) 445.

⁷⁸ As above 432.

⁷⁹ As above 433.

⁸⁰ As above 435.

⁸¹ As above.

importation will restrict future access to medicines the evidence is more that market led development of drugs does not benefit the developing world.

3.9 TRIPS plus

Developing countries are under pressure to accept conditions that go beyond TRIPS obligations or the so-called 'TRIPS plus'.

TRIPS plus is a non-technical term which refers to efforts to extend patent life beyond the twenty-year TRIPS minimum, to tighten patent protection, to limit compulsory licensing in ways not required by TRIPS, or to limit exceptions which facilitate prompt introduction of generics.⁸²

Another major concern is raised by the technical assistance provided by the World Intellectual Property Organization and industrialised countries to the developing world which disregards the health needs of the latter's populations.⁸³

3.10 Conclusion

There are a number of flexibilities inherent in the TRIPS agreement that make the agreement appropriate for the protection of the human right to health. These flexibilities include

- The power for states to issue compulsory licences for essential medicines,
- The power for states to import generic medicines through the WTO system.

However these flexibilities need to be used, both in the law and practice. It does not meet the obligations of a state under ICESCR to include provisions in a country's Patents Act allowing compulsory licensing but actually failing to issue compulsory licences and to import generics. The obligation under the ICESCR is to provide access to essential medicines and the flexibilities under TRIPS are merely one of the methods a state may use, especially after 1 January 2005, when TRIPS comes into effect for countries like South Africa and Zimbabwe, to protect this right.

⁸² Hoen (note 41 above) 29.

Chapter 4: An assessment of South Africa and Zimbabwe's use of TRIPS flexibilities

4.1 Constitutional Provisions

The Constitution of Zimbabwe was drafted before lawyers and politicians considered including economic, social and cultural rights in constitutions. There is thus no protection of the right to health. The right to life, interpreted in other countries such as Ecuador⁸⁴ to include rights to health care was drafted restrictively to guarantee only a prohibition against arbitrary deprivation of life. The Zimbabwean Constitution is therefore of no use in an attempt to identify the obligations of the Zimbabwean government regarding the right to health, and any analysis of the obligations of the government must be based on its international obligations under the Covenant on Economic, Social and Cultural Rights and the African Charter on Human and Peoples' Rights.

The South African Constitution, on the other hand, has been much celebrated for its protection of socio-economic rights, including the right of access to health care. This right is set out in section 27 of the constitution as follows,

- (1) Everyone has the right to have access to -
 - (a) health care services, including reproductive health care;
 -
- (2) The State must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.

The right protected by the South African Constitution is the right to access to health care services and not a right to health in the manner it is protected in the International Covenant on Economic, Social and Cultural Rights and the African Charter on Human and Peoples' Rights. However, regarding access to essential HIV/AIDS medicines this difference is immaterial since access to essential medicines must be interpreted as an essential part of access to health care services. The second is that subsection 2 delimits the extent of the obligations of the state and the rights of the individual. Applying this understanding of the section the South African Constitutional Court has held that an individual may not claim that the state has breached a minimum core

⁸³ As above 30.

⁸⁴ See the *Edgar Carpio Castro Jofre Mendoza* case (note 6 above) where it was held that the right to health forms an integral part of the right to life.

obligation towards him by failing to provide the essentials of the enjoyment of an economic, social or cultural right, preferring to set out a “reasonable policy” test.⁸⁵ Thus it cannot be argued that under the South African Constitution the state has an obligation to provide an individual with specific medicines (for example anti-retrovirals) but it can be argued that the government must have a reasonable policy, taking into consideration available resources, to adequately deal with the HIV/AIDS crisis.

The constitutionally enshrined direction to use available resources should mean that the state should take all opportunities to make possible the provision of essential medicines, such as anti-retrovirals, for its citizens. Since compulsory licensing and grey importation of generic HIV/AIDS drugs is permitted under international trade law and South African patent legislation (see below) the provision of cheap anti-retroviral drugs on the market and free to the most vulnerable in society should be interpreted as an obligation arising from section 26 (2) of the South African Constitution.

4.2 Domestic Law in South Africa and Zimbabwe

Both Zimbabwe and South Africa have traditionally protected pharmaceutical patents in TRIPS compliant legislation, the countries have protected both process and product patents and have issued patents for periods of twenty years.

4.2.1 The Zimbabwean legislation

Sections 31 to 35 of the Zimbabwean Patents Act govern compulsory licensing and government use of patents. Section 31 deals with the situation where a compulsory licence is sought for on the grounds that patent holder has not manufactured the products protected by the patents in Zimbabwe after the expiration of three years from the grant of the patent, and the applicant had previously unsuccessfully applied for a voluntary licence. The issuing authority (the Patents Tribunal, a governmental department set up in terms of the Patents Act) will consider whether a royalty should be paid but it will give more emphasis to ensuring that the patent is utilised in Zimbabwe. In certain circumstances, for example where it would be uneconomical to the manufacturer, payment of royalties will be waived. While this section may be utilised to issue compulsory licences for pharmaceutical products to meet public

⁸⁵ See the *TAC* case (note 7 above).

requirements during public emergencies it is designed more for the purposes of technology transfer and import substitution. Thus use of this section for public emergencies would open the country to challenges through the WTO for practices negatively affecting free trade.

