

Chapter 11

How countries of the Southern African Development Community (SADC) can use the World Trade Organisation and the European Community flexibilities for better access to affordable HIV/AIDS medicines

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Summary

This paper discusses the ways in which countries of the Southern African Development Community (SADC) can maximise the patent-related advantages that are available to developing countries and regions by flexibilities offered by the World Trade Organisation (WTO) and the European Community (EC). Article 31 of the Agreement on Trade Related Aspects of Intellectual Property (TRIPs) provided only limited derogation to the exclusive rights that a patent holder may have under Article 28 of TRIPs. The entry into force of the agreement in developing countries entailed that important (cheaper) generic medicine manufacturers such as Brazil, China, India and South Africa would not be able to use TRIPs to supply needed medicines. This problem became known as the 'Doha Paragraph 6 Problem' as it was included in the 2001 Doha Declaration under the section of TRIPs and public health. The Declaration called for a solution to the problem by the end of 2002. Although this deadline was not met, an interim solution to the problem was worked out by the TRIPs Council of the WTO. This interim solution provided generous options for countries in need. The decision was integrated into the TRIPs Agreement as a permanent amendment in December 2005. In the EC, Regulation 816/2006 was adopted to apply the system which had been crafted at the WTO. So far only one country (Rwanda) has used the system to purchase affordable HIV/AIDS medicines from Canada. SADC is a region that has high levels of prevalence rates of HIV/AIDS. The WTO and EC flexibilities have not been used by SADC countries. One of the advantages of the flexibilities is that benefits are specifically guaranteed to regional trade arrangements like SADC's. Why has there been use an under-utilisation of the flexibilities? This paper argues that elements such as lack of awareness on the SADC side, the complicated nature of the procedures in the use of the flexibilities, and the actions of international charities explain the limited use of the system in

SADC. It advocates for a more proactive involvement of SADC and its member states in the negotiations on the various ways in which access to medical products (especially second line HIV/AIDS medicines) can be eased for SADC's citizens.

1. Introduction

How can SADC countries^[1] take better advantage of the WTO and EC rules that ease access to essential medicines? Many SADC states have high levels of Human Immuno-deficiency Virus/ Acquired Immune Deficiency Syndrome (HIV/AIDS). The disease negatively affects development in the countries of the region. Response to the crisis has many dimensions including prevention, treatment, and the battle against stigmatisation. This paper dwells mainly on the treatment component to the response. Mindful that there is still no cure for the pandemic, prevention remains an important front in the efforts to deal with the disease. However, given that there are over 32 million people who live with HIV, it is vital that action is taken to assuage their plight. In this regard the treatment dimension of response to the pandemic is crucial. Yet treatment through anti-retroviral (ARV) medicines does not only help to mitigate the pain that patients feel but treatment strategies critically complement the other dimensions of the response strategies including preventing and fighting stigmatisation. In terms of prevention, it has been demonstrated that certain ARVs like nevirapine and zedovudine help in limiting transmission of the virus from mothers to their offspring during pregnancy. In terms of addressing the issue of stigma, treatment possibilities have transformed the manner in which individuals feel about HIV/AIDS. The disease is no longer regarded as a death sentence. So with the knowledge that there are treatment options, some patients increasingly feel more comfortable in disclosing their status and also in seeking treatment. The paper will discuss some of the various possibilities at the WTO and EC levels that exist in terms of easing access to affordable essential medicines for poor countries and regions such as SADC's.

Part two discusses the situation of need on the ground. As such it presents a cross-section of the needs that most of the SADC countries are experiencing in terms of

^[1] The members of SADC include Angola, Botswana, the Democratic Republic of Congo (the DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe. With the exception of island states such as Madagascar and Mauritius the other states have high levels of HIV/AIDS prevalence.

shortages of the essential ARVs. It equally outlines some of the development problems that are posed by the disease for the SADC countries. SADC regional rules and policies that relate to access to affordable health care are also presented. Part three closely examines the nature of ARVs. This is done as a means of providing a substantive context into the nature of the issues under consideration. Having agreed that ARVs (especially the second-line medicines) are relatively more expensive, the fourth part analyses some of the flexibilities that are provided for at WTO level for developing and least developed countries (LDCs) and regions. It is noted that the majority of SADC countries can take advantage of these flexibilities. Part five considers some of the legal provisions that have been put in place by the EC to ensure that poor countries have access to needed medicines. Relevant provisions of the draft Economic Partnership Agreement between the EC and SADC group of countries are equally presented. Part six discusses some of the reasons behind the reluctance that has hitherto characterised the responses of SADC and its member states to the said access-related flexibilities. Part 7 concludes with some thoughts on how the flexibilities could be rendered more amenable for countries that need them.

2. The situation of need and the HIV/AIDS-related development challenges

2.1 Situation at the national level

In SADC countries, there appears to be a *décalage* between the needs and realisation; or between desires and outcomes in terms of the availability of resources to provide affordable ARVs. The countries treated under this heading are selected because they explicitly discuss the nature of their need for affordable HIV/AIDS in their Poverty Reduction Strategy Papers (PRSPs) or National Strategies to combat the pandemic.

In Botswana, for instance, the estimated cost of the national response to HIV/AIDS is about 12.6 billion pulas or about 2.3 billion US dollars (Government of Botswana 2004: 94). A greater part of this sum goes to the provision of ARVs. Although the country (considered a mid-income nation) can afford this option in the short and medium term, it is unclear whether this will continue in the long haul.

The DRC needs about 360 million US dollars per annum to overhaul its decrepit healthcare system. However, the authorities have only been able to come up with the

sum of 82 million US dollars (Government of the DRC 2002: par. 30). It would be difficult for the country to channel needed funds on ARVs mindful that it faces other social and economic problems.

In the PRSP of Malawi, the government makes it clear that the HIV/AIDS pandemic is too severe for the country to handle alone. It notes that Malawi's efforts are inadequate mindful of the spread of the pandemic which dwarfs the scarce resources available to the government (Malawi GDS 2007: xvii).

The issue of need also implicitly underlies the revelation in the Mozambican Poverty Reduction Strategy Paper (PRSP) that the country will scale up its budgetary allocations to deal with HIV/AIDS (Mozambique 2007: par. 201). The Mozambican government itself notes that in March 2004 only about 3000 patients were on ARV therapy against an estimated number of 200000 patients who required therapy in 2004 (Republic of Namibia 2004: 97). The government predicts that at this rate, the demand for ARVs will surge in the foreseeable future (Ibid.:21). Given this reality, it is hard to fathom how the nation will meet such pressures with the limited resources of the country. It is noteworthy that Mozambique is an LDC that is in dire need of funds for alternative and important purposes.

