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So much to do, so little done: The right of access to anti-retroviral drugs post-*Grootboom*

PIERRE DE VOS

Professor of Law, University of the Western Cape

1 INTRODUCTION

South Africa is in the midst of a HIV/AIDS crisis of catastrophic proportions. Although the exact figures are in dispute,¹ most experts agree that between four and six million people in South Africa are presently living with the HIV virus and that this figure will keep rising for the next five years.² According to a recent report prepared by the Medical Research Council of South Africa (MRC), over half the deaths of people between the ages of 15 and 49 have HIV/AIDS-related causes. A disproportionate number of those affected by HIV/AIDS are marginalised because they are female, black, poor, or living in rural areas, or – often – because of a combination of these factors.³ The more marginalised and vulnerable the

1 See for example, iafrica.com 2001 “We are proud of AIDS report – MRC” <<http://iafrica.com/news/sa/824094.htm>> Accessed 12 February 2002; sabcnews.com 2001 “MRC stands by its controversial AIDS report” <www.sabcnews.com/south_africa/health/0,1009,22301,00.html> Accessed 9 February 2002; Independent Online 2001 “AIDS impact difficult to gauge, says Stars SA” <www.iol.co.za/index.php?click_id=125&art_id=cr20011012094232225S32079&set_id=1> Accessed 9 February 2002. See also Medical Research Council (MRC) of South Africa 2001 “The impact of HIV/AIDS on adult mortality in South Africa” <www.mrc.ac.za/bod/index.htm> Accessed 11 November 2001.

2 The Actuarial Society of South Africa (ASSA) model on AIDS estimates that in 2002 6.5 million South Africans will be infected with the HIV virus and that this figure will increase to 7.7 million by 2006 if no intervention is made. If modest interventions are made the total HIV infection in 2002 will be 6.49 million and in 2006, 6.99 million. ASSA 2001 “Actuarial Association of South Africa HIV/AIDS model” <www.assa.org.za/committees/AIDS/summarystats.htm> Accessed 15 November 2001. The Department of Health estimates that 4.7 million South Africans were infected with the HIV virus in 2001. Department of Health 2001a “National HIV and syphilis sero-prevalence survey of women attending public antenatal clinics in South Africa” <<http://196.36.153.56/doh/AIDS/index.html>> par 4.1.4. Accessed 10 November 2001. The MRC makes similar findings, stating that between 5 and 7 million South Africans will die of HIV-related causes by 2001. MRC 2001, *supra* note 1.

3 By the time a South African woman is 22 years old, for example, there is a 24% chance that she has contracted the HIV virus or has developed AIDS. This is borne out by statistics provided by the Department of Health, which estimates that almost a quarter of all pregnant women using public health facilities in 2000 lived with HIV/AIDS. See Department of Health (2001a), *supra* note 2, at par 4.1.1, stating that 24.5% of all pregnant

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group, the more at risk they appear to be of contracting HIV/AIDS. This claim is born out by the state's own HIV/AIDS/STD Strategic Plan, which states that the HIV/AIDS epidemic is severely affecting the young, black and economically poor in South Africa.⁴

In the face of such an overwhelming crisis, the state and other role players clearly have a constitutional duty to take all reasonable steps to address the crisis. This duty to act stems from the state's constitutional obligations to protect the right to life⁵ and human dignity,⁶ to provide access to health care services⁷ and to protect everyone from discrimination on grounds of race, sex, gender, sexual orientation, marital status, age or social origin.⁸ It is difficult, however, to state with any degree of certainty exactly what steps the state is constitutionally required to take. The HIV/AIDS crisis has confronted the state with a complex set of problems of enormous magnitude and it clearly necessitates an integrated and holistic response. To be effective, the state response should address an array of issues, including steps to:

- ensure the prevention of HIV transmission;⁹
- provide adequate and effective treatment, care and support for people living with HIV;¹⁰

women using public health facilities in 2000 are estimated to be living with HIV/AIDS. Women are, of course, particularly at risk. As Albertyn has argued, not only are women physiologically at greater risk of HIV transmission, but their "lack of power over their bodies and their sexual lives, supported and reinforced by their social and economic inequality . . . make[s] them such a vulnerable group in contracting, and living with, HIV/AIDS." Albertyn C 2000 "Using rights and the law to reduce women's vulnerability to HIV/AIDS: A discussion paper" <www.AIDSlaw.ca/durban2000/women/final.pdf> Accessed 9 November 2001. p.1.

4 Department of Health 2001a, *supra* note 2, at 8.

5 The Constitution of the Republic of South Africa Act 108 of 1996, s 11.

6 *Ibid* s 10.

7 *Ibid* s 27(1)(a).

8 *Ibid* s 9(3).

9 In order to be effective such a preventative programme should include a culturally appropriate and sensitive - but honest and direct - campaign to address the population's sexual behaviour. It should also include policies and programmes to provide anti-retroviral drugs to individuals exposed to HIV infection through sexual assault and medical procedures. While the first aspect mentioned above falls outside the scope of this article, the second aspect is dealt with below.

10 This paper deals with only one aspect of the provision of adequate treatment and care, namely the provision of anti-retroviral drugs to individuals living with HIV. However, this is by no means the only important treatment issue when it comes to measuring whether the government response was adequate and appropriate. First, individuals living with HIV often require access to treatment for opportunistic infections caused or exacerbated by a weakened immune system. This means that an individual needs access to other medicine like acyclovir, cotrimoxazole or fluconazole designed to treat symptoms often associated with living with AIDS. According to the policy guidelines issued by the Department of Health in August 2000, it is government policy to treat such opportunistic infections and, in serious cases, to admit such patients to state hospitals where appropriate. See Department of Health 2000a "HIV/AIDS Policy guidelines: Prevention and treatment of opportunistic and HIV-related diseases in adults" August 12-13. However, for a variety of reasons many individuals fail to gain access to treatment prescribed by the Department. Second, people living with HIV/AIDS and needing

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- ensure the effective protection of people living with HIV against discrimination and abuse;¹¹ and
- ensure the adequate tracking of the spread of HIV.¹²

Although it is highly desirable that the state aggressively pursues all these avenues to the best of its capability, the legal question is whether the state is constitutionally *required* to take certain prescribed steps. Embarking on such an enquiry would be a gargantuan task. It is beyond the scope of this article to evaluate the state's HIV/AIDS strategy – which purports to engage with all the above-mentioned aspects – in its entirety. Instead, I shall focus on one aspect of this strategy, namely the state's policies and practices in providing all people with access to anti-retroviral drugs, first, to prevent individuals from becoming HIV positive and, second, to inhibit the spread of HIV in HIV positive individuals. Given the complex and interrelated nature of any adequate response to the HIV/AIDS crisis this distinction is somewhat artificial, but it is impossible to address all these extremely complex and important issues in the limited space available here. I choose to focus on access to anti-retroviral drugs because in the face of the overwhelming crisis, the administering of such drugs in different settings can save countless lives and can indefinitely prolong the lives of countless others. Although they do not destroy the HIV virus and cannot be considered as a cure for the virus, anti-retroviral drugs – correctly administered – hold out the promise of hope to millions of South Africans who live with HIV.

In order to determine the scope of the state's constitutional duty to provide access to anti-retroviral drugs, I endeavour, first, to sketch the basic facts about HIV/AIDS and the possible uses of anti-retroviral drugs in its prevention and treatment. Second, I set out the Constitutional Court's jurisprudence on social and economic rights as it relates to access to health care. Third, I set out and evaluate the state's policies and practices regarding the uses of anti-retroviral drugs to establish whether it is fulfilling its constitutional duties in this regard.

2 HIV/AIDS AND ANTI-RETROVIRAL DRUGS

HIV/AIDS is a progressive disease of the immune system that is caused by the Human Immunodeficiency Virus (HIV).¹³ HIV is transmitted through

treatment in state medical institutions should have access to care of an appropriate quality. Due to a lack of trained staff, of facilities and of leadership at many state hospitals, such care is often not available.

11 This aspect will not be dealt with in this paper. In terms of the legal framework, this aspect of HIV prevention is probably the one in which the government has had most success due to the Constitutional prohibition against discrimination. See for example *Hoffmann v South African Airways* 2000 (11) BCLR 1211 (CC), where the Constitutional Court found that differentiation on the basis of HIV status constituted unfair discrimination in terms of s 9(3) of the Constitution.

12 See Department of Health 2000b "HIV/AIDS/STD Strategic plan for South Africa 2000–2005," ch 5. See also Department of Health 2001b "The South African government's response to the HIV/AIDS epidemic: Controversies and priorities" <<http://196.36.153.56/doh/AIDS/docs/gov-AIDS.html>> Accessed 16 November 2001.