Section 32 allows the grant of compulsory licences for products used as foods or medicines, and the granting authority is directed to balance between the interests of ensuring that the prices of food and medicine are kept down and ensuring that the patentee receives a reasonable payment. Section 34 and 35, read together, regulate government use of any invention, and allow the government to use an invention for any purpose. Whereas section 34 deals predominantly with a situation where the government makes the drugs or procures the drugs from a third party who is specifically allowed to produce the product for state use, section 35 allows a third party, properly licensed by the Minister, to produce drugs for sale in a national emergency. Thus during a national emergency the Minister may issue a licence to a third party to manufacture and sell the product (the declaration of a national emergency being necessary to allow the third party to sell the product). The Patents Tribunal may also issue a compulsory licence allowing the importation of generic drugs under sections 31 and 32 of the Act.

Thus the government may choose to manufacture drugs itself, issue licences under sections 31 or 32 (the second being specifically designed to deal with the prices of medicines) or declare a national emergency and utilise section 35 to authorise a third party to manufacture and sell the product. The government chose the third option and on 27 May 2002 the Zimbabwean government declared a state of emergency on HIV/AIDS in accordance with the Zimbabwean Patents Act and this status has been renewed regularly since then. This legislation has been utilised by the government to allow the manufacture of generic drugs under compulsory licenses.

4.2.2 The South African legislation

In South Africa the Patents Act subsections 56 (2) (a), (c) and (e) allow compulsory licenses where the patented product is not manufactured in South Africa and the South African market is being serviced by expensive imports. The Patents Act allows the government to issue compulsory licences when the use of patents is abused.

Abuse of patents includes failure to manufacture in South Africa, which includes non-working, prevention of local manufacture because of importation, failure to meet demand on reasonable terms, refusal to grant licences where this causes stagnation of the industry in South Africa, and where the market is being met by imported goods whose prices are excessive.⁸⁶ It would therefore be legal for the South African government to issue compulsory licences for expensive drugs where they are being imported into South Africa and sold at an excessive price, even though these products are marketed at a cheaper price in a different country. Section 4 of the Act allows government use but includes a lengthy application procedure, which may be too onerous to be effective, whereas section 56 (4) (a) implicitly allows the holder of a compulsory licence to import the patented goods by stipulating that the commissioner *may* impose restrictions including the restriction that the licensee be disallowed from importing.⁸⁷

After a much disputed amendment to the Medicines and Related Substances Control Act (the Medicines Act)⁸⁸ the new Section 15C apparently facilitates the parallel importation of patent protected (not generic) medicines, which would be cheaper as the drugs can be imported from countries such as India where the prices are lower because of competition with generic drugs.⁸⁹ Thus it has been argued that the amended Act does not introduce grey importation into South African law. For any person to legally import generic versions of patent protected pharmaceutical products that person would need to be granted a compulsory licence under the Patents Act.⁹⁰

⁸⁶ See also Dr Gerntholz Patent Attorneys, "Basic guide to Patents," accessed at <<http://www.gpa.co.za/english/basic/patents.htm>> on 14 October 2004.

⁸⁷ To import generic drugs that are still patent protected in South Africa a company needs a compulsory licence - see the Treatment Action Campaign Statement, "An Explanation of the Medicines Act and the Implications of the Court Victory," at <<http://www.tac.org.za>> accessed on 13 September 2004.

⁸⁸ In one of the most celebrated international cases on intellectual property and HIV/AIDS the pharmaceutical sector stopped the South African government from gazetting the Act for four years before finally withdrawing their case just before the matter came up for trial. See "South African court case ends in climb down by drug corporations" at the World Socialist Website, accessed at <<http://www.wsws.org/articles/2001/apr2001/aids-a21.shtml>> on 8 October 2004, and Love (note 88 above). See below, in Chapter Five, for an analysis of the effect of this litigation on parallel importation and compulsory licensing in South Africa.

⁸⁹ See the TAC case (note 7 above) and A Hooper "Prices of pharmaceuticals to the South African public – will they drop?" on the website of Spoor and Fisher, < <http://www.spoor.com/default.htm> >, accessed on 13 September 2004. The discussion about parallel importation in this Act revolves around the divergent principles of national and national exhaustion. Applying the first principle a country may import a drug from a market where it was introduced by or on behalf of the patent owner; applying the second a patent is only exhausted when it is sold in the domestic market. The TRIPS agreement leaves the determination of which principle to apply to domestic legislation. Love (note 88 above) argues that international exhaustion was already accepted in South African case law before the amendment of the Act.

⁹⁰ TAC case (note 7 above).