The picture may be slightly different in Namibia given that it is a lower/middle income country. However, the resources set aside for component three (on treatment) in the national response strategy to HIV/AIDS is stupendous. While the total set aside for the implementation of the Mid-Term Plan III (MTP III) is about 453 million US dollars, the amount allocated for treatment and care stands at a little over 245 million US dollars (Namibia 2004: 98). In this regard the issue of sustainability of the strategy of supplying expensive ARVs is an extant challenge.

On its part, the South African National HIV/AIDS Council (unlike any other HIV/AIDS control institution in the region) makes it clear that at current prices the provision of anti-retroviral therapy will account for 40 per cent of the total cost of the Strategic Plan for South Africa (SPSA). It further states that this needed service will soon be unaffordable unless certain legal options are exercised. Amongst these is the amendment of the Patent Act, No 57 of 1978 to allow for the use of compulsory licences when necessary. SANAC also proposes that the government should phase

out obstacles to the lengthy registration process of essential medicines (SANAC 2007: 141).

In Tanzania, the issues of need and cost loom equally large. It is stated in the country's Poverty Reduction Strategy Paper (PRSP) that '[equitable] and sustainable access to care, support and treatment are essential to improve the wellbeing and life expectancy of people living with HIV and AIDS, but issues pertaining to finances, infrastructure, human, and logistical weaknesses need to be resolved first, so as not to further weaken an already constrained health system' (Tanzania 2006: 11). The PRSP of Tanzania, unlike the other countries' documents, highlights the distribution problems related to health care in the country. It states that vital constraints in terms of access to essential health services include, amongst others, long distances to health facilities, insufficient and expensive transport systems, poor quality of care, shortage of skilled health care providers, and poor accountability mechanisms (Tanzania 2006: 12).

Zambia faces a Herculean challenge in terms of needs. These include lack of a hospital policy, outdated and obsolete legislation, distance to health facilities and lack of transport. The government further states that "...long distances and lack of transport in a large but sparsely populated country like Zambia is a key determinant of health seeking behaviour' (Zambia 2007: 84). While recognising its deficiencies in terms of transport infrastructure, the picture of the access situation painted in the PRSP still reveals that the issue of sustainability of the government provision of affordable ARVs will be a salient concern. This is because the government is spending about 5% of its annual budget on the provision of ARVs to its citizens (Zambia 2007: 128).

Eight of the SADC countries are least developed countries (LDCs).^[15] By UN standards, their Human Development Index (HDI) is low. Two of the states are emerging from conflicts (Angola and the DRC). One of the countries has been under sanctions from Western nations (Zimbabwe). Most Southern African countries have also been facing other challenges including serious droughts and famine that have compounded the problem of food insecurity (Whiteside 2004: 4). These problems

^[15] Angola, The Democratic Republic of Congo (DRC), Lesotho, Madagascar, Malawi, Mozambique, Tanzania and Zambia.

have not been assuaged by the HIV/AIDS pandemic which has compounded the challenges faced by SADC. SADC has been described as the epicentre of HIV/AIDS – that part of the world worst affected by the disease (Murphy et al. 2007: 42). The region accounts for 3.5% of the world's population but has about 35% of the global prevalence of HIV/AIDS (SADC 2005b: 66).

SADC countries can be classified into developing countries and LDCs. The developing countries include Botswana, Mauritius, Namibia, South Africa, Swaziland and Zimbabwe. The other countries are LDCs. The classification is important in understanding the applicability of certain WTO and EC rules in the countries in question. It is also important for understanding the varying responses of SADC states to the pandemic. In average terms, the SADC developing countries are more advanced in development than the LDCs. However, the prevalence of HIV/AIDS is markedly more acute in SADC's developing countries than in its LDCs.

All the SADC developing countries except Zimbabwe have made important strides to provide affordable or even free ARVs through the public health systems. Conversely, all the LDCs with the exception of Zambia and Malawi have fallen below par in terms of providing affordable ARVs to those in need (UNAIDS 2006). Across the board, provision of ARVs in all the countries is below 50% save for Botswana where 85% of those who need ARVs receive the same.

Some of the member states of SADC have gone to great lengths to ensure the provision of the HIV/AIDS medicines. For instance, Zambia has been spending 7.9% of its annual budget to combat the disease. Of this amount the bulk has been used to provide for ARVs. The real issue relates to the sustainability of ARV provision. In all SADC countries except Zimbabwe, prevalence has been increasing. This means that governments will have to grapple with the issue of those already infected as well as those to be infected.

Table indicating, population, access levels in HIV prevalence in SADC countries (adapted from the Annexes of UNHIV/AIDS 2006 Annual Report)

	Population (in millions)	No of people with HIV/ HIV/AIDS	% of those receiving ARVs	% of adult prevalence	% \$ <2/day
Angola	15.9	320000	6.0	3.7	-
Botswana	1.8	27000	85	24.1	50.1
The DRC	57.5	1000000	4.0	3.2	-
Lesotho	1.8	270000	14	23.2	56.1
Madagascar	18.6	49000	-	0.5	85.1
Malawi	12.9	940000	20	14.1	76.1
Mauritius	1.2	4100	-	0.6	-
Mozambique	19.8	1800000	9.0	16.1	78.4
Namibia	2.03	230000	35	19.6	55.8
South Africa	47.4	5500000	21	18.8	34.1
Swaziland	1.03	220000	31	33.4	-
Tanzania	38.3	1400000	7.0	6.5	59.7
Zambia	11.7	1100000	27	17	87.4
Zimbabwe	13.01	1700000	8.0	20.1	83
Average	17.4	1078793	22.3	14.4	66.6

3. Regional responses

3.1 Legal provisions and Summit outcomes

In presenting the main legal provisions within the SADC legal framework on access to affordable medicines, it is equally worthwhile to discuss the general provisions dealing with HIV/AIDS. Having established the fact that HIV/AIDS compounds and is compounded by poor development prospects, it is important to note that one of the main goals of the SADC Treaty (2001: Article 5(1)(a)) is poverty alleviation through regional integration. Although the treaty falls short of providing an explicit article on health, the SADC Protocol on Health which was adopted on 18 August 1999 makes it clear that cooperation in this area is 'essential for the effective control of communicable diseases and for addressing common health concerns in the Region' (SADC Protocol of Health 1999).¹ In more specific terms, Article 3(b) of the protocol

^[21] 4th recital, SADC Protocol on Health, 18 August 1999.

stipulates that the main goals of the document include the identification, promotion, coordination and support of activities that have the potential to ameliorate the health of the population within the region. It also states that another objective is 'to coordinate regional efforts on epidemic preparedness, mapping prevention, control and where possible the eradication of communicable and non-communicable diseases'.^[1]

Pertaining to the general approach in dealing with the pandemic, Article 10(1) of the Protocol seeks to outline a means through which strategies to deal with the disease can be harmonised in the region. It provides as follows:

In order to deal effectively with HIV/AIDS/STDs epidemic in the Region and the interaction of HIV/AIDS/STDs with other diseases, States Parties shall – a) harmonise policies aimed at disease prevention and control, including cooperation and identification of mechanisms to reduce the transmission of STDs and HIV infection; b) develop approaches for the prevention and management of HIV/AIDS/STDs to be implemented in a coherent, comparable, harmonised and standardised manner; c) develop regional policies and plans that recognise the intersectoral impact of HIV/AIDS/STDs and the need for an intersectoral approach to these diseases.

