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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

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Summary

The HIV/AIDS pandemic poses a great threat to the livelihood of people living in sub-Saharan Africa. Within Southern Africa, Zimbabwe and South Africa are some of the countries worst hit by the pandemic. While the HIV/AIDS pandemic ravages these two countries, there are in existence drugs that can treat the symptoms of HIV/AIDS and also lower the communicability of the virus. The availability of these drugs in the two countries, however, is problematic particularly because of the international patents law regime. The result is that the drugs are very expensive when imported into the countries and therefore unavailable to the people that need them the most. The present article discusses how Zimbabwe and South Africa can effectively guarantee the availability of cheap anti-retroviral drugs to their populations by utilising the flexibilities in the TRIPS agreement to allow compulsory licensing and parallel importation of cheap anti-retroviral drugs. The article also examines the legal framework in the two countries to determine how they may best be utilised to secure the right to health in the present dispensation. The paper posits that the governments in these

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two countries can further the citizenry's right to health in the by fully utilising the flexibilities of the TRIPS agreements to facilitate the availability of cheap anti-retroviral drugs.

1 Introduction

The Agreement on the Trade Related Aspects of Intellectual Property (TRIPS) is part of the World Trade Organisation (WTO) agreement. Although the substantive provisions of TRIPS are restatements of earlier international agreements, TRIPS changed two important things. It strengthened the dispute resolution procedure for intellectual property,[1] and it removed the state's discretion under the Paris Convention to determine the extent of patent protection.[2] For the protection of pharmaceuticals, this change means that states that had traditionally not allowed patent protection for pharmaceuticals, or had limited this protection, had to amend their legislation to become 'TRIPS compliant'. Developing and least developed nations were allowed 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), had to amend their legislation by the end of 2004, while least developed countries (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 national emergencies. These flexibilities are set out 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).

In the second half of the 1990s, the HIV/AIDS pandemic put increasing pressure on developing countries 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 kept 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. Thus, on 30 August 2003, the

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1 I Elangi Botoy 'From the Paris Convention to the TRIPS Agreement: A one-hundred-and-twelve-year transitional period for the industrialised countries' (2004) 7 *Journal of World Intellectual Property* 115-130.

2 T Kongolo 'Towards a more balanced co-existence of traditional knowledge and pharmaceuticals protection in Africa' (April 2001) 35 *Journal of World Trade* 349.

WTO Council of Ministers agreed on a statement establishing procedures for the parallel importation of generics (grey importation), setting out a stringent procedure that has to be followed both by the exporting and importing country.

Accordingly, 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.

Zimbabwe and South Africa are facing an HIV/AIDS pandemic of such proportions that the populations of these countries will markedly decline in the next ten years. This is despite the existence of effective drugs that treat the symptoms of HIV/AIDS and dramatically lower the communicability of the virus. These drugs are under patent protection by 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 and has issued compulsory licences 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 utilised flexibilities inherent in its own legislation.

This paper attempts to measure the effectiveness of the legal norms created by articles 30 and 31 of TRIPS, the Doha Declaration and subsequent Council of Ministers' decisions. Together, these ostensibly provide a framework to allow provision of generic drugs. It further discusses 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 is 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.

The paper attempts to answer the question, 'In what ways have Zimbabwe and South Africa utilised, or failed to utilise, the flexibilities in TRIPS to effectively protect the right to health?' The paper argues that the governments of South Africa and Zimbabwe could increase provision of HIV/AIDS drugs by fully utilising the flexibilities in the TRIPS agreement. It is argued that South Africa could improve its performance in the implementation of the right to access to health care by issuing compulsory licences to local companies to manufacture cheap anti-retroviral drugs.

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. 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.

A number of studies have illustrated 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.[3] However, 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.

2 The duties arising for South Africa and Zimbabwe from the right to health and the effect of TRIPS on these duties

2.1 The right to health in international law

In the 1948 Universal Declaration of Human Rights (Universal Declaration), the United Nations (UN) declared that '[e]veryone has the right to a standard of living adequate to the health of himself and of his family, including . . . medical care'. While the Universal Declaration is important because of its general acceptance by all states, the right to health is more definitively provided for in the International Covenant on Economic, Social and Cultural Rights (CESCR).[4] Article 12(1) of CESCR protects 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.

