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COMPARATIVE ANALYSIS OF ACCESS TO PATENTED HIV/AIDS PHARMACEUTICAL MEDICINES THROUGH THE CANADIAN AND EU TRIPS FLEXIBILITIES MEASURES: ARE THEY EFFICACIOUS OR OVERLY BURDENSOME AND INEFFECTIVE MEASURES?

OS Sibanda*

1 Introduction

Our decision to write on access to patented pharmaceutical medicines was motivated by the need for persons to acknowledge and recognise the public-health rights of healthcare and access to medicine, though often neglected, as fundamental human rights.[1] Every national jurisdiction has some form of legal imperative to enable or make it possible for its citizens to enjoy certain fundamental human rights and civil liberties and freedoms. South Africa, for example, has an obligation to ensure the progressive realisation of all human rights that are not immediately realisable such as, for example, the right of access to healthcare. This obligation arises from the *Constitution of the Republic of South Africa, 1996* (hereinafter the Constitution) and international law.[2] The Constitution states that everyone has the right to have "access to health care services" [3] and that "the state must take reasonable legislative and other measures within available resources to achieve the progressive realisation of these rights".[4] One reads or hears mention on a daily basis of the prevalence of the Human Immunodeficiency Virus (HIV) and the Acquired Immune Deficiency Syndrome[5] (AIDS) in Sub-Saharan Africa[6] (SSA) and the

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1 For very illuminating studies on HIV/AIDS and human rights, see generally Gumedze 2004 *AJHR* 181-200; Kirby 2004 *AJHR* 163-180. See also Singh, Govender and Reddy 2005 *Georgetown Journal on Poverty Law & Policy* 355-388.

2 See generally Chirwa 2003 *SAJHR* 541-566.

3 Section 27(1)(a) *Constitution of the Republic of South Africa*, 1996.

4 Section 27(2) *Constitution of the Republic of South Africa*, 1996.

5 Acquired Immune Deficiency Syndrome (AIDS) occurs when a Human Immunodeficiency Virus (HIV) positive person suffers from lowered immune levels making him/her a target of a different opportunistic infection. The full names were given in the abstract.

6 Sub-Saharan Africa (SSA) is a geographical term used to describe the area of the African continent which lies south of the Sahara (a desert land) or those African countries that are fully or partially located south of the Sahara. The SSA countries are Angola; Benin; Botswana; Burkina Faso; Burundi; Cameroon; Cape Verde; Central African Republic; Chad; Comoros; Congo (Brazzaville); Congo DRC (Zaire); Cote d'Ivoire; Djibouti; Equatorial Guinea; Eritrea; Ethiopia; Gabon; Gambia; Ghana; Guinea; Guinea-Bissau; Kenya; Lesotho; Liberia; Madagascar; Malawi; Mali; Mauritania; Mauritius; Mozambique; Namibia; Niger; Nigeria; Reunion; Rwanda; Sao Tome

challenges of access to patented pharmaceutical medicines. As access to essential medicine is one of the basic pillars of social welfare and human development, urgent attention is required for this dire situation. This serves as the inspiration for this article.

In the landmark judgments of the South African Constitutional Court in *Grootboom*[7] and *Treatment Action Campaign,*[8] the court unequivocally affirmed the principle that measures should be taken by the state for the delivery of socio-economic rights. In a matter that related to housing, the court in *Grootboom* obliged the State to provide an enabling environment for the provision of housing by identifying the relevant "legal, administrative operational and financial hurdles and lowering them over time".[9] In the context of access to antiretrovirals (ARVs) and related treatment, the decision calls for the consideration of all possible ways through which the progressive realisation of this right may be accomplished, including (i) recourse to access initiatives, be they regional or international, (ii) the provision of additional funds, and (iii) the reduction of the cost of medicines through various legislative and regulatory measures.[10] In the context of this study, access initiatives are considered in this article by appraising how and to what extent the Canadian and European access to medicines regimes – discussed in Part 2 – which are based on the flexibilities introduced in the World Trade Organisation (WTO) agreement called the Agreement on the Trade-Related Aspects of Intellectual Property[11] (TRIPS) – discussed in Part 3 – can be used to address the HIV/AIDS challenges in SSA and other developing countries. Arguments against TRIPS-flexibilities are discussed in Part 4.

The United Nations has declared HIV/AIDS in SSA as "a threat against humanity", and that the situation requires "interventions of emergency proportions" and of "urgent and exceptional national, regional and international action".[12] The South

and Principe; Senegal; Seychelles; Sierra Leone; Somalia; South Africa; Sudan; Swaziland; Tanzania; Togo; Zambia; and Zimbabwe.

7 *Government of the Republic of South Africa v Grootboom* 2001 1 SA 46 (CC).

8 *Minister of Health v TAC (No 2)* 2002 5 SA 721 (CC).

9 *Government of the Republic of South Africa v Grootboom* 2001 1 SA 46 (CC) para 45.

10 See generally Hassim, Heywood, and Berger *Health Law and Policy..*

11 *TRIPS Agreement* (1994).

12 See UN 2001 www.who.int.

African Constitutional Court in *Minister of Health v TAC (No 2)*[13] highlighted the HIV and AIDS situation by making reference to the 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".[14] The African Commission on Human and Peoples' Rights, for example, has declared HIV/AIDS in Africa a serious threat against humanity, which needs urgent and exceptional intervention measures.[15] This challenge was acknowledged by African states in the *Maputo Declaration on Malaria, HIV/AIDS, Tuberculosis and other Related Infectious Diseases,*[16] which consequently committed themselves to taking appropriate steps to curb the HIV/AIDS pandemic, including putting in place measures to scale up the treatment for HIV/AIDS.[17] This is a welcome commitment by African countries in the light of Article 16(2) of the *African Charter on Human and Peoples' Rights* (ACHPR) of 1981, which 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".