Different interpretations of the Act existed during the litigation, with the pharmaceutical companies arguing that the Act could be interpreted broadly to allow grey importation of generic versions of patented medicines and the section was thus contrary to the TRIPS agreement. The South African government argued that the section was not aimed at the granting of compulsory licences for either grey importation or domestic manufacture of generic medicines but rather to implement the principle of international exhaustion of patent rights. Under this principle South Africa can legally import drugs manufactured in a third country even though the products are under patent in South Africa as long as the products were originally sold for or by the patent owner.⁹¹ This interpretation of the Act has been confirmed by Love J, who states that

... the South Africa government was trying to expand use of off-patent generic drugs, and also to permit the import of patented medicines, in cases where the patent owner was selling the medicine cheaper in another country. South Africa was then facing higher prices for several medicines than were found in neighbouring countries, or in several cases, than in the US and European markets. At this time, the South Africa government was not pursuing a strategy of issuing compulsory licenses on patents, and saw the act as a rather modest effort to introduce US style cost savings from wider use of off-patent generic drugs, and European style use of "parallel imports" of cheaper foreign branded products. This is very important, but almost entirely misunderstood -- contrary to popular misconception, parallel imports does not involve buying from generic suppliers, but rather just shopping around for the best price a company charges internationally ... Put another way, if South Africa permits parallel imports, it will be able to import an Indian version of Glaxo's AZT, but not CIPLA's generic version of the same drug.⁹²

However, patent experts in South Africa are of the opinion that the Act amended the law to allow grey importation of generic drugs by allowing medical registration of generic drugs identical to brand name drugs already registered so that any person could import such drugs.⁹³ It could be argued that section 15C (1) would be to allow the Minister to suspend all proprietary rights to patents over pharmaceutical products already marketed in South Africa by the holder of the patents. However, the attitude of the South African government throughout the litigation indicates that the Act was never

⁹¹ Love (note 88 above), who noted at the time that, "since 1998, the government has taken the position, in the litigation, that 15c will never be used for compulsory licensing, but only for parallel imports. Effectively, the South African government has been arguing in court that 15C cannot be used for compulsory licensing, and the PMA has been arguing it can. To "win" the lawsuit, the government's legal team has been abandoning any hope of using 15C for compulsory licensing."

⁹² Love (note 88 above).

intended to be used to allow grey importation or local manufacture of generic medicines. The regulations issued under the amended Act confirm that the government does not intend to allow grey importation, limiting the power to grant a permit to import drugs to a person buying the drugs from a foreign country where the drugs are sold with the permission of the patent owner.⁹⁴

4.2.3 Summary

Zimbabwe and South Africa have established duties under international law to protect the right to health and this includes the duty to provide essential medicines. Since both countries are facing HIV/AIDS crises on a huge scale the governments have a duty to ensure that HIV/AIDS medication is made available and accessible to the population. The TRIPS flexibilities allow both countries to engage in either local manufacture under compulsory licence or grey importation of generic drugs. Both Zimbabwe and South Africa have the domestic legislation necessary to implement the flexibilities in the TRIPS agreement. South Africa's Patent Act allows the grant of compulsory licences under certain circumstances as does the Patents Act in Zimbabwe although the Zimbabwean legislation is apparently simpler and easier to implement. Further, the South African Medicines Act appears to allow the Minister of Health to suspend patent rights and thus to allow compulsory licensing and grey importation without following the strict procedure in the Patents Act. The Zimbabwean government has taken the necessary steps to implement the Patents Act by declaring a state of emergency whereas the South African government has not implemented section 15 C (1) to suspend patent rights over drugs.

4.3 The cost effectiveness of generic antiretrovirals in Zimbabwe under the compulsory licensing regime

Field research in Harare, Zimbabwe in July 2004 showed that the market was mainly served by generic anti-retrovirals produced by a Zimbabwean company called

⁹³ A Hooper "The Medicines and Related Substance Control Amendment Bill (B30-97) and its Effect on Intellectual Property Rights," *Spoor and Fisher*, accessed at < <http://www.spoor.com/default.htm>> on 11 October 2004.

⁹⁴ Section 7 of General regulations made in terms of the Medicines and Related Substances Act, 1965 (Act No. 101 of 1965), (as amended) of May 2003.

Varichem (Pvt) Ltd.⁹⁵ Some of the drug names such as Stanalav, which is a three drug combination, appear to be used only in Zimbabwe and cannot be cost compared to other countries while others such as Combivir are easily compared. While prices fluctuated between pharmacies all prices of locally manufactured anti-retroviral drugs were below USD 28⁹⁶ a month. Examples of the prices are as follows: Stanalav was 23 US\$ or 24 US\$, depending on the pharmacy, whereas Nevirapine fluctuated between 3 US\$ and 6 US\$. Combivir (Zidovudine / lamuvidine) was sold for 13 US\$ or 18 US\$ per month. Zerit was on sale for between 12 US\$ and 23 US\$.

Imported drugs were rare on the market, with pharmacies saying that the market had converted to local generics and the high prices of imported brand names made them unpopular. Imported 3TC was available from one pharmacy at 143 US\$ per month and imported Nevilast was available at another pharmacy for 49 US\$ per month. Locally produced antiretroviral drugs, such as Combivir and Zerit, have the same clinical use as the above imported brand name medicines. Imported brand name 3TC was up to eleven times more expensive than locally produced Combivir and 12 times more expensive than locally produced Zerit. While this comparison does not purport to compare effectiveness or other medical issues the vast difference in prices shows the effectiveness of local manufacture of generic medicines in reducing the price of first line anti-retroviral drugs.