The Committee on Economic, Social and Cultural Rights (the Committee on ESCR) has confirmed that state parties to CESCR have obligations to take steps towards implementation of the rights as well as to

[3] SF Musungu 'The right to health in the global economy: Reading human rights obligations into the patent regime of the WTO-TRIPS agreement' in Centre for Human Rights *International yearbook of regional human rights Master's programmes* (2001) 194; R Mahelkar 'Intellectual property rights and the third world' *81 Current Science* (25 October 2001) 955; http://www.ias.ac.in/currsci/oct252001/955.pdf (accessed 28 February 2005); P Hunt 'Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health on his mission to the World Trade Organisation' E/CN.4/2004/49/Add 1*;* P McCalman 'The Doha agenda and intellectual property rights' paper prepared as part of the Asian Development Bank's Regional Technical Assistance 5994: A Study on Regional Integration and Trade: emerging policy issues for selected developing member countries, http://www.adb.org/Economics/pdf/doha/McCalman.pdf (accessed 28 February 2005); R Mayne & M Bailey 'TRIPS and public health' *Oxfam international briefing paper* (2002) http://www.oxfam.org/eng/pdfs/pp020325_trips_health.pdf (accessed 28 February 2005).

[4] See Musungu (n 3 above) 203.

fulfil a minimum core content of these rights immediately.[5] In the *Social and Economic Rights Action Centre v Nigeria*[6] case, the African Commission on Human and Peoples' Rights (African Commission) confirmed that economic, social and cultural rights, which include the right to health, are justiciable under the African Charter on Human and Peoples' Rights (African Charter).

Although national constitutional orders have generally overlooked economic, social and cultural rights, including the right to health, this has been changing. The South African Constitution and constitutional cases, such as the *Minister of Health and others v Treatment Action Campaign and Others* (*TAC* case),[7] have demonstrated that governments may be held accountable in domestic courts for failure to provide health care in certain circumstances. In Ecuador, the Constitutional Court has held that the right to health in the Ecuadorian Constitution extends as far as obliging the government to provide public entities to ensure that the general public has access to health care, demonstrating that the right to health has begun to receive acceptance at the national level.[8]

General Comment No 14, on the substantive issues arising from the application of the right to health, issued by the Committee on ESCR, provides the most detailed explanation of the scope of states' responsibility under the UN system with regards to the right to health.[9] The Committee noted that states could not 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.[10] The Committee outlined the elements of the right to health and defined the requirement of economic accessibility as follows:[11]

> . . . health facilities, goods and services must be affordable for all. Payment . . . 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.

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5 The Committee is a body of independent experts in charge of interpreting and monitoring the application of CESCR. See United Nations Committee on Economic Social and Cultural Rights 'The nature of states parties obligations (art 2 para 1)' General comment No 3 contained in document E/1991/23 (14/12/90).

6 Communication 155/96, ACHPR/COMM/AO44/1.

7 2002 5 SA 703 (CC).

8 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 & Others v Ministry of Public Health and the Director of the HIV-AIDS National Programme (amparo writ)* Resolution No 0749-2003-RA, 28 January 2004.

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

10 n 9 above, para 7.

11 n 9 above, para 9.

The Committee said that state parties had an obligation to create a 'system of urgent medical care in cases of accidents, epidemics and similar health hazards', and that the right to health facilities, goods and services 'includes . . . the provision of essential drugs'.[12]

State obligations relating to economic, social and cultural rights are limited by the concept of progressive realisation within a state's available resources. Thus, generally, a state's duties in relation to health can only 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, interpreting the South African Constitution which refers to 'progressive realisation', has held that the government was required to have a 'reasonable policy'.[13] Although this was a test developed within the constitutional framework of South Africa, it sheds light on the nature of international obligations arising from economic, social and cultural rights.

