

**ACCESS TO ANTIRETROVIRALS:
ARE THERE ANY SOLUTIONS?**

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I certify that the whole dissertation, unless specifically indicated to the contrary in the text, is my own work. It is submitted in fulfillment of the academic requirements for the degree of Master of Laws in the Faculty of Law, University of KwaZulu-Natal.

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ABSTRACT

In South Africa 1 000 people die of AIDS everyday and 100 000 more people require ARVs every year. There is therefore an urgent need to provide access to ARVs and other essential medicines. The South African Constitution requires the government to take reasonable measures to ensure access to health care. The government has cited financial constraints as the major obstacle to fulfilling this constitutional imperative. In an effort to stretch their budgetary resource other medium-income countries have used measures such as compulsory licences, voluntary licences and parallel importation. These measures, provided for in the TRIPS Agreement and the Doha Declaration, are available under South African legislation but have not been properly implemented due to a lack of political will.

The proper use of compulsory licences by the South African government is vital because all twelve of the ARVs on the World Health Organisation's Essential Medicines List are protected in South Africa by our patent laws. However, in order to issue compulsory licences more easily and quickly the South African Legislature will need to pass legislation which clarifies the ambiguities contained in TRIPS and the Doha Declaration. Other methods to lower the price of medicines include the segmentation of the South African market in order to facilitate differential pricing.

The State must balance its use of such measures with programmes to incentivise research and development into neglected diseases and HIV/AIDS. Such programmes will also assist the State's capacity to conduct its own research and development into new medicines, whilst bolstering its domestic pharmaceutical manufacturing capacity.

The ultimate solution to South Africa's access to medicine problem is to create a pharmaceutical manufacturing industry capable of producing the most complex medicines, so as to lessen its dependence on drug manufacturers reducing their prices. The way to create a sophisticated pharmaceutical manufacturing capacity is to use the flexibilities in TRIPS and to uphold South Africa's high patent standards. The Constitutional Court's involvement is essential in order to force the State to implement its own policies so as to provide access to affordable medicines.

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LIST OF ABBREVIATIONS

AAA	Africa, Asia and Australia
AIDS	Acquired Immune Deficiency Syndrome
ALP	AIDS Law Project
ALP	Aids Law Project
ANC	African National Congress
APC	Advance purchase commitments
APIs	Active Pharmaceutical Ingredients
ARV	Anti-retroviral (medication)
CCSA	Constitutional Court of South Africa
CEPPAWU	Chemical, Energy, Paper, Printing, Wood and Allied Workers' Union
CESCR	Committee on Economic, Social and Cultural Rights
CIA	Central Intelligence Agency
CODETEC	Companhia de Desenvolvimento Tecnológico
COSATU	Congress of South African Trade Unions
CRC	Committee on the Convention on the Rights of the Child
CSIR	Council for Scientific and Industrial Research
DNDi	Drugs for Neglected Disease Initiative
FDA	US Food and Drug Administration
FDCs	Fixed-dose combinations
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GATT	General Agreement on Tariffs and Trade
GMP	Good Manufacturing Practice
GSP	Generalized System of Preferences
HHS	Health and Human Services
HIV	Human Immunodeficiency Virus
HIV/AIDS	Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome
IAVI	International AIDS Vaccine Initiative

ICESCR	International Covenant on Economic, Social and Cultural Rights
IDA	International Development Association
KZN	KwaZulu-Natal
MCC	Medicine's Control Council
MDGs	Millennium Development Goals
MSF	Medecins sans Frontieres
PAJA	Promotion of Access to Justice Act No. 3 of 2000
R&D	Research and development
SACU	South African Customs Union
SADC	Southern African Development Community
TAC	Treatment Action Campaign
TDCA	SA-EU Trade Development and Cooperation Agreement
TDR	Training and Research in Tropical Diseases
TRIPS	Agreement on Trade-related Aspects of Intellectual Property Rights
TRM	Tiered Royalty Method
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
UNGASS	United Nations General Assembly Special Session
UNICEF	United Nations' Children's Fund
USTR	United States Trade Representatives
WHO	World Health Organisation
WHO-EML	World Health Organisation Essential Medicines List
WTO	World Trade Organisation

CHAPTER 1: INTRODUCTION

The scale of the Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome (HIV/AIDS) pandemic in South Africa was eloquently summarised by the Constitutional Court in *Minister of Health and others v Treatment Action Campaign and others*¹ (*TAC*) where it began its judgment with the following:

The HIV/AIDS pandemic in South Africa has been described as ‘an incomprehensible calamity’ and ‘the most important challenge facing South Africa since the birth of our new democracy’ and government’s fight against ‘this scourge’ as ‘a top priority’. It ‘has claimed million of lives, inflicting pain and grief, causing fear and uncertainty, and threatening the economy’. These are not the words of alarmists but are taken from a Department of Health publication in 2000 and a ministerial foreword to an earlier departmental publication.²

The government has a policy to combat HIV/AIDS although it has not fully been implemented due to a lack of resources. This is one of the arguments used by the government in the *TAC* case with regard to its rollout of Nevirapine. Whilst it cannot be disputed that ARVs and other medicines are expensive, the government is not making proper use of the funds it has in order to maximise the treatment for those suffering from HIV/AIDS and other diseases. The mechanisms to effect this are discussed in this dissertation and are designed to lower the prices of medicines, which will then assist the government in providing a more comprehensive health care plan. The majority of these mechanisms are contained in the Department of Health’s policy on drug procurement. The Constitutional Court has an integral role to play in ensuring that the State implements these policies.

Creating a comprehensive health care system to provide AIDS medicine, especially antiretrovirals (ARVs), is vital especially due to the fact that South Africa has the highest number of HIV-infected individuals in the world at 28.1 per cent³ and KwaZulu-Natal

¹ *Minister of Health v Treatment Action Campaign* (2) 2002 (5) SA 721 (CC).

² *Ibid* para 1.

³ The National HIV and Syphilis Prevalence Survey South Africa 2007, 11. Available at: <http://www.doh.gov.za/docs/amenatal-f.html> Date viewed: 15 May 2008.

has the highest prevalence in the country at 37.4 per cent⁴. The South African government drafted its first AIDS policy in 1994. However, fourteen years later its record is one of denialism, equivocation and delays⁵. The previous Minister of Health Manto Tshabalala-Msimang systematically delayed instituting policy until forced by the courts through applications by civil society movements. These delays led to more than 330 000 South Africans dying due to HIV/AIDS between 2000 and 2005. These figures were released in October 2008 by the Harvard School of Public Health⁶. The new Minister of Health, Barbara Hogan, was appointed in September 2008. Her appointment was praised by the Treatment Action Campaign⁷ (TAC) and she has already had a positive effect on a number of areas surrounding HIV/AIDS⁸.

In terms of section 27 of the South African Constitution Act No. 108 of 1996 (the Constitution), the government must provide access to health care within its available resources. Yacoob J found in *Government of the Republic of South Africa v Grootboom*⁹ (*Grootboom*) that this requires that the government plan must be comprehensive and reasonable at both conception and implementation. Yacoob J explained further that those whose needs are most urgent and whose ability to enjoy all rights are most in peril must not be ignored. Countries such as India and Brazil have faced the same problems as South Africa but have managed to set up robust health care systems and are stemming the

⁴ Ibid 11.

⁵ As Zackie Achmat said during the TAC's civil disobedience campaign 'after countless attempts at talking, public pressure and even a court case to prevent HIV infection from mother to child, the government allows the deaths to continue while it plays the caring, right-minded diplomat in Africa and the Middle East'. N Natrass *Mortal combat: AIDS Denialism and the Struggle for Antiretrovirals in South Africa* 1 ed (2007) 33.

⁶ 'Researchers Estimate Lives Lost Due to Delay in Antiretroviral Drug Use for HIV/AIDS in South Africa' 20 October 2008. Available at: <http://www.hsph.harvard.edu/news/press-releases/2008-releases/researchers-estimate-lives-lost-delay-arv-drug-use-hivaids-south-africa.html> Date viewed: 22 October 2008.

⁷ 'TAC: Hogan is what we need' Available at: <http://www.thetimes.co.za/News/Article.aspx?id=851013> Date viewed: 7 December 2008.

⁸ The province of the Free State in November 2008 faced an acute shortage of ARVs and was likely to run out of stock by January 2009. The Mail and Guardian explains the steps the new Minister of Health took to rectify the problem immediately. 'Insiders say that once informed that the HIV-positive patients in the Free State could be enduring a life-endangering halt to their treatment in a few weeks, Minister of Health Barbara Hogan immediately told her department to sort out the problem... In the context of the new ministerial regime this meant identifying the problem and solving it. Hogan ordered that a high-level department of health "fix-it" squad be dispatched to the Free State.' Available at: <http://www.mg.co.za/article/2008-11-17-arvs-hogan-acts> Date viewed: 8 December 2008.

⁹ 2001 (1) SA 46 (CC).

tide of disease. It is time that the South African government fully complies with its constitutional imperative and provides complete access to antiretrovirals and other HIV/AIDS medicine. One way in which this can be achieved is by implementing its own policies.

The right to health care is a gateway right. A lack of access to health care means that that people are unable to enjoy the rest of their rights in the Bill of Rights. Without proper medication and treatment HIV/AIDS is a death sentence. One of the most insidious aspects of this disease is that those infected with the disease are at their most infectious when they are asymptomatic and have recently been infected themselves¹⁰. In light of this it is clear that the provision of medication is only one part of the solution to this 'incomprehensible calamity'. There also needs to be proper dissemination of information. This does not mean simply telling people the medical facts regarding the disease. There must be proper dialogue on the disease in a forum where people have time to properly understand the information. This will assist in solving one of the most difficult parts of this disease, its stigma. When people properly understand the disease and its prevention then misconceptions leading to stigma are removed.

Solving the HIV/AIDS pandemic will involve many different fields including the medical and legal fields, civil society and the government. For the purposes of this dissertation I look at legal solutions which can be used to improve access to ARVs and other medicines by examining measures to reduce the cost of medicines which is a significant barrier to access to medicine.

In South Africa one of the major problems in the context of HIV/AIDS has been denialism of the disease at all levels of government, including by former President Mbeki and the then Minister of Health. President Mbeki began questioning AIDS statistics and the safety of ARV therapy in 1999¹¹. On 6 October 2000, President Mbeki announced to the African National Congress (ANC) caucus that the Central Intelligence Agency (CIA),

¹⁰ N Nattrass *Mortal combat: AIDS Denialism and the Struggle for Antiretrovirals in South Africa* 1 ed (2007) 19.

¹¹ *Ibid* 33.

working with drug companies, 'is part of a conspiracy to promote the view that HIV causes AIDS and that Western interests are seeking to discredit him'¹². He supported the Health Minister in her policy of nutritional interventions, such as garlic, lemon, olive oil and African potatoes, on the basis that this could prevent people from dying of AIDS¹³. Although Thabo Mbeki and Manto Tshabalala-Msimang no longer hold their positions in government the effects of their views regarding ARVs and their safety are still present¹⁴.

In 2003 the Department of Health published its Operation Plan; however, it was only in September 2004 that the Department of Health released the ARV treatment guidelines¹⁵. Thereafter the Minister of Health continued to thwart the complete rollout of ARVs by failing to negotiate lower drug prices with the manufacturers as well as by not addressing the human resources crisis in the public health sector¹⁶. At every stage civil society movements, such as the TAC and the Aids Law Project (ALP), have made applications to a number of legal forums including the Competition Commission¹⁷ and the Constitutional Court¹⁸ in order to force the government to comply with its own guidelines and policies as well as its constitutional imperatives.

The Competition Commission has been used to secure lower pricing on medicines, such as in *Hazel Tau and others v GlaxoSmithKline and Boehringer Ingelheim*¹⁹ (*Hazel Tau*)

¹² Ibid 189.

¹³ Ibid 107.

¹⁴ Although the new Minister of Health, Barbara Hogan, has indicated her willingness to expand the ARV rollout and her support for the research into an AIDS vaccine, the public perception of the efficacy and safety of ARVs is still being undermined by members of her Department. KwaZulu-Natal's Health MEC Peggy Nkonyeni has publicly claimed that ARVs are toxic and has indicated her strong support for the Rath Foundation and its claims that Vitamin C is able to block the multiplication of HIV by 99%. It should be noted that these statements were all made in February 2008. The MEC is now asking the Dream Centre, a hospice in Pinetown, to begin integrating the use of traditional medicines, such as uBhejane, into their AIDS treatment protocol. Kerry Cullinan 'KZN Health minister mimics Manto and punts herbal remedies for Aids' Available at: <http://www.thetimes.co.za/News/Article.aspx?id=89063> Date viewed: 23 November 2008.

¹⁵ Natrass (Note 10 above) 128.

¹⁶ Natrass (Note 10 above) 33.

¹⁷ The TAC, Aids Law Project and others laid a complaint with the South African Competition Commission. Statement of Complaint 107.

<http://www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc> Date viewed 15 September 2008.

¹⁸ Note 1 above.

¹⁹ Case no. 2002 Sep226.

which will be discussed later. In response to the government's failure to provide HIV-positive pregnant women with Nevirapine, which prevents mother-to-child-transmission, the TAC made an application to the High Court to force the government to provide Nevirapine²⁰. This culminated in the *TAC* judgment where the Constitutional Court found that the Minister's arguments for stalling the complete rollout were baseless and that restricting its rollout to two treatment sites in each province was unfairly discriminatory²¹. The Court ordered the Minister to provide Nevirapine at all public hospitals and clinics. The effects of this equivocation by the government's leadership is demonstrated by the fact that 35 000 babies were born with HIV between 2000 and 2005²². The medicine that would significantly lowered this number. Nevirapine had been donated by Boehringer Ingelheim for a period of five years²³, from 2000 to 2005.

Whilst it has made significant advances, South Africa is still far below the standards of health care required to stem the tide of this disease. This is clear when one examines the progress made by other middle-income countries such as India and Brazil whose governments have created and funded a thriving health care system and the infrastructure needed to support it. The progress made by India and Brazil will be discussed later. However, it is important to bear in mind that these countries, in creating a developed health care system, used the international flexibilities in the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS)²⁴, such as the use of compulsory licences, and created a high standard of patentability in order to minimise the number of

²⁰ *Minister of Health v Treatment Action Campaign* 2002 (4) BCLR 356 (T).

²¹ Note 1 above, 19.

²² Note 6 above.

²³ *Ibid.*

²⁴ The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). TRIPS was negotiated in 1994 after the Uruguay Round of the GATT (General Agreement on Tariffs and Trade). The Agreement sets standards for a variety of areas of law, such as copyright, patents, trademarks and other aspects of intellectual property rights involving trade. South Africa signed the TRIPS Agreement on 1 January 1995 and since then it has been bound by all the provisions in the agreement. Available at: http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm Date viewed: 22 November 2008. South Africa implemented TRIPS obligations in the field of patents through an amendment to its Patents Act of 1978, the Intellectual Property Laws Amendment Act No. 38 of 1997. 'The amended Patents Act brought South Africa into compliance with TRIPS obligations regarding, inter alia, patentability and compulsory licensing, while at the same time not referring to exhaustion of rights or parallel imports. K Gamharter *Access to Affordable Medicines* 1 ed. (2004) 110.

drugs patented. These are some of the legal mechanisms that South Africa also has at its disposal and should use.

The main reason drug companies can charge high prices for their medicines is because they have a monopoly in the market. This is created when a drug is patented. However, TRIPS and the Doha Declaration contain a number of flexibilities which allow countries to negotiate lower prices with the drug company, such as through threatening to issue compulsory licences. My argument is that, especially at a legal level, the South African government is not using all the flexibilities it has available in both domestic and international law, as India and Brazil have done, to provide high levels of health care. The South African government is enjoined to create and implement a comprehensive policy in order to fulfill its constitutional imperative and it is my argument that its failure to implement the flexibilities in its policy on drug procurement is unreasonable and has had a detrimental effect on the rollout of ARVs.

The evaluation of the State's policies on the basis of reasonableness allows for incremental improvement rather than an objective standard. However, as will be discussed later, the reasonableness standard has been used by the Constitutional Court to avoid delving into government policy. Whilst the government is compelled to provide access to medicines by the Constitution it is unlikely that the Constitutional Court, in the case of a section 27 challenge for ARVs, would make the far-reaching order needed to ensure sustainable access to ARVs and the creation of a domestic pharmaceutical manufacturing capacity in South Africa. However, the Constitutional Court has issued mandatory orders²⁵ against organs of state on a number of occasions and would be likely to do so in this case in order to compel the government to implement its policy on drug

²⁵ The Constitutional Court in *TAC* stated:

The power to grant mandatory relief includes the power where it is appropriate to exercise some form of supervisory jurisdiction to ensure that the order is implemented. In *Pretoria City Council v Walker*, Langa DP said:

[T]he respondent could, for instance, have applied to an appropriate court for a declaration of rights or a *mandamus* in order to vindicate the breach of his s 8 right. By means of such an order the council could have been compelled to take appropriate steps as soon as possible to eliminate the unfair differentiation and to report back to the Court in question. The Court would then have been in a position to give such further ancillary orders or directions as might have been necessary to ensure the proper execution of its order. (Paragraph 104)

procurement, which would have a significant effect on the rollout of ARVs due to the significant price reduction.

On a domestic level South Africa must maintain its high standards for patenting an invention in order to prevent drug manufacturers abusing the system through 'evergreening' a drug, a strategy of manipulating the patent regime of a country in order to get a medicine re-patented. Examples of strong patent standard will be shown in a discussion of India's patent system in Chapter 3. The American patent system is also examined due to a number of provisions it has which may be added to our existing Patent Act in order to maximise the government's ability to access medicines it needs to ensure the survival of its people.

Utilising the flexibilities contained in TRIPS does not come without cost. There has been significant international pressure applied to India and Thailand. The consequences of utilising these flexibilities may include a drug company refusing to provide a medicine in a country in protest²⁶. These consequences need to be weighed against the other benefits to the South African people. The use of the flexibilities in TRIPS and other international agreements vital to ensuring sustainable access to medicine as well as the creation of a robust domestic pharmaceutical manufacturing capacity that is able to manufacture complex medicines such as ARVs²⁷. The balancing act between forcing drug companies to provide medicines cheaply and forcing them out of that area of research to a more lucrative disease where sufferers are capable of paying the high prices, needs to be handled delicately. Solutions may include countries forming groups to create patent pools²⁸ and other mechanisms such as Public-Private Partnerships (PPPs) as well as the creation of a domestic pharmaceutical manufacturing capacity. These are long-term solutions and will take time to implement.

²⁶ As happened in Thailand see Chapter 4.

²⁷ C Sprague, S Woolman 'Moral Luck: Exploiting South Africa's Policy Environment to Produce a Sustainable National Antiretroviral Treatment Programme' (2006) *SAJHR* 337.

²⁸ 'UNITAID moves towards a patent pool for medicines' Available at: <http://www.unitaid.eu/index.php/en/NEWS/UNITAID> Date viewed: 16 August 2008.

Most of the solutions in this dissertation are designed to address the short- and medium-term access to ARVs whilst South Africa expands its own generic manufacturing capacity. The creation of its own generic manufacturing capacity, capable of producing the most complex medicines, is vital to ensuring a long-term solution to the issue of access to medicines at a low price. The flexibilities in TRIPS will also facilitate such development and countries such as Brazil and India are discussed as examples.

Although the Constitutional Court is not the vehicle to effect wholesale change in the State's policies it can play a vital role in forcing the State to implement the policies it already has. These policies will have a significant effect on the prices of ARVs which will increase the availability of ARVs. Finding a solution to providing ARV treatment for all South Africans is a very difficult task because it requires a coordinated effort by Government departments, such as the Department of Health and the Department of Trade and Industry, to negotiate lower prices and ensure wholesale distribution of ARVs. In light of the severity of the disease it is vital that solutions must be found to the problem of providing full-scale access to ARVs.

CHAPTER 2: THE RIGHT TO ACCESS TO MEDICINE

To establish whether the State has complied with its constitutional imperative under section 27 of the Constitution, the State's rollout plan and implementation must be measured against the Bill of Rights. At the outset what must be established is whether the right to access to health care includes the right to access to medicines. This involves an analysis of both South African and international jurisprudence relating to access to medicines. The analysis of South African jurisprudence also includes the cases dealing with socio-economic rights decided by the Constitutional Court in order to determine to what extent the Court will involve itself in policy decisions made by the Minister of Health in establishing the reasonableness of such policies.

The right to access to medicine stems from the right to access to health care services found in section 27 of the Constitution, which states:

1. Everyone has the right to have access to-
 - a. health care services, including reproductive health care;
 - b. ...
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.

In order to establish the ambit of the right and what it requires the government to provide it must be construed in its context. This requires consideration of two types of context: the textual²⁹ setting of the right, which requires exploration of both Chapter 2 of the Constitution and the Constitution as a whole, and the social and historical context of the right.

²⁹ In *S v Zuma and Others* Kentridge AJ said 'While we must always be conscious of the values underlying the Constitution, it is nonetheless our task to interpret a written instrument. I am well aware of the fallacy of supposing that general language must have single "objective meaning". Nor is it easy to avoid the influence of one's personal intellectual and moral preconceptions. But it cannot be too strongly stressed that the Constitution does not mean whatever we might wish it to mean. We must heed Lord Wilberforce's reminder that even a constitution is a legal instrument, the language of which must be respected. If the language used by the lawgiver is ignored in favour of a general resort to "values" the result is not interpretation but divination... I would say that a constitution "embodying fundamental principles should as far as the language permits be given a broad construction.' 1995 (2) SA 642 (CC) 17.

I AMBIT OF THE RIGHT TO ACCESS TO HEALTH CARE SERVICES

(a) Textual setting

Section 27 states:

- (1) Everyone has the right to have access to –
 - (a) health care services, including reproductive health care;
 - (b) sufficient food and water; and
 - (c) social security, including, if they are unable to support themselves and their dependants, appropriate social assistance.
- (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.

(i) Does the right to medicine fall under the right to access to health care?

In terms of section 39(1)³⁰ of the Constitution a court is obliged to consider international law as a tool to interpret the Bill of Rights. This was reiterated by Chaskalson P in *S v Makwanyane and Others*³¹:

Public international law would include non-binding and binding law. They may both be used under the section as tools of interpretation. International agreements and customary international law accordingly provide a framework within which [the Bill of Rights] can be evaluated and understood, and for that purpose, decisions of tribunals dealing with comparable instruments... may provide guidance as to the correct interpretation of particular provisions of the Bill of Rights.

(aa) International Law

Article 25 of the Universal Declaration of Human Rights (UDHR)³² states ‘Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services...’

³⁰ Section 39(1) states: ‘When interpreting the Bill of Rights, a court, tribunal or forum (a) must promote the values that underlie an open and democratic society based on human dignity, equality and freedom; (b) must consider international law; (c) may consider foreign law.’

³¹ 1995 (3) SA 391 (CC).

³² Universal Declaration of Human Rights, GA Res 217 (III), UNGAOR, 3d Sess, Supp. No. 13, UN Doc. A / 810 (1948) 71. This declaration is not strictly binding on South Africa, however it has been termed “semi-binding”. “UNESCO: More about the nature and status of the legal instruments and programmes” Available at:

http://portal.unesco.org/shs/en/ev.phpURL_ID=7092&URL_DO=DO_TOPIC&URL_SECTION=201.html
Date viewed: 17 March 2009.

Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR)³³ states:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
...
 - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

This was given further clarification when the Committee on Economic, Social and Cultural Rights (CESCR) issued General Comment No. 14³⁴ concluding that Article 12 extends access not only to timely and appropriate health care but also to underlying determinants of health, including adequate food, housing, water and sanitation, safe working conditions and environments, and access to health-related education and information.³⁵ General Comment 14 states:

Violations of the obligation to fulfil occur through the failure of States parties to take all necessary steps to ensure the realization of the right to health. Examples include the failure to adopt or implement a national health policy designed to ensure the right to health for everyone; insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health by individuals or groups, particularly the vulnerable or marginalised; ... and the failure to take measures to reduce the inequitable distribution of health facilities, goods or services.³⁶

The CESCR issued General Comment No. 3 regarding the nature of States Parties' obligation. It states:

³³ International Covenant on Economic, Social and Cultural Rights, 19 Dec 1966, 993 U.N.T.S. 3, Can. T.S. 1976 No. 46, 6 I.L.M. 360. South Africa signed the Covenant on 3 October 1994 but has yet to ratify it. Available at: <http://www.unhchr.ch/pdf/report.pdf> Date viewed: 9 December 2008.

³⁴ CESCR General Comment No 14: The right to the highest attainable standard of health 22nd session, 25 April to 12 May 2000 E/C. 12/2000. 4

³⁵ B Baker 'Placing access to essential medicines on the human rights agenda' in *The Power of Pills. Social, ethical and legal issues in drug development, marketing and pricing* Edited by J Cohen, P Eillingworth and U Schuklenk. 1 ed.(2006).

³⁶ Note 34 above, 50.

A State party in which any significant number of individuals are deprived of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education is, prima facie, failing to discharge its obligations under the Covenant. If the Covenant were to be read in such a way as not to establish such a minimum core obligation, it would be largely deprived of its *raison d'être*. By the same token, it must be noted that any assessment as to whether a State has discharged its minimum core obligations must also take account of resource constraints applying within the country concerned. Article 2(1) obligates each State party to take the necessary steps to the maximum of its available resources. In order for a State party to be able to attribute its failure to meet at least its minimum core obligations to a lack of available resources it must demonstrate that every effort has been made to use all resources that are at its disposition in an effort to satisfy, as a matter of priority, those minimum obligations³⁷.

South Africa signed the ICESCR on 3 October 1994 but has yet to ratify it³⁸. This lack of ratification means that the treaty is not legally binding on the South African government. However the ICESCR is part of International Law and, in accordance with section 39(1) of the Constitution, it must be considered in the interpretation of the Bill of Rights.

Argentina ratified the ICESCR in 1984³⁹ and is legally bound by its terms. This has been used to increase access to essential medicines. An Argentinean Court held that the State was required to provide a specific vaccine to all who needed it under Article 12 of the ICESCR⁴⁰. In this case⁴¹, Mariela Viceconte and others launched an application in the High Court arguing that at least 3.5 million people living in their region of Argentina are affected by haemorrhagic fever and did not have adequate access to the vaccination⁴². In response the government argued that they did not have the resources to do the massive

³⁷ CESCR General Comment 3 The nature of States parties' obligations (Art. 2, par. 1) 14/12/90 para 10.

³⁸ Note 33 above.

³⁹ 'Argentina: Demand Immediate Ratification Of Civil Union Law In Rio Negro Province' Available at: <http://www.iglhrc.org/site/iglhrc/section.php?id=5&detail=512> Date viewed: 13 December 2008.

⁴⁰ 'Viceconte, Mariela c. Estado Nacional (Ministerio de Salud y Ministerio de Economía de la Nación) s/ Acción de Amparo' Available at: http://www.esccr-net.org/caselaw/caselaw_show.htm?doc_id=419811 Date viewed: 20 November 2008.

⁴¹ Viceconte, Mariela c. Estado Nacional (Ministerio de Salud y Ministerio de Economía de la Nación) s/ Acción de Amparo Federal Administrative Court of Appeals, 2 June 1998,

⁴² Note 40 above.

immunisation campaign that was required⁴³. The court held that, on the basis of international law including the ICESCR, the government was legally obliged to intervene and made the Ministers of Health and Economy personally liable for production of the vaccine within a specified time schedule⁴⁴.

The Committee on the Convention on the Rights of the Child (CRC)⁴⁵ issued General Comment No 3: HIV/AIDS and the Rights of the Child⁴⁶ which states:

[T]he obligations of States Parties under the Convention extend to ensuring that children have sustained and equal access to comprehensive treatment and care, including necessary HIV-related drugs... It is now widely recognised that comprehensive treatment and care includes antiretrovirals and other drugs, diagnostics and related technologies for the care of HIV/AIDS, related opportunistic infections and other conditions.

Millennium Development Goals (MDGs)

There were eight goals that 189 United Nations members, including South Africa⁴⁷, agreed to try to achieve by 2015. They have become 'a universal framework for development and a means for developing countries and their development partners to work together in pursuit of a shared future for all'⁴⁸. They relate both directly and indirectly to access to medicine and are:

- (1) Eradicating extreme poverty and hunger
- (2) Achieving universal primary education
- (3) Promoting gender equality and the empowerment of women
- (4) Reducing infant mortality
- (5) Improving maternal health
- (6) Combatting HIV/AIDS, malaria and other diseases, specifically with regard to HIV/AIDS: to halt and begin to reverse the spread of HIV/AIDS

⁴³ Ibid.

⁴⁴ Ibid.

⁴⁵ Convention on the Rights of the Child, 20 November 1989, 1577 U.N.T.S. 3, 28 I.L.M. 1456 (came into force 2 September 1990). South Africa ratified the Convention on 16 July 1995. Available at: <http://www.unhchr.ch/pdf/report.pdf> Date viewed: 9 December 2008.

⁴⁶ HIV/AIDS and the Rights of the Child, Committee on the Rights of the Child, 32 session, UN Doc CRC/GC/2003/1 (2003) 25.

⁴⁷ 'South Africa Millennium Development Goals Country Report' Available at:

<http://www.sarpn.org.za/documents/d0001538/index.php> Date viewed: 11 December 2008.

⁴⁸ Ban Ki Moon *Millennium Development Goals Report 2007* Available at: <http://www.un.org/millenniumgoals/pdf/mdg2007.pdf> Date viewed: 30 September 2008.

- by 2015; and the achievement, by 2010, of universal access to treatment of HIV/AIDS for all those who need it
- (7) Ensuring environmental sustainability
 - (8) Developing global partnerships for development.

This commitment by South Africa indicates that the State considers HIV/AIDS to be a significant problem and that the provision of treatment is vital to the achieving its goal under Goal (6).

In 2003 the Joint United Nations Programme on HIV/AIDS (UNAIDS) and the UN High Commissioner for Human Rights held a consultation on HIV/AIDS and Human Rights and issued a revised Guideline 6: Access to prevention, treatment, care and support stating⁴⁹:

States should enact legislation to provide for...safe and effective medication at an affordable price. States should also take measures necessary to ensure for all persons, on a sustained and equal basis, the availability and accessibility of quality goods, services and information for HIV/AIDS ... treatment ..., including antiretroviral and other safe and effective medicines, diagnostics and related technologies for preventive, curative and palliative care of HIV/AIDS and related opportunistic infections and conditions.⁵⁰

It is demonstrated above that international law states that medicines are vital to providing access to health care. Therefore the right to access to health care in section 27(1) includes the right to access to ARVs. However there is an internal limitation of section 27(2) which allows the State to demonstrate that it is doing all it can within its available resources. The rights dealing with health care in the ICESCR are also subject to a similar limitations clause. Article 4 of the ICESCR states:

The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.

⁴⁹ 'HIV/AIDS and Human Right International Guidelines Revised Guidelines 6: Access to prevention, treatment, care and support' Available at: <http://whqlibdoc.who.int/publications/2002/9291730254.pdf>
Date viewed: 2 October 2008.

⁵⁰ Ibid 11.

(ii) Internal limitation of section 27(1)

Section 27(2) requires ‘the state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of each of these rights.’ This limitation of the rights contained in section 27(1) is discussed in more detail later in this Chapter; however from a textual stand point it is important to note that section 27(1) is not a self-standing right⁵¹. This was held by the Constitutional Court in *Soobramoney v Minister of Health and others*⁵²(*Soobramoney*) and *TAC*..