4.4 Cost of antiretroviral drugs in South Africa

International prices of antiretroviral drugs have declined as a result of competition from generic medicines produced in India and Brazil. Thus in South Africa the private sector is served by brand name antiretrovirals at a price of approximately USD 84 per month for triple therapy.

As a result of competition, the prices offered by companies for triple therapy in South Africa have fallen from the initial patented price of approximately US\$10,000 per patient per year to approximately US\$1000. Yet the offers from the pharmaceutical giants do not nearly match the recent offers from generic companies in India. Aurobindo, an Indian generic company, recently offered triple-therapy regimen for US\$295 per person per year.⁹⁷

⁹⁵ Interviews were held with pharmacists, medical wholesalers, the patent office, Varichem (Pvt) Ltd (the generic manufacturer) and the Ministry of Health.

⁹⁶ The US\$ values are based on an exchange rate of 7 000 Zimbabwean dollars to 1 US\$, valid at 31 July 2004.

⁹⁷ Oxfam GB "South Africa vs. the drug giants," accessed at <http://www.oxfam.org.uk/what_we_do/issues/health/drugcomp_sa.htm> on 14 October 2004.

Meanwhile, in the public sector, voluntary licences have made cheaper antiretroviral drugs available to the government and to NGOs working on HIV/AIDS. For example the South African manufacturer Aspen Pharmacare is providing the government with generic medicines at the cost of “about US \$1 a day for a first-line regimen.”⁹⁸ Commentators have claimed that such voluntary licence agreements limit the scope of the licence to supplying drugs only to the South African public health sector,

Aspen Pharmacare has been given the patents to generically produce and supply anti-retroviral drugs to the government health service and to non-profit making anti-Aids charities. Under the agreement, the South African company is not allowed to profit from the sale of the drugs, AZT, 3TC and Combivir, or export them to any other African country Industry sources estimate Aspen's generic Combivir would cost about \$1.80 per patient per day, with AZT priced at \$1.60 and 3TC at just over 60 US cents, which is still above the cost of generics being offered by Indian drug makers at \$1 per day.⁹⁹

Therefore while the drugs supplied to the South African government are cheaper than drugs supplied on the open market they are still more expensive than generic drugs from India or Brazil. Patients that rely on the private sector in South Africa and patients in neighbouring countries do not benefit at all. If antiretrovirals remain expensive in the private sector and are free in the public sector demand to use the public sector drugs will increase, burdening the state. Another effect of the disparity between private and public sector prices for anti-retrovirals will be that people on medical aid schemes will not benefit as they will continue to obtain their antiretroviral supplies through the private sector.

4.5 Comparison of Prices between South Africa and Zimbabwe

A direct comparison of prices in South Africa as quoted by the BBC and the cost of generics on the open market in Zimbabwe show that Combivir in Zimbabwe is between 43 and 60 US cents per day, whereas it was provided to the South African government and South African NGOs at 1, 80 US\$ per day. Zerit prices in Zimbabwe

⁹⁸ IRIN 'Cost-effectiveness of Antiretroviral Treatment for HIV-Positive Adults in a South African Township' quoted in “South Africa: Antiretroviral therapy is cost-effective, says report,” accessed at <<http://irinnews.org>> on 8 October 2004.

⁹⁹ BBC News “African firm wins Aids drug permit,” on Monday, 8 October, 2001, accessed at <<http://news.bbc.co.uk/1/hi/business/default.stm>>. The situation appears to be that while a full licence was granted for Zerit, all other drugs were restricted to the public health sector. The BBC noted that before the agreement the multinational concerned, GSK, was already providing combivir to the South African public health sector for 2 US\$ a month.

were between 40 and 77 US cents per day whereas in South Africa the price under the voluntary licence was estimated to be in the region of 1 US \$ per day.¹⁰⁰ This comparison has shown that drugs manufactured under compulsory licensing in Zimbabwe are marginally cheaper than drugs manufactured under voluntary licences in South Africa (although a difference of between 20 US cents and 1 US \$ may be of importance when considering economics of scale). However, the price analysis does not take into consideration that the Zimbabwean prices are retail prices¹⁰¹ while the prices quoted by the BBC for the Aspen produced generics will be wholesale prices for drugs delivered to the government or to NGOs, implying that there would be a further mark up if these drugs were supplied on the open market. Prices in the private sector in South Africa for triple therapy was approximately USD 84 per month whereas in Zimbabwe Stanalav, a locally produced triple therapy drug, was sold for 22 US\$ per month, around four times cheaper than triple therapy available to the private sector in South Africa.

4.6 Parallel and Grey importation of antiretrovirals compared with local manufacture

Parallel and grey importation of drugs has become an increasingly popular answer to high drug prices, and the present contest in the United States between drug companies and people importing cheaper drugs from Canada is an example of the advantages to consumers of the parallel importation of drugs sold at cheaper prices in other countries,

For example, if the US actually gets around to permitting parallel imports of medicines, US consumers could buy branded and patented medicines from the Canadian and Europe markets, where prices are often lower. Parallel imports are basically about free trade versus a company having the right to engage in price discrimination, by country.¹⁰²

¹⁰⁰ W Chege "South Africa Firm Offers Zerit (stavudine) as Continent's First Locally Made Generic Drug," 8 September 2003, at *HIV and AIDS top stories* accessed at <http://www.hivandhepatitis.com/hiv_aids.html> on 8 October 2004. The Zerit license was the only one that allowed the sale of the generic to the private market; although Aspen received voluntary licences for Combivir, zidovudine, lamuvodine, didanusine and Nevirapine but these licences restricted the company to selling to the government, see HIV Newsroom, "South African Generic Drug Maker to Produce Country's First Generic Antiretroviral Drug," *The Body: an AIDS and HIV information resource* accessed at < <http://www.thebody.com/index.shtml>>.

