The ability of select sub-Saharan African countries to utilise TRIPs Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries

by

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Executive Summary

The impact of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) on access to essential medicines in the developing world is an issue that has gripped stakeholders for years. The landmark Doha Declaration on TRIPs and Public Health, the 30 August Agreement of the WTO General Council (2003), and most recently, the December 2005 Decision of the TRIPs Council to permanently amend Article 31 of TRIPs, have increased the legal certainty on flexibilities available to developing countries. These developments have been criticised as remaining insufficient to address concerns about drug prices, and consequently, increased access to treatment for the poor. Instead of focusing on the debate above, this paper examines the degree to which countries in eastern and southern African have utilised the flexibilities contained in the 30 August Agreement to increase access to treatment in their countries. Three countries were chosen for their diversity in pharmaceutical manufacturing capacity and developmental status.

South Africa, which in the context of this paper is seen as a potential exporter of anti-retroviral drugs (ARVs) and other essential medicines for malaria and tuberculosis, has the most advanced pharmaceutical capacity on the continent and was not as affected by the Decision of 30 August 2003 as it was by the Doha Declaration. However, the Decision of 30 August could affect South Africa's ability to export pharmaceuticals. A number of flourishing generic companies exist and South African companies have both the capacity and the necessary licensing approval from patent-holding companies to export substantial quantities of first-line ARV treatment regimens to southern African neighbours and beyond.

Within the region, South Africa also has the most advanced regulatory framework with TRIPs flexibilities included in three pieces of legislation: the Patents Act, the Medicines Control and Related Substances Act and the Competition Act. The adequacy of South Africa's regulatory framework is not without its critics and although South Africa's regulatory framework is the most advanced on the continent, there still remain a few areas that could be improved. For example, South Africa still has not taken full advantage of all available flexibilities available to it through the TRIPs Agreement. While no compulsory licence has ever been issued for an essential medicine, having the correct regulatory framework in place has been

indispensable assistance to generic companies in the negotiating and granting of licences to produce generic versions of essential medicines. To date, the factors that have prevented South African producers from exporting larger volumes to other African countries are the lack of licences and an adequate domestic legal framework in most sub-Saharan countries, and the incompatibility of the regulations of specific domestic systems.

Kenya was included in this study because of its role as both an importer and potential exporter of essential medicines. Though not as developed as South Africa, Kenya has an entrenched and growing generic industry. Kenya together with Tanzania and Uganda is part of the East African community (EAC)–a customs union whose members are predominantly Least Developed Countries (LDCs), which entitles them to additional flexibilities as contained in Paragraph 7of the 30 August Agreement. Much like South Africa, Kenya's role as an exporter is hampered by the differences of pharmaceutical regulations in the three countries. The medicines regulations of the three countries that comprise the customs union will have to be addressed to facilitate intra-regional trade. The TRIPs flexibilities contained in the Kenyan Industrial Property Act have played a role in the negotiation of two voluntary licences in 2004 although not enough licences have been granted to result in a significant drop in pharmaceutical prices. It is also suggested that the compulsory licensing provisions be modified and the number of instances in which legal recourse is available, be decreased.

Zambia was included in the study on account of its status as an LDC, and, in addition, because of the compulsory licence that was recently issued by the Ministry of Commerce, Trade and Industry after no agreement had been reached between a generic manufacturer and the patent holding company. The paper notes that the products for which a compulsory licence was issued were not under patent in Zambia and that technically there might not have been a requirement for the licence to be issued. This illustrates the need for countries to first ensure that domestic legislative changes have taken place before compulsory licences or government use orders are issued. As with the Kenyan Industrial Property Act, the paper recommends that the Zambian Patents Act be modified to decrease the number of instances where legal challenges could delay the issuing of a compulsory licence.

The paper further examines the use of competition law and policy as a tool for reducing prices and consequently increasing access to essential medicines and points out the advantages to developing countries of using competition law and policy: first, the TRIPs Agreement accords member countries considerable flexibility in implementing competition law and policy most appropriate for its purposes; second, countries have leeway to define what constitutes anti-competitive behaviour; third, competition law and policy is well suited to implementation by an independent competition authority vested with strong investigative powers; and finally, competition law and policy has been successfully employed by South African activists and stakeholders to reduce the prices of essential medicines.

In using the South African Act as an example, it is noted in this paper that there are a number of sections in the Competition Act that could provide a basis for challenging anticompetitive practices in the pharmaceutical sector including restrictive practices and abuse of a dominant position. Excessive pricing provisions featured prominently in both complaints brought before the competition authorities in South Africa. In the first case of *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, the complainants alleged that the prices charged by GSK and BI for their essential medicines were directly responsible for the premature, predictable and avoidable loss of life. The Competition Commission found both companies guilty of excessive pricing and two additional grounds relating to the failure of the companies to license generic manufacturers in certain circumstances; and it referred the matter to the competition tribunal for a ruling. In a bid to avoid a damaging precedent, both companies entered into a number of agreements with the Commission and the complainants, which allowed the generic versions of products still on patent to become available in South Africa for the first time.

The second, *Treatment Action Campaign v Bristol-Myers Squibb* came about when civil society actors threatened to lodge an excessive pricing complaint against Bristol-Myers Squibb (BMS) for charging inflated prices for a product that was off patent, but for which the patent holder still held a *de facto* monopoly and was charging far lower prices in some developed countries. The matter was settled out of court with BMS agreeing to lower prices by approximately 80%. Despite these two legal successes, there are ways in which the Competition Act could be amended to increase its effectiveness as a tool for reducing prices of essential medicines. The most important

changes would be for the Act to expressly confer the power onto the commission to issue compulsory licences, to recommend a suggested royalty rate in the event of such an order, and to expressly allow for the export of products manufactured as a result of a compulsory licence.

Despite these successes in using competition law to reduce drug prices in South Africa, the prospects of other countries in the SADC region for being able to utilise competition law and policy to attain similar objectives are not high due to a lack of institutional capacity (in some cases) and a lack of expertise. By an initial focus on domestic legislation, SADC countries may ultimately pave the way for a form of regional harmonisation for competition policy. As developments in South Africa have shown, national competition policy can ensure that national markets function efficiently, assure consumers of competitive prices and product choices, and promote other such efficiency-plus objectives. However, it is true that market developments tend to outstrip policy and regulatory developments. This region demonstrates perhaps one of the most confusing and complex arrays of overlapping membership of regional trade organisations with various countries being members either of SACU, SADC or COMESA. Given the spaghetti bowl of multiple memberships of regional trading organisations in the region, it is suggested that the two most viable (but by no means exclusive) options to explore for a regional competition policy are COMESA and SACU

With deepening regional integration in southern Africa, the role of competition law and policy increases. While trade remedies still play an important role in free-trade areas, deeper integration requires that competition policy check for anti-competitive practices. National competition policy can go some way to providing oversight in cases of anti-competitive conduct but the longer term solution lies in a regional competition policy. There is currently a shortfall of qualified professionals in competition authorities and there will have to be a redoubling of training efforts to ensure that sufficient experts are available.

Abbreviations and acronyms

AIDS	Acquired Immune Deficiency Syndrome
ARIPO	African Regional Intellectual Property Organisation
ART	Anti-Retroviral Therapy
ARV	Anti-Retroviral
AU	African Union
BI	Boehringer Ingelheim
BMS	Bristol-Meyers Squibb
BLNS	Botswana, Lesotho, Namibia, Swaziland
CET	Common External Tariff
COMESA	Common Market for Eastern and Southern Africa
DOH	Department of Health
EAC	East African Community
ECJ	European Court of Justice
EDL	Essential Drugs List
ESA	Eastern and Southern Africa
EU	European Union
FDA	Food and Drug Administration (United States)
FDC	Fixed Dose Combination
FTA	Free Trade Agreement
HIV	Human Immunodeficiency Virus
GATT	General Agreement on Tariffs and Trade
GSK	GlaxoSmithKline
IP	Intellectual Property
KIPI	Kenyan Industrial Property Institute
LDC	Least Developed Country
MCC	Medicines Control Council
MFN	Most Favoured Nation
MSF	Médecins sans Frontières
NGO	Non-Governmental Organisation
PMA	Pharmaceutical Manufacturers' Association
R&D	Research and Development
SADC	Southern African Development Community
SACU	Southern African Customs Union
SSA	Sub-Saharan Africa

TAC	Treatment Action Campaign
TRIPs	Agreement on Trade Related Aspects of Intellectual Property Rights
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Programme
US	United States
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organization

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1. Introduction

Sub-Saharan African countries remain the worst affected by the HIV/AIDS pandemic with 60% of all cases of HIV/AIDS occurring in a region of the world that is home to 10% of the world's population.[1] There are also still very high prevalence rates of tuberculosis and malaria in the region with the latter still responsible for more than a million deaths globally, with 80% of these occurring in sub-Saharan Africa.[2]

Region	Total No. (%) Living with HIV/AIDS end of 2005	Newly Infected in 2005	Adult Prevalence Rate
Global Total	**40.3 million (100%)**	**4.9 million**	**1.1%**
Sub-Saharan Africa	25.8 million (64.0%)	3.2 million	7.2%
South/South-East Asia	7.4 million (18.4%)	990,000	0.7%
Latin America	1.8 million (4.5%)	200,000	0.6%
Eastern Europe/Central Asia	1.6 million (4.0%)	270,000	0.9%
North America	1.2 million (3.0%)	43,000	0.7%
East Asia	870,000 (2.2%)	140,000	0.1%
Western/Central Europe	720,000 (1.8%)	22,000	0.3%
North Africa/Middle East	510,000 (1.3%)	67,000	0.2%
Caribbean	300,000 (.7%)	30,000	1.6%
Oceania	74,000 (.2%)	8,200	0.5%

Source: UNAIDS, Aids Epidemic Update December 2005

As a public health instrument, the importance of the 2001 Doha Declaration on TRIPs and Public Health (Doha Declaration) together with the WTO General Council 30 August Decision (30 August Decision) cannot be overstated. Various factors arise, for example, the different levels of pharmaceutical production and procurement, together with the question of political will; the existence of policy space and the ability of some countries to claim exemptions from the application of the TRIPs Agreement because of their Least Developed Country (LDC) statuses. In addition, there is bilateral pressure from countries such as the US and a strong industry-lobby that small countries have to also contend with. These factors have largely determined the use of the flexibilities contained in the Doha Declaration and the 30 August WTO General Council Decision. Despite the price of essential medicines having significantly declined in the past few years, they still remain out of the reach of most

[1] See UNAIDS. 2005. **AIDS Epidemic Update (Sub-Saharan Africa)**. [Online}. Available: http://www.unaids.org/epi/2005/doc/EPIupdate2005_pdf_en/Epi05_05_en.pdf

[2] According to a press release from the World Health Organisation on 6 June 2005. [Online}. Available: http://www.who.int/mediacentre/news/releases/2005/pr24/en/index.html

people living in the region. Although the 30 August Decision was meant to be a temporary pathway until a permanent solution was found for countries with no or insufficient capacity, negotiations to establish a permanent solution at the TRIPs Council of the WTO have missed several deadlines.[3]

This paper has three objectives. First, the paper aims to conduct an examination of the implementation of the 30 August Agreement by select eastern and Southern African (ESA) countries at various levels of development. For the purposes of this portion of the paper, South Africa, Kenya and Zambia will be examined. The countries were chosen because of their different levels of development and pharmaceutical manufacturing capacity. Second, the paper examines the use of competition legislation and policy as a tool by developing countries in the region that have both competition legislation and authorities as a means of reducing the prices of essential medicines. Finally, the paper examines the role that can be played by a regional competition policy, by commenting on existing regional competition policies - primarily the Common Market for Eastern and Southern Africa (COMESA) - as an alternative regulatory tool with which to regulate anti-competitive practices of essential medicines in the ESA region.

2. The implementation of the 30 August Agreement in South Africa

The changes that have taken place in South Africa since the Doha Declaration of November 2001 are manifested in changes in government policy, an increase in the production of pharmaceutical products and the negotiation of a number of voluntary licences between patent holding companies and their generic manufacturing counterparts. The primary legal breakthrough on public health-related issues in South Africa in recent years was the complaint brought before the Competition Commission in late 2002, which is discussed in detail later in the paper. The outcome of the complaint before the Competition Commission that found GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) guilty of anti-competitive behaviour, allowed for the subsequent conduct of negotiations and the signing of voluntary licences between brand name and generic companies. This, together with ubiquitous political pressure, an escalating public health crisis and the increased investment by the generic drug

[3] See Avafia, Tenu. 2005. *TRIPS and Public Health: The Unresolved Debate*. tralac Trade Brief 2/2005, June 2005. [Online}. Available: http://www.tralac.org/scripts/content.php?id=3716

manufacturing industry in the past few years were factors in the South African government's decision in August 2003 to start providing ARVs through its public healthcare system.