13 Morgan *et al* (2001: 143–145). It might seem superfluous to provide footnote references for this almost universally accepted statement, but due to the scepticism expressed by

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intimate contact involving the exchange of bodily fluids, including exposure to or reception of contaminated blood, fluids produced during sexual intercourse, fluids produced during childbirth, and mothers' milk. All available scientific evidence (endorsed by the Constitutional Court)¹⁴ points to the fact that HIV is a human retrovirus that affects essential white blood cells, erodes the immune system and eventually leads to its complete deterioration. This progression of HIV is generally divided into four stages. During the first stage, called the acute stage, the individual contracts the virus and experiences flu-like symptoms. In the second stage, called the asymptomatic immunocompetent stage, the individual is HIV positive but the number of CD4+ lymphocytes (white blood cells) that are being attacked by the virus is still above 500 cells per micro litre of blood. During the third stage, called the asymptomatic immune-suppressed stage, the CD4+ counts dips below 500 cells per micro litre of blood. In the last stage, called AIDS, the CD4+ count drops below 350 cells per micro litre of blood and the individual becomes vulnerable to opportunistic infections.¹⁵ At this fourth stage an individual is said to have contracted AIDS because his or her immune system is so profoundly depleted that the individual becomes prone to opportunistic infections that may prove fatal because of the body's inability to fight them.¹⁶

However, steps can be taken to limit the risk of infection. They include the use of condoms during sexual intercourse, the early treatment of other sexually transmitted diseases, the administration of anti-retroviral drugs after exposure to the HIV virus due to medical accidents, rape or sexual assault, and strategies to reduce the transmission of HIV from HIV positive mothers to their children.¹⁷ Such strategies include – but are not limited to – various options regarding the provision of anti-retroviral drugs to mothers before and during labour and to babies shortly after birth.¹⁸

Once infected, the majority of people living with HIV/AIDS will die prematurely of illnesses that destroy their immune system, their quality of life and their dignity. However, the life of a HIV positive individual can be prolonged and his or her quality of life improved by ensuring early diagnosis, clinical management, the medical treatment of opportunistic infections and the appropriate use of anti-retroviral therapy.¹⁹ Opportunistic

President Thabo Mbeki about the link between HIV and AIDS it is essential to demonstrate that the basic facts about HIV/AIDS are not in dispute. In the legal sense, this is not difficult because South Africa's Constitutional Court has endorsed these basic facts in Hoffmann, *supra* note 11, par 11-15.

14 Hoffmann *ibid*.

15 *Ibid* par 11.

16 *Ibid*.

17 Department of Health 2001b, *supra* note 12, par 1.1; 1.2; 1.3.

18 See Connor *et al* 1994; Lindegren *et al* 1999; Guay *et al* 1999.

19 See US Health and Human Services 2001 "Guidelines for the use of anti-retroviral agents in HIV-infected adults and adolescents" <www.hivatis.org> Accessed 3 February 2002; Palella *et al* 1998. The Department of Health agrees with this statement. See Department of Health 2000a: 9, *supra* note 10: "Current research strongly indicates that suppressing HIV viral activity and replication with anti-retroviral therapy combinations prolongs life and prevents opportunistic infections."

infections, which usually occur after significant deterioration of an individual's immune system, can be treated relatively effectively. It is the stated policy of the South African state to provide such appropriate treatment for opportunistic infections and the question of whether or not state policy and practice meet the constitutional benchmark is not discussed in this paper. Instead, the paper is concerned with the issue of providing access to anti-retroviral drugs, which are either administered to prevent HIV infection, or, if administered in the latter stages of the progression of the HIV virus (usually in stage four), to combat the virus and ensure the stabilisation of an individual's CD4 count.

Anti-retroviral drugs can also be administered to individuals who might have been exposed to the virus in order to lower the chances of HIV infection. In such cases patients are usually given one dose or a short course of a particular anti-retroviral drug. When anti-retroviral drugs are administered as a treatment option, a patient is usually required to take a combination of at least three drugs. This therapy, usually referred to as Highly Active Anti-Retroviral Therapy (or HAART),²⁰ is capable of completely suppressing the replication of the virus within an HIV positive individual. With successful HAART treatment, the individual's immune system recovers with a consequent significant improvement in survival rates and life expectancy.²¹ HAART treatment is not appropriate for all people living with HIV and is usually only prescribed for individuals whose CD4 count has dipped below the 350 mark.

3 THE CONSTITUTIONAL COURT AND THE RIGHT OF ACCESS TO HEALTH CARE

3.1 Introduction

The state's constitutional duty to provide individuals with access to anti-retroviral drugs to prevent the transmission of HIV or to prevent the replication of HIV in the blood of a person living with HIV/AIDS, derives mainly from the right of access to health care services guaranteed in section 27 of the Bill of Rights.²² The Constitutional Court has had the opportunity to consider the scope and content of section 27 on two previous occasions.²³ The Court has also provided extensive analysis of the nature of the duties that social and economic rights place on the state in the case of *Government of the Republic of South Africa and Others v*

²⁰ Hoffmann, *supra* note 11, par 13.

²¹ *Ibid.* See also US Health and Human Services, *supra* note 19.

²² S 27 states:

- (1) Everyone has the right of 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.
- (3) No one may be refused emergency medical treatment.

²³ *Soobramoney v Minister of Health, KwaZulu-Natal* 1998 (1) SA 765 (CC), 1997 (12) BCLR 1696 (CC) (hereafter *Soobramoney*); *Minister of Health and Others v Treatment Action Campaign and Others* 2002 (5) SA 721 (CC), 2002 (10) BCLR 1033 (CC) (hereafter *TAC*).

Grootboom and Others.²⁴ These judgments confirm that the right of access to health care services protected in section 27 of the Constitution is clearly justiciable.²⁵ It also confirms that the constitutionality of state action or inaction must not be measured in the abstract, but in the light of the specific social and historical context of South Africa.²⁶ This context is one that recognises inequality and the vast disparities in wealth between rich and poor. Any understanding of the state's obligation to provide access to health care must therefore be rooted in an understanding that the Constitution contains a commitment to address inequality, poverty and unemployment in order to "transform our society into one in which there will be human dignity, freedom and equality", and that this "lies at the heart of our new constitutional order".²⁷

This means that in evaluating whether state action or inaction in providing access to anti-retroviral drugs will constitute an infringement of section 27, one has to take cognisance of:

- the fact that many of South Africa's poorest citizens have little or no access to health care services, while many of the richest citizens have access to some of the best health care facilities in the world;
- the fact that newly born children of poor parents do not have immediate access to life saving medicine; and
- the magnitude of the HIV/AIDS crisis in South Africa and the disproportionate effect of this epidemic on the poor and marginalised sections of the community.

It is clear that the nature of the state's obligations in providing access to health care in the HIV/AIDS field will be influenced by the severity of the crisis and the seriousness of the consequences of a failure to act appropriately. What might have been reasonable and acceptable in an ordinary health crisis may become completely unreasonable – even irrational – in the face of a health crisis on the scale of that now facing South Africa as a consequence of HIV/AIDS.

It is with reference to this specific context that I shall now distil the basic principles enunciated by the Constitutional Court regarding the enforcement of the right of access to health care.

3.2 The duties engendered by the right of access to health care services

3.2.1 *Negative obligation on the part of the state and other role players to respect the right of access to health care*

Section 27 places a negative obligation on the state and other relevant role players to desist from preventing or impairing the right of access to

24 *Government of the Republic of South Africa and Others v Grootboom and Others* 2001 (1) SA 46 (CC), 2000 (11) BCLR 1169 (CC) (hereafter *Grootboom*).

25 *Ex parte Chairperson of the Constitutional Assembly: In Re Certification of the Constitution of the Republic of South Africa*, 1996 (10) BCLR 1253 (CC) par 78.

26 *Grootboom*, *supra* note 24, par 25; *TAC*, *supra* note 23, par 24.

27 *Grootboom*, *ibid* quoting from *Soobramoney*, *supra* note 23, par 8.

health care services.²⁸ Any action by the state that takes away existing access to health care services or makes it more difficult for an individual to gain access to existing health care services, would thus potentially result in an infringement of this right. In the context of providing access to anti-retroviral drugs for all people exposed to HIV or people living with HIV/AIDS, any action by the state to, say, prohibit doctors in either the public or private health sector from dispensing a specific anti-retroviral drug would constitute a *prima facie* infringement of the right.²⁹ The negative aspect of this right is further spelt out in section 27(3), which states that no one may be refused emergency medical treatment. A person who suffers a sudden catastrophe – such as rape, for example – that carries with it a threat of contracting HIV and that calls for immediate medical attention, should thus not be refused treatment where such treatment can be provided and is necessary to stabilise the patient's condition.³⁰

3.2.2 The positive obligation on the state to protect, promote and fulfil the right of access to health care

Section 27 of the Constitution places a positive obligation on the state and other relevant actors to “protect, promote and fulfil” the right of access to health care services.³¹ What is required is for the state to devise and implement a comprehensive plan to ensure full realisation of the right of access to health care for all.³² This plan cannot merely be aimed at providing individuals with basic medicine, primary health care services and access to hospital care.³³ Following a holistic approach, such a plan must be aimed at providing all South Africans with access to adequate, comprehensive health care that will enable them to live healthier and more productive lives.³⁴ Implicit in this approach is the understanding that the right of access to health care services does not entitle any applicant to *individual* relief in the sense of immediate access to adequate health care.³⁵

28 Certification judgment, *supra* note 25, par 20; *Grootboom*, *supra* note 24, par 34; *TAC*, *supra* note 23, par 46.

