EXPLORING THE LEGAL MEANS OF ENHANCING ACCESS TO ESSENTIAL MEDICINES IN SOUTH AFRICA

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PROGRAMME: MASTER OF LAWS (LLM)

COURSE: HUMAN RIGHTS LAW

COURSE CODE: PBL 6034S

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Research dissertation presented for the approval of Senate in partial fulfilment of the requirements for the Master of Laws (LLM) degree in approved courses and a minor dissertation. The other part of the requirement for this qualification was the completion of a programme of courses.

I hereby declare that I have read and understood the regulations governing the submission of dissertations, including those relating to length and plagiarism, as contained in the rules of this University, and that this dissertation conforms to those regulations.

Signed by candidate

Signature: Date: 02 JULY 2008

DEDICATION

I dedicate this work to my late mother, Forgiveness Fatima Matutu, for her enduring spirit to engage in the struggle against poverty and deprivation. A decade up the line, this study testifies that her inspirational encouragement has outlived her physical existence.

To the millions of poor citizens that are haunted by HIV/AIDS and other public health tragedies of comparable magnitude across the globe.

ACKNOWLEDMENTS

Far from being merely cosmetic, my acknowledgements here are a heartfelt articulation of appreciation to those who took their time to make this study successful. Unfortunately, limited space denies me the opportunity to mention all of you here. I am grateful to my research supervisor, Professor Danwood M Chirwa, for his patience and scholarly guidance during my research. I benefited a lot from his capability to raise issues that inspire independent research. This study would not have been successful if he were not a scholar of reputable expertise in the field of human rights law. His assistance extended to ensuring my moral and social well-being throughout my quest for excellence at the University of Cape Town. I thank him for his unwavering support and persevering inspiration.

I also thank the Head of Department for Public Law, Professor Christina Murray, for her emotional support throughout this research. Many thanks to members of my family, who had to persevere the pain of living for over a year in the absence of a breadwinner. I thank them for their understanding and invaluable support.

The financial assistance of the Department of Science and Technology (DST) towards this research is hereby acknowledged. Opinions expressed and conclusions arrived at, are those of the author and are not necessarily to be attributed to the DST.

Apologies to those overlooked or unnoticed.

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ABBREVIATIONS

ACHPR	African Charter on Human and Peoples' Rights
AIDS	Acquired Immuno-deficiency Syndrome
API(s)	Active Pharmaceutical Ingredient(s)
ARV(s)	Antiretroviral(s)
CEDAW	Convention on the Elimination of All Forms of Discrimination Against Women
CESCR	Committee on Economic, Social and Cultural Rights
CERD	Convention on the Elimination of All Forms of Racial Discrimination
CRC	Convention on the Rights of the Child
DST	Department of Science and Technology
GDP	Gross Domestic Product per capita
ICESCR	International Covenant on Economic, Social and Cultural Rights
IP	Intellectual Property
MTCT	Mother-to-child-transmission of HIV/AIDS
PMTCT	Prevention of mother-to-child-transmission of HIV/AIDS
R&D	Research and development
SADC	Southern African Development Cooperation
TRIPS	Trade Related Aspects of Intellectual Property Rights
WHA	World Health Assembly
WHO	World Health Organisation
WTO	World Trade Organisation

CHAPTER 1: INTRODUCTION

The introduction of ARVs to the care and treatment of HIV and AIDS must comply with South African patent law and international obligations under the TRIPS agreement. However, the prices of patented and/or branded drugs supplied by the manufacturers may prevent equitable access to necessary drugs for South Africans. Recent international trade agreements and the South African law provide a number of ways to address this dilemma. *Therefore, if it is deemed necessary and expedient, the government may consider the implementation of measures such as voluntary licensing, compulsory licensing and parallel importation to purchase drugs at affordable and favourable prices* (my emphasis).[1]

1.1 Background to the study

The HIV/AIDS pandemic is the greatest threat to public health in the world today.[2] With South Africa alone having an estimated 5.5 million afflicted by HIV/AIDS in the year 2005,[3] there is no doubt the pandemic has gathered momentum in the last two years. Since the majority of HIV/AIDS-related deaths claim the lives of the economically active age group, the pandemic inevitably has negative socio-economic consequences.[4] The consequences are multi-faceted, physically lethal and economically devastating. Economic studies have indicated that the South African GDP will register a 17 percent decrease—equivalent to $22 billion in revenue—in 2010 as a result of HIV/AIDS.[5] The gravity of the pandemic explains why South Africa must deal with it as an emergency.

HIV/AIDS adversely affects the country's demography, its economy and education. HIV/AIDS claims lives of the economically active group and those working at middle and upper levels of public and private sector management.[6] The demographic impact of HIV/AIDS indicators reflect that the pandemic accounts for 71% of deaths in the 15—49

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[1] Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa, Press release (8 August 2003) at 39-40.

[2] UNAIDS '2006 Report on the global AIDS epidemic: Annex 2: HIV and AIDS estimates data, 2005 and 2003' available at http://data.unaids.org/pub/GlobalReport/2006/2006_GR_ANN2_en.pdf (accessed 21 October 2007). UNAIDS revealed more recently that 38.6 million people lived with HIV/AIDS globally. Of this number, 24.5 million live in Sub-Saharan Africa.

[3] Ibid.

[4] JM Berger 'Tripping over patents: AIDS, access to treatment and the manufacturing of scarcity' (2001-2002) 17 *Connecticut Journal of International Law* 157 at 159.

[5] M Ganslandt et al 'Developing and distributing essential medicines to poor countries: The DEFEND proposal' (2001) 24 *World Economy* 779 at 785.

[6] Nicolus Cook 'AIDS in Africa' available at http://www.fas.org/sgp/crs/row/IB10050.pdf (accessed 2 April 2008).

year age group.[7] The HIV/AIDS pandemic has worsened the shortage of skilled labor and has shrunken the South African economy by one percent each year.[8]

In 2006, an estimated 350,000 South Africans died of HIV/AIDS.[9] The World Health Organisation (WHO) estimates that around 90% of South Africans who needed antiretrovirals (ARVs) were not receiving them at the end of September 2006.[10] The pandemic has been cited as the major cause of premature deaths in South Africa, with HIV/AIDS-related deaths (especially deaths caused by opportunistic infections) estimated to have accounted for almost half of all deaths in 2006.[11] The overall death rates, from all causes, have increased by an estimated 80% due to HIV/AIDS.[12] Worse still, there were more than one million AIDS orphans and an estimated 290 000 children (below 18 years of age) living with HIV/AIDS in 2005.[13]

These figures are staggering and they indicate the severity with which HIV/AIDS is affecting population and economic growth. The degree to which HIV/AIDS has permeated South Africa society shows that the responsibility to treat current and prevent further infections largely belongs to public health institutions. The state should therefore play a key role in enhancing access to essential medicines in South Africa. In that light, this study explores the implications of the right to health care services for state obligations concerning access to life-saving medicines. Adequate health is important for a dignified life and is a prerequisite for meaningful citizen participation in all walks of life.

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[7] Centre for Actuarial Research, South African Medical Research Council and Actuarial Society of South Africa 'The demographic impact of HIV/AIDS in South Africa-national and provincial indicators' (2006, November) available at http://www.mrc.ac.za/bod/DemographicImpactHIVIndicators.pdf (accessed 30 October 2007).

[8] KM Bombach 'Can South Africa fight AIDS? Reconciling the South Africa Medicines and Related Substances Act with the TRIPS Agreement' (2001)19 *Boston University International Law Journal* 273 at 276.

[9] Department of Health 'Republic of South Africa: Progress Report on Declaration of Commitment on HIV and AIDS' (2006) available at http://www.doh.gov.za/docs/reports/2006/ungass/part1.pdf and http://www.doh.gov.za/docs/reports/2006/ungass/part2.pdf (accessed 30 October 2007) (hereinafter referrred to as Progress Report).

[10] WHO/UNAIDS '2006 report on the global AIDS epidemic' available at http://data.unaids.org/pub/GlobalReport/2006/2006_GR_ANN1M-Z_en.pdf (accessed 4 April 2008) (hereinafter Global AIDS Report).

[11] Progress Report (note 9).

[12] Ibid.

[13] Global AIDS Report (note 10).

The right to life would be severely threatened if the sick do not have access to treatment. In combating the HIV/AIDS crisis, South Africa must reconsider priorities and divert national resources to national health institutions.[14]

However, as noted in the Operational Plan, patented medicines are too expensive for universal access. This study argues that without forcing causation too hard, patent protection encourages price distortions. The cost of patented medicines must be considered against the background of the majority of South Africans being so poor or un(der)employed that they cannot afford to purchase ARVs from their private coffers and the number of those who need ARVs (90% of those infected in 2006) being too enormous that the state's already stretched health budget cannot achieve universal provision. Given the state's plan to speed access within the confines of the Trade Related Aspects of Intellectual Property Rights (Trips Agreement), this study examines whether and if so, how the TRIPS Agreement create a conducive legal framework for the state to adopt policy options that facilitate access to medicines. It also explores the implications of compulsory licencing for patent protection and access to essential medicines. The study also examines the South African regulatory framework for compulsory licencing and whether this framework is consistent with the TRIPS Agreement. This includes an analysis of the provisions of the Patents Act[15] and the Constitution.[16]

This study demonstrates how South Africa may exploit the flexibilities codified in domestic and international intellectual property (IP) laws to combat public health tragedies such as AIDS. Thus, the state must ensure that its health policies are complimented by pharmaceutical pricing mechanisms towards a united front in fighting South Africa's disease burden. Public health institutions must be responsive to the health care needs of the population and drug prices must reflect a commitment to curb the spread of HIV/AIDS. To achieve this balance, the state should weigh challenges to and opportunities for improving public health facilities and services by exploiting the legal

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[14] See AL Taylor 'Making the World Health Organisation work: a legal framework for universal access to conditions for health' (1992) 18 *American Journal of Law & Medicine* 301 at 303.
[15] 57 of 1978.
[16] The Constitution of the Republic of South Africa, 1996.

options codified in the Patents Act and the TRIPS Agreement. In that light, this study analyses the magnitude of the AIDS pandemic in South Africa, identifies major factors hampering access to essential medicines, the gaps that exist in current HIV/AIDS policy-making and reconsiders the responses to the problems slowing down the provision of essential drugs, particularly ARVs, to poor patients.

1.2 Statement of the problem

There is consensus among HIV/AIDS scholars that patent protection and the lack of political will are major impediments to universal access to treatment in South Africa.[17] It is unanimously conceded that political will plays a key role in formulating and implementing a national ARV rollout programme. Sprague and Woolman have argued that a major impediment to a universal ARV programme is the lack of political will and not resource constraints.[18] They further argue that in South Africa, 'access to ARVs has no meaningful legal barrier or insuperable financial constraints.'[19] On the contrary, Berger contends that the major obstacle to HIV treatment remains high drug prices which (according to him) are a concomitant result of strong patent protection.[20] Similarly, the South African Cabinet has indicated that 'antiretroviral drugs are too costly for universal access' and that it is committing itself to striving for the lowering of drug costs.[21]

Much has been written and said on the role of political will and IP laws in enhancing or impeding access to essential drugs. However, current literature does not adequately address how the challenges presented by IP laws could be overcome by exploiting the

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[17] See for example Pierre de Vos 'So much to do, so little done: The right of access to anti-retroviral drugs post-*Grootboom*' (2003) 7 *Law, Democracy and Development* 83; Berger (note 4); L Ferreira 'Access to affordable HIV/AIDS drugs: The human rights obligations of multinational corporations' (2002-2003) 71 *Fordham Law Review* 1133; T Collins 'The pharmaceutical companies versus AIDS victims: A classic case of bad versus good? A look at the struggle between intellectual property rights and access to treatment' (2001-2002) 29 *Syracuse Journal of International Law and Commerce* 159; D Halbert 'Moralised discourses: South Africa's intellectual property fight for access AIDS drugs' (2002) 1 *Seattle Journal of Social Justice* 257; Global HIV Prevention Working Group 'Global mobilisation for HIV prevention: A blueprint for action' (2002-2003) 1 *Seattle Journal of Social Justice* 297; TJ Bollyky 'Balancing private rights and public obligations: Constitutionally mandated compulsory licensing of HIV/AIDS-related treatments in South Africa' (2002) 18 *SAJHR* 530.

[18] C Sprague and S Woolman 'Moral luck: Exploiting South Africa's policy environment to produce a sustainable national antiretroviral treatment programme' (2006) 22 *SAJHR* 337 at 370.

[19] Ibid.

[20] Berger (note 4) at 163.

[21] Cabinet Statement on HIV/AIDS (17 April 2002).

flexibilities within the existing regulatory framework for patent protection and public health. The way in which patent protection and the lack political will impede access to drugs has been over-emphasised at the expense of the need to devise the effective means through which the provision of HIV drugs to vulnerable groups can be enhanced. This study demonstrates how South Africa may use TRIPS flexibilities to develop a programme for universal access to ARV therapy without challenging the current statutory provisions governing the procurement of essential drugs for public health purposes.

International and local patent law permits the government to adopt coercive mechanisms (for example compulsory licensing and parallel importation) and non-coercive mechanisms (voluntary licensing) for public health purposes. Thus, policy decisions not to use either of these mechanisms must be bonafide and reasoned. The government's policy choices on the regulation of IP rights must be considered in the light of its constitutional obligations to respect, protect, promote and fulfill the human right of access to health care services.

1.3 Aims of the study

The aims of this study are:

(a) to examine the implications of the right to health care services for state obligations regarding access to essential medicines;

(b) to examine whether and if so, how the TRIPS Agreement create a conducive legal framework for the state to adopt policy options that facilitate access to medicines;

(c) to examine in great detail the implications of compulsory licencing for patent protection and access to essential medicines;

(d) to explore the South African regulatory framework for compulsory licencing. This includes an analysis of the provisions of the Patents Act and the Constitution. Given that the government is aware that compulsory licencing is within the ambit of the flexibilities of the TRIPS Agreement and national legislation, it is also fitting to consider why the government has not used compulsory licences and why it should or should not; and

(e) ultimately, to come up with recommendations concerning the effective means through which the state can better ensure universal access to essential medicines in South Africa.

1.4 Significance of the study

This study is significant in that it explores the means through which South Africa can respond to the opportunities and challenges raised by political, legislative and socio-economic factors in providing universal access to essential drugs. Due to poverty, unemployment and underemployment, public health institutions still service up to 80% of the population. The demand for treatment in these institutions far outweighs the supply. This study demonstrates how a balance between need and supply can be achieved by exploiting the regulatory flexibilities within the existing legislative framework for patent protection and public health.

The gravity of the HIV/AIDS pandemic combined with the magnitude of its adverse impact on education, the economy and population growth also highlight the significance of this study to this country. The depth of skills loss and shortage in the public and private sectors, a shrinking economy and the growing number of orphans (currently at one million) will continue to haunt South Africa if she remains too reluctant to exploit other alternatives to curb the HIV/AIDS tide. In proposing a road-map on how the state could possibly commit itself to an effective policy shift, this work underscores the need for strategic and constructive engagement between the government and pharmaceutical companies.

This study also demonstrates that the state is constitutionally bound to ensure positive provision of patented medicines. It shows the implications (for state policy) of health care rights and how this calls the state to adopt a multidimensional approach to IP and public health. This study is therefore important because it shows that the government is bound to create a legal regulatory framework that balances IP rights and the need to ensure the sustainable supply of ARVs to overcome South Africa's disease burden.

1.5 Methodology

The research is largely qualitative and desk top based. The primary sources of information will comprise of the Constitution; statutes and bills; policies and regulations; official government documents; decided cases and international treaties and instruments. Secondary sources will include books and journal articles. Emphasis is placed mainly on recent publications on socio-economic rights in South Africa and beyond. Internet materials from reputable websites will be used where they contain current information and/or in situations where no published work is available.

1.6 Conclusion

This chapter has shown the magnitude of the HIV/AIDS pandemic in South Africa and why the severity of the plight of those who are HIV/AIDS positive demands an urgent government response. It has also identified the statement of the problem, aims of this study, its significance and its intended methodology. In South Africa, the real problem is not so much whether patent protection or the lack of political will impedes access to essential drugs but to what extent has the government proposed a multidimensional policy framework that supports constructive engagement with drug companies. The answer to lack of access to treatment lies in a generous interpretation of the TRIPS Agreement and South African patent legislation.

1.7 Chapter synopsis

This study has five chapters. This chapter introduces the study, outlines the aims of this work and identifies the gaps that exist in current literature on access to essential treatment. In the light of international health rights jurisprudence, chapter two portrays essential medicines as a non-derogable core of health care rights under the South African Constitution. In locating the IP/public health interface, chapter three explores the international legal regulatory framework for patent protection and compulsory licencing under the TRIPS Agreement. This involves an analysis of the implications of compulsory licencing for patent protection and access to essential drugs. Chapter four examines in great detail the South African regulatory framework for compulsory licencing and whether South Africa should or should not use compulsory licencing. Chapter five

comprises of a conclusion and recommendations based on the findings made during discussion in the preceding chapters. The ultimate goal is to come up with the effective means through which the state may better ensure universal access to essential medicines

Chapter 2: THE RIGHT TO HEALTH IN INTERNATIONAL AND MUNICIPAL LAW

2.1 Introduction

The previous chapter has indicated how dire the need for life-saving drugs throughout the country is. This chapter presents a detailed discussion of the implications of health care rights for state obligations. It starts by tracking down the emergence of the essential medicines concept before demonstrating, based on international jurisprudence, how the right to health may be interpreted to impose the right to equitable, non-discriminatory, affordable and safe drugs as a minimum core obligation of the state. It is argued that the state's obligation to ensure positive provision of essential medicines commands the government to make the necessary drugs available. As a result, although the Constitutional Court's denial of a minimum core may have an adverse impact on access to treatment in general, it should not be allowed to affect the provision of essential drugs at the minimum.

2.2 The concept of essential medicines

The concept of essential medicines dates back to 1977 when a WHO Expert Committee introduced a Model List of Essential Medicines (the Model List) that identified 208 medicines to fight the global disease burden.[22] Although the concept is a brainchild of the Expert Committee *stricto sensu,* the idea of a Model List was developed when the World Health Assembly (WHA) requested 'WHO to assist [M]ember [S]tates in selecting ... essential medicines, assuring good quality and reasonable cost.'[23] All Southern African countries have adopted their own national lists.[24] Chirwa argues that 'the adoption of national lists constitutes evidence of state practice and *opinio juris* of a customary

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[22] WHO '10 facts about essential medicines' available at http://www.who.int/features/factfiles/essential_medicines/en/index.html (accessed 16 November 2007).

[23] DM Chirwa 'The right to health in international law: its implications for the obligations of state and non-state actors in ensuring access to essential medicine' (2003) 19 *SAJHR* 541at 554.