2.1 Profile of major pharmaceutical generic companies in southern Africa

Aside from brand pharmaceutical companies, the only country in southern Africa with a well- established and entrenched generic manufacturing industry is South Africa. Although there is evidence of a mushrooming generic industry in other southern African countries, no other country in the SADC[4] region possesses the requisite capacity or expertise needed to establish a multi-company generic drug industry. The research based pharmaceutical industry in southern Africa is well represented with GSK, Boehringer Ingelheim, Abbott, Bristol Meyers Squibb (BMS) and Merck, Sharp and Dohme (MSD), a few of the several multi-national pharmaceutical companies with local offices in South Africa. The following generic companies form part of the South African generic manufacturers' list of companies:

2.1.1 Aspen Pharmacare

Aspen pharmacare is Africa's largest manufacturer of generic pharmaceutical products and is also the largest listed company on South Africa's Johannesburg Stock Exchange (JSE). As a multinational, Aspen has subsidiaries in the UK and Australia, and provides the South African market with more than 650 products, including ARV medication as well as treatment for opportunistic infections and accompanying pandemics of HIV/AIDS and TB. In the past year the company has taken important steps by:

a) Significantly increasing its pharmaceutical manufacturing capacity with the acquisition of Fine Chemicals Corporation (a manufacturer of molecules);

b) Obtaining US Federal Drug Administration (FDA) approval for some of its ARVs (a combination pill containing AZT, 3TC and nevirapine);

[4] The Southern African Development Community (SADC) currently comprises 14 Member States belonging to the community: Angola, Botswana, Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, South Africa, Swaziland, United Republic of Tanzania, Zambia and Zimbabwe.

c) Concluding an agreement with the American firm Gilead Sciences (incorporated) to produce tenofivir and to distribute it not only in South Africa but also further on the continent; as well as

d) Obtaining the single largest portion of the South African government's tenders to provide ARVs for the public healthcare system.

The approval by the FDA of Aspen's co-packaging of a combination pill of two (AZT/3TC) and a single agent pill (nevirapine) is a very important development as it creates the possibility for generics destined for South African consumers to be purchased with funds from the President's Emergency Plan For Aids Relief (PEPFAR) funds, which can only be used for purchasing FDA approved drugs. Aspen has also increased its ability to produce active pharmaceutical ingredients (APIs) by concluding a memorandum of understanding with Indian based Matrix Laboratories Limited (Matrix). Although there are an increasing number of generic companies being awarded voluntary licences by the patent holders to manufacturer ARVs in South Africa by various patent holders, Aspen (possibly as a result of its local incorporation, competitive prices, ability to provide a sustainable supply of generics and the investments made in increasing its production output and technical capacity) was awarded by far the largest portion of the South African Government's tender to supply ARVs for its ARV public rollout.[5] With the news on 19 July 2005 that it had been granted a non-exclusive and royalty-free licence to produce efavirenz by the patent holder MSD[6], Aspen has now concluded the voluntary licences necessary to produce all ARVs required by the WHO for a first line treatment regimen. Other generic ARVs currently being produced by Aspen include Stavudine (d4T), didanosine (ddI), both available through BMS[7], nevirapine licensed by BI, as well as AZT, 3TC and a combination of the two as licensed by GSK. Most of the licences allow Aspen to export ARVs throughout sub-Saharan Africa.

[5] The South African government announced the successful applicants for a public healthcare ARV programme (RT71/2004) valid from September 2004 until August 2007.
[6] **Aspen Completes ARV Line-up**. 2005. *Business Day*. 19 July 2005. [Online}. Available: http://transcripts.businessday.co.za/cgi-bin/transcripts/t-showtranscript.pl?1121815570
[7] It is not immediately clear whether BMS 'licences' for ddI and d4T were actual licences, or simply agreements not to enforce exclusive rights on the relevant patents.

2.1.2 Enaleni-Cipla

Enaleni (a generic company incorporated in South Africa in 2003) bought all shares in Cipla-Medpro in December 2005. Cipla-Medpro had been a joint venture between the giant Indian manufacturer Cipla and Medpro Pharmaceuticals, a South African generics supplier. Cipla-Medpro was one of the first companies to register generic ARVs in South Africa. It should be remembered, that registration on the South African market does not entitle a company to begin production. It is only after a medicine has been registered and a licence, either voluntary or compulsory, has been issued, that production may begin.[8] Enaleni-Cipla is now the third largest manufacturer of generics in sub-Saharan Africa and a potential provider of a first line regimen of ARVs. It provides AZT or zidovudine, 3TC or lamivudine, combivar (AZT/3TC combination) as well as nevirapine and d4T or stavudine, and provides a portion of the d4T used for government's ARV rollout.

2.1.3 Ranbaxy South Africa and Sonke Pharmaceuticals

Ranbaxy has been present in South Africa for a number of years, having previously operated under the name Thembalami Pharmaceuticals which was a joint venture between Ranbaxy and Adcock Ingram. Thembalami was one of the companies that were able to conclude a number of voluntary licence agreements with brand name pharmaceutical companies to produce ARVs locally. In February 2006, an announcement was made that Ranbaxy was entering into a joint venture agreement with Community Investment Holdings (CIH) to establish Sonke pharmaceuticals, whose mandate is to market and to distribute ARVs manufactured by Ranbaxy. This joint venture much like the Cipla-Enaleni joint venture opens the Southern African market up to a major international generic producer

2.1.4 Other generic companies

Other generic pharmaceutical companies that have an interest in manufacturing ARVs include Adcock Ingram, and Feza pharmaceuticals. As discussed above, Adcock Ingram formed a joint venture with a locally incorporated version of Ranbaxy

[8] According to The Economic Times of India, 22 September 2003. [Online}. Available: http://economictimes.indiatimes.com/articleshow/194236.cms

to form Thembalami, which still has a joint licence from GSK and BI for the production of AZT, 3TC and combivar as well as nevirapine. Feza Pharmaceuticals is a joint venture between Creative Outsourcing Solutions International (CSOI) and African Healthcare Solutions and has a licence for the manufacture, import, distribution and sale of ARVs containing AZT or 3TC. To date, however, Feza has not been selling the said ARVs in the South African market. A host of generic manufacturers established the National Association of Pharmaceutical Manufacturers (NAPM).[9]

South Africa's potential role in supplying essential drugs to Sub-Saharan African countries was underlined by the 30 August 2003 Decision which expressly authorised developing countries with inadequate or no manufacturing capacity to import generics produced from other countries. As explained above, recent developments in domestic manufacturing have meant that South Africa has increased its production capacity of generics for HIV/AIDS, TB and malaria not only for its own market but also to export a significant amount of generics to countries within the SADC and SACU[10] regions which, incidentally, are the hardest hit by the HIV/AIDS pandemic in terms of prevalence rates. No compulsory licences have been issued by the South African authorities.[11] This means that to date, South Africa has not had to make use of the 30 August Agreement. As a result of the Pharmaceutical Manufacturers' Association (PMA) case[12] and the Competition Commission complaint discussed in detail later in this paper,[13] voluntary licences have been negotiated between generic

[9] Members of the NAPM are Adcock Ingram, Alliance Pharmaceuticals, Aspen Pharmacare, Be-Tabs Pharmaceuticals, Biovac SA, Bodene, Cipla Medpro, Columbia Pharmaceuticals, Enaleni Pharmaceuticals, Hexal Pharma SA, Medreich SA, Merck Generics, Meyer Zall Laboratories, Natal Bioproduct Institute, Pharmafrica, Ranbaxy SA, Rolab, and Sekunjalo Medical.

[10] The Southern Africa Customs Union Countries (SACU) are Botswana, Lesotho, Namibia, South Africa and Swaziland.

[11] The official with the authority to issue compulsory licensing orders in terms of Section 56 of the Patents Act 57 of 1978 is the Patents Commissioner.

[12] On 30 October 1997, the South African Parliament passed the Medicines Control and Related Substances Amendment Act 90 of 1997, which contained provisions including Section 15C, which appeared to allow a Minister of State broad discretionary powers to authorise parallel importation. The Pharmaceutical Manufacturers' Association (PMA) launched a High Court application to prevent the Act coming into operation, *inter alia*, because of what it perceived to be the unfair wide-ranging powers which could be improperly used. After intense domestic and international lobbying by activists, the PMA withdrew its application. It appears that the lobbying effort had an extremely negative impact on the public image of brand name pharmaceutical companies and has also been used by generic companies to negotiate voluntary licences in South Africa for ARVs. Soon after the case was concluded, the Department of Health (DOH) issued a statement that Section 15C of the Medicines Amendment Act would only be used for parallel importation.

[13] 11 Complainants including the Treatment Action Campaign (TAC) filed a complaint at the Competition Commission in September 2002 against GSK and BI for charging excessive prices for their patented ARVs. In a landmark decision in October 2003, the Commission found the two brand

companies and patent holding companies for a limited number of ARVs. The question of whether the number of voluntary licences that have been granted is sufficient enough to result in increased competition and subsequently, better prices for consumers, is one thatl be dealt with below. There is no doubt, though, that the voluntary licences that have been negotiated in South Africa have allowed more competitors to enter the market and have resulted in a reduction of drug prices.

Aside from the existence of effective compulsory licensing legislation and mechanisms, two other factors play an important role in South Africa's ability to produce affordable, quality generic essential medicines:

a) The manufacturing capacity of South African generic drug companies; and
b) The process of registering generic essential medicines with the country's Medicines Control Council (MCC).

2.2 Voluntary licences in South Africa

Initially, the voluntary licences that were agreed between research-based companies and their generic counterparts contained severe restrictions imposed by the patent holding companies. For example, the voluntary licensing agreement with GSK for combivar contained a geographical restriction to SADC countries. These restrictions fell away after the South African Competition Commission found GSK and BI guilty of charging excessive prices (in violation of the competition Act) for AZT, 3TC, nevirapine and lamivudine, and settlement agreements were subsequently concluded between the parties. This finding highlights the importance of having in place not only effective policies and regulations, but also institutions that are able to implement applicable policies and legislation.

As stated above, no recourse has yet been made in South Africa to the administratively burdensome Decision of 30 August. Therefore it is not immediately clear whether there is a need to utilise this Decision or not. Indeed, there are some

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name pharmaceutical companies guilty of excessive pricing, denying a competitor access to an essential facility and engaging in an exclusionary act. Although the Commission had wanted to refer the matter to the Competition Tribunal, a settlement agreement was reached between the two brand name pharmaceutical companies in question and the complainants in the complaint that has implications for generic companies. A further confidential settlement agreement was also reached with the Competition Commission which agreed not to refer the matter to the Tribunal.

arguments that given South Africa's significant manufacturing capacity[14], it had no need to have recourse to the Decision. Instead, the aim of the Decision of 30 August was to enable countries with no or insufficient capacity to import generics produced under compulsory licence. With the development of new ARVs and other essential medicines, however, it may become more difficult for generic manufacturers to conclude voluntary licensing agreements with brand name pharmaceutical companies. This was highlighted by the recent rejection of a few voluntary licensing applications in South Africa by some patent holding companies. This situation leaves a limited number of suppliers in the local market. In the past, MSD for instance, entered into a voluntary licensing agreement only with the generic producer Thembalami and refused to conclude licensing agreements with any other generic manufacturer on the basis that two manufacturers of efavirenz were sufficient for the South African market.[15] Although the matter of a single licence for efavirenz has subsequently been resolved, it aptly illustrates the difficulties associated with having a limited number of producers. It is widely accepted that only after a number of generic producers have entered the manufacturing market do prices drop significantly, thereby passing the benefits on to the consumer.

2.3 Provisions of South Africa's Patents Act relevant to the 30 August Agreement

South Africa's legislative framework, although relatively access-friendly when compared with the laws of some developing and most other African countries, is nevertheless not quite adequate for the country's needs. In particular, the Patents Act 57 of 1978 has yet to be amended by Parliament to take full advantage of the public health safeguards and regulatory flexibilities permitted by the TRIPs agreement despite submissions to this effect by civil society.