29 See, for example, the recent case where an NGO that provided voluntary counselling and testing and anti-retroviral drugs to rape survivors was evicted from a state hospital in Nelspruit. Yende 2001 “Health MEC evicts anti-rape activists” <www.iol.co.za/general/news/newsprint.php?art_id=ct20010512174013225R136168> 12 May. Accessed 17 March 2002.

30 In *Soobramoney* the Constitutional Court made clear that “emergency medical treatment” does not refer to any ongoing medical treatment for someone whose life is not immediately being threatened. Rather, it ensures that a person is treated in case of a medical emergency. *Soobramoney*, *supra* note 23, par 18 and 20.

31 See s 7(2) which states that the state “must respect, protect, promote and fulfil the rights in the Bill of Rights.”

32 *Grootboom*, *supra* note 24, par 38.

33 *Ibid* par 35, where the Court stated that the right of access to housing “requires more than brick and mortar.”

34 In the context of HIV/AIDS, what is required is access to primary health care services, to information about HIV, to voluntary testing and counselling facilities, to provision of anti-retroviral drugs, etc.

35 *Grootboom*, *supra* note 24, par 94–95.

When devising and implementing this plan, the state must take cognisance of the conditions and capabilities of people of all economic levels of our society.³⁶ Those who can afford to pay for health care should do so themselves, but where people have no money to pay, the state has a duty to take steps to unlock the system through legislation and other measures. The state must address the needs of both those who can afford health care and those who cannot. More importantly, the “poor are particularly vulnerable and their needs require special attention”.³⁷

However, the state’s obligation in this regard is not unqualified. The extent of the state’s obligation is defined by three key elements set out in section 27(2), namely:

- (1) whether legislative or other measures are reasonable;
- (2) progressive realisation of the right; and
- (3) to do so within available resources.

(1) The state must take reasonable legislative and other measures

Courts must enquire whether the steps taken by the state to meet its constitutional obligations imposed by section 27 are reasonable. Such steps will be reasonable where they are based on coherent and comprehensive policies and programmes that are reasonable both in their conception and implementation.³⁸ A reasonable plan might include the adoption of legislation invariably supported by appropriate, well-directed policies and programmes implemented by the executive. Such programmes must be determined by all three spheres of government and each sphere of government must accept responsibility for the implementation of particular parts of the programme. However, the national sphere of government must assume responsibility for ensuring that the laws, policies, programmes and strategies are adequate to meet the state’s obligations.³⁹ Such programmes must be capable of facilitating the realisation of the right and must be reasonable both in their conception and their implementation. The programmes must be “balanced and flexible”. One that “excludes a significant segment of society cannot be said to be reasonable”.⁴⁰ To be reasonable, measures cannot leave out of account the degree and the extent of the denial of the right they endeavour to realise. Those whose needs are the most urgent and whose ability to enjoy all rights are most in peril, must not be ignored by the measures aimed at achieving the realisation of the goal. Where measures, though statistically successful, fail to respond to those most desperate, they may not pass the test of reasonableness.⁴¹

(2) Progressive realisation of the right

The second requirement of progressive realisation signals that the right cannot be realised immediately. The state is nevertheless under a duty to

³⁶ *Ibid* par 35.

³⁷ *Ibid* par 36; TAC, *supra* note 23, par 70.

³⁸ Grootboom, *supra* note 24, par 42.

³⁹ *Ibid* par 40.

⁴⁰ *Ibid* par 43; TAC, *supra* note 23, par 68.

⁴¹ Grootboom, *supra* note 24, par 44; and TAC, *supra* note 23, par 68

begin to take steps immediately to progressively facilitate access to health care services as expeditiously and effectively as is reasonably possible. In effect this means that legal, administrative, operational and financial hurdles towards realising the right should be examined and, where possible, lowered over time. Health care must thus be made more accessible not only to a larger number of people, but also to a wider range of people as time progresses.⁴² Any deliberate retrogressive measures in that regard would also require the most careful consideration and would need to be fully justified by reference to the totality of the rights provided in the Bill of Rights.⁴³

(3) Resource constraints

To determine whether the state's action or inaction is reasonable, one has to take into account the resources available to realise the right in question. There always has to be a balance between goal and means. The measures have to be calculated to attain the goal expeditiously and effectively, but the availability of resources will always be an important factor in determining what was reasonable in a particular case.⁴⁴ While it would be inappropriate for the Court to make orders directed at rearranging budgets, a determination of the unreasonableness of state action or inaction might well have budgetary implications.⁴⁵ Where resources are clearly insufficient to attain any meaningful access to certain forms of health care, a lack of action on the part of the state may be found to be reasonable, compared with cases where the resource constraints are less severe.

4 HIV/AIDS, ANTI-RETROVIRAL DRUGS AND THE STATE'S RESPONSE TO HIV/AIDS EPIDEMIC

4.1 Introduction

Anti-retroviral drugs can be used in at least two distinct ways. First, they can be used to prevent the transmission of the HIV virus in cases where individuals have been exposed to it in various circumstances. Second, anti-retroviral therapy can be administered to HIV positive individuals at an advanced stage of the progression of the HIV virus to suppress HIV viral activity and thus to prolong and improve the person's quality of life. In the following sections I deal with these two distinct issues separately, first mapping out the steps that the state has taken in providing access to anti-retroviral drugs in various situations and then evaluating these steps with reference to their Constitutional duties as set out in the previous section of this paper.⁴⁶

42 *Grootboom*, *supra* note 24, par 44.

43 *Ibid* par. 45.

44 *Ibid* par 46.

45 *TAC*, *supra* note 23, par 38.

46 The government's policy is in flux and it is sometimes difficult to ascertain its exact nature and the steps taken to implement it. On 17 April 2002 – after the completion of a first draft of this paper – the Cabinet issued a statement in which it seems to indicate that several changes in government policy were in the pipeline. This statement was

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4.2 Anti-retroviral therapy and the *prevention* of HIV infection

4.2.1 *Exposure of medical personnel to HIV*

(a) State response

Health care workers are often exposed to HIV in the course of their duties and therefore often risk becoming HIV positive. Those whose work involves blood collection or the use of sharp instruments such as needles, the insertion of intravenous catheters or minor or major surgery, are at increased risk of exposure to HIV. Although the risk is relatively low, the Department of Health has laid down clear guidelines to deal with it.⁴⁷ According to the guidelines, the most effective way of dealing with high-risk exposure is to administer a combination of anti-retroviral drugs within an hour or two after exposure.⁴⁸ To avoid delays in starting this treatment, the guidelines recommend that starter packs of the relevant drugs be made available in all health care settings. The guidelines also recommend that treatment be continued for up to four weeks after the incident. The policy also requires that supportive counselling be made available to the exposed health care worker.⁴⁹

It is unclear whether the relevant drugs are always available in all health care settings. Anecdotal evidence suggests that adequate and appropriate storage facilities are not available at all state health care facilities and that the policy has not been implemented at some rural clinics.

(b) Evaluation of the state's response

Health care workers are in a special position, distinguishable from other people exposed to HIV. First, they are employed by the state and put themselves in harm's way in the ordinary course of their duties. Second, they form a relatively small group and the cost of providing them with access to anti-retroviral drugs is therefore minimal. Given this context, a failure by the state to formulate and implement a policy providing health care workers exposed to HIV access to anti-retroviral drugs could well be considered unreasonable in the terms contemplated by section 27. This does not mean that the state is failing in fulfilling its constitutional duty if its policy does not provide every health care worker in the public health sector with access to a prophylactic regime of anti-retroviral drugs. After

elaborated upon in a statement of 9 October 2002. I shall attempt to provide an overview of the changing government policy before evaluating it in detail. See South Africa Government Online 2002a "Cabinet statement on HIV/AIDS" <www.gov.za/speeches/cabinetAIDS02.htm> Accessed 17 April 2002; and South Africa Government Online 2002b "Continuity and change in HIV/AIDS policy" <www.gov.za/projects/hiv/hivpolicy02apr.htm> Accessed 17 April 2002.

47 Department of Health 1999 "Management of occupational exposure to HIV" <<http://196.36.153.56/doh/AIDS>> Accessed 20 April 2002.

48 The drugs prescribed by the guidelines are Zidovudine (AZR) administered in combination with Lamivudine (3TC). It is recommended that Indinavir be added for very high risk exposures, for example where high volumes of blood are involved, where a deep injury has occurred and if the source patient has been on Zidovudine for longer than six months. See Department of Health 1999, *supra* note 47, 10-11.

49 *Ibid* 11.

all, the right in section 27 is not an individual right but a right to a reasonable policy reasonably implemented.

Thus, what is required is for the state to conceptualise and implement a flexible and comprehensive policy that will allow an ever-increasing number of health care workers an ever-widening access to anti-retroviral therapy after exposure to the virus.

At present, all available evidence suggests that such a reasonable policy does exist and that it is being implemented reasonably, given the limited resources available for health care in South Africa. However, this conclusion does not mean that the state has no further duty to improve the access of health care workers to anti-retroviral drugs. For example, if the state fails to take any further steps to broaden access of anti-retroviral drugs not only to a larger number of health care workers but also to a wider range of workers in terms of their rank and geographical distribution, the reasonableness of its inaction in terms of the Constitution might well become an issue. Furthermore, if the state refuses in future to provide access to anti-retroviral therapy to health care workers exposed to HIV who previously had access to such treatment, this might well give rise to a constitutional issue as such a step might be interpreted as a deliberate retrogressive measure.

