

# Parallel importation and compulsory licensing in Kenya and South Africa as measures to access HIV/AIDS medicine

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This article briefly examines the legal framework and the use of parallel importation and compulsory licensing in South Africa and Kenya, and the extent to which the two countries utilise these measures to enhance access to HIV/AIDS medicine. The study reveals that both countries have adopted appropriate TRIPs-compliant parallel importation and compulsory licensing legislation. However, this legislation is yet to be used significantly to address the HIV/AIDS pandemic. Some of the perceived restrictions and complexities of the conditionalities of TRIPs flexibilities are notable disincentives. Although South Africa and Kenya have some pharmaceutical manufacturing capacity, this is found to have some critical limitations.

## Parallele invoer en verpligte lisensiering in Kenia en Suid-Afrika ten bate van toegang tot HIV/VIGS-medikasie

Hierdie artikel ondersoek kortliks die regsraamwerk en die gebruik van parallele-invoer en verpligte lisensiering in Suid-Afrika en Kenia, en die mate waarin die twee lande hierdie maatreëls gebruik om toegang tot HIV/VIGS-medikasie te verbeter. Die studie stel bekend dat albei lande gepaste parallele invoer- en verpligte lisensieringswetgewing aanvaar het wat aan TRIPs-vereistes voldoen. Hierdie wetgewing is egter nog nie betekenisvol gebruik om die HIV/VIGS-pandemie te hanteer nie. Sommige van die waargenome beperkings en probleme van die voorwaardelikheid van TRIPs-buigsaamheid is aansienlike hindernisse. Alhoewel Suid-Afrika en Kenia 'n mate van farmaseutiese vervaardigingskapasiteit het, is bevind dat dit sekere kritieke beperkings het.

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History will judge all of us by our response to HIV/Aids. That response must meet the high ambition and bold commitments ... Access for All. Let us now go and put it into practice.<sup>1</sup>

The prevalence of Human Immunodeficiency Virus (HIV) and the Acquired Immune Deficiency Syndrome (AIDS), as well as access to essential pharmaceutical medicine remain global concerns. The greatest concern is the prevalence of HIV and AIDS in Africa, in particular in the sub-Saharan African (SSA) countries.<sup>2</sup> Statistical estimates<sup>3</sup> on HIV and AIDS show a staggering prevalence rate in the SSA region. For example, a report by the UNAIDS/WHO indicated that, at one point, of the 42 million people living with HIV and AIDS (PLWHA) 70% were in sub-Saharan Africa (Mabika 2006).<sup>4</sup> This is an alarming revelation considering the fact that SSA has just over 10% of the world's population. It was estimated in 2001 that approximately 9 million people in the SSA region died of HIV and AIDS, and that approximately 25 million people will become infected by 2011 if no proper intervention mechanisms are put in place (cf Heyns & Killander 2007: 279). A report by the Joint United Nations Programme on HIV and AIDS shows that in 2003 SSA accounted for 75% of the three million world HIV and AIDS deaths (Moss 2006: 70).

In South Africa alone, the number of PLWHA is staggering. In 2005, for example, the prevalence of HIV and AIDS was estimated at 81.8%. The number of adult males was estimated at 5,300,000;

- 1 Remarks by the Director General of the World Health Organization at the 15th international AIDS conference held in July 2008 in Bangkok, Thailand. Cf WHO 2004: Online.
- 2 Sub-Saharan African countries include Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Congo, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Guinea, Guinea Bissau, Ivory Coast, Kenya, Lesotho, Liberia, Mali, Malawi, Mauritania, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia.
- 3 The author has been mindful of the controversies and divergence in statistical reports. Be that as it may, this should not derogate from the fact that HIV and AIDS are serious health problems in Africa.
- 4 Currently the figure may be higher.

women at 3,100,000; children at 1,200,000. The total number of HIV and AIDS deaths was estimated at 320,000 in 2005, with approximately 1,200,000 orphaned by the end of 2005 (cf HIV-InSite 2006).<sup>5</sup> A study by Collins (2001: 160) reports that approximately 5,500 people die from HIV- and AIDS-related diseases daily in South Africa. In July the situation was highlighted by the Constitutional Court in the case of Minister of Health *versus* Treatment Action Campaign (No 2)<sup>6</sup> when it opened its judgment by referring to the South African Department of Health's HIV/AIDS & STD Strategic Plan for South Africa 2000-2005, which described the HIV and AIDS pandemic in South Africa as "an incomprehensible calamity" and "the most important challenge facing South Africa since the birth of our new democracy".