Many people have died from HIV and AIDS in developing countries - about 30 million plus to date. In some SSA countries AIDS has wiped out entire communities and families.[18] Part of the burden of HIV and AIDS prevalence in SSA is the high number

13 *Minister of Health v TAC (No 2)* 2002 5 SA 721 (CC).

14 *Minister of Health v TAC (No 2)* 2002 5 SA 721 (CC) para 1.

15 The declaration of the African Commission on Human and Peoples' Rights (ACHPR) contained in a compendium by Heyns and Killander *Key Human Rights Documents* 279.

16 See AU 2003 www.iss.co.za. Alongside the HIV/AIDS pandemic, malaria is one of the most devastating diseases in Africa. The disease is transmitted when a person is bitten by a mosquito carrying the parasite that causes the disease. According to the Malaria Research Programme of the Medical Council of South Africa, malaria is a killer disease in SSA, with a greater prevalence than cases of TB, AIDS, measles and leprosy combined. It is therefore the leading cause of morbidity and mortality in SSA. The Malaria Research Programme (MRP), formerly National Malaria Research, was established in 1992 as a lead programme of the South African Medical Research Council (MRC) focusing on malaria-vector research, insecticide evaluations, research on the malaria parasite, and drug resistance in malaria. See Keiser *et al* 2004 *American Journal of Tropical Medicine and Hygiene* 118-127. Another challenge with HIV also lies in its ability to change its profile with deceptive flexibility to cause death and disability through pneumonia, skin cancer, tuberculosis, and other opportunistic diseases. For countries like South Africa, which struggle with the spread of tuberculosis, this makes the situation even worse.

17 See Heyns and Killander *Key Human Rights Documents* 279.

18 Schoofs illustrates the debilitating effect of HIV and AIDS through the life of Arthur Chinaka, who in 1990 was 19 years old and in high school. His father died of AIDS and other opportunistic diseases. In 1992, his uncle Edward died of AIDS. In 1994, his uncle Richard died of AIDS. Another uncle, Alex, died of AIDS in 1996. In the same year his aunt Eunice and a fourth uncle

of orphans among the survivors, and the stigma that people continue to place on HIV- and AIDS-infected individuals and their affected families.[19] Stigmatised people continue to be discriminated against and treated with prejudice as social outcasts, overtly or covertly. Some of the people so stigmatised even face unfair labour practices, including dismissal from work under the pretext of occupational disability[20] and automatic dismissals due to their refusal to disclose their HIV status.[21] A study published by UNESCO's International Institute for Educational Planning (IIEP) reveals the high numbers of orphans among the survivors as one of the consequences of the impact of HIV and AIDS on children in developing countries, and that SSA has a huge number of orphaned children of less than 10 years of age.[22] These children are expected to head their households from as young as seven years of age. The country-specific HIV and AIDS outlook is equally unsatisfactory. In South Africa, for example, it was estimated in 2010 that the "overall HIV prevalence rate is approximately 10,5%, and that the total number of people living with HIV is estimated at approximately 5,24 million".[23] People living in poor rural and urban informal settlement areas are at highest risk of HIV infection. These people are mainly the have-nots and find it difficult to access HIV and AIDS treatment and medicines without government help.

2 TRIPS, protection of intellectual property, and public health

The WTO governs matters relating to the protection of intellectual property rights (IPRs) primarily through TRIPS. Part of the preventative rights afforded to patent holders by TRIPS is that the production, distribution and other forms of exploitation of their pharmaceutical products must be done within the context of the rules under TRIPS. Thus, TRIPS gives the producers of pharmaceutical products recourse to protect their profits by allowing them to register patents over their products. A

also died of aids. Almost his entire family was wiped out by HIV and AIDS. See Schoofs 1999 www.village.

19 See Tsoose 2010 *PELJ* 423-428.

20 See, for example, *Hoffmann v South African Airways* 2000 ZACC 17, and *Bootes v Eagle Inc System KZ Natal (Pty) Ltd* 2008 29 ILJ 139. For more on dismissals based on HIV and AIDS status, see generally the SALC 2011 www.unaids.org.cn

21 See, for example, *Allpass v Mooikloof Estates (Pty) Ltd t/a Mooikloof Equestrain Centre* 2011 ZALC 2.

22 UNESCO-IIEP 2002 www.unesco.org.iiep.

23 Statistics South Africa 2010 www.statssa.gov.za 3-5.

negative effect of this patent protection in the context of healthcare rights has been the restriction in the access to and flow of patented medicines.