2.3.1 Compulsory licences

As the most widely discussed TRIPs flexibility in general, compulsory licensing is a viable and more relevant remedy for South Africa because of the country's increasing manufacturing capacity. For this reason, it is extremely important for the compulsory

[14] Apart from its capacity to produce drugs, the prices submitted by Aspen during the tendering process, when compared with those submitted by CIPLA and others, reveal that South Africa was not going to be reliant on the Decision of 30 August, unlike other countries in the region.
[15] Since the demise of Thembalami, Aspen is now the holder of the single Efavirenz licence.

licensing provisions in the Act to be transparent and easy to apply. An excellent example of the results that can achieved by a country with compulsory licensing provisions must be Brazil, which has used the existence of accessible compulsory licensing legislation as an effective bargaining chip with patent holding medicines.

Section 56(a) of the South African Patents Act makes provision for the granting of compulsory licences in the event of the abuse of a patent, and contains four clear and broad grounds on which the Patent Commissioner is entitled to issue a compulsory licence. These grounds occur in the event that

a) The patented invention is not being worked on a commercial scale or to an adequate extent, four years after an application for a patent has been made or three years after the sealing of the patent if the Patent Commissioner cannot find a satisfactory reason for such nonworking of the patent;

b) The demand for the patented product in South Africa is not being met to an adequate extent and on reasonable terms;

c) By reason of the refusal of the patentee to grant a licence or licences upon reasonable terms, a relevant role-player in the pharmaceutical industry 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; or

d) The demand for the patented product is being met by importation and the price charged for the patented article by the patentee, his licensee or agent is excessive in relation to the price charged in the country of manufacture.

There is nothing in South Africa's Patent Act which prevents a pharmaceutical product produced under compulsory licence in South Africa from being exported to other countries with no or insufficient manufacturing capacity. Nonetheless, a provision that clearly allows for the exportation of essential medicines manufactured under compulsory licence to other countries where there is either an insufficient or no manufacturing capacity is desirable. This is even relevant given the expansion of

South Africa's capacity to manufacture and supply ARVs to other sub-Saharan countries.[16]

The challenges of the South African market to become a sustainable and significant supply option lie in the volumes of essential medicine production, the lack of adequate domestic legislation and policies in most sub-Saharan Countries, and the incompatibility of the regulations of specific domestic countries. For instance, a South African generic manufacturer was recently prevented from exporting generic ARVs to four sub-Saharan countries because domestic registration of the ARVs had not occurred despite the manufacturer having obtained United States FDA approval for the ARVs.[17] It should be remembered that to date, Section 56 has never been used successfully to obtain a compulsory licence, but it has been used, at least once, to obtain a voluntary licence. Previous attempts to obtain compulsory licences should be distinguished from the current situation in that they were not related to public health. In terms of section 4 of the South African Patents Act, the obligation on the state when negotiating compulsory licences is limited to the terms and conditions and not the grant of the licence.

2.3.2 Miscellaneous provisions

Section 4 of the Patents Act entitles either the Ministers of Health or Trade and Industry to '…use an invention for public purposes on such conditions as may be agreed 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'.

Section 4 of the Patents Act is generally understood to empower the Minister of Health (or the Minister of Trade and Industry or another relevant minister, where applicable) to issue compulsory licences for a public purpose, such as ensuring access to a sustainable supply of affordable medicines. This understanding is based on an interpretation of the provision that takes into account relevant foreign case law

[16] See, for instance, a news report detailing a licensing agreement involving a South African generic manufacturer and a US based pharmaceutical manufacturing company. [Online}. Available: http://www.suntimes.co.za/zones/sundaytimesNEW/business/business1114434517.aspx

[17] Refer to a *Boston Globe* newspaper report , 20 June 2005 [Online}. Available: http://www.boston.com/news/world/africa/articles/2005/06/20/aids_drugs_hit_roadblock_in_africa?mode=PF

and the state's positive constitutional obligations in respect of the right to have access to health care services. Interestingly, the provision has yet to be used by the state nor has it been subject to any definitive interpretation by a South African court

3. Implementation of the 30 August Agreement in Kenya

Because of its classification as a developing country, Kenya was required to become TRIPs compliant by 1 January 2000. The Industrial Property Act was passed in 2001 and came into force in May 2002.[18] As a country that is both an importer and an exporter of essential medicines, Kenya could be well-placed to export essential medicines to other members of the East African Community (EAC) namely Tanzania and Uganda. The Kenyan drug manufacturing industry is significant and growing, with an investment of more than US$ 40 million said to have been made by three of the largest manufacturers in 2004.[19] There had been some parallel importation of ARVs by NGOs such as MSF, but the volumes of importation were inconsequential and occurred before the most recent version of the Act came into force. The other important dynamic to remember about Kenya is that by virtue of its membership of the EAC along with Tanzania and Uganda (which are both classified as LDCs), Kenya is entitled to export medicines produced or imported under compulsory licence to its EAC partners with far fewer restrictions. This entitles Kenya[20] to export medicines produced or imported under compulsory licence to the other EAC members.

Shortly after the 30 August 2003 Agreement was announced by the WTO General Council, the Kenyan manufacturing firm Cosmos Pharmaceuticals announced its intention to begin producing generic drugs for the East African market after winning a

[18] In terms of Legal Notice No. 53 of 2002 of April 2002.

[19] See a statement made by Dr WO Wanyanga, Manager Regulatory Affairs, Cosmos Limited (25 May 2004) referred to by: Lettington and Munyi. 2005. *Willingness and Ability to use TRIPs Flexibilities: Kenya case.* DFID Issue paper, September 2004, p. 12. [Online}. Available: http://www.dfid.gov.uk/pubs/files/dfidkenyareport.pdf

[20] Through Paragraph 6 of the 30 August Agreement, of which the relevant portion 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… 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 that 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 licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question.'

government tender to supply the latter with generic ARVs.[21] After difficulties between the Ministry of Health and the Ministry of Trade and Industry protracted negotiations with the patent holder GSK,[22] in September 2004, a voluntary licence was negotiated and agreed between Cosmos and GSK for the production of AZT, 3TC and combivar.[23]

The possibility of Kenya's providing its EAC neighbours Tanzania and Uganda[24] with ARVs is made fairly challenging because of differing regulations on the manufacture, import, export and distribution of pharmaceutical products in each of the EAC countries. While the need for domestic regulation about the efficacy and quality of medication is unquestionable, there is a need for harmonisation by the three countries, which has not been realised to date. The essential drugs produced by a Kenyan manufacturer will have to be included in the WHO's Essential Drug List to prevent the type of difficulties experienced by Aspen Pharmacare of South Africa when attempting to export ARVs to Ethiopia, Nigeria, Tanzania and Uganda in June 2005.

3.1 Key provisions in Kenya's Industrial Property Act of 2001

Kenya's Industrial Property Act contains provisions on a range of TRIPs flexibilities and safeguards, including the international exhaustion of rights, the rights of government use, compulsory licensing, 'mailbox' legislation, and *Bolar* exception provisions, to name the most relevant. In a recent review of Kenya's patent legislation, it was suggested that, because there were no questions raised about the validity of any of the aforementioned flexibilities, Kenyan legislation is regarded as having complied with the minimum standards imposed by the TRIPs Agreement.[25] Regarding Government use provisions, the Kenya Industrial Property Institute (KIPI) determines the amount of compensation to be paid to the owner of the patent. Such

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[21] Refer to a BBC news report. [Online}. Available: http://news.bbc.co.uk/1/hi/world/africa/3123008.stm

[22] According to reports on http://www.essentialdrugs.org/edrug/archive/200409/msg00027.php the Ministry of Health ordered that generic drugs be produced while the Ministry of Trade and Industry refused to allow the issuing of a compulsory licence despite protracted negotiations for a voluntary licence between the generic producer and GSK.

[23] According to a report that appeared in the Kenyan newspaper, *The Daily Nation*, on 22 September 2004. [Online}. Available: http://www.nationmedia.com/dailynation/

[24] The three countries signed a protocol in 2004 to establish a customs union by 1 January 2005.

[25] Refer to Lettington & Munyi, above footnote 16, page17.

compensation must be equitable with due regard to all the circumstances of the case and in particular, to the economic value of the patent.

3.1.1 Voluntary licences in Kenya

Unlike the South African Patents Act which does not make explicit reference to voluntary licensing, the Industrial Property Act gives a licensor the right to confer on a licensee the rights that the licensor has over an invention. An important condition for the purposes of verification is that all voluntary licensing agreements must be registered with the KIPI, which retains the right to refuse to register an agreement if it is not satisfied that all the conditions for a voluntary licensing agreement have been met. This is an important regulatory function which ensures that public health objectives are not jeopardized by voluntary licences that might be counterproductive to promoting access to essential medicines.

The Managing Director of the KIPI can reject a voluntary licence in terms of Section 69 of the Act for a number of reasons[26] and also retains the power to make a discretionary decision to invalidate a licence where he or she is of the opinion that a voluntary licence or any clause contained therein imposes a restriction which results in the contract being harmful to the economic interests of Kenya.[27] The conditions under which the registration of a licence can be refused are meant to prevent the registration of restrictive licences that would hinder the distribution of essential medicines.

Although voluntary licensing has not been used to its maximum potential to date, the developments in September 2004, which resulted in a local manufacturer being able to successfully conclude a licence from GSK for the first time, indicate an encouraging start. Shortly after the first announcement of a voluntary licence, a second licensing agreement between Cosmos Pharmaceuticals and BI was announced for the production of nevirapine.[28] BI and GSK, incidentally, are the same

[26] Some of the grounds contained in Section 69 for the refusal of a voluntary licence include cases where the contract requires the payment of a price or royalty that is disproportionate to the value of the technology, a restriction on the volumes of production, a quantitative or other restriction on the exportation of the licensed product, price fixing and the imposition of alternative quality standards.
[27] Refer to Lettington & Munyi, above footnote 16.
[28] As reported by an Associated Press article on 1 October 2004, [Online}. Available: http://www.ctv.ca/servlet/ArticleNews/story/CTVNews/1096679934011_66?s_name=&no_ads

two companies that concluded voluntary licensing agreements in South Africa in 2003. However, with the existence of only two voluntary licences, it is unlikely that sought-after price drops would be significant. As with South Africa, there is likely to be greater room for the negotiating and concluding of voluntary licensing agreements. The negotiating of voluntary licences as well as the eventual issuing of compulsory licences could be facilitated by the inclusion of a time frame into the Patents Act within which negotiations for a voluntary licence should be concluded.

3.1.2 Compulsory licences in Kenya

Compulsory licensing is provided for in terms of the Act[29] but unlike the South African Act, which contains four grounds as a basis for compulsory licensing, Kenya has two:

a) Broadly, in terms of Section 72(1) of the Act, an applicant may apply to the Kenyan Industrial Property Tribunal[30] if a patented invention is not being supplied on reasonable terms in Kenya; and
b) More specifically, in terms of Section 73(1) of the Act in terms of which compulsory licences may be granted for new patented products where an inventive step has been taken on an existing invention.

The applicability of these limited grounds for compulsory licensing is made more complicated by the imposition of several conditions in the Act, which must be met before a compulsory licence is issued. In addition, provisions which might facilitate the issuing of a compulsory licence are missing. Some limitations[31] are that:

a) A compulsory licence may not be granted where the patent holder can prove that there are justifiable reasons why the patented product is not being supplied to the Kenyan market on reasonable terms;[32]
b) Unless there is a situation of extreme urgency, the applicant for the compulsory licence must demonstrate that a request for a voluntary licence was either not

[29] See Sections 72-78 of the Act.
[30] The tribunal is established in terms of Section 113(1) of the Act and consists of a Chairperson who must be a lawyer who has been, or is qualified to be, a judge of the High Court, two lawyers with at least seven years of practice each and two other members with industrial, scientific or technological expertise. Tribunal members are appointed by the Minister of Trade and Industry.
[31] See Lettington & Munyi above footnote 16, page 23, for a thorough discussion of existing conditions on compulsory licensing in the Industrial Property Act
[32] Section 72(2).

answered within a ‘reasonable time’ or ’reasonable commercial’ terms have been refused.[33]

c) The applicant of the compulsory licence is expected to offer assurances that the deficiencies in the supply of the product, which resulted in the need for a compulsory licence, will be remedied. In other words, there must be an assurance that the unsatisfactory situation that gave rise to the compulsory licensing order in the first place is remedied, or else the compulsory licence can be revoked.[34]

The key point regardless of the suitability (or lack thereof) of the provisions is that, to date, there have been no compulsory licences issued in Kenya. The two licences that currently exist are voluntary licences and, given the complexity and legal uncertainty that a judicial interpretation of these provisions might cause, it is likely that neither a potential applicant nor the patent holder would be particularly interested in instituting or defending a compulsory licensing application.