¹⁰¹ Pharmaceutical wholesalers refused to disclose their prices, claiming confidentiality.

¹⁰² Love (note 88 above).

Grey importation, available to developing countries such as Zimbabwe and South Africa under the WTO Ministerial Decision of 30 August 2003, would allow either country to import generic drugs from companies in Brazil or India, which produce the drugs without authority from the patent holders and therefore at a vastly lower price. Neither Zimbabwe nor South Africa has taken advantage of this Decision to register a system of compulsory licences with the WTO and to import generic drugs from countries such as India, although the procedures are complicated as explained in section 3.7 above. However Médecins sans Frontières (MSF) have been treating patients in South Africa on generic antiretrovirals purchased abroad from countries such as Brazil and India under a 2001 agreement with the Brazilian Ministry of Health after receiving drug approval from the South African Medicines Control Council. This situation is in violation of the WTO Ministerial Decision as there has been no registration of the agreement and no compulsory licence issued for the export from Brazil and the import into South Africa.¹⁰³

MSF has stated that the drugs it purchases from Brazil are half the price of discounted drugs offered in South Africa from the brand name producers. MSF has given a comparison of the different costs it had to pay for grey imported and discounted brand name drugs offered in South Africa as set out in table 1, based on discounted prices offered to the South African government by GlaxoSmithKline and Boehringer Ingelheim compared to prices offered by the Brazilian company, FarManguinhos.¹⁰⁴

Table 1: Cost of Brazilian generic drugs

Name of drug	Brand Name price in south Africa	Generic Price from Brazilian company
AZT/3TC	USD 2 per day	USD 0, 96 per day
Nevirapine	USD 1, 19 per day	USD 0, 59 per day
AZT	USD 1, 60 per day	USD 0, 09 per day
3TC	USD 0, 64 per day	USD 0, 41 per day

¹⁰³ No country since 30 August 2003 has taken advantage of the WTO Ministerial Decision and registered a system to import generic drugs.

¹⁰⁴ MSF "Brazilian generic ARV drugs in South Africa - the background, A historical account of the use of Brazilian drugs in MSF's antiretroviral programme in South Africa," 29 January, 2002, accessed at <<http://www.accessmed-msf.org>> on 9 October 2004.

Generic drugs manufactured in India are also markedly cheaper than other drugs available to South Africa or Zimbabwe as seen by the table below showing the prices of antiretroviral drugs in India as compared to Africa and the developed world.¹⁰⁵

Table 2: Indian antiretroviral prices				
Drug (Company)	US Price	Cipla	Hetero	Latest Company Offer in Africa
Zerit (Bristol-Myers)	3,589	70	47	252
3TC (Glaxo)	3,271	190	98	232
Crixivan (Merck)	6,016	N.A.	2,300	600
Combivir* (Glaxo)	7,093	635	293	730
Stocrin (Merck)	4,730	N.A.	1,179	500
Viramune (Boehringer)	3,508	340	202	483

Note: Prices are for AIDS drugs per patient per year in the US and Africa offered by drug multinationals and two Indian generic drug companies. Prices are in USD.

These figures indicate that grey importation of antiretroviral drugs would be the cheapest procedure for the procurement of antiretrovirals. However, neither the Zimbabwean nor South African government have indicated any intention of relying on grey importation of antiretroviral drugs relying respectively on compulsory and voluntary licences to bring prices down.

4.7 The effect of the two countries' strategies

Antiretroviral medicines manufactured in Zimbabwe under compulsory licences are cheaper than antiretroviral medicines available in the private sector in South Africa. The medicines produced in South Africa under voluntary licence and offered to the

¹⁰⁵ This table is taken from K Singh "Patents vs. patients: AIDS, TNCs and drug price wars," accessed at *Third World Network*, < <http://www.twinside.org.sg/index.htm> > on 11 October 2004.

public sector health sector are more expensive than the same drugs provided on the open market in Zimbabwe (and thus available both to the government and NGOs in Zimbabwe at the lower price). Judging the two countries purely on the pricing of drugs Zimbabwe has been more successful in its obligation to provide affordable drugs.

However, generic drugs produced in countries with a more developed generic manufacturing capacity, such as Brazil or India, are markedly cheaper even than drugs produced under compulsory licence in Zimbabwe and the failure by Zimbabwe to rely on grey importation under the WTO Ministerial Decision means that the prices charged by Varichem (Pvt) Ltd are essentially monopoly prices. Prices in Zimbabwe would be reduced by the issuing of compulsory licences under the WTO Ministerial Decision to import drugs from India and Brazil.