WTO members have been aware of the restriction on access to pharmaceutical products as a result of the application of TRIPS provisions. Consequently, a few important decisions in relation to TRIPS have been adopted to address the challenges of access to medicines necessary to deal with the public-health problems facing many developing countries. Notable among these decisions are: Decision on Paragraph 17 of the Main Doha Declaration of 14 November 2001 (Doha Decision on Paragraph 17 of TRIPS); the Declaration on the TRIPS Agreement and Public Health of 14 November 2004[24] (Doha Declaration on TRIPS of 2001); the Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for LDC Members for Certain Obligations with Respect to Pharmaceutical Products of 27 June 2002 (Decision on TRIPS Extension for LDCs); the Decision on LDC Members' Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products of 8 July 2002 (Decision on LDC Members' Obligations under Article 70.9 of TRIPS); the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003 (TRIPS Decision of 2003); the Decision on the Amendment of TRIPS Agreement of 6 December 2005[25] (TRIPS Amendment); the Hong Kong Ministerial Declaration on TRIPS and Public Health (the Hong Kong Ministerial Declaration on TRIPS); and the Decision of 17 December 2009 to extend the deadline for accepting TRIPS Agreement Amendments.

The Doha Declaration on TRIPS was adopted by the WTO Ministerial Council at its conference held from 9 to 14 November 2001 in Doha, Qatar, to introduce flexibilities into TRIPS as identified in the Doha Decision on Paragraph 17 of TRIPS. Most importantly, it required that TRIPS must be interpreted and implemented in a manner that is supportive of public health. The Decision on TRIPS Extension for Least-Developed Countries (LDCs) and the Decision on LDC Members' Obligations under

24 *Doha Declaration on TRIPS* (2001).

25 *TRIPS Amendment* (2005). The amendments to TRIPS Agreement were to be made by 1 December 2007 or after at least two-thirds of the members had accepted them, or by any such later date as may be decided by the Ministerial Conference. The 1 December 2007 deadline failed and was extended to December 2009. This has been further extended to 31 December 2011.

Article 70.9 of TRIPS created a special dispensation for least-developed countries. In terms of the former, LDCs did not have to protect pharmaceutical patents and test data until 1 January 2010. Moreover, LDCs had the right to seek further extensions to this period. The latter Decision allows LDCs not to give exclusive rights to pharmaceuticals that are subject to patent application until 1 January 2016.

The TRIPS Decision of 2003 gives effect to the Doha Declaration on TRIPS by removing limitations on exports under compulsory licence to countries that cannot manufacture the pharmaceutical themselves. WTO Member states need to build flexibilities into TRIPS or to amend TRIPS to allow countries to address adequately their public health problems and situations of national emergency or extreme urgency.[26] The importance of the TRIPS Decision of 2003 was reaffirmed by the WTO during the Hong Kong Ministerial Declaration on TRIPS. In brief, the TRIPS Decision of 2003 primarily attempts to loosen the restrictive nature of the protection of IPRs in the TRIPS Agreement, and thus the effect it has on access to patented pharmaceutical products. Article 31 of TRIPS permits the unauthorised exploitation of intellectual property rights (IPRs) by WTO members. Pursuant to Article 31(f), the unauthorised production of patented pharmaceutical medicines may be justifiable in cases of national emergencies and other circumstances of extreme urgency, subject to the license or exploitation of the IPRs being "predominantly for supply of the domestic market of the authorizing Member". Article 31(f) is restrictive in that it allows compulsory licensing predominantly for domestic production for the supply of a country authorising such use only. The restriction becomes more severe when applied to a country with insufficient or no pharmaceutical manufacturing capacity, which would mean that such members lacking the capacity or infrastructure to manufacture pharmaceuticals have to rely on imported pharmaceuticals. In brief, Article 31 on its own is inflexible.[27]

According to paragraph 2 of the TRIPS Decision of 2003, the WTO members may manufacture pharmaceutical products under compulsory licence and export them to eligible WTO member(s), which include all least-developed countries and any member who notifies the TRIPS Council of his/her intention to use the system under

26 See generally Sibanda 2009 *Acta Academica* 187.
27 See generally Sibanda 2009 *Acta Academica* 191-192.

the TRIPS Decision of 2003. The TRIPS Decision of 2003 further permits the re-exportation of imported pharmaceutical products by developing or least-developed members to other developing and least-developed countries.

The TRIPS Decision of 2003 is a temporary measure, which is to be replaced by permanently amending the relevant provision of TRIPS through the insertion of Article 31*bis* after Article 31 of TRIPS, and also by inserting the Annex to the TRIPS after Article 73. It is hoped that the TRIPS Amendment will effect permanent changes to the TRIPS Agreement.[28] Article 31*bis*(1) expressly precludes recourse to Article 31(f) in order to deny the grant of compulsory licences 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 31*bis*(3) reiterates the importance of members developing and improving the necessary pharmaceutical production capacity, and interregional assistance in cases where such capacity is lacking. Therefore, a pharmaceutical product produced or imported under a compulsory licence by one member may be exported legitimately to the markets of those other developing or least developed country parties to the regional trade agreement "that share the health problem in question".

3 The legislative framework for compulsory licensing systems under the Canadian and EU access regimes

3.1 General

In keeping with the flexibilities introduced to TRIPS in May 2004, Canada passed the *Act to Amend the Patent Act and the Food and Drugs Act - The Jean Chrétien Pledge to Africa.*[29] The *Jean Chrétien Pledge to Africa*, which will from here onwards

28 Article 31*bis* is not markedly different from the TRIPS Decision of 2003. It is more of an adaptation of the TRIPS Decision of 2003 and the regulatory essence of the two is the same. Several identical aspects exist between the TRIPS Decision of 2003 and the TRIPS Amendment. For example, like the TRIPS Decision of 2003, a 31*bis* lists detailed conditions which must be complied with before using TRIPS flexibilities. Notable among these is the adequate remuneration of the patent right holder pursuant to a 31*bis*(2). Most importantly, a 31*bis*(4) provides that any measures taken in fulfilment and conformity with the conditions of a 3 “shall not be challenged”.