The state has an obligation under CESCR 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.[14] This duty includes ensuring that medicines of acceptable quality are sold at prices affordable to the poor and other vulnerable sectors of society. This protection can take several forms, including enacting legislation regulating the prices of drugs.[15]

The duty to fulfil is traditionally seen as implying expenditure by the state. 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, such as public or private health insurance.

In the context of the right to health under CESCR, states have an obligation to ensure the availability and accessibility of essential medicines. 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.

The Committee has interpreted CESCR as including the requirement of immediately fulfilling a minimum core obligation for each protected right. With respect to health, the Committee held that the minimum core obligations with regard to the right to health include the obligation:[16]

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12 n 9 above, para 16.

13 See *Government of the Republic of South Africa & Others v Grootboom & Others* 2001 1 SA 46 (CC). See also *Soobramoney v Minister of Health, KwaZulu-Natal* 1998 1 SA 765 (CC) and the *TAC* case (n 7 above).

14 General Comment No 14 (n 9 above) para 35. See also para 51.

15 This approach has, eg, been utilised in Egypt.

16 General Comment No 14 (n 9 above) para 43.

(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.

General Comment No 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 population and that if a significant proportion of the population does not have access to such medicines, the state has violated its obligations.

The African Charter enshrines and protects economic, social and cultural 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 African Charter limiting the enforcement of economic, social and cultural rights to progressive realisation within available resources. Thus it has been argued that the obligations arising from the African Charter are immediate, regardless of the nature of the rights concerned.[17] However, in the *Purohit and Moore v Gambia* case, the African Commission apparently implied the limitation of available resources into the right to health under the African Charter.[18]

In General Comment No 14, the Committee on ESCR states that ensuring access to essential medicines for the large majority of the population is one of the minimum core obligations of the state. The 2002 World Health Organisation list of essential medicines contained 325 individual drugs, including 12 anti-retroviral medicines for the symptomatic treatment of HIV/AIDS.[19] Applying General Comment No 14, states parties owe a duty to develop a policy that will incrementally ensure the provision of essential medicines to all individuals within the state. In addition, the state has an immediate responsibility, as a core minimum, to ensure that no significant proportion of the population is denied access to essential medicines.

2.2 The effect of intellectual property rights on the right to health

Because of the industrialised nature of modern society, the implementation of many rights protected at international and national law implies

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[17] O Odinkalu 'Implementing economic, social and cultural rights' in M Evans & R Murray (eds) *The African Charter on Human and Peoples' Rights. The system in practice, 1986-2000* (2002) 178 196. Although Odinkalu posits that this interpretation does not apply to the right to health, it is argued that the Charter does not limit the enforcement of the right, but rather the content where it refers to 'best attainable state of health'. This should be interpreted as meaning that individuals cannot claim breaches of their rights where they do not have perfect health, where the condition is not medically curable or treatable.

[18] Communication 241/200, decided at the 33rd ordinary session of the African Commission (15-29 May 2003).

[19] The current list can be found at http://mednet3.who.int/eml/diseases_disease_group_order.asp (accessed 4 September 2004).

the provision of patented products and products manufactured by a patented process.[20] The health of the individual may depend on access to certain medicines that are protected by a patent and the manufacture of which is legally monopolised by the patent holder.

Prior to the deadline given under TRIPS to most developing countries of January 2005, many developing countries did not provide patent protection, or provided only limited protection, for pharmaceutical products. Under TRIPS rules, from this date these countries will be legally bound to give full patent protection to pharmaceutical products. Many of the medicines in the developing world are generic medicines manufactured by a process of reverse engineering in countries such as India and Brazil.[21] 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.

The conflicting duties of the state — to protect the rights of the patent holder and the rights 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.

TRIPS was one of the agreements reached after the Uruguay Round of the General Agreement on Trade and Tariffs and was signed by 125 governments.[22] Provisions of TRIPS reflect the strong influence of the United States of America in the negotiations 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.[23]

There are a number of flexibilities in the TRIPS agreement relating to the working of patent-protected products. 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. Much

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20 Musungu (n 3 above) 211.

21 P Drahos 'Access to medicines: After Doha' *Trade hot topics commonwealth* No 20.

22 n 21 above, 213.