[24] 'WHO Countries' available at http://www.who.int/countries/en/ (accessed 16 November 2007). Of the 193 WHO member states, including all members of the Southern African Development Cooperation (SADC), 156 have adopted their own essential medicines lists based on the Model List.

international rule that the provision of essential medicine[s] is an [integral] element of the right to health.'[25]

The first Expert Committee defined essential medicines as those that are 'of utmost importance, basic, indispensable and necessary for the health care needs of the population.'[26] The 1983 Expert Committee amended this definition and described 'essential medicines' as '[t]hose that satisfy the needs of the majority of the population; they should therefore be available at all times in adequate amounts in appropriate dosage forms.'[27] Although the motivation behind this definition is unclear, successive committees relied on it until 1999 when the ingredient of affordability was introduced.[28] Worse still, useless as it were and offering little or no guidance as it did, the 'majority of the population' requirement remained part of the definition until 2002.

To resolve problems of implementation arising from lack of precision in the definition, the WHO Secretariat proposed that the term 'essential medicines' should comprise of three components, namely definition, selection criteria and purpose.[29] The Secretariat proposed that by definition 'essential medicines are those that satisfy the priority health care needs of the population.'[30] The Secretariat further proposed that essential medicines should be selected 'with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness.'[31] According to this proposal, essential medicines should be 'available within the context of functioning health systems at all

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[25] Chirwa (note 23) at 554.

[26] WHO 'Model list of essential medicines' available at http://en.wikipedia.org/wiki/WHO_Model_List_of_Essential_Medicines (accessed 16 November 2007).

[27] WHO 'Agenda 2: Outstanding technical issues: description of essential drugs' available at http://mednet3.who.int/EML/expcom/expcom12/ed_description.doc (accessed 16 November 2007).

[28] DM Chirwa (note 23) at 554.

[29] E-Drug 'Description/definition of essential drugs by WHO' available at http://www.essentialdrugs.org/edrug/archive/200204/msg00036.php (accessed 16 November 2007).

[30] Ibid.

[31] Ibid. Although disease prevalence remains a decisive factor in considering whether drugs are essential, this choice is not without problems. See MM Reidenberg 'Are drugs for rare diseases "essential"'? available at http://www.who.int/bulletin/volumes/84/9/06-034447.pdf (accessed 27 May 2008), arguing that it is unjust to exclude other citizens from treatment on the basis that the diseases inflicting them are less prevalent and suggests that the primary standard for including drugs into a Model List should be whether such drugs are cost-effective. However, Reidenberg is concerned about the monetary cost of medicines and forgets that diseases have different social costs, kill different numbers of persons and that it may be wise to consider cost in the sense of human lives claimed by a particular disease.

times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.'[32]

Taking cognisance of these developments, the 2002 Expert Committee defined essential medicines as—

> those that satisfy the priority health care needs of the population. They are selected with due regard to public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality and adequate information, and *at a price the individual and the community can afford.* The implementation of the concept of essential medicines is intended to be flexible and adaptable to many different situations; *exactly which medicines are regarded as essential remains a national responsibility* (emphasis mine).[33]

There are many improvements in this definition of essential medicines. First, unlike its predecessors, it introduces drug quality and access to information on drug use as elements of access to medicines.[34] Second, it addresses the WHO Secretariat's proposal that the definition should comprise of the definition, selection criteria and purpose.[35] Third, the new description makes no reference to the vague expression 'majority of the population' and it also includes the requirements of priority, adequacy, quality, availability and affordability, which the Committee on Economic, Social and Cultural Rights (CESCR) has used in describing other socio-economic rights.[36]

To a large extent, the 2002 definition addresses the grievance of the CESCR that goods, services and information for the treatment of HIV/AIDS should, at the minimum, be made available and accessible to patients.[37] Thus, the concept entails the need to

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[32] Ibid.
[33] WHO 'Essential drugs and medicines policy' available at http://www.who.int/countries/eth/areas/medicines/en/ (accessed 9 November 2007).
[34] E-Drug (note 27).
[35] Ibid.
[36] Chirwa (note 23) at 555.
[37] The CESCR has identified the principles of availability, accessibility, quality and acceptability as the essential elements of all socio-economic rights, including the right to health. 'Availability' means that relevant programmes, facilities, goods and services must be made available in sufficient quantity within the territory of a given state. 'Accessibility' means that the goods and services must be accessible in sufficient quantity, at an affordable price and physically without discrimination to all within the given state's territory. See CESCR General Comment No 15 'The right to water' (adopted on the 29th Session, 11-29 November 2002) para 12 (c) (iii); see also CESCR 'General Comment 14, 'The right to the highest attainable standard of health' (adopted on the 22nd Session, 8 November 2000) para 8; See Committee on the Rights of the Child 'General Comment No 3: HIV/AIDS and the rights of the child' (17 March 2003) paras 15-29; See CESCR General Comment 3 'The nature of states parties obligations' E/1991/23 (1991).

continuously revise medicines selection to mirror emerging therapeutic options and ever-changing curative health care needs, the need to evaluate drug quality, the desirability for ongoing development of safer drugs for existing or rare diseases and medicines for new drug resistance patterns.[38] To be essential, medicines must not only be safe and cost effective, but they must be carefully selected, be based on agreed clinical guidelines, be rationally prescribed, be affordable and address the health care needs of the community at large.[39]

Apart from introducing cost as an element of essential medicines, the new definition emphasises that countries and institutions should develop their own lists of essential medicines.[40] The 2002 Committee stated that essential drugs 'are intended to be flexible and adaptable to many different situations; exactly which drugs are regarded as essential remains a national responsibility.'[41] While not implying that the selection of essential medicines should not be context-sensitive, it is patent that context-sensitivity may leave extensive scope for members to compromise the standards required by the WHO. It is arguable that the gravity of the HIV/AIDS pandemic warrants the conclusion that all drugs that safely reduce viral activity must be regarded as 'essential'.

2.3 The right to health in international law

2.3.1 Recognition in international and regional instruments

The recognition of health as a human right dates back to 1946 when the WHO stated in the preambular provisions of its Constitution that 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'.[42] Since then, the right to health, especially for particularly vulnerable groups, has been codified in many international treaties. One of them is the Convention on the Elimination of All

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[38] WHO 'Essential medicines' available at http://www.who.int/medicines/services/essmedicines_def/en/index.html (accessed 16 November 2007).
[39] WHO 'Essential drugs and medicines policy' (note 33).
[40] E-Drugs (note 29).
[41] Ibid.
[42] The Constitution was adopted at the International Health Conference held in New York from 19 June to 22 July 1946, signed on 22 July 1946 by representatives of 61 states, and entered into force on 7 July 1948.

Forms of Racial Discrimination (CERD).[43] Article 5(e)(iv) of the CERD shoulders on members the obligation to prohibit and eliminate racial discrimination in all its forms and to guarantee the right of everyone to equality before the law in the enjoyment of the right to 'public health, medical care, social security and social services'.

Similarly, Article 12(1) of the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW)[44] commands states to 'take all appropriate measures to eliminate all forms of discrimination against women in the field of health care in order to ensure, on a basis of *equality of men and women*, access to health care services, including those related to family planning.' Reference to equality of men and women implies that the government has an obligation to prevent preferential treatment of women if such treatment is not permissible in terms of Article 12(2). Article 12(2) of the same Convention obliges states, despite the provisions of Article 12(1), 'to ensure to women appropriate services in connection with pregnancy, confinement and the post-natal period, granting free services where necessary, as well as adequate nutrition during pregnancy and lactation'. This permits the state to take affirmative measures to protect women in certain circumstances even if this means treating them differently from men.

The Convention on the Rights of the Child (CRC)[45] contains specific provisions relating to children's right of access to health care. In terms of Article 24(1), 'parties recognise the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and the rehabilitation of health. States parties shall strive to ensure that no child is deprived of his or her right of access to such health care services'.[46] To ensure full implementation of this right, states must take measures targeted at—

- reducing infant and child mortality;

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[43] International Convention on the Elimination of All Forms of Racial Discrimination, adopted 21 December 1965, 660 U.N.T.S 195, entered into force 4 January 1969.
[44] Convention on the Elimination of All Forms of Discrimination Against Women, adopted 18 December 1979 G.A Res.34/180, U.N. GAOR, 34th Session, Supp.No.46, U.N.Doc. A/34/46 (1980), entered into force 3 September 1981.
[45] Convention on the Rights of the Child, adopted 20 November 1989, G.A.Res.44/25, U.N.GAOR, 44th Session., Supp. No. 49, U.N.Doc. A/44/49 (1989), entered into force 2 September 1990.
[46] Article 24(1) of the Convention on the Rights of the Child.

- ensuring the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;
- combating disease and malnutrition, within the framework of primary health care, through, among other things, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking water, taking into consideration the dangers and risks of enviromental pollution;
- ensuring appropriate pre- and post-natal care for mothers; and
- developing preventive health care.[47]

Reference to 'necessary medical assistance' and 'primary health care' is consistent with the concept of essential medicines. The African Charter on Human and Peoples' Rights (ACHPR)[48] recognises that 'every individual shall have the right to enjoy the best attainable standard of physical and mental health' and obliges states parties to 'take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick'.[49] Arguably, these provisions establish at the very minimum a right of access to the most essential treatment that is necessary for a dignified existence. In *Purohit and Another v The Gambia,*[50] the African Commision found that the right to the best attainable standard of health entails the right to health facilities, goods and services.[51] This imposes on states the obligation to take 'concrete and targeted steps' to ensure full realisation, within available resources, of everyone's right to health without discrimination.[52]

Reference to 'the best attainable standard of health' in the ACHPR echoes the wording of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which

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[47] Article 24(2) of the CRC. The African Charter on the Rights and Welfare of the Child also codifies health as a human right. Article 14 of this Charter is, save for a few additions, is a cut and pasted version of Article 24 of the CRC.

[48] African Charter on Human and Peoples Rights, adopted June 27, 1981, OAU Doc. CAB/LEG/67/3 rev. 5, 21 I.L.M. 58 (1982), entered into force Oct. 21, 1986.

[49] Article 16(1) and (2).

[50] (2003) AHRLR 96 (ACHPR 2003).

[51] Para 80.

[52] See *Social and Economic Rights Action Center (SERAC) and Another v Nigeria* (2001) AHRLR 60 (ACHPR 2001), paras 52-54, where the Commission, directly relying on the ICESCR, found that the state had failed to take necessary steps or measures to safeguard everyone's right to the best attainable standard of health.

provides for a right to the 'highest attainable standard of health'.[53] Similarly, reference to 'concrete and targeted steps' incorporates the CESCR's command that states must take 'deliberate, concrete and targeted' steps 'towards the full realisation of the right to health'.[54] Thus, the African Commission is more inclined to use the established jurisprudence of the CESCR to shape its own evolving jurisprudence even in cases in which the respondent has not ratified the ICESCR. It is arguable that South African courts should use the jurisprudence of both the CESCR and the African Commission for purposes of interpreting rights concerning health under the South African Constitution. In fact, as will be shown below, the Constitutional Court has relied on the CESCR's jurisprudence to interpret socio-economic rights in the Constitution. Given that position, it becomes desirable to consider briefly the nature of obligations the international 'right to the highest attainable standard of health' has been construed to impose on the state.

2.3.2 State obligations under international law

Article 12 of the ICESCR unambiguously commands states to take steps to progressively realise the right to health. Therefore, states must take steps that clearly show that they are duty-bound to provide essential medicines. Measures to widen access to ARV should be an intrinsic part of the state's plan to meet its Article 12 obligations.[55] Second, the duty to provide access to medicines binds the state to 'create conditions which would assure to all, medical service and medical attention in the event of sickness.'[56]

The CESCR has indicated that this obligation includes, *inter alia*, the provision of equal and timely access to curative health services, essential drugs and suitable mental treatment.[57] The CESCR has recommended that although the terms 'progressive realisation' and 'to the maximum of available resources' are indispensable flexibility

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[53] See Article 12 of the ICESCR.
[54] See General Comment 14 (note 37) para 30, referring to 'deliberate, concrete and targeted' steps towards the full realization of the right to health; see also General Comment 3 (note 37) para 12, referring to the implementation of 'targeted programmes'.
[55] Chirwa (note 23) at 548.
[56] See Article 12(2).
[57] General Comment 14 (note 37) para 17, states that this includes 'the provision of equal and timely access to basic preventive, curative, rehabilitative health services and health education; regular screening programmes; appropriate treatment of prevalent diseases, illness, injuries and disabilities, preferably at community level; the provision of essential drugs; and appropriate mental health treatment and care.'

devices in socio-economic rights claims, Article 2(1) requires states to move as expeditiously and effectively as possible towards realising these rights.[58]

Chirwa argues that 'access to essential medicines in particular and access to medical care in general ... form a central part of the right to health...The duty to provide essential medicines is in fact a minimum and non-derogable core obligation inherent in the right to health.'[59] This ties in well with the concept of minimum core obligations which prevents countries from pleading resource constraints if the minimum essential levels of each right in the Covenant has not been realised.[60] For states to plead resource constraints in meeting their minimum core obligations, they must demonstrate that every effort has been made to use all resources at their disposal to provide core needs.[61]

The CESCR has emphasised that as part of their core obligations, states are bound to provide access to essential drugs as defined under the WHO Action Programme on Essential Drugs, to take measures to treat epidemics, and to ensure non-discriminatory access to and equitable distribution of health facilities, goods and services.[62] Similarly, the Maastricht Guidelines state that countries infringe their minimum core obligations imposed by health rights if a significant segment of their citizens are denied 'essential primary health care.'[63]

Likewise, the Alma-Ata Declaration also refers to the control of locally endemic diseases; appropriate treatment of common diseases and the provision of essential drugs as core elements of the primary health care package.[64] This translates into sufficient justification for concluding that access to essential medicines is a minimum core of the international right to health. Whether this should be so in South African law depends on

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[58] General Comment 3 (note 37) para 9.
[59] Chirwa (note 21) at 543.
[60] General Comment 3 (note 37) para 10.
[61] Ibid.
[62] General Comment 14 (note 37) paras 44(a), (d)-(e); 44(c).
[63] Maastricht Guidelines, para 9. The Guidelines were adopted in Maastricht, the Netherlands, on 22-26 January 1997.
[64] The Declaration of Alma Ata 'International Conference on Health Care, Alma Ata, USSR' (6-12 September 1978) available at http://www.who.int/hpr/NPH/docs/declaration_almaata.pdf (accessed 12 May 2008) para VII(3).

how the courts interpret state obligations in the light of the evolving jurisprudence on health rights at the international level. It is to this aspect that I now turn.

2.4 Access to health care services under the South African Constitution

The South African Constitution does not provide for a right to health proper but guarantees all citizens 'the right of access to health care services.'[65] A right of 'access to health care services' may limit the transformative potential of international health rights jurisprudence because it does not guarantee the provision of underlying conditions of health.[66] 'Access to health care services' is admittedly a narrower construction than the international right to the highest attainable standard of health.[67] This absolves the government of its wider public health obligations. The realisation of 'access rights' is subject to the availability or otherwise of resources and this grants states a fair measure of leeway to plead budgetary constraints in socio-economic rights claims.

To understand the nature of state obligations in matters concerning health, it is desirable to consider the provisions of section 7(2) of the Constitution. Section 7(2) states that '[t]he state must respect, protect, promote and fulfill the rights in the Bill of Rights.' The scope of these duties is considered in the light of international health rights jurisprudence because the Constitutional Court heavily relies on international law to give content to socio-economic rights and to shape its own evolving jurisprudence.

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[65] Section 27 provides that:

1 Everyone has the right to have access to

(a) Health care services, including reproductive health care;

(b) .....

(c) .....

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.

[66] Access rights in the context of health are limited to access to health facilities, goods and services but health rights proper cover the underlying conditions of health including sanitation, adequate housing, clean water, food, sanitation, a health working climate and a healthy environment. See for example C Shinn 'The right to the highest attainable standard of health: public health's opportunity to reframe a human rights debate in the United States' (1999) 4(1) *Health and human rights* 115 at 119.

[67] L Forman 'Ensuring reasonable health: health rights, the judiciary and South African HIV/AIDS policy (2005) 33 *Journal of Law, Medicine and Ethics* 711at 713.

2.4.1 The duty to respect

Respecting access to health care services requires the state to commit itself to three objectives: first, when possible the state has to avoid interfering with citizens' current enjoyment of this right; second, the state must take steps to mitigate the impact of its interference (when interference is imperative) and third, the state should not impair (potential) access to medical facilities, goods and services.[68] The state must therefore exercise self-restraint towards people who are currently enjoying access to medication. It may not place undue obstacles against people gaining access to treatment.

Access to health care obliges states to abstain from preventing equitable access to preventive, curative and palliative health services.[69] The state may not market unsafe drugs or withhold health-related information.[70] Each state disobeys the duty to respect if it misrepresents essential health-related information, suspends or adopts laws to interfere with the enjoyment of health care rights and disregards obligations imposed on it by the right to health when entering into agreements with other states or organisations.[71]

The injunction—not to refuse emergency medical treatment to anyone—imposes on the state a negative obligation to respect existing or potential access to treatment.[72] The Court in *Soobramoney v Minister of Health, KwaZulu-Natal*[73] read section 27(3) to require the state to desist from refusing patients emergency medical treatment where it exists. Alston and Scott warn that this restrictive reading makes section 27(3) purely redundant.[74] Section 27(3) is not explicitly subjected to the internal limitations that typically govern the realisation of socio-economic rights.[75] Therefore, violations of section 27(3) should not only be construed as violations of the negative duty to respect health care rights.

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[68] See *Government of the Republic of South Africa v Grootboom* 2001 (1) SA 46 (CC), para 34; see also Chirwa (note 23) at 558.
[69] General Comment 14 (note 35) para 34.
[70] Ibid.
[71] Ibid para 50.
[72] Section 27(3) read with section 7(2).
[73] 1998 (1) SA 765 (CC).
[74] P Alston and C Scott 'Adjudicating constitutional priorities in a transitional context: a comment on *Soobramoney*'s legacy and *Grootboom*'s promise' (2000) 16 *SAJHR* 206 at 245-48.
[75] D Brand 'Introduction to socio-economic right in the South African Constitution' in Brand and C Heyns (eds) *Socio-economic rights in South Africa* (2005) 1 at 4.