29 *Act to amend the Patent Act and the Food and Drugs Act - The Jean Chrétien Pledge to Africa,* S.C. 2004, c. 23.

be broadly referred to as the Canada Access to Medicine Regime (CAMR), is a pledge by the government of Canada to assist specifically African countries in alleviating their problem of access to medicine essential in the fight against health pandemics besetting them. The EU implemented the TRIPS Decision of 2003 through Regulation (EC) No 816/2006[30] of the European Parliament (EP) and the European Council (EC) of May 2006. In the words of someone who has been affected greatly by HIV/AIDS, Jack Kay, Apotex President and its Chief Operations Officer, recourse to such flexibilities is "… the right thing to do for the people dying from AIDS in Africa".[31] The Canadian and European flexibility regimes respectively have as their objectives making pharmaceutical products more accessible. The CAMR was the first of such legislation pursuant to the TRIPS Decision of 2003, and was later followed by the EU Regulation, whose essential elements are drawn primarily from the TRIPS Decision of 2003.[32]

3.1.1 Canada

The CAMR has been described as a historical and ground-breaking "crucial piece of legislation"[33] from the perspective of the WTO discipline on access to essential medicine. Canada is the first country in the world to enact legislation implementing the TRIPS Decision of 2003. It was unanimously passed into law in May 2004 and came into effect on 14 May 2005 together with its accompanying regulations, which were later published on 1 June 2005 as Part II of the *Canada Gazette* to deal with the compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to eligible countries.[34] This enactment meant that Canada became the first member of the WTO to enact the law that amended its *Patent Act* of 1985[35] in order to implement the TRIPS flexibilities. This was true to the country's September 2003 announcement of its intention to implement the TRIPS Decision of 2003 into national law.

30 EU 2006 www.cptech.org. See also Cornides 2007 *JWIP* 70.
31 Quote taken Apotex 2008 www.apotex.com.
32 EU 2006 www.cptech.org.
33 Per Mr J Leprince, president of Aventis Pharma (Canada), giving evidence before the Standing Committee on Industry, Science and Technology, 37th Parl. 3d sess., No. 004 (26 February 2004).
34 Eligible in terms of para 1.03(1)(b) of the *Patent Act*, R.S.C. 1985.
35 *Patent Act*, R.S.C. 1985.

The CAMR resulted from extensive consultation with pharmaceutical industry stakeholders, non-governmental organisations (NGOs) and parliamentarians. Interestingly, it was also a subject of review in 2007. The review was necessitated by the fact that the new access to the medicine system has never been used since its inception, apparently because of the flaws in the JCPA, which make it unworkable.[36]

3.1.2 European Union

The EU Regulation, which entered into force on 29 June 2006, has been praised as an indication that the EU has "lived up to the engagement it has made at the Doha Ministerial Conference".[37] The Regulation now enables the manufacture of patented pharmaceutical products under licence by someone other than the patent holder for export to countries with public-health problems. The Regulation underwent serious and intensive informal scrutiny by the EC and the EP, with the particular intention of shaping its text to properly balance public and private interests. The commission's proposal of 29 October 2004 was highly instrumental in shaping the nature of the EU Regulation. One should note the EC's approach, possibly a very important approach from the perspective of the WTO, of not deviating materially from the TRIPS Decision of 2003. In this regard, the Commission proposed that no further conditions or restrictions should be imposed, except the conditions for the application and grant of compulsory licences akin to those found in voluntary licensing agreements.[38] Another feature of the EU system is that it has been agreed that member states should decide on the administrative and formal requirements necessary for the "efficient processing of the [compulsory licensing] application" under the EU Regulation.[39] The Regulation discourages litigation related to IPRs and their use by countries to "pursue industrial or commercial policy objectives".[40]

36 Human Rights Working Group 2007 www.camr-rcam.gc.ca 3.
37 Cornides 2007 JWIP 74.
38 See generally EU 2006 www.cptech.org.
39 Cornides 2007 JWIP 73.
40 Clause 6 of the preamble to the Regulation (EU 2006 www.cptech.org.).

3.2 Comparative appraisal of selected provisions of the EU and Canadian measures in comparison with the WTO provisions

3.2.1 Eligible importers and beneficiary countries

3.2.1.1 The WTO Provision

The WTO regulatory framework and associated agreements apply to the WTO members. As noted earlier, paragraph 2 of the TRIPS Decision of 2003 and Article 31*bis* of the TRIPS Amendment, for example, allowed the WTO members to manufacture pharmaceutical products under compulsory license and export them to eligible WTO member(s) only, and for WTO members of developing and least-developed states to re-export such imported pharmaceutical products to other developing and least-developed WTO member countries with whom they are party to a regional trade agreement. In effect, non-WTO members, particularly poor and least-developed countries, often with non-existent and/or poor levels of development of pharmaceutical industry capacity, are left out of the beneficiary fold.

3.2.1.2 The CAMR

Pursuant to paragraph 21.03(1)(b) of the *Patent Act*, some 50 least-developed countries have been listed as eligible importers of essential medicines from Canada under the TRIPS flexibility system, including some non-WTO members. In this regard Canada exceeded all expectations by setting the precedent of allowing both WTO members and non-WTO members to import pharmaceutical products under a compulsory licence. This apparently moral and humanitarian approach in the Canadian legislation should be commended and applauded for its indiscriminate accommodation of the health needs of least-developed and low-income countries. However, the CAMR sets a differential standard and rules for members and non-members using the procedure. While WTO member countries need merely to make an application based on a state of emergency, non-member countries need to prove the existence of their state of emergency. Therefore countries which are in serious need of pharmaceutical medicines for HIV and AIDS but are not WTO members may find it challenging to access these medicines under the CAMR.