23 P Wojahn 'A conflict of rights: Intellectual property under TRIPS, the right to health, and AIDS drugs' (Fall 2001/Winter 2002) 6 *UCLA Journal of International Law and Foreign Affairs* 465 479. Musungu (n 5 above) 214 and G Velasquez & P Boulet *Globalisation and access to drugs: Perspectives on the WTO/TRIPS agreement* (1999), http://www.eldis.org/static/DOC11519.htm (accessed 10 September 2004) claim that Pharmaceutical Trans-National Companies (TNCs) pressurised developing countries, through the governments of developed countries, in favour of strict intellectual property protection.

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).[24]

Article 31 of the agreement applies to compulsory licensing, parallel importation and government use.[25] 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.[26]

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 and the requirement to pay compensation.[27] 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 cheaper than under voluntary licence.

2.3 The Doha Declaration

The flexibilities in TRIPS were clarified in the Doha Ministerial Declaration.[28] The Doha Ministerial Declaration on 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.[29] The Doha Declaration reaffirmed the

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[24] See I Elangi Botoy 'Potential and substantial benefits of the TRIPS agreement to the member countries of the African Intellectual Property Organisation in the patent field' (2001) 4 *Journal of World Trade Law* 91; 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' (2002) *36 Journal of World Trade* 721; T Haag 'TRIPS since Doha: How far will the WTO go toward modifying the terms for compulsory licensing?' (2002) 84 *Journal of the Patent and Trademark Office Society* 945, Drahos (n 21 above) 3. For a view that art 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.

[25] Government use is specifically allowed under art 44(2) of TRIPS.

[26] Musungu (n 3 above) and art 31 of TRIPS as read with art 5(A)(2) of the Paris Convention.

[27] Although in public emergencies, some of these requirements are relaxed.

[28] 'Declaration on the TRIPS agreement and public health, Ministerial Conference, 4th session, Doha 9-14 November 2001' WT/MIN (01)/DEC/W/2 14 November 2001 (Doha Declaration).

[29] n 28 above, para 5.

right of each state to grant compulsory licences and determine the conditions of these licences.[30]

The Doha Declaration was important because the WTO specifically said that governments could issue compulsory licences for the manufacture of generic medicines. The declaration thus assured developing countries that the granting of compulsory licences would not lead to litigation before the WTO dispute settlement bodies.[31]

While the Doha Declaration clarified the situation of countries with manufacturing capacity, there was no solution for countries that do not have manufacturing capacity and need to rely on parallel importation to ensure a supply of anti-retroviral drugs. Parallel importation is the 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.[32] Parallel importation is a suitable solution for countries that do not have infrastructure to manufacture generics through compulsory licensing. However, TRIPS does not allow parallel importation of generics, which shuts the door on a cheap source of medicines.[33] 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.[34] This means that parallel importation of medicines manufactured under a compulsory licence would *prima facie* breach the TRIPS agreement.[35]

Article 6 of the Doha Declaration called on states to create a system to allow developing and least developed states to import medicines from other states manufacturing generic drugs. 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.[36] The decision waives the obligations of members of the WTO under subarticles 31(f) and 31(h) (the conditions that the products be predominantly for the local market and the requirement to pay compensa-

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30 As above.

31 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 ' *per* Elangi (n 24 above) 95.

32 Musungu (n 3 above) 220.

33 S Joseph 'Pharmaceutical corporations and access to drugs: The 'fourth wave' of corporate human rights scrutiny' (2003) 25 *Human Rights Quarterly* 423 449-450.

34 Drahos (n 21 above) 2.

35 n 34 above 3; K Gopakumar 'The WTO deal on cheap drugs: A critique' (2004) 7 *The Journal of World Intellectual Property* 99 100; J James 'Drug patents and developing countries: Problems remain' *AIDS Treatment News* Issue 385 November 2002. The Ministerial decision is WT/L/540 2 September 2003.

36 Gopakumar (n 35 above) 99.

tion 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.[37]

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, firstly, the power for states to issue compulsory licences for essential medicines; and, secondly, the power for states to import generic medicines through the WTO system. However, these flexibilities need to be used. It does not meet the obligations of a state under CESCR to include provisions in a country's patents legislation allowing compulsory licensing, but failing to actually issue compulsory licences and/or to import generics. The obligation under CESCR is to provide access to essential medicines and the flexibilities under TRIPS are merely one of the methods a state may use to protect and fulfil this right.