4.2.2 Exposure to HIV through sexual assault

(a) State response

A victim of rape or another form of sexual assault runs the risk of being exposed to and infected with HIV. There is strong evidence that survivors of rape or sexual assault can substantially reduce their risk of infection by taking a course of anti-retroviral therapy immediately after the exposure and by continuing treatment for a further two to six weeks. Before the Cabinet statement of 17 April 2002, official state policy prohibited the provision of anti-retroviral drugs in state hospitals to the survivors of sexual assault.⁵⁰ In at least one province – Mpumalanga – the MEC for health went further, evicting a volunteer NGO from state hospital premises for providing anti-retroviral drugs such as AZT and 3TC to survivors of rape and sexual assault.⁵¹ The Cabinet statement of 17 April 2002 has brought a change in this position. According to the new policy, in cases of sexual assault, “government will endeavour to provide a comprehensive package of care for victims, including counselling, testing for HIV,

50 See Baloyi S 2001 “Sorry, no drugs here” Independent Online 17 December < www.iol.co.za/general/news/newsprint.php?art_id=ct20011207202014981A61618 > Accessed 13 February 2002; Clarke S 2001 “Ethical war looms after rape-baby AZR row” Independent Online 18 October < www.iol.co.za/general/news/newsprint.php?art_id=ct2001101820274670B00022 > Accessed 13 February 2002.

51 See Yende 2001, *supra* note 29. The MEC argued that the NGO, Greater Nelspruit Rape Intervention Project (Grip) was undermining the ANC, embarrassing the President and poisoning black patients. She also argued that the group was putting her Department in an awkward position because rape survivors elsewhere in the province were demanding anti-retroviral drugs.

pregnancy and STDs".⁵² The policy also provides for counselling for survivors of rape and sexual assault on the uses and dangers of anti-retroviral drugs, and for providing those who so choose with access to the appropriate anti-retroviral drugs in accordance with state guidelines and protocols. The relevant protocols were developed and distributed to provinces by May 2002 and by October of the same year implementation of the programme had started. Additional funding was also provided for additional staff training, testing for HIV and the cost of the drugs themselves.⁵³

(b) Evaluation of the state's response

This change in the state's policy goes a long way towards satisfying the requirements of section 27 of the Constitution. The state now has a comprehensive and coherent policy aimed at progressively providing survivors of rape and other forms of sexual assault with access to anti-retroviral drugs. Because the state health care system lacks the necessary infrastructure,⁵⁴ not all survivors of sexual assault will immediately gain access to the requisite counselling and – where appropriate – anti-retroviral drugs. But the policy provides for the progressive expansion of the programme, and funds have been earmarked for training additional staff and for the cost of the drugs. The policy allows those health care facilities where the requisite capacity already exists to provide the service, thus reversing the illogical and unreasonable aspect of the previous policy.

In the *TAC* case the Constitutional Court confirmed – in the context of a mother-to-child transmission (MTCT) prevention programme – that a policy which prohibited the administration of a potentially lifesaving drug like Nevirapine in the state health care sector, in cases where the cost to the state would be minimal and where the capacity to administer the drug existed, was inflexible and thus unreasonable.⁵⁵ The present policy thus appears adequately flexible to ensure that survivors of sexual assault will progressively gain access to counselling and anti-retroviral drugs.

The only potential problem with the new policy relates to the requirement that access should not only be provided progressively to a larger number of people but also to a wider range of people. Thus, if – over time – the policy succeeds in assisting more rape survivors to gain access to post-rape counselling and to anti-retroviral drugs, but some of the most vulnerable survivors of rape, such as rural women, are completely left behind, then the policy could become problematic and perhaps even unreasonable. In such a case the policy itself might be reasonable but its implementation might be considered to be unreasonable. At this stage, however, it is too early to judge the reasonableness of the implementation of the new policy.

52 See South Africa Government Online 2002a, *supra* note 46.

53 South Africa Government Online 2002c: "Update on Cabinet's statement of 17 April 2002 on fighting HIV/AIDS. 9 October 2002: Lend a hand in the campaign of hope against HIV/AIDS" <www.gov.za/issues/hiv/cabinetAIDS9oct02.htm> Accessed 3 December 2002.

54 Some anti-retroviral drugs must be stored at specific temperatures to ensure their continued efficacy. Health care professionals also need to be trained to ensure that the drugs are administered correctly and safely. Many health care facilities might lack the necessary facilities or the trained staff required to administer the drugs.

55 *TAC*, *supra* note 23, par 80.

4.2.3 MTCT of HIV

(a) The basic facts

MTCT of HIV is the primary source of HIV infection in young children. Over 90% of children living with HIV in South Africa became infected because of the transmission of the virus from their mothers. The transmission of HIV takes place during pregnancy, labour, delivery, or even after childbirth during breast-feeding, but the vast majority of infections occur close to or during delivery, and after childbirth because of breast-feeding.⁵⁶ In the absence of breast-feeding, about two-thirds of infections occur around the time of delivery, with the majority of the remaining infections occurring during the last two months of pregnancy. But in populations where breast-feeding is the norm, it accounts for more than a third of all transmissions.⁵⁷ Other factors – although less important – also increase the risk of MTCT of HIV.⁵⁸ Foetal trauma, for example, and premature birth, may also increase the chances of an infant born HIV negative becoming infected due to breast-feeding.⁵⁹

The number of infants infected with HIV can be significantly reduced by providing at least one dose of an anti-retroviral drug like Nevirapine to a pregnant mother during childbirth and to the infant shortly after birth.⁶⁰ In addition to the use of anti-retroviral drugs, prevention of MTCT requires voluntary counselling, testing and various support services. UNAIDS has also stressed that providing mothers with formula feed as a substitute for

56 Department of Health 2000c "Prevention of mother-to-child HIV transmission and management of HIV positive pregnant woman" <<http://196.36.153.56/doh/AIDS/>> p 5.

57 Joint United Nations Programme on HIV/AIDS 2000 "UNAIDS technical update Mother-to-child transmission of HIV" <www.unaids.org/publications/documents/mtct/MTCT_TU4.doc> Accessed 21 March 2002.

58 These are: the immune status of the mother, the viral load of the mother, vitamin A deficiency, behavioural factors such as cigarette smoking, drug taking and unprotected intercourse during pregnancy, placenta infections, and the mode of delivery of the baby. See Department of Health 2000c, *supra* note 56, 6–7.

59 *Ibid* 7.

60 See Connor *et al* 1994, Lindergrén *et al* (1999); Guay *et al* 1999: 354. The provision of anti-retroviral drugs to HIV positive mothers during pregnancy and at birth has become part of the generally accepted package of minimum care for treatment of HIV positive pregnant mothers all over the world. Thus, UNAIDS recommends that the "minimum standard package of care" for the treatment of HIV positive mothers and their children should include, in the first instance, preventative interventions in the form of some form of anti-retroviral drug. It recognises that the benefit of decreasing MTCT by administering such anti-retroviral drugs "greatly outweighs any theoretical concerns related to development of drug resistance." UNAIDS acknowledges that it is not advisable to prescribe the regimen to be adopted, and thus allows for a choice to be made in the context of regional variations, particularly in respect of the availability and quality of antenatal care, affordability and concerns relating to practical implementation. See UNAIDS 2000 "Press release 2000: Preventing mother-to-child HIV transmission: Technical experts recommend use of antiretroviral regimens beyond pilot projects" <www.unaids.org/whatsnew/press/eng/geneva251000.html> 25 October. Accessed 15 February 2002. See also Treatment Action Campaign (TAC) 2001a "Bredell consensus statement on the imperative to expand access to anti-metoviral (ART) medicines for adults and children with HIV/AIDS in South Africa" <www.tac.org.za> 19 November. Accessed 12 February 2002.

breast milk will further lower the transmission rate, but the absence of such a programme will not nullify the effects of an anti-retroviral programme.⁶¹

Although research has shown that some of these regimes are more effective than others, the most pertinent programme for South African use is associated with the drug marketed under the name Nevirapine by the pharmaceutical company, Boehringer Ingelheim. Nevirapine has been registered by the Medicines Control Council for use to reduce the risk of MTCT of HIV intrapartum – that is, in the mother's womb before delivery. Moreover, there is ample evidence that the drug could have some success even without administering it in courses over weeks or even months.