It is instructive to recall that issues relating to access to medicine received prominence in the WTO after concerns were expressed that the rules of the TRIPS Agreement have the effect of excluding a large number of poor people and developing countries from access to affordable medicine. This situation was compounded by a skewness in the manufacture, pricing and distribution of patented pharmaceutical products,[41] the lack or insufficiency of domestic pharmaceutical research and manufacturing capacity, and the lack of an appropriate legal framework.[42] In this context, the inclusion of non-WTO member countries as eligible importers under the Canadian compulsory licensing scheme should be applauded.

In terms of 21.04(2)(f) of the *Patent Act*, NGOs and other entities may import pharmaceutical products, provided they get the permission of an eligible importing country. This requirement for having the permission of an eligible importing country has been viewed by NGOs, including the Access to Medicines Movement,[43] as rather unnecessary and burdensome from the perspective of public health. They believe that it limits the role played and that can be played by NGOs and other similar groups in the procurement of essential medicines.[44] However, we are of the opinion that the requirement should be allowed to stand. The importing countries have the responsibility of public-health issues in their territories, and must therefore be allowed the final say in the distribution of medicines within their borders. It is hard to imagine a situation whereby any organisation freely and without any notification to a particular sovereign country distributes and dispenses medicines within the territory of such a country, with complete disregard for the public health system of the country.

3.2.1.3 EU Resolution

The European Commission had initially proposed to follow the WTO and limit the beneficiary countries to WTO members. The move was mooted, however, as

41 Bluestone 2001 *Tropical Medicine and International Health* 162; Froneman 2000 www.panos.org.ukss; Ngwena 2002 *SAPL* 24-25.

42 Masungu, Villanueva and Blasetti 2004 www.ipsonline.org.resource.docs.

43 Access to Medicines Movement is an informal coalition of civil society organisations such *as Medicins Sans Frontieres* (Doctors without Borders), Treatment Action Campaign (TAC), Health GAP, Oxfam, and Knowledge Ecology International.

44 See generally Bubela and Morin 2010 dev.ulb.ac.be.

"undesirable" and it was decided that the Resolution should be extended to "all least developed and low-income countries, including those who are not members of the WTO".[45] This compromise was a welcome humanitarian decision which made essential medicine more accessible globally. In terms of Article 4 of the EU Regulation, the beneficiary countries include least-developed countries as designated by the United Nations. As far as NGOs' involvement in the importation is concerned, the Netherlands is one of the few countries in the EU that allows NGOs to import pharmaceutical products without requiring permission from the government of the importing country.[46] It is left to the importing country to determine issues of permision for importing such products. It is submitted that the importing country will in most cases insist on the requisition of such permission as part of its responsibility to ensure that imported medical products are safe for use in its territory.

3.2.2 Eligible pharmaceutical products

3.2.2.1 The CAMR

In what many have described as the constriction of the pharmaceutical products needs of the importing countries, the CAMR introduced a Schedule 1 for products possible to import under the compulsory system of the CAMR. Schedule 1 is modelled on the WHO Model List for Essential Medicines,[47] which serves as a guide for the development of national and institutional essential medicine lists. The TRIPS Decision of 2003 on which the CAMR is based does not require such listing of eligible pharmaceutical products.

Several valid criticisms of this provision have been expressed. The list is accused of being excessively narrow.[48] To start with, the Schedule 1 list contains only 57 drugs or vaccines, dominated by antiretroviral medicines. Only three drugs are for tuberculosis, malaria and trypanosomiasis. Others like enalapril, etopiside, morphine

45 Cornides 2007 *JWIP* 72.
46 Ng and Kohler 2008 *Health Law Journal 154.*
47 WHO 2007 whqlibdoc.who.int.
48 Cohen-Kohler, Esmail and Cosio 2007 www.globalizationandhealth.com.

and timol are already off-patent.[49] This skewed list overlooks the fact that the TRIPS flexibilities are designed to ensure access for even non-communicable diseases that pose public health problems. This misapprehension is due to the fact that the TRIPS Decision of 2003 was designed for only HIV/AIDS, Malaria, and Tuberculosis. Reference to HIV/AIDS, Malaria and Tuberculosis in the Doha Decision is only of illustrative significance.

Medicines and treatment for other pandemics not expressly mentioned in the Doha Decision may be made available through other measures in compliance with TRIPS flexibilities. Unfortunately, the misinterpretation of the Doha Decision has seen efforts by the pharmaceutical sector to resist efforts of countries like Thailand to use TRIPS flexibilities for diseases such as acute heart disease, which efforts are viewed as a violation of WTO rules.[50] With respect to off-patent drugs, it seems a vain exercise to implement a special medicine regime for such a patent since they are available for public use anyway, or can be sourced from countries like India, which has been providing much-needed ARV drugs to SSA.[51] Of course there are safety implications in regard to these off-patent drugs which should not be lightly dismissed, and any efforts made to ensure their safety and fitness for purpose are welcome.[52]