3 An assessment of South Africa and Zimbabwe's use of TRIPS flexibilities

3.1 Legal provisions

3.1.1 Constitutional provisions

The Constitution of Zimbabwe has no protection of the right to health. The right to life was drafted restrictively in Zimbabwe to guarantee only a prohibition against arbitrary deprivation of life. However, Zimbabwe has ratified CESCR and the African Charter and is thus bound by international law to respect and implement this right.

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, which is set out in article 27 of the Constitution. However, the South African Constitutional Court has held that an individual may not claim that the state has breached a minimum core 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.[38] Thus it cannot be argued that, under the South African Constitution, the state has an obligation to provide an individual with 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.

[37] Gopakumar (n 35 above) 105.
[38] See the *TAC* case (n 7 above).

3.1.2 International treaties

South Africa is not a party to CESCR,[39] but it is a party to the African Charter and is thus bound by article 16 of the Charter, which may be interpreted to give rise to immediate obligations by the South African government. Alternatively, article 16 may be interpreted with reference to articles 61 and 62, to include the concept of minimum core obligations.

Both South Africa and Zimbabwe are obliged to take progressive steps towards the realisation of the right to health and are obliged to immediately realise minimum core obligations. These minimum core obligations include ensuring that there is no significant proportion of the population that does not have access to essential medicines, which include anti-retrovirals.

Since compulsory licensing and grey importation of generic HIV/AIDS drugs are 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 article 26(2) of the South African Constitution.

3.1.3 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.

Section 32 allows the grant of compulsory licences for foods or medicines. Sections 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.

The Zimbabwean legislation therefore clearly makes the manufacture

[39] As above.

and importation of generic drugs legal under certain circumstances. The procedure to be adopted by the government is relatively straightforward and empowers the government to meet national health emergencies in accordance with its international obligations. The government may choose to manufacture drugs itself, issue licences under sections 31 or 32 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. The government of Zimbabwe has therefore taken the necessary legislative steps to ensure compliance with its international obligations.

In South Africa, section 56(2) of the Patents Act allows compulsory licences 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 and serving the market with imported goods whose prices are excessive.[40] 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. 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.[41]

After a much disputed amendment to the Medicines and Related Substances Control Act (the Medicines Act),[42] the new section 15C apparently facilitates the parallel importation of patent protected 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.[43]

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[40] See also Dr Gerntholz Patent Attorneys 'Basic guide to patents' http://www.gpa.co.za/english/basic/patents.htm (accessed 14 October 2004).

[41] 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' http://www.tac.org.za (accessed 13 September 2004).

[42] 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, http://www.wsws.org/articles/2001/apr2001/aids-a21.shtml (accessed 8 October 2004); J Love 'Report on court case over South African Medicines Act' http://www.aids-bells.org/index.html (accessed 28 February 2005).

[43] See A Hooper 'Prices of pharmaceuticals to the South African public — Will they drop?' on the website of Spoor and Fisher http://www.spoor.com/article.php?no=451 (accessed 13 September 2004).

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.[44] 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.[45] This interpretation of the Act has been confirmed by Love J, who states the following:[46]

> [P]arallel imports does not involve buying from generic suppliers, but rather just shopping around for the best price a company charges internationally . . . 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.

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.[47] It could be argued that section 15C(1) allows 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 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.[48]

The legislation in South Africa does not clarify whether grey importation is legal, although the Patents Act does appear to make it possible

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44 *TAC* case (n 7 above).

45 Love (n 42 above).

46 As above.

47 A Hooper 'The Medicines and Related Substance Control Amendment Bill (B30-97) and its effect on intellectual property rights' Spoor and Fisher, http://www.spoor.com/article.php? no=451 (accessed 11 October 2004).