3.1.3 Government use provisions in Kenya

The Act lists two grounds[35] which entitle the government to use a patent without the permission of the patent holder:

a) Where it is considered to be in the public interest (such public interest being national security, nutrition, health, environmental conservation or the development of other sectors of the economy which are considered vital for economic development) provided that equitable compensation is paid to the patent holder. The term adequate compensation is not without its ambiguities, though.[36]

b) When the Managing Director of the KIPI at his discretion decides that the manner in which a patented invention is being exploited is not competitive, a recommendation can be made to the Minister of Trade and Industry to issue a government use order.[37]

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[33] Section 74(1)(a).
[34] Section 74(1)(b).
[35] Section 80.
[36] Section 80(1)(a).
[37] Section 80(1)(b).

There has been one attempt to utilise Kenya's government use provisions to date. In July 2003, Cosmos Pharmaceuticals was awarded a tender issued by the Ministry of Health to supply generic ARVs. Possibly sceptical of obtaining favourable conditions under a voluntary licence, the company made an application for a government use order. Before a decision granting the government use order had been taken by the Minister of Trade, a voluntary licence was negotiated between the patent holder and Cosmos Pharmaceuticals.

There are a few instances where it can be said that Kenya does not make use of existing TRIPs flexibilities. First of all, the Act requires that prior consultation should take place between the government or applicant and the patent holder,[38] which is not a formal requirement in terms of Article 30 or 31 of the TRIPs Agreement or Articles 41 to 44 dealing generally with issues of administrative process which would be relevant to a government use order. Another additional requirement imposed by the government use provisions which is not contained in the TRIPs Agreement, is the requirement that an applicant for a government use order has to first negotiate with the patent holder.[39]

4. Implementation of the 30 August Agreement in an LDC: a Zambian example

Zambia is classified as an LDC, with a GDP per capita of US$ 870 in 2001, and was ranked 143 out of 162 surveyed countries in the Human Development Index (HDI) of the UNDP in 2001.[40] Aside from an HIV/AIDS prevalence rate among pregnant adult women of 18-20%[41], there are approximately 3 million clinical cases of malaria every year resulting in some 50 000 deaths annually. According to Article 66(1) of TRIPs, which is an acknowledgement that the need for development outweighs the case for stringent intellectual property protection for the time being,[42] LDCs were only expected to become TRIPs compliant in 2006 with an additional 10-year extension granted for pharmaceutical products in terms of the Doha Declaration on TRIPs and

[38] Section 80(1)(b).
[39] Section 80(2).
[40] United Nations Development Program. 2001. ***Human Development Report***. Lusaka, Zambia.
[41] See UNAIDS. 2005. **Report on the Global Epidemic.** [Online}. Available: http://www.unaids.org/epi/2005/doc/EPIupdate2005_pdf_en/Epi05_05_en.pdf
[42] The relevant portion of which reads as follows:
'In view of the special needs and requirements of least developed members, their economic, financial and administrative constraints and their need for flexibility to create a viable technological base'.

Public Health.[43] This changed with the TRIPs Council decision of 29 November 2005, which accorded developing countries an additional extension of time by which compliance with TRIPs must be achieved. LDCs now have until 1 July 2013 to implement the provisions of the TRIPs agreement although there is no extension at this stage for pharmaceutical patents beyond 2016.

There are a number of flexibilities that LDCs could utilise through the enactment of domestic legislation. LDCs could continue either to provide no patent protection at all, or to provide patent protection for a period that is less than the minimum 20-year period prescribed by TRIPs. Countries that under their national laws extend patent protection to 'processes' and not to 'products' could further continue to apply these rules, despite the TRIPs Agreement being applicable to both products and processes. Since the transitional period applicable to developing countries expires on 1 January 2005, all of these countries would have to ensure that their national laws fully conform to the provisions of the TRIPs Agreement relating, *inter alia*, to the duration of patents and the extension of protection to both products and processes. There is still a need for updated intellectual property legislation to govern, for instance, the prevention of re-exportation of generics produced under compulsory licence by third parties.

Zambia is one of three Southern African countries that have issued either a compulsory licence or government use order for pharmaceutical products in the last two years, the other two being Mozambique[44] and Zimbabwe.[45] In Zambia's case, a compulsory licence[46] was issued in late September 2004 for lamivudine, stavudine and nevirapine. Like Zimbabwe, Zambia first declared a state of emergency (Article 31 of TRIPs does not require that a state of emergency exist in order for a

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[43] The relevant portion of Paragraph 7 reads as follows:
*'*We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement*.'*

[44] Mozambique's Deputy Minister of Industry and Commerce issued a Compulsory Licence order 01/MIC/04 in April 2004 for the production of AZT, 3TC and stavudine by a local manufacturer while capping royalty rates at 2%. A translated version of the licence is available. [Online}. Available: http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf

[45] The government of Zimbabwe issued a *de facto* compulsory licence in May 2004 by announcing a state of emergency as a result of the HIV/AIDS pandemic and invoking Article 35 of the Patents Act. [Online}. Available: http://www.cptech.org/ip/health/c/zimbabwe/zim05242002.html

[46] Entitled Licence no. DC 01/2004. [Online}. Available: http://www.cptech.org/ip/health/c/zambia/zcl.html

compulsory licence to be issued) before proceeding with its compulsory licensing order. The justification for the issuing of the compulsory licence was that the patent holders of the three ARVs in question were not able to come to an agreement for the manufacture of a Fixed Dose Combination (FDC), which was imperative to government's AIDS treatment plan. The Ministry of Commerce, Trade and Industry awarded a tender to a local manufacturer, PHARCO, LTD, to produce the said combination of ARVs for use only in Zambia[47] and placed a royalty cap of 2.5% to be paid to the patent holders.

The compulsory licensing order for Zambia differs slightly from what was envisaged by Article 31(f) of TRIPs because the two patent holders of the ARVs concerned, BMS and BI, have not applied for their patents to be registered in Zambia. Therefore, the prescribed royalty rate of 2.5%[48] would apply only in the event that there is an attempt by either BI or BMS to register a patent while the compulsory licence is still valid.[49] This example together with a similar example in Mozambique in 2004 serves as an illustration of the need for countries to first ensure that domestic legislative changes have taken place before compulsory licences or government use orders are issued.

4.1 Duration of a patent

Some aspects of the Zambian Patents Act make use of its classification as an LDC. For instance, Section 29 of the Patents Act gives a patent protection for a minimum of 16 years (from the filing of the patent) as opposed to the standard 20-year period prescribed by the TRIPs Agreement. However, a 5-year extension can be given upon application with the possibility of further a 10-year extension in exceptional cases.

4.2 Compulsory licensing provisions

The recent Zambian compulsory licence was issued through the Statutory Instrument 83 of 2004.[50] Although there is no requirement in terms of Article 31(f) of TRIPs, the Doha Declaration or the 30 August Agreement requiring that a state of emergency be

[47] In line with Regulation 4 of the Patents (Manufacture of Patented Anti-Retroviral Drugs) (Authorisation) Regulations, 2004.
[48] This is 2.5% of the total turnover of the products under compulsory licence at the end of every financial year of PHARCO LTD.
[49] According to a letter written by the Ministry to BMS and BI, the licence is valid until 31 July 2009. [Online}. Available: http://www.cptech.org/ip/health/c/zambia/zambia-bms09302004.html
[50] Titled the Patents (Manufacture of Patented Antiretroviral Drugs) (Authorization), Regulations, 2004.

present before the issuing of a compulsory licence, such a national state of emergency was declared in Statutory Instrument 83 of 2004.

Compulsory licensing is also provided for in terms of Section 37 of the Patents Act, which allows any *bona fide* applicant to apply for a compulsory licence if the applicant can show that he or she has been unable to obtain a licence on reasonable terms. There is a three-year waiting period from the sealing of the patent or a four-year waiting period from the filing of the patent before an application for a compulsory licence can be made. There is the possibility of legal challenge on a number of broad grounds[51] by either the patentee or any other person, which could hinder the timely application for a compulsory licence. However, there are several grounds contained in the Act, the existence of which would nullify the opposition of a compulsory licensing application, including:

a) no satisfactory reason for the non-working of a patent;
b) inadequate working of the patent on a commercial scale by the patentee;
c) not meeting the demand for the patented article on reasonable terms or in adequate amounts;
d) anti-competitive behaviour by the patentee; and
e) the unreasonable refusal by the patentee to license the patent to a third party on reasonable grounds.

4.3 Government use provisions

There is a broad government use provision[52] which authorises any person acting on behalf of a government department to make use of a patented invention without having to pay any royalties in certain circumstances. Furthermore, provision is made for the possible use of a government use licence outside Zambia when it is considered to be in the best interests of the country. In addition, it is possible to sell patented inventions produced under government use order and there is no express prohibition on selling for non-commercial purposes.[53]

[51] Section 37(4).
[52] Section 40 of the Act.
[53] Section 40(6) and (7).

4.4 Special provisions

In addition to compulsory licences and government use orders, there are some miscellaneous provisions in the Patents Act provisions, which create flexibilities similar to those envisaged by both paragraphs 4[54] and 6 of the Doha Declaration. Section 41 authorises a Minister of State to declare a period of emergency as a consequence of which the said minister is allowed to use any patented invention for the maintenance or the securing of supplies and services essential to the life of the community. This broad and uncomplicated provision allows the Zambian government to take whatever steps it considers necessary to deal with public health emergencies (such emergencies being exclusively determinable by the Zambian government). This broad provision creates much sought after policy space to deal with health emergencies as deemed fit by developing country governments.

5. Using competition law and policy to increase access to a sustainable supply of affordable medicines[55]

5.1 Introduction

This section of the paper focuses on the potential role of competition law and policy in advancing public health by increasing access to a sustainable supply of affordable essential medicines. It does so by briefly considering the broader framework provided by the WTO's TRIPs Agreement before looking at the appropriateness of using competition policy within a developing country context. In countries where legal change is slow, where court processes are unduly time-consuming and not particularly user-friendly, and where laws often exist only on paper, the introduction and successful implementation of a complex and comprehensive competition policy

[54] Paragraph 4 of the Declaration (discussed below) 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.'

[55] This section draws from Berger, Jonathan. 2004. *Advancing public health by other means: using competition policy to increase access to essential medicines.* Bellagio Series on Development and Intellectual Property Policy: Policy Options for Assuring Affordable Access to Essential Medicines, ICTSD, 2004. [Online]. Available: http://www.iprsonline.org/unctadictsd/bellagio/dialogue2004/bell3_documents.htm

framework will require a significant degree of political will and technical support, which may not always be forthcoming. Why then even consider competition law and policy?

There are four key reasons why developing countries should – if at all possible – use the regulatory tools available in terms of competition law and policy to ensure access to a sustainable supply of affordable essential medicines. In so doing, however, they should also seek to make full use of the public health safeguards and flexibilities elaborated upon by the Doha Declaration.[56] That agreement, adopted at the WTO's ministerial meeting in Doha, Qatar, in November 2001, sets out what can and cannot be done to ensure access to medicines insofar as patent law and policy are concerned.

First, TRIPs accords member states considerable flexibility in dealing with anti-competitive practices. Importantly, it also recognises the particularly egregious nature of anti-competitive conduct.[57] The broader international trade law framework provided by TRIPs is relevant largely because it provides some degree of guidance for determining in what circumstances it may be appropriate to invoke competition policy to increase access to essential medicines.[58]

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[56] *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, 20 November 2001, at paragraphs 1 and 4.

[57] There are five key provisions in TRIPs that directly or indirectly provide the framework within which competition policy can operate. These range from broad principles regarding the need to deal with the potentially negative consequences of IP protection and concerns relating to issues, such as public health and socio-economic development, to specific provisions dealing with competition policy. While differing in focus, each of the five provisions underscore the proposition that TRIPs provides significant scope within which competition policy may be employed to advance a public health agenda that may be compromised if IP protection is left unchecked. For more detail on these provisions, see Berger, above note 51 at 3.