(b) The state response

Until the handing down of the Constitutional Court judgment in the *TAC* case, the state's policy towards the prevention of MTCT of HIV was confusing and difficult to ascertain. The policy established 18 'research sites' – two in each province – where Nevirapine would be provided to HIV positive pregnant mothers at childbirth,⁶² reaching about 10% of pregnant mothers in South Africa. The pilot sites were launched to assess the operational challenges inherent in introducing an anti-retroviral regimen for the reduction of vertical transmission in both rural and urban settings in South Africa. There was some confusion on behalf of the state about whether the sites were also launched to investigate the efficacy of Nevirapine.⁶³ However, the policy placed an absolute ban on health care professionals in state health care facilities other than the 18 pilot sites from administering Nevirapine to HIV positive pregnant mothers.⁶⁴ This meant that mothers and their babies who could not afford private health care and did not have access to one of the pilot sites, could get no access to anti-retroviral treatment.⁶⁵

This policy was challenged in the *TAC* case, where the Constitutional Court rejected the arguments put forward by the Ministry of Health and found the policy regarding MTCT of HIV to be unreasonable and thus unconstitutional. First, the state argued that it could not provide Nevirapine outside the pilot sites because of:

- the lack of evidence regarding the efficacy of the drug;
- the fear that the use of Nevirapine would lead to resistance in subjects;
- fears about the safety of the drug; and
- a lack of capacity to administer the drug in all state hospitals.⁶⁶

61 UNAIDS 2000, *supra* note 60. The UNAIDS recommendations insist that the woman herself should make the decision regarding breast-feeding, after receiving information on the risks and benefits of various feeding options and taking the specifics of her circumstances into consideration. If breast-feeding is indeed chosen, exclusive breast-feeding for the first months of life is recommended, to be discontinued when alternative forms of feeding become feasible.

62 Department of Health 2001b, *supra* note 12, par 1.3 See also Smith 2001 and Mail & Guardian 2001.

63 See Business Day (2001).

64 See *TAC*, *supra* note 23, par 10-11

65 *Ibid* par 17.

66 *Ibid* par 51-54.

The Court rejected these reasons on the basis of evidence provided by, among others, the representatives of the state itself,⁶⁷ and stated that the only question to be answered was whether or not the policy of confining Nevirapine to research and training sites was reasonable.

The Court found that the policy was indeed unreasonable because it failed to address the needs of those mothers and their newborn children with no access to pilot sites. The policy failed to distinguish between the evaluation of programmes for reducing MTCT and the need to provide access to health care services required by those who do not have access to the sites.⁶⁸ The policy was therefore unreasonable because it was not balanced and flexible and it excluded a significant segment of society.⁶⁹

The state had not provided any cogent and reasonable explanation for their inflexible and unbalanced policy, considering that:

- the case was concerned with newborn babies, whose lives might be saved by the administration of Nevirapine to mother and child at the time of birth;
- the safety and efficacy of the drug for this purpose had been established;
- the drug was being provided by the state itself to mothers and babies at pilot sites;⁷⁰ and
- the administration of Nevirapine is a simple procedure.⁷¹

Furthermore, the Court pointed out that the right of access to health care had to be read with the right of children to family care or parental care and the right to basic health care services as set out in sections 28(1)(b) and (c). While the primary duty to provide basic health care services rests on those parents who can afford to pay for such services, the state policy had to address the needs of those children whose parents could not afford to do so. Echoing wording in the *Grootboom* judgment, the Court in the TAC case held that:

Their needs are 'most urgent' and their inability to have access to Nevirapine profoundly affects their ability to enjoy all rights to which they are entitled. Their rights are 'most in peril' as a result of the policy that has been adopted and are most affected by a rigid and inflexible policy that excludes them from having access to Nevirapine.⁷²

The Court argued that the second question – whether the state had a comprehensive plan to combat MTCT of HIV – was intertwined with the refusal to permit Nevirapine to be prescribed at public hospitals and clinics outside the research sites.⁷³ After evaluating the relevant evidence, the Court found the measures taken by the state in respect of the prevention of MTCT of HIV were unreasonable. Although health services in South Africa are over-extended and although HIV is just one of many illnesses

⁶⁷ *Ibid* par 57–66.

⁶⁸ *Ibid* par 67.

⁶⁹ *Ibid* par 68.

⁷⁰ *Ibid* par 72.

⁷¹ *Ibid* par 73.

⁷² *Ibid* par 78.

⁷³ *Ibid* par 82.

that require attention, the HIV pandemic is of such a serious nature that the state has a constitutional duty to act. The Court held as follows:

The rigidity of government's approach when these proceedings commenced affected its policy as a whole. If, as we have held, it was not reasonable to restrict the use of Nevirapine to the research and training sites, the policy as a whole will have to be reviewed. Hospitals and clinics that have testing and counselling facilities should be able to prescribe Nevirapine where that is medically indicated. The training of counsellors ought now to include training for counselling on the use of Nevirapine. As previously indicated, this is not a complex task and it should not be difficult to equip existing counsellors with the necessary additional knowledge. In addition, government will need to take reasonable measures to extend the testing and counselling facilities to hospitals and clinics throughout the public health sector beyond the test sites to facilitate and expedite the use of Nevirapine for the purpose of reducing the risk of mother-to-child transmission of HIV.⁷⁴

The Court therefore ordered the state:

- to immediately remove the restrictions preventing Nevirapine from being made available for the purposes of reducing MTCT of HIV;
- to permit and facilitate the use of Nevirapine for the purpose of reducing the risk of MTCT of HIV;
- to make provision if necessary for counsellors based at public hospitals and clinics other than the pilot sites to be trained for the counselling necessary for the use of Nevirapine to reduce the risk of MTCT of HIV; and finally,
- to take reasonable measures to extend the testing and counselling facilities at hospitals and clinics throughout the public health sector to facilitate and expedite the use of Nevirapine for the purpose of reducing the risks of MTCT of HIV.⁷⁵

The Court stressed that these orders did not preclude the state from adapting its policy in a manner consistent with the Constitution if equally appropriate or better methods became available to it for the prevention of MTCT of HIV. At the same time the Court also made clear that the order did not leave the state with a choice as to which hospitals and clinics should be 'allowed' to prescribe Nevirapine. The choice was left in the hands of the medical practitioners acting in consultation with the medical superintendent of the facility concerned.

The Constitutional Court judgment was pre-empted to some degree by an announcement by the Cabinet on 17 April 2002 that signalled an apparent change of heart on the part of the state. This statement confirmed that the state would begin to provide anti-retroviral drugs to HIV positive pregnant women as required by the High Court judgment. It also stated that "where there is capacity to provide the package of care that is needed, *and where the demands of research dictate*, [pilot] sites are being extended". The statement also indicated that towards the end of 2002, tests would be done on the babies while mothers would be monitored,

74 *Ibid* par 95.

75 *Ibid* par 135.

and the results would determine whether the state would move to provide universal access of Nevirapine. A universal roll out plan in this regard was being worked on and would be released in due course.⁷⁶ This statement was followed up by another Cabinet statement on 9 October 2002 in which the state confirmed that, following the Constitutional Court ruling, all provinces had been provided with guidelines for the implementation of the Prevention of Mother-To-Child Transmission (PMTCT) package. According to the statement, provinces would “expand the services according to their differing capacities, but training is already in progress in all provinces to broaden access to Nevirapine”.⁷⁷ The statement suggested that no universal roll out was envisaged in the near future and that each province would gradually broaden access to Nevirapine as facilities, budgets and human capacity allow.

(c) Evaluating the state’s response

The state’s response to the *TAC* judgment suggests that it has changed its policies regarding the prevention of MTCT of HIV to fall in line with the requirements set out by the Court. It has provided provinces with guidelines for implementing MTCT prevention programmes. However, it is left to each individual province to devise and implement a roll out plan, taking into account its own capacity. The national government will only play a monitoring role in overseeing the implementation of this plan. It has lifted the ban on providing Nevirapine outside the pilot sites and is overseeing the training of counsellors. The policy therefore appears less rigid and more balanced and flexible and is beginning to address the needs of those most at peril. On the face of it, the policy and the steps taken so far to implement it seem, at the time of writing, to be reasonable and in line with the state’s constitutional duties as set out by section 27.

However, as *Grootboom* made clear, the national government has the final responsibility for ensuring that the action taken is adequate to meet the state’s constitutional requirements. The fact that individual provinces are left to devise their own roll out plans may therefore become problematic where implementation of the programme in individual provinces falls short of what is constitutionally required. An ongoing evaluation of the state’s programme will therefore have to focus on the way in which the programme is implemented in the various provinces. While KwaZulu-Natal and the Western Province have extended coverage to a significant number of pregnant women, other provinces, such as Mpumalanga and the Eastern Cape, are lagging behind.⁷⁸ It will be recalled that the reasonableness of the state’s response will be assessed not only with reference to the formulation of the plan, but also its implementation. The state’s response will also fall short where it broadens access of pregnant women to Nevirapine, but fails to address the needs of those most in need. If provinces such as the Eastern Cape and Mpumalanga fail to make significant

76 South Africa Government Online (2002a), *supra* note 46.

77 South Africa Government Online (2002c), *supra* note 53.

78 SABCnews 2002 “TAC calls on Mpumalanga to roll out Nevirapine” <www.sabcnews.com/south_africa/health/0,1009,48419,00.html> Accessed 17 January 2003.

progress with the design and implementation of programmes to prevent MTCT within a reasonable period of time, such inaction may well give rise to further constitutional complaints, including possible contempt of court charges.⁷⁹ It would then have to be established whether these provinces are failing to take constitutionally mandated reasonable steps to provide access to Nevirapine to HIV positive pregnant women and their unborn children. Such failure could either involve not extending access to women and children who are most in need, or not devising and implementing a balanced and flexible programme that would allow for extension over time.