In Kenya, the number of PLWHA is estimated at 2,5 million, of which 2,000,000 are children, 900,000 men and 1,4 million women (Kalla & Cohen 2007: 16). Approximately 1,100,000 Kenyan children under the age of 17 were HIV/AIDS orphaned by the end of 2005 (Kalla & Cohen 2007: 17). It is argued that the situation is further compounded by skewness in the manufacture, pricing and distribution of patented pharmaceutical products (Bluestone 2001: 162, Foreman 2000, Ngwena 2002: 24-5), and the lack or insufficiency of domestic pharmaceutical research and manufacturing capacity (Masungu *et al* 2004: 23-34).

According to the United Nations (UN), the prevalence of HIV and AIDS in Africa has created an emergency which "needs urgent and exceptional national, regional and international action".<sup>7</sup> The African Commission on Human and Peoples' Rights has noted with great concern the prevalence and escalation of HIV and AIDS in the SSA region. The Commission's concern was so great that it has declared HIV and AIDS in the region a "threat against humanity" in need of "interventions of emergency proportions", of "urgent and exceptional

5 For more information on the South African HIV and AIDS prevalence status, cf Garbus 2002: Online.

6 Minister of Health *versus* Treatment Action Campaign (No 2) 2002 (5) SA 721 (CC), par 1.

7 Cf UN Declaration on Commitment on HIV/AIDS 2001.

national, regional and international action” (Heyns & Killander 2007: 279). The Commission has also called upon the international pharmaceutical industries “to make affordable and comprehensive health care available to African governments for urgent action against HIV/Aids” (Heyns & Killander 2007: 279). It is perhaps also apposite to highlight that Article 16(2) of the 1981 African Charter on Human and Peoples’ Rights (ACHPR) requires State Parties to “take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick”. In the *Maputo Declaration on Malaria, HIV/AIDS, Tuberculosis and other Related Infectious Diseases*, the African Union (AU) member governments recognised that “appropriate policies including legal and programmatic frameworks [...] should be adopted and applied” to curb the pandemic of HIV/AIDS (AU 2003: 2). In particular, the governments committed themselves to ensuring that all measures and initiatives “for scaling up treatment for HIV/Aids are pursued energetically and creatively ...” (AU 2003: 2).

This article will examine the legal framework of compulsory licensing and parallel importation measures in South Africa and Kenya as critical tools to enhance access to HIV and AIDS medicine, pursuant to the World Trade Organisation (WTO) regime.<sup>8</sup> In this instance compulsory licensing refers to the use of IPRs without the consent or authorisation of the right holder or right owner, either by the government for government use or by third parties,<sup>9</sup> while “parallel importation”, or “re-importation” as it is sometimes called, refers to the import and resale in a country, without the consent of the patent holder, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent (Arfwedson 2003: 1).

8 The World Trade Organisation (WTO) was established on 15 April 1994 in Marrakech, Morocco as the main international trade regulatory institution, by the Marrakech Agreement establishing the World Trade Organisation of 1994, which came into effect on 1 January 1995. It replaces the then *de facto* institution, the General Agreement on Trade and Tariffs of 1947.

9 In this article the terms government use and compulsory licence are used interchangeably. For more on the definition and purpose of compulsory licensing, cf Vaughan 2001: 96-7, Collins 2001: 164, Ford 2000: 942.