The Constitutional Court in *TAC*⁵³ held:

Section 27(1) of the Constitution does not give rise to a self-standing and independent positive right enforceable irrespective of the considerations mentioned in section 27(2). Section 27(1) and 27(2) must be read together as defining the scope of the positive rights that everyone has and the corresponding obligations on the state to ‘respect, protect and fulfil these rights. The rights conferred by section 26(1) and section 27(1) are to have ‘access’ to the services that the state is obliged to provide in terms of section 26(2) and 27(2).

The effects of section 27(2) on a challenge to the right to access to ARVs are discussed further on in this Chapter. Before dealing with that, the social and historical context of Chapter 2 of the Constitution must be evaluated to establish the full ambit of the right.

b) The social and historical context

Chaskalson P in *Soobramoney* describes the context in which Chapter 2 should be interpreted.

We live in a society in which there are great disparities in wealth. Millions of people live in deplorable conditions and in great poverty. There is a high level of unemployment, inadequate social security, and many do not have access to clean water or to adequate health services. These

⁵¹ Note 1 above, 39

⁵² 1998 (1) SA 765 (CC). The Court held: ‘What is apparent from these provisions is that the obligations imposed on the State by Sections 26 and 27 in regard to housing, health care, food, water and social security are dependent upon the resources available for such purposes, and that the corresponding rights themselves are limited by reason of the lack of resources.’ 11

⁵³ Note 1 above, 39

conditions already existed when the Constitution was adopted and a commitment to address them and to transform our society into one in which there will be human dignity, freedom and equality lies at the heart of our new Constitutional order. For as long as these conditions continue to exist that aspiration will have a hollow ring.⁵⁴

The Constitutional Court has heard two cases specifically involving HIV/AIDS. The first was *Hoffmann v South African Airways*⁵⁵. In this case the Court found that not employing HIV-positive people as flight attendants amounted to unfair discrimination. The Court in reaching its decision held:

People who are living with HIV constitute a minority. Society has responded to their plight with intense prejudice. They have been stigmatised and marginalized... People who are living with HIV/AIDS are one of the most vulnerable groups in our society... In view of the prevailing prejudice against HIV-positive people, any discrimination against them can, to my mind, be interpreted as a fresh instance of stigmatisation and I consider this to be an assault on their dignity.⁵⁶

In the second case, namely *TAC*⁵⁷, the Court dealt with the government's failure to provide Nevirapine at all public hospitals. The Court began its judgment with the following:

The HIV/AIDS pandemic in South Africa has been described as 'an incomprehensible calamity' and 'the most important challenge facing South Africa since the birth of our new democracy' and government's fight against 'this scourge' as 'a top priority'. It 'has claimed million of lives, inflicting pain and grief, causing fear and uncertainty, and threatening the economy'. These are not the words of alarmists but are taken from a Department of Health publication in 2000 and a ministerial foreward to an earlier departmental publication.⁵⁸

These cases demonstrate the Constitutional Court's view that HIV/AIDS is a significant problem, that those who are infected with the disease deserve special protection from discrimination and that the government must 'fight this scourge as a top priority'. However, Yacoob J in *Grootboom* discussed the difficulties confronting the state in the

⁵⁴ Note 52 above, 8.

⁵⁵ 2001 (1) SA 1 (CC).

⁵⁶ Ibid 28.

⁵⁷ Note 1 above.

⁵⁸ Ibid 1.

light of South Africa's history in addressing issues concerned with the basic needs of people⁵⁹. He stated:

This case shows the desperation of hundreds of thousands of people living in deplorable conditions throughout the country. The Constitution obliges the State to act positively to ameliorate these conditions. The obligation is to provide access to housing, health care, sufficient food and water, and social security to those unable to support themselves and their dependants. The State must also foster conditions to enable citizens to gain access to land on an equitable basis. Those in need have a corresponding right to demand that this be done.⁶⁰

From this it is clear that those in need of medicines have the right to demand from the State that it provide access to health care. However, this right is tempered by what Yacoob J goes on to say in his judgment:

I am conscious that it is an extremely difficult task for the State to meet these obligations in the conditions that prevail in our country. This is recognised by the Constitution which expressly provides that the State is not obliged to go beyond available resources or to realise these rights immediately. I stress however, that despite all these qualifications, these are rights, and the Constitution obliges the State to give effect to them. This is an obligation that Courts can, and in appropriate circumstances, must enforce.⁶¹

In light of both domestic and international law it is clear that the right to access to health care includes the provision of ARVs, although this right is constrained by section 27(2). Before embarking on a discussion regarding the internal limitations contained in section 27(2), and the standard of reasonableness, it is important to discuss the previous decisions by the Constitutional Court on socio-economics rights to establish how far the Constitutional Court has intervened previously in similar cases, such as *TAC* and *Grootboom*.

⁵⁹ Note 1 above, 24.

⁶⁰ Note 9 above, 93.

⁶¹ *Ibid* 94.

c) The Constitutional Court's socio-economic rights jurisprudence

The Constitutional Court's jurisprudence on socio-economic rights has been one of limitation. This can be seen in the following areas: in the extent to which it will interfere with the State's policies; in the scope of its order and in monitoring the implementation of its order. The Court has avoided an objective standard, such as the minimum core, to measure the State's compliance with the Constitution preferring to adopt the reasonableness measure⁶². The use of the minimum core is discussed later in this Chapter. The reasonableness standard has been used by the Court to avoid involving itself in the creation of the State's policy, especially regarding socio-economic rights, in order to respect the separation of powers⁶³.

(i) Reasonableness

The reasonableness standard was first outlined by Yacoob J in *Grootboom* when deciding the ambit of the internal limitation in section 26(2)⁶⁴. Reasonableness is a flexible

⁶² The issue of the use of a minimum core as a standard in determining the State's compliance with the provision of the Bill of Right was discussed in *Soobramoney*, *Grootboom* and *TAC*. The Court in *TAC* outlined the content of a minimum core: 'This minimum core might not be easy to define but includes at least the minimum decencies of life consistent with human dignity. No one should be condemned to a life below the basic level of dignified human existence. The very notion of individual rights presupposes that anyone in that position should be able to obtain relief from a Court' (paragraph 28). After analysing the decisions of *Soobramoney* and *Grootboom* the Court in *TAC* held '... the socio-economic rights of the Constitution should not be construed as entitling everyone to demand that the minimum core be provided to them. Minimum core was thus treated as possibly being relevant to reasonableness under section 26(2), and not as a self-standing right conferred on everyone under section 26(1)... A purposive reading of section 26 and 27 does not lead to any other conclusion. 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 act reasonably to provide access to the socio-economic rights identified in sections 26 and 27 on a progressive basis'(paragraph 35).

⁶³ The Court in *TAC* stated: 'It should be borne in mind that in dealing with such matters the courts are not institutionally equipped to make the wide-ranging factual and political enquiries necessary for determining what the minimum-core standards called for by the first and second amici should be, nor for deciding how public revenues should most effectively be spent. There are many pressing demands on the public purse. As was said in *Soobramoney*: "The State has to manage its limited resources in order to address all these claims. There will be times when this requires it to adopt a holistic approach to the larger needs of society rather than to focus on the specific needs of particular individuals within society." Courts are ill-suited to adjudicate upon issues where court orders could have multiple social and economic consequences for the community. The Constitution contemplates rather a restrained and focused role for the courts, namely, to require the state to take measures to meet its constitutional obligations and to subject the reasonableness of these measures to evaluation. Such determinations of reasonableness may in fact have budgetary implications, but are not in themselves directed at rearranging budgets. In this way the judicial, legislative and executive functions achieve appropriate constitutional balance.' (Paragraph 38).

⁶⁴ Yacoob J said: '[t]he State is required to take reasonable legislative and other measures. Legislative measures by themselves are not likely to constitute constitutional compliance. Mere legislation is not

standard and is not capable of being measured objectively. It is decided on the circumstances of the case⁶⁵, in a similar manner to the reasonableness review ground in section 6 of the Promotion of Access to Justice Act No. 3 of 2000 (PAJA). The reasonableness enquiry must be viewed in the context of the Bill of Rights as a whole whilst remembering that ‘society must seek to ensure that the basic necessities of life are provided to all if it is to be a society based on human dignity, freedom and equality.’⁶⁶

When evaluating the reasonableness of the State’s policy the Court does not investigate whether there are other more desirable measures or whether the money could have been spent better. This is because the Court must show a level of deference to the decision maker who reviewed a wide range of possible options which could have been adopted⁶⁷. However this does not mean that the State’s policies cannot be evaluated by courts in order to establish their reasonableness.⁶⁸

Reasonableness appears to be a good way of measuring the State’s progress, especially as South Africa is still developing its economy and trying to uplift the status of a significant proportion of the population. The reasonableness standard allows the government to develop the policies it needs in order to fulfill this upliftment over time. However, on a practical level this standard has been used by the Constitutional Court to make decisions which do not diminish its legitimacy with the other branches of government⁶⁹. Its

enough. The State is obliged to act to achieve the intended result, and the legislative measures will invariably have to be supported by appropriate, well-directed policies and programmes implemented by the Executive. These policies and programmes must be reasonable both in their conception and their implementation. The formulation of a programme is only the first stage in meeting the State’s obligations. The programme must also be reasonably implemented. An otherwise reasonable programme that is not implemented reasonably will not constitute compliance with the State’s obligations.’ Paragraph 42 *Grootboom*.

⁶⁵ *Bato Star Fishing (Pty) Ltd v Minister of Environmental Affairs and Tourism* 2004 (4) SA 490 (CC) Paragraph 45. (*Bato Star*)

⁶⁶ Note 9 above, 44.

⁶⁷ *Ibid*.

⁶⁸ As O’Regan said in *Bato Star*: ‘...a Court should pay due respect to the route selected by the decision-maker. This does not mean, however, that where the decision is one which will not reasonably result in the achievement of the goal, or which is not reasonably supported on the fact or not reasonable in the light of the reasons given for it, a Court may not review that decision. A Court should not rubber-stamp an unreasonable decision simply because of the complexity of the decision or the identity of the decision-maker. Paragraph 48.

⁶⁹ T Roux ‘Principle and Pragmatism on the Constitutional Court of South Africa’ (2008) Vol 1 *International Journal of Constitutional Law* 1, 32. Roux argues: ‘Many South African legal academics

decisions to avoid usurping the power of the Executive or Legislature and draft the policy that it wants, Roux argues that this is to ensure that the Constitutional Court's decisions are still respected by the other branches of government, he states 'it is ... the proper function of the CCSA [Constitutional Court of South Africa] to devise review standards that allow it to remain sensitive to the political nature of its role'.⁷⁰

The use of the reasonableness standard has caused one of the fundamental problems with the socio-economic rights jurisprudence, namely that the Court in making its decisions has failed to provide the content of the rights contained in the Bill of Rights. In the case of section 27 it should be established by the Court what the services are to which one is entitled to claim access⁷¹. This lack of content means that the Court is much freer to make its decision based on the circumstances of the case rather than what the right requires.⁷² It also means that it is much harder to challenge one of the State's policies on the basis that it is unreasonable as the Court has not established what the State should be providing in terms of the Constitution⁷³.

(aa) Minimum core

The Court could have established the content of the right to access to health care through the use of minimum core obligations, however this was rejected⁷⁴. The minimum core

were quite indignant at the time about the CCSA's [Constitutional Court of South Africa] rejection of the minimum core content approach, which they argued amounted to an abdication of its responsibility to enforce socio-economic rights. As soon as one accepts, however, that the CCSA's concern in these cases may have been to *devise a review standard that allowed it greater flexibility to manage its relationship with the political branches*, much of the force of the criticism falls away.' (emphasis added).

⁷⁰ Ibid 32.

⁷¹ D Bilchitz 'Health' in Woolman et al (eds) *Constitutional Law of South Africa* (2006) 2nd ed 56A-21.

⁷² Ibid.

⁷³ Ibid.

⁷⁴ The Constitutional Court in *Grootboom* played down the normative strength of the ICESCR and the General Comments of UNCESCR, relating to determining the minimum core of the right of access to housing. Yacoob J stated that it is not possible to determine the minimum threshold for the progressive realisation of the right to access to adequate housing without first identifying the needs and opportunity for enjoyment of such a right. These will vary according to factors such as income, unemployment, availability of land and poverty. The difference between city and rural communities will also determine the needs and opportunity for enjoyment of this right. The UN committee has developed this concept over many years of examining reports by reporting states and the Court did not have comparable information. (Paragraph 32) The Constitutional Court in *TAC*, referring to the judgement in *Grootboom* said: Although Yacoob J indicated that evidence in a particular case may show that there is a minimum core of a particular service that should not be taken into account in determining whether measures adopted by the state are

obligations were developed by the United Nations Committee on Economic, Social and Cultural Rights (UNCESCR)⁷⁵. It requires every state to fulfill the minimum core obligations by ensuring the satisfaction of a minimum essential level of socio-economic rights⁷⁶. Had the Constitutional Court decided to use the minimum core obligations it would have created a far more objective standard with which to measure the level of the State's compliance. This would have allowed the Court far more room to explore the various options that were available to the State when deciding and implementing its rollout of ARVs.

(bb) Constitutional Court and the implementation of its orders

The limitations of the Court's reasonableness standard are also demonstrated in the scope of its orders⁷⁷ especially in cases involving socio-economic rights, which is clear in both *Grootboom* and *TAC*. The Court has preferred to use Chapter Nine institutions⁷⁸ such as the South African Human Rights Commission to monitor the State's progress, as was the case in *Grootboom*. The Court also declined to exercise supervisory jurisdiction over the implementation of its order in *TAC*. Instead it issued a mandatory order that Nevirapine be made available to all public hospitals and clinics. This lack of a structural interdict led to delays in the rollout of Nevirapine in a number of provinces and it can be argued that this would have been avoided if the Court had taken a more interventionist approach⁷⁹.

reasonable, the socio-economic rights of the Constitution should not be construed as entitling everyone to demand that the minimum core be provided to them. Minimum core was thus treated as possibly being relevant to reasonableness under section 26(2) and not as a self-standing right conferred on everyone under section 26(1). (Paragraph 34 *TAC*)

⁷⁵ International Covenant on Economic, Social and Cultural Rights, adopted by General Assembly Resolution 2200A (XXI) of 16 December 1966.

⁷⁶ General Comment 3 issued by the UNCESCR states '...a State party in which any significant number of individuals is deprived of essential foodstuffs, of essential primary health care, of basic shelter and housing, or of the most basic forms of education, is prima facie failing to discharge its obligations under the Covenant'. CESCR General Comment 3 The Nature of States parties obligations (Art. 2, par. 1) 14/12/90 10.

⁷⁷ D Bilchitz (Note 71 above) 56A-24

⁷⁸ These are the Public Protector, the Commission for the Promotion and Protection of the Rights of Cultural and Religious and Linguistic Communities, the Commission for Gender Equality and the South African Human Rights Commission (SAHRC).

⁷⁹ D Bilchitz (Note 71 above) 56A-24; W Trengrove 'Judicial Remedies for Violations of Socio-economic Rights' (1999) 1(4) *ESR Review* 8.

In 2003 Kameshni Pillay⁸⁰ carried out research concerning the implementation of the *Grootboom* order. According to Pillay ‘there has been little tangible or visible change in housing policy so as to cater for people who find themselves in desperate need or crisis situations.’⁸¹ The Western Cape Provincial Administration spent almost a year deciding on where the locus of responsibility⁸² lay with regard to the implementation of the *Grootboom* judgement, and even then, it failed to make systematic policy changes so as to cater for all people in crisis situations⁸³. The implementation of the judgement in the Cape has focused specifically on the Grootboom community⁸⁴ and there has been little sign that the government has established a comprehensive programme that caters for all those in situations of crisis.⁸⁵

Pillay’s research clearly demonstrates the need for stricter enforcement of socio-economic rights. In response to the fears of the court that supervision by the court over implementation of its orders amounts to an excessive interference in the workings of other branches of government, it can be argued that a failure to retain such supervision demonstrates an undue deference by the court to other branches of government and ‘evinces an unwillingness on its part to retain responsibility for the effectiveness of its orders.’⁸⁶

It is clear that the Constitutional Court has previously shown much deference towards the policies of the Executive and Legislature. However, the Court has the power to issue mandatory orders⁸⁷ where it finds the State’s policy or its implementation was

⁸⁰ K Pillay ‘Implementing Grootboom: Supervision needed’ (2002) 3 *ESR Review* 13.

⁸¹ *Ibid.*

⁸² *Ibid.*

⁸³ *Ibid.*

⁸⁴ The community received R200 000 to buy basic building materials; ten taps were installed and twenty toilets constructed. However the land upon which these facilities lie has no drainage which, after rain, has led to stagnant water creating unhealthy living condition. It has also been alleged that the municipality has failed to maintain these facilities or provide them with basic services. K Pillay ‘Implementing Grootboom: Supervision needed’ (2002) 3 *ESR Review* 13.

⁸⁵ *Ibid.*

⁸⁶ D Bilchitz ‘Towards a Reasonable Approach to the Minimum Core: Laying the Foundations for Future Socio-economic Rights’ 2003 *SAJHR* 1 paragraph 26.

⁸⁷ The Court in *TAC* stated: ‘A dispute concerning socio-economic rights is thus likely to require a Court to evaluate State policy and to give judgment on whether or not it is consistent with the Constitution. If it finds that policy is inconsistent with the Constitution it is obliged in terms of s 172(1)(a) to make a

unreasonable⁸⁸. What must be established is to what extent the Court would have to involve itself in the Department of Health's policy on ARV procurement and distribution in order to effect the significant increases in the provision of ARVs needed. The question is whether the Court would have to become involved in the policy decisions which the Minister of Health made when drafting the policy or whether the Court would need simply to order the Department of Health to implement its policy. In order to establish the extent to what the Constitutional Court's involvement is needed in the policies of the Department of Health, its policies dealing with drug procurement and methods of securing lower priced medicines must be evaluated in terms of reasonableness. If it is found that the policy itself is unreasonable then the Court is likely to refer the policy back to the Minister of Health for it to be redrafted. However, if the policy is found to be reasonable but the implementation thereof is unreasonable then the Court is likely to order the Minister to implement the department's policy.

(d) Department of Health's policies dealing with medicines procurement

The Department of Health's policies regarding medicines procurement at affordable prices are contained in the Medicines and Related Substances Control Amendment Act 90 of 1997 and the Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa, released in October 2003. As will be demonstrated, these policies are reasonable because they provide the Minister of Health with the necessary tools to secure medicines at more affordable prices. This reduction in prices would mean that the government would be able to provide greater access to medicines. However, the measures contained in these policies have largely gone unimplemented.

declaration to that effect. But that is not all. Section 38 of the Constitution contemplates that where it is established that a right in the Bill of Rights has been infringed a court will grant 'appropriate relief. It has wide powers to do so and in addition to the declaration that it is obliged to make in terms of s 172(1)(a) a Court may also 'make any order that is just and equitable.' Paragraph 101.

⁸⁸ The Constitutional Court has issued mandatory orders against organs of State. An example of this is *Dawood and another; Shalabi and Another v Minister of Home Affairs and Other; Thomas and Another* 2000 (3) SA 936 (CC). In this case the Court granted a mandatory order requiring immigration officials and the Director General take into account the constitutional rights of people applying for temporary immigration permits, or the extension of these permits, as O'Regan found that this was the most appropriate relief which protected the rights of the applicants (Paragraph 67).

(i) Medicines and Related Substances Control Amendment Act 90 of 1997

One of the aims of this Act is to ‘provide for measures for the supply of more affordable medicines in certain circumstances’⁸⁹. This Act did not deal specifically with the medicines needed to treat HIV/AIDS; however it is capable of being used for ARVs and other medicines. To facilitate this the Act affords the Minister of Health wide powers to utilise the measures set out in the Act in order to access affordable medicines. The Act provides for the issuing of compulsory licences⁹⁰ and the use of parallel importation⁹¹. The Act provides a framework within which the Minister of Health can use these measures to protect public health⁹².

Section 15C states:

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and in particular may—

- (a) notwithstanding anything to the contrary contained in the Patents Act 1978 (Act No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for as well as the use of the medicine referred to in paragraph (b).

⁸⁹ Preamble to the Medicines and Related Substances Control Amendment Act 90 of 1997.

⁹⁰ Section 15C (a) of the Medicines and Related Substances Control Amendment Act 90 of 1997.

⁹¹ Section 15C (b) of the Medicines and Related Substances Control Amendment Act 90 of 1997.

⁹² ‘Access to Essential Medicines’, in A Hassim, M Heywood & J Berger (eds) *Health and Democracy: A Guide to Human Rights, Health Law and Policy in Post Apartheid South Africa*. (2007) 452.

In section 15C(a) the Minister of Health is afforded wide powers to exceed the boundaries of South African Patent Law. This is achieved by the phrase ‘*notwithstanding* anything contained in the Patents Act’⁹³ (emphasis added), which means that the Minister of Health is able to override the exclusive rights of patents. This provision is important for the full use of compulsory licences and parallel importation. Section 15C(b) deals specifically with parallel importation, Regulation 7 of the General Regulations made in terms of the Medicines and Related Substances Act⁹⁴ provides the details for the use of parallel importation. It prescribes the following:

- Only medicines under patent in South Africa are allowed to be imported under section 15C(b)⁹⁵.
- The Minister of Health has the power to approve the use of parallel importation where the applicant complies with the formal requirements detailed in Regulation 7(2)⁹⁶. The Minister also has the power to cancel his/her permission regarding the parallel importation of a medicine.

Compulsory licensing and parallel importation are discussed in greater detail in Chapter 4. It is vital that provision has been made for the use of compulsory licence and parallel importation because otherwise the government would not be able to utilise the other mechanisms under international law, detailed in Chapter 4, to obtain medicines at lower prices.

(ii) Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa (Operational Plan)

The Operational Plan was published in October 2003 with the goal of having 54 000 people on ARV treatment by March 2004 and one million people on treatment by 2008⁹⁷. It provides for a variety of areas surrounding HIV/AIDS, including the prevention,

⁹³ Note 90 above.

⁹⁴ Regulation 510 of 10 April 2003. Government Gazette No. 24727

⁹⁵ Regulation 7(1)(e)(i).

⁹⁶ Regulation 510 of 10 April 2003. Government Gazette No. 24727

⁹⁷ Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa, 248.

treatment and care, research and promotion of human rights⁹⁸. The Operational Plan aims to accomplish two interrelated goals, namely ‘to provide comprehensive care, management and treatment for people living with HIV and AIDS; and to facilitate the strengthening of the national health system in South Africa’⁹⁹. Whilst the Plan deals with a number of areas surrounding HIV/AIDS treatment this section focuses just on drug procurement and methods to ensure lower prices for medicines.

The Operational Plan deals specifically with drug procurement and states that it ‘attempts to secure antiretroviral drugs at prices well below today’s best international prices with a view towards creating fully integrated production facilities for those drugs in SA’¹⁰⁰. The Operational Plan also deals with the relevant Intellectual Property Law. It states:

All ARVs on the market are still under patent protection. The maintenance of strong intellectual property rights is essential to foster innovation and industrial development, however, the costs of patented medicines may prevent equitable access to essential medicines.¹⁰¹

The Operational Plan then discusses a number of methods to facilitate access to AIDS medicines, especially ARVs, including voluntary licences¹⁰², compulsory licences¹⁰³ and parallel importation¹⁰⁴. The use of these methods is discussed in detail in Chapter 4. The methods if implemented would allow the Minister of Health to access ARVs and other medicines at a greatly reduced price. This price reduction is vital to ensuring greater access to ARVs in the public sector because the government has limited resources with which to purchase ARVs and this money is best spent on the most affordable ARVs which are the best for the patients.

⁹⁸ South African Human Rights Council’s 6th *Economic and Social Rights Report* (August 2006) Chapter 3: Health Available at: http://www.sahrc.org.za/sahrc/cms/downloads/Chapters%201_5.pdf. 34. Date viewed: 13 November 2008.

⁹⁹ Note 97 above, 24.

¹⁰⁰ Ibid 143.

¹⁰¹ Ibid 143.

¹⁰² Ibid 151

¹⁰³ Ibid 151.

¹⁰⁴ Ibid 152.

(iii) Implementation of the Operational Plan

The fulfilment of this plan was stalled a number of times by then Health Minister Manto Tshabalala-Msimang. This can be seen in the fact that it took until September 2004 for her to release the ARV¹⁰⁵ treatment guidelines¹⁰⁶ needed to use these medicines in the public sector. Although there are mechanisms provided in the Operational Plan and the Medicines and Related Substances Act for the Minister of Health to achieve lower prices for medicines, the then Minister of Health failed to negotiate with pharmaceutical companies in order to obtain a price reduction¹⁰⁷. In March 2005 the government drug tender was awarded; more than half the tender was awarded to Merck, Sharp and Dohme (MSD) and Abbott Laboratories, both of which manufacture the most expensive ARVs on patent¹⁰⁸. The then Minister also failed to heed calls by civil society movements including the TAC to utilise the mechanisms in the Operational Plan¹⁰⁹ to access medicines more cheaply.

After the Operational Plan began to be implemented the then Minister began undermining the public's perception of ARVs through the promotion of alternative treatment for AIDS such as the Rath Health Foundation¹¹⁰ and the eating of the African potato and garlic as a means of controlling the disease. However, it has been established that the active ingredients in these foods may be harmful for HIV-positive people¹¹¹.

Whilst ARV rollout has increased steadily since 2003 the Operational Plan's target of one million people on ARVs by 2008¹¹² it is not likely that this has been met¹¹³ and there are

¹⁰⁵ National Treatment Guidelines. Available at <http://www.doh.gov.za/docs/hivaids-progressrep.html>
Date viewed: 1 December 2008.

¹⁰⁶ Natrass (Note 10 above) 129.

¹⁰⁷ Ibid

¹⁰⁸ Hassan, F. 'Let Them Eat Cake: A Short Assessment of Provision of Treatment and Care 18 Month after the Adoption of the Operational Plan.' 2005 *Aids Law Project and Treatment Action Campaign*, 13.

¹⁰⁹ Natrass (Note 10 above) 142.

¹¹⁰ Ibid

¹¹¹ 'The African potato extract has been shown to reduce CD4 counts and cause bone-marrow suppression in HIV-positive people; and when given to cats with feline AIDS, it actually hastens the progression to death. It also has the potential to interact with HIV-drug-metabolising enzymes (which could lead to drug resistance and drug toxicity). Likewise, garlic has been shown to reduce blood levels of Saquinavir (a protease inhibitor) and is thus not recommended for people on this ARV treatment.' Natrass (Note 10 above) 143.

¹¹² Note 97 above, 248.

also at least 500 000¹¹⁴ people in urgent need of ARVs. Most of the mechanisms to obtain medicines at affordable prices have not been used by either the former or present Ministers of Health, who have failed to issue any compulsory licences or authorise the parallel importation of medicines. The voluntary licensing agreements that have been concluded have largely been through private negotiations by generic manufacturers, such as Aspen Pharmacare, or as part of a legal settlement to Competition Commission hearings¹¹⁵.

Having explored the provisions of the State's policy its implementation will now be measured against the standard of reasonableness required by section 27(2).

(e) Section 27(2)

Section 27(2) requires the State to take reasonable legislative and other measures, within its available resources, to achieve the progressive realisation of the right. Yacoob J in *Grootboom* discussed the ambit of this limitation. Although he was referring to section 26(2) his words are equally relevant for section 27(2). He said:

[t]he State is required to take reasonable legislative and other measures. Legislative measures by themselves are not likely to constitute constitutional compliance. Mere legislation is not enough. The State is obliged to act to achieve the intended result, and the legislative measures will invariably have to be supported by appropriate, well-directed policies and programmes implemented by the Executive. These policies and programmes must be reasonable both in their conception and their implementation. The formulation of a programme is only the first stage in meeting the State's obligations. The programme must also be reasonably implemented. An otherwise reasonable programme that is not implemented reasonably will not constitute compliance with the State's obligations.¹¹⁶

¹¹³ This is due to the fact that only 371 731 people received ARV treatment in 2007, according to the Department of Health in its UNGASS Report. UNGASS Progress Report, 29.

¹¹⁴ The figures were released by the South African government in its UNGASS Progress Report for the period January 2006 to December 2007. 29. Available at: http://data.unaids.org/pub/Report/2008/south_africa_2008_country_progress_report_en.pdf Date viewed: 15 April 2008.

¹¹⁵ Note 19 above.

¹¹⁶ Note 9 above, 42.

From this it can be seen that the primary assessment of whether the State's policy complies with section 27 involves deciding whether it is reasonable.

Reasonableness is a flexible standard and is not capable of being measured objectively. It is decided on the circumstances of the case¹¹⁷, in a similar manner to the reasonableness review ground in section 6 of PAJA. The reasonableness enquiry must be viewed in the context of the Bill of Rights as a whole and the injunction that 'society must seek to ensure that the basic necessities of life are provided to all if it is to be a society based on human dignity, freedom and equality.'¹¹⁸

When evaluating the reasonableness of the State's policy the court does not then investigate whether there are other more desirable measures or whether the money could have been spent better. This is because the courts must show a level of deference to the decision maker who reviewed a wide range of possible options which could have been adopted¹¹⁹. However this does not mean that the State's policies cannot be evaluated by courts in order to establish their reasonableness.¹²⁰

(i) The effect of the lack of implementation of State's policy

A lack of access to ARVs means that people's ability to enjoy their rights is infringed. Those who require ARVs need them urgently because their body is failing and their immune system is unable to cope. Their needs are the most urgent and their ability to enjoy all their rights is most at peril. The State's lack of proper provision of ARVs for these people is clearly demonstrated by the statistics released by the South African government in February this year in their United Nations General Assembly Special Session on HIV/AIDS (UNGASS) Progress Report. In 2007, of the 889 000 people

¹¹⁷ Note 63 above, 45.

¹¹⁸ Note 9 above, 44.

¹¹⁹ Ibid 41.

¹²⁰ As O'Regan said in *Bato Star*: '...a Court should pay due respect to the route selected by the decision-maker. This does not mean, however, that where the decision is one which will not reasonably result in the achievement of the goal, or which is not reasonably supported on the fact or not reasonable in the light of the reasons given for it, a Court may not review that decision. A Court should not rubber-stamp an unreasonable decision simply because of the complexity of the decision or the identity of the decision-maker.' Page 32 Paragraph 48.

requiring ARVs only 371 731¹²¹ people actually received the treatment. This means that 517 269 people did not receive ARVs¹²². This clearly demonstrates that the State's policy is unreasonable in its implementation because it has failed to provide ARVs to 58 per cent of those needing it. The UNGASS Progress Report also demonstrates that demand for ARVs is increasing, from 764 000 people in 2006 to 889 000¹²³ people in 2007. This significant increase is not a once-off event and the number increases significantly every year. This means that every year more people will desperately need ARVs and, if the government fails to implement its policy on access to ARVs at the lowest possible price, fewer and fewer people will have to access to ARVs. This adds significantly to the urgency of the problem.

The South African Human Rights Commission's 6th Economic and Social Rights Report¹²⁴ summarised the situation in the public health system with regards to the government's compliance with its obligations. It states:

Government's goal to strengthen the National Health Service and to reverse the spread of AIDS has yet to be fulfilled. South Africa is losing many of its economically productive workers and this will impact negatively on the lives of not only those living with AIDS, but also those affected by the disease (families and friends). Last, but not least, HIV/AIDS will affect the future economic growth of the country. South Africa will be well advised to honour its national and international obligations with respect to the right to health, and ensure equal access to quality health care services for everybody.¹²⁵

(ii) Progressive realisation

Section 27(2) also provides that the right must be progressively realised. Yacoob J examined the meaning of 'progressive realisation' *Grootboom*:

The term 'progressive realisation' shows that it was contemplated that the right could not be realised immediately. But the goal of the Constitution is that the basic needs of all in our society be effectively met and the requirement of progressive realisation means that the state must take steps

¹²¹ Note 114 above.