2.4.2 The duty to protect

The duty to protect invites the government to adopt legislative and other measures to safeguard equal access to health facilities, goods and services. This includes the duty to control the marketing of medicines by third parties, the attainment of certain levels of education and the observance of certain ethical codes of conduct by health professionals.[76] The state must also ensure that privatisation 'does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities.'[77]

The African Commission has noted that the duty to protect entails 'the creation and maintenance of an atmosphere or framework by an effective interplay of laws and regulations so that individuals will be able to freely realise their rights and freedoms.'[78] Establishing 'an effective regulatory system' providing for 'independent monitoring, genuine public participation and imposition of penalties for non-compliance'[79] is integral to protecting health care rights. States are thus commanded to protect citizens from exorbitant pricing of essential medicines by drug companies.[80] This involves a duty to regulate the conduct of third parties who may interfere with existing or potential access to medicines.[81] The obligation to create an effective regulatory framework that protects health care rights also extends to standard setting concerning the safety and quality of medicinal goods.[82]

2.4.3 The duty to fulfill

The state is bound to take affirmative measures to realise the provision of health care services—it may not fold its arms and do nothing.[83] The duty to fulfill substantially

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[76] General Comment 14 (note 37) para 35.
[77] Ibid.
[78] *SERAC* (note 52) para 46.
[79] General Comment 15 (note 37) para 24.
[80] See for example Chirwa (note 23) at 559.
[81] The role of pharmaceutical companies in setting the prices of patented drugs looms large in this respect.
[82] South Africa, for example, has formulated a National Drug Policy that aims, among other things, to (a) ensure that drugs that are reaching patients are safe, effective and meet approved standards; (b) promote the availability of effective drugs at the lowest possible cost; (c) promote rational drug choice in accordance with the Essential Drugs Concept; and (d) ensure adequate supply or effective supply of safe drugs to all South Africans.
[83] The text of section 27 is peremptory: 'the state must take reasonable legislative and other measures to achieve the progressive realisation of these rights.'

overlaps with the duty to promote.[84] The latter enjoins the state to ensure that individuals exercise their fundamental rights and freedoms by promoting tolerance, elevating consciousness and constructing the requisite infrastructure.[85] Each state must ensure equitable distribution of health-related facilities across its territory by running appropriate training for doctors and other medical staff as well as providing an adequate number of hospitals and clinics.[86]

The duty to fulfill enjoins public health providers to guarantee the individual enjoyment of health rights through legislative implementation and the development of a health policy with a detailed plan.[87] This duty shoulders on the state the obligation to ensure positive provision of essential drugs and other immediate health care needs of the population. The text of section 27(1) of the Constitution clearly suggests that health care rights are not mere restraints on intrusive state action but create concrete entitlements that require the state to provide resources necessary for the enjoyment thereof. Section 27(1) and (2) require the state to take positive redistributive measures at the political level to meet the health care needs of its population.[88] Ngwena and Cook argue that the fact that section 27 imposes positive duties on the state 'to provide health care according to need rather than ability to pay' underscores its broad transformative potential.[89] Thus, the obligation to provide essential medicines relates to the duty to fulfill the right of access to health care services. To measure the state's compliance with its obligations, the Constitutional Court has adopted the reasonableness test.[90]

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[84] General Comment 15 (note 37) para 25 stipulating that the duty to fulfill encompasses the responsibility 'to facilitate, promote and provide.'
[85] *SERAC* (note 52) para 46.
[86] General Comment 14 (note 37) para 36.
[87] Ibid.
[88] See also General Comment 14 (note 37) para 37, stating that states are bound to take positive measures to enable individuals and communities (if they are unable to privately raise the required resources) to gain access to health care goods and services
[89] C Ngwena and R Cook 'Rights concerning health' in D Brand and C Heyns (eds) *Socio-economic rights in South Africa* (2005) 107 at 132.
[90] See *Grootboom* (note 68) and *Minister of Health v Treatment Action Campaign* 2002 (5) SA 721 (CC).

2.4.4 Reasonableness

Although access to health care may be realised progressively, this does not absolve the state of its immediate duty to take steps towards achieving this goal.[91] The measures used must reasonably be connected to the purpose for which they were adopted. They must be capable of achieving the intended purpose.[92] This must be done through the adoption and reasonable implementation of a comprehensive health plan.[93] In *Grootboom,* the Court acknowledged that the state's housing plan was 'a major achievement' but took issue with the state's failure to include targeted measures to provide housing to those in desperate need.[94]

The plan must be comprehensive and co-ordinated, must be reasonable both in conception and implementation and must at least avoid deliberate retrogression (which ordinarily constitutes a *prima facie* breach and requires sufficient justification).[95] Thus co-ordination requires that the plan be entirely coherent to enable easy allocation of functional areas to various spheres of government.[96] In this respect 'progressive realisation' demands more than paper policies or plans that are not practically implemented.[97] Sensibly, the Court in *Kutumela* required the provincial authorities to implement effectively an affirmative measure that enjoyed conceptual rather than practical recognition.[98]

To be reasonable, the measures adopted must be targeted, 'balanced and flexible', must consider short-, medium- and long-term needs and may not exclude 'a significant

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[91] *Grootboom* (note 68) para 45.
[92] Ibid para 41.
[93] Ibid para 42.
[94] Ibid para
[95] Ibid paras 39 and 45.
[96] Brand (note 75) at 47.
[97] In *Kutumela v Member of the Executive Committee for Social Services, Culture, Arts and Sport in the North West Province* Case 671/2003, 23 October 2003 (B), the plaintiffs applied for grants but, although they qualified, never received them. The North West Province argued that it had not committed the requisite financial resources to meet its obligations. The Court fashioned a remedy that bound the authorities to devise a plan for effective administration and payment of the grant. Brand (note 73) at 14, argues that '[i]n essence, the state was ordered to make good on a statutory commitment to give effect to an aspect of the right to have access to social assistance, with the result that the grant would in future be available to all eligible persons…'
[98] Brand (note 75) at 49.

segment of society.'[99] Measures are reasonable if they consider 'the degree and extent of the denial of the right' and if they meet the needs of those who live in desperate need.[100] In *Treatment Action Campaign*, measures to combat mother-to-child transmission (MTCT) of HIV were held to be unconstitutional because they 'failed to address the needs of mothers and their newborn children who [did] not have access' to any of the sites that provided nevirapine.[101] In confining the provision of nevirapine to 18 pilot sites, the government's plan was inflexible, rigid and unreasonable because it denied mothers and children (who had no access to the research sites) safe access to nevirapine within the state's available resources.[102] The Court also added the lack of transparency as a ground for concluding that the measures adopted by the state were unreasonable.[103] To be reasonable, the 'contents' of the programme must be communicated 'appropriately' to all those who are affected.[104]

Sunstein argues that it is unclear whether the reasonableness test involves 'sensible priority-setting, with particular attention to the plight of those in desperate need'[105] Brand argues that *Grootboom* required the state to consider the needs of the most desperate without proposing that the needs of this group must supersede other needs.[106] *Grootboom* required no more or less than mere inclusion in state policies and plans of significantly vulnerable groups.

To be reasonable, a health plan should make available the required financial and human resources.[107] When the state undertakes to take a particular course of action to provide health care services, then it is under a legal obligation to reasonably adapt its allocational choices to meet the resource needs for the provision of those services. If the state fails to

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[99] *Grootboom* (note 68) para 43.
[100] Ibid para 44.
[101] Ibid para 67.
[102] Ibid para 80.
[103] Ibid para 123.
[104] Ibid. Transparency in the public administration enables those affected to participate in decision-making on matters of topical concern, saves time and resources usually lost through litigation that could have been better avoided, and enables citizens to describe their complaints in concrete and precise terms.
[105] CR Sunstein 'Social and economic rights? Lessons from South Africa' (2001) 11(4) *Constitutional Forum* 123 at 127 cited in Brand (note 75) at 50.
[106] Brand (note 75) at 50.
[107] See *Grootboom* (note 68) para 39.

honour its promises, the Court may direct it to make the necessary resources available for the enjoyment of health care rights even if the government had not seriously planned on doing so. In *Kutumela*, the Court ordered the responsible authorities to provide the necessary human, financial and institutional resources for the enjoyment of the Social Relief of Distress Grant because the state had made a statutory promise to do so and the applicant qualified for this grant.[108] The inadequacy of financial and human capacity could not stand in the way of a successful litigant entitled to a statutorily protected right.

In *Treatment Action Campaign,*[109] the Court had three reasons to hold that there was no insuperable financial constraint to the provision of nevirapine at public health facilities where the counseling and monitoring infrastructure already existed. First, the fact that manufacturers of nevirapine had offered to provide the drug at no cost for five years and that infrastructural facilities were already in place meant the state would incur minimal additional costs.[110] Second, the fact that other provinces like Gauteng expanded their provision of nevirapine to public health facilities other than the research sites during litigation also meant resource constraints were more hypothetical than real.[111] Third, 'provided the requisite political will [was] present' and in the light of substantial funds added for HIV/AIDS treatment in the interim, all financial constraints had been overcome.[112]

The state was then ordered, without delay, to lift restrictions that prevented the provision of the Prevention of Mother To Child Transmission (PMTCT) at public health institutions other than the pilot sites; to allow and expedite the use of nevirapine for PMTCT when nevirapine was medically indicated; and to provide for the training of counselors at public health institutions where necessary for the effective use of nevirapine for PMTCT.[113] The practical effect of this judgment was that the government was required to make available the resources—human, institutional and financial—it had not planned to

[108] *Kutumela* (note 97).
[109] *Treatment Action Campaign* (note 90).
[110] Paras 19 and 71.
[111] Para 118.
[112] Paras 119 and 120.
[113] Para 135.

provide in the first place, as part of its obligation to fulfil the right of access to health care services. The order was both intrusive and directory because the state had failed to substantiate with any tangible evidence its claims that a comprehensive plan for PMTCT was not within its economic reach and therefore not unreasonable.

2.4.5 Minimum core obligations

The Constitutional Court had occasion to consider whether sections 26 and 27 impose minimum core obligations on the state. The amici in the *Grootboom* and *Treatment Action Campaign* cases argued that sections 26 and 27 establish a minimum core that cannot be derogated from. In other words, the amici argued that each of these rights entails minimum essential levels below which state conduct to realise these rights may not unjustifiably fall. In *Grootboom,* the Court rejected the concept on several grounds. The Court observed that the general comment (from which this concept emerges) never spells out precisely what the concept means.[114] The court held that it is impossible to determine the minimum threshold without first identifying individual needs and opportunities for the enjoyment of the right of access to housing.[115] The Court further held that determining a minimum core involves complex questions of fact which could not be addressed because information on what the minimum core should be according to the Constitution was unavailable.[116]

In *Treatment Action Campaign*, the Court rejected the minimum core because, it held, the concept implies that section 27(1) creates independently enforceable and self-standing rights which may not be limited by the qualification in subsection 27(2).[117] The Court further held that it was impracticable to ensure immediate universal access to a basic or core service and that determining a minimum core involved 'wide-ranging factual and political inquiries' that fall outside the institutional competence of the courts.[118] In evaluating state compliance, the Court opted instead for the standard of reasonableness which has been considered in detail above.

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[114] *Grootboom* (note 68) para 30.
[115] Ibid para 32.
[116] Ibid paras 32-33.
[117] Para 39 read with para 29.
[118] Paras 35 and 37.

2.4.6 Towards a useful role for minimum core obligations

The idea that each right has a concrete meaning and must therefore be given content is integral to the recognition of minimum core obligations. Thus, the right to have access to health care services must involve the basic services to which individuals are entitled as a matter of right. This does not mean, as the Constitutional Court appears to imply,[119] that a court has to dictate to the state the details concerning what the state needs to do in order to comply with its obligation to fulfil a particular right. Taylor argues that 'when we look at the issue of core obligations of states with regard to socio-economic rights, we need to push to the centre of the debate the concern that certain fundamental human needs should be non-negotiable.'[120] Each right entails core standards of protection that are generally universal and inalienable.

Ironically, Ackermann J adopted a similar approach in *Bernstein v Bester*[121] when he approved of the German approach to the protection of privacy thus:

> [A] very high level of protection is given to the individual's intimate personal sphere of life and the maintenance of its basic preconditions and there is a final untouchable sphere of human freedom that is beyond interference from any public authority. *So much so that, in regard to this intimate core of privacy, no justifiable limitation thereof can take place* (my emphasis).[122]

This is synonymous to what Taylor calls 'non-negotiable human needs'. Although socio-economic rights are limited by the availability of resources, the existence of these rights is not determined by the availability of resources. The availability of resources only determines the extent to which these rights are realised. This raises the question whether it is possible to recognise the existence of a right even if such right cannot be immediately fulfilled due to resource constraints? Bilchitz correctly argues that even

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[119] In *Grootboom* (note 68) para 33, the Court observed that it will be difficult to determine in the abstract what the minimum core should be for each individual because 'there are those who need land, others need both land and houses; yet others need financial assistance.'

[120] Professor V Taylor, Programme Coordinator (Development), UN Commission on Human Security, New York in her closing address to the colloquium organised by the Community Law Centre, *Realising socio-economic rights in South Africa: Progress and challenges,* Cape Town, 17-19 March 2002 cited in S Liebenberg 'South Africa's evolving jurisprudence on socio-economic rights: An effective tool in challenging poverty?' available at http://www.communitylawcentre.org.za/Socio-Economic-Rights/research-project/2002-vol-6-law-democracy-and-development/liebenberg-12-march.pdf/ (accessed 16 June 2008).

[121] 1996 (2) SA 751 (CC).

[122] Para 77.

under conditions of impossibility of fulfilment, citizens retain their right to have their core needs met once conditions change.[123] He further argues that recognising currently non-realisable rights demonstrates that there are some needs to which individuals are entitled solely by virtue of their status as human beings, keeps the state aware of its pending obligations and obliges the state to engage in social provisioning as soon as resources become available.[124] The recognition of minimum core obligations does not require the state to attempt achieving the impossible but to provide core needs when the capacity to do so exists or becomes available. In *Grootboom*, the Court rightly observed that resource constraints only qualify the content of the obligation (not the right) concerning 'the rate at which it is achieved as well as the reasonableness of the measures employed to achieve the result'.[125]

Therefore, it is not possible for the courts to determine whether a right has been infringed or whether a measure is unreasonable without first delineating the content of the right. To assess reasonableness, state conduct must be evaluated against certain yardsticks on what the right means.[126] The Court in *Treatment Action Campaign* held that it is 'impossible to give everyone access even to a "core" service immediately. All that is possible, and all that can be expected of the state, is that it acts reasonably to provide access to socio-economic rights identified in sections 26 and 27 on a progressive basis'.[127]

Bilchitz notes that this echoes a failure to recognise the existence of 'interests that can be classified as of great urgency and that must be realised as a matter of priority in order to ensure [human] survival.'[128] It will be remembered that one of the shortcomings of *Grootboom* is its failure to hold that apart from mere inclusion in state plans, the needs of the most vulnerable must be given priority. Liebenberg argues that the fact that the

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[123] Bilchitz 'Towards a reasonable approach to the minimum core: Laying the foundations for future socio-economic rights jurisprudence' (2003) 19 *SAJHR* 1 at 18.
[124] Ibid at 20-2.
[125] *Grootboom* (note 68) para 46.
[126] Liebenberg (note 120) argues that '[the] component of the reasonableness test requiring government programmes to provide relief for those in desperate need and living in intolerable conditions is vague and lives many questions unanswered.'
[127] Para 37.
[128] Bilchitz (note 123) at 14.

'reasonableness test requires specific measures to cater for the urgent needs of vulnerable groups achieves the same net effect as that desired by proponents of the minimum core obligations'.[129] Arguably, even the Constitutional Court itself recognises, without being aware it does so, the intrinsic content of a right as an acontextual standard of guidance in evaluating state compliance with constitutional obligations in different contexts.[130] Thus, reasonableness determinations are only possible when there are targets that the state has to achieve.[131]

Minimum core obligations establish varying standards of provision; the state can be compelled to provide immediately a minimum core whilst having to improve the standard of provision progressively at the macroeconomic level.[132] When the Court in *Treatment Action Campaign* holds that immediate fulfilment of all 'core' needs is unrealistic, it says no more than the Committee's observation that assessing state compliance with minimum obligations 'must take account of resource constraints'.[133] Therefore, even if the minimum core is relatively rigid, its realisation is flexible because it is contingent upon the availability of resources. All the state is required to do is to show that 'all the effort has been made to use' all available resources to satisfy, as a matter of priority, its minimum core obligations.[134] Alternatively, the state could plead that resource constraints constitute a justifiable limitation of the right(s) in question in terms of section 36 of the Constitution.

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[129] Liebenberg (note 120) at 17.

[130] See *Grootboom* (note 68) at para 31, where the Court observes that the 'minimum core obligation is determined by having regard to the needs of the most vulnerable group that is entitled to the protection of the right in question.'

[131] See Bilchitz (note 123) at 10, arguing that '[t]he context bound nature of a determination of reasonableness requires that we have at least some specification of standards we wish to be met such that we can appraise the government's actions in a variety of contexts in terms of their potential to meet these standards'.

[132] See Bilchitz (note 123) at 13, arguing that '[t]he idea of a minimum core obligation suggests that there are degrees of fulfilment of a right and that a certain minimum level of fulfilment takes priority over a more extensive reaslisation of the right.'

[133] General Comment 3 (note 37) para 10.

[134] This ties in very well with the Court's additional requirement on reasonableness in *Treatment Action Campaign* that government programmes must be transparent and accountable.

2.4.7 Reasonableness, minimum core obligations and access to essential medicines

As shown above, reasonableness is a vague standard of scrutiny and although the Court has given content to the reasonableness test, this does not determine the content of rights. Giving content to reasonableness instead of spelling out the non-derogable essential levels of human existence protected by each right creates only a vague right to 'reasonable government action' in the stead of core entitlements to tangible benefits such as access to essential medicines. Examining the reasonableness of state conduct while not recognising the core needs to which citizens are entitled in terms of section 27(1) may serve to defeat the purpose behind constitutionalising the right to health care services. Thus, despite the Constitutional Court's rejection of the minimum core, it is still an essential component of the right to health under the South African Constitution and may be considered an integral part of the reasonableness inquiry.

Recognising the existence of core needs echoes the essential medicines concept. Like essential medicines that have to be available at all times in functioning health systems, minimum core obligations bind the state to take steps to provide for individuals' basic health care needs. Given that the right to health is codified in many international instruments and the Constitution, it should be accepted that this right has at its core a duty to provide essential medicines, particularly ARVs, to poor patients. The gravity of the HIV pandemic and the magnitude of deprivation that confronts those who lack access to medicines should cause the government to prioritise cost-effective, safe and affordable ARVs for this category of persons.

2.4.8 'Progressive realisation within available resources'

Recognising resource constraints as a legitimate defence for state failure to realise socio-economic rights is consistent with the concept of 'progressive realisation'. States are bound to fulfil these rights over a period of time and not with immediate effect or on demand[135]. These rights are not meant to paralyse under-resourced countries. The Court in *Grootboom* accepted the CESCR's interpretation that 'progressive realisation' should be construed to mean that states 'have a specific and continuing obligation to move as

[135] *Grootboom* (note 68) paras 94 and 95.

expeditiously and effectively as possible towards the full realisation' of the right to health care.[136] The state has to take steps to provide health care treatment, care and support.

However, the availability of resources will feature significantly in determining whether the state's steps are consistent with the obligations imposed on it by section 27. The Court in *Grootboom* concluded that for a programme to be reasonable, 'there must be a balance between goal and means.'[137] The resources at the state's disposal should justify the degree to which health care needs are met. In*Treatment Action Campaign*, the additional funds allocated to the Department of Health did not support the state's intention to confine the provision of nevirapine to 10% of the population that had access to the research sites.[138] The courts may not as the Constitutional Court did in *Soobramoney*, simply accept the state's claim (even if made rationally and in good faith) that resources for providing a specific health care service are inadequate.[139]

The state bears the obligation to demonstrate to the Court that resource constraints justify the prejudice or harm suffered by the patient who is being denied access to treatment. There must be a connection between available resources and the degree of access to treatment. In determining whether the state has demonstrated this connection, the Court may have to consider the actual budgetary allocation for health but may not dictate to the executive what its policies should have been or should be at the macro-economic level. The Court in *Grootboom* held that reasonableness determinations exclude 'enquir[ing] whether other more desirable or favourable measures could have been adopted, or whether public money could have been better spent.'[140] However, the relevance of resource constraints in socio-economic rights adjudication does not mean that courts should not make orders that have budgetary implications.