[58] While TRIPs is not alone in regulating the use of competition law and policy in this regard (see, for example, UNCTAD. 2000. *The United Nations Set of Principles and Rules on Competition: The Set of Multilaterally Agreed Equitable Principles and Rules for the Control of Restrictive Business Practices*, (Geneva: UNCTAD), originally adopted by the General Assembly at its 35th session in resolution 35/63 of 5 December 1980 and reaffirmed as valid by the Fourth Conference to Review All Aspects of the Set in resolution TD/RBP/CONF/10.Rev.2 of 4 October 2000), it is the only international law framework that legally binds all WTO members at the moment. Some limitations already exist (and others may very well arise at a later stage) in regional and/or bilateral trade agreements that seek to impose TRIPs-plus standards of IP protection (see, for example, Carlos Correa, Chapter 22: Formulating effective pro-development national intellectual property policies in Bellmann, Christophe et al (eds.). 2003. *Trading in Knowledge: Development Perspectives on TRIPS, Trade and Sustainability* (London and Sterling, VA, USA: Earth scan Publications Ltd, pp. 211 – 212; and ICTSD/UNCTAD.2003. *Policy Discussion Paper – Intellectual Property Rights: Implications for Development.* Geneva, Switzerland: ICTSD and UNCTAD. [Online}. Available: http://www.ictsd.org/iprsonline at 56).

Second, unlike the degree of consensus reflected in the Doha Declaration, which clearly sets the boundaries of what is permissible in terms of patent law and policy, there is sufficient disagreement between and within developed countries on the relationship between competition policy and intellectual property to provide with significant space within which to manoeuvre. This is not to imply that developing countries should take their lead from the industrialised world if and when it reaches consensus on the relevant issues. Instead, it is simply to draw attention to the window of opportunity that such a lack of consensus provides.

Third, competition law and policy is well suited to implementation by an independent competition authority vested with strong investigative powers. Unlike patent law, the effective use of competition law is ordinarily not reliant on the conduct of certain parties that may be reluctant to act. In particular, it may facilitate action by a range of interested parties other than the state and generic pharmaceutical manufacturers, providing a mechanism for action that does not necessarily require such parties to invest significant resources in risky litigation that may drag on for years. Instead, the regulatory authority may pursue the matter in the public interest simply on the basis of a third party complaint.

Fourth, the rich (albeit limited) experience of South Africa in using competition law to increase access to medicines for the treatment of HIV infection and AIDS-related illnesses provides helpful insights into the potential benefits of exploiting competition law and policy in a developing country context. While South Africa may differ in many respects from its African neighbours and other developing countries, the lessons learnt in two abuse-of-dominance matters (both of which focused on allegations of excessive pricing) are of broader application.

The two South African case studies are considered in more detail below. The other three reasons advanced in support of using competition law and policy are explored in greater detail elsewhere.[59] When taken together, they provide a particularly strong basis for the creative and expansive use of anti-competitive regulatory tools to ensure access to a sustainable supply of affordable medicines.[60] But in and of themselves,

[59] See Berger, above footnote 52, at note 56.

[60] It is generally understood that the simple exercise of exclusive rights in patents cannot in and of itself provide a basis for using competition policy to advance public health. In such circumstances, which Patent law ordinarily does not regard as abusive, states are nevertheless permitted by TRIPs to

such policy instruments are insufficient. As already mentioned, developing countries should also seek to make full use of the public health safeguards and flexibilities identified in and clarified by the Doha Declaration. For competition policy tools to be used efficiently and effectively, they need to be viewed as complementary to the regulatory instruments identified in the Doha Declaration.[61]

5.2 Using South Africa's Competition Act 89 of 1998

South Africa's new competition law framework has been in force for almost six years.[62] While it is possible – and indeed constitutionally mandated – to interpret the Competition Act in a manner that takes full advantage of the regulatory flexibility permitted by TRIPs,[63] this has largely not been achieved outside of academic, activist and advocacy circles. In particular, the jurisprudence developed by the specialist bodies[64] primarily charged with adjudicating competition disputes has not begun to consider the interface between competition law principles and exclusive rights in

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take a range of regulatory measures to increase access to essential medicines and other patented technologies necessary for safeguarding public health. (See, in particular, Articles 7, 8, 27.2, 30 and 31 of the TRIPs Agreement, as well as the Doha Declaration.) But, as is discussed in greater detail elsewhere (see Berger, above note 51), there are various ways in which competition policy may appropriately be used to advance the public interest even where the conduct of the exclusive rights holder is not necessarily abusive nor have any direct anti-competitive effect. The various regulatory options available under competition policy can be divided into three broad but interrelated categories: remedies, preventative measures and measures that serve the public interest by promoting competition, whether directly or indirectly. Thus the simple existence of measures to remedy anti-competitive practices, for example, may act as a sufficient disincentive for exclusive rights holders to engage in abusive or otherwise problematic conduct. In such cases, there may be no need to deal proactively with the problematic conduct. This may be important for those countries without significant institutional capacity to regulate proactively. In contrast, those countries with capacity may rather choose to frame such measures in the language of prevention, such as by subjecting licensing agreements to prior approval processes of the sort ordinarily associated with merger regulation.

[61] This is particularly important given that not all types of problematic conduct on the part of patentees or other exclusive rights holders in patents can or should be seen as anti-competitive. In addition, not all states are unwilling to act against exclusive rights holders. Where they are, patent law provisions may be easier and more powerful to use.

[62] While a few provisions of the Competition Act came into force on 30 November 1998, the Act – as a whole – has been in force since 1 September 1999.

[63] Section 39(2) of the Constitution provides – in relevant part – as follows: 'When interpreting any legislation, … every court, tribunal or forum must promote the spirit, purport and objects of the Bill of Rights.' In section 27, the Bill of Rights expressly recognises a right to have access to health care services. Section 27(2) mandates the state to take 'reasonable legislative and other measures, within its available resources, to achieve the progressive realisation' of this right. In addition, the Competition Act itself states in section 1(2) that it must be interpreted 'in a manner that is consistent with the Constitution' and 'in compliance with the international law obligations of the Republic [of South Africa]'.

[64] These bodies are the Competition Tribunal and the Competition Appeal Court, set up in terms of Sections 26 and 36 of the Competition Act respectively. While other bodies (the Supreme Court of Appeal and the Constitutional Court) also have jurisdiction to adjudicate on competition matters, the nature of their limited appellate jurisdiction means that these specialist bodies will develop the vast bulk of competition jurisprudence.

patents. While a plain reading of the Competition Act shows that the exercise of exclusive rights in patents is not ordinarily exempt from the reach of competition law,[65] the nature and extent of the reach of the law in this arena remains in significant doubt.

Interestingly, however, the competition authorities have already considered a wide range of health-related matters.[66] Recently, the Competition Tribunal refused to sanction a merger between two health care groups in the 'capitated managed care' market, which seeks to provide low-income earners with access to private health care services. In its decision, the Tribunal gave an indication of the approach that it is likely to adopt in interpreting the provisions of the Competition Act, relevant for increasing access to a sustainable supply of affordable medicines. In setting out it approach to section 12A, which sets out the considerations relevant to the approval of mergers, the Tribunal held as follows:

> Section 12A(2)(e) of the Act provides that when determining whether or not a merger is likely to substantially prevent or lessen competition we should take account of 'the dynamic characteristics of the market, including growth, innovation and product differentiation.' … Pertinent to our consideration [of the proposed merger] are the general state of healthcare provisioning in South Africa, the policy objectives of the South African government in the realm of healthcare provision, the mechanisms whereby government intends achieving those objectives, and the place and role of the private sector.[67]

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[65] See, for example, the provisions in Section 10(4) dealing with exemptions from the application of the chapter on prohibited practices to any 'agreement or practice, or category of agreements or practices that relates to the exercise of intellectual property rights'.

[66] See, for example, *National Association of Pharmaceutical Wholesalers and Others v Glaxo Wellcome (Pty) Ltd and Others* (Competition Appeal Court, case no: 29/CAC/JUL03, 18 February 2005, available at http://www.comptrib.co.za/CAC/Pharmaceutical%20vs%20Glaxo1.pdf) dealing with interim relief in a matter considering vertical agreements between pharmaceutical manufacturers and exclusive distributors.

[67] *Medicross Healthcare Group (Pty) Ltd and Prime Cure Holdings (Pty) Ltd* (Competition Tribunal, case no: 11/LM/Mar05, 13 October 2005. Berger, Jonathan. 2004. Advancing public health by other means: using competition policy to increase access to essential medicines. *Bellagio Series on Development and Intellectual Property Policy: Policy Options for Assuring Affordable Access to Essential Medicines, ICTSD,* 2004. [Online]. Available: http://www.iprsonline.org/unctadictsd/bellagio/dialogue2004/bell3_documents.htm http://www.comptrib.co.za/decidedcases/doc/11LMMar05.doc) at paragraph 55

On 31 January 2006, the Competition Appeal Court overturned the ruling of the Competition Tribunal and approved the merger unconditionally. To date, it has yet to issue reasons for its decision.

There are potentially a number of sections in the Competition Act that could provide a basis for challenging anticompetitive practices in the health sector broadly and in the pharmaceutical sector in particular. These are set out in Chapter 2, which deals with 'prohibited practices' in two parts: 'Restrictive Practice'" in Part A and 'Abuse of a Dominant Position' in Part B. In Part A, the Competition Act prohibits certain 'restrictive horizontal practices',[68] such as price fixing between competitors,[69] as well as certain 'restrictive vertical practices',[70] such as agreements between a supplier and a customer relating to minimum resale prices.[71] Part B deals with four main categories of prohibited abuse of dominance.[72] Section 8, the primary provision dealing with the abuse of dominance which is of significant importance and relevance to essential medicines, provides as follows:

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;

[68] Section 4.
[69] Subsection (1)(b)(i).
[70] Section 5.
[71] Subsection (2).
[72] Sections 8 and 9.

(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 services* 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.

Three terms, which are defined in section 1 of the Competition Act, merit further attention:

> *essential facility* means an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide *goods or services* to their customers;
>
> *excessive price* means a price for a good or service which –
> (aa) bears no reasonable relation to the economic value of that good or service; and
> (bb) is higher than the value referred to in subparagraph (aa);
>
> *exclusionary act*' means an act that impedes or prevents a *firm* entering into, or expanding within, a market.

Collectively, when considered in the context of a legal system based on the authority of a Constitution that expressly recognises that all people have a right of access to health care services[73] – and which places corresponding positive obligations on the state regarding the progressive realisation of the right[74] – they potentially provide a range of tools to challenge various anticompetitive practices such as unjustifiable refusals to license intellectual property and price gouging. To date, Section 8 of the

[73] Section 27(1) of the Constitution.
[74] Section 27(2) of the Constitution.

Competition Act has been used successfully to challenge both, even though the matter that resulted in the grant of 'non-voluntary' licences was in fact framed as an excessive pricing claim.

This section now considers the two excessive pricing matters that have managed to use competition law effectively in order to increase access to a sustainable supply of affordable essential medicines. The first, *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, dealt with antiretroviral (ARV) medicines for the treatment of HIV infection. The second, *Treatment Action Campaign v Bristol-Myers Squibb*, considered an antifungal medicine used to treat cryptococcal meningitis, an AIDS-related opportunistic infection. In both matters, the stakes could not be higher – literally matters of life and death. Unsurprisingly, neither matter proceeded to adjudication. Both were settled.