¹²² Ibid 29.

¹²³ Ibid.

¹²⁴ Note 97 above.

¹²⁵ Ibid 44.

to achieve this goal. It means that accessibility should be progressively facilitated: legal, administrative, operational and financial hurdles should be examined and, where possible, lowered over time.¹²⁶

In dealing with the provision of ARVs it can be argued that the State has taken too long to realise the rollout of ARVs. The requirement of progressive realisation is important; however it must not be used by government as justification for failing to implement its policies

(iii) Available resources

Finally, section 27(2) states that the State must fulfill the content of the right within its available resources. The lack of resources argument has been used in a number of cases. In *Soobramoney* the court's decision was based on a lack of resources.¹²⁷ In finding that the State lacked the resources to provide the Applicant with treatment for his chronic renal failure the court stated that this was because:

the cost of doing so would make substantial inroads into the health budget. And if this principle were to be applied to all patients claiming access to expensive medical treatment or expensive drugs, the health budget would have to be dramatically increased to the prejudice of other needs which the State has to meet.

The State's argument¹²⁸ to a challenge to its ARV rollout policy in *TAC* was that it lacked the resources needed in order to do more¹²⁹. However by implementing the State's policies on drug procurement the State will be able to provide the services it already does in a far more cost-effective manner. That will then free up some of the previously used resources to channel into improving access. This will mean that the government will not

¹²⁶ Note 9 above, 45.

¹²⁷ Note 71 above, 56A-8.

¹²⁸ The Constitutional Court did not deal with this argument in great detail. The Court stated: 'The cost of Nevirapine for preventing mother-to-child transmission is not an issue in the present proceedings. It is admittedly within the State's resources.' (Paragraph 71)

¹²⁹ This is demonstrated by Dr Ntsaluba in an affidavit lodged by the applicant in *TAC* in which he raised the issue of resources as justification for the very limited rollout of Nevirapine. He said that the provision of Nevirapine required the creation of infrastructure involving counselling, provision of formula as a substitute for breastfeeding and vitamin supplements and antibiotics. He then states, 'There are significant problems in making this package available. There are problems of resources insofar as counselling and testing are concerned and budgetary constraints affecting the expansion of facilities at public hospitals and clinics outside the research and training sites.' *Minister of Health v Treatment Action Campaign (2)* 2002 (5) SA 721 (CC) 48 – 51.

have to prioritise this right over other rights because it will be using funds it has already allocated to ARVs.

(f) Possible order by the Constitutional Court

In terms of section 27(1) the State is under an obligation to provide access to ARVs. The State has not fulfilled this obligation as more than 500 000 people who need ARVs have not received them. In the *TAC* case one of the government's justification for its failure to rollout Nevirapine was that it lack the resources necessary. However in view of the lack of support for ARVs by the then President and Health Minister, it can be argued that the State used the argument of a lack of resources, as a pretext to avoid rolling out ARVs fully. Since the new Minister of Health Barbara Hogan assumed the position there has been a distinct shift in policy¹³⁰ and it is possible that the State would not use this argument now. However the government has certainly failed to implement its policy on drug procurement which would greatly reduce the cost of medicines and free up resources for the Department of Health. The government has therefore acted unreasonably.

It has been established above that it is unlikely that the Constitutional Court would make the wide-ranging order involving the Court redrafting the Department of Health's policy. However, the Court has in previous matters ordered the State to implement its policy and this is likely to be the extent of the Court's direct involvement in a challenge regarding the provision of ARVs by the Department of Health. However, there are a number of different measures to improve access to ARVs which do not require the Court's direct involvement.

¹³⁰ The province of the Free State in November 2008 faced an acute shortage of ARVs and was likely to run out of stock by January 2009. The Mail and Guardian explains the steps the new Minister of Health took to rectify the problem immediately. 'Insiders say that once informed that the HIV-positive patients in the Free State could be enduring a life-endangering halt to their treatment in a few weeks, Minister of Health Barbara Hogan immediately told her department to sort out the problem... In the context of the new ministerial regime this meant identifying the problem and solving it. Hogan ordered that a high-level department of health "fix-it" squad be dispatched to the Free State.' Available at: <http://www.mg.co.za/article/2008-11-17-arvs-hogan-acts> Date viewed: 8 December 2008.

These measures will form the remainder of this dissertation. These measures include the maintenance of high standards of patentability to prevent abuse of the patent system by drug manufacturers, and the use of the flexibilities contained in TRIPS to bypass patents such as compulsory licences, voluntary licences and parallel importation. The cost-effectiveness of using the flexibilities in TRIPS is clearly demonstrated in Brazil, where the Minister of Health issued a compulsory licence for Efavirenz, a highly effective ARV. This led to a massive reduction in the proportion of their health budget for ARVs which had been used to purchase Efavirenz. The percentage of the health budget now used on Efavirenz is 4 per cent of the health budget for ARVs as opposed to the 11 per cent which was previously being used¹³¹. Such a significant reduction in South Africa would have a positive impact on the cost of ARVs.

¹³¹ A N da Costa 'Brazil to make generic version of key AIDS drug' (REUTERS) Available at: <http://www.reuters.com/article/healthNews/idUSN17530960200880917?sp=true> Date viewed: 23 October 2008.

CHAPTER 3: PATENT PROTECTION

The role of patent protection in South Africa is a complex issue. There are a number of competing interests including the drug manufacturers' desire for protection of its inventions, in order to ensure its financial viability, and the need for patients to access medicines at affordable prices. Patents are a significant barrier to access to affordable medicine as they allow the holder to exclude others from making, using, distributing or importing the patented product or process¹³². As a result the patent holder is able to charge a higher price because the holder has a monopoly over the market. This is especially so in South Africa where all twelve of the ARVs on the World Health Organisation's Essential Medicines List¹³³ (WHO-EML) are under patent¹³⁴, which means that the patent holders are able to charge very high prices for their medicines without the risk of generic competition. Due to its limited resources the South African government has to restrict the number of patented ARV medicines it can buy, which means that the majority of drugs bought are generic versions of medicines no longer on patent. These are the older medicines which have greater side effects¹³⁵ than the newer medicines. On the other hand patent protection is integral to creating incentives for scientists to conduct research into new medicines because without patents the scientists and manufacturers would not be able to recoup their expenses. A lack of incentive to

¹³² Article 28(1) of TRIPS establishes the ambit of patent protection at the international level. It states: 'A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.'

¹³³ The WHO's Essential Medicines List was first released in 1977 with the 'aim of providing a model for governments in select medicines to address local public health needs and create national lists'. WHO Fact Sheet No. 325 'Essential Medicines List' Available at: <http://www.who.int/medicentre/fs325/en/> Date viewed: 2 December 2008.

¹³⁴ Note 97 above, 150.

¹³⁵ These side effects include: stomach pains, diarrhoea, loss of appetite, nausea, vomiting, liver problems, kidney stones, lactic acidosis, pancreatitis, lipodystrophy and peripheral neuropathy. ['Antiretroviral (ARV) Treatment Fact Sheet 06: Side effects of ARVs – detailed' Available at: http://www.aidsalliance.org/custom_asp/publications/view.asp?publication_id=186 Date viewed: 2 December 2008]

manufacture medicines has significant negative consequences for patients¹³⁶. A possible middle ground between these competing interests is the use of strict patent standards so that only those medicines that are actually new inventions will receive patent protection. This will result in fewer patents being granted by the South African Patent Office, which will then leave room for generic manufacturers to produce those medicines that are not patented, at an affordable price.

I PATENT SYSTEMS AND THE ROLE OF STANDARDS OF PATENTABILITY

A patent system which has strict standards for granting a patent creates a situation where only truly new medicines are patented. This has two primary results: firstly, the manufacturer that has a medicine which has already had a patent, cannot alter the medicine slightly and get a second patent which would mean that the manufacturer has a monopoly for a further twenty years on the medicine. Secondly, because this re-patenting is prevented by strict patent standards, generic manufacturers are then able to enter the market and produce generic versions of the medicine without delay – which is beneficial to both the generic manufacturer and the patients, who are then able to access the medicine at a greatly reduced cost¹³⁷. This is vital for South Africa in order to bolster its own generic pharmaceutical manufacturing capacity and increase access to medicines at lower prices.

Patent systems can be open to abuse by manufacturers seeking to re-patent a medicine which has already had a patent or to combine a number of medicines into one medicine in order to secure a separate patent. Correa argues that the defining of inventive step and novelty are critical aspects of a patent regime because they determine the standards required to obtain a patent and the corresponding limitation on competition¹³⁸. If these standards are interpreted strictly they will prevent the abuse discussed above. In light of

¹³⁶ A lack of incentive to develop new tuberculosis medicine has meant that there have been no new medicines for treating tuberculosis in over 30 years. Drugs for Neglected Diseases Brochure Available at: http://www.dndi.org/cms/public_html/images/article268/An%20Innovative%20Solution.pdf Date viewed 12 October 2008.

¹³⁷ C M. Correa 'Pharmaceutical Inventions: When is the granting of a patent justified?' *Int. J. Intellectual Property Management*, Vol. 1, Nos. 1 / 2, 2006. 5.

¹³⁸ *Ibid.*

this it is essential that countries have strict requirements for the patenting of a medicine. India has a particularly strict patent system which has strengthened its generic manufacturing capacity. The Indian example, which is discussed in greater detail later, demonstrates how its strict patent laws have been used to benefit its generic manufacturing capacity. This is very important for South Africa in the development of its domestic pharmaceutical manufacturing capacity.

TRIPS provides a guide for patent requirements but leaves the interpretation of these requirements up to each country in their domestic legislation. Article 27(1) of TRIPS states ‘...patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial applicability.’ This pluralism in patent standards has led to both high and low standards of patent, which are discussed below.

II STANDARDS OF PATENTABILITY

a) **Low standards of patentability and its effects**

In a country with low standards of patentability it is much easier for a drug manufacturer to gain a patent on its drug. A low standard allows a drug manufacturer to re-patent medicines under the guise of being a new medicine¹³⁹ when a new metabolite is used, a new use or indication for an existing medicine is found; or a variation of existing chemical entities is developed¹⁴⁰.

These lower standards encourage ‘evergreening’ of patents and other mechanisms used by the drug companies to ensure the longevity of their patents and their profits. Countries such as the United States try to persuade developing countries to legislate low standards of patentability in exchange for apparently favourable free trade agreements¹⁴¹. A low standard means that it is far more difficult to cultivate a generic drug manufacturing

¹³⁹ C Fink & P Reichenmiller ‘Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements’ *The World Bank Group Trade Note* 20, 2

¹⁴⁰ *Ibid* 2.

¹⁴¹ B Baker ‘US Trade negotiations with the South Africa Customs Union undermine access to medicines and violate US Law’ *Health Gap*. Available at: <http://www.cptech.org/ip/health/trade/sacu/hgap07072003.html> Date viewed: 5 August 2008.

market. This is due to the fact that the most potent drugs do not come on the market for decades because drug companies are able to receive another patent for their medicine by altering the medicine slightly¹⁴², which would not be considered a sufficient alteration to receive a patent under a high standard of patent.

b) High standards of patentability and its effects

High standards of patentability are designed to weed out minor variations, such as combining medicines which have already had a patent. These standards are better for the patenting country because they result in fewer patent applications and establish room for generic manufacturers¹⁴³ to produce those medicines that are not granted a patent, thus cultivating a strong generic manufacturing market.

In light of the above the importance of high standards of patentability has been demonstrated. South Africa's patent system will now be analysed to establish the standards of patent. Thereafter India's patent system is examined in order to draw parallels between the two systems and to show how India has used its patent system to grow its generic manufacturing capacity. Correa's argument above, the requirements of novelty and inventive step are used in the following analysis as the basis for determining South Africa's patent standards and to compare South Africa and India's patent system.

III SOUTH AFRICA'S PATENT SYSTEM

Section 25(1) of the Patents Act 57 of 1978 states that a patent may be granted for any new invention which involves an inventive step which is capable of being used or applied in trade, industry or agriculture¹⁴⁴. This section contains three elements namely:

1. It must be a new invention;
2. The invention must involve an inventive step;
3. The invention must have industrial capability.

¹⁴² Note 134 above, 3.

¹⁴³ '2007 Victories – Fewer Patents, More Compulsory Licenses: The Knock-Off Effects of India's Strict Patent Act and Thailand's Compulsory Licenses' Available at: www.healthgap.org/documents/2007PatentandCLVictories.doc Date viewed: 10 December 2008.

¹⁴⁴ Section 25(1) of Patents Act 57 of 1978.

In ascertaining the patent standards of South Africa, in the context of medicines, the first two requirements, namely that the invention must be new, or novel, and that it must involve an inventive step, are relevant. This is because if these elements are interpreted in such a way as to create high standards it will prevent abuse by manufacturers. And mean that a medicine receives only one patent when that patent has expired generic manufacturers will be able to produce generic versions of these medicines, which will be much sooner than if the patent holder was able to re-patent the same medicine.

a) New invention or novelty

A new invention is one that ‘does not form part of the state of the art immediately before the priority date of that invention’¹⁴⁵. The state of the art is defined, in section 25(6) of the Patents Act, as comprising ‘all matter (whether a product, a process, information about either, or anything else) which has been made available to the public (whether in the Republic or elsewhere) by written or oral description, by use or in any other way’¹⁴⁶. Therefore in order to establish that a patent is new, it must be demonstrated that it did not form part of the state of the art before the priority date.

Problems arise in the interpretation of this requirement where a patent holder or other person wishes to patent a new use for a medicine which already has a patent. This is known as a Swiss type of claim¹⁴⁷. Such claims have been permitted where the use of the patented product is for the ‘manufacture of a medicament for a specified new and inventive medical use’¹⁴⁸. Falconer J, in the European Patents Court in *Wyeth’s Application*¹⁴⁹ stated:

the Swiss type of use claim directed to use of a known pharmaceutical in the manufacture of a medicament, not novel in itself, for a novel second (or subsequent) therapeutic use, the required novelty of the claimed process may be found in the new second (or subsequent) therapeutic use.

¹⁴⁵ Section 25(5).

¹⁴⁶ Section 25(6).

¹⁴⁷ T D Burrell *Burrell’s South African Patent and Design Law* 3rd ed (1999) 240.

¹⁴⁸ S Thorley, R Miller; G Burkill, C Birss *Terrell on the Law of Patents* Sweet & Maxwell 15 Rev ed edition 25 May (2000) 26; B C Reid *Practical Guide to Patent Law* Sweet & Maxwell 3rd ed (1999) 15.

¹⁴⁹ [1985] R.P.C. 545.

Therefore an enforceable new use, or second use, must be an inventive second medical use and not a mere discovery about an old use¹⁵⁰. South African courts have followed the English Courts' decisions discussed above¹⁵¹ which means that the provisions in the South African Patent Act also require a high level of novelty to be demonstrated in order for a patent to be granted.

The South African position on second use patents is bolstered by section 25(9) of the Act which states that:

In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of any claim to the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.

Therefore if a party wishes to acquire an enforceable patent for a new use of a medicine it must be established that the 'invention' is in fact new, i.e. not just a 'mere discovery about an old use'¹⁵², and involves an inventive step¹⁵³, which is discussed below. The requirement of an invention actually being new, rather than just another use, means that it is more difficult for a manufacturer to simply re-patent a medicine which has already been patented. This leads to a situation where a South African generic manufacturer such as Aspen Pharmacare¹⁵⁴ is able to manufacture generic versions of any of the medicines which do not receive a patent under South African law¹⁵⁵. It will also increase the number of ARVs because such manufacturers are allowed to manufacture because there are fewer under patent protection. It will also open the South African market to other domestic generic manufacturers which will lead to lower prices for these medicines due to increased competition.

¹⁵⁰ S Thorley, R Miller; G Burkill, C Birss (Note 148 above) 27.

¹⁵¹ *Elan Transdermal Ltd v Ciba Geigy Pty (Ltd)* 1994 BP 1 (CP) 11D.

¹⁵² [1985] R.P.C. 545.

¹⁵³ T D Burrell (Note 147 above) 239.

¹⁵⁴ Available at: <http://www.aspenpharma.com> Date viewed: 8 October 2008.

¹⁵⁵ 'AIDS, drug prices and generic drugs' Available at: <http://www.avert.org/generic.htm> Date viewed: 8 October 2008.

b) Inventive step

The other important requirement in establishing South Africa's patent standard is the interpretation of the requirement that the invention must involve an inventive step. An invention that fulfils the requirement of novelty is unenforceable, or invalid, if it lacks an inventive step. Section 25(10) of the Act provides guidance on how to determine the presence of an inventive step. It states:

[A]n invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art by virtue only of subsection (6) (and disregarding subsections (7) and (8)).

Plewman JA in *Ensign-Bickford (SA) (Pty) Ltd And Others v AECI Explosives and Chemicals Ltd*¹⁵⁶ explains the inquiry. He states:

As is pointed out in *Roman Roller CC and Another v Speedmark Holdings (Pty) Ltd* 1996 (1) SA 405 (A) at 413, in order to apply these provisions to a particular case it is necessary to determine what the art or science to which the patent relates is, who the person skilled in the art is and what the state of the art at the relevant date was. But the inquiry, in my view, must then proceed further. After those factors have been determined, a more structured inquiry must be undertaken. For this it is appropriate to adopt tests formulated in certain English authorities. The tests proposed do not differ from some of the inquiries suggested in the earlier practice in our Courts but they are conveniently arranged in a suitable sequence in the case of *Mölnlycke AB and Another v Procter & Gamble Ltd and Others (No 5)* [1994] RPC 49 (CA) at 115. Four steps are identified. They include or restate in part what has been said above but may be taken to conveniently list the inquiries to be made:

- 1) What is the inventive step said to be involved in the patent in suit?
- 2) What was, at the priority date, the state of the art relevant to that step?
- 3) In what respect does the step go beyond, or differ from, that state of the art?
- 4) Having regard to such development or difference, would the taking of the step be obvious to the skilled man?¹⁵⁷

The test for obviousness is explained in *Pfizer Ltd's Patent* where Laddie J stated:

The question of obviousness has to be assessed through the eyes of the skilled but non-inventive man in the art. This is not a real person. He is a legal creation. He is supposed to offer an objective test of whether a particular development can be protected by a patent. He is deemed to have looked at and read publicly available

¹⁵⁶ 1999 (1) SA 70 (SCA)

¹⁵⁷ Ibid 80.

documents and to know of public uses in the prior art. He understands all languages and dialects. He never misses the obvious nor stumbles on the inventive. He has no private idiosyncratic preferences or dislikes. He never thinks laterally. He differs from all real people in one or more of these characteristics. A real worker in the field may never look at a piece of prior art ... or he may be put off because it is in a language he does not know. But the notional addressee is taken to have done so ... Anything which is obvious over what is available to the public cannot subsequently be the subject of valid patent protection even if, in practice, few would have bothered looking through the prior art or would have found the particular items relied on. Patents are not granted for the discovery and wider dissemination of public material and what is obvious over it, but only for making new inventions. A worker who finds, is given or stumbles upon any piece of public prior art must realise that that art and anything obvious over it cannot be monopolised by him and he is reassured that it cannot be monopolised by anyone else.¹⁵⁸

When a manufacturer attempts to patent a combination of medicines, which may occur in the creation of fixed-dose combinations¹⁵⁹ (FDCs) of ARVs, the manufacturer must demonstrate the presence of an inventive step which means that they must comply with the requirements outlined above by Plewman JA in the *Ensign Bickford* case and Laddie J in the *Pfizer* case. It must not just be the placing side by side of integers¹⁶⁰ so that 'each performs its own proper function independently of any of the other'¹⁶¹. The combination must rather be 'where the old integers when placed together have some inter-relation producing new or improved results'¹⁶². It is clear, under South African law, that the patenting of a mere combination of medicines will not fulfill the requirement of an inventive step. This is a crucial part of South Africa's patent standards in medicines because it creates room for generic manufacturers in South Africa, such as Aspen Pharmacare, to produce FDCs.

¹⁵⁸ *Pfizer Ltd's Patent* [2001] F.S.R. 16, 226.

¹⁵⁹ A fixed dose combination is a single medicine that is made up of a number of other medicines that ordinarily would be taken in conjunction with each other. FDCs of ARVs are particularly beneficial because they reduce the number of tablets and, often, the frequency of the dosage. This leads to better patient adherence. 'Fixed dose combination ARV for children Available at: <http://www.essentialdrugs.org/edrug/archive/200707/msg00032.php> Date viewed: 4 December 2008.

¹⁶⁰ Correa states: 'Unless the combination generates a *new synergy* (appropriately described and proven in the patent specifications, for instance, on the basis of biological tests) between the components, or a new and distinct effect, the combination should be deemed anticipated by prior art, and not patentable. There is no invention when the effect is to be relied on, it must be possessed by everything covered by the claims and should be the manifestation of an inventive step.' C M. Correa 'Pharmaceutical Inventions: When is the granting of a patent justified?' (2006) Vol. 1 *Int. J. Intellectual Property Management* 7– 8.

¹⁶¹ Lord Tomlin in *British Celanese Ltd v Courtaulds Ltd* (1935) 52 RPC 171, 193.

¹⁶² *Ibid.*

From the discussion above it is clear that South Africa does have high standards of patentability and is therefore protected from abuse by international drug manufacturers, which is important to ensure the growth of South Africa's pharmaceutical manufacturing capacity. South Africa has a number of generic pharmaceutical manufacturers including Aspen Pharmacare¹⁶³ and Thembalani¹⁶⁴. Both these manufacturers have voluntary licensing agreements¹⁶⁵ with Boehringer Ingelheim and GlaxoSmithKline to produce certain ARVs¹⁶⁶. If South Africa follows India's example it will then be able to expand the number of medicines it can manufacture thereby bolstering its manufacturing capacity.

IV INDIA'S PATENT REGIME

India's patent system was specifically designed to ensure the continued growth of its generic pharmaceutical manufacturing capacity. For this reason India's patent system and how it has been used will now be examined in order to establish lessons for South Africa, leading to the creation of a similarly robust generic pharmaceutical manufacturing capacity. India is the largest manufacturer of generic pharmaceuticals and the primary source of affordable ARVs¹⁶⁷. In light of this most aid programmes involved with AIDS, use India's generic pharmaceutical medicines in their programmes. Médecins Sans Frontières purchases from India 80 per cent of the ARVs it distributes to 30 different countries¹⁶⁸. 70 per cent of the ARVs provided by The United Nations' Children's Fund (UNICEF), The International Development Association (IDA), The Global Fund and the Clinton Foundation are purchased from India¹⁶⁹. These generics also have a high standard of quality because 89 per cent of them are approved by the US Food and Drug

¹⁶³ Available at: <http://www.aspenpharma.com> Date viewed: 8 October 2008.

¹⁶⁴ M Wines 'Agreement Expands Generic Drugs in South Africa to Fight AIDS' 11 Available at: <http://query.nytimes.com/gst/fullpage.html?res=9505E0D8163CF932A25751C1A9659C8B63> Date viewed: 25 November 2008.

¹⁶⁵ 'The Price of Life: Hazel Tau and Others vs. GlaxoSmithKline and Boehringer Ingelheim' 5. Available at: http://www.alp.org.za/viwe.php?file=/camps/20030910_PatRights.xml Date viewed: 25 November 2008.

¹⁶⁶ Ibid.

¹⁶⁷ E Kameni 'Implications of Indian Intellectual Property Law on Sub-Saharan African Countries' (2008) Volume 2 No.1 *The Botswana Review of Ethics, Law and HIV/AIDS* Available at: http://www.bonela.org/doc/brela_vol2_2008.pdf 63. Date viewed: 3 December 2008.

¹⁶⁸ Ibid.

¹⁶⁹ Ibid.

Administration (FDA)¹⁷⁰. In order to become TRIPS compliant, India's Legislature passed the Patents (Amendment) Act 15 of 2005. The Legislature drafted this Act in a manner that would protect India's robust generic manufacturing capacity from challenges by patent holders of medicines of which it produces generic versions¹⁷¹. This protection was created by enacting strict patent standards¹⁷².

When India signed TRIPS they made use of the leniencies available to developing, and least-developed countries¹⁷³, in order to become TRIPS compliant¹⁷⁴. These leniencies consisted of a moratorium of ten years for all developing and least-developed countries in order to afford them time to become TRIPS compliant¹⁷⁵. They also include the fact that medicines registered before 1995 are not subject to TRIPS. And India can therefore produce these medicines free from sanction¹⁷⁶. Between 1995 and 2005 India was required to collect pharmaceutical patent applications in a 'mailbox'¹⁷⁷, which meant that for that period of time India was allowed to continue manufacturing generic versions of medicines still on patent, but that the companies requiring patent protection could apply for it. These applications were stored in a 'mailbox' until 2005 when India became fully TRIPS compliant and then processed these applications.¹⁷⁸

In amending its patent system through the Patents (Amendment) Act 15 of 2005, India adopted almost all of the flexibilities granted by TRIPs which were confirmed by the

¹⁷⁰ Ibid.

¹⁷¹ T Amin and K M Gopakumar 'A critical view of the new Indian Patent (Amendment) Act 2005' Page 2 Available at:

<http://www.altlawforum.org/PUBLICATIONS/A%20critical%20view%20of%20the%20Indian%20Patent%20Act.doc> Date viewed: 29 August 2008.

¹⁷² Ibid.

¹⁷³ 'L'économie politique du brevet au sud : variations Indiennes sur le brevet pharmaceutique' Available at: http://www.cairn.info/resume_p.php?ID_ARTICLE=RIDE_212_0185 Date viewed 12 December 2008.

¹⁷⁴ South Africa did not utilise these leniencies because it has always provided the requisite patent protection for medicines, unlike India, and it did not have a generic pharmaceutical manufacturing industry which produced medicines in contravention of TRIPS.

¹⁷⁵ 'TRIPS and public health' Available at: <http://infochangeindia.org/200405096068/Trade-Development/Intellectual-Property-Rights/TRIPS-and-public-health.html> Date viewed: 11 December 2008.

¹⁷⁶ J Mueller 'Taking TRIPS to India – Novartis, Patent Law and access to medicines' The New England Journal of Medicine. Volume 356 Number 6. 8 February 2007. 543. Available at: <http://www.content.nejm.org/cgi/content/full/356/6/541> Date viewed: 10 August 2008.

¹⁷⁷ Ibid.

¹⁷⁸ Ibid.

Doha Declaration to ensure access to more affordable generic medicines including compulsory licence mechanisms¹⁷⁹, export licences¹⁸⁰; licences of right for generic producers already producing ‘mailbox’ generics, even if 1995-2005 patent applications were granted; and strict definitions of patentability¹⁸¹. These strict definitions are discussed below.

a) India’s patent requirement

(i) Novelty

A ‘new invention’ is defined in section 2(1)(l) of the Patents (Amendment) Act 15 of 2005 as

a feature of an invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e. the subject matter has not fallen in the public domain or that it does not form part of the state of the art.

This is very similar to section 25(5) of the South African Patent Act and also excludes the patenting of new uses for inventions already patented, which is integral to maintaining its generic pharmaceutical manufacturing capacity.

(ii) Inventive step

Section 2(1)(j) of the Indian Patent Act states that an ‘inventive step’ means a ‘feature of an invention that involves a technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art’. The Indian Patent Act also excludes the patenting of combinations, on the basis that the mere fact that it is a combination should not itself be considered evidence of increased efficacy¹⁸². This is significant given the role that therapeutically appropriate fixed-dose combination medicines have played in treating

¹⁷⁹ Section 90 (vii) – (ix).

¹⁸⁰ Section 92A (1) – (3).

¹⁸¹ Sections 2(1)(j); 2(1)(l); 3(d) of the Patents (Amendment) Act 15 of 2005.

¹⁸² Note 171 above.

resistance-prone diseases like AIDS, TB, and malaria, as well as their benefits for patient adherence¹⁸³.

From the above discussion it can be seen that the South African Patent Law and Indian Patent Law are very similar. However, there is no equivalent of section 3(d) of Indian Patents (Amendment) Act in the South African Patent Law. Section 3(d) details what are not inventions. It states:

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation – For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

Section 3(d) is drafted with the specific peculiarities of medicines in mind, particularly the ‘explanation’ which prevents the abuse of its patent system by refusing a new patent for a medicine that has only been altered slightly. Section 3(d) creates a presumption of non-patentability for ‘modifications of known chemicals combinations’¹⁸⁴ which shifts the burden of rebutting this presumption onto the manufacturer applying for a patent.

Through the establishment of clear legislation, especially the ‘explanation’ in section 3(d), on medicines, the Indian Legislature has closed the door to possible abuse from drug manufacturers which slightly alter the medicines in order to secure a new patent. The ‘explanation’ and the presumption of non-patentability, discussed above, are requirements which the South African Legislature should include in the Patent Act especially because section 3(d) has been used by the Indian Patent Office to refuse to register some medicines, which has led to only 274¹⁸⁵ patents being granted, out of the 8

¹⁸³ Note 155 above.

¹⁸⁴ Note 176 above.

¹⁸⁵ Note 171 above.

926¹⁸⁶ patent applications lodged. However, the validity of section 3(d) was challenged by Novartis in the Chennai High Court; this will be discussed in greater detail later. Although Novartis was unsuccessful it demonstrates the possible consequences that will ensue should South Africa enact similar legislation. Had Novartis been successful in its challenge India's generic manufacturing capacity would have been significantly compromised because a large number of patent applications for medicines would have had to be approved. This would result in many of the newer and more sophisticated ARVs, of which India currently produces generic versions, being subject to patent protection. This would be seriously detrimental to ARV programmes all over the world, especially in developing countries, because aid agencies would not be able to access the medicines they need at the low prices they do currently.

(b) Novartis challenges the validity of India's patent regime

In 1998 Novartis filed a 'mailbox' application for a new beta-crystalline form of imatinib mesylate, the active ingredient in a blockbuster anti-cancer drug, Glivec¹⁸⁷. While Glivec was still in the 'mailbox,' six generic companies began manufacturing a generic version of Glivec and selling it at one-tenth of the cost. In January 2004 Novartis obtained an interdict against the six generic companies preventing further sales of the drugs¹⁸⁸. However, in accordance with India's new Patent Act of 2005 the generic manufacturers were permitted to resume production although they were required to pay royalties to Novartis¹⁸⁹.

Novartis then asked the Indian Patent office to process its patent application for its drug Glivec¹⁹⁰. The Indian Patent Office, in January 2006, refused to grant a patent on Glivec, as it found that Novartis had not shown a significantly increased efficacy¹⁹¹ which would

¹⁸⁶ Note 171 above.

¹⁸⁷ This drug is used to combat Chronic Myeloid Leukaemia and Gastrointestinal Stromal Tumour (GIST). Available at: <http://www.glivec.com> Date viewed: 1 December 2008.

¹⁸⁸ T Iren, S Gerhardsen 'Novartis Persists With Challenge To Indian Patent Law Despite Adversity' Available at: <http://www.ip-watch.org/weblog/index.php?p=430> Date viewed: 19 October 2008.

¹⁸⁹ Ibid.

¹⁹⁰ Ibid.

¹⁹¹ Ibid.

have entitled Novartis to a new patent¹⁹² because Glivec was actually a medicine that had already been patented in 1993 before TRIPS. This brought to a head the question of the validity of India's high patentability standards, especially section 3(d) of the Patent Acts and whether it was in accordance with the provisions of TRIPS.