3.2.3 Remuneration

3.2.3.1 The WTO Provision

The TRIPS flexibilities do not do away with the need to compensate IPR holders. Article 31(h) of the TRIPS Agreement requires the WTO members to put in place a system that will ensure that the patent right-holder or owner is adequately remunerated. Yet both the TRIPS and the TRIPS Decision of 2003 do not provide a

49 For the patent status of many drugs see the United States Federal Drug Administration Date Unknown www.fda.gov.

50 See generally Savoie 2007 *Va Int'l L* 211.

51 Bhattacharya 2008 *Va J Int'l L* 396, 398.

52 The United States legislation, *Best Pharmaceuticals for Children Act* of 2002, Public Law (P.L.) 107-109, reauthorizes the pediatric studies provision of the *Food and Drug Administration Modernization and Accountability Act* of 1997 to improve the safety and efficacy of off-patent drugs that are used in children.

formula for the determination of adequate remuneration. Under ordinary circumstances remuneration would be determined based on the standard of reasonableness applying in the importing country, or any other functionally equivalent standard, on a case-by-case basis, taking into account the economic value derived from compulsory licensing.[53]

3.2.3.2 The CAMR Provision

Article 31(h) of the TRIPS Agreement has been echoed in the CAMR. IPR holders are entitled to remuneration upon the licensing of their patents. However, no formula for the calculation of the remuneration is provided.

3.2.3.3 The EU Provision

Unlike the TRIPS and the CAMR, the EU Regulation provides for a formula to calculate adequate remuneration. In terms of Article 10(9)(a) of the Regulation, remuneration is limited to 4% of the price paid by the importing country when pharmaceutical products concerned are used in situations of national health emergencies without prior negotiation. Article 10(9)(b) permits a different approach in situations that cannot be described as constituting national emergencies. In this regard the 4% remuneration ceiling may be applied, but the authority granting the compulsory licence may base the amount of renumeration payable on any other considerations, including the economic value of the intended use under license to the importing country, and the humanitarian or non-commercial circumstances relating to the intended use.

3.2.4 Safety, quality, and efficacy standards review

3.2.4.1 The CAMR

In addition to meeting the requirements of the *Food and Drugs Act*, the CAMR requires that the generic pharmaceutical products destined for export also receive

53 See generally Ng and Kohler 2008 *Health Law Journal* 160-161.

the approval of Health Canada regarding their safety, quality and efficacy standards. *Prima facie*, the Health Canada review looks like an unnecessary bureaucratic hurdle which has the potential to cause delay in accessing pharmaceutical products, particularly in respect of countries that require the WHO's pre-qualification of imported pharmaceutical products.[54]

However, the review process in the CAMR is a policy consideration which, when examined closely, carries benefits for importing countries. The dominant perspective on this requirement should be that of the demand for individually safe medicines. With some studies revealing a high degree of serious adverse reactions to the use of such medicines, even resulting in deaths in countries like the United States, every necessary safety measure is welcome irrespective of the origin of the medicine.[55] Therefore, with product liability class cases possible in countries like South Africa,[56] pharmaceutical companies may want to rethink the call to discard safety requirements in such circumstances.

3.2.4.2 EU Regulation

Like the CAMR, the EU Regulation makes reference to safety and efficacy in medical products. In terms of Article 18(1)(a) and (b) of the Regulation, licensees can avail themselves of the scientific opinion procedure under Article 58 of Regulation (EC) 726/2004,[57] or any similar procedure prescribed under national law such as scientific opinions or export certificates for medicines intended exclusively for markets outside the Union.[58]

54 See Human Rights Working Group 2007 www.camr-rcam.gc.ca 6.
55 A 1998 study by Sasjack 2008 *AJLM* 10 reports that there are about two million adverse medicine reaction hospitalisations and a million deaths in the United States annually.
56 Under the *Consumer Protection Act* 68 of 2008 (CPA). The CPA was signed by the President of the Republic of South Africa on 24 April 2009 and published in the *Government Gazette* on 29 April 2009. The Act came into force on 1 April 2011.
57 EU 2004 ec.europa.eu.
58 See Cornides 2007 *JWIP* 74.

3.2.5 Anti-diversion of products

3.2.5.1 The WTO Provision

The anti-diversion provisions as set out in paragraph 2(b)(iii) of the TRIPS Decision of 2003 require the information on the quantity of pharmaceutical products shipped to each destination, and the distinguished features of the products to be posted on the licensee's website.

3.2.5.2 The CAMR

Canada has added to the stated WTO anti-diversion provision by requiring "information identifying every known party that will be handling the products while in transit from Canada".[59] According to *Medicins Sans Frontiers,* this additional requirement is one that "increase[s] the complexity of the process" of obtaining the compulsory licence in addition to the "overly cumbersome" TRIPS Decision of 2003.[60]

4 The unjustified rhetoric of the rejection of TRIPS flexibilities

Interestingly, there has been little enthusiasm by countries to take advantage of the TRIPS flexibilities. In South Africa, for example, although the courts have not been hesitant in making rulings that ensure a significant degree of realisation of the right of access to health care for HIV/AIDS patients,[61] there has been no movement by the State towards taking advantage of the WTO-inspired flexibilities. It would seem that this reluctance to take advantage of TRIPS flexibilities is a common feature in many regions. For example, out of many of the east and southern African countries (ESA countries) that battle with HIV/AIDS challenges, only Zambia had accepted the Protocol Amending TRIPS at the time of writing this research.[62] Many of the ESA

59 *Act to amend the Patent Act and the Food and Drugs Act,* s 21.06.
60 Medicins Sans Frontiers 2006 www.msf.ca 6.
61 For example, *Minister of Health v TAC (No 2)* 2002 5 SA 721 (CC) and *EN v Government of South Africa* 2007 1 All SA 74 (D). In *EN v Government of South Africa* the Durban High Court ordered the government in the Westville Prisoners case 16 forthwith to provide ARV treatment to affected prisoners. (Also refer to the more commonly known *TAC* case).
62 WTO 2011 wto.org.

countries' laws, including those of South Africa, do not explicitly include TRIPS flexibilities. This is very unfortunate given the fact that South Africa has the capacity to assist the region with cheaper drug exports because of its relatively advanced pharmaceutical regulatory setup and infrastructure.