4.3 Access to anti-retroviral therapy and the treatment of HIV positive individuals

4.3.1 *The background facts*

South Africa's ability to deal effectively with the human drama unfolding in the light of the spiralling HIV/AIDS crisis will depend, to a large degree, on whether the majority of those living with the virus are able to gain access to essential drugs for both inhibiting the virus and treating the opportunistic infections associated with it.⁸⁰ All available credible evidence indicates that HAART anti-retroviral therapy can improve and prolong the quality of life of most people living with HIV/AIDS. People living with HIV do not generally become prone to opportunistic infections until HIV progresses to the stage where the CD4+ cells per micro litre of blood drop below 500. When those living with HIV are successfully treated with a cocktail of anti-retroviral drugs, the progression of HIV is dramatically altered. In many cases, this results in a marked improvement in the CD4+ count with a concomitant improvement in the survival rate and in life expectancy. Successful treatment leads to a prolonged and healthier life along with a reduction in vulnerability to opportunistic infections.

The Department of Health guidelines indicate that while people who suffer from opportunistic infections related to HIV will be treated in state hospitals, they will not be provided with any access to anti-retroviral drugs.⁸¹ HAART therapy is therefore only available to individuals with access to private health care and the means to pay for it.⁸² In this section of the paper I will explore if and how the state could broaden access to HAART therapy for those who need it. I will first look at the state's current response before evaluating it in the light of the state's constitutional commitments.

79 TAC 2002 "TAC launches urgent contempt of court application against Mpumalanga Health MEC" <www.tac.org.za/newsletter/ns17_12_2002.html> Accessed 17 January 2003.

80 Whiteside *et al* 2000: 66.

81 Department of Health 2001b, *supra* note 12, par 2.1.

82 *Ibid* par 2.2. Even individuals who have access to medical aid cannot always afford HAART therapy. When these drugs were first introduced, the cost for South Africans who could afford it was around R4 000 per month. At present the cost for such treatments is between R600 and R1 000 per month. See Black 2001.

4.3.2 *The state's response*

The state has endorsed the view that anti-retroviral treatments can help improve the condition of people living with HIV/AIDS. At the same time it has pointed out that these drugs are, at present, too costly for universal access, while incorrect use of them could cause harm.⁸³ In its statement of 17 April 2002, the Cabinet committed itself to "continue to work for the lowering of the cost of these drugs".⁸⁴ In October it confirmed that the ultimate objective was to ensure that all South Africans living with AIDS could have access to the treatment they needed under conditions that would benefit them.⁸⁵ In order to achieve this goal, the state would need to strengthen the health care system while also taking steps to lower the cost of drugs, the single biggest barrier to cheaper prices being the strict enforcement of patents.⁸⁶ Where this enforcement takes place, drug companies are free to charge the prices they wish. In the absence of drastic state intervention the prices of life-saving drugs – including anti-retrovirals – will thus remain out of reach of most South Africans.

The state took the first steps towards lowering the costs of drugs in 1997 when it adopted the Medicines and Related Substances Amendment Act.⁸⁷ This legislation amended the Medicines Act, allowing the introduction of three measures that would be important in bringing down the price of drugs. First, the amendments made provision for the generic substitution of off-patent medicines and medicines imported and produced under compulsory licenses. This means the Act compels pharmacists to prescribe a cheaper generic version of a medicine, if one exists, when presented with a prescription by a patient. Generic medicines are

83 South Africa Government Online 2002c, *supra* note 53. For a discussion of additional barriers, see Rozek *et al* 1999: 81). The authors argue that "in many instances, the prices of pharmaceuticals are not the cause of access problems. If the patient does not have access to a physician, or lacks accurate information, prices are irrelevant." While the affordability of drugs is clearly not the only barrier to effective treatment, what remains clear is that, for as long as drugs remain out of reach for most people with HIV/AIDS, governments have little incentive to put systems in place to deal with efficient distribution and strict compliance with often complicated drug-taking regimes. Further, for as long as drugs remain inaccessible, the debate about health system infrastructure remains purely academic. In addition, for many people with HIV/AIDS high drug prices are the only or at least most important obstacle in the way of access to treatment. Of course, one may also argue that any comprehensive and adequate programme to progressively provide access to HIV/AIDS treatment and care programmes will act as a catalyst to the development of health infrastructure. This is an important point, but cannot be discussed further in the context of this paper.

84 South Africa Government Online 2002a, *supra* note 46.

85 South Africa Government Online 2002c, *supra* note 53.

86 Brazil remains the clearest example of this point. For further information on the correlation between weaker patent protections and increased access to essential drugs, see Rosenberg 2001. The pharmaceutical industry argues that patents are not the problem with access to AIDS drugs in the developing world because the infrastructure is not available and circumstances are too chaotic to make drug delivery realistic. But this is a simplistic view, especially in a country like South Africa where the required infrastructure does exist in many places.

87 Act 90 of 1997 amending the Medicines and Related Substances Control Act 101 of 1965.

usually produced when the patent on a drug has lapsed. As most anti-retroviral drugs are still protected by patent, this provision will not have any great effect on the cost of anti-retroviral drugs.⁸⁸ Second, the Act amended the Medicines Control Act to allow for the parallel importation of patented medicines.⁸⁹ This measure allows the state to import patented medicines from countries where they are sold at a lower price than in South Africa. Because pharmaceutical companies do not charge the same price for identical drugs in different countries, this section would allow the state to import patent-protected drugs from countries like India and Brazil, for example, at a cheaper price than the relevant pharmaceutical company charges in South Africa.

Third, the amendments provide for a transparent medicine pricing system through the establishment of a pricing committee. This section requires pharmaceutical companies to justify the prices they charge and empowers the pricing committee to make recommendations to the Minister of Health on the introduction of a transparent pricing system.⁹⁰

All three provisions were challenged by 39 pharmaceutical companies in the Transvaal Provincial Division of the High Court towards the end of 2000, in *The Pharmaceutical Manufacturers' Association and Others v The President of the Republic of South Africa and Others*.⁹¹ The pharmaceutical companies challenged the constitutionality of the three provisions of the Act as set out above, *inter alia*, on the basis that they infringe on the right to property protected in section 25 of South Africa's Constitution. Under severe public pressure in South Africa and the rest of the world, the companies abandoned their case and in effect agreed that the state had a right to implement the provisions set out above.⁹² At the time of writing, the state had not yet issued regulations to make these sections of the amendments operative and had therefore neither started to import cheaper patented drugs from elsewhere nor begun to regulate the pricing of drugs. Nor had it taken any other tangible measures in any attempt to bring down the prices of anti-retroviral and other life-saving drugs.

88 See TAC 2001b "An explanation of the Medicines Act and the implications of the court victory" <www.tac.org.za> 24 April. Accessed 26 April 2001. While many key anti-retroviral drugs used in the fight against HIV/AIDS are still subject to patent protection for a number of years, the patents on others, such as Pfizer's Diflucan (fluconazole) and Glaxo SmithKline's Retrovir (zidovudine or AZT), are nearing expiration.

89 Act 90 of 1997, s 15C.

90 *Ibid* s 22G.

91 *The Pharmaceutical Manufacturers' Association and Others v The President of the Republic of South Africa and Others* Case no. 4183/98, High Court of South Africa (Transvaal Provincial Division) March 2001.

92 It has been argued that this withdrawal by the pharmaceutical companies was a good tactical move as the amendments they had challenged – including the amendment that would provide for parallel importing of cheaper drugs from elsewhere – were not particularly threatening to their profits and interests. What pharmaceutical companies fear most, so the argument goes, is legislation that allows for the issuing of compulsory licences by the state to enable other manufacturers to manufacture patented drugs. Rosenberg 2001.

4.3.3 *Evaluation of the state's response*

South African courts will be hesitant to interfere with the state programme to extend access to anti-retroviral treatment to all South Africans who need it – even where the steps taken by the state seem uninspiring and lacking in urgency. Providing access to HAART-type treatment is a complex issue, requiring a nuanced and well thought out response from the state. Any such programme will also have enormous implications for the allocation of resources by the state. It would therefore be difficult – but not impossible – to demonstrate failure by the state in its constitutional duty to take reasonable steps to progressively provide access to HAART therapy to a larger number and a wider range of people living with HIV/AIDS.

When evaluating state action or inaction, one will have to address at least three interrelated aspects in order to begin to make a case that the state has failed to take reasonable measures to provide access to health care in terms of section 27 of the Constitution. First, one will have to demonstrate that, given the state's wide array of health commitments, special emphasis should be placed on the provision of HAART therapy. Second, one will have to show that the latent capacity exists in at least part of the public health system to oversee the implementation of such a system and provide support to ensure the continued success of such therapy. Third, one will have to determine whether the cost of providing access to anti-retroviral therapy to all people living with HIV in South Africa, who are unable to afford it, would be within the state's available resources. I will deal with these three issues separately in the following sections.