On 6 August 2007 the Chennai High Court¹⁹³ ruled against Novartis's challenge to the constitutionality and TRIPS-compliance of section 3(d) of the Patent Act on three main grounds. Firstly, in terms of Article 57 of the Indian Constitution, treaties signed by India are not self executing, due to the fact that TRIPS had not been domesticated into India's positive law Novartis could not challenge TRIPS compatibility¹⁹⁴. If Novartis wishes to challenge the compatibility of section 3(d) it would have to get its government, the Swiss Government, to institute dispute settlement proceedings at the Dispute Settlement Body at the World Trade Organisation¹⁹⁵ (WTO). However Felix Addar, the Deputy General of the Swiss Federal Institute of Intellectual Property has stated 'the issue of a WTO panel is not on the agenda of the Swiss Government at this point'.¹⁹⁶ Secondly, the meaning of 'enhancement of efficacy' was not so vague, uncertain, or discriminatory¹⁹⁷ as to render section 3(d) unconstitutional or unreasonable. And finally, there was no unconstitutional delegation of a legislative function to the Patent Office¹⁹⁸.

In response to the Chennai High Court's decision, Tido von Schoen-Angerer, the Director of the Doctors Without Borders Campaign for Access to Essential Medicines stated:

¹⁹² J Tremblay 'Novartis Loses India Patent Case: Drug maker Cipla will File to Market Generic Forms of Gleevec' Chemical & Engineering News. Available at: <http://pubs.acs.org/cen/news/84/i06/8406india.html> Date viewed: 19 October 2008.

¹⁹³ Novartis AG v Natco Pharma and Others, Indian Patent Office, Application No.1602/MAS/1998 (25 January 2005): Available <http://lists.essential.org/pipermail/ip-health/2006-March/009200.html> Date viewed: 10 December 2008.

¹⁹⁴ Note 188 above.

¹⁹⁵ 'Novartis Glivec battle with India – patentability of pharmaceutical extension patents' <http://duncanbucknell.com/articles/109/Novartis-Glivec-battle-with-India--patentability-of-pharmaceutical-extension-patents> Duncan Bucknell Co. 27 August 2008.

¹⁹⁶ Note 176 above.

¹⁹⁷ R Chandramouli 'Novartis loses fight for cancer drug patent' Available at: http://timesofindia.indiatimes.com/india/Novartis_loses_fight_for_cancer_drug/articleshow/2260719.cms Date viewed: 18 October 2008.

¹⁹⁸ Note 188 above.

...The Court's decision now makes Indian patents on the medicines that we desperately need less likely. We call upon multinational drug companies and wealthy countries to leave the Indian Patents Act alone and stop pushing for ever stricter patent regimes in developing countries¹⁹⁹.

The implications of this case were very important because 67 per cent of India's generic production is exported to developing countries²⁰⁰. Those receiving ARV treatment have benefited greatly from this because 70 per cent of them receive treatment with low-cost generic drugs of assured quality from India²⁰¹. Due to market competition from Indian companies, first-line AIDS treatment regimes now cost approximately \$90 to \$130 per patient per year²⁰², a quarter of the price of the R&D industry's 'discount' prices, and 1 per cent of what R&D companies charge in US and European markets²⁰³.

The majority of India's 'mailbox' applications were for new uses or new combinations of drugs already patented. The vast majority of the 8 926 pharmaceutical patents²⁰⁴ were patent applications that were lodged between 1995 and 2005 were for new uses or combinations. In accordance with India's high standard of patentability only 274 of these applications were actually granted patents²⁰⁵. This has greatly assisted the creation of the robust generic market in India and clearly demonstrated the advantages of high standards of patentability.

Although India's new Patent Act met with opposition from the pharmaceutical industry its high standards have ensured that its generic manufacturing industry has been strengthened. India's is a good example of the use of patent law to ensure the continued growth of its pharmaceutical manufacturing industry.

¹⁹⁹ E Silverman 'Novartis Gleevec Patent Bid Rejected in India' Available at: <http://www.pharmalot.com/2007/08/novartis-Gleevec-patent-bid-rejected-in-India> Date viewed: 29 August 2008.

²⁰⁰ 'Fact Sheet: Changes to India's Patents Act and Access to Affordable Generic Medicines after January 1, 2005' Available at: http://www.healthgap.org/press_releases/04/121404_HGAP_FS_INDIA_patent.pdf Date viewed: 15 September 2008.

²⁰¹ Ibid.

²⁰² Ibid.

²⁰³ Ibid.

²⁰⁴ Note 171 above.

²⁰⁵ Ibid.

South Africa must maintain its high patent standards and follow the Indian example, by incorporating a section similar to section 3(d) in its Patent Act to bolster its generic manufacturing capacity, which is the long-term solution to providing access to affordable medicines. Whilst the South African manufacturing capacity is expanding to meet the demand for low cost ARVS, the State must continue to explore other ways to achieve access to cheaper medicines in the meantime. These solutions involve the bypassing of patent protection in order to import medicines at a lower price than currently available in South Africa. This price reduction would allow the State to provide a greater quantity of medicines and enable the State to afford newer ARVs with fewer side effects and increased efficacy. These solutions to bypass patents are discussed in Chapter 4.

CHAPTER 4: FLEXIBILITIES IN TRIPS

High patent standards create a solid foundation from which to utilise the flexibilities available in Intellectual Property Law, to bypass patents where necessary to ensure access to medicines. These flexibilities are contained in TRIPS which was negotiated during the Uruguay Round of the GATT (General Agreement on Tariffs and Trade) and came into force as part of the WTO Agreement in 1995. TRIPS sets standards for a variety of areas of Intellectual Property Law, such as copyright, patents, trademarks and other aspects of intellectual property rights involving trade²⁰⁶. It requires all WTO Member States to provide patent protection for any inventions, whether products or processes, in all fields of technology, including pharmaceuticals, provided they are new, involve an inventive step²⁰⁷ and are capable of industrial application²⁰⁸. Patent protection must, in terms of Article 33 of TRIPS, be granted for a minimum of twenty years from the date of filing²⁰⁹. The patent must also afford the patent holder the exclusive right to prevent a third party from making, using, offering for sale, selling or importing for such purposes, a product that is the subject of his or her patent.²¹⁰

The reason TRIPS is important in this discussion on access to medicines is that it also contains a number of flexibilities which assist in the provision of goods which are under patent without the permission of the patent holder. These include compulsory licences, parallel importation, and voluntary licences. These measures have been used successfully by a number of different countries, such as Thailand. Although South Africa has provision for some of these flexibilities, including compulsory licences and parallel importation, it has not utilised them fully unlike other countries. These flexibilities offer great savings on the price of medicines, especially with regard to ARVs as most are still under patent and therefore prohibitively expensive.

²⁰⁶ Gamharter (Note 23 above) 17.

²⁰⁷ Art 27 (1).

²⁰⁸ Gamharter (Note 23 above) 7-18.

²⁰⁹ Art 28 (1).

²¹⁰ Ibid.

It has been argued by pharmaceutical manufacturers that patents do not restrain access to medicines²¹¹. They argue that an ineffective health care system and a lack of funding are to blame²¹². Whilst a lack of funding and an ineffective health care system are restraints to access to medicines, patents are still significant barriers to access. Without patents, patients in need of life-prolonging medicines, such as ARVs, are able to access these medicines at a cost most can afford, or their governments can afford. However, without a patent, a manufacturer will have little incentive to produce medicines as it will not be able to recoup its expenses and make a profit. For this reason the flexibilities in TRIPS, designed to bypass patents whilst still providing manufacturers with adequate remuneration, are vitally important.

Utilising all possible methods of bypassing patents is critical in South Africa, where all twelve of the antiretrovirals listed on the WHO-EML²¹³ are under patent²¹⁴. Such a concentration of patents is probably due to the country's growing capacity to produce pharmaceuticals. Médecins Sans Frontières (MSF) reports that access to low-cost generic ARVs in South Africa is still severely lacking due to widespread patenting²¹⁵. Each of these flexibilities has its own positive and negative aspects, which are discussed individually below.

²¹¹ S Flynn, 'Legal Strategies for Expanding Access to Medicines' 17 *Emory Int'l Rev* 535, 539.

²¹² *Ibid.*

²¹³ The WHO defines 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.

²¹⁴ UNAIDS, '2004 Report on the Global AIDS Epidemic: 4th Global Report' UN Doc. UNAIDS/04.16E

At 1 Available at: http://www.unaids.org/bangkok2004/GAR_pdf/UNAIDS-GlobalReport2004_en.pdf
Date viewed: 23 November 2008.

²¹⁵ 'Surmounting Challenges: Procurement of Antiretroviral Medicines in Low- and Middle-Income Countries' (Geneva: Médecins Sans Frontières, November 2003) online: Campaign for Access to Essential Medicines. Available at: www.accessmed-msf.org/documents/procurementreport.pdf Date viewed: 22 November 2008.

I COMPULSORY LICENCES

A compulsory licence is authorisation by a government permitting itself or a third person to make, use or sell a patented invention without the patent owner's consent²¹⁶. The provisions for the issuing of compulsory licences are contained in Article 31 of TRIPS. Licences can be used to serve any public purpose, and increasing access to affordable medicines is a public purpose recognised by the WHO²¹⁷, the United Nations²¹⁸, International Human Rights Law and in the interpretation of TRIPS by a WTO Ministerial Committee²¹⁹. In reality compulsory licences can be issued for any reason, although there are expedited procedures for matters of extreme urgency and emergency. These procedures are discussed later. Examples of where compulsory licences have ordinarily been issued include where the patent holder has failed to use the patented invention; during an emergency or extreme urgency; for non-commercial or government use; to remedy anti-competitive practices; and for any other public interest grounds²²⁰.

a) Requirements for issuing compulsory licences

The requirements are outlined in Article 31 of TRIPS. It requires that prior to the issuance of compulsory licences, the proposed user must have made efforts to obtain authorisation from the patent holder, on reasonable commercial terms and conditions and within a reasonable period of time²²¹. This requirement is waived in a national emergency or in matters of extreme urgency or in cases of public non-commercial use²²². The patent holder does have the right to be informed as soon as reasonably practicable²²³.

²¹⁶ Article 31 of TRIPS.

²¹⁷ G Velásquez and P Boulet, 'Globalization and Access to Drugs: Implications of the WTO/TRIPS Agreement' 9-15 (1999 ed.) Available at: <http://www.who.int/medicines/library/dap/who-dap-98-9rev.pdf>
Date viewed: 13 September 2008.

²¹⁸ Declaration of Commitment on HIV/AIDS, U.N. GAOR, 26th Special Session. Agenda Item 8, at paragraph 15, U.N. Doc. A/RES/5-26/2 (2001).

²¹⁹ Declaration on the TRIPS Agreement and Public Health, Nov. 14 2001, 4th Session, Doha Ministerial Conference, WT/MIN (01) EC/2. It stated that TRIPS 'can and should be interpreted and implemented in a manner supportive of the WTO Members' right to protect public health and, in particular, to promote access to medicines for all' and 'Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.'

²²⁰ Article 31 of TRIPS

²²¹ Article 31(b) of TRIPS.

²²² Ibid.

²²³ Ibid.

The scope and duration of the compulsory licence is limited to the purpose for which it is authorised²²⁴. If the circumstances that led to the licence being issued ‘cease to exist and are unlikely to recur’²²⁵ the licence is then terminated.

The compulsory licence is issued for the predominant supply of the domestic market of the authorising country²²⁶. This requirement is problematic for countries which lack the requisite manufacturing capacity in order to produce the medicines themselves, such as South Africa. This will be discussed later.

The patent holder has the right to adequate remuneration, which is to be determined in the circumstances of each case²²⁷. It is also subject to judicial review by the highest authority in the proposed user’s country²²⁸.

TRIPS also makes provision for the granting of compulsory licences in order to remedy anticompetitive practices. In such a case the requirements of prior negotiation and that production is predominantly for the supply of the domestic market are waived²²⁹. This Article has been used by the South African government as a threat to force drug companies to negotiate a voluntary licence, to avoid an unfavourable ruling by the Competition Tribunal²³⁰.

It should be noted that TRIPS contains a number of ambiguities with very little guidance as to its interpretation²³¹. Article 31 also requires a number of very time-consuming procedures in order to issue a compulsory licence, which means that patients who are in

²²⁴ Article 31(c).

²²⁵ Article 31(g).

²²⁶ Article 31(f).

²²⁷ Article 31(h).

²²⁸ Article 31(j).

²²⁹ Article 31(k).

²³⁰ S Flynn ‘Using Competition Law to Promote Access to Medicines’ Program on Information Justice and Intellectual Property. American University Washington College of Law. Available at: <http://www.wcl.american.edu/pijip/competitoinpolicyproject.cfm> Date viewed: 10 December 2008.

²³¹ N A Bass ‘Implications of the TRIPS Agreement for developing countries: Pharmaceutical patent laws in Brazil and South Africa in the 21st century’ (2002) *George Washington International Law Review* 6. Available at: http://findarticles.com/p/articles/mi_qa5433/is_200201/ai_n21309524/pg_1?tag=artBody:coll Date viewed: 10 December 2008.

urgent need of the medicine will have to wait until all procedures have been complied with. In addition, for countries lacking the capacity to produce their own medicines, compulsory licences in the form detailed in Article 31 will restrict their access to medicines²³². This restriction occurs due to the requirement that compulsory licences be predominantly for domestic use²³³. Therefore if the country which is manufacturing the drug has a far smaller need for ARVs then it can only export an amount less than what it needs for its domestic market²³⁴. This may be far lower than the importing countries' needs.

(i) Article 31(b) prior negotiations

Article 31(b) states:

[S]uch use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.²³⁵

Article 31(b) requires that the proposed user enters into prior negotiations with the right holder seeking a voluntary licence on commercially reasonable grounds for commercially reasonable period of time. These requirements are vague and because of this there is a large scope for their abuse of these requirements by drug companies. The idea of 'commercially reasonable terms and conditions' is difficult to pin down to an objectively definable standard and the drug companies abuse this lack of clarity by unnecessarily drawing out negotiations until their patent expires thereby defeating the point of issuing a licence.

²³² Article 31(f).

²³³ Ibid.

²³⁴ Gamharer (Note 23 above) 100.

²³⁵ Article 31(b).

If a Member notifies the WTO that it has a situation of national emergency or other circumstance of extreme urgency then the requirement of prior negotiation is waived²³⁶. However, because there is no guidance as to what amounts to a national emergency or extreme urgency drug companies have been known to dispute the presence of such an emergency²³⁷.

(ii) Article 31 (g) Limitation of scope and duration

Article 31(g) states:

Authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances.

This means that once the problem which the licence was granted to remedy, has ceased then the licence will terminate. This would have detrimental effect on the generic producer, especially if that licence was for the only medicine it produced. However this Article is unlikely to be problematic for generic producer of HIV/AIDS medicines, especially in sub-Saharan Africa, as it is unlikely that the pandemic will cease to exist within the life of most patented medicines.

(iii) Article 31 (h) Adequate remuneration

Article 31 (h) states: 'The right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation'. TRIPS offers little guidance as to what amounts to 'adequate compensation'.

South Africa could bypass this lack of guidance by drafting legislation that properly defines what is adequate remuneration. There have been a number of attempts to create a

²³⁶ Article 31(b).

²³⁷ N A Bass 'Implications of the TRIPS Agreement for developing countries: Pharmaceutical patent laws in Brazil and South Africa in the 21st century' (2002) *George Washington International Law Review* Page 6. Available at:

http://findarticles.com/p/articles/mi_qa5433/is_200201/ai_n21309524/pg_1?tag=artBody;coll Date viewed: 10 December 2008.

system to determine what amounts to adequate remuneration in each circumstance²³⁸. In 2001, the United Nations Development Programme (UNDP) published its Human Development Report, in which it recommends that the normal royalty be set at four per cent of the generic price²³⁹. Its recommendation also contains a possible modification of two percent based on ‘evidence relating to the therapeutic value of the product or the government’s role in financing the research and development’²⁴⁰.

In 1998, the Japanese Patent Office issued royalty guidelines on government-owned inventions²⁴¹. The normal royalty rate was set at between two and four per cent although provision was made for a higher rate where the invention generated higher profit margins²⁴². It also took into account the importance of the patented invention in the product. Love argues that this type of determination is well suited to the case where there are multiple patents in one product, such as FDCs of ARVs, and where patent coverage for the different components varies²⁴³. The third method, the Tiered Royalty Method (TRM), was developed in 2005. As Love explains:

TRM begins with a base royalty, which is four per cent of the price of a discount in high-income markets. This base royalty is adjusted downward to reflect relative capacity to pay, according to either the relative per capita income or relative gross domestic product per patient population for countries facing particularly high rates of disease burden. The TRM is considerably higher for countries with the highest income, and much lower for countries with both low incomes and high burdens of disease.²⁴⁴

It is clear from this that the TRM is a good method for achieving a rational system for royalty payments and should be considered by the South African legislature when deciding on a system to determine what amounts to adequate remuneration.

²³⁸ J Love, ‘Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D’ 40 *U.C. Davis L. Rev.* 679, 690.

²³⁹ *Ibid* 691.

²⁴⁰ *Ibid* 690.

²⁴¹ *Ibid* 690.

²⁴² *Ibid* 690.

²⁴³ *Ibid*, 679.

²⁴⁴ *Ibid*, 691.

The problem of interpreting what constitutes adequate remuneration under TRIPS is exacerbated by the fact that generic medicine prices are considerably less than the price of the branded medicines and royalty rates average between four per cent and seven per cent of the generic sale price²⁴⁵. Therefore the patent holder is going to receive far less money in royalties than it were selling their branded medicine. This raises the important question of whether this would amount to adequate remuneration especially in light of the drug companies' argument that research and development is very expensive and they require sufficient remuneration to continue the research that is vital in HIV/AIDS. Some HIV/AIDS drug developers may move to conduct research on different diseases, in order to concentrate on more lucrative diseases affecting people in developed countries who can pay the full price²⁴⁶. The difficult act of forcing a drug company to offer the lowest price possible whilst still ensuring that they continue to invest money in R&D in HIV/AIDS is discussed later in this dissertation.

(iv) Article 31(f) 'Predominantly for domestic use' rule

A major limitation on the use of compulsory licences is the Article 31(f) requirement. Article 31(f)²⁴⁷ requires that compulsory licences be authorised 'predominantly for the supply of the domestic market of the Member authorising such use.' The full extent of this restriction is felt by those countries which lack the manufacturing capacity to produce generic medicines. Countries that lack such capacity are predominantly developing countries that have the highest HIV/AIDS infections. Correa explains that:

... in practical terms, that Members with large markets, like India, the UK or the USA, typically could easily grant compulsory licences for the

²⁴⁵ A McBeth 'When Nobody Comes to the Party: Why Have No States used the WTO Scheme for Compulsory Licensing of Essential Medicines' Research Paper No. 2006/35 *Faculty of Law, Monash University* Page 82. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1076082 Date viewed: 9 December 2008.

²⁴⁶ A Jack 'Roche to drop HIV therapy research' *Financial Times* 11 July 2008. Available at: http://www.ft.com/cms/s/0/9816be17-4f79-11dd-050-000077b07657.html?nclick_check=1 Date viewed' 12 July 2008. In announcing its decision to cancel its 'programme for the compounds in development that were targeting two different ways to attack HIV'²⁴⁶ Roche's HIV Franchise Global Leader Jenny Edge-Dallas said 'While we had initially been hopeful about their potential, we now have concluded that none would provide a true incremental benefit for patients compared to medicines currently on the market'.

²⁴⁷ Article 31(f) states 'any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use'.

supply of patented medicines to meet public health needs (for instance, those arising from the threat of bioterrorism). However, for Member countries with small markets, like the African countries where the AIDS crisis is most severe, it might be extremely difficult to establish economically viable production if the manufactured product has to be ‘predominantly’ sold in the local market.²⁴⁸

Article 31(f) also limits the countries ability to authorise the quantities of medicines they can export, which constrains their capacity to achieve the sufficient economies of scale. Sufficient economies of scale are necessary for developing countries with fledgling pharmaceutical manufacturing industry to be financially capable of producing generic medicines²⁴⁹. Article 31(f) is a significant barrier to the use of compulsory licences by developing countries for two reasons. Firstly, it prevents countries which cannot manufacture the required medicines from importing sufficient quantities of the medicines. Secondly, it hinders countries with a developing capacity to manufacture medicines from achieving sufficient economies of scale. This is because article 31(f) requires that the medicines manufactured under a compulsory licence must be predominantly for domestic use. In light of this and the other problems discussed above, the Doha Declaration on TRIPS and Public Health was issued on 14 November 2001. Its aim was to find a solution to these barriers. However, before discussing the barriers the Thai example of the effects of issuing compulsory licences will be discussed.

b) Thailand’s use of compulsory licences

The response that South Africa may receive from the international community if it issues compulsory licences under Art 31 may be similar to the experience that Thailand had when it issued compulsory licences in 2004 and 2006. This experience is discussed in greater detail later in this Chapter. Since Thailand issued these licences many international organisations have indicated their support of Thailand’s actions, including

²⁴⁸ C Correa ‘Implications of the Doha Declaration on the TRIPS Agreement and Public Health’ Health Economics and Drugs EDM Series No. 12 WHO/EDM/PAR/2002.3 World Health Organisation, 19.

²⁴⁹ F M Abbott, ‘Compulsory licensing for Public Health Needs: the TRIPS Agreement at the WTO after the Doha Declaration on Public Health’ (2002), *Quaker United Nations Office – Geneva, Occasional Paper* 9, 27.

the WTO, the WHO and the World Health Assembly²⁵⁰. This may mean that South Africa could receive more international support if it issued compulsory licences, especially for ARVs due to the immense HIV/AIDS crisis in South Africa.

i) Thai Patent Act

Section 51²⁵¹ of the Thai Patent Act B.E. 2522 (1979), as amended by the Patent Act (No. 2) B.E. 2535 (1992) and the Patent Act (No.3) B.E. 2542 (1999), permits any ministry, bureau or department of the Government to issue a licence for 'public consumption' of generic medicines without prior negotiations with the patent holder, subject to an obligation to set a royalty rate which is thereafter reviewable by the patent holder. The section is based on Article 31(b) of TRIPS, which allows countries to issue compulsory licences for public non-commercial use, without notice or prior negotiation²⁵².

Although not required by TRIPS, the Thailand government has limited its use of compulsory licences to five circumstances. It is limited to drugs on the National Essential Drug List; drugs that are necessary to solve important public health problems; necessary in emergency or matters of extreme urgency; necessary to prevent or control outbreaks, epidemics and pandemics or necessary for the saving of lives²⁵³.

²⁵⁰ 'WHA Agrees On Health, Innovation And IP After Initial Divisions' Available at: http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.060701.htm Date viewed: 11 December 2008.

²⁵¹ Section 51 states:

In order to carry out any service for public consumption or which is of vital importance to the defense of the country or for the preservation or realization of natural resources or the environment or to prevent or relieve a severe shortage of food, drugs or other consumption items or for any other public service, any ministry, bureau or department of the Government may, by themselves or through others, exercise any right under Section 36 by paying a royalty to the patentee or his exclusive licensee under paragraph 2 of Section 48 and shall notify the patentee in writing without delay, notwithstanding the provisions of Section 46, 47 and 47bis. In the circumstances under the above paragraph, the ministry or bureau or department shall submit its offer setting forth the amount of remuneration and conditions for the exploitation to the Director-General. The royalty rate shall be as agreed upon by the ministry or bureau or department and the patentee or his licensee, and the provisions of Section 50 shall apply mutatis mutandis.

²⁵² B Baker 'International Trade and IPR Rules: Myths and Facts'. International Conference on Compulsory Licensing: Innovation and Access for All – Bangkok, Nov. 21-23. Available at: www.healthgap.org Date viewed: 14 July 2008.

²⁵³

ii) Thailand issues compulsory licences

Between 2004 and 2006 the Thai government negotiated with Abbott, Merck and Sanofi-Aventis for price discounts, although it was not required to do so by either TRIPS or section 51 of its Patent Act²⁵⁴. These negotiations did lead to some concessions (the price of Kaletra went from \$ 6 000 to \$ 2 200) but they were not sufficient to ensure universal access in the public sector where the vast majority of Thais access their medicines²⁵⁵. On 29 November 2006²⁵⁶, Thailand issued its first government-use compulsory licences for Efavirenz, an AIDS drug manufactured by Merck. Shortly after this on 24 January 2007 Thailand issued two more licences for Kaletra, also an AIDS medicine manufactured by Abbott, and Plavix, an anti-platelet drug manufactured by Sanofi-Aventis²⁵⁷. The terms of the licences ensured that the manufacturers were not completely forced out of the Thai market. The drug patent holders were paid a 0.5 per cent royalty²⁵⁸.

Each of these three drugs has significant therapeutic advantages and issuing compulsory licences would save costs considerably. Efavirenz is much less toxic than Nevirapine, a drug used in the first-line regimen, and the generic is 42 per cent of Merck's price²⁵⁹.

²⁵⁴ D Shuettler 'Thai AIDS patients suffer as drug squabble drags on' Available at:

<http://www.reuters.com/article/healthNews/idUSBKK12342120070522> 2 Date viewed: 2 September 2008.

²⁵⁵ Under Thailand's National Health Security Act of 2002 the State is mandated to achieve universal access to essential medicines for all Thais. From 2001, every citizen is covered under three national public health insurance schemes: (1) The Civil Servant Medical Benefit Scheme; (2) The Social Security Scheme; (3) Universal Coverage Scheme. 'Facts and Evidences on the 10 Burning Issues: Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand. Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent' Ministry of Public Health and The National Health Security Office Thailand February 2007. 45.

²⁵⁶ The Director General of the Department of Disease Control issued a public notice it laid out the conditions on which the compulsory licence was issued:

(1) The use of the above patent rights are effective from today to the 31st December 2011.

(2) The use of the above patent rights will be limited to the provision of Efavirenz to not more than 200 000 patients per year, for those covered under the National Health Security System Act B.E. 2545, Social Security B.E. 2533, and the Civil Servants and government employees medical benefits scheme...

(3) A royalty fee of 0.5 per cent of the Government Pharmaceuticals Organisations total sale value of the imported or locally produced Efavirenz will be paid to the patent holder. Available at: <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> Date viewed: 3 November 2008.

²⁵⁷ Available at: <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> Date viewed: 3 November 2008.

²⁵⁸ Ibid.

²⁵⁹ The Director General of the Department of Disease Control issued a public notice explaining that the licence is needed to respond to a shortage of Efavirenz in public treatment programmes for people with AIDS. It states:

Kaletra is a Liponavir and Ritonavir combination needed to bolster Thailand's second-line regimen²⁶⁰, a regime 20 per cent of Thai AIDS patients are on; its the generic price is 42 per cent of Abbott's price. Plavix is the only anti-platelet drug that can be used with a coronary artery stent²⁶¹ and the price of the generic is a mere 10 per cent of the Sanofi-Aventis price.

After the licences were issued the parties began to negotiate. Merck offered to lower its Efavirenz price to \$401.50 per patient per year²⁶² but Thailand could secure the generic form from Ranbaxy, an Indian generic company, for \$ 170 per patient per year²⁶³. In light of this Thailand placed an initial 66 000 bottle order.

Efavirenz is a highly effective and safe anti-retroviral. It is also placed in the Thailand's National List of Anti-retrovirals. However, the price of the patented Efavirenz is twice of those generics produced by WHO certified GMP factories in India. With this higher price, the budget allocated from the Thai Government can only cover some with Efavirenz, whereas the rest have to use other non-patented more toxic anti-retrovirals. Available at: <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> Date viewed: 3 November 2008.

²⁶⁰ The Director General of the Department of Disease Control stated in a notification re: Exercising of Right under Drugs and Pharmaceuticals Products Patent for Combined Formulation of Lopinavir and Ritonavir that:

The combined formulation of Lopinavir and Ritonavir has already been proved so far to be one of highly effective HIV antiretroviral drugs for patients resistant to basic formulations of HIV antiretroviral drugs. It has also been placed in the National System for Secured Accessibility to HIV Antiretroviral Drugs... The price of the combined formulation of Lopinavir and Ritonavir in Thailand is currently a lot higher than the price of the same drug which is generic drug in some countries. Therefore, many patients who are resistant to basic formulations of HIV antiretroviral drugs are unable to access to this drug, leading to opportunistic infections and death. Hence, being able to domestically produce or to import HIV antiretroviral drugs with the same generic name into Thailand to replace the original one will lead to the price reduction and the increase in accessibility for patients to this HIV antiretroviral drug. Available at: <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> Date viewed: 3 November 2008.

²⁶¹ The Director General of the Department of Disease Control issued a public notice re: exercising of Right under Drugs and Pharmaceuticals Products Patent for Clopidogrel. It states:

Myocardial ischemia and cerebro-vascular accident are the most serious public health burden because of high mortality and disability loss. Its mortality rate is in top three annual ranking... Clopidogrel or the trade name in Thailand namely Plavix has evidence based effectiveness for prevention of myocardial ischemia, ischemia, cerebro-vascular accident and coronary stent implantation by inhibition of platelet aggregation. However, the medicine is expensive thus has hindered their accessibility. Owing to its patent exclusive right, there is no competition. Government Pharmaceutical Organisation or other manufacturers can not produce or import the medicine for price competition. Available at: <http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf> Date viewed: 3 November 2008.

²⁶² 'The efficacy of compulsory licenses and international cooperation: Thailand and Brazil, the Clinton Foundation HIV/AIDS Initiative and generic companies, and UNITAID and WHO all combine forces to lower AIDS drug prices' Health GAP, Essential Action NGO Analysis. 2. [Available at: <http://www.aids-treatment-access.org/itpc5th.pdf> Date viewed: 4 December 2008.]

²⁶³ Ibid, 3.

iii) Abbott's reaction

However, not all the drug companies negotiated. On 14 March, Abbott Laboratories announced that it was withdrawing drug registration applications on 7 medicines²⁶⁴, including the new heat-stable form of LPN/r, Aluvia, a drug far more appropriate for tropical Thailand. Only 600²⁶⁵ Thai's are currently receiving LPN/r capsules and in order to maintain the integrity of the medicine users of Kaletra must purchase and carry ice each day²⁶⁶. This is very expensive for the majority of patients who are poor. The six other drugs are the painkiller Brufen; an antibiotic, Abbotic; a blood clot drug, Clivarine; the arthritis drug Humira; the high-blood pressure drug Tarka; and the kidney disease drug Zemplar²⁶⁷.

iv) Protests by civil society movements

On 21 March 2007, the Thai activists announced a consumer boycott of all of Abbott's products. This was followed by other demonstrations in Massachusetts, Chicago and a cyber attack on Abbott's website. On 5 April, 2007, Cipla, a major Indian generic company, announced that it had formulated a heat-stable generic equivalent of Abbott's LPN/r²⁶⁸. The announced price was approximately \$1 560 per patient per year. Two other Indian companies, Emcure and Hetero, also make a heat-stable equivalent. The problem is that none of these generics are as yet WHO prequalified²⁶⁹ - for safety, efficacy or quality - or registered in Thailand, which means that Thailand cannot import these generics.

Following the Cipla announcement, the consumer/medical-provider boycott of Abbott in Thailand, and meetings with the WHO, in an effort to salvage its public image, Abbott

²⁶⁴ Ibid.

²⁶⁵ Note 254, above.

²⁶⁶ Ibid.

²⁶⁷ Ibid.

²⁶⁸ N Geffen, P Clayden, J Berger, G Consalves, M Kardas-Nelson 'Accessing life-saving medical technologies for HIV' (2007) Available at: <http://www.tac.org.za/documents/AccessingEssentialMedicalTechnologiesFINAL-20070625.pdf> Date viewed: 5 December 2008.