In August 2001, SADC leaders amended the founding treaty of the organization. In the amended text one of the goals of the grouping, as stipulated in Article 5(1)(i) is to combat HIV/AIDS or other deadly and communicable diseases. This aspiration to deal with the pandemic has been strengthened by the fact that the issue of HIV/AIDS has been made a recurrent and standing element in the agenda of all SADC Summit meetings of Heads of State and Government. At their Summit meeting in Luanda on 3 October 2002 the leaders noted that HIV/AIDS was a major developmental challenge for SADC. They called on all the member states to mobilise more resources to address the pandemic (SADC 2002: par. 27). During the Maseru Summit held in July 2003 the Heads of State and Government regretted the fact that their region had become the epicentre of the disease in the world (SADC 2003: par. 9). They recognised the fact that the 'epidemic has increased levels of poverty,

^[23] *Id.*

decimated households, and resulted in high levels of school dropouts and child headed households' (SADC 2003a: par. 18).

In charting a clear response that is commensurate with the challenge, the leaders adopted the Maseru Declaration on the Fight against HIV/AIDS in the SADC region (SADC 2003a: par. 30). The Maseru Declaration on HIV/AIDS (2003) outlines a multisectoral strategy on interventions. As revealed below, the framework set by the Declaration permeates all the anti-HIV/AIDS strategies adopted since 2003 in SADC.

On 26 August 2003, the SADC Summit took an important decision in the regional effort against the pandemic. They approved the establishment of a regional fund to pool money needed in fortifying the fight against HIV/AIDS. The fund will mainly finance the implementation of the SADC HIV/AIDS Strategic Framework and Programme of Action 2003–2007 (SADC 2003a: par. 29). By 2004 the Summit still averred to the fact that the pandemic was showing no signs of abating. As a result it paved the way for discussions on access to traditional approaches to contain the pandemic (SADC 2004: par. 30). By all means, this statement was a landmark – mindful that both within the SADC secretariat and in most of the SADC member states, efforts to strengthen African traditional approaches had hardly even received lip service.^[31]

During their 2005 Summit meeting SADC leaders called attention to the devastating impact of the disease on the agricultural sector and also on vulnerable children. Their statement equally addressed the link between the spread of HIV and the movement of mobile populations within and across borders. It also called for the establishment of guidelines in terms of all these aspects and endorsed the creation of a regional forum for national anti-HIV/AIDS authorities (SADC 2005a: par. 37).

It is worthy of note that with specific emphasis on access to affordable HIV/AIDS medicines the SADC Health Protocol considered above provides that 'States Parties shall cooperate and assist one another in a) the harmonisation of procedures of pharmaceuticals, quality assurance and registration; b) production, procurement and

^[31] For example in a correspondence dated 7 May 2004 addressed to SADC Executive Secretary Praega Ramsamy (as he then was) by Pascal Mulenga of the Botswana Traditional Health Organization pleading for funds to participate in a Johannesburg conference on "Traditional Health Practitioners HIV/AIDS and Natural Remedies Forum," the Executive Secretary declined (in a mail of 18 May 2004) to offer any assistance to the traditional practitioners.

distribution of affordable essential drugs' SADC 1999: Art. 29(a)(b)). In pursuance of the goal of access to affordable HIV/AIDS medicines, the SADC Summit of 2000 held in Namibia recalled the principles that SADC's Council of Ministers had approved regarding the Guidelines on Negotiations with Pharmaceutical Companies on Provision of Drugs for Treatment of HIV/AIDS and related conditions (SADC 2000b: par. 24). The Summit stressed the need for supplies of medicines to be sustainable, equitable, affordable, and accessible (SADC 2000b: par. 24). Accepting the fact that exorbitant prices for ARVs were prohibitive, the Summit agreed that the element of bulk purchasing and manufacturing of generic drugs should be accorded top priority in the implementation of the Strategic Framework (SADC 2003a: par. 22).

It is worth recalling that SADC has also enacted a Code on HIV/AIDS and Employment (SADC 1997). Amongst the main clauses of this document is a stipulation to the effect that '[Employees] with HIV related illness should have access to medical treatment and should be entitled, without discrimination, to agreed existing sick leave provisions' (SADC 1997: Clause 6.2).

3.2 SADC's Policy Framework on Access to Affordable Health Care and Medicines

Amongst the first important SADC Summit meetings that took bold steps to address the issue of HIV/AIDS was the extraordinary meeting that was held in March 2001 in Windhoek, Namibia. The Summit declared that HIV/AIDS presented a major hurdle in the attainment of the goals of the organisation (SADC 2001a: par. 2.3.1.3). Another important summit took place in 2001 in Blantyre, Malawi. In assessing progress made in dealing with the pandemic, SADC leaders welcomed the fact that a common approach had been adopted for dealing with pharmaceutical companies. They further noted that both sides had arrived at a common understanding in dealing with HIV/AIDS. An agreement was ultimately reached with seven of such companies in June 2001 (SADC 2001b: par. 6.5.3). In an ordinary meeting of the Summit that was held in Luanda, Angola in January 2002, SADC leaders abhorred the fact that conflicts and poor treatment of women had helped to accentuate the rates of infections. They noted that the pandemic had evolved into 'a complex social and economic emergency', adding that HIV/AIDS had become the greatest threat to health and development in Southern Africa (SADC 2002: par. 5.4.1).

One of the first overt SADC Council statements regarding HIV/AIDS was made in September 1998 during the Grand Bay Summit in Mauritius. The ministers highlighted the need for cooperation in dealing with infectious diseases such as HIV/AIDS. They referred to the benefits of collective actions in addressing common diseases and they noted that cooperation was needed to ensure economies of scale in terms of bulk purchase of medicines^[42] and sharing of expensive medical equipment and facilities (SADC 1998: par. 4.5). They also accorded the health sector coordinating unit in South Africa with the powers to develop a framework for the harmonisation of legislation and practice on negotiations with pharmaceutical companies for more affordable medicines (SADC 1998: par. 4.5.1.4). During the SADC Council of Ministers meeting that was held in August 1999 the demands on states in fighting HIV/AIDS was further underscored. The countries that had not implemented the code on employment were implored to do so (SADC 1999: par. 4.2.1.2). The ministers also approved the consolidation of the HIV/AIDS policy Surveillance Task Force on HIV/AIDS. This was to be chaired by Zambia (SADC 1999: par. 4.7.1.4). The Task Force was to include members from other sectors of SADC and this was done to facilitate a multi-sectoral approach to the pandemic (SADC 1999: par. 12.8.2). They equally regretted the fact that the rate of the pandemic was seriously escalating throughout the region (SADC 1999: par. 4.8.1.2).