The WTO maintains important access to medicine enabling provisions in the *Agreement on the Trade-Related Aspects of Intellectual Property* (TRIPs agreement), and its associated flexibility, *Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health* (TRIPs decision). In particular, the extent to which these legal frameworks have been used or may be used is determined.<sup>10</sup> The study will not be complete without a passing reference to the *Amendment to the TRIPs Agreement: Decision of 6 December 2005* (TRIPs amendment).<sup>11</sup> The TRIPs amendment is set to replace the TRIPs decision.<sup>12</sup> South Africa and Kenya are among the key governments that constituted the African group, whose proposals were instrumental in the introduction of TRIPs flexibilities. The findings in this study reveal that both Kenya and South Africa have the appropriate legal framework to use TRIPs flexibilities with regard to compulsory licensing and parallel importation. However, these flexibilities have not been used optimally. In addition to the complexities or pitfalls of these flexibilities, the failure to use TRIPs flexibilities may also be attributed to, among others, lack of poli-

10 Note that to date few African governments have used TRIPs flexibilities for HIV/AIDS-related matters including Ghana on October 2005 through government use order to import (from selected generic pharmaceutical companies in India) generic versions of selected ARVs that are patented in Ghana; Mozambique in March 2004 through a compulsory license granted for the local manufacture of a first-line triple-combination ARV; Zambia in September 2004 through a compulsory grant to permit the local production of first-line ARV therapy, and Zimbabwe in May 2002 when the government gave authorisation to override patents to permit the local production or import of ARV medicines under the “Declaration of Period of Emergency (HIV/Aids),” which is effective until 31 December 2008 through Statutory Instrument 32 of 2003.

11 In December 2005 the WTO members agreed to the amendment to the TRIPs agreement: Decision of 6 December 2005, Doc – W/T/L/641 (8 December 2005).

12 The TRIPs amendment was to come into effect by 1 December 2007, or after at least two-thirds of the members had accepted them by any such later date as may be decided by the Ministerial Conference. At the time of the submission of this article the author was not aware of any development in this regard. One of the important features of the TRIPs amendment is Article 31 bis (4), which provides that any measures taken in fulfilment and conformity with the conditions of Article 3 “shall not be challenged”.

tical will to implement TRIPs-compliant measures, the political economy of the healthcare system and the state of the pharmaceutical manufacturing capacity. There are other complexities which may not be attributed to the TRIPs agreement such as the state of the healthcare system in these countries.

It must be pointed out from the outset that, although anti-competition measures are permissible under Article 31(k) of the TRIPs agreement, such measures are beyond the scope of this article. Article 31(k) is a remedial recourse for anticompetitive behaviour of a patent holder (Haag 2002: 978-9). The author would also like to acknowledge the contribution made by the courts to the issue of access to HIV and AIDS medicine, and to further acknowledge the national plan on HIV and AIDS.<sup>13</sup> However, it must be noted that this contribution is beyond the scope of this article. It suffices to indicate that there has been limited success by both Kenya and South Africa in utilising these measures, for example, in the files of competition law.<sup>14</sup>

13 Notable, for example, is the Constitutional Court decision in *Minister of Health versus Treatment Action Campaign (No 2)*, in which the government was enjoined to ensure a wider distribution of a medicine called Nevirapine used in the prevention of mother-child transmission (MTCT), and called for the implementation of a national plan for the preventing of MTCT. The national plan, officially known as the Operational Plan for Comprehensive HIV and Aids Care, Management and Treatment for South Africa (HIV/AIDS Operational Plan) was declared on 19 November 2003.

14 In the case based on competition law, the South African Competition Commission (2003), for example, inquired into the conduct of two pharmaceutical firms, GlaxoSmithKline South Africa (Pty) Ltd (GSK) and Boehringer Ingelheim (BI) impacting on the accessibility of HIV/AIDS-related medicine. The Commission found that the firms maintained highly abusive and restrictive practices in the antiretroviral market, which is prohibited by the Competition Act 89 of 1998. According to the Commission, the two firms refuse to grant patent licenses to generic manufacturers, and their HIV/AIDS “drugs are not affordable”. For more information on the role played by large companies in the fight against HIV and Aids, cf Dickinson & Steven 2005: 286-95.

## 1. The WTO regime

### 1.1 General

The TRIPs agreement sets minimum standards and rules for the WTO members' national laws related to intellectual property. These standards and rules are designed, among other things, to strike a balance between intellectual property rights (IPRs) holders and users by enjoining members to align their national laws with the TRIPs agreement. For this purpose the minimum standards for the granting and protection of IRPs must be adopted. Most important in the context of this study are Articles 6, 7, 8, 28(1)(a) and 28(2), 30 and 31. Article 6 permits parallel importation of patented goods. Article 7 of TRIPs calls for IPRs to be conducive to social and economic welfare, and that their use should not hinder the promotion and protection of public interests. Article 8 permits WTO members to adopt measures necessary to protect public health, provided such measures are consistent with the provisions of the TRIPs agreement. Article 28(1)(a) of the TRIPs agreement affirms the exclusive right of the patent owner. Article 28(2) gives the patent owner the right to license or not to license such patent to third parties. Article 30 read with Article 31 refers to compulsory licensing.