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[136] General Comment 14 (note 37) para 31, cited with approval in *Grootboom* (note 68) para 45.
[137] *Grooboom* (note 68) para 46.
[138] *Treatment Action Campaign* (note 90) paras 119 and 120.
[139] See *Soobramoney* (note 73) para 29, where the Court stated that '[a] court will be slow to interfere with rational decisions taken in good faith by the political organs and medical authorities whose responsibilities it is to deal with such matters'.
[140] *Grootboom* (note 68) para 41.

The Court in *Treatment Action Campaign* observed that although its reasonableness inquiry is not 'directed at rearranging budgets', this inquiry 'may in fact have budgetary implications.'[141] This means that while resource constraints prevent the courts from questioning the wisdom of the government's initial allocational choices, this fact alone will not bar the courts from enquiring whether state policies to address public health concerns are reasonable, even though a finding that such policies are unreasonable will be tantamount to telling the state that it has to rearrange its budget.[142] The *Treatment Action Campaign* judgment ordered the government to provide nevirapine to other areas which were initially excluded from its PMTCT programme although this meant committing more resources than the state was willing to expend initially.

Thus, the Court doubted the authenticity of the state's object (ensuring drug efficacy first before universal provision) for limiting the provision of nevirapine to research sites and discarded the evidential base—resource constraints—for concluding that the employed criterion (pregnant women who had access to research sites) justified differential treatment of other pregnant women in similar circumstances. Therefore, resource constraints do not deny the courts an opportunity to invite the state to demonstrate that its allocational choices in fact provide the required resources to fulfil health care rights. In its redistributive decisions, the state must rationalise its choice of eligibility criteria, its definition of disadvantage and the purpose behind limiting a service (such as emergency medical treatment) to a particular category of persons.[143] In all circumstances the state's conduct should neither be less than available resources permit nor be regressive.

2.5 Conclusion

The Constitutional Court's denial to adopt a minimum core should not be allowed to override the state's obligation to provide essential drugs. For the Court to assess the reasonableness of the measures adopted by the state, it had to rely on the existence of core or non-negotiable human needs. The Court did so by observing that those who are living under intolerable conditions should be part of the state's measures to alleviate

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[141] *Treatment Action Campaign* (note 90) para 38.
[142] Brand (note 75) at 53-4.
[143] See S Friedman 'Substantive equality and the positive duty to provide' (2005) 21 *SAJHR* 163 at 171-80.

poverty. Without determining the minimum content of the right in question, the state may not know what it is expected to do, the individual may not know what they are entitled to and the court will be at sea as to the benchmarks against which state compliance with constitutional duties must be measured. Arguably, the provision of essential medicines as a core element of the right of access to health is integral to reasonableness review under section 27 of the Constitution. To be reasonable, a health plan should be targeted at providing essential medicines, especially ARVs, to the majority of South Africans who find the cost of drugs prohibitive for individual access.

CHAPTER 3: THE INTERNATIONAL REGULATORY FRAMEWORK FOR PATENT PROTECTION

3.1 Introduction

Chapter two has shown that health care as a human right imposes binding obligations primarily on the state to provide access to ARVs (as essential medicines) if the constitutional requirement of reasonableness is to be met. It has also demonstrated that the state has to strive towards making the resources necessary for the fulfilment of health care rights, available. This chapter explores the interplay between access to essential medicines and international patent laws. Due to exclusive marketing rights enjoyed by rights holders, the costs of patented medicines are prohibitive for universal access. In attempting to resolve the inevitable conflict between IP rights and public health, this chapter heavily dwells on the flexibilities within the Trade Related Aspects of Intellectual Property Rights Agreement (TRIPS) and how these flexibilities can be used to harness resources towards public health needs. The implications of compulsory licencing for patent protection and access to essential medicines are thoroughly considered in this chapter.

3.2 How and why are patents protected?

According to international patent law, it is unlawful for any person to produce, use, sell or import another person's patented invention—whether a product or process—without the patent rights holder's consent.[144] Subject to few exceptions, the patent holder enjoys exclusive marketing rights for a period of 20 years from the day the invention is filed.[145] Theoretically speaking, this period reflects the amount of time it takes the inventor to recover research and development (R&D) costs incurred in discovering new drugs.[146] It is generally accepted that the primary purpose of a patent is to provide an incentive for

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[144] See Article 28 of the TRIPS Agreement.

[145] In terms of TRIPS Article 33, patent protection endures for a period of 20 years from the date the patent application was filed.

[146] This basis for patent protection is highly contested. See Bombach (note 8) at 284, arguing that most drugs have significant marketability for a period of about ten years. This is because of the subsequent emergence of competing drugs which are more effective and have limited adverse effects. The older drug becomes 'obsolete'. The author concludes that 'when drug companies enforce their patent rights beyond the duration of profitability, they are simply preventing generic companies from producing lower cost equivalents, and hence depriving those in need from accessing essential medicines.'

invention by protecting the right holder's IP through a monopoly on the invention.[147] Developing essential medicines depends on knowledge of drug compounds that treat diseases. Given that knowledge can easily be appropriated, and that this in turn makes it difficult for the inventor to curb piracy,[148] it becomes desirable for the inventor to protect their knowledge through the law of patents. To reward the inventor, a number of legal systems introduce patent protection to grant patentees exclusive rights of exploitation for a certain time period.

To counter the potential detriment that arises from exclusive rights of exploitation conferred on knowledge-makers, knowledge-makers 'are required to share their knowledge so that others may build upon it and create future innovation.'[149] While no one is allowed to make or sell a patented article without the patentee's permission, patent protection also prevents the withholding of information that may benefit society. Whether the granting of a patent is necessary for encouraging innovation has ever been a subject for debates that never yield consensus. In reality the controversy 'translates into a debate about whether patent protection should be granted at all, or the extent to which patents should be protected.'[150] Unfortunately, it is not possible in this work to consider seriously whether inventions should really be given legal protection in the first place or whether alternatives for encouraging innovation exist. Fallible and highly contested as it is, the traditional economic justification for patent protection will stand.

3.3 Defending pharmaceutical patents

3.3.1 Incentivising innovation

The primary purpose of a patent is to provide an incentive for invention by protecting the right holder's IP through a monopoly on the invention.[151] Patent rights are necessary to provide incentives for R&D by granting the inventor exclusive marketing rights over new

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[147] R Weissman 'A long, strange TRIPS: The pharmaceutical industry's drive to harmonize global intellectual property rules, and the remaining WTO alternative available to Third World countries' (1996) 17 *University of Pennsylvania Journal of International Economic Law* 1069 at 1069-72.

[148] The fact that knowledge can be appropriated without its source diminishing further complicates the matter and points to the need for patent protection.

[149] Kerry Williams 'Pharmaceutical price regulation' (2007) 23 *SAJHR* 1 at 12.

[150] Ibid at 13.

[151] Weissman (note 147) at 1069-72.

medicines.[152] IP rights are therefore intended to encourage innovation by heightening the prospects of a pecuniary benefit that enables rights holders to recover their research investments and to make some profit.[153] Correa argues that:

> One increasingly widespread view is that the role of patents in promoting innovation is less substantial than usually claimed, and that "incremental increases in patent protection are unlikely to influence incentive activity significantly and incremental reductions might actually enhance economic welfare". Patents may even stifle the very innovation they are supposed to foster, such as in the case of...overbroad claims that impede follow-on research (footnotes omitted).[154]

The role of patents in stimulating innovation is thus not a given and should not be taken as an article of faith because it is based on the existence of a market—a socially constructed condition—which is immeasurable at the time the invention is made. Protecting IP before it establishes a recognisable market assumes away the possibility that some products may not be able to establish such a market were it not for the scarcity created by monopolising their production.

Collins argues that the patent protection afforded to new drugs provide a conducive environment for pharmaceutical giants to charge exorbitant prices, thereby making essential 'drugs unaffordable for most of South Africa's AIDS patients.'[155] She further contends that 'patent abuse has become an obstacle to the provision of medicines to the majority of the people in the world.'[156] In South Africa, rights holders have been accused of charging extremely high prices for their drugs. Abuse of market dominance and anti-competitive conduct by drug developers constitute practices which unreasonably restrain trade and bar any meaningful competition on the drug market.[157]

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[152] AM Curti 'The WTO dispute settlement understanding: An unlikely weapon in the fight against AIDS' (2001) 27 *American Journal of Law and Medicine* 469 at 476.

[153] For a counter-argument, see CM Correa *Trade Related Aspects of Intellectual Property Rights: A commentary on the TRIPS Agreement* (2007) 95, arguing that IP rights create scarcity of knowledge despite the fact that knowledge is non-rivalrous in nature.

[154] Ibid 99.

[155] Collins (note 17) at 159.

[156] Z Achmat 'We can use compulsory licensing and parallel imports: a South African case study, Aid Law Project' cited in T Collins (note 17) at 164.

[157] See J Berger 'Advancing public health by other means: using competition policy' available at http://www.iprsonline.org/unctadictsd/bellagio/docs/Berger_Bellagio3.pdf (accessed 24 September 24, 2007).

In this country, exclusive IP rights are being used to derive an unfair advantage that materialises when excessively high prices are used to extract a benefit that does not ordinarily flow from the exercise of such rights. This runs counter to the spirit of Article 8 of the TRIPS Agreement which sanctions the adoption of measures not only to protect public health and nutrition but to curb abuse of IP rights and 'practices which unreasonably restrain trade.' High prices are not necessary for maintaining incentives to innovate. As a result of patent monopolies on ARVs, escalating prices have made ARV therapy unaffordable for many South Africans. Without forcing causation too hard, patent protection encourages price distortions, and by necessary implication, limits access to life-saving medicines.

3.3.2 Recouping research and development costs

The drug industry's standpoint has ever been that revenues generated from firm patent protection in developing countries are used for R&D towards new medicines.[158] Admittedly, the drug development process is lengthy, costly and risky. The average cost of developing a new chemical entity in the 1990s was approximately $300 million and in some cases substantially higher.[159] More recently, studies have shown that if the cost of capital and failed attempts at drug development is considered, the total average cost will exceed $800 million.[160] Any measure to reduce patent revenues earned by pharmaceutical companies would necessarily reduce the reserve of funds for R&D, and would consequently inhibit the development of new medicines for the benefit of all countries.[161]

Failed attempts at innovation result from research investment made in pursuit of ineffective or unsafe chemical therapies. Moreover, safety and efficacy regulatory requirements have to be met before getting the product to the market. This means paying more money in the form of regulatory approval costs. Approval is not an overnight event and is often complicated, resulting in further costs incurred between the time a new

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[158] See HE Bale Jr 'The conflict between parallel trade and product access and innovation: The case of pharmaceuticals' (1998) 1 *Journal of International Economic Law* 637 at 640.
[159] Ganslandt et al (note 5) at 787.
[160] F Abbott 'The WTO Medicines Decision: The world pharmaceutical trade and the protection of public health' (2005) 99 *American Journal of International Law* 317 at 324-26.
[161] Ibid at 325.

pharmaceutical product is developed and the time the product reaches the market. Williams argues that 'launching products in different countries also adds to costs incurred by manufacturers as regulatory requirements often differ substantially between nations.'[162] In addition, pharmaceutical companies incur huge costs in manufacturing new drugs and distributing them to the market (manufacturing and distribution costs).

Generally speaking, research and development costs are a global shared burden or at least a shared burden for consumers in territories where the drugs are launched. Williams notes several problems that precipitate from the fact that these costs remain constant regardless of the number of consumers who will purchase the drug and demonstrates how patent protection overcomes these problems. He argues that:

> The difficulty is that it is not possible to rationally allocate R&D costs between individual consumers. Additionally, although the regulatory costs might be broadly allocated to consumers in each country, it is also a cost that will be incurred regardless of the number of consumers who purchase the drug, and cannot be rationally allocated to particular consumers within each country. For similar reasons the manufacturing and distribution costs also cannot be rationally allocated nationally. Therefore the solution to the difficulty...has been to award patent protection for innovative drugs so that the costs are spread between consumers. Patent protection allows costs to be recovered without competition for a fixed period of time. Without patent protection competition would force drug prices down to marginal cost and manufacturers would not be able to recover their R&D costs. As a result there would be no incentive to innovate. [163]

Justifying R&D costs is a difficult task because even costs that are incurred on failed attempts at innovation, the launching of drugs on new markets, securing regulatory approval and distributing new medicines to the market are all included in the umbrella term of R&D costs. There is a chronic failure or persistent refusal on the part of drug developers to disclose transparently the R&D costs that form the basis of the prices they charge and this in turn has led to allegations of patent abuse through monopoly pricing.[164]

Exactly how much cost is incurred to finance R&D remains under lock and key. National governments and individuals alike remain at sea in this regard. Drug developers' R&D costs for particular pharmaceuticals are seldom known or difficult to estimate accurately because costs are incurred over noticeably lengthy periods of time and at times, in respect

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[162] Williams (note 149) at 13-4.
[163] Ibid at 14.
[164] Ferreira (note 17) at 1142.

of failed attempts at innovation.[165] Williams argues that 'due to informational failures emanating from pharmaceutical companies it is also difficult to separate regulatory approval costs, and manufacturing and distribution costs from R&D costs.'[166] Worse still, at the time of negotiations for national price-setting, R&D costs 'are largely sunk.'[167] The fact that R&D costs are usually inaccessible leaves room for abuse of patents by unscrupulous rights holders. Before claiming a valid justification for an incentive-based argument or an argument based on research costs, drug developers must disclose their precise R&D costs and profits.[168]

Abott has indicated that only about 15% of pharmaceutical companies' revenue is used to finance R&D while a fairly larger share finances 'administration, advertising and promotion.'[169] Some argue that profits from selling drugs to the South are relatively low because only seven industrialised countries account for 80% percent of total income from drug sales while the entire African continent constitutes one percent of the market share.[170] In 2006, South Africa constituted no more than 0.3 percent of the global market share for drug developers.[171] Arguably, South Africa's contribution to R&D costs is relatively negligible.

As a result, Bailey contends that 'it does not [necessarily] follow that....[compulsory licensing] will lead to a significant reduction from present levels of research or even that such a reduction would be socially undesirable.'[172] Bailey insists that 'the present incentives to invest are so strong that they would have to be weakened considerably before there would be any reduction in the amount of pharmaceutical research.'[173] The

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[165] Williams (note 149) at 8.
[166] Ibid.
[167] Ibid.
[168] Bombach (note 8) at 284.
[169] Abott (note 160) at 325.
[170] B Gellman 'An unequal calculus of life and death: As millions perished in pandemic, firms debated access to drugs' Washington post (27 December 2001) available at http://www.popline. org/docs/1368 /156228.html (accessed 09 April 2008) (citing IMS Health data which supplies market data to the pharmaceutical industry).
[171] Sprague and Woolman (note 18) at 372.
[172] TC Bailey 'Innovation and access: The role of compulsory licencing in the development and distribution of HIV/AIDS drugs' (2001) *University of Illinois Journal of Law, Technology and Policy* 193 at 216.
[173] Ibid at 215.

problem is compounded by the fact that it is not clear precisely what fraction of the income is specifically devoted to R&D of new treatments.

This leaves the debate concerning the impact of patents on R&D or access to medicines wide open because there is a significant number of 'unknowables' that have to be considered before making any objective finding.[174] However, the question is not whether inventions should be patented but to what extent should they be patented and under what circumstances should protection be overriden. It is clear that IP protection will not disappear and that there are circumstances in which denial of access to medicines has little or nothing to do with the pharmaceutical research mission. Exactly when these circumstances exist is a subject marred by controversy, but it is arguable that patent protection should not threaten public health by unreasonably restricting access to medicines. In balancing public health and IP protection, regard should be had to the provisions of the TRIPS Agreement and the interpretative guidelines enunciated in the Doha Declaration.

3.4 Patent protection under TRIPS

3.4.1 Overwiew

The Uruguay round of agreements, to which South Africa is a signatory, requires domestic IP laws to conform to the minimum standards set by TRIPS. The WTO makes it crystal clear that TRIPS constitutes a 'minimum standard' for IP protection. Thus, while TRIPS is the standard baseline below which patent protection given by member states may not fall, the TRIPS Agreement gives considerable leeway to member states to prescribe national patent protection standards within their territorial limits.[175]

Article 27 of TRIPS states that member states are under an obligation to ensure that patents protect both process and product inventions. A process patent protects the knowledge as to how the product was manufactured while a product patent protects the

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[174] Abott (note 160) at 325.

[175] See Article 1(1) of the TRIPS Agreement which states that 'members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement.'

end product itself. The TRIPS Agreement also codifies the conventional requirements for patentability, namely, that the invention must be new and must involve an inventive step capable of industrial application for a period of twenty years. The exclusive marketing rights thus conferred on rights holders mean that third parties may not use, sell or import the patented invention—whether the product or the process.

Patent protection leaves no room for further development of new processes to make similar drugs that introduce competition into the market. Qutterson contends that TRIPS-compliant laws allow the innovator to charge higher prices under monopolistic conditions, that the prices substantially exceed R&D costs, that the higher prices make access to essential medicines more difficult for low income people globally and that this inhibits innovation because knowledge takes longer to enter the public domain.[176] However, the TRIPS Agreement has provisions that present members with alternative regulatory measures that may speed up access to patented medicines.[177]

3.4.2 Flexibilities within the TRIPS Agreement

The TRIPS Agreement establishes minimum standards of patent protection and members are allowed to take TRIPS-plus measures to protect IP rights. Certain flexibilities within its text may be exploited by member states seeking to enhance access to essential medicines. These flexibilities relate to the doctrine of exhaustion of rights, the exceptions to the granting of exclusive marketing rights, parallel importation and the granting of compulsory licences.[178] Article 30 provides that member states may allow for 'limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner...'

Williams argues that Article 30 governs the traditional exceptions, for example research and fair use but it does not limit 'circumstances in which patent protection must be

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[176] K Qutterson 'Pharmaceutical arbitrage: Balancing access and innovation in international prescription drug markets (2005) 5 *Yale Journal of Health Policy Law & Ethics* 193 at 201-02.
[177] These flexibilities are mentioned in Articles 7, 8, 30 and 31.
[178] These flexibilities are found in articles 6, 7, 8, 27(2), 30 and 31.

conferred.'[179] It is submitted that this interpretation is correct because coercive use of patented articles in terms of Article 31 cannot be said to be consistent with the normal exploitation of a patent. Article 31 of the TRIPS Agreement permits use, of 'the subject matter of a patent without the authorisation of the right holder', for certain reasons and subject to specific conditions. This provision permits the issuance of compulsory licences for the production and importation of generic medicines.