The main policy initiatives that have incorporated the issue of access in SADC include the Regional Indicative Strategic Development Plan (RISDP), the SADC HIV and AIDS Strategic Framework and Programme of Action 2003-2007, the SADC HIV/AIDS Business Plan and SADC Principles and Guidelines and negotiations with pharmaceutical companies. The RISDP is the main document serving as the platform on which all SADC regional actions are developed (SADC 2003c). An important requirement of the RISDP is that there should be joint procurement and manufacturing of essential education materials and health services, including essential drugs and ARVs, research, as well as mechanisms for referral of patients for tertiary care, and combating of major diseases such as HIV and AIDS (SADC 2003c). The SADC HIV and AIDS Strategic Framework and Programme of Action 2003–2007 ('Strategic Framework') is the main document that elaborates the

^[42] SADC now tends to focus more on joint rather than bulk purchase of medicines. Interview, Joseph Mtethwa, SADC Officer in charge of relations of pharmaceutical companies, 11 June 2007.

approach that the organisation is to adopt to deal with the pandemic within a period of five years (2003–2007) (SADC 2004: 12). Amongst the target goals in this regard are the following: the provision of care and treatment including the use of ARVs, assistance in the area of providing nutritional therapies and traditional herbs, bulk procurement of drugs and medical supplies for HIV/AIDS, and, finally, the establishment of policy guidelines on ameliorating access to care and treatment to the most vulnerable social groups (SADC 2004: 12).

The decision to formulate the SADC HIV/AIDS Business Plan (the 'Plan') was adopted in Dar es Salaam in August 2003 (SADC 2004: 4). Amongst the goals of the Plan is the harmonisation of policies for care and support. One of the focal areas in this regard is regional 'joint procurement of drugs, medical supplies and testing reagents... (SADC 2004: 4). The Business Plan is to be financed from three main sources including contributions from SADC member states to the regular budget of the organisation, funds from International Cooperation Partners for specific projects, and, importantly, funds from the SADC HIV/AIDS Trust Fund (SADC 2004: 16). The implementation of the HBP is mainly the attribution of the SADC HIV/AIDS Unit (the 'Unit'). The Plan makes it clear that the '... broad mandate of the HIV/AIDS Unit is to lead, coordinate and manage SADC's response to the epidemic through the operationalisation of the HIV/AIDS Strategic Framework (2003–2007) and the Maseru Declaration' (SADC 2004: 12). In executing this task, the Unit is to direct its attention towards certain focal areas amongst which are procurement and manufacturing of drugs.

SADC has been finalising its principles to guide negotiations with pharmaceutical companies on the provision of drugs for treatment of HIV/AIDS and related conditions. Amongst the important aspects of the proposed principles is the close involvement of ministers in the actions and decisions that are taken by the companies to ease access (SADC 2000a: par. 5.13.2.2).^[57] Other vital elements of the principles include 'recognition of the critical role that poverty and malnutrition play in the epidemic [HIV/AIDS], provision of equipment, maintaining the continuum of care, and supplies of appropriate drugs to ensure sustainability, equitability, affordability and accessibility (SADC 2000a: par. 5.13.2.3)'. The Council of Ministers has also

^[57] Decisions of the SADC Council of Ministers, 2000(1) SADC/CM/2/2000/1, para. 5.13.2.2.

been keen to assert that other aspects of access such as the provision of laboratory support and infrastructure be regarded as one of the significant constituents of a holistic response to the pandemic (SADC 2000a: par. 5.13.2.4).

4. The nature of anti-retroviral medicines

ARVs were first developed in the 1990s. Apart from the fact that they are expensive drugs they also share the characteristic of having extremely debilitating side effects. Also, ARVs are to be taken in combination if they are to be effective. That is why it is often said that they are administered in 'cocktails'. Each drug in a combination therapy deals with the virus in a specific way. For instance, fusion inhibitors are used to attain goals that are different from those of protease inhibitors. This necessarily leads one into a discussion of the types of ARVs.

There is a variety of ARVs mainly distinguished by the manner in which they deal with the virus. In the first place, nucleoside transcriptase inhibitors (NTIs) are drugs that 'prevent the viral RNA from changing into the DNA by the use of an enzyme found in the cytoplasm of [a person's] host cells called reverse transcriptase enzymes' (Goosby 2004: 102-103). NTIs are associated with severe liver problems. Examples are abacavir (Trizivir), didanosine (DDI), lamivudine (Epivir), stavudine (Zerit) and zidovudine (AZT or Retrovir).^[61]

Second, nucleoside reverse transcriptase inhibitors (NRTIs) incorporate themselves into the DNA of the virus leading to the termination of the chain or replication. An example includes tenofovir (Viread). NRTIs are associated with the inflammation of the pancreas as well as with liver problems (Goosby 2004: 104).

Third, the non-nucleoside transcriptase inhibitors (NNTIs) mainly upset the bonding propensity of the reverse transcriptase enzyme. Good examples include efavirenz (Stocrin) and nevirapine (Viramune). While efavirenz is associated with severe depression amongst a minority of the patients, nevirapine has the effects of severe rash as well as hepatitis (Goosby 2004: 105).

Fourth, protease inhibitors are aimed at distorting the coalescence of the virus by curbing the performance of protease. Protease is an enzyme used by HIV for the

^[61] The names in brackets represent the marketing names of the drugs.

collage of nascent proteins needed for the assembly of novel virions. Protease inhibitors such as indinavir (Crixivan), lopinavir/retonavir (Kaletra), nelfinavir mesylate (Viracept) and saquinavir (Invirase) are very virulent in destroying HIV. But this only happens when combined with reverse transcriptase inhibitors (Goosby 2004: 105). Protease inhibitors have been associated with increased bleeding in haemophiliacs and also contribute to body fat redistribution.

Finally, fusion inhibitors 'prevent the attachment of the virus to the CD4 receptor on the cell surface. In short, they block HIV's ability to infect healthy CD4 cells (Goosby 2004: 108). An example of a fusion inhibitor is enfuvirtide (Fuzeon). Other categories of ARVs that are still undergoing clinical trials include integrase inhibitors that seek to distort the activities of an enzyme known as integrase. Integrase is the main enzyme that ensures the incorporation of the HIV's DNA into the DNA of the infected cells.

5. WTO TRIPs flexibilities which SADC countries can benefit from

The main flexibilities that poor countries can benefit from in terms of TRIPs can be understood better by considering the TRIPs provisions that refer to technical cooperation, temporal derogations for developing and least developed countries, the Doha Declaration on TRIPs and public health and the 2003 Decision later incorporated, *mutatis mutandis*, as the TRIPs amendment of December 2005.