### 1.2 Parallel importation

WTO members may pursuant to Article 6 of the TRIPs agreement use parallel importation as a regime for the exhaustion of rights without challenge. Article 6 clearly states that where there is a dispute related to TRIPs "nothing in this agreement [TRIPs] shall be used to address the issue of exhaustion of intellectual property rights". WTO members have more latitude to determine the extent and nature of parallel importation provisions in their national laws.

### 1.3 Compulsory licensing

Article 31 permits the unauthorised exploitation of IPRs by WTO members. This applies when authority had previously been sought from the patent holder on "reasonable commercial terms and conditions"

and was refused.<sup>15</sup> Under the circumstances authorisation will be disregarded in cases of “national emergency and other circumstances of extreme urgency” or cases of “public non-commercial use”.<sup>16</sup> A further qualification, whose interpretation and application have been contentious, is Article 31(f), in terms of which the unauthorised use for the production of patented pharmaceutical medicines under conditions of national emergencies and other circumstances of extreme urgency is subject to license or exploitation of the IPRs being “predominantly for supply of the domestic market of the authorising Member”. Thus, Article 31(f) is restrictive in that it only allows compulsory licensing predominantly for the supply of a country authorising such use. The restriction becomes more severe when applied to a country with insufficient or no pharmaceuticals manufacturing capacity, which would mean that such members who lack the capacity or infrastructure to manufacture pharmaceuticals have to rely on imported pharmaceuticals. Article 31(f) on its own is inflexible.

In light of the challenges faced by countries in implementing the TRIPs agreement, in particular Article 31(f), the TRIPs decision was taken by the TRIPs council in August 2003 as a follow-up to the acknowledgments and commitments made by WTO members in the *Doha Declaration on TRIPs Agreement and Public Health* (Doha declaration on TRIPs). The latter was adopted by the WTO Ministerial Council<sup>17</sup> at its conference held from 9 to 14 November 2001 in Doha, Qatar, to introduce flexibilities into TRIPs. In paragraph 1 of the Doha declaration on TRIPs, read with paragraph 2, WTO members acknowledged that the TRIPs agreement should form an integral part of national and international efforts to address public health problems that have befallen many of the WTO members. More specifically, the Ministerial Council recognised the

15 Cf article 31 of the TRIPs agreement.

16 Cf article 31(b) of the TRIPs agreement.

17 The WTO consists of a multilevel structure comprising several interrelated bodies. The structure is headed by the Ministerial Council, which is tasked with carrying out the functions of the WTO and enjoys supreme authority, including the authority to “take decisions on all matters under any Multilateral Trade Agreement”.



gravity of the public health problems affecting many developing and least-developed countries, especially those resulting from HIV and AIDS, tuberculosis, malaria and other epidemics. It was therefore agreed that TRIPs should not prevent members from taking necessary measures to protect public health in cases of national emergency or other situations of extreme urgency.

The TRIPs decision primarily attempts to loosen the restriction to the domestic supply requirements of Article 31(f) of the TRIPs agreement. Article 31(f) does not *per se* prohibit exports when read with the TRIPs decision. The WTO members may thus, under paragraph 2 of the TRIPs decision, manufacture pharmaceutical products under compulsory license and export them to eligible member(s), which includes all least-developed countries and any member who notifies TRIPs council of its intention to use the system under the TRIPs decision.

The TRIPs decision further permits the re-exportation of imported pharmaceutical products by developing or least-developed members to other developing and least-developed WTO member countries with whom they are party to a regional trade agreement. In this instance the main obligation for the “importing members” is to prevent trade diversion of compulsory license products, which can occur through the re-exportation of products that were imported into their territories under the TRIPs decision.

The TRIPs decision also sets some conditionalities and safeguards for its use. The most obvious condition or requirement is that there should exist a national emergency or national urgency. It is left to the discretion of members to set and define for themselves the situation of emergency or urgency. Clearly, the prevalence of HIV and AIDS may be characterised as a situation of national emergency or extreme urgency.