48 Sec 7 of General Regulations made in terms of the Medicines and Related Substances Act 101 of 1965 (as amended) of May 2003.

for an importer to be granted a compulsory licence to allow it to import generic medicines. The new Medicines Act does not appear to have changed the position much, mainly because the government does not appear prepared to utilise the legislation to allow the registration of generic medicines. Generally, the South African legislation is less empowering of the government to allow parallel importation, placing the emphasis in the Patents Act on individual applications for licences, whereas the Zimbabwean legislation allows the state to take a lead in manufacturing or facilitating third parties to manufacture generic medicines.

3.1.4 Summary

Zimbabwe and South Africa have 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. 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 domestic flexibilities to suspend patent rights over HIV/AIDS drugs.

3.2 The cost-effectiveness of generic anti-retrovirals

3.2.1 Zimbabwe

Field research in Harare, Zimbabwe in July 2004 showed that the market was mainly served by generic anti-retrovirals produced by a Zimbabwean company, Varichem (Pvt) Ltd.[49] 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 28 a month.[50] Examples of the prices are as follows: Stanalav was US $23 or US $24, depending on the pharmacy, whereas Nevirapine fluctuated between US $3 and US $6. Combivir (Zidovudine/Lamuvidine) was sold for US $13 or US $18 per month. Zerit was on sale for between US $12 and US $23.

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

[50] The US dollar values are based on an exchange rate of 7 000 Zimbabwean dollars to one US dollar, valid at 31 July 2004.

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 at US $143 per month and imported Nevilast was available for US $49 per month. Locally produced anti-retroviral 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 11 times more expensive than locally produced Combivir and 12 times more expensive than locally produced Zerit. The vast difference in prices shows the success of local manufacture of generic medicines in reducing the price of first line anti-retroviral drugs.

3.2.2 South Africa

International prices of anti-retroviral 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 anti-retrovirals at a price of approximately US $84 per month for triple therapy: '[T]he prices offered by companies for triple therapy in South Africa have fallen . . . to approximately US $1 000 (per patient per year) . . .'[51]

Meanwhile, in the public sector, voluntary licences have made cheaper anti-retroviral drugs available to the government and to NGOs working on HIV/AIDS. 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 and the cost is still higher than generic drugs imported from India:[52]

> 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.

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 (see below) or generics manufactured in Zimbabwe. Patients that rely on the private sector in South Africa and patients in neighbouring countries do not benefit at all.

3.2.3 Comparison of prices between South Africa and Zimbabwe

A direct comparison of prices in South Africa as quoted by the BBC[53]

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[51] Oxfam GB 'South Africa vs. the drug giants' http://www.oxfam.org.uk/what_we_do/issues/health/drugcomp_sa.htm (accessed 14 October 2004).

[52] BBC News 'African firm wins AIDS drug permit' 8 October 2001, http://news.-bbc.co.uk/ 1/hi/business/1586355.stm (accessed 5 September 2004). The BBC noted that before the agreement, the multinational concerned, GSK, was already providing Combivir to the South African public health sector for US$ 2 a month.

[53] As above.

and the cost of generics on the open market in Zimbabwe shows 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 US $1,80 per day. Zerit prices in Zimbabwe 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 US $1 per day.[54] This comparison has shown that drugs manufactured under compulsory licensing in Zimbabwe are cheaper than drugs manufactured under voluntary licences in South Africa. (A difference of between 20 US cents and US $1 is important when considering economics of scale, as the marginal variance is significant for annual per capita expenditure.) Further, the price analysis does not take into consideration that the Zimbabwean prices are retail prices,[55] 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 were approximately US $84 per month, whereas in Zimbabwe, Stanalav, a locally produced triple therapy drug, was sold for US $22 per month, approximately four times cheaper than triple therapy available to the private sector in South Africa. The granting of compulsory licences in Zimbabwe has therefore made generic drugs available on the open market at much cheaper prices than comparable medicines in South Africa. The Zimbabwean legislation and policy in this regard are more successful in making generic drugs available to its population in compliance with its international obligations.

3.4 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:[56]

> [I]f the US actually gets around to permitting parallel imports of medicines, US consumers could buy branded and patented medicines from the Canadian and European markets, where prices are often lower.