5.1 Technical Cooperation and temporal derogations for poor countries under TRIPs

The main articles that are in the interest of developing countries and LDCs refer to technical cooperation and transitional provisions. There are a number of provisions in the TRIPs agreement that give term to the fostering of technical cooperation between rich and despondent countries in the field of IPRs.

In the first place, the sixth recital to the preamble of the TRIPs Agreement is recognition by the members of the special needs of the least-developed country members in respect of maximum flexibility in the domestic implementation of law and regulations in order to enable them to create a sound and viable technological base.

In addition, Article 66(1) of the TRIPs Agreement states that LDCs will have ten years to implement the provisions of the document.^[66] The article also stipulates that the ten-year period may be extended by the Council for TRIPs if the request is made by an LDC member. Such an extension has been accorded to LDCs. They will therefore be expected to start full implementation of TRIPs obligations in 2013 (and 2016 for pharmaceutical products) and not 2005 as originally provided for. Developing countries had to commence full implementation of TRIPs in 2000,^[67] but this was extended to 2005. While these provisions on extended time lags for developing countries and LDCs are worthwhile, *prima facie*, the real test of their utility is a counter-factual inquiry into the effects of the absence of such temporal exemptions. And to this inquiry one may add that the existence of the broad temporal favours granted LDCs have hardly been used by them for their development. Rather, businesses in some advanced developing countries (for instance, Brazil and India) as well as in the developed countries have been the main beneficiaries of such advantages. In most cases they have simply shifted some of their operations to certain LDCs. For instance, Brazil plans to establish a generic manufacturing company in Mozambique.

Mindful of the fact that the LDCs will eventually have to fully implement TRIPs in any event it is futile to surmise what will eventually come to pass (Robbani 2005: 571). However, such cynicism can hardly be justified when one is talking about the real technical cooperation benefits that poor countries may reap from stipulations such as Article 66(1) which states that developed country members should provide incentives to their enterprises so that they will in turn transfer their know-how and technology to LDCs. The more pointed provision that sanctions technical cooperation under the TRIPs Agreement is Article 67 which states:

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and

^[66] But a proviso is also provided in this regard: application of Articles 3, 4 and 5 are to be immediate.

^[67] TRIPs Agreement, Article 65(2). Developed countries had to succumb full to the terms of TRIPs within a year of the signing of the Agreement, that is, 1996: TRIPs Agreement, Article 65(1).

enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

The WTO and the World Intellectual Property Organisation have also been cooperating in disseminating information in the field of intellectual property to some third world countries. Some developed states have been supporting developing countries and LDCs in putting in place the necessary mechanisms needed to bolster the protection of IPRs. Countries such Canada, Norway and some EC members have provided reports to the WTO secretariat on their activities in this regard.

5.2 Doha Declaration and access to affordable medicines

The Doha Declaration was the outcome of the WTO Ministerial Meeting that was held in the United Arab Emirates (UAE) in November 2001.^[69] The Declaration contained specific statements on various issues. One of such issues with a separate declaration was the Declaration on the TRIPs Agreement and Public Health ('the Declaration').^[70] The Declaration was the zenith of discussions that had commenced within the TRIPs Council at the urging the African Group. The spokesperson for the group at the time was the representative of Zimbabwe (Ambassador Boniface Chidyausiku) who was equally the chair of the TRIPs Council.^[71] The EC^[72] and Brazil (acting on behalf of many developing countries and LDCs)^[73] had also submitted important documents on the issue prior to the June 2001 council meeting. Zimbabwe and many third world countries were of the opinion that the Ministerial Conference in Qatar in November 2001 had to be an opportunity to demonstrate members' commitment and contribution to preventing further deaths and saving lives through facilitating easier access to medicines at affordable prices.^[74] The gist of its proposal was that members issue a special declaration on the TRIPs Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in

^[69] Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, Adopted on 14 November 2001.

^[70] Declaration on the TRIPs Agreement and Public Health, WT/MIN(01)/DEC/2, adopted on 14 November 2001 (hereafter, the Declaration).

^[71] Council for TRIPs, Special Discussion on Intellectual Property and Access to Medicines, IP/C/M/31, 18-22 June 2001.

^[72] IP/C/W/280.

^[73] IP/C/W/296.

^[74] IP/C/M/31, par. 2 and 3.

the TRIPs Agreement should prevent members from taking measures to protect public health.^[75]

Zimbabwe recalled the plight of the young South African AIDS patient and activist (Nkosi Johnson) and the scourge of HIV/AIDS in developing countries. Its precise demands included a) an extension for the transition period for developing countries respecting patent protection; b) the adoption of a moratorium on dispute settlement to allow members to adopt measures that are protective of public health; and c) the placing of a moratorium on dispute settlement specifically on developing countries that take action to promote public health.^[76] The discussions led to the adoption of the special declaration on public health as had been requested by Zimbabwe. The Declaration contained seven paragraphs. Paragraph 1 restated the awareness of the issue by the members.^[77] The ministers were quite keen to stress that the TRIPs Agreement should be regarded as part of the solution to the issue. Members were equally cognisant of the importance of maintaining the balance of interests in the intellectual property system.^[78]

The very core of the Zimbabwean proposal was contained in Paragraph 4 which was a recognition of the fact that the 'TRIPs Agreement does not and should not prevent Members from taking measures to protect public health ... [It] 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'. A commitment was also made for allowing countries in need to use compulsory licenses as deemed appropriate.^[79] In a significant way, the members also noted that states will reserve the right to determine what constitutes national emergency or case of extreme urgency with the understanding that diseases such as HIV/AIDS, tuberculosis, malaria and other epidemics may come under such a narrow category.^[80]

Paragraph 6 contained specific terms aimed at addressing a crucial issue that has come to be known as the 'Paragraph 6 problem'. The problem emanates from the

^[75] *Id.*

^[76] *Id.*, at 6.

^[77] The Declaration, para. 1.

^[78] The Declaration, para. 3.

^[79] *Id.*, para. 5(b).

^[80] *Id.*, para. 5(c).

wording of Article 31(f) of the TRIPs Agreement that allows for the authorisation of other use of intellectual property products (without the consent of the patent holder) for the predominant supply of the domestic market. This basically means that countries that have the capacity to use compulsory licensing, for instance in the mass provision of vital drugs such as ARVs, can only do so to (mainly) meet the demand of the domestic market. Export of such consignments to foreign countries that are in need ought to be minimal or very limited (Sherer 2004: 367). In addressing this issue contracting parties recognised 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.^[82] They also mandated the Council for TRIPs with the task of finding a speedy solution to the problem and report to the General Council before the end of 2002.