An important element of the TRIPs decision is that it does not discard the WTO member’s obligation to adequately compensate IPR holders in terms of Article 31(h) of the TRIPs agreement which obligates the WTO members to create a system that will ensure that the patent right holder or owner is adequately remunerated.

In addition, when using the TRIPs Decision, a WTO member must demonstrate, to the satisfaction of the TRIPs council, the expected quantity of the products needed; that it has insufficient or no manufacturing capacity in the pharmaceutical sector for the production of goods and, if a pharmaceutical product is patented in its territory, that it has granted or intends to grant a compulsory license in terms of Article 31 of the TRIPs agreement.

## 2. The South African and Kenyan frameworks

### 2.1 Compulsory licensing

#### 2.1.1 South Africa

South Africa has the appropriate legal foundation and some level of pharmaceutical capacity to enhance the accessibility of HIV and AIDS medicine. In fact, compulsory licensing either by the government for government use or by third parties has been on the statute books since 1978 under the Patent Act of 1978.<sup>18</sup> The only difference is that the Patent Act contained no specific provision to deal with compulsory licensing for pharmaceutical patents to enable access to life-saving drugs in cases of HIV and AIDS and other epidemics, as is now the case in patent legislation in the world. Section 56 of the Patent Act permits the granting of compulsory licenses in cases of the abuse of a patent.<sup>19</sup> Section 4 provides for the government use of a patent for public purposes. In my view section 4 of the Patent Act captures “public non-commercial use” in Article 31(b) of the TRIPs agreement, commonly referred to as government use exception, and it is therefore consistent with Article 31(b) of the TRIPs agreement (Bollyky 2002: 546).

18 Cf also the Intellectual Property Laws Rationalisation Act of 1996, which together with the Patent Act governs patents in South Africa.

19 Abuse of a patent exists where: (a) the patent right holder refuses to grant a license, under certain conditions and in the public interest, to role-players in the pharmaceutical industry, and such players are being prejudiced; (b) the patented product is imported into the Republic at an excessive price in relation to the price charged in the country of manufacture.

The infamous Medicines and Related Substances Control Amendment Act (MRSCAA) of 1997<sup>20</sup> introduced amendments to the Medicines and Related Substances Act of 1965. In terms of section 15, the MRSCAA was enacted to enable the Minister of Health, among others, to introduce measures “so as to protect the health of the public”, and to make pharmaceuticals more affordable. Section 15C(a) of the MRSCAA can be read as permitting compulsory licensing in that it allows for the institution of any measures for the availability of patented medicines notwithstanding the rights of patent holders as provided for under the Patent Act 57 of 1978.

As noted above, the TRIPS decision relaxed the domestic supply requirements in Article 31(f) of TRIPS, and does not *per se* prohibit exports of patented essential drugs procured under a compulsory license. Taking advantage of the TRIPs flexibilities that permit the re-exportation of imported pharmaceutical products by developing or least-developed members to other developing and least-developed WTO members with whom they are party to a regional trade agreement, South Africa may import pharmaceutical drugs from countries such as India to address its HIV and AIDS problem, and still export the same drugs imported from India to Botswana, Namibia or Swaziland, all members of the Southern African Custom Union (SACU) and the Southern African Development Cooperation (SADC), to enable them to address their HIV and AIDS problem.

### 2.1.2 Kenya

The appropriate TRIPs-compliant legislation in Kenya is the 2001 Industrial Property Act (IPA), passed in terms of Legal Notice No 53 of April 2002 (cf Lewis-Lettington & Munyi 2004: 1). IPA came into being after a review process undertaken by the Kenya Industrial Property Institute (then Kenya Industrial Property Office) to make the country’s industrial property regime TRIPs compliant.

The legislative foundation of compulsory licensing is found in section 74 read with section 75 of IPA. In terms of section 74(1)(a) of IPA, the applicants for a compulsory license must demonstrate to the

20 The Medicines and Related Substances Control Amendment Act No 90 of 1997 [hereinafter MRSCAA].

Industrial Property Tribunal that they have requested a voluntary license and have either been refused reasonable commercial terms or have not received a response within a reasonable time. Section 74(2) further states that the condition in section 74(1) may be waived in the case of “national emergency or other circumstances of extreme urgency”, in light of the TRIPs decision.