Chapter 5: Other factors affecting supply of antiretroviral drugs

Both South Africa and Zimbabwe have undertaken to provide anti-retrovirals in public hospitals. Neither country has fully realised this aim. Zimbabwe has only provided free antiretroviral drugs in the two main referral hospitals in Harare and Bulawayo as pilot projects to test the mechanisms of administering the drugs. In South Africa the government announced a nationwide rollout of anti-retroviral drugs shortly before the presidential elections in early 2004¹⁰⁶ but by June 2004 only three provinces were actually administering antiretroviral drugs to patients, while the other provinces were still registering patients. It was apparent from the statement by the Minister of Health that drug costs was an issue in the delayed “roll out” of antiretrovirals as she stated that the tender procedure for the supply of antiretroviral drugs would be extensive.¹⁰⁷ The same report indicated the South African government would continue to rely on voluntary licenses; the Minister of Health was reported as saying that more generic drugs had been registered by the Medicines Control Council after voluntary licenses had been obtained. Neither country is supplying enough drugs to its people although for different reasons.

5.1 Lack of resources and donor distrust in Zimbabwe

Zimbabwe’s health system has suffered much of the pressure of the economic collapse in the country and is receiving minimal support from international donors. Recently the Global Fund to fight AIDS, Malaria and Tuberculosis refused Zimbabwe’s application for funds to pay for the roll out of antiretrovirals to around seventy thousand people, citing technical reasons. However, it has been suggested that concerns for the government’s autocratic abuses was a factor in the decision by the fund. Further, bilateral donors, such as Britain and the USA, have been giving much less towards the HIV/AIDS crisis in Zimbabwe than in all neighbouring countries.¹⁰⁸ It

¹⁰⁶ Although earlier decisions to “roll out” antiretroviral drugs had been made by the government (see *The Economist* of 25 April 2002, “The government finally gets serious about treating people infected with HIV,” accessed at <<http://www.economist.com/science/displayStory.cfm?>> on 9 October 2004.

¹⁰⁷ V Mohapeloa “Aids drug rollout continues: Govt” accessed on 9 October 2004 from <http://www.southafrica.info/ess_info/sa_glance/health/aidsdrugs>.

¹⁰⁸ S LaFraniere “Donor mistrust worsens AIDS in Zimbabwe,” *New York Times* of 12 August 2004, reproduced in *The Zimbabwe Situation* <http://www.zimbabwesituation.com/aug13_2004.html> accessed on 11 October 2004.

is estimated that less than 1000 people are receiving antiretroviral drugs in the public (state and NGO-assisted) sector in Zimbabwe.¹⁰⁹

5.2 Lack of political will in South Africa

In South Africa delay has mainly been caused by government's disinclination to provide antiretrovirals, caused apparently by the South African President's stated disbelief in the link between HIV and AIDS.¹¹⁰ NGOs had to take the government to the Constitutional Court to obtain an order that the government provide antiretroviral drugs to prevent mother to child transmission of the disease.¹¹¹ The provision of antiretrovirals depended on political will and early in 2004 a decision was made that antiretroviral drugs should be provided across the country. By June 2004 three provinces had begun to provide antiretroviral drugs and it was estimated that in these three provinces 3 593 people were receiving antiretroviral treatment although some who were under non-government schemes are not included in this number.¹¹²

5.3 Multi-national pharmaceutical companies and the price of medicines

South Africa was put under intense international and domestic pressure between 1997 and 2001 to withdraw its amendments to the Medicines Act, which had been passed by Parliament in 1997 and arguably allowed the government greater powers to issue compulsory licences and to allow the grey importation of generic medicines. The effects of the amendment have been discussed above. The international pressure came mainly from the United States of America,

The US Government has a recent history of applying pressure to South Africa and other countries to apply stronger patent protection (so-called 'TRIPS-plus' protection) than the TRIPS minimum standards, and the clear basis for this pressure is implicit linkage to other trade provisions and measures that give developing world countries incentive to be viewed as 'model WTO citizens' in general.¹¹³

The United States of America placed South Africa on its section 301 watch list, a list of countries threatened with trade sanctions unless they correct certain trade practices,

¹⁰⁹ LaFraniere (Note 108 above).

¹¹⁰ MSF (note 104 above).

¹¹¹ The *TAC* case (note 7 above).

¹¹² Mohapeloa (note 107 above).

and suspended benefits under the Generalised System of Preferences to South Africa, for its passing of the amendment.¹¹⁴

Meanwhile multinational drug manufacturers sued the South African government in the South African Courts, claiming that the Medicines Act violated intellectual property laws and the South African constitution, which suit delayed the promulgation of the Act for four years. In April 2001 the case was settled with the drug companies announcing that they were withdrawing the case against the South African government without condition. In the agreement issued between the parties the South African government reiterated its right to legislate to “broaden access to medicines” under the Medicines Act. At the same time the Treatment Action Campaign, a South African NGO that had been joined to the case as an *amicus curiae*, was assured that there had been no waiver by the South African government of its right to issue compulsory licences for the manufacture and import of generic drugs.¹¹⁵

Although regulations have been issued in accordance with section 15 C of the amended Medicines Act, they have concentrated on the pricing of drugs, rather than compulsory licences or grey importation.¹¹⁶ The pricing procedure affects local pharmacies and doctors but not multinational drug companies.¹¹⁷ At the time caution was urged about welcoming the apparent success of the court case,

¹¹³ S Cleary and D Ross “The 1998-2001 legal interaction between the South African government and the international pharmaceutical industry: a game-theoretic analysis” accessed at <<http://www.uab.edu/philosophy/faculty/ross/AIDS%20paper.htm>>.