5.3 The Decision of 30 August 2003

To address the Paragraph 6 problem, members started negotiations within the TRIPs Council that were geared at reaching a solution that was acceptable to both the rich and poorer countries. The negotiations proved difficult. In the first instance, some of the members like the EC initially expressed preference for a TRIPs Article 30 solution. However, the community later retracted from this approach and declared its intention to go with the majority of the members who expressed a predilection for a TRIPs Article 31 solution. The essence of the Article 31 solution was modification of Article 31(f) in a manner that would reflect the needs of countries that had a public health problem yet lacked sufficient capacity to deal with the issue. The modification would allow those with sufficient capacity to go beyond the TRIPs requirement of manufacture aimed 'predominantly' at the domestic market. It should be noted that Paragraph 6 of the Declaration stated that the TRIPs Council had to report a solution to the General Council by the end of 2002. This deadline later proved unrealistic because of the reservations that the US expressed on the scope of the medicines as well as the number of countries that could benefit from such a waiver of Article 31(f) obligations. The US as well as other Western countries was equally concerned that, if introduced, such a waiver system for Article 31(f) would lead to abuse as some members may actually seek to use the initiative for commercial purposes. After much

^[82] The Declaration, para. 6.

debate and clear assurances that were later included in the statement of the chairman of the General Council, the US succumbed. The EC was very instrumental in helping to allay the fears of the US and this helped to secure the eventual agreement on the decision regarding the Paragraph 6 problem.^[83]

The provisions of the 30 August 2003 decision were important as they waived the obligation of Article 31(f) and also put in place a dispute settlement moratorium on those countries that sought to depart from the strict wording of Article 31(f) to meet public health concerns. Some of the relevant paragraphs of the decision are worth examining.

Paragraphs 2 and 3 are strict measures on notification and labelling that potential users have to respect. While Paragraph 5 sets out a generic safeguard provision for all members to avoid diversion and re-exportation of the products imported under the system, Paragraph 6 is a crucial statement that is very relevant for regional trade agreements (RTAs) such as SADC.^[84] One of the crucial aspects of paragraph six as mentioned above is that if half of the members of a Regional Trading Agreement (RTA) is made up of LDCs, the requirements of Article 31(f) shall be waived. SADC is composed of eight LDCs and six developing countries. This means that SADC non-LDCs can make use of the waiver of Article 31(f), and such states may also be excused from the obligation of providing justification for the need of the system as elaborated under Paragraph 2(a)(ii). This means, of course, that the SADC Group

^[83] Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540, 1 September 2003 (hereafter, the Decision). For an upbeat albeit cautious assessment of the potential positive fallout of the Decision in terms of access to medicines for a broad array of diseases in developing countries see Abbott (2005: 322-323 and 358) (concluding that although the 'adoption of the Decision shows that the WTO can address important issues of social concern ... [the] WTO's effectiveness will be better assessed if, and when, developing countries actually use the Decision to address their public health needs').

^[84] Paragraph 6 states:

With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products;

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of the Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

Economic Partnership Agreement (EPA), on the other hand, cannot take advantage of such a provision, mindful that the majority of the members of SADC Group EPA are members of the Southern African Customs Union (SACU) that are developing and not least-developed countries.

The use of compulsory licensing has been limited in regions and countries which one would have thought are in need of the system set out in the 2003 Decision. As at the time of writing, only the Rwandan Government through its Centre for the Treatment and Research on AIDS (TRAC) has made a notification under the system. In the document, announcing the decision by Rwanda to use the system, its permanent representative in Geneva noted that ‘bBased on Rwanda’s present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine ... manufactured in Canada by Apotex, Inc’.^[85]

The example of Rwanda shows that, contrary to the interventions of Kenya and Pakistan in TRIPs Council meeting of 16 June 2004, the system could be used by developing countries and that the conditions set are not as difficult as they averred.^[86] However, there is room for improvement in the administrative red tapes that affect access to the system. For instance, in the example of Rwanda, nine Canadian patents were in question: four by Glaxo Group, two by Wellcome Foundation, two by Shire Biochem, and one by Boehringer Ingelheim and Dr Karl Thomas GmbH. Going through the negotiations with all the parties can be difficult for poor countries. Little wonder Hestermeyer (2007) has argued that a poor country like Rwanda could have simply ordered the drugs from India without even using the system at a more cost-effective rate.^[87]

6. EC rules on access to medicines

6.1 Use of compulsory licensing

Following the adoption of the Decision of 2003 at the level of the WTO, the EC adopted a regulation to apply the terms of the WTO Decision at the level of the

^[85] TRIPs Council, 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/RWA1, 19 July 2007.

^[86] IP/C/M/44, par. 91 and 115.

^[87] Holger P. Hestermeyer, “Canadian-made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines,” 11 *American Society of International Law Insight* (December 2007).

community. In this regard therefore, Regulation 816/2006 was adopted by the European Council.^[88] In terms of the operative provisions of the regulation, Article 1 explicitly demarcates the leitmotif for the document. The text establishes a procedure for the grant of compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products, in order to address public health problems.^[89]

This provision is quite expansive when collated and juxtaposed with a similar clause in the Commission's proposal CEC 2004). Article 1 of the proposal did not make mention of 'eligible importing members' but rather it alluded to 'eligible WTO members' thereby limiting the scope of potential beneficiaries. While the law itself contains the salient concept of 'need' as being determinative of a decision to use the system, the proposal was silent in this regard. In terms of eligibility proper, Article 4 of the regulation states: The following are eligible importing countries: (a) any least-developed country appearing as such in the United Nations list; (b) any member of the WTO, other than least-developed country members referred to in point (a), that has made a notification to the Council for TRIPs of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way; (c) any country that is not a member of the WTO, but is listed in the OECD Development Assistance Committee's list of low-income countries with a gross national product per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way.

The wording of this clause is in stark contrast to Article 4 of the Commission's proposal which was limited to WTO members. The proposal's reference to eligibility stated that the following are eligible importing WTO members: (a) a least-developed country member of the WTO (b) any other member of the WTO that has made a notification to the Council for TRIPs of its intention to use the system as an importer,

^[88] Regulation (EC) N° 816/2006 of the European Parliament and the Council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems, OJ L 157/1.

^[89] *Id.*, Article 1.

including whether it will use the system in whole or in a limited way.^[91] It is worth noting that the Commission's proposal did not include countries such as Botswana, Namibia and South Africa in its list of countries that could be beneficiaries. However the regulation widened the pool of potential beneficiaries to these HIV/AIDS afflicted countries.

Article 6 of the regulation outlines the conditions that are to be met in order to apply for a compulsory licence. Any person may submit an application for a compulsory licence or a supplementary protection certificate.^[92] The application has to clearly outline the name and contact details of the applicant,^[93] the name of the product;^[94] the amount of the product that is to be produced under the compulsory licence^[95] and the importing country or countries.^[96] Another important requirement to be met is that the applicant has to show evidence of negotiation with the right holder prior to the request for a compulsory licence.^[97] One other obligation that the applicant has is that of notifying the right holder of the use of the patented product or process in question.^[98]

Article 8 of the regulation refers to the verification that national competent authorities have to conduct an inquiry to ensure that the application is in line with the WTO Decision of 2003.^[99] This provision is similar to Article 6 of the Commission's proposal and indicates the extent to which the compulsory licensing system under EC law is in line or aligned with that of the WTO. This is more so because the regulation itself makes it clear that the products that are imported should not exceed what was notified at the WTO or at the Commission, as the case may be.