Interestingly, shortly after the TRIPs Decision, Cosmos Pharmaceuticals of Kenya announced that it intends exporting generic HIV and AIDS drugs to Tanzania and Uganda (BBC News 2003), who are least-developed countries and who together with Kenya form the East African Community (EAC).<sup>21</sup>

## 2.2 Parallel importation

### 2.2.1 South Africa

In South Africa, the legislative foundation of parallel importation of pharmaceuticals is found in section 15C(b) of the MRSCAA:

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner may be imported.

The requirements and procedures for parallel importation of medicines are substantially dealt with in the South African Medicines Control Council’s “Guidelines for parallel importation for medicines in South Africa of 2003”. Parallel importation is defined as

the importation into the Republic of a medicine protected under patent and/or registered in the Republic that has been put onto the market outside the Republic by or with the consent of the patentee in respect of such medicine.<sup>22</sup>

21 The EAC is an intergovernmental organisation consisting of Kenya, Uganda and Tanzania established on 30 November 1999. EAC was originally formed in 1967 but disbanded in 1977.

22 SAMCC 2003: 3.

Section 4 of the Guidelines sets requirements for importation, which includes application to the Minister of Health for a permit to parallel import a medicine.

In *Pharmaceutical Manufacturers' Association and Others versus The President of the Republic of South Africa* it was asserted that section 15C(b) of the MRSCAA was in breach of South Africa's obligations under TRIPs, and, among other issues, that parallel importation will result in pharmaceutical companies losing profits.<sup>23</sup> Interestingly though, the case was against a system that has been in place for years. Parallel importation has been a feature of the South African patent regime in terms of the Patents Act of 1978 as amended (Sheppard 1994: 23).

### 2.2.2 Kenya

Lewis-Lettington & Munyi (2004: 17) reckon that Kenyan law and policy on parallel importation form a "touchstone" of the country's access to medicine since mid-1999. The relevant provision of IPA, as amended by the Statute Law (Miscellaneous Amendments) Act, 2002, states:

The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya *by the owner of the patent or with his express consent.*<sup>24</sup>

Kenya has benefited from the flexibility on parallel importation under IPA from June 2002 with imports of HIV and AIDS-related drugs from India (Lewis-Lettington & Munyi 2004: 20).

23 Another incidental and relevant issue related to "price fixing" and "generic substitution".

24 The italics show the inserted amendment.

### 3. Real and perceived challenges of using TRIPs flexibilities

#### 3.1 Complexities and stringent conditionalities

As correctly stated by Varela (2004: 542), the number of PLWHA in South Africa, for example, justifies the country taking measures based on national emergency within the confines of the TRIPs flexibilities. Both Kenya and South Africa have the appropriate legal framework to use TRIPs flexibilities. Unfortunately, these flexibilities have not been used optimally due to some real and perceived challenges. While there may be real complexities or pitfalls in respect of the use of TRIPs flexibilities, some of the much relied upon “complexities” are just perceived and merely excuses for nonaction by governments without making efforts to exploit the opportunities presented by such flexibilities.

It has been argued that the TRIPs decision is a classical case of one good step forward and three steps backwards due to stringent conditionalities. In my view, and borrowing from the language used by the World Intellectual Property Organisation (WIPO), it is “overly simplistic and wrong” to attribute the nonuse or lack of effective use of TRIPs flexibilities to requirements and conditionalities (IPI 2000: 52).<sup>25</sup> Instead, the fact that the TRIPs decision unlocked the pharmaceutical patent protection system to enable countries to address their healthcare crises such as HIV and AIDS should be appreciated. Consider, for example, Kenya’s dissatisfaction with the *Act to amend the Patent Act and the Food and Drugs Act (JCPA)*<sup>26</sup> passed in May 2004 by the Government of Canada to give effect to, among others, the TRIPs decision. The JCPA allows Canadian manufacturers to export medicines to countries lacking manufacturing capacity pursuant to the TRIPs decision. The arguments by Kenya that the JCPA discards this requirement smack of naivety and overplaying