5.2.1 Hazel Tau takes on GlaxoSmithKline and Boehringer Ingelheim

As part of a national campaign to increase access to treatment for HIV/AIDS, which includes taking steps to ensure access to a sustainable supply of affordable HIV-related medicines, a group of concerned individuals and organisations lodged a complaint against the GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) groups of companies with South Africa's Competition Commission in September 2002. Acting in terms of section 49B(2)(b) of the Competition Act, which permits 'any person' to 'submit a complaint against an alleged prohibited practice', the complainants argued that the two companies were acting in violation of competition law by charging excessive prices for certain of their ARV medicines to the detriment of consumers.[75]

In essence, the complainants alleged that the prices charged by GSK and BI for their essential medicines were directly responsible for the 'premature, predictable and avoidable loss of life'.[76] Deliberately adopting a conservative approach to the issue

[75] In addition to the Treatment Action Campaign (TAC), South Africa's largest and most effective organisation advocating for the rights of people living with HIV/AIDS (PLWHAs), the complaint was lodged by the AIDS Law Project on behalf of a number of PLWHAs who are open about their status, health care workers treating PLWHAs, the AIDS Consortium and a number of trade unions. In June 2003, before the matter was resolved, one of the complainants died of AIDS-related complications.
[76] See the Statement of Complaint at paragraph 107. [Online]. Available: www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc

of prohibited excessive pricing, they argued that even when full allowance was made for the costs of research and development, the incentive to develop new drugs, higher profits and licensing fees,[77] the prices of these patented medicines remained excessive and unjustifiable.[78] Whilst argued in terms of the Competition Act, the complainants located their arguments firmly within the broader context provided by the public health emergency of HIV/AIDS in South Africa, as well as the constitutional guarantee of access to health care services.[79]

At the time that the complaint was lodged, the South African government had yet to commit itself to the development and implementation of a public sector ARV treatment programme.[80] This meant that access to appropriate treatment in the public sector was not an option. In a country where the vast majority of people are reliant on the public sector for the provision of health care services, this meant no access to ARV treatment for most of those in need. But access for some was still possible, albeit limited. In essence, there were only three options available to people in South Africa for accessing this life-saving treatment: out-of-pocket purchase from private pharmacies; medical scheme (health 'insurance') cover; and employer-funded workplace treatment programmes for uninsured workers. By challenging the high prices of drugs, the complaint 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'.[81]

Given the paucity of jurisprudence on the use of competition law to increase access to patented medicines, the lack of clarity in the Competition Act regarding the patent law and competition policy interface, and the inherent risks of litigation, the complainants decided to tread cautiously. Their goal was to make best use of the available legal framework to ensure access to a sustainable supply of affordable ARV

[77] Where applicable, as is the case with the ARV medicine lamivudine, marketed by GSK in South Africa as 3TC® (and in many other places as Epivir®).
[78] See Beresford, Belinda. 2003. *The Price of Life: Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*, [Online]. Available: http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=222 at 41.
[79] In terms of section 39(2) of the Constitution, 'every court, tribunal or forum', when 'interpreting any legislation … must promote the spirit, purport and objects of the Bill of Rights'.
[80] The *Operational Plan for Comprehensive HIV and AIDS Care, Management and Treatment for South Africa* was adopted on 19 November 2003, some 20 days before the complainants entered into settlement agreements with both GSK and BI.
[81] Beresford, above note 75 at page 5.

medicines and to break the paralysis resulting from state inaction. After much internal debate, a decision was taken to focus on allegations of excessive pricing in respect of three medicines sold in the private sector. If successful, the case would go some way towards achieving the goal of the broader treatment access campaign. But in and of itself, it was never intended to be – nor was it executed as – the 'magic bullet'. In fact, the very nature of litigation precludes such an approach.

Even though other provisions of the Competition Act were identified as providing alternative courses of action,[82] the singular focus on excessive pricing was deliberate. On its own, the excessive pricing case brought enough legal obstacles to clear, such as market definition and the impact of patent protection on market definition and the determination of dominance within the relevant market. In addition, the complainants recognised that broadening the scope of the enquiry had the potential to shift the focus away from the compelling facts to a technical and largely legal sideshow (the patent/competition policy interface) concerned with, amongst other things, the circumstances within which an exclusive rights holder can legitimately refuse to license a potential competitor. Any course of action that brought additional hurdles was considered as too risky to contemplate.

However, the deliberate focus on excessive pricing was not adopted simply to avoid addressing difficult (and potentially complicating) legal issues, such as whether intellectual property constitutes an essential facility or a refusal to license – in certain circumstances – falls within the concept of an exclusionary act. Rather, the complainants believed that the manner in which they framed their case was most likely to get the respondent drug companies to take the matter seriously, because answering an excessive pricing claim would very likely result in the forced public disclosure of costing models. This, the complainants believed, was something that GSK and BI would seek to avoid at all costs. Further, it was the one ground – if properly approached – that was most likely to elicit broad public support, because it could avoid challenging the patent system head-on whilst still focusing on the abuse

[82] See, for example, 'Media Release 30: Competition Commission finds pharmaceutical firms in contravention of the Competition Act', identifying three separate legal bases for referring the matter to the Competition Tribunal for adjudication. [Online]. Available: http://www.compcom.co.za/resources/media2003.asp?level=1&child=2),

of exclusive rights in patents with which any person who has ever needed medical care could identify.

The complaint was not only pursued through the formal means provided by the Competition Act. Instead, the legal case provided the basis for a larger public campaign that included the production of popular materials, including the glossy booklet entitled *The Price of Life – Hazel Tau and Others vs GlaxoSmithKline and Boehringer Ingelheim: a report on the excessive pricing complaint to South Africa's Competition Commission*[83] and numerous press releases, fact sheets and advertisements.[84] Other actions aimed at supporting the complaint included a series of legal literacy workshops held across the country for staff members, provincial office bearers and volunteers of the TAC, in which the intricacies of the complaint were explained and debated, as well as the use of high profile events such as the first South African AIDS Conference in August 2003 to popularise the case.[85]

Settlement negotiations with GSK began on 11 September 2003, almost a year after the complaint had been lodged. At that point, BI did not seem to be interested in entering into a settlement. But two events shortly thereafter appeared to shift the balance. On 26 September 2003, two not-for-profit organisations formally requested non-exclusive voluntary licences from BI 'to import into South Africa, and to use, offer to dispose of and dispose of in South Africa, and to export from South Africa, nevirapine'.[86] That case – which was based on Section 56 of the Patents Act, which allows for an interested person to be awarded a compulsory licence if it is able to be shown that the exclusive rights in a patent are being abused – sought to develop the jurisprudence consistent with the constitutional guarantee of access to health care

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[83] See above note 78.

[84] See, for example, TAC News Service, 'WE WILL SAVE LIVES AND END DRUG COMPANY PROFITEERING: TAC STATEMENT ON EXCESSIVE PRICING COMPLAINT TO COMPETITION COMMISSION' (19 September 2002). [Online]. Available: http://www.tac.org.za/Documents/DrugCompaniesCC/statement.txt. See also the TAC advertisement captioned 'Support Legal Action against GlaxoSmithKline and Boehringer Ingelheim!' that appeared in the largest financial daily newspaper in South Africa (*Business Day*) in October/November 2002. A copy of the advertisement is available online at http://www.tac.org.za/Documents/Pamphlets/TACBUSDAYAD.jpeg.

[85] A presentation as part of the main conference programme (entitled 'Using the law to increase access to treatment: *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim*') was used to raise awareness as well as to launch the publication 'The Price of Life'.

[86] See TAC Electronic Newsletter (29 September 2003), 'Generic Antiretroviral Procurement Project (GARPP) and TAC Treatment Project Request Permission to Import Generic Nevirapine'. [Online]. Available: http://www.tac.org.za/newsletter/2003/ns28_09_2003.htm.

services. In the alternative, it sought to declare Section 56 unconstitutional in the event of its being understood as not allowing the granting of licences in the circumstances. But instead of proceeding to litigation, which brought with it the risk of South Africa's first compulsory licence, the request resulted in the grant of non-exclusive royalty-free voluntary licences largely for the importation of generic nevirapine products.[87]

And just three weeks after the request by the not-for-profit organisations for non-exclusive voluntary licences, the Competition Commission decided to refer the *Hazel Tau* matter to the Competition Tribunal for adjudication. As a result of its year-long investigation, the Competition Commission had found sufficient evidence to support the referral to the Competition Tribunal on the basis of prohibited excessive pricing as well as two additional grounds, both of which deal with the failure of GSK and BI to license generic manufacturers in certain circumstances. BI may have been late in coming to the negotiating table, but when it came, it was prepared to reach a comprehensive agreement in a reasonably short period.

Simply put, the Commission found that GSK and BI were using their exclusive rights in the patents to deny appropriate licences to other manufacturers, whilst simultaneously keeping their own prices high. By early December 2003, within two months of the Commission's referral announcement, GSK and BI had entered into separate settlement agreements with the complainants and the Commission respectively.[88] In essence, the two groups of companies agreed to open up the market for these drugs to generic competitors.[89] For the first time in South Africa, generic versions of on-patent drugs were to become commercially available.

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[87] The agreement which sets out the terms and conditions of the settlement, is available online: http://www.tac.org.za/Documents/DrugCompaniesCC/GARPP-BI-Settlement-20031209.pdf.

[88] The settlement agreements with the complainants are available online: http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=225.

[89] At the time that the complaint was lodged, both GSK and BI had granted licences (on unacceptable terms and conditions) to South Africa's Aspen Pharmacare. In the case of GSK, for example, sales were permitted only to the South African public sector, subject to a 30% royalty rate. That licence was amended in accordance with the settlement agreement to extend sales to the private sector, also allowing for exports to all sub-Saharan African countries and a royalty rate of not more than 5%. By the end of 2004, GSK and BI had licensed five and three generic manufacturers respectively, although GSK's licensees included two companies that do not appear to be able to make use of the licences in the short- to medium-term. A third GSK licensee (one of BI's three licensees) – the joint venture of South Africa's Adcock Ingram and India's Ranbaxy Laboratories named Thembalami Pharmaceuticals – is no longer trading. Aspen and Cipla-Medpro, both licensed by GSK and BI, have placed their ARV products on the market, resulting in significantly lower prices and ensuring sustainability of supply. To date, it appears as if neither Adcock Ingram nor Ranbaxy has managed to secure licences from GSK and BI.

Hazel Tau shows that competition policy instruments can indeed be used to great effect, particularly in a context where other key role-players – such as developing country governments and generic pharmaceutical manufacturers – are either unwilling or unable to act. In this case, civil society was able to take the lead in advancing a public health agenda, not being constrained by the failure of others to take appropriate action.[90] Faced with the adverse findings of an independent investigation, a protracted public hearing into its pricing practices and the potential for the strengthening of the legal framework through unfavourable jurisprudence, all of which were strong possibilities, GSK and BI acted as any rational corporation would do and decided to settle.

For their part, the complainants chose to abandon a particularly strong case in favour of a relatively speedy resolution of the matter, despite the historical complaint and the complex legal and regulatory issues that remain unresolved. Knowing that the public sector ARV treatment plan was in the process of being finalised, that not only price but also sustainability of supply would become increasingly relevant, and that thousands of deaths could be averted if the matter were resolved, the complainants had no reasonable alternative but to settle the matter. Even when viewed in hindsight, the decision to settle appears to remain appropriate.

5.2.2 Bristol-Myers Squibb sidesteps an attack

On 15 February 2005, acting on behalf of the TAC and the Southern African HIV Clinicians' Society, the AIDS Law Project (ALP) threatened to lodge an excessive pricing complaint against Bristol-Myers Squibb (BMS) regarding amphotericin B (AmB), referred to in the letter of demand as 'the antifungal agent of choice to treat cryptococcal meningitis, a common cause of death amongst people living with HIV/AIDS in Africa having a mortality rate of between 25 and 40 per cent'.[91] Unlike *Hazel Tau*, the medicine at the centre of this dispute was no longer on patent. Nevertheless, BMS still enjoyed a de facto monopoly for its version of AmB marketed

[90] One generic company (Cipla-Medpro) had unsuccessfully attempted to use the Competition Act, arguing that because it was both willing and able to provide certain ARV medicines at significantly lower prices than the exclusive rights holder was doing, the latter was charging excessive prices to the detriment of consumers.

[91] The letter of demand also hinted at other forms of legal action, which are not relevant to this discussion. The correspondence between the ALP and BMS is available online: http://www.tac.org.za.

as Fungizone® (as generic AmB was not (and is still not) available for sale in South Africa), for which it used to charge excessive prices.

According to the letter of demand, generic AmB was sold in Brazil for a fraction of the South African price. Fungizone® itself was alleged to be priced in the British National Formulary at less than 30% of the public sector price in South Africa. Various other comparisons supported a strong case that the South African price of the essential medicine could not be justified. On this basis, and with a complaint in terms of Section 8(a) of the Competition Act clearly in mind, BMS was put on terms 'to reduce the public and private sector prices of Fungizone to no more than that charged for AmB in a comparable country such as Brazil'.