Specific requirements are contained in terms of prior negotiation. For instance, the applicant has to show evidence to satisfy the competent authorities that strides have been made to obtain the consent (voluntary licence) from the right holder. S/he has to also show that 'such efforts have not been successful within a period of thirty days

^[91] COM(2004) 737, Article 4.

^[92] Regulation 816/2006, Article 6(1).

^[93] *Id.*, Article 6(3)(a).

^[94] *Id.*, Article 6(3)(b).

^[95] *Id.*, Article 6(3)(c).

^[96] *Id.*, Article 6(3)(d).

^[97] *Id.*, Article 6(3)(e).

^[98] *Id.*, Article 7.

^[99] *Id.*, Article 8(1)(a).

before submitting the application'.^[100] A similar provision is contained in Article 7 of the Commission's proposal. However in the proposal the period of thirty days is not referred to. Rather, the proposal evokes the notion of 'reasonable period of time'. So the regulation itself has the strength of being clearer than the wording of the proposal in this regard. Article 9(2) of the regulation provides an exemption to the broad prescription of Article 9(1). It states that the requirement in Paragraph 1 shall not apply in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPs Agreement.

The conditions that the compulsory licence has to meet are contained in Article 10. This provision takes up the tenor of Article 8 of the proposal. The broad demands of Article 10 refer mainly to the fact that the licence shall not be used to produce an excess of what is needed;^[101] the applicant has to indicate the duration of the licence^[102] and that no re-exportation shall be made 'except where an importing country avails itself of the possibilities under subparagraph 6(i) of the Decision to export to fellow members of a regional trade agreement that share the health problem in question'.^[103] In addition, the product has to be clearly identified and any distinction should be feasible without significantly affecting the price.^[104] Moreover, the applicant shall post on a website the quantities being supplied under the licence.

Another important provision relates to remuneration. The licensee is expected to pay the rights holder an amount to be determined by competent authorities. First, in those cases where the application for the compulsory licence is made to respond to an emergency as envisaged in Article 9(2), 'the remuneration shall be a maximum of 4% of the total price to be paid by the importing country or on its behalf'. Second, in all the other cases the remuneration shall be determined taking into account the 'economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the licence'.^[105]

^[100] *Id.*, Article 9(1).

^[101] *Id.*, Article 10(2).

^[102] *Id.*, Article 10(3).

^[103] *Id.*, Article 10(4).

^[104] *Id.*, Article 10(5).

^[105] *Id.*, Article 10(9).

6.2 Non diversion of products sold on basis of differential pricing

The basic ideas behind the differential or tiered pricing system is that pharmaceutical companies are encouraged to provide needed and essential medicines at lower prices to LDCs and countries where the need has been expressed. Although the approach is good because it is based on the volition of the pharmaceutical companies (Gamharter 2004:11)^[106] and because it also eases access to life-saving medicines, it has been criticised because it can easily be abused by free riders who desire to divert the products for purposes of re-exportation back to the rich markets. The problem is succinctly formulated by Scherer and Watal (2004: 370) in these terms:

[Wholesalers] in a low-price country direct supplies through international trade channels to nations in which the manufacturer is attempting to maintain high prices, undermining the high prices (and their contribution to research and development expenditures) in the wealthier nations and, if quantitatively substantial, in inhibiting the manufacturer's willingness to supply at low prices in the low-income nation.

This and other reasons explain why in some countries, pharmaceutical companies are not quite keen on the approach (Subramanian 2001:325). That said, differential pricing makes sense in situations where trade diversion can be controlled. At the level of the EC, Regulation 953/2003 has been enacted in a bid to control the possibility that certain operators could divert medical products that are sold at tiered prices and aimed at poor countries.

6.3 The SADC Economic Partnership Agreement with the EC and Access to Medicines

The Economic Partnership Agreement between the eight members of the SADC EPA Group is meant to replace the trade cooperation parts of the EC-SADC relations that were formerly dealt with under the framework of the Yaoundé, Lomé and Cotonou Agreements. The EPA negotiations are still ongoing and may, at first sight, appear remote to the issues regarding access to affordable HIV/AIDS medicines in Southern Africa. This could not be further from the truth. In the first place, the SADC EPA

^[106] See also EC intervention in the TRIPS Council meeting: IP/C/M/40, par. 32.

threatens the cohesive nature of SADC as a regional organisation. As a regional body notified under Article XXIV of the General Agreement on Trade and Tariffs (GATT), SADC has many LDCs and this affords it the possibility of using the regional flexibilities built into the WTO Decision of 30 August 2003 that granted developing countries advantages such as the use of compulsory licensing. SADC EPA, on the other hand, cannot take advantage of these flexibilities given that more than 50% of its members will be non-LDCs.

On a more positive side, however, the inclusion of South Africa into the EPA can be hailed as one positive aspect of the negotiations because its erstwhile participation status as an observer left many institutional questions unresolved. South Africa has one of the highest HIV/AIDS prevalence rates. So do most of the SADC EPA members. Given that the pandemic is better handled when approached from a regional perspective (for instance, pooled ARV procurement) it makes sense to include rather than sequester South Africa from the other EPA members.

Moreover, to the extent that EPAs contain Intellectual Property Rights (IPR) rules that ensure better access to affordable medicines and to the degree that SADC countries are poised to implement the rules at the regional and national levels, international pharmaceutical corporations, brand and generic, could be encouraged to set up companies in SADC countries where they will be able to produce their drugs at cheaper rates because of the relatively cheaper factors of production (for example labour). Such companies would not only produce ARVs but other medicines that can compete well with the generics from India and Brazil. So in this instance, the introduction of balanced IPR rules in the EPA for SADC will have positive fallout for SADC EPA states. However, the introduction of such rules in the EPAs could have a negative aspect in the sense that it could lead poor countries to prematurely introduce strong IPR rules that can, in turn, constrain access to patented or protected technologies.

Furthermore, EPA negotiations are about the exchange of concessions on trade terms. The substratum of the negotiations is market access. When EC markets can be easily accessed without technical barriers and tariff barriers, the SADC producers benefit. SADC producers and poor farmers who benefit are often the breadwinners of families. With better access and productivity they can plan ahead and also set aside

income for health care. Another way of looking at the connection is that when people are ill they simply cannot be viable and productive. Therefore it makes very little sense to attract investments in a country of sick people who cannot be productive and who lack access to medicines.^[109]

Finally, and of the greatest importance, is that the EC has promised to align the EPA with the provision of development money. This means that SADC countries which are in the EPA will be able to use such funds for the improvement of the health services, infrastructure and equipment. In the absence of such funds, it could be argued that the EPA would lead to a diminution of customs and excise revenues from EC imports. It should be noted that most poor countries rely on such funds to provide for social services, including access to affordable health services.