3.5 Compulsory licences

3.5.1 Definition

By definition, a compulsory licence is an authorisation to produce, import, use or sell a patented invention without the patent holder's consent.[180] Compulsory licencing enables governments to coerce patent holders to licence their patented inventions to other manufacturers before the expiry date of the patent. By issuing a compulsory licence, the government allows another person to reproduce the patented product or process without the consent of the patent owner.[181] Bombach argues that compulsory licencing 'overrides existing IP protection by compelling the holder of a patent to grant licences to local manufacturers who will in turn charge lower prices.'[182]

3.5.2 Conditions for granting

The justifiability of issuing a compulsory licence is considered in the light of the circumstances of each case.[183] This implies that compulsory licencing should be founded on solid grounds in law, may not be used arbitrarily and may not be tantamount to a blanket approval for overriding patents in a particular field of technology.[184] This is meant to protect the patent owner against arbitrary exploitation of compulsory licencing and to permit compulsory licencing when it is in the public interest to do so.

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[179] Williams (note 149) at 22.
[180] SM Ford 'Compulsory licencing provisions under the TRIPS agreement: Balancing pills and patents' (2000) 15 *American University International Law Review* 941 at 942
[181] WTO 'Compulsory licencing of pharmaceuticals and TRIPS' available at http://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf (accessed 15 November 2007).
[182] Bombach (note 8) at 276.
[183] Article 31(a) of the TRIPS Agreement.
[184] This reading is consistent with the provisions of Article 27. Article 27(1) states that 'patent rights shall be enjoyable without discrimination as to the place of the invention, the field of technology and whether products are imported or locally produced.'

In terms of Article 31(b), countries may resort to compulsory licencing only after making unsuccessful efforts, 'within a reasonable time period, to obtain authorisation from the right holder on reasonable terms and conditions.' This provision obliges both parties to confine their demands to what is 'reasonable' in the circumstances.[185] The reasonableness of the terms and conditions largely depends on the amount of compensation for the infringement of IP rights to be determined in the light of the drug prices the patentee charges. However, the duty to negotiate with the patent holder may be waived under Article 31(b) if there is a 'national emergency or other circumstance of extreme urgency or in cases of public non-commercial use.'[186] In cases of 'national emergencies or extreme urgency', the patent right holder must be notified of the decision as soon as possible.

In *all* circumstances, the licencee will be bound to pay a certain amount of compensation to the patent holder. Article 31(h) stipulates that the patent holder is entitled to commensurate compensation to be calculated in the light of 'the circumstances of each case, taking into account the economic value of the authorisation.' Although the patent holder's anti-competitive conduct may be a relevant factor in calculating the amount of compensation, states are bound to pay 'adequate' compensation despite the cause for the issuance of a compulsory licence.[187] Whether compensation is 'adequate' depends on whether it is issued to remedy an anti-competitive practices or whether an emergency sanctioned the adoption of a particular measure. In the former case, compensation should carry a punitive element to reflect the undesirability of abusing market exclusivity. What is 'adequate' therefore also depends on whether the compensation sufficiently discourages anti-competitive conduct if such conduct has been established and this in turn determines whether the terms are reasonable under Article 31(b).

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[185] Both the government and the patent holder are thus obliged to discuss the issuance of a compulsory licensing on 'reasonable commercial terms and conditions'.

[186] M Blakeney *Trade related aspects of intellectual property rights: A concise guide to the TRIPS Agreement* (1996) 91, argues that 'typically, non-commercial public use will be in the fields of public health and national defence.' Thus, the government can forego the need to discuss with pharmaceutical companies by exploiting the 'public non-commercial use' exception.

[187] Article 31(k) read with Article 31(h) of the TRIPS Agreement.

Compulsory licencing must be authorized predominantly for supplying the domestic market of the authorising state.[188] Such use may not be exclusive.[189] It may not be assignable unless the assignment includes the goodwill enjoyed by the use.[190] Compulsory licences may not outlive the purposes for which they were granted unless the conditions which led to their issuance are likely to recur.[191]

3.5.3 Grounds for granting

3.5.3.1 The 'public interest' exception

Article 8(1) of the TRIPS Agreement is constructed in a permissive way to encourage states to 'adopt measures necessary to protect public health and nutrition'.[192] This article grants members a fair measure of latitude to frame legislative responses to public health and other public interest needs. While extending the adoption of legislative responses to public interest sectors other than health, the express mention of 'public health' as a basis for legislative policy shifts underscores the importance the TRIPS Agreement lends to public health.

The 'public interest' measures permitted under Article 8(1) must be read in conjunction with Article 31(b) which permits compulsory licencing, without prior negotiation with the patent holder, 'in cases of public non-commercial use.' Governments may use these provisions as grounds to fulfil their 'public interest' duties to meet health needs. Members may also invoke Article 7,[193] which envisions the maintenance of social and

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[188] Article 31(f) of the TRIPS Agreement.
[189] Article 31(d) of the TRIPS Agreement.
[190] Article 31(e) of the TRIPS Agreement.
[191] Article 31(c) read with Article 31(k) of the TRIPS Agreement.
[192] Article 8 states that:

(1) Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
(2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.'

[193] Article 7 reads:
The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of

economic welfare as one of the objectives of the TRIPS Agreement. The flexibilities within and the objectives of Article 7 grant members the freedom to preserve a measure of domestic control and legislative elasticity over IP post-TRIPS.[194] Article 7 explicitly states that 'the protection and enforcement of [IP] rights should contribute...to the social and economic welfare' of member states.

It should be noted that public health policies are integral to the protection of social and economic welfare and 'promotes the public interest' in health, social and economic concerns. Therefore, the adoption of public health policies that address the priority health care needs of the population 'promotes the public interest in [a] sector of vital importance to [the] socio-economic development' of South Africa as envisaged in Article 8(1).[195] Articles 7 and 8 may serve as a basis for adopting regulatory policies limiting the enjoyment of exclusive rights under Article 31.[196]

3.5.3.2 Anti-competitive practices

Article 8(2) permits members to adopt measures to 'prevent the abuse of [IP] rights by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.'[197] Anti-competitive practices include failure to work the patent locally, refusal to deal, monopolistic pricing and failure to meet the domestic demand for the patented product.[198] To secure a licence on the ground of

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producers and users of technological knowledge and in a manner conducive to social and economic welfare, and a balance of rights and obligations.

[194] JH Reichman 'Implications of the Draft TRIPS Agreement for developing countries as competitors in an integrated world market' United Nation Conference on Trade and Development, Discussion Paper No. 73 (November 1993) 17.

[195] See Chapter 2. It will be recalled that economists have indicated South Africa could lose $22 billion in revenue in 2010 due to HIV/AIDS.

[196] JH Reichman 'Universal minimum standards of intellectual property protection under the TRIPS component of the WTO Agreement' in CM Correa and AA Yusuf *Intellectual property and international trade: The TRIPS Agreement* (2008) 23 at 33, argues that Article 7 provides 'further grounds for regulatory action limiting grants of exclusive rights in appropriate circumstances.'

[197] As is shown below, the international transfer of technology becomes very important in enhancing the manufacturing capacity of members who cannot manufacture their own drugs due to capacity concerns.

[198] Most of these grounds are inferable from Article 31(b), read with Article 31(k) of the TRIPS Agreement. According to GHC Bodenhausen *Guide to the application of the Paris Convention for the Protection of Industrial Property as revised at Stockholm in 1967,* (1968) 71, patent abuse occurs if the patentee fails to work the patentee locally, 'refuses to grant licences on reasonable terms and thereby hampers industrial development, or does not supply the [domestic] market with sufficient quantities of the patented product, or demands excessive prices for such products.'

refusal to deal, the applicant bears the burden to prove that the patent holder is rejecting a request for a voluntary licence under reasonable commercial terms and conditions.[199]

The rights holder's anti-competitive conduct plays a key role in determining the amount of compensation the holder should be paid.[200] This shows that anti-competitive conduct is seriously discouraged under international IP law. The need to curb anti-competitive conduct should be decisive in determining the remuneration payable in such cases because the amount paid serves as a remedy for and a disincentive against patent abuse. Therefore, Articles 7 and 8, read with article 31, sanction the implementation of compulsory licencing measures to protect public health and prevent abusive conduct by rights holders.[201] It is important to note that under all circumstances, the granting of a compulsory licence should be in harmony with the TRIPS Agreement, particularly its purpose and principles as envisaged in Articles 7 and 8, respectively.

3.5.3.3 National emergency or extreme urgency

Article 31(b) of the TRIPS Agreement permits countries to bypass the requirement of prior negotiations with a patentee if a 'national emergency or extreme urgency' exists. This ground for granting compulsory licences is relatively new to international IP law and highlights the need for flexibility in balancing competing IP rights and public policy objectives. Even though it was intended to give states some flexibility in determining what constitutes an emergency, any state can declare an emergency where there is no emergency at all or for highly questionable reasons. The absence of any guidance regarding eligible countries, diseases and drugs leaves members in a state of uncertainty as to the scope of internationally protected activity.

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[199] CM Correa 'Patent Rights' in CM Correa and AA Yusuf (eds) *Intellectual property and international trade: The TRIPS Agreement* (2008) 227 at 248.

[200] Article 31(k) of the TRIPS Agreement.

[201] Correa (note 199) at 234, argues that 'The TRIPS Agreement merges [the] broader concept of abuse with the public-interest exception for purposes of compulsory licensing under Article 31.'

Until the Doha Declaration,[202] it was unclear what this tantalising phrase—'national emergency or extreme urgency'—really meant.[203] Paragraph 5(c) of the Doha Declaration unequivocally grants states the 'right to determine what constitutes a national emergency or other circumstance of extreme urgency, it being understood that public health crises such as HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.'

Paragraph 5 is particularly important for three reasons. First, it makes it clear that 'public health crises' constitute 'a national emergency or extreme urgency.' Thus if a 'public health crisis' exists, countries may grant compulsory licences (when provided for under national law) without the obligation for prior negotiations with the patent owner. Second, the use of the terms 'including' and 'other epidemics' shows that the list of the epidemics is not a closed one and leaves room for individual countries to determine whether a disease has assumed such serious proportions as to be labelled 'a national emergency or other circumstance of extreme urgency.' Third, as Correa notes, reference to HIV/AIDS, tuberculosis, malaria and other epidemics' explains that an 'emergency' may be short term or long term, and that the listed epidemics are merely illustrative.[204]

It is evident from the individual autonomy paragraph 5 gives to states to determine what constitutes a 'national emergency or extreme urgency' that the burden of proving that an emergency or extreme urgency does not exist, lies on the state party doubting that determination.

The TRIPS Agreement does not spell out an exhaustive list of grounds upon which coercive measures may be taken to address public health objectives. This gives member states considerable latitude to decide whether circumstances suggest the adoption of these

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[202] The WTO Ministerial Conference 'The Doha Declaration on the TRIPS Agreement and Public Health' adopted at Doha, Qatar, on 14 November 2001.

[203] Even after the Doha Declaration, the uncertainty still remains because a declaration is not legally binding. However, it has persuasive authority if one considers it as evidence of subsequent state practice after the signature and ratification of the TRIPS Agreement.

[204] CM Correa 'The implication of the Doha Declaration on the TRIPS Agreement and public health' available at http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf (accessed 31 March 2008).

measures or not. Article 31 merely refers to instances where the law of a state permits for 'other use' without authorisation of the patent holder. Government conduct will remain TRIPS-compliant even if the government issues compulsory licences to secure drugs at prices lower than the patent right holder might have charged, provided that the government's actions, on the whole, do not undermine the object of the TRIPS Agreement.

Further, the inclusion of the catch-all 'national emergency or extreme urgency' phrase, the need to protect public health and to promote the public interest, provide solid bases for concluding that the TRIPS Agreement envisions compulsory licencing for the purposes of combating HIV/AIDS. The government could declare that certain 'public health crises' or epidemics such as HIV/AIDS constitute 'national emergencies' for purposes of the TRIPS Agreement. Chapter one has already shown that the HIV/AIDS epidemic in South Africa affects every level of the population pyramid, the economic, health and education sectors. Therefore, HIV/AIDS in South Africa has reached such crisis proportions as to be called a 'national emergency' within the meaning of the TRIPS Agreement.

In fact, there have been frequent calls in South Africa for HIV/AIDS to be declared a 'national emergency' in order to pave way for the South African government to use TRIPS flexibilities, notably compulsory licencing, to enhance access to ARVs. If HIV/AIDS were to be declared a 'national emergency' or if South Africa were to rely on any of the exceptions to IP protection under the TRIPS Agreement, such a policy choice would present this country with an opportunity to produce generic versions of ARVs for distribution across the whole country.[205]

Despite the call, South Africa has not officially declared the AIDS crisis a 'national emergency.'[206] President Thabo Mbeki has come in for particular criticism for his position on the pandemic and whether it should be declared a 'national emergency.' In

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[205] Bombach (note 8) at 290.

[206] See Jon Jeter 'South Africa resists call for AIDS 'emergency', The Washington Post, 15 March 2001, at A1.

March 2001, the President turned down appeals that the National Assembly declare the HIV/AIDS pandemic a 'national emergency'.[207] The President emphasised that in terms of South African law, a state of emergency could only be declared to restore peace and order and that no such threats to the country's security existed.[208] He likens an 'AIDS emergency' to a 'state of emergency' under section 37 of the Constitution.

Literally, an 'AIDS emergency' meets the first requirement of a section 37 emergency because AIDS is a 'natural disaster or other public emergency [that] threaten[s] the life of the nation.'[209] However, the second requirement—'necessary to restore peace and order'—is difficult to meet in the context of AIDS unless one argues that those directly affected or infected by AIDS do not have peace of the mind and are therefore living in a state of psychological unrest, confusion and exclusion. This, however, is synonymous to a bizzare or absurd interpretation of constitutional provisions to make them mean whatever we may want them to mean.

Assuming that the 'AIDS emergency' met the requirements enumerated in section 37, it would still be difficult to reconcile that assumption with the President's observation that AIDS is not a threat to national security. The difficulty arises from the President's failure to realise that while the section 37 emergency permits the state to suspend fundamental rights under certain circumstances, an 'AIDS emergency' requires the state to take regulatory and other measures to fulfil health care rights. Although IP rights may be overridden in the process, the primary goal is not to give the state a licence to trump these rights but to remind the state that it has a legal obligation to provide for the health care needs of those living with AIDS, through compulsory licencing of patented drugs.

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[207] Nicolus Cook (note 6).

[208] Ibid. The President explained that the country's laws were enough to increase access to medicines.

[209] Section 37(1) of the Constitution states that '[a] state of emergency may be declared only in terms of an Act of Parliament, and only when—

(a)the life of the nation is threatened by war, invasion, general insurrection, disorder, natural disaster or other public emergency; and

(b) the declaration is necessary to restore peace and order.

Even if one were to assume that overriding patent rights makes the 'AIDS emergency' a section 37 emergency, it should be noted that the latter normally sanctions the suspension of individual human rights and not the suspension of property rights or the disruption of business activities. Thus, the South African government was simply being informed to use the magnitude of the pandemic to justify their use of the flexibilities in Articles 7, 8 and 31 of the TRIPS Agreement.

However, it is inconceivable that the President is unaware of the distinction between an 'AIDS emergency' and the section 37 emergency. His denial must be viewed in the context of his broader perception about AIDS. It will be remembered that the President's denial to call AIDS an emergency surfaced in the aftermath of his April 2000 letter to then American President Bill Clinton and other heads of states. The letter defended dissident scientists who maintain that HIV does not cause AIDS. Sensibly, it stands to reason that he could not envision declaring AIDS an 'emergency' when he doubted the scientific explanation of its causality in the first place. Observers are convinced that the proportion of HIV/AIDS infection in South Africa could have been reduced or slowed if the President understood the reality and magnitude of the pandemic.[210]

3.5.4 Compulsory licencing, cheaper drugs and access to medicines

All proponents for compulsory licencing argue that by authorising the production of generic versions of patented drugs, compulsory licencing will encourage competition and drastically reduce sky-rocketing prices to minimal levels.[211] Compulsory licencing suppresses pricing models that cannot be objectively justified within a particular market and promotes corporate social responsibility by calling companies to share the benefits of their research with the community.

In explaining the link between compulsory licencing and low drug prices, Halbert argues that '[t]here is significant evidence that when generic drugs are available, or other mechanisms are in place to provide competition, drug prices fall. Losing control of the

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[210] Ibid.
[211] See for example Bollyky (note 17) at 533.

market would open the window for an evaluation of the pricing structures of many pharmaceutical products.'[212] In the same vein, the WHO has observed that 'compulsory licences are the easiest and most effective way to increase the supply of products, by acting directly on marketing conditions or by deterring patent holders from taking measures that would arbitrarily reduce supply or artificially or excessively increase prices.'[213]

This is particularly so when a compulsory licence is given to remedy abuse of IP rights by rights holders or when the patent holder fails (or relies on imports) to meet the demand of the local market. Pharmaceutical pricing data clearly reveals that the prices of patented medicines usually register a dramatic 30% decrease every time a generic equivalent enters the market.[214] In 2002, a month's supply of original HIV/AIDS drugs cost R1176 whereas generic equivalents of the same drugs pre-qualified by the WHO cost R377.[215] The Treatment Action Campaign states that in 2003, a month's supply of nevirapine, AZT/lamivudine, lamivudine and AZT cost R369, R800, R640 and R582, respectively.[216] These prices fell to minimal levels when generic versions entered the market as agreed by the parties in the TAC Competition Complaint.[217] This demonstrates the downward trend

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[212] Halbert (note 17) at 267.

[213] WHO 'Globalization and access to drugs: implications of the WTO/TRIPS Agreement' available at http://www.who.int/medicinedocs/collect/medicinedocs/pdf/whozip35e/whozip35e.pdf (accessed 14 April 2008)

[214] Health Action International 'Globalization and pharmaceuticals: Implications for public health policy perspectives' available at http://www.who.int/medicinedocs/collect/medicinedocs/pdf/whozip35e/whozip35e.pdf (accessed 14 April 2008).

[215] See complaint in *Hazel Tau and Others v GlaxoSmithKline South Africa (PTY) Ltd and Others,* filed before the Competition Commission (hereinafter referred to as 'TAC Competition Complaint') para 44 stating that a course of combivir and nevirapine treatment costs R9733.33 and R4380 per patient per year, respectively; see also See also Ganslandt et al (note 5) at 786, where the authors argue that even if viramune (AIDS drug) was offered at $483 (original version) and $340 (generic version) in South Africa, instead of $3,508 for the same drug in the United States, these prices were still beyond the reach of AIDS victims in Sub-Saharan Africa.

[216] See for example Treatment Action Campaign, 'Competition Commission settlement agreements secure access to affordable life-saving antiretroviral medicines' available at http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm (accessed 15 April 2007).