²⁶⁹ The WHO Prequalification Project is designed to 'facilitate access to medicines that meet unified standards of quality, safety and efficacy for HIV/AIDS, Malaria and Tuberculosis.' The WHO Prequalification Project Available at: <http://www.who.int/mediacentre/factsheets/fs278/en/index.html> Date viewed: 5 December 2008.

offered a new low- and lower-middle income country price to 45 countries²⁷⁰ of \$1 000 per patient per year and maintained its \$500 no-profit price to least developed and African countries²⁷¹. However, it still refused to register Aluvia, the heat stable form of Kaletra, in Thailand²⁷².

v) International pressure

Then Thailand began to experience significant international pressure when on 30 April 2007 the United States Trade Representatives (USTR) placed Thailand on its Special 301 Priority Watch List²⁷³. The USTR Special 301 Report 2007 explained the reasons for elevating Thailand to the Priority Watch List as follows:

In addition to the longstanding concerns with deficient IPR protection in Thailand, in late 2006 and early 2007, there were further indications of a weakening of respect for patents, as the Thai government announced decisions to issue compulsory licences for several patented pharmaceutical products. While the United States acknowledges a country's ability to issue such licences in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. These actions have compounded previously expressed concerns such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval.²⁷⁴

Thailand also experienced the loss of its trade privileges under the Generalized System of Preferences (GSP)²⁷⁵. The European Commission's Director of Trade, Peter Mandelson

²⁷⁰ These countries are Albania, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Brazil, China, Colombia, Dominican Republic, Ecuador, El Salvador, Fiji, Georgia, Guatemala, Guyana, Honduras, India, Indonesia, Jamaica, Jordan, Kazakhstan, Kyrgyzstan, Marshall Islands, Micronesia, Moldova, Mongolia, Nicaragua, Pakistan, Papua New Guinea, Paraguay, Peru, Phillipines, Serbia and Montenegro, Sri Lanka, Suriname, Syria, Tajikistan, Thailand, The FYR-Macedonia, Tonga, Turkmenistan, Ukraine, Uzbekistan and Vietnam.

²⁷¹ 'Abbott Agrees with World Health Organization (WHO) Director-General to Expand Access to Kaletra/Aluvia (lopinavir/ritonavir)' Available at: http://www.abbott.com/global/url/pressRelease/en_US/60.5:5/Press_Release_0442.htm Date viewed: 28 November 2008.

²⁷² 'Compulsory licensing controversy in Thailand' Available at: https://www.wcl.american.edu/pijip/thai_comp_licenses.cfm Date viewed: 3 December 2008.

²⁷³ The office of the US Trade Representative releases an annual 'Special 301' report on the adequacy and effectiveness of Intellectual Property Rights protection by their trading partners.

²⁷⁴ USTR Special 301 Report 2007 (April 30 2007) Available at: http://www.ustr.gov/Document_Library/Press_Releases/2007/April/SPECIAL_301_Report.html Date viewed: 8 December 2008.

²⁷⁵ 'Generalize Systems of Preferences (GSP) Changes Effective June 28th 2007. Issue 20, July 2007. <http://www.cbp.gov> Date viewed: 15 November 2008.

wrote to the Thai government challenging Thailand's compulsory licence policy. He expressed his concern that it had decided on 'systematic use' of compulsory licensing in cases where they 'viewed the price of a patented drug as prohibitive, as this approach would damage innovation.'²⁷⁶

vi) International support

However there was support for Thailand from a number of international forums. In May 2007, the World Health Assembly backed Thailand's use of compulsory licences²⁷⁷. In July the European Parliament adopted a resolution calling on the European Commission and European governments to support countries issuing TRIPS-compliant compulsory licences and not undermine the Thai government's effort to ensure access to medicine²⁷⁸.

There have been some developments for those needing Aluvia in Thailand. On 17 October the Thai FDA announced the approval of the generic produced by Matrix, an Indian generic manufacturer²⁷⁹. Thailand has also been vindicated, to some extent, in its use of compulsory licences by the WHO which issued a report confirming Thailand's right to issue compulsory licences²⁸⁰. But the battle is not over because, although Abbott has agreed to register the paediatric formulation of Aluvia in Thailand, it has yet to relent and register the adult formulation²⁸¹. Thailand's experiences regarding the issuing of compulsory licences illustrate what would probably happen to South Africa if they were issued here. However, international pressure should not prevent the South African government from issuing compulsory licences.

²⁷⁶ S Shashikant 'Health: Recent Thai compulsory licenses and the aftermath' Available at: <http://www.twinside.org.sg/title2/health.info/2008/twnhealthinfo20080402.html>. Date viewed: 15 November 2008.

²⁷⁷ 'WHA Agrees On Health, Innovation And IP After Initial Divisions' Available at: http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.060701.htm Date viewed: 11 December 2008.

²⁷⁸ Available at: <http://www.keionline.org/misc-docs/thai/08-1674-Letter.pdf> Date viewed: 12 December 2008.

²⁷⁹ 'Thailand's FDA Registers Generic Version Of Abbott's Antiretroviral Aluvia For Use Under Compulsory Licensing Program' Available at: <http://www.medicalnewstoday.com/articles/85893.php> Date viewed: 9 December 2008.

²⁸⁰ 'WHA Agrees On Health, Innovation And IP After Initial Divisions' Available at: http://www.twinside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.060701.htm Date viewed: 11 December 2008.

²⁸¹ 'Compulsory licensing controversy in Thailand' Available at: https://www.wcl.american.edu/pijip/thai_comp_licenses.cfm Date viewed: 3 December 2008.

Apart from the significant international pressure developing countries have faced when issuing compulsory licences the practical effects of the procedures required Article 31 clearly defeat one of the objectives of the TRIPS flexibilities, namely providing the mechanisms to bypass patent protection in order to increase access to much-needed medicines. The effects of Article 31, as discussed above, constitute a significant barrier to access to medicines for developing countries. This problem has been rectified to some extent by the Doha Declaration on TRIPS and Public Health²⁸². However, as will be demonstrated, the system it created, namely the 30 August 2003 system, is almost overwhelmed by complicated procedures which make the process of using it almost impossible.

II THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH

The Fourth Ministerial Conference in Doha, Qatar, marked a significant victory for developing countries battling to provide medicines to its people to deal with their public health crises. The Declaration on TRIPS and Public Health issued the day after the conference on 14 November 2001 contains a number of provisions designed to reinforce the fact that the TRIPS flexibilities are not and should not be a barrier to Members protecting their country's public health.

Paragraph 4 states:

We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

This paragraph is very important in light of the fact that developing countries that have

²⁸² Ministerial Declaration of the WTO's Fourth Ministerial Conference WT/MIN(01)/DEC/1 http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

issued compulsory licences on medicines, in accordance with the requirements of TRIPS, have faced immense international pressure, examples of this are discussed below. These countries include Thailand. In the previous Chapter it was shown the extent of the negative effects a country may experience if it issues a compulsory licence. This paragraph demonstrates the WTO's approval of the use of compulsory licences for the protection of public health.

Paragraph 5 lists specific examples of the flexibilities in paragraph 4, although it does not constitute an exhaustive list²⁸³. It states:

Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognise that these flexibilities include:

- (a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objective and principles.
- (b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- (c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- (d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

Paragraph 5(c) is important for three reasons²⁸⁴. Firstly, it clarifies that 'public health crises' can represent 'a national emergency or other circumstances of extreme urgency'; this allows the granting of compulsory licences when provided for under national law and, pursuant to TRIPS Article 31(b), without the obligation for prior negotiation with

²⁸³ Gamharter (Note 23 above)140.

²⁸⁴ C Correa 'Implications of the Doha Declaration on the TRIPS Agreement and Public Health' Health Economics and Drugs EDM Series No. 12 WHO/EDM/PAR/2002.3 World Health Organisation 16.

the patent owner. Secondly, reference to HIV/AIDS²⁸⁵ indicates that an emergency may be not only a short-term problem, but a long-lasting situation²⁸⁶. Thirdly, if a Member complains about the qualification of a specific situation by another Member as a ‘national emergency or other circumstances of extreme urgency’ it bears the onus of proving that such an emergency or urgency does not exist, because paragraph 5(c) places this burden on the complaining Member. This shift makes it more difficult for a complaining Member to lay a valid complaint because it is difficult to prove that there is no emergency in that country, especially in the area of HIV/AIDS.

Paragraph 5(d) reinforces the authorisation of parallel importation of medicine. Correa argues that this is a key component for developing countries to address their public health needs²⁸⁷. It is also important to note the section that states that ‘the effect of the provisions in the TRIPS Agreement... is to leave each Member free to establish its own regime for such exhaustion *without* challenge’²⁸⁸ (emphasis added). This section serves to reassure Members that wish to use the international exhaustion principle²⁸⁹ that it is fully consistent with the TRIPS Agreement²⁹⁰.

Perhaps the most important paragraph in the Declaration is Paragraph 6 as it highlights the effects of the restrictive nature of Article 31(f). This was the first step in the creation of a solution²⁹¹ to the problems created by Article 31(f). It states:

We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council

²⁸⁵ ‘this recognition may be deemed an important achievement for developing countries in the Doha Declaration, since it implies that specific measures to deal with an emergency may be adopted and maintained as long as the underlying situation persists.’ C Correa ‘Implications of the Doha Declaration on the TRIPS Agreement and Public Health’ Health Economics and Drugs EDM Series No. 12 WHO/EDM/PAR/2002.3 World Health Organisation 16.

²⁸⁶ Ibid, 16 and 17.

²⁸⁷ Ibid, 18.

²⁸⁸ Paragraph 5(d).

²⁸⁹ The international exhaustion principle involves parallel importation and is discussed in Chapter 4.

²⁹⁰ Gamharter (Note 24 above) 142.

²⁹¹ Ibid 143.

for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.²⁹²

(a) 30 August 2003 Decision

Although required to find a solution to the problem highlighted by the Doha Declaration by the end of 2002, consensus could not be reached and the Chairman's text on public health was only adopted on 30 August 2003²⁹³. Paragraph 1 contains definitions of terms relevant to the 30 August 2003 Decision. Specific reference is made to HIV/AIDS, tuberculosis, malaria and other epidemics which clearly demonstrated the WTO's commitment to providing medicines for HIV/AIDS and other diseases predominantly found in developing countries. This list is not exhaustive; however the focus is clearly on epidemics and diseases affecting developing countries.

(i) Eligible importing Members

Paragraph 1(b) defines who is eligible to use the system as an importer. It states:

'Eligible importing Member' means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(ii) Exporting Members

In terms of Paragraph 1(c) there are no requirements in order to be an exporter. It states that an 'exporting Member' means a Member using the system set out in the 30 August 2003 Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

²⁹² WT/MIN(01)/DEC/2 (20 November 2001) Available at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm Date viewed: 5 December 2008.

²⁹³ 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health' Available at: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm Date viewed: 11 December 2008.

(iii) Waiver

The most important section of the 30 August 2003 Decision is the waiver of Article 31(f) of TRIPS. This is designed to be the solution to the problems highlighted in Paragraph 6 of the Doha Declaration, in that the exporting Member is allowed to export the medicine in a greater quantity than what is needed for the predominant supply of the exporter's domestic market.

Paragraph 2 states:

The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph.

Paragraph 2(a) details the terms upon which an eligible importing Member may import patented medicines under the system:

- (a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that:
- (i) specifies the names and expected quantities of the product(s) needed;
 - (ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision²⁹⁴; and
 - (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision;

Paragraph 2(b) and 2(c) outlines the requirements for exporting a medicine under the system:

- (b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

²⁹⁴ Part (ii) of the Annex to the Decision, dealing with demonstrating a lack of pharmaceutical manufacturing capacity, states: 'Where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply'.

- (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
- (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
- (iii) before shipment begins, the licensee shall post on a website the following information:
 - the quantities being supplied to each destination as referred to in (i) above; and
 - the distinguishing features of the product(s) referred to in (ii) above;

(c) the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

The fundamental problem with the 30 August 2003 Decision is that its procedures can be extremely time-consuming. Whilst these procedures are important to protect the patent holder's rights they can lead to unnecessary delays in the providing of much-needed medicines. Each of these procedures is examined separately in order to establish their purpose and effect.

Paragraph 2(a)(ii) states that the importing Member must establish that it has insufficient manufacturing capacities through one of the ways detailed in the Annex; essentially that the Member has examined its capacity and found that it is insufficient for the purposes of manufacturing the pharmaceuticals. This is a factual enquiry. However, because the Member determines its capacity, this decision may be challenged by the patent holder. There is some debate as to whether 'insufficient ... manufacturing capacities' refers to a country's general capacity to produce pharmaceuticals or to whether the country has the capacity to manufacture highly intricate medicines, such as ARVs where production and

quality control standards are vital due to the risk of drug resistance and toxicity.²⁹⁵ However, Correa argues that ‘a reasonable reading of Paragraph 6 suggests that it is intended to address both the cases of general and particular lack or insufficient capacity, since otherwise it would not be possible for the concerned country to address its ‘health problems’ (Paragraph 1) and to ‘protect public health’ (Paragraph 4).’²⁹⁶

These time-consuming procedures are primarily contained in Paragraph 2(b) and 2(c). These procedures have been implemented in order to safeguard the interests of the patents holders, for example, through the prevention of re-exportation of the medicines to other countries²⁹⁷. Whilst it is important to ensure the interests of the patent holder these procedures restrict access to medicines²⁹⁸.

In terms of Paragraph 2(b)(i) a compulsory licence is only issued by the member for a specified amount of the medicines. Should the importing country need more of the medicine it has to negotiate another compulsory licence²⁹⁹. This is problematic in the area of ARVs because more and more people need ARVs as time progresses and the situation may arise that by the time the exporting country exports the medicines the importing country may need far more medicines than they had negotiated. This is because there might be new infections before the ARVs actually reach the importing country.

Paragraph 2(b)(ii) is designed entirely to prevent the re-exportation of the licensed medicine to other countries in an effort to undercut the patent holder’s market. It requires that the exporter must alter the labelling or marking of the medicine in such a way as to ‘be clearly identified as being produced under the system’. These include the use of special packaging, colouring and shaping in order to establish a distinction between it and the patented medicine. The use of distinguishing characteristics is crucial to the

²⁹⁵ Note 248, 16.

²⁹⁶ Ibid.

²⁹⁷ Paragraph 2(b)(ii).

²⁹⁸ ‘Frequently asked questions about compulsory licences’ Available at: <http://lists.essential.org/pharm-policy/msg00006.html> Date viewed: 9 December 2008.

²⁹⁹ Paragraph 2(b)(i).

prevention of re-exportation because it enables the customs authorities and other relevant personnel to immediately establish when the medicine is being re-exported. Whilst this is very important, the extent to which the exporting member is expected to alter the medicine significantly, depending on the medicine, may be time-consuming. This is also an unnecessary expense for the manufacturer which can sell their medicine to other buyers that do not require such alterations.

The problem of time-consuming procedures is exacerbated by the requirement that two compulsory licences must be issued³⁰⁰: one compulsory licence issued by the exporting state and one issued by the importing state. This leads to further administrative delays.

b) Use of the 30 August 2003 Decision

The system outlined by the 30 August 2003 Decision has only been used once, between Canada and Rwanda. This began on 17 July 2007 when Rwanda notified the Council for TRIPS of its intention to import 260 000 packs of Apo TriAvir³⁰¹, a fixed-dose combination ARV of Zidovudine, Lamivudine and Nevirapine, produced by Apotex. Inc in Canada. Then, on 4 October 2007, Canada notified the Council for TRIPS that it had authorised the manufacturing and export of the Apo TriAvir³⁰². Canada agreed to export the medicine at \$0.197 per tablet, resulting in a treatment regimen of \$146 per patient per year. This is the lowest price from a generic source as of March 2008³⁰³. However, the process of securing both licences and complying with the other requirements took a long time. Richard Elliott, the Executive Director of the Canadian HIV/AIDS Legal Network³⁰⁴ said

³⁰⁰ Note 248, 16.

³⁰¹ Notification under paragraph 2(a) of the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. IP/N/9/RWA/1 19 July 2007.

³⁰² Notification under paragraph 2(c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. IP/N/10/CAN/1 4 October 2007.

³⁰³ Available at: <http://www.accessmed-msf.org/main/hiv-aids/price-guide-to-aids-drugs.htm> Date viewed: 28 November 2008.

³⁰⁴ Richard Elliott 'Canada finally poised to deliver on promise of affordable medicines to developing countries' Available at: <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1373> Date viewed: 28 November 2008.

getting this far has required an extraordinary amount of work by one company and various non-governmental organisations. This is not sustainable. How many lives could have been saved in the meantime if this law had worked smoothly the way it should and could?' Elliott argues that the requirements of separate negotiations and a separate licence for each country and each order of medicines is unsustainable. He suggests that a simple one-licence solution is what should be implemented³⁰⁵.

The 30 August 2003 Decision is by no means the complete solution to the problems of access to medicines under patent. However, the 30 August 2003 Decision is a significant step for developing countries and it clearly shows a willingness on behalf of the Council for TRIPS to introduce measures to improve these countries' access to medicines.

Developing countries with the manufacturing capacity to produce ARVs have made use of the Article 31 flexibilities. However they have encountered significant international pressure as a result. It is important to examine the possible negative effects which South Africa may experience should it decide to issue either an Article 31 compulsory licence or a 30 August licence. In the examination that follows Thailand, as a developing country, and the United States of America, as a developed country, are discussed.

III AMERICA'S USE OF 'GOVERNMENT USE COMPULSORY LICENCES'

America, despite its condemnation of Thailand's issuance of compulsory licences, has a highly advantageous system to bypass patents. It stands in stark contrast to South Africa's somewhat arthritic flexibilities in its patent system, and offers some guidance as to provisions the South African Legislature may include in the Patents Act. It is also a model from which a number of lessons can be learnt in the area of State involvement in the securing access to essential medicine.

The US has permitted involuntary use in three contexts: to permit government use; to remedy anticompetitive behaviour; and in specific contexts to advance public-interest goals³⁰⁶. The issuance of compulsory licences has been used in both the public and

³⁰⁵ Ibid.

³⁰⁶ 'Frequently asked questions about compulsory licences' Available at: <http://lists.essential.org/pharm-policy/msg00006.html> Date viewed: 12 December 2008.

private sectors including those in respect of patents held by companies such as AT&T, General Electric, IBM and Xerox³⁰⁷

Under US patent law, the government may use any patented invention, or authorise its contractors to use such an invention, without providing prior notification to the patent holder, subject only to the patent holder's right to claim 'reasonable and entire compensation from the United States in the United States Court of Federal Claims'³⁰⁸. US Code: Title 28 section 1498 was used by the then Health and Human Services (HHS) Secretary Tommy Thompson to threaten drug company Bayer in order to persuade them to enter into an agreement for the provision of ciprofloxacin, as a defence against the possible anthrax attacks in 2001³⁰⁹. In terms of this agreement HHS agreed to pay 95c per tablet for the total order of 100 million tablets³¹⁰. This is a marked discount from the previous discounted price of \$1.77 per tablet.³¹¹ This section was also used, as a threat, in 2005 to secure Tamiflu as a drug used to treat avian flu³¹². In November 2005 HHS Secretary Michael Levitt stated that 'he had effectively required the patent owners for Tamiflu (Roche/Gilead) to invest in US manufacturing facilities for the product, so that the United States government would have access to Tamiflu if confronted with an avian flu pandemic'³¹³

a) **The Bayh-Dole Act**

US Code Title 35 section 203(1) states 'With respect to any subject invention in which a small business firm or nonprofit organisation has acquired title under this chapter, the Federal agency under whose funding agreement the subject invention was made shall have the right ...to grant such a licence itself.' These rights were used by the Centre for

³⁰⁷ S Flynn, A Hollis & M Palmedo, 'An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries' Available at: http://www.america.edu/pijip_static/documents/flynn05222008.pdf?rd=1 Date viewed: 25 August 2008.

³⁰⁸ 28 U.S.C. § 1498

³⁰⁹ Press release issued by HHS press office 'HHS, Bayer agree to CIPRO purchase' Available at: www.cptech.org/ip/health/cl/cipro/dhhs10242001.html Date viewed: 27 August 2008.

³¹⁰ Ibid.

³¹¹ Ibid.

³¹² Ibid.

³¹³ Excerpts from 8 Nov 2005 Hearings of the Subcommittee on Health and the House Committee on Energy and Commerce. Available at:

<http://www.cptech.org/ip/health/tamiflu/hearingsexcerpts11082005.html> Date viewed: 2 September 2008.

Disease Control to threaten the issue of compulsory licences on the reverse genetics required to produce the avian flu vaccination³¹⁴. This section has also been used in the ARV market, where the US has a 'royalty-free, non-exclusive, worldwide statutory licence to the patent; for Stavudine/D4T and Ritonavir³¹⁵. This is in accordance with section 203(1) because the US had given funding to the development of both products³¹⁶. This section allows the US government to fund the development of medicines which may not otherwise be produced due to lower profit margins and receive a return on their investment³¹⁷.

From the above discussion it can be seen that the system of compulsory licences in the US is very powerful. The US legislation has been used very successfully to ensure the security of its access to essential medicines at low price. The use of compulsory licences would be very useful for the South African government, despite the international pressure placed on other countries that have utilised them. There is a possibility that South Africa may not experience such significant international pressure because of the very large scale of the disease in South Africa. Subsequent to Thailand's use of compulsory licences many international bodies have also come out in support of the use of this mechanism. In order for South Africa to fully utilise this mechanism, provided under TRIPS and the Doha Declaration, there must be provision in South Africa's domestic legislation. South Africa's legislative framework will now be analysed to establish how far these international agreements have been implemented.

IV SOUTH AFRICA'S LEGISLATIVE FRAMEWORK FOR THE USE OF COMPULSORY LICENCES AND OTHER FLEXIBILITIES

Section 15C of the Medicines and Related Substances Act specifically provides for the use of compulsory licences as one of the methods, at the disposal of the Minister of Health to increase access to HIV/AIDS drugs. It states:

³¹⁴ J Love 'Recent examples of the use of compulsory licences on patents' Knowledge Ecology International. 31 March 2007. Available at: <http://www.keionline.org> Date viewed: 2 September 2008.

³¹⁵ Ibid.

³¹⁶ Ibid.

³¹⁷ Ibid.

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and, in particular may:

- (a) notwithstanding anything to the contrary contained in the Patent Act 1978 (Act No. 57 of 1978), determine that the rights with regards to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine or with his or her consent;
- (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic. But which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;
- (c) prescribe the registration procedure for. as well as the use of the medicine referred to in paragraph (b).

This section establishes the State's readiness to utilise compulsory licences to protect public health. It also affords the Minister wide discretionary powers in the areas of Patent Law, medicine registration and the importation of medicine.

Section 4 of the Patents Act states:

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.

This allows cabinet members the power to issue compulsory licences to the benefit of state entities or private companies³¹⁸. Section 55 of the Patents Act 57 of 1978 states that the Commissioner is not entitled to grant such a compulsory licence unless:

- (a) the invention claimed in the dependent patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the prior patent;
- (b) the proprietor of the dependent patent granted the proprietor of the prior patent on reasonable terms a cross-licence to use the invention claimed in the dependent patent; and
- (c) the use authorised in respect of the prior patent is not assignable except with the assignment of the dependent patent.

³¹⁸ T D Burrell (Note 147 above) 309 - 310.

If an agreement cannot be reached the issue will be resolved by the Commissioner of Patents, a judge of the Pretoria High Court. The issuing of compulsory licences is dealt with under section 56 of the Patents Act.

Section 56(1) of the Patents Act allows any interested person to apply to court for a compulsory licence³¹⁹. This section creates a number of problems for parties seeking a compulsory licence³²⁰. In order to have locus standi the applicant must be able to show an interest and an interested person cannot be a civil society organisation that ‘has an interest in ensuring that licences are issued, but does not actually produce or import generic medicines’³²¹. Interested persons must show that they are in the business of drug manufacture or import. However if the definition of ‘interested person’ were expanded to include parties other than those in the business of drug manufacturing, civil society movements could play a more active role in the patenting process. This is especially important as the South African government has entered into a number of agreements with drug companies³²² and is unlikely to want to apply for a compulsory licence for fear of the repercussions.

Section 56(2) contains a list of examples of abusive practices on which compulsory licences can be issued. However it is unclear whether this is a closed list. The examples contained in this list are examined in order to establish whether they offer more protection than that required by the TRIPS Agreement.

a) Abusive practices under Section 56

i) Section 56(2)(a)

Section 56(2)(a) outlines the first abusive practice. It states:

The rights in a patent will be deemed to be abused if:

³¹⁹ Section 56(1) states: 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.

³²⁰ A Hassim; M Heywood & J Berger (eds) ‘Health and Democracy’ Chapter 14 in *Access to Essential Medicines* (2007) 459 and 460.

³²¹ *Ibid.*

³²² These agreements are discussed in detail under the discussion on voluntary licences.

the patented invention is not being worked in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed, whichever period last expires, and there is in the opinion of the commissioner no satisfactory reason for such non-working.³²³

ii) Section 56(2)(c)

This section states 'the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms'. 'The demand' must be an actual one and not merely one which an applicant for a compulsory licence hopes and expects to be in a position to create if and when he has obtained a licence and commenced business³²⁴.

iii) Section 56(2)(d)

The section states:

by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, the trade or industry or agriculture of the Republic or the trade of any person or class of person 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 licence or licences should be granted.

What constitutes 'licence upon reasonable terms' was discussed by Eloff JP in *Afitra (Pty) Ltd and Another v Carlton Paper of SA (Pty) Ltd*³²⁵. He made it clear that a claim of unreasonable terms is not established merely on proof that the applicant can sell the same sort of article at a lower price than the patentee.³²⁶ He said:

³²³ T D Burrell (Note 147 above) 311.

³²⁴ Ibid 313 and *James Lomax Cathro's Applications* (1934) 51 RPC 75 at 82. In *Re Boulton's Patent* the British Comptroller stated: 'It was also urged that there was no obligation on the part of the patentee to show any substantial manufacture here, until a demand for the patented article or process has arisen or been created. In my view, it is not possible to accept the argument thus widely stated. The consideration of the adequacy of manufacture in this country does, no doubt, depend 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 existing, there is no obligation on a patentee to start an industry here. If he does in fact manufacture in foreign countries, and if there is in fact a demand for the article or process abroad, the absence of any demand here does not seem to be a valid excuse. The patentee must, in such cases, make an effort to create a 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.'

³²⁵ 1992 BP 331.

³²⁶ T D Burrell (Note 147 above) 314.

On the charge of not granting a licence the Court should be provided with evidence indicating, with reasonable precision, what reasonable terms are. The close reasoning adopted by the Court of Appeal in *Smith Kline & French Laboratories Ltd's (Cimetidine) Patents* 1990 RPC 203, shows the sort of evidence that is expected in that type of case. The reasonable terms are not necessarily those offered by the applicant or those offered by the patentee. If possible the Court should be afforded the guidance of what terms are normally applied to that type of licence.

This would be useful if South Africa faces a situation similar to Thailand where a drug company withdraws its medicine from the market. In that situation the government could issue a compulsory licence on the basis of this section because an industry is being prejudiced and it is in the public interest for the drug to be made available to the public.

Although there are some flexibilities in section 56, they are not designed to be usable by the people most affected by the lack of access, as discussed above. The fundamental problem with section 56(2) is that it offers greater patent protection than TRIPS because its list, although not a closed list, fails to include some of the grounds detailed in TRIPS which are designed specifically to facilitate access to medicines, such as the ability to issue compulsory licences in situations of national emergency or matters of extreme urgency. This extra protection is a completely unnecessary burden in light of the fact that TRIPS specifically provides for circumstances, such as a national emergency, to be grounds for issuing a compulsory licence, especially for a developing country with an access to medicine crisis.

A compulsory licence is one of the flexibilities which South Africa should use as a means of securing medicines, especially ARVs under patent, whilst its generic manufacturing capacity is expanding to be able to produce generic versions of these ARVs. Like compulsory licences the other flexibilities have both positive and negative aspects. However if used in conjunction with the other flexibilities, and the maintenance of high patent standards, they will achieve the best possible access to medicines for South Africa.

V OTHER FLEXIBILITIES IN TRIPS

(a) Voluntary licences

A voluntary licence allows a third party to use a patent holder's patent to produce, market or otherwise distribute the patented product in exchange for a royalty or licensing fee. The patent holder may impose restrictions on the sale or transfer of the licence as well as on geographical distribution, marketing and the duration of the agreement³²⁷. Unlike compulsory licences, these licences are largely unregulated. This means that pharmaceutical companies can impose their own terms on the amount of compensation to be paid, permitted usages, distribution and especially exportation³²⁸.

There are a number of advantages to voluntary licences: they minimise the potential for re-exportation of the drugs thereby curtailing the real dangers to patients associated with black and grey imports³²⁹; and, in a legal context, they place ARV production on a solid legal footing and avoid legal wars of attrition³³⁰.

The use of voluntary licences is one of the Intellectual Property mechanisms mentioned in the Operational Plan. These licences have successfully been negotiated in South Africa by generic manufacturing such as Aspen Pharmacare³³¹. Voluntary licences were agreed after the Competition Commission's ruling in *Hazel Tau*³³² matter. GlaxoSmithKline and Boehringer Ingelheim negotiated licences with Aspen Pharmacare and three other generic companies allowing for the manufacture of AZT, 3TC and Combavir in exchange for royalty payments of no more than 5 per cent³³³. Aspen also agreed to give 30 per cent of net sales to one or more non-governmental organisation fighting HIV/AIDS in South Africa³³⁴. If the South African government used voluntary licences more often it would ensure the provision of ARVs at reduced prices and bolster

³²⁷ Note 155 above.

³²⁸ Note 85 above, 151.

³²⁹ Note 27, 373.

³³⁰ Ibid.

³³¹ Ibid.

³³² Case no. 2002 Sep 226.

³³³ 'Competition Commission Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines' TAC Newsletter – 10 December 2003. Available at: http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm Date viewed: 20 July 2008.

³³⁴ Ibid.

the domestic generic manufacturing capacity by increasing the number of medicines these manufacturers can produce.

However, voluntary licences are by no means the perfect solution. These licences are based on the agreement of the drug companies and cannot be used without this agreement, unlike compulsory licences. Even if the companies agree, the government which secures the voluntary licence is then beholden to the drug company and therefore will be unlikely to issue compulsory licences or utilise other flexibilities in TRIPS for fear that the drug company will withdraw its agreement to the voluntary licence. However, they do have an important role to play, as demonstrated by the *Hazel Tau* matter, as a means of settling other legal disagreements.

(b) **Parallel importation**

Parallel importation permits the importation of goods, in this case pharmaceuticals, without the direct consent of the patent holder which has been marketed in another country by that patent holder or its authorised licensee³³⁵. The right to parallel importation stems from Article 6 of TRIPS which permits countries to adopt the principle of national exhaustion, as discussed below. Article 6 states: 'For the purposes of dispute settlement under this Agreement, subject to the provisions of Article 3 and 4, nothing in this Agreement shall be address the issue of the exhaustion of intellectual property rights.'

The principle of national exhaustion holds that the patent holder may only recoup profits on its patented product, in this case medicines, from the first sale of that product³³⁶. It translates into the following scenario: if a company sells a drug to Namibia more cheaply than it does to India, Namibia can resell the drug to India. The patent holder's rights of those drugs were exhausted after the first sale meaning that the patent holder is not entitled to royalties or any kind of payment for this second sale. Parallel importation is vital part in securing access to affordable medicines because it means that if a medicine is

³³⁵ K M Bombach, 'Can South Africa Fight AIDS? Reconciling the South African Medicines and Related Substances Act with the TRIPS Agreement' 19 *B.U. Int'l L. J* 273, 278.