Considered from these perspectives, the EPA negotiation for SADC becomes crucial. And that is why the SADC EPA negotiations provide a proper trial (the document is still draft) medium through which one can look into the coherent nature of the EC's contributions in a variety of areas and its development pledge as contained in Article 177 of the **Treaty establishing the European Community (TEC)**, on the other. But how are issues of coherence regarding the various aspects of access integrated in the SADC draft EPA?^[110]

Title V of the draft is on trade-related issues and addresses aspects of competition (Chapter 1), innovation and intellectual property (Chapter 2), public procurement (Chapter 3), the environment (Chapter 4), and social aspects including labour rights (Chapter 5). Chapter 2 on IPR treats all the main forms of IPRs. It also makes provision for patents (Article 10). But the patent-related clause that is relevant for this study is Article 10(2), entitled 'patents and public health'. It states:

(1) The EC Party and the Signatory SADC States recognise the importance of the Doha Declaration on the TRIPs Agreement and Public Health adopted on 14 November 2001 by the Ministerial Conference of the WTO. In interpreting and implementing the rights and obligations under

^[109] Interview: Official, Embassy of Mauritius in Brussels (3 May 2007).

^[110] Economic Partnership Agreement between the SADC Group of States, of the one part, and the European Community and its member states, of the other part (*Draft EC consolidated proposal – each party reserves its right to submit further changes to this text*), as tabled for consideration on 5 June 2007.

this Article, the EC Party and the Signatory SADC States are entitled to rely upon this Declaration. (2) The EC Party and the Signatory SADC States shall contribute to the implementation and respect the Decision of the WTO General Council of 30 August 2003 on paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, and take the necessary steps to accept the Protocol amending the TRIPs Agreement, done at Geneva on 6 December 2005.

7. Why Has SADC countries not used the systems provided for by the WTO and EC flexibilities

As noted above, Rwanda is the only one of the poor countries that has applied and used the system that was guaranteed by the WTO in 2003. Mindful of the difficult negotiations that led to the realisation of the Decision of 2003, one would have been led to believe that poor countries would hasten in order to notify the WTO of their wish to use the flexibilities regarding access to medicines. This has not been the case. Regional integration organisations (such as SADC) that can also benefit from the system have largely been reticent in terms of using the advantages. What could the reasons be?

First, SADC and national officials dealing with issues of health and issues of trade are simply not sufficiently aware of the system. Even in those instances where there is awareness about the existence of such advantages, there are hardly experts in the various regional and national offices who have sufficient knowledge about the details of the rules in question. Interviews conducted within the framework of this research at the SADC Secretariat confirmed this.

Second, some of the SADC member states that have high levels of HIV/AIDS prevalence, are recipients of assistance from the United States Government under the framework of President's Emergency Plan for AIDS Relief (PEPFAR). PEPFAR lays more emphasis on aspects of prevention in the response to combat the disease. This is not to say that the priority PEPFAR countries do not incorporate the treatment dimension in their responses. However, PEPFAR has contributed in fortifying the view that prevention comes first. In this regard, countries tend to lay more emphasis on prevention strategies.

Third, related to the preceding is the fact that most poor countries in SADC rely on international donors to supplement their response strategies. For instance, the Global Fund has been one of the major contributors in assisting countries in their response strategies. Private collectives (such as the Global Business Coalition), non-governmental organisations (e.g. Médecins sans Frontières) and private foundations (e.g. the Bill and Melinda Gates Foundation and the Clinton Foundation) are some of the bodies that have been at the forefront in assisting countries to ease access to more affordable HIV/AIDS medicines. Mindful that the countries can easily make recourse to the services of such entities (that are often involved in the negotiation of the prices of medicines), the capacity-strapped countries often prefer to rely on the services of such private outfits. Such entities have contributed in lowering the prices of first-line drugs that are now provided for free in some countries. The real challenge remains access to second-line expensive medicines. One can partly attribute the reluctance of SADC and its member states to use the WTO/EC flexibilities on the already reduced prices that have been negotiated by the private entities.

Finally, the very nature of the process to apply for the use of the system is protracted and can be very burdensome for some of the countries that already lack the human resources in the fields of intellectual property and trade rules. As argued in the case of Rwanda, the complexities in which the system is underlain can actually set off any potential gains that could have been made by the poor countries in using the system. In the example of Rwanda, it is revealed that as many as nine patents were involved and that this only contributes in making the use of such as system burdensome. But what can be done to ease the use of the flexibilities?

8. Conclusion: using and improving the systems

As argued earlier, the treatment component of the response strategy impacts on prevention as well as the struggle against stigmatisation. The efforts to ease access to affordable HIV/AIDS medicines in SADC countries and also in other developing countries have been important. Cynics may retort that providing medicines may not be an affordable and sustainable strategy in view of the cost of second-line drugs. They can also argue that providing drugs only widens the pool of those with the malady especially in those cases where patients do not adopt responsible behaviour. These are all important considerations. However, efforts to continuously reduce the

prices of ARVs need to be sustained because a) second-line and even third-line medicines will increasingly be needed and they will be more expensive, and b) in the event of the discovery of a vaccine, it will be vital that the systems maintained by the WTO and the EC for access to medicines be applied as well to vaccines. But for these advantages to be maximised by the states and regions of the south some vital points need to be taken up.

In the first place, both at the WTO and EC levels the conditions that are meant to be met by those poised to use the system are too strict. Applicants are supposed to deal with protracted paper work processes. For instance, both the applicant/importing country and the exporting country have to notify the WTO of the use of the system. This means that in the event of the involvement of multiple patents as in the Rwanda application, many parties have to be involved in the process. In the light of this difficulty, the system could be simplified by requesting a notification only for the country that is importing. Alternatively both applications or notifications could still be maintained on condition that a one-stop shop and accelerated procedure be used in the exporting country when multiple patents are in question. Put alternatively, and as the case may be, in situations where multiple patents are in question, a single focal point or patent holder could be designated by the exporting country to represent the interests of all the owners whose patents are to be used. Second, pooled/regional procurement and notification under the system need to be highlighted in a more effective way. The WTO and EC should widen the pool of regions that can use the systems by removing the derogation that only RTAs, 50% of whose membership is made up of LDCs, be entitled to use the system. Both systems could be simplified by extending such an advantage to all RTAs in the developing world. In this way SACU and SADC EPA states will be able to apply to use the systems without any encumbrances. Third, SADC itself needs to include stronger provisions on access in its protocol on health or in its pending protocol on Sexually Transmissible Diseases. Any provisions that would be included should incorporate the wording of the Doha Declaration and should be made directly applicable in SADC member states.

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