¹¹⁴ Singh (note 105 above). In 2000, after intense NGO pressure, the Clinton government rescinded these actions and indicated it would not pressure sub-Saharan governments over compulsory licensing and parallel importation of HIV/AIDS drugs, although the Bush administration subsequently considered rescinding the Clinton decision, see J Love “Bush considers reversing Africa Executive Order” accessed at <<http://lists.essential.org/pipermail/pharm-policy/2001-January/000606.html>> on 11 October 2004.

¹¹⁵ Treatment Action Campaign statement, “Victory for activists, people With HIV/AIDS and poor people everywhere! Pharmaceutical companies beaten!” issued on 19 April 2001, accessed from <http://www.globaltreatmentaccess.org/content/press_releases/index.htm> on 11 October 2004.

¹¹⁶ Section 7 of the regulations restricts import of drugs to drugs that were made available to a foreign market with the approval of the patent holder, excluding grey importation from the procedure under the Act.

¹¹⁷ The government has concentrated on the pricing of medicines, appointing a Medicines Pricing Committee to implement the legislation, which limits the mark up allowed by pharmacies on medicines, see the South African government, “Paving way for cheaper medicines,” accessed at <http://www.southafrica.info/ess_info/sa_glance/health/medicinespricing_190803.htm> on 8 October 2004. See also C Freeman “Medicine prices to be slashed” at <http://www.southafrica.info/ess_info/sa_glance/health> on 11 October 2004; Hooper, A, “Update - pricing of pharmaceuticals to the South African public,” accessed at Spoor and Fisher, <<http://www.spoor.com/default.htm>> on 25 September 2004. See also Agence France-Presse, January 15, 2004, “South Africa to regulate medicine prices with cuts of up to 70 percent,” accessed at <<http://www.afp.com/>> on 15 September 2004. Commentators have noted that the projected negative

South Africa's Foreign Minister Nkosazana Dlamini-Zuma was in the United States meeting Secretary of State Colin Powell and national security adviser Condoleezza Rice as the drug companies dropped their case. In an interview with the *Washington Post*, Rice said, "We have assured them [the pharmaceutical companies] that we don't want to undermine patent rights." She said that the South African government was "willing to work with [the industry] in drawing up the regulations" that would implement the 1997 Medicine Act.¹¹⁸

The impression is given that the South African government was more prepared to tackle doctors and pharmacists in South Africa than to fight the multinational companies by relying on compulsory licensing and grey importation of generic drugs. The official government position has been that there are a number of other issues that lead to high drug prices in South Africa and compulsory licensing and grey importation are not the answer to all these problems.¹¹⁹ However, the analysis of the prices of drugs available from India and Brazil indicate that the prices of drugs could be slashed by about half if the government is prepared to utilise grey importation of drugs.

Despite withdrawing the court action against the South African government pharmaceutical companies continued to charge excessive prices for medicines. The Treatment Action Campaign brought a complaint against GlaxoSmithKline and Boehringer Ingelheim to the South African Competition Commission for charging excessive prices for pharmaceutical products. In September 2003 the South African Competition Commission held that the two companies' excessive prices were abusive business practices and recommended waiver of the companies' rights to their patents.¹²⁰ The commission was quoted as follows,

Our investigation revealed that each of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty ... We will request the Tribunal to make an

effect of the regulations on pharmacists and doctors will be very serious, see Hooper-Box, C, "A long-term cure for medicine prices," *The Sunday Independent*, 14 May 2004, accessed at <<http://news.hst.org.za/archives.php3>> on 12 September 2004, "Nationally, pharmacists stand to lose revenue of R580-million once the new medicine pricing regulations are in place, and doctors will lose R503-million, according to new research by Discovery Health."

¹¹⁸ "South African court case ends in climb down by drug corporations" at the World Socialist Website, accessed at <<http://www.wsws.org/articles/2001/apr2001/aids-a21.shtml>> on 8 October 2004.

¹¹⁹ Dr Manto Tshabalala-Msimang, South African Minister of Health, statement issued on 11 March 2001 "... compulsory licensing is only one way of addressing the issue of affordable medicines and it is useful only in specific circumstances. If we want to make a meaningful impact on the overall cost of medicines in this country, in the public and private sectors, for AIDS drugs and many other essential medicines, we need a comprehensive approach. There are many inequities and non-rational practices in the marketing of pharmaceuticals and they demand different remedies."