[217] In the TAC Competition Complaint, the complainants later withdrew their complaint because the parties made settlement agreements. The terms of the agreement legally bound GlaxoSmithKline (GSK) to grant licences to four generic companies (including Aspen Pharmacare and Thembalami Pharmaceuticals) to produce, import, sell and distribute AZT, lamivudine and nevirapine. The settlement agreements approximately reduced the prices to a monthly cost of about R55 - R80 for nevirapine, R110 – R140 for AZT/lamivudine, R35 – R55 for lamivudine and R85 – R100 for AZT. This was important in that it enabled generic manufacturers to produce triple-drug fixed dose combinations, then manufactured only by

that prices take when generic equivalents of brand-name drugs enter the market after the issuance of a compulsory licence.

Activists argue that the prices of numerous AIDS-related drugs will be reduced by 50—90% if countries were allowed to produce generic substitutes of patented medicines through compulsory licencing.[218] Davis argues that through issuing compulsory licences, South Africa could reduce the price of essential drugs by as much as 90%.[219] Compulsory licencing or the threat thereof enables governments to intervene to correct market failures that result from the oligopolistic nature of pharmaceutical compnies. The American and Brazilian experiences have shown this to be the case.[220]

The WHO has observed that price is a major determinant of access to essential drugs and that every time patent monopolies enable companies to inflate prices out of the economic reach of consumers, public health severely suffers.[221] Therefore, price reductions

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two generic companies. Another significant improvement was that the royalty fee on the licences was substantially reduced from the 30% and 15% of the net sales of antiretrovirals that GSK and Boehringer Ingelheim (BI) respectively wanted to charge, to five percent of the net sales.

[218] Collins (note 15) at 164.

[219] LJ Davis 'A deadly dearth of drugs' available at http://www.motherjones.com/commentary/power_plays/2000/01/AIDS_drugs.html (acessed 14 April 2008). Davis has indicated that the fact that dual or triple therapy drugs cost $12000 per year per head means that the majority of South Africans, with an annual income of $3000, cannot afford to buy these drugs; see also Halbert (note 17) at 260 who argues that the fact that an average African country spends $10 per person per year on medical care means that the $12000 price tag is obviously too expensive for the poor to afford; see also S Singh cited in Collins (note 17) arguing that in South Africa, the majority cannot afford to buy these drugs because more than 60% of employed people in this country earn less than $250 a month.

[220] In response to the heightened sense of risk following the possibility of an anthrax epidemic post-September 11 2001, the United States threatened to order millions of doses of Cipro (a drug that treats anthrax) from generic manufacturers if Bayer (a German Cipro developer) refused to sell the drug at a lower cost. Canada had just done so and the United States threatened to follow suit. See for example Agence France Press 'France suggests U.S double standards over generic drugs', 2 November 2001, suggesting that because of its relatively stronger bargaining power, the United States was successful in getting Bayer to lower the cost of Cipro from $1.77 per tablet to 95 cents. The United States thus exploited the threat of compulsory licencing to lower the price of a medicine needed by American consumers. Brazil's success story is a bit different. In 1997, the Brazilian health ministry decided to finance projects of the Far-Manguinhos state-owned laboratories to reverse engineer drugs used to treat HIV/AIDS. Drug prices fell to normal levels. Thus the competence Far-Manguinhos have to reverse engineer ARVs ensures that Brazil's threat to use compulsory licencing continues to pay dividends. Reverse engineering is a process for discovering the manufacturing process of a product starting from the finished product. This practice is usually used to reproduce original drugs in countries that either exclude pharmaceutical products from patentability or permit generic manufacturing of patented drugs through compulsory licencing.

[221] WHO 'Globalization and access to drugs: implications of the WTO/TRIPS Agreement' available at http://www.who.int/medicinedocs/collect/medicinedocs/ pdf/whozip35e/whozip35e.pdf (accessed 14 April 2008); see also Bollyky (note 15) at 558-59, arguing that lower drug prices would 'greatly enhance the

following compulsory licencing will always translate into a corresponding increase in patients' buying power. More people would then afford to purchase life-saving medicines in the private sector.[222]

3.5.5 Members with no manufacturing capacity

Generic drugs produced under a compulsory licence should be used predominantly for the supply of the domestic market and the licence itself is non-assignable.[223] Thus states with severe public health epidemics, but with no sufficient manufacturing capacity could not assign a compulsory licencing to a member with the necessary capacity to manufacture and sell generics at affordable cost. To remedy this anomaly, the WTO continued negotiating the Doha Agenda. The negotiations culminated in the passage of the Implementation Decision which permitted exports of drugs manufactured under a compulsory licence to countries that had no capacity to make drugs.[224] The General Council, on recommendation of the Chairman, made the Implementation Decision permanent by amending the TRIPS Agreement. This means that countries without adequate manufacturing capacity are now permitted to import generic drugs made under a compulsory licence in an eligible exporting country.

However, the conditions attached to compulsory licencing for export or import purposes are so onerous there will be few exporting countries under this new regime. The exporting country must notify the Council for TRIPS the names and expected quantities of goods, must confirm that the importing country has established insufficient drug

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ability of private health care clinics and non-governmental organizations to meet the needs of HIV-positive individuals, [would] ensure the sustainability of ARV treatment currently provided by most medical schemes, would help guarantee continuous coverage for beneficiaries receiving ARVs through medical schemes [and would be] critical for individuals who have no access to medical schemes or whose medical schemes have been terminated.'

[222] See Centre for Actuarial Research, University of Cape Town 'The cover provided for HIV/AIDS benefits in medical schemes in 2002' available at http://www.commerce.uct.ac.za/Research_Units/CARE/Monographs /Monographs/mono10.pdf (accessed 15 April 2008), noting that at the close of the previous century, 'the prices of ARVs in South Africa have been substantially reduced leading to [a sharp] increase in accessibility to those who previously could not afford them, even with private sector medical scheme cover.'

[223] Article 31(e) and (f).

[224] See WTO General Council Decision 'Implementation of Paragraph 6 of the Doha Declaration on the TRIPS and Public Health' (August 30, 2003).

manufacturing capacity and must confirm that it has or will issue a compulsory licence pursuant to Article 31.[225]

Moreover, the exporter's compulsory licence must specify the quantity of drugs to meet an eligible member's needs, must sanction the exportation of all drugs thus made, must clearly identify the goods through marking, labelling or packaging and must ensure the licencee posts the quantities exported to each destination on its website.[226] These and other additional formalities[227] discourage countries to issue compulsory licencing for export purposes. These formalities were meant to combat the risk of trade diversion—a situation that arises when goods imported at low cost are re-exported to other affluent markets for profit.

For countries with 'some' manufacturing capacity such as South Africa to rely on these provisions, they have to show that they carried a thorough feasibility study that established that their capacity is insufficient for purposes of fulfilling their needs.[228] Admittedly, this is difficult to establish in the absence of a socio-economic model that classifies countries according to their economic performance at the global level. However, it is inconceivable to imagine South Africa qualifying as a member with insufficient manufacturing capacity when Brazil—equivalent to South Africa in economic development terms—has the world's sixth largest petrochemicals industry.

At the moment, the system may not attract more exporting countries that must be prepared to face insurmountable procedural obstacles in order to help a country without manufacturing capacity. Members exporting medicines under compulsory licencing already have capacity to meet their domestic needs and are not under any pressure to perform. It is regrettable that the new system depends on the willingness of countries that

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[225] Ibid para 2.
[226] Ibid.
[227] In terms of paragraph two, the exporting country must also notify the TRIPS Council of the licence and its conditions. This includes the name and address of the licencee, the licenced product, and permitted quantities, the importing country and the duration of the licence.
[228] Annex to the Implementation Decision.

do not 'feel' the urgency of access to treatment because their own disease burdens are under control.

3.5.6 Compulsory licencing in other jurisdictions

After issuing a 'government use order', Malaysia in February 2004, permitted local companies to import patented triple-therapy drugs from Cipla—an Indian firm—for distribution at public health facilities.[229] Data from the Malaysian Ministry of Health indicated that the average annual cost per patient fell from $315 to $58—an 81% reduction—following the introduction of generic drugs.[230] In Zimbabwe, the government declared a 'health emergency' to make way for compulsory licencing under its patent law.[231] Afterwards, the government granted compulsory licencing to three companies to import or produce patented drugs.[232] The Health Ministry observed that brand-name drug prices were threefold the price of generic versions.[233]

In 1999, Thailand threatened to invoke section 51[234]—if Merck (the patent holder) refused to reduce the price of efavirenz (an effective ARV)—of its Patent Act, which allows compulsory licencing in the public interest or to prevent severe shortages of essential drugs.[235] After unsuccessful attempts to negotiate affordable prices, the Thai Ministry of Health issued the first compulsory licence for efavirenz in November and another one for other AIDS drugs in January 2007.[236] Thailand cited its patent law and the Doha Declaration as the grounds on which it established its compulsory licencing

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[229] S Shashikant 'More countries use compulsory license, but new problems emerge' available at http://www.twnside.org.sg/title2/health.info/twninfohealth004.htm (accessed 2 June 2008).
[230] Ibid.
[231] Ibid.
[232] Ibid.
[233] Ibid.
[234] Article 51 authorizes the state use of patents to "carry out any service for public consumption" or to meet a list of specific public needs, including "to prevent or relieve a severe shortage of . . . drugs or other consumption items."
[235] A Assavanonda 'Thailand a step closer to become first developing country to use compulsory licensing' available at http://lists.essential.org/random-bits/msg00185.html (accessed 2 June 2008).
[236] R Steinbrook 'Thailand and the compulsory licensing of efavirenz' (2007) 356(6) *New Endland Journal of Medicine* 544 at 544.

regime. Merck was entitled to receive 0.5% of the net sales as compensation.[237] Brazil then followed suit.

Brazil contested that the price—approximately $580 per patient per year—at which Merck sold efavirenz in Brazil was 136% higher than the price paid by the Thais to the same company for the same drug.[238] Generics were costing between $163.22 and $166.36 per patient per year.[239] After lengthy and inconclusive negotiations, Brazil issued a compulsory licence on 4 May 2007 when Merck failed to meet the government's demand for a 60%—Merck made a 30% price rebate offer which the government denied—price reduction.[240] Brazil's issuance of compulsory licences could have been for 'public non-commercial use' under the TRIPS Agreement although the government only cited its national laws as permitting issuance in the public interest.[241] As shown above, Brazil's success story was made possible by the capacity public-sector laboratories had to reverse engineer brand-name drugs.[242] Thus, other developing countries have exploited the opportunities envisaged in their national laws as well as the flexibilities in the TRIPS Agreement to issue compulsory licences to enhance access to essential drugs.

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[237] Ibid.

[238] S Shashikant and Third World Network 'Brazil moves on to use compulsory licence after failed talks with drug company' available at http://www.twnside.org.sg/title2/wto.info/twninfo050703.htm (accessed 2 June 2008).

[239] Ibid. The Brazilian Ministry of Health argued that buying efavirenz at the generic cost would save $30 million per year (from 2007) and would translate into an estimated $236.9 million savings by 2012 (the year when the patent on efavirenz expires).

[240] K Alkorn 'Brazil issues compulsory licence on efavirenz' available at http://www.aidsmap.com/en/news/0550CE62-3F90-4603-932C-EF69E1B4485D.asp (accessed 2 June 2008).

[241] See for example The Ministerial Ordinance No. 866 of 24 April 2007, declaring that 'there exists the possibility of compulsory licencing for patents in the public interest', as provided in national laws, and decides 'to declare public interest in relation to efavirenz for the purposes of the granting of compulsory licensing for public non-commercial use, in order to guarantee the practicability of the National STD and AIDS Programme, ensuring the continuity of universal and free access to all medicines necessary for the treatment of people with HIV and AIDS.'

[242] According to M Cassier and CM Correa 'Patents, innovation and public health: Brazilian public-sector laboratories' experience in copying AIDS drugs' available at http://www.usc.es/epip/documentos/Cassier's%20paper.pdf (accessed 4 June 2008), the Ministry of Health's laboratories had the capacity to produce about 40% of the ARVs needed to meet the treatment needs of Brazil's HIV patients, with 'the remaining 60% being shared between other state-owned laboratories and private sector industry.' See also M Harvey 'Government has two weeks to legalise Generic AIDS drugs—TAC' cited in Halbert (note 17) noting that Brazil recorded a 50% reduction in death rate following 'broad access to affordable generic [ARV drugs].'

3.6 Conclusion

Public international law has long created the legal regulatory framework for enhancing access to essential medicines in the world. This chapter has indicated the opportunities international law creates for enhancing access to essential medicines. It has also shown how compulsory licencing translates into access to essential medicines at affordable cost. In the light of comparative jurisprudence and the absence of any recognised side effect of compulsory licencing in other jurisdictions, it is advisable that the government consider compulsory licencing as a mechanism for enhancing access to affordable medicines. Lessons on how to create a typical climate for compulsory licencing may be learnt from other developing economies such as Brazil.

CHAPTER 4: THE SOUTH AFRICAN REGULATORY FRAMEWORK FOR COMPULSORY LICENCING

4.1 Introduction

Chapter three has explored the possibilities that South Africa could exploit to use compulsory licencing within the confines of the TRIPS Agreement. It has shown that compulsory licencing enables the production of generic medicines, which in turn drive prices down towards universal access to drugs at affordable cost. This chapter explores the South African regulatory framework for compulsory licencing, with particular reference to the relevant provisions of the Patents Act and the Constitution. In considering compulsory licences under South African legislation, this chapter seeks to assess whether the provisions of the Patents Act are consistent with the TRIPS Agreement and the right to health. This chapter analyses whether lack of access to essential medicines is caused by the inadequacy of legislation governing patents or the inadequacy of government policy choices on patent protection and health care.

4.2 The Patents Act

4.2.1 Overview

South Africa has not implemented the compulsory licencing provisions of the TRIPS Agreement and the Patents Act. The fact that these provisions have not been the subject of civil litigation means that their content and limits have not been judicially determined. As a result, there is no guidance on the actual meaning of the sections permitting compulsory licencing. In interpreting both section 56(2) and section 4 of the Patents Act, regard will be had to judgments of foreign courts which had occasion to deal with similar provisions in their own patent regimes.

It must be recalled that the TRIPS Agreement establishes a standard baseline for patent protection.[243] This means that national patent laws may not give lesser protection than that which is granted by the TRIPS Agreement. As such, provisions relating to the scope and duration of patent protection in South Africa have been amended to meet the requirements of the TRIPS Agreement. These changes have been inserted into the Patents

[243] Article 1(1) of the TRIPS Agreement.

Act by the Intellectual Property Laws Amendment Act.[244] The changes include conditions (for granting compulsory) that are similar to those in the TRIPS Agreement.[245] This makes a discussion of the conditions for granting compulsory licences (under the Patents Act) purely redundant. As a result, general provisions governing patent protection are not discussed in this chapter because they are similar to the provisions of the TRIPS Agreement. However, it is worthwhile to consider in great detail the grounds for compulsory licencing under the Patents Act.

4.2.2 Grounds for granting compulsory licences

4.2.2.1 Abuse of market dominance

Section 56(1) of the Patents Act states that 'any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent.'[246] The service of a notice of motion, accompanied with evidence on affidavit, on the patentee or any person with an interest will suffice as the 'prescribed procedure.'[247] Therefore, the allegations must be well-grounded. The fact that the applicant is invited to apply 'in the prescribed manner' and to prove 'abuse' may pose insurmountable evidential and procedural obstacles to potential litigants who have *prima facie* cases of 'abuse' but cannot prove such 'abuse' on a balance of probabilities. This is particularly so in the light of informational failures on the exact cost of R&D of new medicines and the exact income of drug companies referred to in chapter three.

Section 56(1) of the Patents Act requires applicants, who may not establish 'abuse' because of these informational failures, to do more than they are required to in terms of international law. It will be remembered that Article 31 of the TRIPS Agreement allows both governments and third parties to use a patented invention without permission from

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[244] Act 38 of 1997.

[245] These conditions, stated in section 4 and 56(2), (3), (4) and (5) include the duty to negotiate on reasonable terms; the undesirability of meeting local demand by importation; non-exclusivity and non-assignability of a compulsory licence; termination of a compulsory licence when conditions that led to its issuance cease to exist and are unlikely to recur; and the importance of the need to combat 'abuse' when determining compensation or resolving disputes.

[246] Section 56(1) of the Patents Act.

[247] Regulation 96 of The Patents Regulations 1978.

the rights holder if national laws provide for such use. There is no command to do more than negotiating with the patentee on reasonable terms and conditions, failure which the government or third party may use the patented invention without a go-ahead from the patentee. In the latter case, the unauthorised user will have to inform the patentee of their unauthorised use and will also have to pay 'adequate' compensation to the rights holder. However, it could be argued that the Patents Act favours the compulsory licencee because it deems 'abuse' to have occurred even if, factually speaking, there was no 'abuse' in the first place.

Section 56(2) of the Patents Act spells out the grounds on which 'abuse' is deemed to have occurred.[248] The fact that this section is a 'deeming' provision means that the patentee bears the onus of proving that their conduct does not constitute 'abuse' of rights. Once any ground listed in section 56(2)(a)-(e) of the Patents Act is established, 'abuse' is presumed and the patentee bears the burden to prove that the facts upon which the presumption is based do not exist. The patentee may not argue that although one of the grounds in paragraphs (a)-(e) has been established, it does not constitute 'abuse', but may prove the determination that any of these grounds exists to be unfounded or untrue. This argument does not apply to section 56(2)(a) of the Patents Act if satisfactory reasons exist

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[248] Section 56(2) 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 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 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, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under license from the patentee or his predecessor or successor in title.

for the patentee's failure to work.[249] The presumption of 'abuse' gives governments and third parties the opportunity to issue compulsory licences without proving abuse as envisaged in subsection 56(1) of the Patents Act. The inclusion of a presumption, being a TRIPS-plus measure to facilitate use of compulsory licences, does not violate the minimum standards laid down by the TRIPS Agreement.

4.2.2.2 Failure to work the patented invention

In terms of section 56(2)(a), 'abuse' is deemed 'if the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent and there is no satisfactory reason for such non-working'.[250] The Patents Act does not define what constitutes working on a commercial scale. This term could mean that the patentee should exploit the patent in a manner that shows their willingness to maximise their profit. The term 'adequate extent' implies that, in the context of health for example, the extent to which the patent is being exploited must be proportionate to the health needs of the population. Failure to exploit the patent is deemed to exist 'after the expiry of a period of four years subsequent to the date of application for the patent or three years subsequent to the date on which the patent was sealed, whichever period last expires'.[251] The extent to which the patented invention is manufactured cannot meet the requirement of adequacy if it is less than it would have been save for the reason that the inventor has elected to exploit his right to prejudice the South African industry or market.[252]

However, the patentee could argue that satisfactory reasons exist for the non-working of the patent. There is no guidance on what reasons may justify the patentee's failure to work, but it is suggested that this could include factors like *vis major* or *causus fortuitus* culminating in impossibility of performance by the patentee. Nonetheless, it can be argued that the patentee still bears the onus to convince the commissioner that the reasons advanced for non-working are not remotely linked to the patentee's failure to work. For

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[249] Article 56(2)(a).
[250] Ibid.
[251] Ibid.
[252] See *Re Hatschek'Patents* cited as (1909) 26 RPC 228 at 241.

the patentee to justify failure to work, there should be an inherent or direct link between the reasons given and the patentee's failure to work.