Despite an initial response that seemed to indicate a willingness on the part of BMS to fight,[92] the matter was resolved within a relatively short time through a series of letters that were faxed between the ALP and BMS's legal representative. On 28 April 2005, a little over ten weeks after sending the letter of demand, the ALP informed BMS's legal representative that in the light of his client's 'decision to lower the price of Fungizone in South Africa to R22.60, effective 1 July 2005 and applicable in both the public and private sectors, we have advised our clients not to pursue this matter by way of legal action against your client'. In effect, the new price represented a reduction of more than 80% and 85% of the public and private sector prices of Fungizone® respectively.[93]

In many ways, the particular facts and timing of the Fungizone® matter represented the perfect case. Coming hot on the heels of the *Hazel Tau* case, where GSK and BI had been forced to settle in a case that presented a greater legal challenge to the complainants, BMS was on the back foot from the start. In addition, its product was already off-patent, meaning that the 'incentives to innovate' argument often trotted

[92] BMS's initial substantive response (15 March 2005) raised concerns about the relevant market and whether BMS was dominant in that market, and that given the uncertainty regarding the medicine pricing regulations issued in terms of the Medicines and Related Substances Act, 101 of 1965, it was 'premature, if not inappropriate, to seek to resolve … [the] concerns under Section 8(a) of the Competition Act … rather than under the process set forth in the Pricing Regulation'. The ALP responded that its clients were 'not prepared to engage in a debate on the applicability of South African competition law or the medicine pricing regulations' as this was 'better suited to an appropriate legal forum, if and when the matter proceeds to litigation'. Instead, it expressly demanded that BMS 'justify the price at which Fungizone is sold in South Africa'.

[93] Subsequent to the price reductions BMS failed to anticipate the extent of increased demand for the drug and it ran out of stocks earlier this year in South Africa. According to BMS the problem has since been resolved.

out in defence of high medicine prices was unavailable. Moreover, the substantially lower price for the same medicine in Great Britain appeared to provide clear evidence of price gouging in South Africa. The facts spoke for themselves and BMS acted rationally. Understandably, it persisted in the argument that it had 'no legal obligation' to reduce the price of the medicine.

5.3 Amending South Africa's Competition Act

South Africa's Competition Act clearly has the potential to deliver in the public interest. Indeed, as the two case studies presented here show, it has already done so. However, if it is to deliver on its promise, certain structural and legal changes are inevitable. Consider, for example, one of the central reasons that limited the scope of the *Hazel Tau* complaint to a single ground – the complex set of hurdles that had to be overcome before the substance of the matter could be addressed. In short, the complainants had to deal with complex issues (such as market definition and the establishment of dominance) in the absence of limited statutory (and no regulatory) guidance and without being able to rely on the financial and institutional resources that were within the grasp of their corporate counterparts. With each hurdle, the odds of a successful challenge for the exposure of unjustifiable pricing practices were lowered.

There are numerous ways in which such barriers could be addressed. First, the statute could be fine-tuned to ensure that form does not stand in the way of substance by providing clearer guidance on the extent to – and the manner in – which it applies to various forms of intellectual property. Second, the Competition Commission could make use of its powers in section 79(1) of the Competition Act to 'prepare guidelines to indicate … [its] policy approach' to the patent law/competition policy interface. Such guidelines, which must be published in the *Government Gazette* and are not binding on anyone, would nevertheless provide much-needed direction for all role-players, including both holders of exclusive rights in patents as well as consumers.[94] Third, the Commission should be empowered to make

[94] In publishing guidelines, the Commission would not be doing anything particularly groundbreaking. See, for example, US Department of Justice and Federal Trade Commission. 1994. *Antitrust Guidelines for Licensing of Intellectual Property* (6 April 1994). [Online]. Available: http://www.usdoj.gov/atr/public/guidelines/ipguide.htm.

resources available to complainants, such as access to certain information held by industry that is ordinarily inaccessible.

Most crucial in the field of access to medicines, however, is an amendment that expressly recognises the grant of a compulsory licence as appropriate relief for certain forms of prohibited conduct. In terms of the provisions of Section 58(1) of the Competition Act, the Competition Tribunal may 'make an appropriate order' upon a finding of an abuse of dominance as contemplated by Section 8 of the Act, including—

a) An order that the prohibited practice stop;[95]
b) An order that goods be supplied 'on terms reasonably required to end a prohibited practice', that is, at non-excessive prices;[96]
c) A declaration that the conduct be regarded as a prohibited practice for purposes of a damages claim;[97] and
d) The imposition of an administrative penalty.[98]

Clearly, Section 58(1) does not expressly mention compulsory licensing. Whether or not its provisions permit the issuing of a compulsory licence will depend largely on how, when and to what extent the Competition Tribunal and the Competition Appeal Court interpret the concepts of an 'essential facility' and an 'exclusionary act'. In addition, whether or not Section 58(1) is interpreted as empowering the Tribunal to grant a compulsory licence following a finding of prohibited excessive pricing of a patented product will depend on whether the Tribunal and the Appeal Court view the subsection as a closed list of permitted orders, and how, when and to what extent they interpret what is meant by an 'appropriate order'.

While there are strong arguments in favour of interpreting the provisions on relief as permitting the granting of compulsory licences to prevent and control prohibited practices, such as excessive pricing, the lack of express recognition remains problematic. There is sufficient uncertainty to discourage the active use of the Competition Act for the purpose of seeking the early market entry of generic

[95] Section 58(1)(a)(i).
[96] Section 58(1)(a)(ii).
[97] Section 58(1)(a)(v).
[98] Section 58(1)(a)(iii).

competition, as well as weaken the deterrent effect of the law insofar as the conduct of patentees and other exclusive rights holders is concerned. Further, one cannot disregard the possibility that competition law jurisprudence may develop which excludes such a form of relief.

To provide sufficient clarity and avoid unnecessary litigation, an appropriate amendment of Section 58 would require the following minimum components:

a) An express recognition that the Competition Tribunal has the power to order the grant of a non-exclusive compulsory licence to any firm that is able to satisfy a published list of objective criteria;
b) Detailed provisions relating to the amount of the royalty to be paid, such as 4% or 5%, for example;
c) An express mechanism to adjust the royalty rate – either upwards or downwards – in exceptional circumstances, taking into consideration a range of factors, including:

    The actual research and development (R&D) undertaken by the patentee in respect of the patented product concerned;

    The extent of publicly-funded R&D in respect of the product concerned, whether in South Africa or elsewhere; and

    The public interest in varying the royalty rate;
d) In accordance with Article 31(k) of the TRIPs Agreement,[99] express provisions permitting exports of all products produced pursuant to the grant of the licence to all countries where such products are either not patented or in respect of which compulsory or voluntary licences are – or have been – issued.

Both the *Hazel Tau* and the Fungizone® matters have focused attention on the need to draw together the separate statutes dealing with competition policy, patents and the regulation of medicines in a cohesive and rational way. A TRIPs-plus patent law has ensured limited action on the part of generic pharmaceutical manufacturers and 'forced' civil society (in the *Hazel Tau* case) to make creative use of a competition law framework that does not yet fully understand its implications for products

[99] Article 31(k) exempts members from legislating certain conditions attached to the grant of compulsory licences, such as the restrictions on exports, where such licences are issued 'to remedy a practice determined after judicial or administrative process to be anti-competitive'.

protected by patents and other forms of intellectual property. A lack of competition authority jurisdiction was asserted in the Fungizone® matter in the wake of the confusion generated by the uncertain relationship between competition and medicines regulation law. But the type of comprehensive and co-ordinated legal framework required is dependant on political will that has yet to surface in South Africa. For as long as the regulatory framework remains unchanged or undeveloped, either through a lack of jurisprudence or legislative reform, the Competition Commission would be advised to invoke its powers to issue guidelines.

5.4 The potential impact in SADC: lessons from South Africa

Despite the significant regulatory flexibility regarding competition policy accorded to all WTO members under the TRIPs Agreement, some SADC members may have found that they have neither the level of expertise nor the institutional capacity to take full advantage, particularly insofar as enforcement is concerned. With this in mind, such countries may have decided against investing resources in giving effect to competition policy unless and until required to do so. Instead, they may have chosen to focus attention on the public health safeguards and flexibilities under patent law, particularly given the requirement under TRIPs to provide a minimum level of patent protection.[100] It lies beyond the scope of this paper to consider why such an approach may prove to be an unfortunate and short-sighted way of advancing public health. This is done in some detail elsewhere.[101]

Instead, this paper has focused on the effective use of competition law and policy in South Africa, against the backdrop of the failure of that country to take advantage of the Doha Declaration in the four years since its adoption by the WTO.[102] In short, three separate but complementary approaches have been identified and implemented. First, competition law has been used to great effect by civil society organisations to ensure access to a sustainable supply of certain ARV medicines at

[100] Other than LDCs that have until 1 January 2016 to provide patent protection for pharmaceutical products, all developing countries were required as of 1 January 2005 to provide minimum levels of IP protection, including patent protection for all technologies.
[101] See Berger, above note 56 at 15.
[102] Furthermore, a powerful TRIPs-compliant government-use provision in section 4 of the South African Patents Act that allows 'a Minister of State … [to] use an invention for public purposes' remains unused, despite repeated calls by civil society groups for either the Minister of Health or her Trade and Industry counterpart to use it. To date, the South African government has failed to issue – or even threaten to issue – compulsory licences for the importation or local production of affordable generic ARV medicines.

affordable prices. Second, a third party application for a compulsory licence sought to develop the jurisprudence in a manner more consistent with a constitutional guarantee of access to health care services, as well as to give added boost to a separate competition law matter regarding the same medicine. Third, activists have started to step up their demands on government to take the requisite executive action by issuing licences for the local production and/or importation of certain generic ARV medicines.[103] This is an integral part of their demands for the state to develop the comprehensive and co-ordinated legal framework discussed above.

South Africa's difference is important. The approaches adopted and the principles applied in the case studies presented cannot simply be exported to its African neighbours, many of whom may not have comprehensive competition laws and competent authorities – if at all. And even where such authorities may exist, they may simply be lacking in capacity. But this needn't be fatal. There are potential benefits to SADC countries of incorporating access-friendly provisions into their domestic law, even if simply to ensure that they are in a position to benefit from positive developments in other SADC countries with generic pharmaceutical manufacturing capacity, such as South Africa. But more important, perhaps, is the need for regional harmonisation, in part as a result of the economic interdependence of SADC countries. By an initial focus on domestic legislation, SADC countries may ultimately pave the way for the type of regional harmonisation that transforms the success stories of South Africa from isolated exceptions to the generalised rule.

6. From national to regional market governance: regional competition policy development

As the South African case indicates, national competition policy can assist ensuring that national markets function efficiently, and, to the extent that public interest provisions are included in such policy, can assure consumers of competitive prices and product choices, and promote other such efficiency-plus objectives. However, it is true that market developments tend to outstrip policy and regulatory developments. The extent of the gap between the two provides greater or lesser opportunities for behaviour on the part of market participants that many run counter, in this case to the

[103] See TAC. 2005. *TAC Electronic Newsletter,* 19 May 2005. [Online]. Available: http://www.tac.org.za/newsletter/2005/ns19_05_2005.htm, demanding that the Minister of Health issue licences for the local production and/or importation of generic efavirenz products.

broad objectives of competition policy, relevant TRIPS provisions and specifically the WTO 30 August Agreement.

In the case of southern and eastern Africa, the process of market integration, as firms (entrepreneurs) seek and take advantage of opportunities, is racing ahead, while policy and associated legal and institutional development (for policy implementation) is nowhere near catching up, either at the national or the regional level.

This region demonstrates perhaps one of the most confusing and complex arrays of overlapping membership of regional trade organisations. Significant within this spaghetti bowl, however, is South Africa's membership of such organisations. South Africa is a member of SACU, of SADC, but not of COMESA. This is significant in that South Africa's pharmaceutical manufacturing capacity, and in particular its growing production of generics, could provide supply sources for countries in the region.

On the competition policy front, there is much activity at the national level in the region, with many countries having recently revised their policies and amended legislation or embarked on a policy development process. At the regional level the picture is mixed. The 2002 SACU Agreement requires that all member states have a competition policy, and that they cooperate in competition policy enforcement. There is no explicit provision requiring a regional policy or institution for enforcement.