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[54] W Chege 'South Africa firm offers Zerit (Stavudine) as continent's first locally made generic drug' 8 September 2003, *HIV and AIDS top stories,* http://www.hivandhepatitis. com/recent/developing/08083.html (accessed 8 October 2004). The Zerit licence 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. These licences restricted the company to selling to the government. See HIV Newsroom 'South African generic drug maker to produce country's first generic anti-retroviral drug' *The body: An AIDS and HIV information resource,* http://www.thebody.com/kaiser/2003/aug7_03/south_africa_generic.html (accessed 28 February 2005).

[55] Pharmaceutical wholesalers refused to disclose their prices, claiming confidentiality.

[56] Love (n 42 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 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. However, Médecins sans Frontières (MSF) has been treating patients in South Africa on generic anti-retrovirals purchased from Brazil 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.[57]

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.[58]

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

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 anti-retroviral drugs in India as compared to Africa and the developed world.[59]

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

[58] MSF 'Brazilian generic ARV drugs in South Africa — The background. A historical account of the use of Brazilian drugs in MSF's anti-retroviral programme in South Africa' 29 January 2002, http://www.msf.org/countries/page.cfm?articleid=F8557436-9860-4D00-BC5FO476D8B7A5E1 (accessed 9 October 2004).

[59] This table is taken from K Singh 'Patents vs patients: AIDS, TNCs and drug price wars' *Third World Network*, http://www.twnside.org.sg/title/twr131c.htm (accessed 11 October 2004).

Table 2: Indian anti-retroviral 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 per patient per year and are in USD.				

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

3.5 The effect of the two countries' strategies

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

4 Other factors affecting supply of anti-retroviral 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 anti-retroviral 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 roll-out of anti-retroviral drugs shortly before the general elections in early 2004,[60] but by June 2004 only three provinces were actually administering anti-retroviral 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 anti-retrovirals, as she stated that the tender procedure for the supply of anti-retroviral drugs would be extensive.[61] Neither country is supplying enough drugs to its people, although for different reasons.

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. The Global Fund to Fight AIDS, Malaria and Tuberculosis refused Zimbabwe's application for funds to pay for the roll-out of anti-retrovirals to around 70 000 people, citing technical reasons. However, it has been suggested that concerns over human rights 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 to all neighbouring countries.[62] Although Zimbabwe's isolation may have been a factor in its ability to issue compulsory licences (as it was not subject to the same pressure utilised against South Africa), this situation has made it very difficult for the government to deliver the medicines to the population. It is estimated that less than 10000 people are receiving anti-retroviral drugs in the public sector in Zimbabwe.[63]

In South Africa, the delay has mainly been caused by government's disinclination to provide anti-retrovirals, caused apparently by the South African President's stated disbelief in the link between HIV and AIDS.[64] NGOs had to take the government to the Constitutional Court to obtain an order that the government provide anti-retroviral drugs to prevent mother-to-child transmission of the disease.[65] However, early in 2004 a decision was made that anti-retroviral drugs should be provided across the country. By June 2004, three provinces had begun to provide

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60 Although earlier decisions to 'roll out' anti-retroviral 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', http://www.economist.com/science/displayStory.cfm? (accessed 9 October 2004).

61 V Mohapeloa 'AIDS drug rollout continues: Government', http://www.southafrica.info/ ess_info/sa_glance/health/aidsdrugs (accessed 9 October 2004).

62 S LaFraniere 'Donor mistrust worsens AIDS in Zimbabwe' *New York Times* 12 August 2004, reproduced in *The Zimbabwe situation*, http://www.zimbabwesituation.com/aug13_2004.html (accessed 11 October 2004).

63 As above.

64 MSF (n 58 above).

65 *TAC case* (n 7 above).

anti-retroviral drugs, and it was estimated that in these three provinces 3 593 people were receiving anti-retroviral treatment.[66]

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 international pressure came mainly from the United States of America:[67]

> The US Government has a recent history of applying pressure to South Africa . . . to apply stronger patent protection than the TRIPS minimum standards, and the clear basis for this pressure is implicit linkage to other trade provisions and measures . . .