(a) *The importance of HAART therapy*

Given the serious personal and public consequences of the HIV/AIDS epidemic, the life-prolonging nature of HAART therapy and the mitigating effect of HAART therapy on the burgeoning social problems associated with the epidemic – such as the problems associated with taking care of AIDS orphans – it will not be too difficult to demonstrate the therapy's importance. As the introduction of HAART therapy will literally prolong the lives of hundreds of thousands of South Africans, who will thus remain economically productive and capable of taking care of their loved ones, HAART therapy becomes a life or death issue. The importance of HAART therapy can furthermore be illustrated with reference to international human rights law. In its General Comment No. 14, the United Nations Committee on Economic, Social and Cultural Rights (CESCR) set out “core obligations” for states parties in relation to the right to “the highest attainable standard of health” protected in article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). One such obligation was to provide all individuals in a state with access to essential drugs, as defined in the World Health Organisation (WHO) essential drugs list.⁹³ This list, updated every two years, sets out those drugs that are considered essential to meet the health care needs of the majority of the

93 General Comment No. 14 (Twenty-second session, 2000) The right to the highest attainable standard of health (art 12 of the Covenant) UN doc. E/C.12/2000/4, par 43 (d).

population and which are supposed to be available at all times in adequate amounts and in appropriate dosage form.⁴⁴ At the 12th meeting of the Expert Committee on the Selection and Use of Essential Medicines, anti-retroviral medicines were included in the essential drugs list and the prescription of combination anti-retroviral therapy was endorsed.⁴⁵ The use of combinations of three to four different anti-retroviral drugs was strongly recommended in treatment guidelines for HIV/AIDS in resource poor settings.

This means that access to HAART therapy becomes part of the 'minimum core' entitlements in international law. Where a court in South Africa is called upon to evaluate the reasonableness of the steps taken by the state in broadening access to anti-retroviral drugs for all South Africans, the fact that the provision of such drugs forms part of the minimum core obligations of a state may have an impact on the assessment of the reasonableness of the state's conduct.⁴⁶ Although the Court did not imply that that minimum core entitlement would affect the burden of proof in order to show the reasonableness of the states' action, it did confirm that it is one of the factors to be taken into account when assessing the reasonableness of the state's response. Reasonableness will have to be assessed with reference to all relevant factors, including those mentioned in the previous paragraph. Taken together, all these factors strongly suggests that the state has a special duty to take steps to provide anti-retroviral drugs to a larger and wider group of those who need it.

(b) Lack of capacity

It is often argued that administering anti-retroviral therapy makes very specific demands on the public health system. As the drugs are only successful if taken at the correct times and in dosages appropriate for the specific patient, a plan aimed at successfully implementing the provision of anti-retroviral drugs to people who are HIV positive will have to have a number of components. These include:

- training health providers on the appropriate use of the drugs;
- provision of laboratory facilities to regularly monitor the effect of the drugs in order to tailor therapy to individual patients;
- establishing the appropriate infrastructure to procure and safely distribute these drugs; and
- creating a supportive environment to facilitate compliance with the therapy by patients.⁴⁷

It is furthermore argued that successfully implementing such an anti-retroviral therapy regime is particularly difficult in a developing country

94 See World Health Organisation (WHO) 2002a "The WHO list of essential drugs (EDL 1999)" <www.who.int/medicines/organization/parledl/infedlmain.shtml> Accessed 22 May 2002.

95 See WHO 2002b "12th Expert Committee on the Selection and Use of Essential Medicines meeting, 15-19 April 2002" <www.who.int/medicines/organization/parledl/expertnotes.shtml> Accessed 22 May 2002.

96 TAC, *supra* note 23, par 34.

97 Department of Health 2001b, *supra* note 12, par 2.2.

like South Africa because many patients are uneducated and will find it difficult to take their medication as prescribed. This can, in turn, lead to toxic side effects and can do patients more harm than good.

Despite the complexity of the various regimens and the many side effects associated with anti-retroviral drugs, and despite the infrastructural requirements, anti-retroviral drugs can play an important role in the effective treatment of people living with HIV and AIDS in South Africa. Data from two major HIV trial sites demonstrate that high levels of adherence are achievable by South African patients. These studies show that levels of adherence were as good as, or better than, that attained in many first world countries.⁹⁸ Furthermore, innovative treatment options are being used for resource-poor settings.

Given these facts, it becomes clear that the state may well have a duty to begin the process of progressively providing access to anti-retroviral therapy to people living with HIV/AIDS. A comprehensive, multi-layered plan is needed, along with steps to ensure its effective implementation. Such a plan must progressively provide access to HAART treatment to people living with HIV and AIDS. Although the state may argue that it would be more reasonable to roll out in areas where infrastructure to monitor usage is more developed, any plan will also have to begin to address the needs of those most vulnerable and least capable of gaining access themselves: poor, black, often female individuals living in rural areas of South Africa. A constitutionally valid plan would have to engage with the issues raised above and would have to begin to address the infrastructure and capacity issues that constitute barriers to the provision of HAART therapy. The state cannot be expected to immediately improve the public health system to the extent that it is capable of providing and overseeing a comprehensive anti-retroviral therapy programme for all those in need. However, it can be expected to factor these problems into planning and budgeting processes to demonstrate that it is taking reasonable steps to gear the public health system towards coping with this national emergency. Failure to do anything would, on its own, be seen as unreasonable and would compromise the constitutionality of the state's health policy. The costs of such improvements to the state's public health capacity are not irrelevant and the Court would probably accord the state a wide margin of discretion in implementing any policy geared towards addressing the national emergency resulting from the HIV/AIDS crisis. However, this does not mean that the state cannot be held constitutionally accountable for a failure to take reasonable steps to improve its capacity to provide anti-retroviral therapy in the public health sector.

In many state hospitals the necessary capacity already exists to provide a full support service to people on anti-retroviral therapy. I therefore conclude that the state has a duty to take steps to progressively extend that capacity to other areas where none exists to ensure that it is equitably distributed. Where especially marginalised and vulnerable people have no chance of gaining access to a state health care facility that does have

98 Abdullah *et al* 2001.

capacity, state action should prioritise those areas. The first requirement is a clear indication that state public health care plans include provision for greater access by all South Africans to health care facilities where anti-retroviral therapy could be provided and monitored. The second is that this plan also targets those most in need of access to treatment.

(c) **The cost of anti-retroviral drugs**

By all accounts the cost of anti-retroviral drug therapy is high.⁹⁹ The Department of Health argues that, at current prices, these drugs are not affordable and hence they have no choice but to stick to the policy of not providing access to anti-retroviral therapy to people living with HIV/AIDS. In legal terms, the argument could be framed as follows: While the state has a duty to take reasonable legislative and other measures to progressively provide individuals living with HIV/AIDS access to health care, anti-retroviral therapy is so expensive that the state cannot afford it at all. It would therefore be senseless to take any measures to progressively provide access to anti-retroviral drugs, as the state will never be able to afford to provide them to all. It would be unfair and unreasonable to provide such drugs only to some people, so it is more equitable not to provide them to anyone. All the state can afford to do is to treat the opportunistic infections that occur due to the weakening of the immune system of individual people living with HIV/AIDS.

There are, however, two lines of reasoning that may be pursued to challenge this view. One relates to the cost effectiveness of anti-retroviral therapy and the other to steps that could be taken to lower the cost of the drugs themselves.

- **The cost effectiveness of anti-retroviral therapy:** It has been argued, quite convincingly, that the provision of anti-retroviral drugs in the public health system will be cost effective as it will bring about vast savings in the costs of treating HIV positive individuals. Two different studies, published in the *New England Journal of Medicine* in March 2001, demonstrate that anti-retroviral drugs can be cost-effective in comparison to the medical treatment of people with full-blown AIDS.¹⁰⁰ Brazil's nationwide anti-retroviral treatment programme is based on the findings that the direct savings achieved in keeping people healthy compensates for the cost of the drugs. These studies are based on the assumption that people who succumb to opportunistic infections will have access to adequate, humane and effective treatment in the public health system, something to which the South African government is committed.¹⁰¹ If it can indeed be conclusively shown that it is cost effective to provide anti-retroviral therapy rather than merely to wait for people to fall ill and then to treat their opportunistic infections, the

⁹⁹ See *supra* note 80.

¹⁰⁰ Freedberg *et al* 2001, Bozzette *et al* 2001.

¹⁰¹ In practice, of course, this policy does not mean that such adequate treatment is actually provided to all who need it. While the Department of Health's policy guidelines provide for such treatment, lack of funds and bad management often lead to a situation where the requisite treatment is not available in state hospitals.

failure to work towards the provision of anti-retroviral therapy for all people who may fall back on the public health system for treatment would clearly be unreasonable, if not irrational. In the context of the life and death choices that these two options present, the unreasonable nature of any failure to act in this regard will become even more apparent.¹⁰²

- **Lowering of drug prices:** While the cost of anti-retroviral therapy is currently very high, the state could take steps to ensure it is lowered. This will enable more middle-income people with access to private health care to access anti-retroviral therapy. It will also reduce the cost of providing anti-retroviral therapy in the public health sector, where it may enable progressive access to such therapy. As indicated above, the biggest stumbling block to providing more people with better access to anti-retroviral therapy remains high drug prices, mainly due to the strict enforcement of patents. There are two interrelated reasons for this: First, domestic laws dealing with patents may be formulated strictly, making it difficult for a country to provide cheaper alternatives to drugs priced at the high end of the market by name-brand pharmaceutical companies. Second, even where governments are willing to weaken patent laws to ensure cheaper medicines, the World Trade Organization (WTO) agreement on intellectual property rights – commonly known as TRIPS¹⁰³ – has strengthened the international protection of such rights to effectively narrow the scope of national patent policies.¹⁰⁴

But the state can take steps within the existing national and international patent law framework to influence the price of drugs. This can be done, first, through direct regulatory mechanisms, including price controls on the sale of pharmaceutical products and the parallel importation of patented products from where they are sold at the lowest international price. This is exactly what the state attempted to do when it passed the amendments to the Medicines Control Act discussed above. However, they have not yet issued the requisite regulations allowing for the parallel importation of cheaper generic versions of drugs.