³³⁶ *Ibid* 278.

available in another country at a price lower than the price in South Africa, the Minister of Health can import the medicine from this country at that cheaper price.³³⁷

As with all international treaties, in order for flexibilities in TRIPS to be enforceable in a country they must be incorporated into the country's domestic law. South Africa has made provision for parallel importation in section 15C³³⁸ of the Medicines and Related Substances Control Amendment Act and reiterated its value in the Operational Plan³³⁹.

(c) **Bolar amendment**

The name of this flexibility comes from the American case of *Roche Products Incorporated v Bolar Pharmaceutical Company*³⁴⁰ which decided that the testing of a medicine for the purposes of drug regulatory authority approval could not take place before the patent had expired. However this position was changed by the amendment, in US Code Title 35 section 271(e) which states:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.³⁴¹

This amendment is provided for broadly under the limited exceptions under Article 30 of TRIPS, which states:

Members may provide 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, taking account of the legitimate interests of third parties.

³³⁷ Ibid.

³³⁸ Section 15C states:

The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public and, in particular may: (a) notwithstanding anything to the contrary contained in the Patent Act 1978 (Act No. 57 of 1978), determine that the rights with regards to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicines...

³³⁹ Note 97 above, 152.

³⁴⁰ 722 F.2d 858 (Fed. Cir 04/23/1984).

³⁴¹ This Section is an exception to Section 271(a) which states that 'except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent.' 35 USC 271(e).

The South African Patents Act was amended in 1978 and section 69A was included.

Section 69A states:

It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product.

Section 69A allows a generic company to take all necessary steps to register drugs with the Medicine's Control Council (MCC), although local production of the drugs can only begin after patent expiry. This means that even if the patent has not expired, or the generic company has not been able to secure a licence, it may register its products with the MCC. The advantage of this provision is that generic companies are able to start selling immediately after the patent expires, thereby bypassing lengthy delays inherent in the registration and approval process. The incorporation of the amendment is good for the pharmaceutical manufacturing industry, especially in the field of generics manufacture.

(e) Section 78 of the South African Patent Act

In an attempt to create a similar provision to the Bayh-Dole Act in the US, section 78 makes provision for the Minister of Trade and Industry to acquire a patent 'on behalf of the state...on such terms as may be agreed upon'. However, the problem with this section is that the state may acquire a patent only with agreement from the patent holder³⁴². It is likely that the patent holder will only agree where a patent is no longer profitable. It is unlikely that this will be the happen in the highly lucrative AIDS medicine market. Adila Hassim et al argue that 'section 78 would be a more effective regulatory mechanism if it allowed for a court to set the terms and conditions of the acquisition when there is a dispute'.³⁴³

³⁴² A Hassim; M Heywood and J Berger (Note 320 above) 462.

³⁴³ Ibid.

From the above discussion it can be seen that South Africa has made provision for the use of some of the flexibilities; however the compulsory licences provisions in the Patents Act should be amended to include compulsory licences for national emergencies and public non-commercial use. The inclusion of these measures would be one of the ways ‘to further reinforce the comprehensive legal environment to enable broad access to affordable medicines and to facilitate secure and sustainable local supply’³⁴⁴, as stated in the Operational Plan.

In South Africa perhaps the most successfully utilised flexibility in TRIPS relating to compulsory licences is the use of compulsory licences issued on the grounds of anti-competitive practices. Although these licences have not actually been utilised, the threat of them and the threat of an unfavourable ruling by the Competition Tribunal have led to a number of voluntary licensing agreements³⁴⁵. These agreements might not have been concluded on such favourable terms had Competition Law not been used.

VI COMPETITION-BASED LICENCES

These are licences granted to remedy anticompetitive practices and are more user-friendly because they bypass many of the primary pitfalls of government-use compulsory licences, discussed above. In a competitive market producers are price takers; the price is set more by the market than if you were a strong producer or the only producer in the market. Competition Law is designed to protect competition between companies and the rights of consumers³⁴⁶ especially when there is one producer. Competition Law seeks to prevent an abusive of dominance by a company, such as the setting of excessive prices. The use of Competition Law shifts the inquiry from whether the government should use its discretion to limit patent rights to whether the company was acting illegally to the

³⁴⁴ Note 97 above, 151.

³⁴⁵ *Hazel Tau* Case no. 2002 Sep226.

³⁴⁶ A Hassim, M Heywood and J Berger (Note 320 above) 463.

detriment of social welfare³⁴⁷. TRIPS specifically incorporates Competition Law in Articles 1.1³⁴⁸; 8; 31(k) and 40.

a) **TRIPS provisions**

i) Article 8

Article 8³⁴⁹ recognises the authority of countries to address the ‘control of anticompetitive practices in contractual licences’ and powers of ‘specifying in their legislation licensing practices of conditions that may in particular cases constitute abuse of intellectual property rights having an adverse effect on competition in the market.’³⁵⁰

ii) Article 31(k)

Article 31(k) states:

Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive. The need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

Waiver of Article 31(b)³⁵¹ means that negotiation between the parties before the issuing of a compulsory licence to remedy anticompetitive practices is not required. The waiver

³⁴⁷ S Flynn ‘Using Competition Law to Promote Access to Medicines’ Program on Information Justice and Intellectual Property. American University Washington College of Law. Available at: <http://www.wcl.american.edu/pijip/competitionpolicyproject.cfm> Date viewed: 28 November 2008.

³⁴⁸ Article 1.1 states: ‘Members shall give effect to the provisions of this Agreement. 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. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.’

³⁴⁹ Article 8 states:

‘1. Members may, in formulating or amending their 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.’

³⁵⁰ Note 284 above, 7.

³⁵¹ Article 31(b) states: ‘such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be

of Article 31(f)³⁵² is an attempt to level the playing field and restrain the company from competing illegally in. These waivers allow a far quicker procedure for the issuing of licences, a significant advantage over the other types of compulsory licences discussed above³⁵³.

Also contained in Article 31(k) is a reduction in royalty payments. The Article states that ‘the need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases’. This allows for the non-payment of royalties if there is evidence of egregious anticompetitive practices³⁵⁴.

On a practical level Article 31(k) licences mean that if a competition ground is used to authorise compulsory licences, local supplies may be exported to any country where there is no patent on the product or any country that itself issued a compulsory licence. The authorisation of unlimited exports allows the licence holder to serve a larger range of markets, which may provide the economies of scale necessary to meaningfully compete with the patent holder and set up a robust generic industry. For countries that have ambitions to create or maintain competitive generic industries, this is the most important flexibility in the TRIPS agreement.

iii) Article 40

Art 40(2)³⁵⁵ outlines some examples which amount to abusive practices on the basis of which the competition compulsory licences may be authorised. It should be noted that

waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.’

³⁵² Any such use shall be authorized predominantly for the supply of the domestic market of the Member authorising such uses.

³⁵³ Note 347 above.

³⁵⁴ Ibid.

³⁵⁵ Article 40(2) states: ‘Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions,

this is not an exhaustive list and the article specifically allows countries to specify their grounds in their legislation which must be incorporated into domestic law not just signed by TRIPS.

The examples contained in Article 40 are the following:

- ‘Exclusive grantback conditions’ where a patent holder licences technology to another company in order that they can produce the medicine. The corollary is that if they have any advances in the technologies they have to grant back in a compulsory licence to the original licensor³⁵⁶.
- ‘Conditions preventing challenges to validity’ in this case the patent holder gives a potential challenger to a licence on the basis that they will not then challenge the patent in court.³⁵⁷
- ‘Coercive package licensing’ whereby a drug company insists the generic producer has to purchase other licences that they do not want or are possibly not capable of manufacturing.³⁵⁸

b) General doctrine of Competition Law

In establishing whether a company is acting anticompetitively the general doctrine is that the following are relevant³⁵⁹:

- Whether the drug company is a dominant firm. This raises the questions of whether the drug company has market power, also known as a monopoly. Generally, in Competition Law, a company is said to have market power when there is no substitute for the manufacturer’s product³⁶⁰. However, the AIDS medicine market is unique in that a specific medicine may be the only one in its therapeutic class, which raises the issue of whether this is a monopoly under Competition Law.

conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.’

³⁵⁶ Article 40(2).

³⁵⁷ Ibid.

³⁵⁸ Ibid.

³⁵⁹ ‘Common forms of anti-competitive conduct’ Available at:

<http://www.ictregulationtoolkit.org/en/Section1714.html> Date viewed 13 December 2008.

³⁶⁰ Available at: <http://stats.oecd.org/glossary/detail.asp?ID=3199> Date viewed: 12 December 2008.

- Is there a practice that excludes competition or amounts to an abuse of dominance³⁶¹? Examples are those discussed above in Article 40(2) of TRIPS.
- Is the harm of the practice outweighs the benefits. This requires an analysis of policy and taking into account whether all drug donations are illegal, on the basis that they amount to predatory pricing as it undercuts the local market³⁶². An example of a monopoly which, arguably, is more beneficial than harmful is the manufacture of (FDCs) which are only capable of being manufactured by generic companies. These drugs are vital for the treatment of AIDS in developing countries.

c) South Africa's use of competition-based licences:

Section 8³⁶³ and section 9 of the South African Competition Act No. 89 of 1998 outline three categories of abuse of dominance in relation to access to medicines. These are:

1. Excessive pricing or charging prices that cannot be objectively justified³⁶⁴.
2. Refusing to licence generic manufacturers. Abuse of dominance is 'refusing access to an essential facility when it is economically feasible to do so'³⁶⁵.
3. Engaging in prohibited price discrimination³⁶⁶. Price discrimination means charging excessively low prices in one sector or market to limit or exclude

³⁶¹ Note 359 above.

³⁶² Ibid.

³⁶³ Section 8 states:

'It is prohibited for a dominant firm to:

- (a) charge an excessive price to the detriment of consumers;
- (b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;
- (c) engage in an exclusionary act, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweighs its technological, efficiency or other pro-competitive, gain; or
- (d) engage in any of the following exclusionary acts, unless the firm concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act:
 - (i) requiring or inducing a supplier or customer to not deal with a competitor;
 - (ii) refusing to supply scarce goods to a competitor when supplying those goods is economically feasible;
 - (iii) selling, goods or services on condition that the buyer purchases separate goods or practices unrelated to the object of a contract, or forcing a buyer to accept a condition unrelated to the object of a contract;
 - (iv) selling goods or services below their marginal or average variable cost; or
 - (v) buying-up a scarce supply of intermediate goods or resources required by a competitor.'

³⁶⁴ Section 8(a).

³⁶⁵ Section 8(b).

competition. It also may take place when a company deliberately charges excessively low prices to drive competition out, and this is followed by sudden price hikes once the competition has been destroyed.³⁶⁷

i) *Hazel Tau* and the Competition Commission

In September 2002, the TAC, ALP, Congress of South African Trade Unions (COSATU), the Chemical, Energy, Paper, Printing, Wood and Allied Workers' Union (CEPPAWU) and the AIDS Consortium lodged a complaint against GlaxoSmithKline and Boehringer Ingelheim with the South African Competition Commission³⁶⁸. They alleged that the prices charged by these two companies for their medicines were 'directly responsible for the premature, predictable and avoidable loss of life'³⁶⁹. At that time the

³⁶⁶ Section 9.

³⁶⁷ Section 9 states:

- '1) An action by a dominant firm, as the seller of goods or services, is prohibited price discrimination, if-
- a) it is likely to have the effect of substantially preventing or lessening competition;
 - b) it relates to the sale, in equivalent transactions, of goods or services of like grade and quality to different purchasers; and
 - c) it involves discriminating between those purchasers in terms of-
 - i) the price charged for the goods or services;
 - ii) any discount, allowance, rebate or credit given or allowed in relation to the supply of goods or services;
 - iii) the provision of services in respect of the goods or services; or
 - iv) payment for services provided in respect of the goods or services.
- 2) Despite subsection (1), conduct involving differential treatment of purchasers in terms of any matter listed in paragraph (c) of that subsection is not prohibited price discrimination if the dominant firm establishes that the differential treatment-
- a) makes only reasonable allowance for differences in cost or likely cost of manufacture, distribution, sale, promotion or delivery resulting from the differing places to which, methods by which, or quantities in which, goods or services are supplied to different purchasers;
 - b) is constituted by doing acts in good faith to meet a price or benefit offered by a competitor; or
 - c) is in response to changing conditions affecting the market for the goods or services concerned, including-
 - i) any action in response to the actual or imminent deterioration of perishable goods;
 - ii) any action in response to the obsolescence of goods;
 - iii) a sale pursuant to a liquidation or sequestration procedure; or
 - iv) a sale in good faith in discontinuance of business in the goods or services concerned.'

³⁶⁸ J Berger, 'ICTSD-UNCTAD Dialogue on Ensuring Policy Options for Affordable Access to Essential Medicines' Bellagio, 12-16 Oct 2004. 17.

³⁶⁹ Note 17 above, 107.

government had neither developed nor implemented an ARV treatment programme in the public sector³⁷⁰. The complainants sought:

to ensure that people living with HIV/AIDS who are working can afford to buy medicines to save their lives; that medical... insurers treat people living with HIV/AIDS without going bankrupt; and that employers are able to pay for the treatment of workers on a sustainable basis.³⁷¹

On 16 October 2003, after a year-long investigation the Competition Commission decided to refer the complaint to the Competition Tribunal³⁷². In reaching its decision the Commissioner, Menzi Simelane, said in the media release from the Competition Commission:

Our investigation revealed that each of the firms has refused to licence their patents to generic manufacturers in return for a reasonable royalty. We believe that this is feasible and that consumers will benefit from cheaper generic versions of the drugs concerned. We further believe that granting licences would provide for competition between firms and their generic competitors³⁷³.

The Commission demanded licences and also threatened to seek a financial penalty from the company equal to 10 per cent of its gross revenues in South Africa over the preceding year³⁷⁴. Also on 16 October 2003, GlaxoSmithKline announced that it would reduce its price for Combivir to 65 cents and extended its voluntary licences with Aspen Pharmacare to include both the public and private sectors as well as all the countries in the Sub-Saharan region³⁷⁵. Boehringer Ingelheim agreed to grant licences to three generic companies, including Aspen Pharmacare, to produce, import, sell and distribute Nevirapine³⁷⁶. The royalty fees on these licences are no more than 5 per cent of net sales of the medicines. Prior to the agreements with these manufacturers the royalty fees

³⁷⁰ Note 368 above, 17.

³⁷¹ Note 164 above, 5.

³⁷² Media Release from the Competition Commission Available at: <http://www.compcom.co.za/resources/Media%20Releases/MediaReleases%202003/Jul/Med%20Rel%2030%200f%2016%20Oct%202003.asp> Date viewed: 8 December 2008.

³⁷³ Ibid.

³⁷⁴ Ibid.

³⁷⁵ 'Competition Commission Settlement Agreements Secure Access to Affordable Life-saving Antiretroviral Medicines' TAC Newsletter 1. Available at:

http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm Date viewed: 15 November 2008.

³⁷⁶ Ibid.

requested by GlaxoSmithKline were 30 per cent and by Boehringer Ingelheim 15 per cent.³⁷⁷

After the Competition Commission the TAC targeted Bristol Myers Squibb regarding their antifungal medicine for opportunistic infection in AIDS patients³⁷⁸. Before formal filing was presented to the Competition Commission, the company dropped the price in South Africa by 85 per cent³⁷⁹. There are no voluntary licences authorising full competition for any AIDS drug in South Africa. The TAC filed a complaint against Merck, alleging that licences granted for the generic production of Efavirenz are insufficient and therefore do not license the lowest cost suppliers nor allow the production of co-formulation products combining Efavirenz with other FDCs. However the recent Merck complaint indicates a shift in the use of Competition Law in South Africa³⁸⁰. Flynn argues that the legal debate is now about the extent of the obligation to license on the part of the AIDS drugs suppliers' rather than whether the obligation exists in the first instance³⁸¹.

Although competition licences are a significant tool to be used in accessing medicine, drug companies still have the option of not registering a drug in a country, as Abbott did with Aluvia in Thailand. The solution to this type of reaction by a drug company may lie in the use of the essential facilities doctrine.

d) **The essential facilities doctrine**

The essential facilities doctrine states that if you have a monopoly of an essential facility then you have to serve everyone. *Hecht v Pro Football Inc*³⁸² states:

The essential facility doctrine, also called the 'bottleneck principle' states that 'where facilities cannot practicably be duplicated by would-be competitors, those in possession of them must allow them to be shared on fair terms. It is an illegal

³⁷⁷ Ibid.

³⁷⁸ 'Reducing the Prices of Antiretroviral Medicines: Answers to Frequently Asked Questions' Available at: <http://www.tac.org.za/Documents/DrugCompaniesCC/20031028-CompetitionComm-furtherq-and-a.htm>
Date viewed: 5 December 2008.

³⁷⁹ Ibid.

³⁸⁰ Note 347 above, 14.

³⁸¹ Ibid.

³⁸² 570 F. 2d 982(D.C. Cir. 1977)

restraint of trade to foreclose the scarce facility.’ ... To be essential a facility need not be indispensable; it is sufficient if duplication of the facility would be economically infeasible and if denial of its use inflicts a severe handicap on potential market entrants. Necessarily, this principle must be carefully delimited: the antitrust laws do not require that an essential facility be shared if such sharing would be impractical or would inhibit the defendant’s ability to serve its customers adequately.³⁸³

The factors amounting to the monopoly of an essential facility are that the facility is non-duplicable; that it is essential to competition; and that it is feasible to share the facility³⁸⁴.

The Court in *United States v Terminal Railroad Association*³⁸⁵ dealt with a matter brought under Sherman Antitrust Act which required the owner of the only bridge across the Mississippi river to share access to the resource with all competitors ‘upon such just and reasonable terms and regulations as will...place every such company upon as nearly as equal plane as may be’³⁸⁶. Sharing of property may be required by the anti-monopoly law where such a duty would promote ‘the greatest public utility and public advantage’³⁸⁷.

The Court in *Otter Tail Power Company v United States*³⁸⁸ the enforcement of a duty to share access to electricity transmission lines with competing generators has permitted isolated towns to bypass local generation monopolies and purchase power from preferred sources transmitted over the local monopoly’s lines³⁸⁹. The Court was confronted with argument by property holders that duties to share are contrary to the essence of the property right and therefore should be rejected. Courts rejected that argument, holding that property rights, as others, are legitimately qualified by valued regulatory purpose. It stated:

The record made abundantly clear that Otter Tail used its monopoly power in the towns in its service area to foreclose competition or gain a competitive advantage, or to destroy a competitor, all in violation of the

³⁸³ Ibid 992 – 993.

³⁸⁴ Ibid 993.

³⁸⁵ 224 US 383 (1912)

³⁸⁶ Ibid 411.

³⁸⁷ Ibid 409-410.

³⁸⁸ 410 US 366 (1973)

³⁸⁹ M Hirsh, G A. Richeimer, ‘The Essential Facilities Doctrine: Keeping the Word ‘Epithet’ from Becoming One’. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=389200 Date viewed: 14 November 2008.

antitrust laws. Given the difficulties and problems of . . . isolated electric power systems, such as those in Otter Tail's service areas, interconnection with other utilities is frequently the only solution.³⁹⁰

These cases demonstrate occasions where the courts have used the essential facilities doctrine to prevent an abuse. This could be used in a situation similar to what happened in Thailand, where Abbott withdrew Aluvia from the Thai market. It can be argued that Aluvia is an essential facility and therefore Thailand may have been able to use Competition Law to remedy the situation. The essential facilities doctrine has also been used in South Africa and is discussed below.

i) South Africa's use of the essential facilities doctrine

Section 8(b) of the South African Competition Act No. 89 of 1998 states that to 'refuse to give a competitor access to an essential facility when it is economically feasible to do so' amounts to an anticompetitive practice. In the *Hazel Tau* case the competition commission found that the practice whereby AIDS drug manufacturers refuse to licence competitors whilst maintaining extraordinarily high prices violates the essential facility doctrine³⁹¹. Their reasoning was that the facility is not duplicable and that it is feasible to share it because the patent could have negotiated licences at an economically feasible cost through royalty payments³⁹². This indicates a shift to the position now where a patent is a right to be compensated. Sean Flynn argues the use of Competition Law to facilitate access to medicines allows 'treatment activists to shift the public narrative from stories about the drug company voluntarily lowering their prices to South Africans to one about a pricing investigation about whether the companies were acting illegally by pricing their products out of the reach of the majority while blocking competition.'³⁹³

This has proved to be the most successful use of the TRIPS flexibilities in South Africa to date. However, Berger suggests that the use of Competition Law to issue compulsory licences could be improved by creating guidelines drawing together the separate statutes

³⁹⁰ 410 US 366 (1973) 377 – 378.

³⁹¹ Note 372 above, 1.

³⁹² Note 372 above, 1.

³⁹³ Note 347 above, 10.

dealing with Competition Law, Intellectual Property Law and the regulation of medicines to create a cohesive policy³⁹⁴. He says that such guidelines will ‘provide much-needed guidance for all role-players, including both holder of exclusive rights in IP as well as consumers.’³⁹⁵

Each of these flexibilities discussed in this chapter has its own limitations but if the examples of the US, India and Thailand are used the South African government will be able to provide far greater access to ARVs. These flexibilities need to be used in a balanced way and with care not to cause the drug companies to move their research to other diseases. The South African government must utilise the TRIPS flexibilities more widely in order to provide the improved access to medicines that is so desperately needed and to create a robust pharmaceutical manufacturer capacity which is the best long-term solution.

The presence of some of the flexibilities in South African legislation is a good foundation; however if the State does not use these flexibilities then there is little value in having the legislation. Therefore the fundamental part of ensuring access to anti-retrovirals for all South Africans is that the State must take the lead, rather than be coerced by civil society movements and the courts. The significant negative effect of this lack of State leadership and cooperation is demonstrated by the fact that in July 2000 Boehringer Ingelheim offered Nevirapine free for five years in order to prevent mother-to-child-transmission of HIV³⁹⁶. However, the State only allowed provision of Nevirapine at two pilot sites in each province until December 2002³⁹⁷. It was only after court action and much lobbying by civil society movements that a national programme for the prevention of mother-to-child-transmission in August 2003 and a national ARV treatment plan in 2004 were launched³⁹⁸. Over two years of free Nevirapine were almost entirely unused due to a lack of political will³⁹⁹. In October 2008, the Harvard School of

³⁹⁴ Note 368 above, 19.

³⁹⁵ *Ibid.*

³⁹⁶ Note 6 above, 1.

³⁹⁷ Note 1 above, 19.

³⁹⁸ Note 6 above, 1.

³⁹⁹ *Ibid.*

Public Health released a report estimating that 35 000 babies⁴⁰⁰ were born with HIV during the period from 2000 to 2005 because a ‘feasible mother-to-child-transmission prophylaxis program using Nevirapine (an anti-AIDS drug) was not implemented’. This illustrates how important the State’s role is in policy implementation and the significant negative consequences where the State fails to do this.

The Brazilian government has created a robust generic manufacturing capacity capable of producing highly complex pharmaceuticals, including ARVs. The policies introduced by its government have been very successful and demonstrate what is achievable when the State is committed to solving the problem of access to medicines. The Brazilian example is especially relevant because it has similar economic constraints to South Africa but has utilised them in a far more beneficial manner. Brazil is discussed in the next Chapter.

⁴⁰⁰ Ibid.

CHAPTER 5: LESSONS FROM BRAZIL AND THE IMPORTANCE OF THE CREATION OF PHARMACEUTICAL MANUFACTURING CAPACITY

Brazil is an example of what can be done with proper State involvement in an economic climate similar to that of South Africa. This Chapter illustrates how it achieved a robust pharmaceutical market. Whilst the circumstances in South Africa are not identical to those in Brazil there are a number of lessons that can be taken from this success.

Brazil's ARV distribution programme is the biggest success story among developing countries. It is characterised by strong government involvement, utilising its limited resources in the best ways to provide sustainable health care for its citizens. Its significant successes are clear in light of the fact that mortality rates have fallen by 50 per cent⁴⁰¹ since 1996, due to the free and universal distribution of combined antiretroviral therapy. In addition the State saved \$1.1 billion between 1997 and 2001 because its ARV programme led to significant reductions in hospital admissions⁴⁰². The achievements of Brazil clearly demonstrate how important it is to cultivate a thriving domestic pharmaceutical manufacturing capacity and how well this can be achieved when the government gives its full support.

I BRAZIL'S LEGAL FRAMEWORK

In 1988, Brazil became a constitutional democracy freeing itself from military dictatorship. The Constitution outlined its commitment to democracy and the rule of law, and was designed to form the basis of action to root out corruption that had been rife in both the public and private sector. Article 37 of the Constitution provides that, in general, public works, purchases and services should be contracted through a public tendering process. This led to the 1993 Call for Tender Law⁴⁰³ which required all government contracts to be awarded under conditions of fair competition through public

⁴⁰¹ P R Teixeira, M A Vitoria & J Barcarolo 'Antiretroviral treatment in resource poor settings: the Brazilian experience' (2004) AIDS Volume 18 June 2004 released by the WHO. 6.

⁴⁰² Ibid 6.

⁴⁰³ Law No. 8666 of 21 June 1993.

tender. The Tender Law gave preference to ‘(i) goods produced or services supplied by domestic companies; (ii) goods produced in Brazil; (iii) goods produced or services provided by companies established in Brazil’⁴⁰⁴ when the bids were equivalent in terms of price, quality and delivery time⁴⁰⁵. This preference was subsequently removed by a constitutional amendment in 1995 which opened the Brazilian market to the international community⁴⁰⁶. This liberalisation stimulated growth in the pharmaceutical industry which created conditions for the local production of ARVs⁴⁰⁷.

Possibly the most significant steps towards the creation of a robust pharmaceutical industry was the creation of the parastatal called *Companhia de Desenvolvimento Tecnológico* (CODETEC)⁴⁰⁸ and the suspension of Brazil’s Intellectual Property laws governing pharmaceuticals⁴⁰⁹. CODETEC’s function was to provide support for scientists engaged in reverse-engineering of active pharmaceutical ingredients (APIs) which are the key ingredients in all drugs. Its goal was to create synthetic variations of APIs⁴¹⁰. Once this knowledge was created it was then transferred to the private sector which had the capacity to manufacture the final product⁴¹¹. Whilst this may have been contrary to international Intellectual Property law, Brazil had suspended these laws⁴¹². These steps played an important part of the creation of a robust pharmaceutical industry. However, the Brazilian pharmaceutical industry is not entirely autonomous. It is still dependent on China and India for the raw materials⁴¹³ which form the basis the production

⁴⁰⁴ Note 263 above, 345.

⁴⁰⁵ WT/TPR/S/21, 4 October 1996, 102.

⁴⁰⁶ Note 27 above, 345.

⁴⁰⁷ Ibid.

⁴⁰⁸ Ibid.

⁴⁰⁹ Ibid.

⁴¹⁰ Ibid.

⁴¹¹ Ibid.

⁴¹² Ibid 341.

⁴¹³ These materials are known as APIs and are the essential ingredients needed for the creation of a specific medicine. The cost of these ingredients amounts to approximately 70 per cent of the total manufacturing cost.

of pharmaceuticals⁴¹⁴. However, India is showing every sign of being willing and able to provide these materials on an ongoing basis⁴¹⁵.

The 1996 Patent Law, passed in order to allow Brazil to join the WTO, brought the Brazilian Intellectual Property regime in line with the requirements of TRIPS⁴¹⁶. However, this development has not been entirely negative for its generic pharmaceutical industry. As in India, those drugs in circulation prior to 1996 can still be produced without permission from the patent holder, because these medicines are not under patent in Brazil⁴¹⁷.

Although diminished by international competition and stricter patent law, Brazil has already laid a solid foundation for the creation of a robust generic manufacturing industry. This is one of the reasons why the State has been able to commit significant state resources to the free, universal rollout of ARVs⁴¹⁸.

This foundation has been built on continually by the Brazilian Health Ministry. An example of this is the Health Ministry's decision, in 1997, to fund a state-owned laboratory to reverse engineer ARVs⁴¹⁹. Such reverse-engineering builds the capacity needed to conduct research and development and also ensures technology transfers to both the public and private sector⁴²⁰. This investment ensures that Brazil will have the capacity to produce generic ARVs in the event where a pharmaceutical company refuses to supply them at a cost affordable to the Brazilian government. This insulates the State's ARV rollout from bullying by pharmaceutical companies. It also adds weight to the threat of issuing compulsory licences, which is something South Africa needs to do to bolster its use of flexibilities as discussed in this dissertation.

⁴¹⁴ 'The Brazilian company, Labogen, is capable of producing APIs, but it may be driven out of business due to its inability to compete with Asian suppliers.' Note 263 page 3.

⁴¹⁵ Section 92A(1) of India's Patent Amendment Act states that the scope of its compulsory licences includes patented pharmaceutical products including APIs.

⁴¹⁶ Note 27 above, 348.

⁴¹⁷ Ibid 347.

⁴¹⁸ Ibid 350.

⁴¹⁹ Ibid 348.

⁴²⁰ Ibid 345.

Brazil demonstrates what can be achieved when the State is the driving force in the creation of a full-scale ARV rollout. The South African government should strive to limit the high cost of ARVs by creating a domestic manufacturing capacity capable of producing some ARVs, initially through the reverse-engineering of medicines, as well as utilising the flexibilities in TRIPS and negotiating with pharmaceutical companies in order to ensure the lowest possible prices for ARVs.

CHAPTER 6: OTHER MECHANISMS TO INCREASE ACCESS

Apart from the flexibilities contained in TRIPS there are other mechanisms which ought to be explored so as to find ways to increase access. Each of the mechanisms discussed below is designed to create differential pricing between rich and poor markets⁴²¹. Differential pricing is ideally suited to countries which have markets with a high disparity between the rich and poor, such as South Africa, because there is a market for both the higher and lower priced markets. Differential pricing is beneficial because the prices in high- and middle-income countries are used to pay for the research and development costs of the manufacturer and the lowered prices in developing countries would be used to cover marginal costs⁴²². This is a key part of ensuring greater access to medicines especially for those in poor markets, as was recognised by the WHO, WTO, the Foreign Ministry and the US-based Global Health Council in their three day workshop on Pricing and Financing of Essential Drugs⁴²³ in April 2001⁴²⁴. They concluded:

There was broad recognition that differential pricing could play an important role in ensuring access to existing drugs at affordable prices, particularly in the poorest countries, while the patent system would be allowed to continue to play its role in providing incentives for research and development into new drugs.⁴²⁵

It is also beneficial for the drug companies as they are still able to charge their high prices in markets where patients can afford such prices, such as the private sector in developing countries. Drug companies are also able to have access to a large group of people who need the medicine but would not ordinarily buy it because the prices are too high for them to afford⁴²⁶.

⁴²¹ M R Morgan 'Medicines for the Developing World: Promoting Access and innovation in the Post-TRIPS Environment' 64 *Univ of Toronto Fac of Law Review* 45.

⁴²² P Danzon 'At What Price?: Differential pricing could make global medicines affordable in developing countries. But drugs for disease that have no market in the developed world will require additional subsidies' *Outlook: Neglected Diseases. Nature*. Vol. 449 (2007). 176.

⁴²³ S Vankin, Ph.D 'Global Differential Pricing' Available at: <http://samvak.trip.com/pp151.html> Date viewed: 4 December 2008.

⁴²⁴ 'WHO/WTO Workshop On Pricing And Financing Of Essential Drugs' Available at: <http://www.who.int/inf-pr-2001/en/pr2001-20.html> Date viewed 7 December 2008.

⁴²⁵ Note 423 above.