There have been about three requests for compulsory license under the CAMR, including the 13 February 2006 request from Biolyse Pharma Corporation for patents on oseltamivir phosphate, which is sold by Roche under the brand name Tamiflu.[63] At the time of writing this paper only Rwanda has benefited from the Canadian access regime by importing HIV drugs through a Canadian company called Apotex,[64] following its successful application to the Canadian authorities for the manufacture and export of a fixed combination for the treatment of AIDS.

The Canadian and the EU measures have come under attack from public health access movement and advocacy groups for allegedly falling short of making pharmaceutical products more accessible. Critics like Oxfam, which is part of the Access to Medicines Movement, argue that the fact that no compulsory licence has been granted since the Doha Decision was adopted in 2003 until recently when Canada exported mecidines to Rwanda shows that the flexibility system is a "complete failure".[65]

These criticisims are very interesting, because they hardly address alternative access regimes, and fall short of considering the role played by other factors in the failure of the compulsory licensing system for pharmaceutical products, such as the patents' monopoly. The criticism tends to be oblivious to the opportunities presented by these measures to assist in the alleviation of the disease burden in countries in SSA. Some of the arguments are not entirely valid and lack substance. They fail to acknowledge the important incentives and benefits that can be reaped by taking

63 Love 2007 keionline.org.

64 See generally Hestermeyer 2007 www.asil.org. Hestermeyer reports that on 17 July 2007, Rwanda notified the World Trade Organization's (WTO) Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) that it plans to import the HIV-drug TriAvir from Apotex, and that on 4 October 2007 Canada notified the Council for TRIPS of the compulsory license. The drugs were exported to Rwanda in May 2008.

65 See Cornides 2007 *JWIP* 70.

advantage of these flexibilities from the perspective of access to health as a human right instead of the purely commercial perspective.

Let us consider the following: TRIPS sets out minimum standards for the protection of all WTO members, including a substantial increase in terms of patent protection with product patent replacing process patent in all fields including pharmaceutical products.[66] The fundamental purpose and the value of the patent protection system cannot be underestimated. The patent protection system provides the IPR holder with a monopoly on the invention, expecting that the value to broader society would be the encouragement of innovation.[67] However, the system has some undesirable consequences. There are several challenges to accessing patented and off-patent medicines, some of which are attributable to the primarily profit-driven conduct of the pharmaceutical sector. Firstly, the high prices charged by IPR holders and related competitive behaviours impede access to essential medicine.[68] This has led to jurisdictions like the EC undertaking an enquiry into the practices of the pharmaceutical sector.[69] It is noteworthy in the context of this paper that the EC Report found that IPR holders contribute to the delay in the production, dissemination and access to generic medicines through using a "variety of instruments to extend the life of their medicines".[70] The strategies include dilatory patent-filling strategies;[71] patent-related exchanges and litigation;[72] and patent settlement in which the marketing capacity of the generic sector is restricted.[73]

In 2003, for example, the South African Competition Commission found that *GlaxoSmithKline South Africa (Pty) Ltd (GSK)* and *Boehringer Ingelheim* (BI)'s were involved in anti-competitive conduct that impacted on the accessibility of HIV/AIDS-related medicine. According to the Commission the firms maintained highly abusive

66 It is interesting that the practice of product patent was once prohibited in several jurisdictions. In Germany, product patent was explicitly excluded under the law of 25 May 1877 and was later introduced in 4 September 1967. The Constitution of Switzerland explicitly prohibited product patents for pharmaceuticals until 1977. Spain introduced product patents in 1986 after accession to the European Economic Community (EEC). See Li 2008 www.wider.unu.edu 1.

67 CIPR 2002 www.iprcommission.org 1.

68 Saggi 2007 www.iprsonline.org 5.

69 European Commission 2009 ec.europa.eu.

70 European Commission 2009 ec.europa.eu para 3.2.

71 European Commission 2009 ec.europa.eu para 3.2.1.

72 European Commission 2009 ec.europa.eu para 3.2.2.

73 European Commission 2009 ec.europa.eu para 3.2.4.

and restrictive practices in the antiretroviral market, which is prohibited by the Competition Act 89 of 1998, and had refused to grant patent licences to generic manufacturers.[74] Moreover, the Commission found that their HIV/Aids drugs "are not affordable" to many South African living with HIV.[75] The undesirable behaviour of pharmaceutical companies was evident in 1999 when the pharmaceutical sector opposed the implementation of the *Medicines and Related Substances Control Amendment Act* (MRSCAA) 90 of 1997. One of the aims of the MRSCAA was to enable the Minister of Health to introduce measures "so as to protect the health of the public", and to make pharmaceuticals more affordable.[76] The issue ended up in the Pretoria High Court in *Pharmaceutical Manufacturers' Association and Others v the President of the Republic of South Africa,*[77] in which the constitutionallity of certain provisions of MRSCAA were challenged as denying intellectual property owners the protection required by TRIPS Agreement. It was also claimed that by implementing MRSCAA, South Africa would be in breach of its obligations under TRIPS, in particular Articles 28 and 27.[78] Unfortunately the case was withdrawn, and the court could not decide on the matter. The other related barrier to access to essential medicines is the TRIPS-Plus trade arrangements.