25 Note that the Report referred specifically to the TRIPs agreement before the 2003 flexibilities were introduced.

26 *Act to amend the Patent Act and the Food and Drugs Act — the Jean Chrétien Pledge to Africa*, Bill C-9 (JCPA). The JCPA came into effect on 14 May 2005.

the generosity of the Canadian system. It also amounts to myopically downplaying the importance and the moral significance of the Canadian initiative in enhancing access to essential medicines.<sup>27</sup>

### 3.2 Political will and the healthcare system

The South African political will and the political economy of the healthcare system offers a clear example of other inhibitors to use TRIPs-compliant measures. It is widely known that in South Africa the HIV/AIDS political wrangling has contributed to the problem of access to essential medicine in order to fight the pandemic. The wrangling ranges from the globally condemned questioning of the link between HIV and AIDS by President Thabo Mbeki to the politically charged disagreements by the Ministry of Health, headed by Minister Dr Manto Shabalala-Msimang, on the safety and effectiveness of some antiretroviral drugs.<sup>28</sup>

### 3.3 External pressures

South Africa, for example, is yet to issue a compulsory for patented pharmaceutical drugs pursuant to TRIPs flexibilities. Instead there has been a move towards seeking voluntary licenses and use of the country's competition laws to curb the escalating prices of patented pharmaceuticals.<sup>29</sup> The problem with the voluntary licensing approach is that its application can easily be rejected by patent-holding companies.

27 To start with, the JPCA makes access possible by eligible African countries, whether or not they are WTO members. Countries should seize the opportunity and stop looking the gift horse in the mouth.

28 The row involved AZT, a drug used to prevent the transmission of HIV from pregnant mother to child (MTCT). The president's position on the link between HIV and AIDS and his Health Minister's stance on the effectiveness and safety of AZT impacted negatively on the country's HIV and AIDS healthcare system. Cf Heywood 2003: 281-3 who explains the link between the "AIDS denial" and the problems that consequently marred the national programme on the prevention of MTCT.

29 Cf footnote 19.

The hiatus in South Africa's use of TRIPS flexibilities may be attributed to the pressure exerted by pharmaceutical industries and patent holders on developing countries to abandon or change their policies and measures in this regard (Ashcroft 2005: 124). The typical example is the dispute that led to a case before the Pretoria High Court, the Pharmaceutical Manufacturers' Association and Others *versus* The President of the Republic of South Africa,<sup>30</sup> in which the constitutional justiciability of certain provisions of the MRSCAA was challenged as denying intellectual property owners protection required by TRIPs agreement (cf Berger 2001, Collins 2001), and the claim made that by implementing the MRSCAA South Africa will be in breach with her obligations under TRIPs, in particular Articles 28 and 27. The two Articles in general require the protection of the exclusive right of the IPRs holders. The other argument was that the MRSCAA violated the IPRs holders' right to protection of property as entrenched in Section 25 of the South African Constitution Act of 1996. Specific to compulsory licensing, the Pharmaceutical Manufacturers' Association (PMA) also argues that Section 15C, which refers to parallel importation, is written overly broadly, in that it expands the powers of the Minister of Health to allow her to issue compulsory licenses.

The crisis relating to the amendments resulted in the listing in April 1999 of South Africa under the Watch List pursuant to Section 301 of the Trade Act of 1974<sup>31</sup> by the USA's administration. Section 301 listing meant that the USA considered South Africa as a country that does not adequately and effectively protect American drug patents.

Later in the same year South Africa was removed from the Watch List of Section 301, mostly after pressure was brought to bear on the USA by groups such as Consumers International, Health Action International and Act Up! (IIPi 2000: 16). Interestingly, on 10 May 2001 the Clinton administration issued an executive order, entitled

30 Case no 4183/98.

31 Trade Act of 1974, Pub L93-618, 93 Stat 144, 236. Section 301 is a tool used by the USA to deal with laws, policies, practices or measures of foreign governments or institutions that are inconsistent with the provisions of trade agreements to which the USA is a party, or that "deny" benefits to the USA under such agreements.



*Access to HIV/Aids Pharmaceuticals and Medical Technology*, which introduced the policy of nonintervention in patent laws of beneficiary or designated sub-Saharan countries, including South Africa. The order seeks to regulate and promote access to HIV and AIDS pharmaceuticals and technologies consistent with the TRIPs agreement. Such designated sub-Saharan countries could produce or import generic HIV and AIDS drugs without fear of trade sanctions.