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, and suspended benefits under the Generalised System of Preferences to South Africa, for its passing of the amendment.[68]

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.[69]

Although regulations have been issued in accordance with section 15C of the amended Medicines Act, they have concentrated on the pricing of drugs, rather than compulsory licences or grey importation.[70]

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66 Mohapeloa (n 61 above).

67 S Cleary & D Ross 'The 1998-2001 legal interaction between the South African government and the international pharmaceutical industry: A game-theoretic analysis' http://www.uab.edu/philosophy/faculty/ross/AIDS%20paper.htm (accessed 28 February 2005).

68 Singh (n 59 above). In 2000, after intense NGO pressure, the Clinton government rescinded these actions and indicated that it would not pressure sub-Saharan governments over compulsory licensing and parallel importation of HIV/AIDS drugs.

69 Treatment Action Campaign Statement 'Victory for activists, people with HIV/AIDS and poor people everywhere! Pharmaceutical companies beaten!' issued on 19 April 2001, http://www.globaltreatmentaccess.org/content/press_releases/01/041701_TAC_PR_lwsuit_win.html (accessed 11 October 2004).

70 Sec 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.

The pricing procedure affects local pharmacies and doctors but not multinational drug companies.[71]

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.[72] However, the analysis of the prices of drugs available from India and Brazil indicates 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.[73] The Commission was quoted as follows: '[E]ach of the firms has refused to license their patents to generic manufacturers in return for a reasonable royalty . . .'[74]

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

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71 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 South African government 'Paving way for cheaper medicines', http://www.southafrica.info/ess_info/sa_glance/health/medicinespricing_190803. htm (accessed 8 October 2004); C Freeman 'Medicine prices to be slashed', http://www.southafrica.info/ess_info/sa_glance/health (accessed 11 October 2004); A Hooper 'Update — Pricing of pharmaceuticals to the South African public' Spoor and Fisher, http://www.spoor.com/default.htm (accessed 25 September 2004).

72 Dr Manto Tshabalala-Msimang, South African Minister of Health, statement issued on 11 March 2001.

73 MSF 'MSF welcomes decision of South African Competition Commission to promote access to medicines', press statement issued on 16 October 2003, http://www.accessmed-msf.org/prod/publications.asp?scntid=17102003935123$contenttype=para$ (accessed 28 February 2005).

74 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', http://www.healthgap.org (accessed 12 September 2004).

case reinforces the impression that the South African government is not prepared to confront pharmaceutical companies.

5 Conclusion and recommendations

Anti-retroviral drugs have become cheaper in the last five years. One of the most important considerations has been the manufacture of cheap generic anti-retrovirals in 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 anti-retroviral 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 anti-retroviral drugs in South Africa would have the effect of reducing prices across Southern Africa. Economics of scale means 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). South Africa has failed to utilise and implement the flexibilities inherent in TRIPS, and this has resulted in its failure to meet its international obligations and has kept the prices of essential medicines in the region artificially high. To some extent, this has been because South Africa has had access to cheaper anti-retroviral drugs through agreements with drug companies and through donor funding. However, the prices of drugs in the private sector are still excessively high compared to markets served with generic anti-retrovirals.

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. Where one local manufacturer with no generic competition serves the market, as in Zimbabwe, 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 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. Zimbabwe, therefore, must promote the importation of generic medicines to ensure compliance with its international obligations. Thus,

although Zimbabwe has allowed generic manufacture of first line anti-retroviral drugs, this does not mean that the country has fully implemented the flexibilities in the TRIPS agreement. Zimbabwe must ensure that cheaper imported generic drugs are made available and that second line generic anti-retroviral drugs are either imported or manufactured in Zimbabwe.

Both Zimbabwe and South Africa face a very difficult task in dealing with the HIV/AIDS crisis and the lower drug prices can be pushed, the easier this task will be. However, anti-retroviral drugs will not be the complete solution to 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.

The following recommendations are made: South Africa should implement its laws and the flexibilities in the TRIPS agreement, allowing the compulsory licensing of anti-retroviral 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. Considering the urgency of the matter, it is not acceptable to further postpone the Zimbabwean application, as the Fund has been doing.