4.2.2.3 Failure to meet demand on reasonable terms

Section 56(2)(c) of the Patents Act deems the abuse of rights 'if the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms'. This provision is intended to prevent deliberate rationing of the supply of patented products in order to heighten demand for that product. In short, the patentee or their licencee may not manufacture scarcity. The demand for the patented invention must be actual, but this does not mean that the patentee has no obligation to produce if no demand exists.[253]

The phrase 'reasonable terms' is not defined in both the Patents Act and the TRIPS Agreement. However, as argued in chapter three, 'reasonable terms' refers to the reasonableness of the price charged by the patentee or the compensation given to the patentee on compulsory licencing for 'abuse'. The price balances competing IP and health care rights. The price should not oppress patients and the amount of compensation should not oppress patent holders. Whether prices are reasonable could be determined by asking whether such prices serve the purposes the TRIPS Agreement seeks to achieve. If the patentee is apprehended while 'manufacturing scarcity' in order to charge excessive prices, such conduct should establish a failure to meet demand on reasonable terms. Whether or not the terms are reasonable cannot be governed by strict exhaustive rules but depends on the circumstances of each case.[254]

4.2.2.4 Refusal to grant a licence on reasonable terms

Section 56(2)(d) of the Patents Act supposes 'abuse' if 'by reason of the refusal of the patentee to grant a licence on reasonable terms...and in the public interest, the trade or

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[253] In *Re Boult's Patent,* cited as (1909) 26 RPC 383 at 387, the British Comptroller said that:
'The consideration of the adequacy of manufacture in this country does, no doubt, depends to some extent upon the demand existing for the article here or in neutral markets, but it does not follow that, if there is no demand, there is no obligation on a patentee to start an industry here...The patentee must make an effort to create demand here, and the establishment of an industry will in itself help to create in many cases a demand for the article or process in question'.

[254] See for example *Brownie Wireless Co Ltd's Applications* cited as (1929) 46 RPC 457 at 473.

industry of the Republic or any person or the establishment of any new trade or industry is being prejudiced'. The applicant bears the onus to prove that the patentee refused to grant the former a licence on reasonable terms (as discussed above), that the trade of South Africa or any person or the establishment thereof is being prejudiced by the refusal to grant a licence and that the 'public interest' is better served by the granting of a licence.[255]

The terms 'trade or industry' are not defined in the Patents Act and must therefore carry their ordinary grammatical meanings. According to the Collins Dictionary, 'trade' means 'the act of buying and selling either goods or services on the domestic or international markets' and 'industry' means 'organised economic activity concerned with the manufacture, extraction and processing of raw materials.'

In the *Brownie* case, Luxmoore J held that the term 'trade or industry of the United Kingdom' was 'capable of the most general interpretation' and that 'the establishment of any trade or industry of the United Kingdom' was also 'capable of the widest possible interpretation.'[256] Luxmoore J held that the words 'new trade or industry' could mean 'that the working of a new invention may be of sufficient importance to constitute a new trade or industry, and this may also be so even though the new invention is itself dependent on the working of an existing invention.'[257]

Whether one gives a dictionary meaning to the phrase 'trade or industry' or adopts the 'widest possible interpretation' referred to by Luxmoore J does not seem to make any substantial difference. The bottom line is that the refusal to grant a licence should not 'prejudice' the establishment or continued existence of a 'trade or industry' if it is in 'the public interest' to grant such a licence.

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[255] In *Brownie Wireless Co Ltd's Applications* (note 254) at 472-473, Luxmoore J said that the applicant must prove: (1) 'that the patentee has refused to grant the applicant a licence on reasonable terms; (2) the trade or industry either of the United Kingdom or the trade of any person or class of persons trading in the United Kingdom or the establishment of any new trade or industry in the United Kingdom is prejudiced by the refusal of the grant; and (3) that it is in the public interest that a licence should be granted...'

[256] At 473.

[257] Ibid.

Ultimately, as required by Article 7 of the Trips Agreement, the 'protection and enforcement of IP rights' under the Patents Act 'should contribute to the promotion of technological innovation; and to the transfer and dissemination of technology.' The 'transfer of technology' may occur through domestic or international trade, which may in turn stimulate the establishment or continued functioning of industries (including pharmaceutical industries). Section 56(2)(d) of the Patents Act, read together with Article 7 of the TRIPS Agreement, therefore prevents patent holders from unreasonably refusing to licence third parties whose trades or industries may be harmed by the patentee's refusal to promote their access to available 'technological innovation'.

If it is 'in the public interest' to grant a licence, the patentee may not refuse to grant a licence to a (potential) competitor, thereby erecting obstacles to the use of patented knowledge, solely on the grounds that he owns the invention. Unjustifiable refusal to grant a licence that facilitates 'transfer of technology' does not only prejudice the 'trade or industry of the Republic' but is also equivalent to the right holder's failure to participate in communal socio-economic development as required by Article 8(1) of the TRIPS Agreement.[258]

To remedy this deliberate 'abuse' of patent rights, section 56(2)(d) of the Patents Act deems 'abuse' to have occurred and permits compulsory licencing if refusal to licence prejudices the establishment or continued existence of a 'trade or industry' which serves a public purpose. This is consistent with Article 8(2) of the TRIPS Agreement which sanctions the adoption of 'appropriate measures to prevent the abuse of [IP] rights by rights holders and the resort to practices which *unreasonably* restrain trade or adversely affect the international transfer of technology.'[259] Technology transfer is very important in the health sector because it enables the government or local companies to produce ARVs to treat HIV-positive patients. Secondly, it will also enable South Africa not only to produce generic versions of patented medicines but to grant compulsory licences backed by the threat of local manufacture. The acquisition of machinery and equipment

[258] Article 8(1) of the TRIPS Agreement.
[259] Article 8(2) of the TRIPS Agreement.

could enable South Africa to follow the Brazilian model and reverse engineer (reproduce) patented medicines.

4.2.2.5 Domestic demand met by importation and at excessive prices

Section 56(2)(e) of the Patents Act permits compulsory licencing for 'abuse' if the demand for the product 'is being met by importation and the price charged is excessive [compared] to the price [the patentee or his licencee] charge[s] therefor in other countries.' This provision is meant to fight third degree price discrimination—a condition that arises from differential pricing depending on customer sensitivity to drug costs. The objective is not only to ensure that other countries do not become free riders in purchasing drugs but also to protect South African consumers from bearing the global burden towards R&D costs.

Section 56(2)(e) must be read together with the condition that only countries with insufficient manufacturing capacity may rely on compulsory licences for parallel importation of products that are patented locally. As has been shown above, South Africa faces an uphill battle in proving that it does not have the requisite manufacturing capacity if she is to rely on importation of drugs because her GDP per capita suggests the capacity to produce or copy drugs exists. It will be recalled that Brazil is in the same stage of economic development as South Africa and has the capacity to (re)produce brand-name drugs in its public laboratories. Assuming South Africa lacks the capacity to produce drugs, there are many procedural and evidential obstacles to be overcome at the WTO because South Africa is not a least-developed country.[260]

4.2.2.6 Use 'for public purposes'

Section 4 of the Patents Act states that:

> a patent shall in all respects have the like effect against the state as it has against a person: Provided that a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the Commissioner on application by or on behalf of such Minister and after hearing the patentee.

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[260] Even then, South Africa will have to amend section 56(2)(d) because Article 31 permits compulsory licencing when the law of a member permits such use. This means that South Africa may not rely on parallel imports if its own law does not permit that practice.

'Use of an invention for public purposes' permits the government to make 'public interest' exceptions to the protection of IP rights. Thus, if the government has a compelling public policy objective like the need to combat the HIV/AIDS pandemic, then it is in the 'public interest' to use compulsory licencing to enhance access to ARV drugs. Section 4 must be read with section 56(2)(d) of the Patents Act which permits compulsory licencing in the 'public interest, Article 8(1) of the TRIPS Agreement which permits the adoption of measures 'to protect public health and to promote the public interest in sectors of vital importance [to South Africa's] social and economic development', and Article 31 of the TRIPS Agreement which permits compulsory licencing 'for public non-commercial use'. The 'public interest' means 'the interest of the community, including the purchasing public.'[261]

The interests of the community in combating epidemics like AIDS must be considered in the light of a constitutionally guaranteed right to health care which binds the state to provide medicines to those in need. Factors like the egregiousness of the alleged 'abuse' of IP rights, the consequences of the 'abuse' on users of patented drugs, the significance of the 'public purpose' the government seeks to achieve, the opportunities HIV/AIDS patients have to enjoy health care rights through individual means and the degree of vulnerability of users of patented drugs, play a key role in determining whether issuance of a compulsory licence serves a 'public purpose' or is in 'the public interest'.[262]

As *Grootboom* has shown, the state may not ignore the 'degree of deprivation' that confronts those living with AIDS in determining whether the granting of a compulsory licence serves a 'public purpose' or is in 'the public interest'. It will be recalled that the duty to protect health care rights invites the government to adopt legislative and other measures to safeguard equal access to health facilities, goods and services. This includes the duty to control the marketing of medicines by third parties through compulsory licencing if it is in 'the public interest' to do so. The government therefore breaches its

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[261] *Brownie*'s case (note 252) at 473-474.

[262] See O' Reagan J in *Ferreira v Levin NO* 1996 (1) SA 984 (CC); 1996 (1) BCLR 1(CC) para 234, and the Court in *Lawyers for Human Rights and Another v Minister of Home Affairs and Another* 2004 (4) SA 125 (CC); 2004 (7) BCLR 775 (CC) paras 18 and 73, for these factors. The Constitutional Court in these cases decided on the question when is litigation in 'the public interest'.

obligations to use compulsory licencing as a measure of ensuring universal access to ARV medication at affordable cost, when it chooses not to use compulsory licencing in deserving circumstances. As argued in chapter two, the magnitude of deprivation that confronts those who lack access to ARVs should cause the government to prioritise—through compulsory licencing—medicines according to need rather than ability to pay.

Unauthorised use 'for public purposes' echoes the injunction 'to adopt measures to protect public health' and 'to promote the public interest' envisioned in Article 8(1) of the TRIPS Agreement. Together these provisions must be interpreted in a manner consistent with the government's constitutional obligation to promote and fulfil health care rights. Chapter two has demonstrated that when the state makes a statutory promise to take a particular course of action to provide health care services, then it is under a legal obligation to reasonably adapt its policy choices to meet the resource needs for the provision of those services. The fact that Parliament foresaw a possibility for unauthorised use of patented products 'for public purposes' binds the government to adapt its policy choices to meet its statutory promises if 'the public interest' warrants such a policy shift. Consequently, it is a dereliction of its constitutional obligation to provide essential medicines for the state to choose not to use compulsory licencing when HIV has reached such crisis proportions as to be called a 'national emergency'.

Grootboom has shown that the state's duty to take reasonable legislative and other measures to realise health care rights extends to the implementation of that legislation or those measures. Arguably, the state may not meet this obligation by passing or amending the Patents Act, and then choose to sit on provisions which could be implemented to meet the treatment needs of patients. Chapter two has shown that the duty is affirmative in nature and binds the state to take expeditious steps to use all available measures (including compulsory licencing) to enhance access to essential treatment at affordable cost. The duty to provide entails more than mere restraints on intrusive executive action and commands the state to provide institutional, financial and human resources to meet its citizens' health care needs. As shown in chapter three of this work, compulsory licencing enhances the state's financial capacity by indirectly driving down drug prices.

It is clear from the submissions made above that international and South African law permit compulsory licencing of patented medicines 'in the public interest' and 'for public purposes'. South Africa is aware of the regulatory flexibilities within both the Patents Act and the TRIPS Agreement but has chosen not to use them in the face of an AIDS pandemic that threatens to shake the foundations of society. Therefore, it is proper to consider briefly the possible reasons for South Africa's non-confrontational approach.

4.3 Why has South Africa not used compulsory licencing?

4.3.1 The obligation to respect and protect property

Section 25 of the Constitution states that 'no one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property'.[263] This begs the question: is IP 'property' in terms of section 25? Section 25 is mainly meant to govern land and other transactions concerning *corporeal* forms of property rather than knowledge that has been accorded commodity status. IP is different

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[263] Section 25 of the Constitution states that:

(1) No one may be deprived of property except in terms of law of general application, and no law may permit arbitrary deprivation of property.

(2) Property may be expropriated only in terms of law of general application—

(a) for a public purpose or in the public interest; and

(b) subject to compensation, the amount of which and the time and manner of payment of which have either been agreed to by those affected or decided or approved by a court.

(3) The amount of the compensation and the time and manner of payment must be just and equitable, reflecting an equitable balance between the public interest and the interests of those affected, having regard to all relevant circumstances, including—

(a) the current use of the property;

(b) the history of the acquisition and use of the property;

(c) the market value of the property;

(d) the extent of direct state investment and subsidy in the acquisition and beneficial capital improvement of the property; and

(e) the purpose of the expropriation.

from traditional forms of property in that it commodifies knowledge.[264] Van der Walt and Pienaar argue that 'property' under section 25 includes immaterial property rights such as patents and incorporeal things such as shares in a company.[265] The term property in section 25 means both that which is the object of the property and the rights the owner has in the object.[266] 'Property' therefore refers to property as rights. According to Cooke, the term 'property' denotes a relationship between a person and an asset, carrying rights in that asset on the strength of which it can reasonably be said that the person owns it or shares in its ownership'.[267]

It will be recalled that section 25(4)(b) of the Constitution states that 'property is not limited to land'. Although IP has no physical existence, the government is under a legal duty to respect and protect it. This means that the state may not arbitrarily deprive patentees of their rights to property on the ground that it is not 'physical'. The Court in *First National Bank of South Africa Ltd t/a Westbank v Commissioner for the South African Revenue Services and Others*[268] held that the state deprives citizens of their property when it interferes with the use, enjoyment and exploitation of private property.[269] Private property includes patented medicines. However, section 25 does not create an absolute and illimitable property right. The duty to protect property does not

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[264] Berger (note 17)at 169, arguing that 'from a social justice point of view, by creating property rights in knowledge and thereby manufacturing scarcity, we render knowledge less valuable. But it is this construction of scarcity that is central to the commodification of knowledge. Scarcity of knowledge allows for it to be accorded commodity status, and thereby treated as property. Once accorded commodity status, knowledge is free to command a price.'

[265] AJ van der Walt and GJ Pienaar *Introduction to the law of property* 5th Edition (2002) 345-46, arguing that for purposes of section 25 of the Constitution;

[266] See I Currie and J de Waal *The Bill of Rights Handbook* 5th Edition (2005) 537-39, arguing that 'the clause [section 25] could refer to the set of legal rules governing the relationship between individuals and physical property—what the common law terms property as rights...property for purposes of [section] 25 should therefore be seen as those resources that are generally taken to constitute a person's wealth, and that are recognided and protected by law.' These rights include ownership, mortage, lease, servitude, contractual entitlements or claim rights against the state, IP rights, the right to use, alienate or dispose of the object of rights and many others.

[267] Lord Cooke, Foreword in J McLean *Property and the constitution* (1999) at (iii).

[268] (2002) 4 SA 768 (CC).

[269] Para 57, where the Court observes that 'any interference with the use, enjoyment or exploitation of private property involves some deprivation in respect of the person having title or right to or in the property concerned'. The Court also observed (at para 58 amd 59) that expropriation (the physical taking of someone's property) also constitutes deprivation in the narrow sense of the word.

explain why the state has not used compulsory licencing because property rights are subject to the internal and the general limitations clauses.

The caveat that only a 'law of general application' may permit deprivation is met because the Patents Act is such a law. The Patents Act is impersonal in the sense that it applies not only to pharmaceutical companies but generally imposes burdens on abstract classes of persons, including individuals.[270] However, the requirement that patent rights be 'limited by a law of general application' will play a very limited role because what is central is the fact that even such a law (the Patents Act in this case) 'may not permit arbitrary deprivation'.[271]

The Constitutional Court has held that deprivation is 'arbitrary' 'when the "law" referred to in [section] 25(1) does not provide sufficient reason for the particular deprivation in question or is procedurally unfair'.[272] 'Sufficient reason' is determined by reference to the relationship between the nature of the deprivation and the purpose of the law in question; the purpose of the deprivation and the person whose rights are infringed by the deprivation; the purpose of the deprivation, the nature of the property and the degree of deprivation.[273]

It is submitted that the grounds upon which compulsory licencing for abuse of IP rights is deemed are 'sufficient' as contemplated in the *First National Bank* case. Procedural fairness is almost guaranteed by the requirement that the patentee be consulted before their patented inventions are compulsorily licenced in the public interest. The nature of deprivation of IP through compulsory licencing does not authorise the taking of the property itself but the use, by others, of an idea that leads to the making of the product. This lessens the gravity of the deprivation because the patentee retains the patented

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[270] See Currie and de Waal (note 266) 542, arguing that the term 'law of general application' implies that the 'limitation of rights is permissible only (i) where it is authorised by law, and (ii) where that law is impersonal in the sense that it imposes burdens on an abstract class, no matter the size of the class'.

[271] A section 25(1) 'law' may not permit arbitrary deprivation.

[272] *First National Bank* (note 268) para 100.

[273] Para 100. Although Ackermann J stresses that the judgment in *First National Bank* 'is not concerned at all with incorporeal property', the broad principles enunciated in that case may serve as a guide to the interpretation of section 25 of the Constitution and the evolution of property law in a constitutional context.

product or process but loses control over the production or use of the product or process by third parties. This leaves considerable leeway for the government to justify in terms of section 25 that the compulsory licencing of patented medicines does not necessarily amount to an 'arbitrary deprivation' of property because it is intended to address a pressing social objective—access to essential medicines.

4.3.2 The obligation to pay compensation

The state could invoke the constitutional provisions permitting expropriation of private property 'for a public purpose or in the public interest'.[274] It has been shown in chapter three that the provision of ARVs to the poor who need them is in the public interest and that combating AIDS is a public health objective or purpose. The expropriation of private property is subject to the payment of 'just and equitable compensation'. The difficulty is whether compulsory licencing amounts to an expropriation of property because compensation is only paid for expropriations, not deprivations.[275] Given that 'expropriation' is a subset or special type of 'deprivation',[276] the provisions on compensation apply to compulsory licencing of patented medicines. Neither the existence of an 'emergency' under the TRIPS Agreement nor the existence of a 'public purpose' under the Patents Act and the Constitution absolves the state of its duty to pay compensation should it compulsorily licence patented drugs.[277] [278]

The determination of compensation by a court heightens the likelihood of incurring further costs during litigation and curtails the state's willingness to use compulsory licencing.[279] Thus, the lack of resources to pay compensation also explains why South

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[274] Section 25(2)(a).
[275] Section 25(2)(b).
[276] *First National Bank* (note 268) para 57.
[277] Section 4 of the Patents Act permits compulsory licencing only after negotiation with the patentee on reasonable terms and approval by the commissioner. The obligation to engage with the patentee is more than mere consultation and imposes the obligation on the parties involved to have consensus on 'reasonable terms and conditions'. The reasonableness of the terms of the negotiations depends on whether the compensation balances IP rights and the public interest in combating AIDS.
[278] Unfortunately, it is not possible in this work to consider the relevance of these factors in detail and how they serve to enhance access to essential medicines while simultaneously avoiding arbitrary deprivation of property.
[279] In terms of section 25(2)(b), if there is no consensus between the parties concerning the amount of compensation, such amount should be approved or determined by a court.