Now that the hurdles which accompanied TRIPs' provisions, in particular Article 31 on compulsory licensing, are displaced by the TRIPs flexibilities, South Africa should be able to make HIV and AIDS drugs more accessible, and sustainable.

### 4.3 Pharmaceutical drugs manufacturing capacity

In 2002 a study by Correa reported poor levels of development of the pharmaceutical industry in Africa. The study was divided into the following sections: countries with sophisticated pharmaceutical industry and research base; innovative capabilities; reproductive capabilities of finished ingredients and finished products; reproductive capabilities of finished products from imported ingredients, and countries with no pharmaceutical industry. According to this study, in the year 2002 only Egypt had the reproductive capability of active pharmaceutical ingredients and finished pharmaceutical products (Correa 2002: 52). Thirty-two other African countries had reproductive capabilities but only with regard to finished products from imported ingredients. Nineteen African countries had no pharmaceutical industry. The study characterised Kenya and South Africa as having reproductive capacities for finished products from imported ingredients only (Correa 2002: 52-3).

Africa's pharmaceutical manufacturing capacity has since developed and improved. South Africa has developed the necessary pharmaceutical manufacturing capacity to take advantage of TRIPs flexibilities. The advanced pharmaceutical capacity of South Africa should ensure that the country fruitfully uses the TRIPs agreement's compulsory licensing measures. Some commentators have noted that a number of South African companies hold the necessary licenses from patent-

holding companies enabling them to export first-line HIV and AIDS drugs to SACU and SADC countries (Avafia *et al* 2006: 2 & 14).

According to Lewis-Lettington & Munyi (2004: 13), a third of the Kenyan pharmaceutical industry was involved in the manufacturing of generic drugs by 2004. However, the country's gradually growing drug manufacturing industry is facing some limitations including the non-availability of pharmaceutical ingredients, cost effectiveness of having to import APIs from countries such as China and India, and the lack or inadequacy of appropriate manufacturing technology (Lewis-Lettington & Munyi 2004: 13-4).

It is important to note in the context of this study that the problem of pharmaceutical manufacturing capacity may to some extent be alleviated, should the TRIPs amendment be operational. In terms of the TRIPs amendment, least-developed country members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector. Article 31bis(1) expressly precludes recourse to Article 31(f) in order to deny the grant of a compulsory license by members "to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)". Article 31bis(3) reiterates the importance of members developing and improving the necessary pharmaceutical production capacity, and of interregional assistance in cases where such capacity is lacking.

## 5. Conclusion

The guarantees to the right of access to healthcare services and to the right to equality, dignity and life, as featured in many African governments' legal frameworks, should oblige African governments to take advantage of whatever flexibility is provided by GATT and the TRIPs agreement in realising the peoples' right to access to essential HIV and AIDS medicines. The Kenyan and the South African governments should therefore consider and employ reasonable measures such as TRIPs flexibilities to facilitate access to HIV and AIDS drugs. Both Kenya and South Africa have fairly comprehensive and flexible legislation to enable them to earnestly discharge their public health

obligations, including addressing the HIV and AIDS pandemic by having recourse to TRIPs flexibilities, among others.

Ways must be found to transcend the perceived complexities and/or pitfalls of the TRIPs flexibilities. Building and/or improving pharmaceutical manufacturing capacity is also important in Africa. The pharmaceutical production capacity should ideally be built via mechanisms such as technical cooperation and technology transfer. African countries should work within their regional trading blocks towards establishing measures making HIV and AIDS medication available, thus creating home-grown solutions, which should at least be able to address the HIV and AIDS challenges facing the African continent. Another possible approach is to have recourse to other recent access measures within the context of TRIPs flexibilities, which are presented for governments in Africa to explore in this regard. The example is the Canadian *Act to amend the Patent Act and the Food and Drugs Act — The Jean Chrétien Pledge to Africa* (JCPA), which enable eligible African countries to improve their access to essential medicines pursuant to the TRIPs decision.<sup>32</sup>

32 On 17 May 2006 the European Union adopted a similar legislation to implement the TRIPs decision, Regulation 816/2006. For more on this regulation cf Cornides 2007: 70-7.

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