⁴²⁶ 'A simulation comparing worldwide pharmaceutical prices, revenues and number of consumers served under a single global price with differential pricing between national markets (that is, one price per country)) found that differential pricing increases consumer access by a factor of roughly four - seven

In order to segment markets, so as to facilitate differential pricing, the following strategies can be used: (1) voluntary price discounts by originator drug companies; (2) bulk procurement; (3) generic substitution⁴²⁷. Like the flexibilities in TRIPS these mechanisms are not the perfect solution but play an important role in lowering the price of ARVs and other life-saving medicines.

I VOLUNTARY PRICE DISCOUNTS

Whilst not philanthropic by nature drug companies do sometimes discount the price of their medicines voluntarily such as in drug donation programmes. Such instances have occurred in South Africa as part of a settlement in a legal action, where drug companies wished to avoid an adverse ruling in a Competition Tribunal, as discussed previously⁴²⁸.

In other countries there have been occasions where drug companies have donated drugs to certain countries. These include Pfizer's Diflucan Partnership Program which donated Diflucan (Fluconazole) for cryptococcal meningitis and oesophageal candidiasis to 20 countries covering 915 health care sites⁴²⁹. Both diseases occur mostly in people infected with AIDS and have devastating and fatal effects on the patients.

The most successful drug donation programme was initiated by Merck in 1987. It donated Mectizan for the treatment of river blindness in sub-Saharan Africa⁴³⁰. Since then other companies have also initiated programmes to donate drugs for diseases such as

compared with uniform pricing. In addition, differential pricing within, as well as between, countries could significantly increase affordability for poor populations in countries that have a skewed income distribution and no national health insurance. Differential pricing would not only increase the use of existing drugs (static efficiency) but should also increase R&D and the flow of new drugs as a result of increased sales revenue (dynamic efficiency). P Danzon 'At What Price?: Differential pricing could make global medicines affordable in developing countries. But drugs for disease that have no market in the developed world will require additional subsidies' *Outlook: Neglected Diseases. Nature* Vol. 449 (2007). 176.

⁴²⁷ Note 422 above, 177.

⁴²⁸ *Hazel Tau* Case no. 2002 Sep226.

⁴²⁹ A Reeler, N Wadonda Kabondo, S Kironde, K Sebati, H Lauver, J Saba,, 'Do drug donation programs have an institutional impact? A study of the Diflucan Partnership Programme in Six Health care Institution in Sub-saharan Africa' International Conference on AIDS (2004) Bangkok Thailand.

⁴³⁰ Global Network for Neglected Tropical Diseases. Available at: <http://www.GNNTDC.org> Date viewed: 4 December 2008.

trachoma, which also causes blindness⁴³¹. One such company is Pfizer which donated its Azithromycin to treat this disease⁴³².

Drug donation programmes should, however, be approached with caution. Drug companies can attach conditions to their donations, such as an agreement that the country's government will not issue compulsory licences against the drug company's medicines⁴³³. Alternatively, the drug company, before donating their drugs to a country may specify the diseases for which this drug may be used for⁴³⁴. This occurred in South Africa where Fluconazole had been donated for the treatment of cryptococcal meningitis but not for the treatment of oesophageal candidiasis⁴³⁵. Oesophageal candidiasis is often the first sign of an HIV infection and without proper treatment the patient will experience significant weight loss, as patients lose their appetite due to the infection, which leads to malnutrition, the wasting syndrome and possible death⁴³⁶.

Although caution should be exercised, drug donation programmes have been successfully used and play an important role in providing access to medicine in the interim whilst South Africa establishes a robust pharmaceutical manufacturing capacity.

II GENERIC SUBSTITUTION

Generic substitution can be created through the use of compulsory licences, voluntary licences and patent waivers. The use of generic medicines is vital in poor countries which are unable to afford the high prices of the medicines under patent. As will be established in Chapter 7, in a segmented market providing the generic form of ARVs that are on patent to low income countries would have very little impact on the revenues of the drug manufacturer because global sales of pharmaceuticals to Africa is very small. This is demonstrated by the fact that for first-line ARVs, in developing countries the

⁴³¹ Ibid.

⁴³² Ibid.

⁴³³ S Lynch, B Baker, A Russell, 'Smoke and Mirrors: Assessing Pharmaceutical Industry Commitments to Making HIV Drugs Affordable and Accessible' International Conference on AIDS 2002.

⁴³⁴ Ibid.

⁴³⁵ Ibid.

⁴³⁶ JA Vazquez, 'Invasive Oesophageal Candidiasis: Current and Developing Treatment Options' *Drugs* Volume 63 Number 10 (2003) 971 – 989.

lowest generic price for triple-combination therapy is available at \$140 person⁴³⁷, whereas in developed countries and rich markets the monopoly prices of the on-patent medicines are still successfully being charged⁴³⁸.

a) South African legislation on generic substitution

In January 2003, the Medicines and Related Substances Amendment Act No. 59 of 2002 was passed. It provides for the generic substitution of medicines prescribed by medical practitioners. Section 22F states:

22F. (1) Subject to subsections (2), (3) and (4), a pharmacist shall—

(a) inform all members of the public who visit his or her pharmacy with a prescription for dispensing, of the benefits of the substitution for a branded medicine of an interchangeable multi-source medicine; and

(b) dispense an interchangeable multi-source medicine instead of the medicine prescribed by a medical practitioner, dentist, practitioner, nurse or other person registered under the Health Professions Act, 1974, unless expressly forbidden by the patient to do so,

(2) If a pharmacist is forbidden as contemplated in subsection(1)(b), that fact shall be noted by the pharmacist on the prescription.

(3) When an interchangeable multi-source medicine is dispensed by a pharmacist he or she shall note the brand name or where no such brand name exists, the name of the manufacturer of that interchangeable multi-source medicine in the prescription book.

(4) A pharmacist shall not sell an interchangeable multi-source medicine—

(a) if the person prescribing the medicine has written in his or her own hand on the prescription the words ‘no substitution’ next to the item prescribed;

(b) if the retail price of the interchangeable multi-source medicine is higher than that of the prescribed medicine; or

(c) where the product has been declared not substitutable by the council.

This section has a number of positive effects including requiring pharmacists to offer the generic version of their prescribed medicine, which results in the patients accessing medicines more cheaply. It also boosts the generic pharmaceutical market which encourages other generic manufacturers to enter the market.

⁴³⁷ Note 421, 18.

⁴³⁸ Ibid.

(i) Compulsory licences

Compulsory licences in poor markets would take the form of the system outlined in the 30 August 2003 Decision⁴³⁹ due to their inability to produce the medicines needed themselves. The 30 August 2003 requires laborious procedural obligations including that licences are only granted on a case-by-case, country-by-country and drug-by-drug basis. Due to these drawn out procedures it may be difficult to establish the economies of scale needed to ensure economic viability, especially in light of the high costs involved in completing the procedure. However the required economies of scale may be achieved if all countries fully implement the flexibilities in TRIPS, the Doha Declaration and the 30 August 2003 Decision into their domestic legislation. Countries with the potential to become robust generic manufacturers, such as South Africa, China and Argentina⁴⁴⁰, need to follow India's example by establishing high standards for patenting a medicine, thus increasing the number of medicines of which it will be able to manufacture generic versions.

(ii) Voluntary licences

As discussed previously, these licences are agreements by the drug company to allow a generic manufacturer to produce its medicine. Voluntary licensing agreements are a way for drug companies to repair their public image or in order avoid further legal action, as in South Africa where Boehringer Ingelheim and Glaxosmithkline concluded agreements to prevent the Competition Tribunal ruling on their anticompetitive practice. These agreements are also concluded in response to a Government's threatening the use of compulsory licences.

(iii) Patent waivers

These would occur in situations where a patent holder elects not to enforce its patent in certain countries⁴⁴¹. Such countries would probably be those without the capacity to manufacture the drugs themselves. However, it is still beneficial for their countries not to

⁴³⁹ See discussion on the 30 August Decision on page 68.

⁴⁴⁰ Ibid 19.

⁴⁴¹ Note 421 above, 22.

have such medicines patented due to the fact that it allows these countries to import such medicines.

III BULK PURCHASING

This strategy involves pooling the demand for drugs from a number of countries and then buying sufficient quantities of those drugs⁴⁴². This would be very useful for the purchasing of medicines still under patent which are ordinarily prohibitively expensive. It is beneficial to both the pharmaceutical manufacturer and the people needing the medicine. Bulk purchasing results in the drugs being priced lower than if each country bought separately. The supplier benefits because it increases his economies of scale and lowers the costs involved in negotiating their agreements⁴⁴³.

Bulk procurement can result in low prices for both on-patent and off-patent drugs. For medicines under patent a bulk order combined with the threat of compulsory licensing may result in lowered prices, even possibly nearing marginal cost⁴⁴⁴. For a medicine which is not under patent an order for a large quantity may create a price competition between generic manufacturers leading to an even more reduced price⁴⁴⁵.

The Clinton Foundation has used bulk procurements and long-term purchasing commitments from African and Caribbean countries⁴⁴⁶ in order to secure a price of \$140 per person per year for first-line triple-therapy ARVs, the cheapest price ever to be secured and around fifty per cent lower than previous offers⁴⁴⁷.

Bulk procurement could be effective in South Africa and surrounding countries because this area has the highest number of infected people in the world. These countries' bargaining power would be bolstered by the fact that South Africa already has a generic

⁴⁴² Ibid 24.

⁴⁴³ Ibid 22.

⁴⁴⁴ Ibid 24.

⁴⁴⁵ Ibid.

⁴⁴⁶ Ibid 23.

⁴⁴⁷ 'Global Fund and Others Announce Cheaper Drug Possibilities for Grant Recipients' *Global Fund Observer Newsletter* 22 Available at: <http://www.aidsplan.org/gfo/archives/newsletter>. Date viewed: 1 November 2008.

pharmaceutical manufacturing capacity which lends weight to threats of issuing a compulsory licence.

The South African pharmaceutical market could be segmented into areas where patients can afford higher prices, usually in the private sector, and areas where only lower prices can be afforded, in public hospitals and clinics. This would create a situation where drug companies would be more amenable to price reductions for the public sector because they will have access to more patients who previously were unable to pay for medicines. Drug companies are then also able to charge the higher prices to the private sector. This would strengthen the State's bargaining position in the negotiation of price reductions in the public sector because they would have access to more patients that previously were unable to access the medicine. The drug companies would also still be able to charge their higher prices in the private sector.

Differential pricing may also result in drug companies continuing research and development in the area of ARVs because they will still be able to make a profit. Utilising measures that increase access to ARVs and also allow the manufacturers to make a profit is essential to ensure continued research and development into new medicines to treat HIV/AIDS. The creation of a segmented pharmaceutical market in South Africa may also enable the public sector to secure further reductions in the prices of medicines.

CHAPTER 7: ECONOMICS OF THE PHARMACEUTICAL INDUSTRY AND METHODS TO INCENTIVISE RESEARCH AND DEVELOPMENT

In order to assess the best methods to incentivise research and development, especially in the field of neglected diseases⁴⁴⁸ it is important to discuss the economics of the pharmaceutical industry. The pharmaceutical industry is not philanthropic in nature; it is governed by profit and finding the best ways to maximise it. Creating new medicines for diseases only affecting developing countries is not the most profitable use of its resources and many companies do not conduct research in these diseases. This profit seeking is leading drug companies to move out of the AIDS medicine area into other conditions affecting developed countries. The most recent example of this is Roche's announcement in July 2008 that it was stopping its research and development in AIDS medicines⁴⁴⁹.

In order to prevent the drug company stopping its research into AIDS medicines, countries must create incentives for them to invest. The mechanisms discussed below should be used by the South African government in order to increase the R&D capability of the South African pharmaceutical industry which is beneficial for the future development of medicines. Before exploring possible incentive mechanisms the economics of pharmaceutical manufacturing will now be examined.

I ECONOMICS OF DRUG COMPANIES

One of the primary goals of a drug company is to extend the patents it already has on the medicines which are the most profitable, so-called 'blockbuster drugs'⁴⁵⁰. Blockbuster drugs are produced in very high volume, for chronic conditions predominantly prevalent

⁴⁴⁸ Neglected diseases are diseases which predominantly affect the developing world and where countries ordinarily cannot afford the high prices of the newer medicines. This has led to drug companies focusing their research and development on other diseases affecting developed countries which are capable of paying their high prices.

⁴⁴⁹ Note 246 above.

⁴⁵⁰ R M Scheffler, V Panthania 'Medicines and Vaccines for the World's Poorest: Is there any Prospect for Public-Private Cooperation' Available at: <http://www.globalizationandhealth.com/content/1/1/10#B12> Date viewed: 21 July 2008.

in rich countries which leads to extraordinary profits. In 2006 there were 114 drugs and each earned more than \$1 billion in sales⁴⁵¹. There are three blockbuster ARV drugs: Tenofovir; Kaletra and Combavir⁴⁵².

As discussed previously drug companies try to extend their patents through 'evergreening'. 'Evergreening' is done through developing minor but patentable variations that allow the extension of patents, as was discussed previously with regard to patent standards. This underlines why it is so important that countries adopt higher standards of patentability to exclude these types of exploitation.

a) Cost of pharmaceutical manufacture

Drug companies argue that they charge high prices in order to recoup their R&D costs. They argue that of every 5 000 medicines tested only one gets registered and, on average, only 3 out of 10 prescription drugs generate revenues that meet or exceed average R&D costs⁴⁵³. It also takes approximately 10 to 15 years to discover and develop new medicines leaving only a few years to recoup the money⁴⁵⁴. The 2006 Federal Trade Commission estimated the costs of the process was \$868 million; however roughly half of this is what is known as the 'opportunity costs of capital – what the money could have earned if it had been invested elsewhere instead of being spent on drug research'⁴⁵⁵. Only about 15 per cent of the total expenditure on a medicine is spent on R&D. The actual out-of-pocket loss is approximately \$ 248 million, but some researchers estimate this to be between \$71 million and \$ 118 million⁴⁵⁶.

⁴⁵¹ Ibid.

⁴⁵² B Baker in his presentation at a seminar on Access to Medicines held in July 2008 in Durban.

⁴⁵³ J A. Dimasi, R W Hansen, H G Grabowski 'The Price of Innovation: New Estimates of Drug Development Costs' Available at: <http://www.cptech.org/ip/health/econ/dimasi2003.pdf> 164 Date viewed 30 November 2008.

⁴⁵⁴ Note 422 above, 176.

⁴⁵⁵ Note 453 above, 164.

⁴⁵⁶ 'Critique of the DiMasi/Tufts Methodology and Other Key Prescription Drug R&D Issues' Congress Watch. Available at: http://www.tradewatch.org/congress/reform/drug_industry/r_d/articles.cfm?ID=6532 Date viewed: 12 December 2008.

Total global sales of pharmaceuticals in 2006 were \$643 billion⁴⁵⁷, with nearly half the sales made in the United States⁴⁵⁸. 31 per cent⁴⁵⁹ of medicines are sold in Europe; Africa, Asia and Australia (AAA) amount to 9.4 per cent, or \$ 62.2 billion⁴⁶⁰. AAA amounts to 72 per cent of the global population and use only 9.4 per cent of the drugs⁴⁶¹. With such a small percentage being sold in AAA it is clear that compulsory licences would not have the significant effects on profits that drug companies claim.

b) Cost components of generic manufacture

The generic industry is very diverse. The R&D of generics typically focuses on manufacturing efficiencies and formulations. The focus is on large production that runs at efficient economies of scale. Generic companies reverse-engineer an existing medicine rather than conducting their own research and development. For that reason their out-of-pocket R&D costs average \$1.5 million per drug⁴⁶². R&D comprises two to three per cent of the generic manufacturer's budget as opposed to 14 per cent of the original manufacturer's budget. There are no long period of preclinical and clinical studies, but they must develop evidence of Good Manufacturing Practice (GMP)⁴⁶³, stability and bioequivalency.⁴⁶⁴

⁴⁵⁷ 'News Releases: IMS Health Reports Global Pharmaceutical Market Grew 7.0 Per Cent in 2006, to \$643 Billion' Available at: <http://www.imshealth.com/portal/site/imshealth/menuitem.a46c6d4df3db4b3d88f611019418c22a/?vgnextoid=c16b1d3be7a29110VgnVCM10000071812ca2RCRD&vgnextfnt=default> Date viewed: 3 December 2008.

⁴⁵⁸ Ibid.

⁴⁵⁹ Ibid.

⁴⁶⁰ Ibid.

⁴⁶¹ Ibid.

⁴⁶² 'Canadian Generic Drug Sector Study' October 2007. 13 Available at: [http://www.competitionbureau.gc.ca/epic/site/cbbc.nsf/vwapj/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf/\\$FILE/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf](http://www.competitionbureau.gc.ca/epic/site/cbbc.nsf/vwapj/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf/$FILE/Competition%20Bureau%20Generic%20Drug%20Sector%20Study.pdf) Date viewed: 15 November 2008.

⁴⁶³ The WHO defines GMP as: 'Good manufacturing practice is that part of quality assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization. GMP is aimed primarily at diminishing the risks inherent in any pharmaceutical production, which may broadly be categorized in two groups: cross contamination/mix-ups and false labelling. Above all, manufacturers must not place patients at risk due to inadequate safety, quality or efficacy; for this reason, risk assessment has come to play an important role in WHO quality assurance guidelines.' Available at: http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html Date viewed: 7 December 2008

⁴⁶⁴ Note 462 above, 13.

Contrary to what drug companies argue compulsory licences in developing countries do not ordinarily undermine R&D incentives. This is, in part, due to the fact that the pharmaceutical market in all developing countries equals only 12.1 per cent of global pharmaceutical sales⁴⁶⁵.

II INCENTIVISING RESEARCH AND DEVELOPMENT FOR DISEASES PREDOMINANTLY AFFECTING DEVELOPING COUNTRIES AND HIV/AIDS

As demonstrated above, the pharmaceutical industry is profit-driven. It primarily conducts research and manufactures drugs for diseases where consumers can afford their excessive prices. This means that a number of diseases, such as tuberculosis, have not had any new drugs in many years because people infected with these diseases are not usually able to afford the medicine. In South Africa the HIV infection rate is particularly high but what is possibly more alarming is large number of HIV-positive people who are also infected with tuberculosis⁴⁶⁶. The presence of drug-resistant TB in South Africa is also worrying in light of the fact that drug companies are focusing their research and development on more lucrative diseases.

When exploring methods of bypassing patents and forcing drug companies to make their drug available more cheaply or for free it is important to remember that if pushed too hard the drug company may discontinue its research on HIV/AIDS medicine. They may then conduct research on medicines for diseases where they will have their patents respected and are able to charge high prices for their medicine.

The Drugs for Neglected Disease Initiative (DNDi) in 2003 examined the reasons for the crisis in research and development of drugs for neglected diseases. It argues that this is a result of a failure of both the market and public policy to promote drugs for neglected diseases. In discussing the failure of the market the DNDi explained:

⁴⁶⁵ Note 457 above, 3

⁴⁶⁶ 'Tuberculosis: HIV/TB Co-epidemic Rapidly Spreading in Sub-Saharan Africa. Available at: http://www.globalhealthreporting.org/article.asp?DR_ID=48620 Date viewed: 5 November 2008.

The vast majority of research and development of new drugs is conducted in the western world, mainly by the pharmaceutical industry, whose research agendas are largely defined by the potential return on investment and reflect market prospects rather than health needs. The populations of poorer nations have limited purchasing power and thus their diseases are ignored.⁴⁶⁷

With regard to public policy the DNDi stated:

In spite of visibly waning private sector interest, governments have been slow to take action against this global problem. In industrialized countries, public policy has long provided incentives such as patents, tax credits and health care insurance systems to encourage private-sector investments in drug research and development, but these rarely target neglected disease. Moreover, in spite of these incentives, there is a bias towards ‘me-too’ and lifestyle drugs for conditions such as impotence and baldness. Governments in less developed countries, on the other hand, are confronted with a combination of lack of financial resources, absence of willingness to invest in long-term health development, and failure to establish public policy incentives that foster a viable domestic drug development capacity.⁴⁶⁸

Countries and organisations must therefore take steps to incentivise research and development, in order to prevent pharmaceutical companies moving to more lucrative diseases. There are two types of mechanisms to incentivise research and development, namely push mechanisms and pull mechanisms.

a) **Push mechanisms**

These are strategies which are designed to push manufacturers to conduct research by providing them with incentives. These strategies include research grants, either of a public or private nature, and tax credits for expenses incurred through research and development⁴⁶⁹. Established in 1975, the purpose of the UNDP/World Bank/WHO Special Program for Training and Research in Tropical Diseases (TDR) is to address ten tropical diseases, namely: african trypanosomiasis; chagas disease; dengue fever; leishmaniasis; leprosy; lymphatic filariasis; malaria; onchocerciasis; schistosomiasis; and

⁴⁶⁷ ‘Intensified Control of Neglected Diseases Report of an International Workshop Berlin, 10–12 December 2003’ Available at: http://whqlibdoc.who.int/hq/2004/WHO_CDS_CPE_CEE_2004.45.pdf Date viewed: 10 December 2008, 3.

⁴⁶⁸ Ibid.

⁴⁶⁹ M Kremer ‘Public Policies to Stimulate Development of Vaccines and Drugs for the Neglected Diseases’ in Commission of Macroeconomics and Health Working Paper Series. Available at: http://www.cmhealth.org/docs/wg2_paper8.pdf Date viewed: 3 November 2008.

tuberculosis. They, in partnership with private entities, have created several new treatments for tropical diseases⁴⁷⁰.

Since the establishment of the TDR there have been a number of other public-private partnership specifically related to HIV/AIDS, tuberculosis and malaria. These partnerships make use of charitable funding and channel this money into existing research capacities in both the public and private sector. These partnerships include the International AIDS Vaccine Initiative, the Medicines for Malaria Venture and the Global Alliance for Tuberculosis Drug Development⁴⁷¹.

Due to a lack of market incentives for other neglected diseases the Drugs for Neglected Diseases Initiative was established in July 2003. Its aim is 'to harness accumulated knowledge and cutting-edge science and technology to develop critically needed drugs for neglected diseases, making sure they are suitable for and accessible to the poorer patients in the world'⁴⁷².

Push mechanisms are very useful in promoting basic research, which is often conducted in public laboratories and universities. Once this has been completed the information which looks promising is then licensed out to private firms which have the financial capacity to produce a medicine⁴⁷³. This research is risky and time-consuming to conduct because it may not yield profitable results⁴⁷⁴. Therefore by providing private manufacturers with this data, the manufacturers are more likely to manufacture a medicine for a neglected disease because much of the basic research has already been done.

⁴⁷⁰ Drugs for Neglected Disease Initiative 'DNDi: An Innovative Solution (DNDi Introductory Brochure)' Available at: www.dndli.org/cms/public_html/images/article268/An%20Innovative%20Solution.pdf Date viewed: 30 November 2008.

⁴⁷¹ Note 421 above, 28.

⁴⁷² Note 470 above, 5.

⁴⁷³ 'Incentivising research and development for the diseases of poverty' IPN Working Papers on Intellectual Property, Innovation and Health. Page 14 Available at <http://www.policynetwork.net/uploaded/pdf/IncentivisingRD.pdf> Date viewed: 11 December 2008.

⁴⁷⁴ Ibid.

Whilst push mechanisms are good at producing incentives for basic research, pull mechanisms are also needed in order to reward actual pharmaceutical development. South Africa has the ability to utilise both these mechanisms through organisations such as the Council for Scientific and Industrial Research (CSIR), which conducts research into a wide variety of areas including ARV⁴⁷⁵s. On 2 December 2008, the CSIR announced that it had developed a low-cost method of producing ARVs⁴⁷⁶.

b) Pull mechanisms

These strategies reward concrete research outcomes rather than basic research. One of the most successful of these is the advance purchase commitments (APC) schemes. This is a ‘donor-financed international advance commitments to purchase and distribute drugs and vaccines for neglected diseases’⁴⁷⁷. In order to ensure the credibility of the commitment there must be specific requirements for eligibility for drug purchases, such as the level of efficacy, safety, quality and cost-effectiveness⁴⁷⁸.

There are limitations to APCs such as the difficulty in deciding what the desired results are ahead of time⁴⁷⁹. However, this difficulty may not be as problematic for neglected diseases or HIV/AIDS as they are well known. This type of research is very expensive⁴⁸⁰ and, in order to have the desired result, provision ought to be made for an increase in the value of the commitment⁴⁸¹. A second limitation is the fact that, to ensure the commitment’s credibility, there must be a guarantee of market exclusivity in order to

⁴⁷⁵ ‘CSIR has way to make ARVs locally’ Daily News 2 December 2008 3. Available at: <http://www.dailynews.co.za/index.php?fArticleId=4742491> Date viewed: 2 December 2008.

⁴⁷⁶ Ibid.

⁴⁷⁷ Note 421 above, 29.

⁴⁷⁸ M Kremer ‘Public Policies to Stimulate Development of Vaccines and Drugs for the Neglected Diseases’ in Commission of Macroeconomics and Health Working Paper Series. Available at: http://www.cmhealth.org/docs/wg2_paper8.pdf Date viewed: 3 November 2008.

⁴⁷⁹ ‘Incentivising research and development for the diseases of poverty’ IPN Working Papers on Intellectual Property, Innovation and Health. Page 14 Available at <http://www.policynetwork.net/uploaded/pdf/IncentivisingRD.pdf> Date viewed: 11 December 2008.

⁴⁸⁰ Kremer argues that \$ 250 million per year over ten years will be the cost of research. M Kremer ‘Public Policies to Stimulate Development of Vaccines and Drugs for the Neglected Diseases’ in Commission of Macroeconomics and Health Working Paper Series. Available at: http://www.cmhealth.org/docs/wg2_paper8.pdf Date viewed: 3 November 2008.

⁴⁸¹ Note 478 above, 81 - 82.

create financial viability⁴⁸². This may lead to price increases due to a lack of generic competition. However, the possibility of APCs for an AIDS vaccine is being explored by the International AIDS Vaccine Initiative (IAVI). The IAVI said ‘the commitment would “pull” on industry to engage in vaccine research and would complement existing “push” mechanisms such as funded research in academic labs and biotechnology companies. To make the concept successful, the global health community must also work on removing barriers to vaccine research across a range of issues, including clinical trials, intellectual property, and liability.’⁴⁸³

The other pull mechanisms include the use of patents buyouts, where the patent holder sells its patents to other manufacturers; and extending patents rights on other drugs to compensate companies for the successful development of drugs for neglected diseases⁴⁸⁴. However, both these options have significant weaknesses. With regard to patent buyouts the original manufacturer may still maintain its monopoly as it still has its trade secrets regarding the processes⁴⁸⁵. The extension of patents as compensation merely shifts the financial burden onto other people rather than keeping it with the State⁴⁸⁶. In light of this the use of APCs is the most beneficial pull mechanism.

c) Orphan Drug Laws

The US has an Orphan Drug Act of January 1983 designed to stimulate research and development for ‘drugs with high therapeutic but low economic value to treat so-called orphan diseases of national public health importance’⁴⁸⁷. The Act offers four push

⁴⁸² ‘Incentivising research and development for the diseases of poverty’ IPN Working Papers on Intellectual Property, Innovation and Health. Page 15 Available at <http://www.policynetwork.net/uploaded/pdf/IncentivisingRD.pdf> Date viewed: 11 December 2008.

⁴⁸³ C. Zandonelle ‘If you build it, they will pay’ International AIDS Vaccine Initiative. IAVI Report 13 June 2005. Available at: <http://www.iavireport.org/Issues/Issue9-3/apc.asp> 1. Date viewed: 1 December 2008.

⁴⁸⁴ Note 478 above.

⁴⁸⁵ Note 421 above, 30.

⁴⁸⁶ ‘Incentivising research and development for the diseases of poverty’ IPN Working Papers on Intellectual Property, Innovation and Health. Page 15 Available at <http://www.policynetwork.net/uploaded/pdf/IncentivisingRD.pdf> Date viewed: 11 December 2008.

⁴⁸⁷ C Milne, K Kaitlin, E Roncti, ‘Orphan Drug Laws in Europe and the US: Incentives for the Research and Development of Medicines for the Diseases of Poverty’ http://www.cmhealth.org/docs/wg2_paper9.pdf referred to in Note 319 above, 35.

incentives and a pull incentive to manufacturers conducting orphan disease research and development. The push incentives include:

- (1) Technical and administrative assistance provided by the FDA;
- (2) FDA grants to cover clinical trial expenses;
- (3) FDA registration fee waivers; and
- (4) Tax credits for clinical development costs.⁴⁸⁸

The pull mechanism is a 'seven-year period of FDA exclusivity against all subsequent therapeutically equivalent drugs'⁴⁸⁹.

South Africa has a fledgling pharmaceutical industry; if the South African government were to promulgate similar legislation it would provide incentives for manufacturers to also conduct AIDS and related infection research. The use of push and pull mechanisms would stimulate research in both the public and private sector which would also bolster South Africa's capacity to manufacture pharmaceuticals. The benefits of these mechanisms can be seen in the fact that the CSIR has found a way to manufacture ARVs more cheaply. This breakthrough illustrates the positive effects the use of these mechanisms has on research and development as well as on South Africa's pharmaceutical manufacturing capacity.

⁴⁸⁸ Note 421 above, 31.

⁴⁸⁹ Note 487 above.

CHAPTER 8: THE CREATION OF A PATENT POOL

Possibly the most positive international step on the road to universal access to anti-retrovirals was the decision by the Executive Board of UNITAID⁴⁹⁰, on 9 July 2008 to ‘approve the principle of establishing a patent pool’⁴⁹¹. This initiative’s focus will be on the creation of more paediatric ARVs and new combinations at affordable prices⁴⁹² which are two important areas for South Africans. The approval marks a major advancement in the battle to provide sustainable access to medicine across the world. Should South Africa join the HIV/AIDS patent pool it will, as a country with a high HIV infection rate, benefit from the lowest royalty payments. It will also be able to utilise the patents in the pool thereby bolstering its pharmaceutical manufacturing capacity, which is fundamental to the creation of robust domestic health care system.

A patent pool is ‘an agreement between two or more patent owners to aggregate their patents and to license them to one another or to third parties’⁴⁹³. The system is used in both the public and private sector to enable patent holders put their patent into a pool. This allows other pharmaceutical manufacturers to access them in exchange for the payment of royalties⁴⁹⁴. The use of a patent pool is unlike a donation programme because the patent owners not only get royalties but are also allowed to use the patents of other patent owners, also in exchange for royalties. As will be established in this Chapter, the creation of a patent pool for ARVs is mutually beneficial for both the patent holder and the generic manufacturer. It also leads to greater generic competition because more manufacturers are able to produce the same drug, leading to lower prices, which will be very beneficial for those in desperate need of these medicines. This competition is the

⁴⁹⁰ UNITAID is an international drug purchase facility designed to provide access to drugs and diagnostics to fight AIDS and neglected diseases for people who need them most.

⁴⁹¹ Note 28 above.

⁴⁹² Ibid 3.

⁴⁹³ ‘IGWG Briefing Paper on Patent Pools’ Knowledge Ecology International. 1. Available at: http://www.keionline.org/index.php?option=com_content&task=view&id=65&Itemid Date viewed: 17 August 2008.

⁴⁹⁴ ‘Taking the Plunge: How a Patent Pool Could Help Solve the Access to Medicines Crisis’ Doctors Without Borders. Available at: <http://www.doctorswithoutbodies.org/events/symposiums/2008/aids/news/?id=2870> Date viewed: 15 August 2008.

fundamental idea behind a patent pool. It is achieved through the provision of ‘more efficient and effective mechanisms for the voluntary or compulsory licensing of patents to generic supplies’⁴⁹⁵.