A TRIPS-Plus provision is a trade agreement that is normally insisted upon by the United States and the European Union under the guise of protecting IPR holders. TRIPS-Plus provisions require a level of intellectual property protection in domestic laws that go beyond the minimum standards required by the TRIPS Agreement.[79] The benefits of TRIPS-Plus arrangements to least-developed and developing countries are mostly at the expense of their public health needs. [80]

SSA countries and NGOs must take advantage of the regulatory flexibilities of Canada and the European Union to provide their communities with essential medicines and treatment for HIV and AIDS.

74 Competition Commission 2004 www.compcom.co.za 1.
75 Competition Commission 2004 www.compcom.co.za 2.
76 See Sibanda 2009 *Acta Academica* 193.
77 *Pharmaceutical Manufacturers' Association and v the President of the Republic of South Africa* Case no 4183/98.
78 See generally Collins 2001 *Syracuse J Int'l L* 158-183.
79 See Lindstrom 2010 *International Law and Politics* 919.
80 See, for example, El-Said 2007 *JWIP* 454, arguing that TRIPS-Plus benefits are often exaggerated and not supported with empirical evidence as in the case of their benefit to Jordan.

5 Conclusion

The CAMR and EU Resolutions have the potential to usher in an era that has great impact and could make a significant contribution to granting access to pharmaceutical products for developing and least-developed countries. Needless to say, the CAMR and the EU Regulations and similar TRIPS-compliant measures have come under attack as falling short of making pharmaceutical products more accessible. Chief amongst the criticism are the bureaucratic requirements and stringent provisions in the measures, which have been blamed for the lack of interest by beneficiary countries in taking advantage of the regime to date. Critics like Oxfam, which is part of the Access movement, argue that the fact that no compulsory licence had until recently been granted since the Doha Decision was adopted in 2003 shows that the flexibility system is a "complete failure".[81] The criticism may be correct in part. Unfortunately, as shown in Part 4, much of the criticism amounts to nothing more than unjustified rhetoric rejecting the inherent benefits of TRIPS-inspired flexibilities, and is myopically slanted towards protecting the commercial gains of pharmaceutical businesses. The critics fail to consider the role played by other factors, as discussed in section 3.2 above, in the failure of the compulsory licensing system, which may include political tug-of-wars and the behaviour of both the patent originators and the generic competitors. Furthermore, it is wrong to measure the success of the new Canadian and European compulsory licensing systems, or of similar initiatives, by the number of licences granted. It is still too early to use numbers as a yardstick.

The health needs of people in developing and least-developed countries cannot afford to wait for an unkown solution while the world is caught up in an academic debate over the effectiveness of the compulsory licensing system. Every effort should be made to make use of measures such as the Canadian and European

81 See Cornides 2007 *JWIP* 70. Rwanda became the first country on 17 July 2007 to notify the WTO's Council for Trade-Related Aspects of Intellectual Property Rights of its intention to import HIV-drug TriAvir from the Canadian pharmaceutical company Apotex. In September 2007 the Canadian authorities issued a compulsory license to enable Apotex to use nine patented inventions to manufacture and export TriAvir to Rwanda. This issuing of compulsory license under the CAMR was later notified to Council for TRIPS on 4 November 2007. For more on this Rwandan case see generally, Amollo 2007 *AJICL*.

systems to bring essential medicines to where they are much needed in SSA. Possible measures may include, for instance, an HIV and AIDS policy change or the enactment of legislation that specifically deals with access to HIV and AIDS treatment and medicines within the framework of TRIPS-flexibilities.

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ACHPR	African Commission on Human and Peoples' Rights / African Charter on Human and Peoples' Rights
AIDS	Acquired Immune Deficiency Syndrome
AJHR	African Journal of Human Rights
AJICL	African Journal of International and Comparative Law
AJLM	American Journal of Law and Medicine
ARVs	Antiretrovirals
AU	African Union
CAMR	Canada Access to Medicine Regime
CIPR	Commission on Intellectual Property Rights
CPA	Consumer Protection Act
EC	European Council
EP	European Parliament
ESA countries	East and southern African countries
EU	European Union
HIV	Human Immunodeficiency Virus
IIEP	UNESCO's International Institute for Educational Planning
IPRs	Intellectual property rights
LDCs	Least-developed countries
JWIP	The Journal of World Intellectual Property
MRC	South African Medical Research Council
MRP	Malaria Research Programme
MRSCAA	Medicines and Related Substances Control Amendment Act
NGOs	Non-governmental organisations
PELJ	Potchefstroom Electronic Law Journal
SAJHR	South African Journal of Human Rights
SALC	South African Litigation Center
SAPL	South African Public Law
SSA	Sub-Saharan Africa
Syracuse J Int'l	Syracuse Journal of International Law

L	
TAC	Treatment Action Campaign
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property
UN	United Nations
Va J Int'l L	Virginia Journal of International Law
WHO	World Health Organisation
WTO	World Trade Organisation