¹²⁰ MSF "MSF Welcomes Decision of South African Competition Commission to Promote Access to Medicines," press statement issued on 16 October, 2003, accessed at <<http://www.accessmed-msf.org>>.

order authorising any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that require these patents, in return for the payment of a reasonable royalty. In addition, we will recommend a penalty of 10% of the annual turnover of the respondents' (antiretroviral drugs) in South Africa for each year that they are found to have violated the Act.¹²¹

This decision confirmed that multinational corporations had continued to resist voluntary licensing of patents and had continued to charge excessive prices for patent protected medicines in South Africa. Considering that the case was brought by an NGO and that despite the decision the government has still not issued compulsory licences the case reinforces the impression that the South African government is not prepared to confront pharmaceutical companies.

¹²¹ Health Gap "South African Competition Commission announces stunning victory for access to cheaper drugs, holds GlaxoSmithKline and Boehringer Ingelheim responsible for excessive pricing and other anti-competitive practices," accessed <<http://www.healthgap.org>> on 12 September 2004. Health Gap noted that the case was important for a number of reasons, primarily because it was based on competition law and therefore absolved the South African government from the "red-tape" inherent in the TRIPS flexibilities and especially the Ministerial Decision of 30 August 2003. The decision was also important Health Gap said, because, "it clarifies: (a) that drug companies' monopoly prices, even when partially discounted, can unnecessarily impede access to medicines; (b) that the refusal of drug companies to issue voluntary licenses to generic competitors can abusively impede competition; and (c) that the refusal to grant licenses can prevent manufacture of fixed-dose combination medicines, thereby complicating patient adherence to multi-pill treatment regimes." It was this case that forced GlaxoSmithKline to issue voluntary licences to Aspen Pharmacare in South Africa to produce cheap antiretroviral drugs for the public sector.

Chapter 6: Conclusion and recommendations

Antiretroviral drugs have become a lot cheaper in the last five years. Much of this has been a result of international NGO pressure against multinational drug companies leading to “voluntary” discounts of prices by pharmaceutical companies and political effort at the international arena leading to funding initiatives such as the Global Fund for AIDS, Malaria and TB and bilateral donations from countries such as the United States of America. However, international NGOs maintain that one of the most important considerations has been the manufacture of cheap generic antiretrovirals by Brazil and India. Prices of generic drugs in these countries have forced the prices of brand name drugs to plummet and the consumer in the third world has benefited.

However, with the implementation of TRIPS in both Brazil and India it will be necessary for governments in the third world to ensure that the flexibilities in TRIPS are utilised to the maximum extent possible. This means that countries with manufacturing capacity should issue compulsory licences to ensure that antiretroviral drugs are available on their domestic markets at the cheapest possible price. Countries without manufacturing capacity should take advantage of the grey importation procedure set out in the Ministerial Decision of 30 August 2003 to allow parallel importation from countries manufacturing generic medicines.

In sub-Saharan Africa South Africa has the largest economy and the most modern pharmaceutical manufacturing industry. Manufacture of generic antiretroviral drugs in South Africa would have the effect of reducing prices across southern Africa, economics of scale mean that the price in South Africa will have a direct effect on prices in the rest of the region (imported drugs in Zimbabwe are bought from either South Africa or India). The voluntary licences given by multinational drug companies to Aspen Pharmacare include agreements that the drugs will not be made available to countries outside South Africa, furthering their strategy to “segment the market.” This has the effect of maintaining high prices in the sub-region. This in turn will affect South Africa, which would benefit by drug reduced prices across the region as the more open the competition is in the region the cheaper the prices will be in South Africa. Further voluntary licences have been shown to be less effective than compulsory licences and grey importation in reducing prices.

Grey importation from countries with developed manufacturing capacity will be the best way of maintaining low drug prices and will have the added benefit of promoting the efficiency of local manufacturers. In Zimbabwe where the market is served essentially by one local manufacturer with no generic competition this may lead to inefficiency and excessive prices. In a situation where the government has chosen to exercise its right to utilise generics it should ensure that the prices charged are the absolute lowest possible. It has been shown that companies in Brazil are interested in providing generic medicines to Africa and that such practices will have the effect of dramatically lowering the prices of drugs.

Both Zimbabwe and South Africa face a very difficult task in dealing with the HIV/AIDS crisis and the lowest drug prices can be pushed the easier this task will be. However, antiretroviral drugs will not be the complete cure for the crisis. Both countries need an improved public health system, and especially they need more doctors and nurses. Reducing prices has only been the first step and while both countries have had some limited success in this aspect, the public health systems in both countries need complete overhaul. Neither country can do this alone, and both will require extensive aid from developed countries, whether as bilateral aid or through the Global Fund for HIV, Malaria and Tuberculosis. The current situation, where the Global Fund has refused to grant money to Zimbabwe, on technical or political grounds, is unacceptable.

6.1 Recommendations

- South Africa should implement its own laws allowing the compulsory licensing of antiretroviral drugs to reduce the costs of the drugs both in the private and public sectors.
- Both Zimbabwe and South Africa should negotiate with Brazilian and Indian companies and issue compulsory licences to allow grey importation into the two countries of cheaper antiretroviral drugs.
- Zimbabwe must urgently renegotiate its position with the Global Fund and this Fund should make every effort to overcome technical and political problems arising from assisting the treatment of HIV/AIDS in Zimbabwe. Considering the urgency of the matter it is not acceptable to further postpone the Zimbabwean application to the next meeting of the fund.

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