A well-known patent pool was created in 1917 by the United States Government to address its need to manufacture airplanes⁴⁹⁶. The manufacture had previously been stifled⁴⁹⁷ by the large number of patents which were held by a few manufacturers⁴⁹⁸. This patent pool enabled the United States Government to significantly reduce the costs of production and led to a massive increase in innovation⁴⁹⁹.

Patent pools are also created in the private sector. They have been used to good effect in the fields of technology, such as radio, DVD and MPEG-2 compression technology⁵⁰⁰. Rapid growth has followed in these areas as a result of patent pools. In the pharmaceutical sector a patent pool for the severe acute respiratory syndrome (SARS) vaccine is being developed through a joint initiative of the WHO SARS Consultation Group and key SARS intellectual property owners⁵⁰¹. This group has advised that, as a result of a multiplicity⁵⁰² and restriction of patents, innovation is significantly hampered, which is why the use of patent pools especially for developing countries is so important.

A patent pool is an independent entity⁵⁰³ which would be created by its sponsors. It is managed by a Board of Directors, which includes representatives from national governments and public health groups⁵⁰⁴. The Board of Directors will develop a list of essential patents needed to produce ARVs which will be put into the pool, in terms of

⁴⁹⁵ Note 493 above, 3.

⁴⁹⁶ Essential Patent Pool for AIDS (EPPA) Background information. Essential Inventions inc. Available at: <http://www.essentialinventions.org> 2. Date viewed: 12 August 2008.

⁴⁹⁷ A report issued by the US Navy directed by Franklin Roosevelt found that, ‘the development of the aircraft industry in the United States was seriously retarded by the existence of a chaotic situation concerning the validity and ownership of important aeronautical patents. This situation was one of great concern to the Government of the United States...’

⁴⁹⁸ Note 496 above, 2.

⁴⁹⁹ Ibid.

⁵⁰⁰ Ibid.

⁵⁰¹ Ibid.

⁵⁰² Ibid.

⁵⁰³ Ibid 3.

⁵⁰⁴ Ibid 3.

their Memoranda of Understanding⁵⁰⁵. Thereafter the directors attempt to enter into voluntary agreements with the patent holders where they will contribute their patents to the pool. These agreements will include the specific terms and conditions governing both parties⁵⁰⁶.

Should the negotiations prove unsuccessful the directors may then seek compulsory licences from the countries which are members of the pool. The countries that join the patent pool must agree to issue licences to any supplier⁵⁰⁷ to manufacture, import and export products as well as to lower barriers to entry for new pharmaceutical companies.

Essential Inventions Inc suggested the use of the 'Equitable Royalty Method'⁵⁰⁸ to determine the remuneration for each product. It is similar to the Tiered Royalty Method (TRM) discussed in Chapter 4 under adequate compensation for Article 31 compulsory licences. This is based on 'the relative therapeutic benefits of products, the affordability of royalties in countries depending upon average incomes and the extent of the HIV/AIDS infection'⁵⁰⁹.

The Equitable Royal Method creates three tiers of royalty payments. The first tier is for countries which are designated as high income by the World Bank, namely Canada, France, Germany, Italy, Spain, the United Kingdom and the United States⁵¹⁰. The base royalty is 4 per cent of the median price of the product in the high-income countries⁵¹¹. The second tier is for countries that are not designated high income and where the HIV/AIDS infection rate is no higher⁵¹² than the average rate for high-income countries. In this tier the royalty payment is calculated as 'the base royalty, multiplied by the

⁵⁰⁵ Note 28 above, 3.

⁵⁰⁶ Note 496 above, 3.

⁵⁰⁷ Ibid.

⁵⁰⁸ Ibid 4.

⁵⁰⁹ Ibid.

⁵¹⁰ Ibid.

⁵¹¹ Ibid.

⁵¹² Ibid.

fraction that is the ratio of that country's per capita GDP, divided by the average per capita GDP for all high-income countries'⁵¹³.

The third tier is for sales of a product in a country not designated as high income but which 'has an HIV/AIDS infection rate *higher* than the average rate' for countries designated as high income⁵¹⁴ (emphasis added). In this case the royalty payment is established by multiplying the base royalty by the fraction 'that is the ratio of that country's GDP per person infected with HIV/AIDS, for all high-income countries'⁵¹⁵.

The creation of a patent pool has a number of very important effects especially in the fields of HIV/AIDS medicine. This can be seen in the manufacture of FDCs antiretrovirals. These are vital in Africa where patient adherence to their ARV regimen is low due to the vast number of tablets to be taken at different times of the day⁵¹⁶. By decreasing the number of tablets through FDCs patient adherence is likely to increase⁵¹⁷. However, generic manufacturers are the only manufacturers which have been manufacturing such medicines due to their bypassing of patents.⁵¹⁸ A patent pool will give all members the opportunity to create FDCs, including combinations with the latest medicines which still have a long period of patent protection. A patent pool will also benefit national governments seeking to develop a robust generic manufacturing capacity because these governments will have access to technical assistance from the patent pool⁵¹⁹.

A patent pool for HIV/AIDS medicine will also lead to significant price reduction in newer medicines. Doctors Without Borders highlights the urgent need for such price reductions:

⁵¹³ Note 377 above, 4.

⁵¹⁴ Ibid.

⁵¹⁵ Ibid.

⁵¹⁶ 'Fixed dose combination ARV for children available' Available at: <http://www.essentialdrugs.org/edrug/archive/200707/msg00032.php> Date viewed: 4 December 2008.

⁵¹⁷ Ibid.

⁵¹⁸ 'Impending flop for Brand Antiretrovirals in the Emerging Market' Available at: <http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2556197> Date viewed: 5 December 2008.

⁵¹⁹ Note 493 above, 4.

The prices of AIDS medicines are on the rise again. The cheapest improved first-line fixed-dose combination recommended by the WHO costs MSF USD 613 per patient per year and can cost up to USD 1 033. That compares with a price of USD 87 for the previous recommended first-line AIDS treatment. With increasing numbers of AIDS patients failing on their first-line therapy, there is also an urgent need to find affordable second-line treatments too.⁵²⁰

Although the patent pool for HIV/AIDS medicine is still under construction, the decision by the Executive Board of UNITAID to create a patent pool is a major advancement in the battle to provide sustainable access to medicine across the world. South Africa will benefit from the lowest royalty payments which means that South Africa will have the lowest price to pay for HIV/AIDS medicines. South Africa's pharmaceutical manufacturers, such as Aspen Pharmacare and Thembalani, would be able to utilise the patents in the pool as they have the capacity to manufacture ARVs⁵²¹. This will bolster their pharmaceutical manufacturing capacity.

⁵²⁰ 'UNITAID gives green light to patent pool' Campaign for access to essential medicines. Available at: <http://www.accessmed-msf.org/main/medican-innovation/unitaid-gives-green-light-to-patent-pool-htm>
Date viewed: 20 August 2008.

⁵²¹ Available at: <http://www.aspenpharma.com> Date viewed: 8 October 2008.

CHAPTER 9: THE USE OF FREE TRADE AGREEMENTS BY THE US

Free Trade Agreements (FTAs) are agreements between countries to offer each other favourable trade conditions, which are not made available to countries not party to the agreement. These agreements have a number of positive aspects⁵²²; however with regard to FTAs with the US these agreements often contain onerous intellectual property provisions, so-called TRIPS-plus provisions⁵²³.

Recently the United States of America has negotiated and concluded a number of bilateral and regional FTAs⁵²⁴. Originally the US used these agreements to 'advance the progressive opening of world markets and to create legally enforceable trade rules'⁵²⁵. However it has moved its focus to the establishment of strict standards for the protection of intellectual property rights. Its Trade Promotion Authority states that its objective was now to promote intellectual property rules that 'reflect a standard of protection similar to that found in United States law'⁵²⁶. These rules include all types of intellectual property instruments and mechanisms to enforce exclusive rights⁵²⁷, many of which are more onerous than those required by TRIPS. It is vital that South Africa avoids entering into

⁵²² South Africa signed a trade agreement with the European Union in October 1999. This Agreement is called the SA-EU Trade Development and Cooperation Agreement (TDCA). This Agreement has had a positive effect on a number of aspects of trade between South Africa and European Union especially in the area of fresh produce. This Agreement did not contain adverse trade conditions for medicines, unlike FTAs with the US. 'Update on Trade Negotiations:: SA-EU Trade Development and Cooperation Agreement (TDCA)' Available at: http://www.nda.agric.za/docs/TDCA_May_2006.doc Date viewed: 22 September 2008.

⁵²³ L Bartels, F Ortino, eds 'Regional Trade Agreements And The WTO Legal System' (2006) *Oxford University Press*, 215. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=947767 Date viewed: 12 December 2008.

⁵²⁴ The US has recently concluded FTAs with Vietnam, Jordan, Singapore, Chile, Morocco and Australia. Carsten Fink & Patrick Reichenmiller 'Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements' The World Bank Group Trade Note 20. 1 Available at: http://www.ds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2005/04/22/000090341_2005042213528/Rendered/PDF/321110TradeNote20.pdf Date viewed: 11 December 2008.

⁵²⁵ Ibid 1.

⁵²⁶ Bipartisan Trade Promotion Authority Act of 2002, available at: <http://www.tpa.gov> Date viewed: 2 September 2008.

⁵²⁷ Note 139 above, 1.

one of these agreements because it will significantly curtail the use of all the flexibilities contained in TRIPS, the Department of Health's policies and the Patents Act.

In 2002 Robert Zoellick, the US Trade Representative, outlined the objectives of the talks regarding the need to address barriers to US exports in South African Customs Union (SACU)⁵²⁸ countries. He highlighted 'high tariffs on certain goods, overly restrictive licensing measures, inadequate protection of intellectual property rights, and restrictions the SACU governments impose that make it difficult for our services firms to do business in these markets'⁵²⁹.

I SPECIFIC REQUIREMENTS IN INTELLECTUAL PROPERTY PROTECTION IN FTAS

a) Patent extensions

The length of patent protection is the same as required by TRIPS, namely 20 years⁵³⁰. However provision is made for extensions of the patent terms when there are delays in the regulatory approval process⁵³¹ or delays in the actual patent granting stage. Patent extensions would be detrimental to sustainable access to medicines in South Africa and its creation of a robust pharmaceutical manufacturing capacity. This is due to the fact that the newer ARVs would be subject to extended patents which would delay the manufacture of generic versions. This situation would be exacerbated if other generic manufacturers such as Brazil and India were not subject to a similar FTA and therefore were able to produce the medicine before South Africa.

b) Scope of patentability

In the United State's FTAs with Australia, Bahrain and Morocco, the scope of patentability allowed the patenting of a new use of known inventions. As discussed

⁵²⁸ The countries party to the South African Customs Union are Botswana, Lesotho, Namibia, Swaziland and South Africa.

⁵²⁹ R Zoellick 'Letter to Senator Byrd' November 2002 Available at: <http://www.mindully.org/wto/Africa-Zoellick-Trade4nov02.htm> Date viewed: 1 October 2008.

⁵³⁰ Article 33 of TRIPS.

⁵³¹ Note 139 above, 2.

previously in Chapter 3, the patenting of new uses allows the patent holder to abuse a country's patent system. In a similar manner to patent extensions, they also shut out generic manufacture which is vital in South Africa for its development of a thriving pharmaceutical manufacturing industry.

c) Use of compulsory licences

The use of compulsory licences is provided for in Articles 31 and 40 of TRIPS. Whilst TRIPS provides a guide it does not set out the circumstances under which a compulsory licence may be issued, allowing each country to determine its own grounds⁵³². Under an FTA the US seeks to limit the use of compulsory licences to just emergency situations, to remedy anticompetitive practices, and to the case of public non-commercial use⁵³³. In the trade negotiations between the US and the SACU the US sought terms limiting the use of compulsory licences as well as a bar on parallel importation⁵³⁴. These limitations would mean that South Africa would not be able to develop its own generic pharmaceutical manufacturing capacity, and would also run the risk of adverse trade effects should South Africa issue a compulsory licence and the US dispute its validity. Signing an FTA with such a provision would effectively mean that South Africa would not be able to use compulsory licences against US medicines because the US has an interest in preventing this. The problem is compounded by the fact that the US produces a significant percentage of medicines.

d) Data exclusivity

In order to register a drug the manufacturer must submit data establishing the safety and efficacy of the drug⁵³⁵. In FTAs the US seeks to protect this data for a period of five years. This effectively excludes generic competition because compilation of the

⁵³² N A Bass 'Implications of the TRIPS Agreement for developing countries: Pharmaceutical patent laws in Brazil and South Africa in the 21st century' (2002) *George Washington International Law Review* Page 6. Available at:

http://findarticles.com/p/articles/mi_qa5433/is_200201/ai_n21309524/pg_1?tag=artBody:col1 Date viewed: 10 December 2008.

⁵³³ Note 139 above.

⁵³⁴ B Baker 'US Trade negotiations with the South Africa Customs Union undermine access to medicines and violate US Law' *HEALTH GAP* July 2003 Available at:

<http://www.cptech.org/ip/health/trade/sacu/hgap07072003.html> Date viewed: 3 November 2008.

⁵³⁵ Note 139 above.

necessary test data will take several years and is very expensive⁵³⁶. In FTAs with Australia, Bahrain and the Dominican Republic and Central American, data exclusivity applied automatically in all FTA jurisdictions⁵³⁷. Data exclusivity would result in the end of both the manufacture and importation of generic medicines, which would mean that South Africans would be dependent on the philanthropy of the manufacturer to provide medicines at a lowered price. In previous US-SACU FTA negotiations the US has made it clear that it requires such data exclusivity⁵³⁸.

e) **Parallel importation**

The FTAs in Australia, Morocco and Singapore provide that a patent holder may prevent parallel importation through contractual means. Parallel importation is a vital mechanism to lower the price of a medicine, which is why the US wishes to ensure the South African government is not able to use it.

These provisions are more restrictive than required by TRIPS and are known as TRIPS-plus provisions. The TRIPS-plus provisions outlined above significantly constrain a government's rights to access medicines. In answer to criticisms that US FTAs are contrary to TRIPS and the Doha Declaration, the General Counsel of the US Trade Representative (USTR), in 2004, stated:

... if circumstances ever arise in which a drug is produced under a compulsory licence, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data protection provision in the FTA would not stand in the way... As stated in the side letter, the letter constitutes a formal agreement between the Parties. It is, thus, a significant part of the interpretive context for this agreement and not merely rhetorical. According to Article 31 of the Vienna Convention on the Law of Treaties, which reflects customary rules of treaty interpretation in international law, the terms of a treaty must be interpreted 'in their context,' and that 'context' includes 'any agreement relating to the treaty which was made between all the parties in connection with the conclusion of the treaty.'⁵³⁹

⁵³⁶ Note 139 above.

⁵³⁷ Ibid.

⁵³⁸ Note 534 above.

⁵³⁹ 'Letter from USTR General Counsel John K Veroneau to Congressman Levin dated July 19 2004 Available at:

This policy was reiterated, in May 2000, by then President Bill Clinton in his Executive Order 13155, which stated:

Section 1. Policy.

(a) In administering sections 301-310 of the Trade Act of 1974, the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the President, that regulates HIV/AIDS pharmaceuticals or medical technologies if the law or policy of the country:

- (1) promotes access to HIV/AIDS pharmaceuticals or medical technologies for affected populations in that country; and
- (2) provides adequate and effective intellectual property protection consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) referred to in section 101(d)(15) of the Uruguay Round Agreements Act (19 U.S.C. 3511(d)(15)).

(b) The United States shall encourage all beneficiary sub-Saharan African countries to implement policies designed to address the underlying causes of the HIV/AIDS crisis by, among other things, making efforts to encourage practices that will prevent further transmission and infection and to stimulate development of the infrastructure necessary to deliver adequate health services, and by encouraging policies that provide an incentive for public and private research on, and development of, vaccines and other medical innovations that will combat the HIV/AIDS epidemic in Africa.

Although this is a positive sign by the US that it will not institute similar provisions to those discussed above, Executive Orders can be rescinded and it may be too great a risk for South Africa to enter into an FTA with the US⁵⁴⁰.

The discussion above clearly demonstrates why an FTA with the US ought to be avoided, as it would completely undo all the work done by civil society movements and the Legislature to ensure access to medicines. Although the negotiations between the US and the SACU have been unsuccessful, it is important that an FTA is not signed with America if it includes TRIPS-plus provisions. The effects of these provisions would be to 'completely eviscerate the Doha flexibilities, dramatically increase IP protection, and shamefully reduce access to more affordable generic products'⁵⁴¹. In addition, the South

http://www.wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2005/04/22/000090341_20050422135028/Rendered/INDEX/321110TradeNote20.txt Date viewed: 3 December 2008.

⁵⁴⁰ Note 534 above.

⁵⁴¹ Note 540 above.

African Department of Trade and Industry must ensure that South Africa is not party to an FTA as part of SACU.

CHAPTER 10: OTHER FACTORS CONSTRAINING ACCESS TO ARVS

Patents and the high price of ARVs are not the only factors constraining access to medicines. However my focus has been on those two factors because there are legal mechanisms to bypass their effect. In South Africa, and other developing countries, there are a number of other problems with access to medicines. Although the solutions to these factors lies outside the scope of this dissertation, these areas also need to be rectified in order to ensure the drastic improvements in the health care sector needed to increase access to medicines. The problems in the health care sector are outlined in the interests of presenting the issue of ARV access in its full context.

I INFRASTRUCTURE

Infrastructure does not just include buildings and equipment but also appropriately trained medical personnel. In South Africa, especially, a lack of medical personnel, including doctors, nurses and pharmacists, is one of the greatest challenges in health care, although the situation has improved slightly due to the creation of a mandatory two-year community service for recently graduated doctors⁵⁴². However, this improvement has been hampered by the attrition into the private sector, as is clear from the fact that only 31.5 per cent of the nurses trained in South Africa between 1996 and 2004 registered with the South African Nursing Council.⁵⁴³ This is likely to hinder the Department of Health's ability to launch a more nurse-centred ARV rollout⁵⁴⁴.

Other problems relating to infrastructure can be seen in rural areas where there are insufficient laboratory facilities, which are fundamental to the monitoring of the progression of HIV/AIDS as well as the administering of ARVs. In remote rural areas there is also a problem of stockouts of medicines due to the lack of a sustained supply, resulting in patients defaulting on their treatment or having to travel to another clinic or

⁵⁴² N Nattrass, 'South Africa's "Rollout" of Highly Active Antiretroviral Therapy: a Critical Assessment'. *Centre for Social Science Research Working Paper No. 158*, 18.

⁵⁴³ *Ibid* 18.

⁵⁴⁴ *Ibid*.

hospital in order to receive their medicines⁵⁴⁵. Travelling may not always be possible as the patients may not be physically capable. This is especially so in the rural areas where patients have long distances to travel for medical treatment. In Namakwa, for example, patients have to travel 400 kilometres to Upington in order to receive the more sophisticated treatments⁵⁴⁶. The problem is compounded by the fact that there is only one ambulance to service the whole area⁵⁴⁷. Further challenges to the roll-out of ARVs are the storage and maintenance of the temperature stability of ARVs.

II PRICES AND FINANCING

Donor funding is essential in order to provide access to medicines. Although developing countries have greatly increase their resource allocation many low-income countries are not capable of shouldering this burden alone. This is demonstrated by the fact that in some countries the average annual expenditure on drugs is less than two dollars per person⁵⁴⁸. Therefore, in such circumstances, even if all medicines were sold at their marginal cost the prices would still be too high for many countries⁵⁴⁹, hence the need for donor funding.

Although it may not be a complete solution for certain countries, lowering the costs of medicines is still important to ensuring sustainable access to medicines. Measures to achieve lower prices have been discussed in previous chapters. In some countries tariffs and duties are added to the prices of medicines by their governments to generate tax revenue. These taxes range between ten and thirty per cent⁵⁵⁰ and are used by countries such as Nigeria, Kenya, Ghana, Burkina Faso and India⁵⁵¹.

⁵⁴⁵ Note 98 above, 34.

⁵⁴⁶ Ibid.

⁵⁴⁷ Ibid 42.

⁵⁴⁸ A. Attaran 'How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?' (2004) 23:3 *Health Affairs* 155, 159.

⁵⁴⁹ Note 421 above, 11.

⁵⁵⁰ Ibid 12.

⁵⁵¹ C. Grace, 'Equitable Pricing of Newer Essential Medicines for Developing Countries: Evidence of the Potential of Different Mechanisms' (2003) 1.

It is clear that ensuring access to medicines will require a significant amount of money. A complete solution is going to take time to achieve, and will require the wholehearted cooperation of the South African government. The reduction in the price of medicines will assist in providing full-scale access because it will free up some of the country's budget for improving aspects of health care services which are in desperate need, as discussed above.

CHAPTER 11: CONCLUSION AND RECOMMENDATIONS

In South Africa, where 1 000 people die of AIDS everyday⁵⁵² and 100 000 more people require ARVs every year⁵⁵³, the need for solutions to access to ARVs and other essential medicines grows more urgent every day. Whilst the South African government is enjoined by section 27(1) of the Constitution to provide access to medicines, it is only expected to take reasonable legislative and other measures to ensure access to health care. The government argues that it lacks the resources to do more and, because the courts do not enter into an in-depth assessment of government policy, its policies to some extent go unchallenged by the judiciary. This deference to the powers of the Executive is in accordance with the doctrine of separation of powers. However, in circumstances as urgent as a lack of proper access to ARVs it may be time for the Courts to play a more active role in ensuring the government's compliance with the Constitution. For the purposes of providing ARVs in accordance with the requirements of section 27, the Court may be able to issue a mandatory order compelling the State to implement its policies on drug procurement.

A number of solutions are already available in South Africa's legislation; however, due to a lack of political will, they have not been properly implemented. It is vital that the government utilises these strategies fully, in the manner recommended in this dissertation, in order to ensure access to medicines in the short and medium term, as well as creating a developed pharmaceutical manufacturing capacity which is the ultimate solution to ensure affordable medicines, especially ARVs, for all South Africans. The use of these solutions by other middle-income countries such as India, Brazil and Thailand demonstrates what can be done when the flexibilities in TRIPS are fully utilised, patents standards are high and, most importantly, the State is actively involved in a positive way.

⁵⁵² Note 6 above.

⁵⁵³ Note 114 above, 29

South Africa's ARV policy has been stymied by a lack of political will and cooperation but there are signs that this may be about to change. Barbara Hogan was appointed Minister of Health in September 2008, when Kgalema Motlanthe became President of South Africa. Hogan has repeatedly affirmed her commitment to speeding up the provision of ARVs and has also been involved in the recent HIV Vaccine Conference where she indicated the Department's commitment to achieving the targets of the National Strategic Plan⁵⁵⁴. It is hoped that Hogan's appointment marks the turning point in the South African government's commitment to solutions in the area of HIV/AIDS⁵⁵⁵.

This commitment will, ideally, lead to South Africa playing a more active role in international initiatives surrounding HIV/AIDS, for example in research initiatives such as the DNDi which would boost the pharmaceutical manufacturing capacity. The development of a sophisticated pharmaceutical manufacturing capacity capable of producing complex medicines such as ARVs is vital to ensuring sustainable and affordable access to medicines. This is demonstrated by the fact that both India and Brazil have created robust health care systems and universal access to ARVs through their ability to manufacture generic versions of these medicines.

From this dissertation I have a number of recommendations, which are discussed below:

I PATENT STANDARDS

The South African Legislature has promulgated patent requirements in line with the requirements of TRIPS. The Patent Act contains high standards in order to comply with the requirements of inventive step and novelty. These standards are essential to ensure that its patent system is not subject to abuse from drug manufacturers who seek to patent a second use of their medicine or patent a combination of medicines already been patented. These standards need to be maintained as they will continue to provide space

⁵⁵⁴ 'Hogan wants a new approach to AIDS' Available at: <http://www.thetimes.co.za/SpecialReports/RightToKnow/Article.aspx?id=862537> Date viewed: 4 December 2008.

⁵⁵⁵ Hogan has already demonstrated her commitment to ARVs, when she provided the Free State's Health Department with R9.5 million to address its shortage of ARVs. Available at: http://www.news24.com/News24/South_Africa/Aids_Focus/0,,2-7-659_2425375,00.html Date viewed: 8 December 2008.

for other generic pharmaceutical manufacturers: if a medicine is not granted a patent in South Africa manufacturers in South Africa are free to manufacture the identical medicine.

II AMENDMENTS TO THE PATENTS ACT

Whilst the high standards of patentability in the Patents Act are important, section 56(1) should be amended to allow civil society movements to be included as an 'interested party'. Section 56(1) states 'any interested person who can show that the rights in a patent are being abused may apply to the commissions in the prescribed manner for a compulsory licence under a patent'. To be an interested person they must show that they are in the business of drug manufacture or importation, which excludes civil society movements. In South Africa such exclusion creates an unnecessary obstacle to the application for a compulsory licence because there are not many companies which are involved in the manufacture or importation of medicines. Civil society movements have played a vital role in other areas of access to medicines strategies, involving Competition Law and other court challenges. Their exclusion significantly hinders the use of compulsory licences under section 56.

The South African Legislature should also include in the Patents Act a provision similar to section 2 (1)(j) of the Indian Patent Act. The inclusion of this section would create a presumption of non-patentability which would require the manufacturer to rebut this presumption. This and others sections in the Indian Patent Act have been instrumental in ensuring that India maintains and increases its pharmaceutical manufacturing capacity. Its inclusion of such a provision would significantly strengthen South Africa's patent standards in the are of medicines.

III GOVERNMENT-USE COMPULSORY AND 30 AUGUST LICENCES

The proper use of compulsory licences by the South African government is of the greatest importance in ensuring access to medicine, especially in light of the fact that all twelve of the ARVs on the World Health Organisation's Essential Medicines List are protected in South Africa by our patent laws. Initially the government will have to utilise the

compulsory licences under the 30 August 2003 Decision because it lacks the pharmaceutical capacity to produce certain ARVs needed locally and is likely to need a greater quantity than allowed by Article 31(k) of TRIPS, especially for ARVs due to the high number of people needing these medicines.

However, in order to issue compulsory licences more easily and quickly the South African Legislature will need to pass legislation which gives a clearer meaning to the ambiguities contained in Article 31 of TRIPS and Paragraph 5 (c) of the Doha Declaration. The most important of these ambiguities is the definition of what amounts to a 'national emergency or matter of extreme urgency'. This definition is important in order to prevent a challenge by a patent holder disputing the existence of such an emergency. Clearer guidance on this provision will also afford civil society movements and other interested parties a stronger footing when lobbying the Minister of Health to issue a compulsory licence. It will also make it easier for a court to determine whether the Minister has complied with his or her obligations.

Ambiguities also arise in the determination of what amounts to adequate remuneration for royalty payments. Whilst possible methods of determining these payments were discussed in Chapter 4 of this dissertation, it is the Legislature's responsibility to provide clear guidance to its interpretation. A further ambiguity involves the interpretation of what constitutes a reasonable period of time for negotiations. This ambiguity allows the patent holders leeway to abuse the system, in that they are able to stall negotiations until the patent expires, or challenge a compulsory licence on the basis of a lack of a reasonable period of time for negotiations. Defining these requirements in legislation will expedite the procedures and also allow for more uniform judicial adjudication on a challenge as the manner in which the Article ought to be interpreted would then be clear.

IV COMPETITION-BASED COMPULSORY LICENCES

These licences should be used more often especially in circumstances where a patent holder refuses to conclude a voluntary licence with another manufacturer. Compulsory licences issued to remedy anticompetitive practices, in particular, are the easiest to use of

the flexibilities in TRIPS, as the South African patent legislation has specific provision for this kind of compulsory licences. This also is a well-established area of law, which has been used successfully in the area of ARVs, where the pharmaceutical manufacturers decided to offer voluntary licences rather than allow the matter to proceed to the Competition Tribunal, after the adverse decision made by the Competition Commission. Nor are these licences subject to a number of the more time-consuming requirements of the TRIPS Agreement, namely the requirements of prior negotiation, or the presence of a national emergency, and the limitation of the period of a licence as well as a limitation on the quantity of medicine allowed to be exported. The absence of these hurdles means that this licence is ideal for the South African context, especially for ARVs.

V DIFFERENTIAL PRICING

The use of differential pricing would allow the government to access medicines at a much lower price. The South African market has the disparity between the rich and poor required to properly segment the market in order to achieve differential pricing. It is beneficial for all parties including patent holders, because they have access to a wider market as it now includes those who could only afford the lowered prices. It is also advantageous to patients because they access their much-needed medicines at a greatly reduced price.

Significant reductions in the price of medicines can also be achieved through the use of bulk purchasing contracts. This could occur where South Africa and other countries, such as the SADC countries, collectively buy the medicines they need. Due to the increased volume, the pharmaceutical manufacturer will charge a lower price than if the countries had bought their medicines independently. Bulk purchasing agreements are also beneficial for the pharmaceutical manufacturer because they then have a large order which increases their economies of scale thereby increasing their profits.

VI RESEARCH AND DEVELOPMENT

When utilising the measures discussed above it is crucial that the State balance the use of these measures with programmes to incentivise research and development into neglected

diseases and HIV/AIDS. Such programmes will also be instrumental in ensuring the creation of the State's capacity to conduct its own research and development into new medicines, whilst also bolstering its domestic pharmaceutical manufacturing capacity. The incentive programmes involve both push and pull mechanisms.

Pull mechanisms are those that involve providing funding at the commencement of research for the research into medicines for neglected diseases, especially tuberculosis which is a significant problem in South Africa. These measures attract researchers to conduct the initial research into medicines, which is often the most expensive part of the research process.

Push mechanisms include mechanisms such as advanced purchase commitments. These occur where a State or donor agrees, before the medicine is developed, to purchase and distribute the medicines for a specific disease. Unlike pull mechanisms these purchase commitments reward actual discoveries rather than just the basic research, which means that this type of funding is likely to be preferred by donors who are looking for return on their investment. However, in concluding the advanced purchase commitment, both parties need to be clear about what their commitments are, such as the specifics of the medicine that they are looking for. This is essential in order to avoid a misunderstanding. The problem with this type of mechanism is that the funding is usually given once the research and development has already been conducted, which means that smaller research facilities are unlikely to be able to participate in such an agreement.

VII FREE TRADE AGREEMENTS

The South African government must guard against the signing of an FTA with the US or other countries if it contains TRIPS-plus provisions. Such an FTA will sabotage all the flexibilities discussed above. It will mean that South Africa is reliant on drug manufacturers to provide lower-priced medicines and will result in this country having almost no bargaining position at all from which to negotiate with the pharmaceutical companies.

By utilising the flexibilities listed above the South African government will lay the foundation for a strong pharmaceutical manufacturing capacity which is the ultimate solution to ensuring sustainable and affordable access to medicines. These flexibilities also provide for short- and medium-term access to medicines at greatly lowered prices so that the government can comply with its constitutional imperative of providing access to medicines.

The provision of cheaper medicines that are widely available in South Africa will have many positive consequences for other areas of HIV/AIDS care. Possibly the most important of these is the fact that lower prices mean that the government can afford newer ARVs such as FDCs and medicines with fewer side effects, which are beyond the resources of the government currently due to their high prices. A reduction in the side effects of ARVs will result in greater patient adherence, which is a significant problem with some of the medicines used by the government currently as patients feel too sick to continue taking their medicines. FDCs will also be instrumental in ensuring patient adherence as there are fewer medicines to take during the day and with greater intervals between dosages.

The Constitutional Court's involvement is essential in order to force the State to implement its own policies, which will include the other mechanisms discussed above. It is critical that the government implement these recommendations and begin to stem the tide of this disease by providing the 517 269⁵⁵⁶ people who did not receive ARV treatment in 2007 with the treatment that they are entitled to under the Constitution.

⁵⁵⁶ Note 114 above, 29.

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