The existing (amended) legislation allows for action that could drastically reduce the prices of anti-retroviral drugs, and thereby progressively facilitate access to affordable anti-retroviral drugs by individuals living with HIV/AIDS. The state's failure to act in terms of this legislation seems deeply unreasonable. In the absence of credible reasons for this delay, the state's inaction could be found to be in breach of its constitutional duties in terms of section 27.

¹⁰² A similar argument was raised in the *TAC* case, but the Court decided that it was not necessary to deal with it because the government had changed its policies already and had committed substantial additional resources to the treatment of HIV. *TAC*, *supra* note 23, par 120.

¹⁰³ General Agreement on Tariffs and Trade – Multilateral trade negotiations (the Uruguay round): Agreement on Trade-related Aspects of Intellectual Property Rights (15 December 1993), (1994) 33 I.L.M. 81 (TRIPS).

¹⁰⁴ For example, pre-TRIPS Brazil completely excluded pharmaceutical products from patentability. See generally Berger 2001.

Second, drug prices can also be reduced through indirect means. Such indirect price regulatory mechanisms can make use of market processes by introducing real competition in the drugs market in the form of generic manufacturers. This can be done in three distinct ways:

1. The state could take steps to allow for the issuing of compulsory licenses. A compulsory license is an authorisation to use a patent without the patent holder's permission.¹⁰⁵ In most cases, such licences will be issued to other companies who would have to pay an agreed fee to the patent holder for the right to produce a generic version of the drug. However, this fee will be drastically lower than the profit the patent holder drug company would have made otherwise.
2. The state could take steps to allow early working provisions to be put in place. Early working provisions ensure the introduction of generic copies of a patented product to the marketplace as soon as patent protection expires, by permitting certain forms of conduct that would otherwise constitute patent infringement.
3. The state could take steps to exclude certain drugs from patentability. This means the patent law will allow specific drugs to be precluded from being granted full patent protection in the first place in specific, well-defined circumstances such as public health emergencies.

It is unclear whether South African patent law¹⁰⁶ allows for the issuing of compulsory licenses for the production of anti-retroviral drugs. The Patent Act contains a provision that allows for limited opportunities to bypass the patent rights of the patent holder. Article 56 permits abrogation of patents only where:

- the patent is not being worked on a commercial scale or to an adequate extent;
- the demand is not being met adequately;
- the trade or industry of the Republic is being prejudiced; or
- the price for the patented article is excessive compared to its price elsewhere.¹⁰⁷

105 Ford 2000, 942. In the pharmaceutical sector, a compulsory license entitles the licensee to manufacture generic versions of a patented drug or to import such products from where they are legally manufactured, either by the licensee itself or by another generic manufacturer.

106 Patents Act 56 of 1978.

107 Article 56 of the Patents Act states that the rights in a patent shall be deemed to be abused if:

- (a) the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working;
- (b)
- (c) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;
- (d) by reason of the refusal of the patentee to grant a license or licenses upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new

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While the last exception may conceivably be used to justify the issuing of compulsory licences, this might lead to protracted court battles akin to the one fought by 39 pharmaceutical companies against the government regarding the amendments to the Medicines Control Act. In any event, the state has not taken any steps to utilise the patent law in this way as it has so far refused to consider any expansion of these restrictions.

The only possible reason for this lack of action on the part of the state – apart from a lack of political will – is its alleged obligations in terms of international trade law. The TRIPS Accord, an international intellectual property rights agreement to which South Africa is a signatory, imposes minimum standards of intellectual property protection on all signatories.¹⁰⁸ TRIPS also expressly allows for the imposition of weaker patent protection in certain circumstances.¹⁰⁹ Although legal avenues for bypassing patent rights therefore do exist, and have been used by many countries for relatively trivial inventions, there has been strong pressure on developing countries from the pharmaceutical industry not to use these provisions to access generic versions of anti-retroviral drugs. But the recent agreement by the Ministerial Conference of the World Trade Organisation in Doha, Qatar, broke new ground, when representatives decisively confirmed that countries should have a right to make exceptions to the TRIPS agreement, including the issuing of compulsory licenses, if a national emergency exists. According to the agreement, a national emergency includes a public health crisis, such as the one related to HIV/AIDS.¹¹⁰ This Ministerial agreement explains the provisions of article 31 of the TRIPS agreement that do allow for the issuing of compulsory licences if certain criteria are met. A country will therefore comply with its TRIPS obligations even when it issues a compulsory license to manufacture anti-retroviral drugs at prices far cheaper than the prices the original patent holder might have charged, provided that it is acting in accordance with the requirements set out in article 31 and because of a national health emergency. These

trade or industry in the Republic, is being prejudiced, and it is in the public interest that a license or licenses should be granted; or

- (e) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee.

¹⁰⁸ World Trade Organization (WTO) 2000 "Overview: The TRIPS agreement" <www.wto.org/english/tratop_e/trips_e/intel2_e.htm> Accessed 20 July 2001.

¹⁰⁹ See, for example, articles 27, 30 and 31.

¹¹⁰ See article 31 of TRIPS accord read with article 5 of WTO 2002 "Declaration on the TRIPS agreement and public health" <www.docsonline.wto.org> Accessed on 22 April 2002, which states:

- (a)
- (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- (d) The effect of the provisions in the TRIPS agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

requirements centre around the need to utilise the drugs manufactured in terms of the issuing of compulsory licences mainly for the domestic market and to adequately remunerate the original patent holder.¹¹¹ However, the

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- 111 Article 31: Other use without authorization of the patent holder (compulsory licensing).
Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
- (a) authorization of such use shall be considered on its individual merits;
 - (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;
 - (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
 - (d) such use shall be non-exclusive;
 - (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
 - (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
 - (g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;
 - (h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;
 - (i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
 - (j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;
 - (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;
 - (l) where such use is authorized to permit the exploitation of a patent ('the second patent') which cannot be exploited without infringing another patent ('the first patent'), the following additional conditions shall apply:
 - (m) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
 - (n) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

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Doha agreement makes clear that in the case of emergencies, such as the HIV/AIDS crisis, member states have a wide discretion and have the final say about the interpretation of these requirements as long as they act in terms of their own domestic law. This leaves the state with an almost unlimited discretion in issuing compulsory licences, for remuneration as determined by the state.¹¹² The state's failure to make use of these provisions and to take steps to allow for the issuing of compulsory licences for manufacturing anti-retroviral drugs in South Africa is indeed perplexing. It has neither taken steps to shorten the time within which it would become acceptable to manufacture certain generic drugs, nor has it done anything that would allow for the issuing of compulsory licenses for manufacturing anti-retroviral drugs.

The test in terms of section 27, as always, is whether the actions or omissions of the state can be said to be reasonable, given the specific context. Given the catastrophic nature of the HIV/AIDS epidemic and the life and death emergency under which its actions should be judged, it is my contention that the state is not acting reasonably in this regard. Its failure to take steps allowing for the compulsory issuing of licenses to manufacture life-saving anti-retroviral drugs at prices that would make them affordable to all seems, in the present context, not only unreasonable but irrational.

5 CONCLUSION

The state has failed to comply with its obligations to provide South Africans with access to anti-retroviral drugs in several ways. While section 27 of the Constitution does not require the state to provide anti-retroviral drugs to all South Africans on demand, it does require it to take reasonable steps to move towards a situation where all South Africans will have access to such drugs. In doing so, it has a special responsibility to include steps to begin to address the fact that it is the most vulnerable sections of the population – poor people, women, people living in rural areas, black people – who have the least access to anti-retroviral drugs, yet are most at risk of becoming HIV positive.

What has been lacking in the state's conduct is the sense of urgency, a sense that this is a life and death situation that requires immediate and drastic measures. In the absence of any such measures, many of the state's policies could be challenged both politically and legally for being unreasonable.

(o) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

¹¹² Although an agreement was reached that patents on HIV, TB and malaria drugs could be broken, there was no agreement as to which other conditions should receive similar exemption. Negotiations to deal with these outstanding issues broke down late in 2002. If a settlement is not reached, senior World Trade Organisation officials warn that any agreements reached in the current round of talks, including the Doha deal in late 2001, which seemed to allow access to generics in the event of "health emergencies", would be nullified. AIDSmap 2003 "Mass murder by complacency' attacked by UN HIV envoy as WTO talks restart" <www.AIDSmap.com/news/newsdisplay2.asp?newsId=1832> Accessed 17 January 2003.

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