Although the Trade Protocol does make provision for a regional competition policy, SADC has not started a policy development process yet. Taking the lead in the region is COMESA, which has developed a regional policy and COMESA Competition Regulations. These countries are now ready to establish a regional competition authority to implement the regional policy. COMESA competition provisions cover any conduct on the part of a firm or firms that restrains competition between member states. It is important to note that while both Kenya and Zambia are members of COMESA, South Africa is not.

With deepening regional integration, the role of trade remedies declines and that of competition law and policy increases. While trade remedies still play an important role in free trade areas, deeper integration requires that competition policy checks for

anti-competitive practices. National competition policy can go some way to providing oversight in cases of anti-competitive conduct, if extra-territorial jurisdiction is provided for in the national policy. It is, however, an imperfect instrument. A regional competition policy becomes increasingly important in such cases. With SACU and the East African Customs Union to be followed by the COMESA and SADC customs unions, the development of regional competition policy that reflects the process of regional integration, both market- and state-led, is important. As state-led integration, with moves to implement customs unions, go ahead, the importance of regional competition policy, and the development of institutions and capacity to effectively enforce this policy, becomes more significant.

What kind of anti-competitive practices are important to the production and trade in pharmaceutical products, especially ARVs? It is perhaps abuse of dominance that requires key focus. It is of course important to keep in mind that the determination of dominance provides challenges, and these may be exacerbated in a regional context. Market share is often used as a proxy for dominance – however this is an imperfect measure, and specifically when the very definition of the relevant market may be complicated by national, geopolitical borders. Dominance refers to the facility to create obstacles to efficient competition in a relevant market – and there may be various factors implicit or explicit in its determination. Abuse of dominance is usually associated with exclusionary practices, such as vertical restraints (including exclusive purchase or supply arrangements) and predatory pricing. More specifically, abuse of dominance may be delineated into three broad categories of behaviour:

a) Foreclosure: preventing new firms from entering a market;
b) predatory pricing practices: aimed at forcing competing firms to exit the market;
c) exclusionary behaviour in which a dominant firm uses its market power to make exclusive distribution arrangements, refuses to deal, ties sales or bundles products in transactions.

It is possible, of course, to combine several of these practices, which can lead to the exit of competitors or their unfair treatment. It is important to keep in mind that the aim of competition policy is not to prevent a dominant market position, but specifically to prevent abuse of that dominant position.

The conclusion is that intraregional trade liberalisation increases opportunities for firm growth in order to realise economies of scale. The market is restructured as inefficient firms leave the market. However, despite the possible efficiency gains, these developments could also provide an opportunity for abuse of dominance. In the context of pharmaceutical markets, there is a strong case for consideration of the public interest – access to medicines, ARVs – that supports an argument for the development of a regional competition policy that assists in ensuring that both efficiency and public interest objectives are not compromised by anticompetitive practices for which national competition policy offers only a partial remedy.

6.1 Capacity for effective enforcement: challenges for regional competition policy

Effective competition policy enforcement requires significant capacity, and not only within the competition authority. A regional competition authority (as well as a national authority) requires a strong team of lawyers and economists to complement each other's skills in an interdisciplinary fashion. Competition law and policy are relatively new disciplines in tertiary institutions in southern and eastern Africa – and in some countries they do not feature at all. This is an area where the interdisciplinary nature of the challenges encountered in enforcement requires very specific legal and economics training.

The experience of many competition authorities, especially in developing countries that have implemented competition law and policy, is that their staff become very mobile, even after relatively short sojourns. This is consonant with the broader capacity requirements for effective enforcement of competition law and policy.

While capacity in the competition authority is indispensable to effective enforcement, capacity with the legal and economics professions, within the private sector (in business associations and private enterprises), as well as among consumers (especially in the current context) and associated institutions is equally important. This is true for national-level enforcement, and even more so in the regional context, keeping in mind that the perpetrators of sometimes-pernicious conduct may be located in one country and the effect on consumers may reside in another. Regional competition law may offer a remedy, but it may be many hurdles away (many more

than if the conduct were engaged in the same country as the impact on the consumer, for example). This situation is exacerbated by the fact that consumers are generally not well organised in most countries in southern and eastern Africa, and if they are, then organisation tends to be nationally bounded. This is where regional civil society organisations can fill the capacity gap to provide recourse for consumers to regional competition remedies. The same would apply to the similar challenges that small businesses encounter.

Nevertheless, as firms (including pharmaceutical manufacturers) seek new opportunities to supply products, and the process of regional integration deepens in southern and eastern Africa, 'relevant' markets are being redefined. This market redefinition requires that redefinition of regulatory regimes, both in terms of substantive and geographic boundaries. The development of a regional competition law and policy is thus a logical step with deepening integration.

An interesting question for the region is whether every country should have a national law and policy and competition authority, if for example a regional law and policy exist. SACU offers interesting insights. The 2002 SACU Agreement requires that each country have a competition policy and that they cooperate in enforcement. It does not specifically provide for the development of a regional law or policy. Overlapping membership of regional trading arrangements is important for SACU, as it is for all other arrangements in the region. Swaziland belongs to COMESA, and will thus be covered by its regional law and policy. All other members belong to SADC, which has not yet made progress towards developing a regional policy.
In addition to South Africa, Namibia has a competition law, and regulations are currently being drafted. Although the SACU Agreement does not explicitly require a regional competition policy, it is possible to develop such a policy, if the Council of Ministers so decides. If SACU concludes a free trade agreement with COMESA, an agreement between SACU and COMESA on enforcement is feasible, and possibly desirable, if the volume of trade between members of the two blocs is significant. Various intensities of agreement are possible. An agreement to share information or to collaborate more intensively (even joint handling of cases) would assist to provide more effective enforcement in the region.

At the national level, certainly for Botswana, Lesotho, Namibia and Swaziland (and this argument applies equally to other small countries in the region), it is important to keep in mind that effective enforcement is capacity-intensive. Effective enforcement is perhaps the best route to competition advocacy and the development of a competition culture. Weak enforcement will ensure a credibility dive for the competition authority, and the effective demise of competition regulation. This is where a regional (SACU) policy, enforced by, for example, the South African Competition Authorities may be an option to consider.

7. Conclusion

There are clearly different levels of implementation of TRIPs flexibilities, the Doha Declaration on TRIPs and Public Health and the 30 August Agreement in various eastern and southern African countries. While some have gone as far as to issue compulsory licences and government use orders, none have to date, made use of the notification mechanism available in terms of the 30 August Agreement for the importation of generic essential medicines. The lack of use of the 30 August mechanism does not mean however, that the 30 August Agreement has been entirely unsuccessful. The express authorisation of countries to import generic essential medicines must have been a factor, together with others, for the increased number of voluntary licences that have been granted by patent holding companies in the past few years.

For countries to make complete use of the 30 August Agreement, a number of fairly complicated industrial property legislative provisions will have to be modified in each country in the region. Even South Africa (which appears to have the most progressive legislation and possesses the capacity to both import and export essential medicines) has yet to take full legislative advantage of the policy space created by the 30 August Agreement. It can be argued that ambiguous provisions, such as Section 4 of the South African patents Act or Section 40 of the Zambian Act, allow countries to take whatever steps are necessary in furtherance of the 30 August Agreement. This contention can be questioned given that no country has as yet made use of the notification mechanism. A number of Acts in the region contain ambiguities that should be clarified. Specific provisions on issues such as royalties, time spans by which negotiations should be concluded and clearly outlining what

powers are available to certain officials would be useful in making the provisions more likely to be implemented.

A number of sub-Saharan countries are involved in the process of drafting either new intellectual property legislation or legislation to replace existing antiquated laws. A number of these countries are also in the process of drafting competition legislation and establishing competition authorities. This process provides a good opportunity for countries to ensure that the most useful TRIPs flexibilities are incorporated into national legislation (where they do not exist) or are at least improved upon (where they do exist). The negotiations over finding a permanent solution to the 30 August Agreement remain important for sub-Saharan countries. It is very important that the greatest amount of policy space is preserved even if legislation does not expressly provide for TRIPs flexibilities and safeguards. As evidenced by the mere existence of the 30 August Agreement, the possibility of possible options can be effectively used to negotiate more flexible voluntary licences with patent holding companies.

Use of the South African Competition Act by activists remains an excellent example of how effectively competition legislation can be used for the lowering of prices of essential medicines. Unfortunately however, the complexities of competition law and policy, but more importantly, the lack of capacity to enforce competition legislation and policy remains an unresolved problem in the eastern and southern African region. The question of how countries with already strained capacity would be able to operate efficient competition authorities begs the question whether a regional competition policy is the best approach. Given the spaghetti bowl of multiple memberships of regional trading organisations in the region, it is suggested that the two most viable (but by no means exclusive) options to explore for a regional competition policy are COMESA and SACU. It should also be remembered that patent and competition legislation are not the only relevant pieces of legislation required to TRIPs flexibilities. For effective utilisation of the 30 August agreement to take place, regulations and legislation pertaining to medicines will also have to be adjusted. The recent example of Aspen Pharmacare encountering problems in its attempts to export medicines to certain eastern and southern African countries demonstrates the clear need for harmonisation of pharmaceutical standards and regulations at a regional level (both for SADC and for the EAC) as well as on a continental level in the longer term.

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Glossary

ARV

Drugs used to treat HIV infection, which stop the virus from replicating. Although they do not cure HIV/AIDS, they can improve patients' quality of life and prolong survival when taken consistently.

Combination therapy (triple therapy)

HIV/AIDS drug therapy using a combination of drugs, usually one protease inhibitor or non-nucleoside reverse transcriptase inhibitor combined with two other drugs – from a third class. Triple therapy has proven to be more effective in the long-term treatment of the disease than treatment options that make use of two drug combinations or only one drug.

Compulsory and voluntary licences

Compulsory licences are licences issued in terms of provisions that are normally found in patent laws[104] that allow public authorities to grant licences to a third party without the consent of the patent holder. Patent-holders receive adequate compensation (ordinarily in the form of a royalty). Compulsory licences may be issued on various grounds of general interest, including public health, and are a common feature of patent law. For example, France authorises them when patented drugs 'are only made available to the public in insufficient quantities or quality or at abnormally high prices'.

A voluntary licence is a licence issued by the patent holding company that allows another company to manufacture a patented product subject to the payment of an agreed royalty fee to the patent holder

The 30 August Decision

The 30 August Decision concluded on 30 August 2003 by the WTO General Council authorises developing and least developed countries with insufficient or no

[104] Sometimes these provisions are found in Competition legislation.

manufacturing capacity for pharmaceutical production to import generic pharmaceuticals produced by compulsory licence from other countries. This right is subject to the fulfilling of several administrative requirements, which are the primary reason why no country to date has made use of the 30 August mechanism.

Government use order

A government use order is specific type of compulsory usually issued in the form of an order by a competent administrative or judicial authority that authorises a government or a party acting on behalf of the government to exploit a patent provided that such exploitation is in the interests of the country in question.

Generic drugs

A generic drug refers to a pharmaceutical product that is the chemical equivalent to the patented product, which is not protected by a patent in the country or is licensed. Generic drugs are marketed either under a non-proprietary or approved name rather than a proprietary name.

Parallel imports and international exhaustion of rights

Companies often charge lower prices for a drug in one country than in another, taking into account a range of market factors. This means that a country with limited resources can sometimes afford more of a patented drug by purchasing it abroad at a lower price and importing it, rather than buying it directly in its domestic market at the higher price. Many countries' patent laws determine that once a patent owner sells its goods in any country, it has no right to control the resale of those goods. In legal terms, the patent owner has 'exhausted' its property rights in the product actually sold – it still keeps the exclusive right to manufacture the product in the first place, but it cannot prevent resale of those units it sells. So an intermediary could buy a patented drug in one country at the lower price being charged by the company, and then resell the drug in another country at a higher price, but at a price that still undercuts what the manufacturer is charging for its patented drug in that country. This is called 'parallel importing'. The TRIPs Agreement (Article 6) explicitly states

that nothing in the Agreement can be used to challenge a country at the WTO for allowing parallel imports under its own laws.

Patent

A patent gives the patent holder (or ‘patentee’) the right to prevent others from making, using, importing, or selling an invention in the country where the invention is patented. In other words, patenting an invention gives the patent owner a monopoly over the invention. A country's domestic laws govern the granting of patents, and these laws are affected by international laws.