Africa does not have a viable petrochemicals industry capable of producing low-cost generics.[280] However, this is one of the weakest arguments against the adoption of compulsory licencing. The time and manner of payment of compensation must be agreed by the parties affected or decided or approved by a court.[281] In considering whether compensation is 'just and equitable', regard must be had to all relevant factors including the history of use and acquisition of the property, state subsidies and investment in the property, the market value of the property and the purpose of the expropriation.[282] Research into medicines is usually subsidised by the Department of Science and Technology (DST). This factor should weigh heavily in the scales and limits the amount of compensation payable below the market value of the property. The fact that the market value of the property is just one of the relevant considerations reflects that IP is not insulated from redistributive measures such as compulsory licencing.

Andre van der Walt argues that the inclusion of market value as one of the factors 'allows for an equitable determination that...subjects it to a full consideration of all the factors that determine the value of the property and the equitable stake of the current owner in it', subject all relevant considerations.[283] If the way property is being currently used establishes one of the grounds for presuming abuse under the Patents Act, this is sufficient cause for public purpose expropriations below the market value of the property. It has been shown that when the patentee refuses to negotiate on reasonable terms or to produce the patented article to an adequate extent or relies on imports to supply the domestic market, abuse is deemed and compensation must carry a punitive element. Thus, the market value of the property may not be allowed to stand in the way of IP regulation and reform through below-market-value and in-the-public-interest public purpose expropriations.

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[280] The subject will then revert back to whether the government has the financial resources necessary to exploit compulsory licencing to enhance access to essential drugs. South Africa's 'limited' financial resources and its already stretched and under-resourced health care budget suggest that it may not be able to pay the requisite compensation to the concerned patentee. Instead of using the limited resources to compensate patentees pursuant to compulsory licencing, these resources could be harnessed to meet competing health care needs.

[281] Section 25(2)(b).

[282] Section 25(3) (a)-(e).

[283] Andre van der Walt 'The constitutional property clause: Striking a balance between guarantee and limitation' in J McLean (ed) *Property and the Constitution* (1999) 109 at 138.

4.3.3 Lack of manufacturing capacity

There is no consensus on whether South Africa has the industrial know-how to manufacture its own generic versions of patented drugs and the cost of permitting compulsory licencing without carrying out a thorough feasibility study may outweigh any attendant benefits. Thus another reason for taking a non-confrontational approach could be the lack of the industrial capacity needed to reverse engineer brand-name drugs. The reduced prices of ARV treatment in Brazil can be attributed to the capacity public laboratories had to produce generic medicines as well as the Ministry of Health's devotion to exploit compulsory licencing.[284] Brazil has thus used 'the threat of local production to leverage substantially lower prices from multinational companies.'[285] Thus, to make momentous use of compulsory licencing, South Africa clearly needs to possess the relevant basic science capacity to reverse engineer the Active Pharmaceutical Ingredients (APIs) involved in making ARVs.

The process of making ARVs is very complex. HIV/AIDS drug compounds usually consist of highly complicated molecular structures that involve between 30 and 100 or more stages of chemical fusion.[286] Extremely complicated as they are, these steps know no shortcuts. Each of them has to be observed during the process otherwise the end product will be dangerous and unsafe. Unlike Brazil, South Africa does not have the requisite industrial capacity to make any significant threat of using compulsory licencing. Sprague and Woolman argue that:

> South Africa does not possess the world's sixth largest petrochemicals industry, a state lab capable of reverse engineering APIs, pharmaceutical companies with vast experience producing generics, a knowledge transfer triangle formed by the state, academics and private technicians capable of moving from the general principles of generics to the specific requirements of production, a long history of patent non-compliance or an odd flirtation...that drives industrial policy in all sectors towards self-sufficiency.[287]

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[284] See R Parker 'Buiding the foundations for the response for HIV/AIDS in Brazil: the development of HIV/AIDS policy, 1992-1996' available at http://www.columbia.edu/itc/hs/pubhealth/p8725/all_week_8_articles.pdf (accessed 27 April 2008).

[285] Sprague and Woolman (note 18) at 369.

[286] See M Cassier and M Correa 'Patent, innovation and public health: Brazilian public-sector laboratories' experience in copying AIDS drugs' (2003) available at http://www.usc.es/epip/documentos /Cassier's% 20paper.pdf (accessed 22 April 2008).

[287] Sprague and Woolman (note 18) at 369.

Besides, the monetary cost of establishing a laboratory for reverse engineering and a plant for manufacturing generics is prohibitive and may far outweigh any attendant benefits. Sprague and Woolman emphasise that at the moment, 'it costs more to source raw materials for APIs in South Africa than it does to offload in Durban a finished API produced in China.'[288] It is advisable that South Africa commit itself to negotiating voluntary licenses (something which the government has not been keen to do) with companies that hold patents on life-saving ARVs.[289] Drug developers have indicated that while they may be willing to circulate their medicines cheaply, their eagerness to retain market exclusivity fetter their willingness to issue compulsory licences.[290] Using compulsory licencing against companies that are willing to lower drug prices in the first place may soil South Africa's reputation at the international level.

4.3.4 Economic effects

Compulsory licencing may lead to the 're-exportation of drugs to markets where companies do see the greater part of the return on their investments.'[291] This work has demonstrated that South Africa constitutes no more than 0.3% of the global market share of the pharmaceutical industry. In the absence of other compelling considerations like abuse of rights, this market position has a chilling effect. The possibility of re-exportation of drugs to affluent countries curtails not only drug developers' enthusiasm to offer them at affordable prices but also the government's enthusiasm to pin its hopes on compulsory licencing. Compulsory licencing could lead to withdrawal of foreign direct investment, withdrawal of financial aid and exclusion from the international family of nations through sanctions.[292] The possibility that compulsory licencing could leave South Africa in the

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[288] Ibid.

[289] In the TAC Competition Complaint, negotiations paid enormous dividends in South Africa because drug developers indicated willingness to lower drug prices through voluntary licensing. In the aftermath of this complaint, the TAC (supported by other pressure groups and NGOs) managed to negotiate voluntary licenses which were issued to four generic manufacturers (including Aspen Pharmacare and Thembalami Pharmaceuticals) at a royalty of only five percent (5%) of the net sales.

[290] Ganslandt et al (note 5) at 780.

[291] Sprague and Woolman (note 18) at 373.

[292] Bollyky (note 17) at 539, see also USTR Press Release: USTR announces results of special 301 review, Office of the United States Trade Representative, Executive Office of the President (30 April 1999) placing South Africa on 301 trade sanctions on for passing the Medicines Act and for letting its representatives, including then Health Minister Nkosazana Dhlamini Zuma, speak at the World Health Assembly that trade rules strongly impeded access to essential medicines in Africa.

generic cold probably explains why it has gone for a non-interventionist approach.[293] However, most if not all of these effects are merely speculative and very remote.

4.3.5 Political will

South Africa lacks the political will needed to use compulsory licencing to curb the AIDS tide. The regulatory framework—both at the domestic and international levels—permits South Africa to use compulsory licencing on various grounds. This reveals that the absence of a compulsory licencing regime in this country is a deliberate policy choice and not a consequence of any regulatory inflexibility. Leadership attitudes on HIV/AIDS confirm that it is not realistic to expect the South African government to consider compulsory licencing as a possible mechanism for combating the pandemic.

The President's AIDS denialism coupled with the health minister's confusing message on the role of nutrition in combating AIDS, reflect a leadership vacuum in HIV/AIDS policy-making and implementation at higher levels of the political ladder. The Minister of Health has been widely criticised for urging patients to take lots of lemon, carrots, garlic and beetroot to fight the effects of viral activity.[294] AIDS denialism explains not only why the government prefers certain policy options than others but also its general response and commitment to public health. Edwin Cameron has noted that:

> '[AIDS denialism] has bedevilled and... continues to bedevil our national response to the disease. Instead of taking immediate action to stem the epidemic and to minimise the devastation it is wreaking, the government has continued to respond with ambivalence...inaction and evasion.'[295]

The ambivalence of state action in *Treatment Action Campaign* saw the government providing ARVs to patients who had access to 18 research sites across the country while not providing ARVs to other patients (who had no access to these sites) for safety reasons. Surprisingly, the government was already using these drugs at the research sites although it was not sure about their safety and efficacy. The Court held that there was no

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[293] See also Bollyky (note 17) at 543-44 arguing that these include the cost of guaranteeing the safety and efficacy of generic substitutes, the cost that would be incurred in capacity building, possible litigation in local courts, withdrawal of foreign direct investment and the threat or use of sanctions by the global North.

[294] See for example N Miles 'South Africa's broken HIV Promises' available at http://news.bbc.co. uk/2/hi/africa/4482007.stm (accessed 2 June 2008).

[295] E Cameron 'The dead end of denialism' available at http://ww2.aegis.org/news/dmg/2003/M G030 410.html (accessed 10 June 2008).

evidence to show 'that a dose of nevirapine to both mother and child at the time of birth will result in harm to either of them'.[296] The point is that the alleged toxicity of ARVs at the time evidenced how too heavily AIDS denialism weighed on the development of a comprehensive and coordinated response to HIV/AIDS. This was shown in the state's commitment to differential treatment of patients confronted by the same affliction.

The denial to declare AIDS an emergency, the reluctance to use the regulatory flexibilities—including compulsory licencing—within the TRIPS Agreement and the lack of capacity to produce generic drugs, must all be considered in the context of the lack of political commitment to combat the HIV pandemic. Chapter two has shown that the Constitutional Court observed the relevance of political will to the magnitude of HIV/AIDS prevalence in this country. In the same vein, this study has pointed to the need for a government response that is targeted at securing international technology transfer to boost the state's capacity to reverse engineer brand-name drugs, if needs be.

The Department of Trade and Industry, partnering with the Department of Health and the DST, must purchase technology targeted at achieving local production of generic medicines in public laboratories. The Health Department must have its own laboratories. Brazil's experience has shown this to be possible. Failure to make the necessary technological resources available when financial capacity and regulatory flexibility permit amounts to the state's repudiation of its constitutional duty to take steps to ensure positive provision of essential medicines to those in need.

4.4 Conclusion

This chapter has demonstrated that the Patents Act and the Constitution are consistent with international standards on IP protection and that it is in the public interest for government to use compulsory licencing to address the pressing need for ARV therapy. It has also shown that reasons for not using compulsory licencing are either remote or boil down to lack of political will to develop a comprehensive response to HIV/AIDS. Therefore, it is desirable that the government adopt a multidimensional approach—from

[296] Para 60.

protecting and fulfilling constitutional rights to securing technology transfer to compulsory licencing—to HIV/AIDS and other public health tragedies.

CHAPTER 5: CONCLUSION AND RECOMMENDATIONS

5.1 Conclusion

The staggering magnitude of HIV/AIDS prevalence in South Africa highlights the urgency with which the government must implement a well coordinated and comprehensive response to the dire need for ARVs in public sector health institutions. In view of the recognition international and regional instruments give to health as a human right, it becomes evident that lack of access to essential medicines is not so much a result of lack of codification but rather an absence of consistent implementation of legislative provisions on health care. The lack of a clear understanding of the meaning and scope of the right to health makes it difficult to implement, and the absence of an established practice of implementation in turn hampers the possibility of obtaining a greater understanding of its meaning and scope.[297] The Constitutional Court has a relatively fair share of blame concerning the lack of tangible entitlements that socio-economic rights seek to protect. The Court needs to reconsider the role of the minimum core in socio-economic rights claims, to enable the state to have clear standard obligations to be met immediately and progressively.[298]

Another serious concern with the Court's rejection of the minimum core is its implicit rejection of the need to set priorities to be met at different levels of social provisioning. Priority-setting is consistent with the essential medicines concept which obligates countries to prioritise medicines according to disease prevalence, need, cost-effectiveness, safety and efficacy. The minimum core (as priority-setting) binds the state to prioritise urgent provisioning of the survival needs of those who are hard-hit by poverty, disease and deprivation at the expense of the needs of more priviledged social classes.[299] States are bound at the immediate level to provide resources to meet core needs (such as ARVs) 'without delay' and to take reasonable steps to improve

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[297] B Toebes 'Towards an improved understanding of the international human right to health' (1999) 21 *Human Rights Qarterly* 661 at 665.

[298] It has been shown in chapter two that the Court has done so in the field of civil and political rights. Given that socio-economic rights are justiciable in South Africa, it is argued that the courts should command the immediate realisation of core needs to socio-economic rights.

[299] See S Liebenberg 'The interpretation of socio-economic rights' in S Woolman et al (eds) *Constitutional law of South Africa* 2nd Edition (2007) 33-1 at 33-28.

progressively the level of social provisioning beyond the minimum threshold.[300] This is consistent with the Court's own approach that the needs of the most desperate are most in peril and should not be left out. The minimum core remains an essential component of the right to health under the South African Constitution and may be considered an integral part of the reasonableness inquiry. To be reasonable, a health plan should be targeted at providing essential medicines (especially ARVs), as a matter of priority, to the majority of South Africans who find the cost of drugs prohibitive for individual access.

The government's desire to comply with domestic patent law and international obligations under the TRIPS Agreement has curtailed eagerness to exploit compulsory licencing to ensure equitable access to necessary ARV drugs.[301] South Africa's reaction to the opportunities to formulate a national strategy within the scope of the minimum standards set by the TRIPS Agreement has been very slow or simply non-existent. The government's readiness to amend its laws to be TRIPS-compliant and its 'willingness' to comply with its international obligations, explains its eagerness to comply with the TRIPS Agreement rather than to make use of the agreement's safeguards. In the light of the chronic shortage of industrial capacity to produce or reverse-engineer brand-name drugs, the government's choice to exclude compulsory licencing from its national strategy to combat HIV/AIDS is nothing but regrettable.

5.2 Recommendations: Towards universal provision of essential medicines

The Constitutional Court should play a central role in infusing minimum core obligations into its review standard of reasonableness. This can be done by requiring the state to justify that all resources available do not support the realisation of core needs in each particular case. In order to pass the reasonableness review standard, a programme must have prioritised the needs of those living in absolute poverty and severe deprivation. The degree to which the poor are denied access to core needs should be supported by sufficient evidence that the state's resources were insufficient to provide such needs. Mere inclusion (of vulnerable groups) into state plans should be considered unreasonable.

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[300] See Biltchitz (note 123) at 11.
[301] See Operational Plan (note 1).

In resolving the impasse between public health and IP rights, the state must commit the necessary financial resources to obtain capacity through international transfer of technology. Infrastructural development, through negotiating technology transfer from companies that have manufacturing capacity, must be part of South Africa's national strategy to combat AIDS. Capacity building is important for the establishment of a petrochemicals industry designed to ensure gradual self-sufficiency in the production of brand-name medicines. In fact, one option for enhancing regular access to essential medicines is national production by state-owned firms, public laboratories, subsidiaries of multinational companies or joint ventures.[302] Pharmaceutical manufacturing capacity makes effective the threat of local production of generic medicines pursuant to compulsory licencing. However, before pursuing compulsory licencing for the generic production of ARVs, South Africa should first negotiate voluntary licences on reasonable terms with patent holders.

South Africa should not grant compulsory licences for the importation of patented medicines for a number of reasons. First, as a measure to combat trade diversion and third degree price discrimination, the Patents Act does not permit drug companies to meet local demand by importation of the patented articles. In fact, this is one of the grounds for which 'abuse' is deemed to pave way for compulsory licencing. Second, South Africa needs to amend the Patents Act to provide for parallel importation before exploiting this policy option because the TRIPS Agreement permits compulsory licencing for importation when the law of a country permits such unauthorised use.

Furthermore, it is not desirable for South Africa to rely on importation to meet local therapeutic needs because the reliability and effectiveness of importation heavily depends on the willingness of eligible exporting countries to export. The new system, introduced by the amendment to the TRIPS Agreement, will not attract enough, if any, exporting countries because it imposes insurmountable evidential and procedural burdens on

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[302] K Balasubramanian 'Access to medicines and public policy safeguards under TRIPS' in Christophe Bellhen et al (eds) *Trading in knowledge* (2004) 135 at 139.

countries acting in goodwill to help other countries without manufacturing capacity. Finally, South Africa herself faces a burdensome task in proving that she does not have the necessary manufacturing capacity because other developing economies such as Brazil and India have the industrial capacity to produce or reverse-engineer brand-name drugs.[303] South Africa should first build her industrial capacity before making effective use of compulsory licencing. The positive duty to provide entails the duty to make available the technological resources necessary to produce or reverse-engineer ARVs if the national fiscus permits.

The Department of Trade and Industry, and the DST should implement measures contemplated in the TRIPS Agreement to secure the international transfer of technology to boost South Africa's industrial capacity. The Department of Health, partnering with academics and other public sector laboratories must form a knowledge transfer triangle in exploiting the existing or newly developed capacity to produce or copy ARV drugs. These challenges can be addressed by looking into Brazil's historical experience that enabled her to own the world's sixth largest petrochemicals industry.[304] Once the technological base is established, South Africa could negotiate, on reasonable terms, voluntary licences backed by the threat of compulsory licencing on any of the grounds listed in the TRIPS Agreement and/or the Patents Act.

South Africa could declare HIV/AIDS a 'national emergency or circumstance of extreme urgency' to found a ground for compulsory licencing under the TRIPS Agreement. In assessing the desirability of declaring AIDS an emergency, leadership attitudes must mirrow emerging public health concerns on HIV/AIDS. This means that leadership attitudes must be responsive to the magnitude of deprivation and suffering that confronts those living with HIV/AIDS. This way, political leaders can respond with unwavering commitment to HIV/AIDS and other epidemics by exploiting the flexibilities of the

[303] See Balasubramanian (note 302) at 139, stating that India is the only country in South and South East Asia that is self-reliant and can meet its ARV needs by local production.

[304] See Cassier and Correa (note 286), explaining that Brazil's universal provision of ARVs was made possible by the Ministry of Health's commitment to embark on a policy of universal access to medicinal drugs and capacity state-owned laboratories had to reverse-engineer brand-name drugs. The Ministry of Health's laboratories manufacture up to 40% of the total production of ARVs in Brazil and the remaining 60% is shared by other public-sector laboratories and private sector industries.

current regulatory framework for patent protection and health care rights. Thus, the government should adopt a multi-dimensional policy framework—from fulfilling binding constitutional obligations concerning health care to exploiting the regulatory framework established by the TRIPS Agreement to compulsory licencing under the Patents Act.

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