OPTIONS FOR THE PROCUREMENT OF PATENTED ESSENTIAL MEDICINES BY SADC MEMBER STATES AFTER TRIPS ARTICLE 31BIS[1]

Lonias Ndlovu*

ABSTRACT

This paper exposes and explores the possible essential medicines procurement options Southern African Development Community (SADC) Member states now have after the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement was amended through Article 31bis. After an expository account of the events that led to the amendment, the paper looks at the options presented by Article 31bis against the membership matrix nd other contextual factors obtaining in the SADC as a regional trade agreement (RTA) and concludes that it is now possible for SADC to rely on Article 31bis in order to ameliorate the precarious access to essential medicines situation in the region. The options presented here may inspire other similarly placed RTAs in Africa and the rest of the developing world to take advantage of Article 31bis.

Keywords: Essential medicines, compulsory licenses, Procurement, SADC, TRIPS Article 31bis

1. INTRODUCTION

The Southern African Development Community (SADC) - constituted by Angola, Botswana, the Democratic Republic of Congo (DRC), Lesotho, Swaziland, Namibia, South Africa, (Zimbabwe, Mozambique, Seychelles, Malawi, Zambia) - is currently an

* Associate Professor and dean of the School of Law, University of Venda, Thohoyandou, in South Africa. He has previously worked at other South African universities, namely, Fort Hare, Zululand and North-West, as a lecturer, senior lecturer and associate professor respectively. He obtained the degrees LLB (2003) and LLM (2005) from the University of Fort Hare and LLD (2014) from the University of South Africa. His doctoral thesis examined the extent to which selectec

[1] This is a revised version of a paper that was presented at the WIPO/WTO Regional Colloquium for Teachers of Intellectual Property held

Madagascar, Mauritius, Tanzania, The Union of Comoros,[2] Zambia and Zimbabwe - faces a massive disease burden. The most prevalent diseases are tuberculosis, HIV/AIDS, malaria and most recently cancer and other lifestyle diseases such as heart disease. In South Africa, apart from HIV/AIDS and tuberculosis, other diseases to watch out for are stroke, ischaemic heart disease, hypertensive heart disease, diabetes and renal disease.[3] Furthermore, the Ebola epidemic that has ravaged parts of West Africa in the past and the DRC recently, also poses a huge threat to the region.[4] The HIV disease burden is not uniformly spread across the region because some countries like South Africa and Botswana carry the highest HIV/AIDS prevalence burden while Zimbabwe, Mozambique and Zambia still have an inexplicable malaria prevalence which is not easy to justify in a modern society.[5] SADC members are also in various stages of economic development and about 50% of the membership consists of Least Developed Countries (LDCs).[6]

The disease burden is made dire by the lack of access to essential medicines, including generic drugs, in most SADC Member states. This is also compounded by poverty and weak political and other institutions in the region

[2] Southern African Development Community, *The Union of Comoros becomes the 16th SADC Member State* (SADC Secretariat) at <https://www.sadc.int/news-events/news/union-comoros-becomes-16th-sadc-member-state/> accessed 27 June 2018.

[3] V Pillay-van Wyk, R. E Dorrington and D Bradshaw, 'Rapidly changing mortality profiles in South Africa in its nine provinces' (2017) 107 South African medical journal = Suid-Afrikaanse tydskrif vir geneeskunde 168.

[4] Gloria C. Nwafor and Anthony O. Nwafor, 'Right to Healthcare of Victims of Ebola Virus Disease: The West African Nations' Experience' (2016) 24 African J Intl & Comparative Law African Journal of International and Comparative Law 389

[5] SADC *Harmonized Surveillance Framework for HIV and AIDS, Tuberculosis and Malaria in the SADC Region* (2009) 6–20 <https://www.sadc.int/files/9214/1171/8930/Harmonised_Surveillance_Framework_forHIV_and_AIDS_Tuberculosis_and_Malariain_the_SADC_Region.pdf> accessed 19 May 2019.

[6] In the context protecting pharmaceutical patents, WTO Members which are LDCs can choose whether or not to protect pharmaceutical patents and clinical trial data until January 2033 (see WTO "WTO members agree to extend drug patent exemption for poorest members",<https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm> accessed 19 May 2019. SADC LDC members are Angola, Malawi, Madagascar, Mozambique, Lesotho, Tanzania, DRC, The Comoros and Zambia.

proposed through a waiver introduced by the General Council Decision of 2003.[18] In order to actualise the spirit of the August 2003 Decision, an amendment to the TRIPS Agreement was proposed in 2005 and opened for ratification by WTO Members.[19] It is important to point out that the proposed amendment explicitly stated that "reservations may not be entered" in respect of any of its provisions without the consent of the other WTO Members.[20] Once fully ratified, the amendment would introduce Article 31bis of the TRIPS Agreement, to override the pre-existing proviso in the TRIPS Agreement

pharmaceutical products and export them to eligible importing Members.

-

4. THE CONTEXT OF SADC AS A REGIONAL TRADE AGREEMENT

Regional Economic Communities (RECs) like SADC have been helping member states to implement TRIPS flexibilities.

5.1. Option 1: The Generic Version of the Needed

benefit of a third country, without being constrained by the provisions of Article 31(f) of TRIPS.[33] This however is subject to the conditions imposed by Article 31(h) of TRIPS.

To make use of this option, SADC Members (both developing and LDC) may notify the rest of the WTO membership about their dire need for a specific drug which:

- Is too expensive or not available in the region;
- cannot be manufactured in the region because there is insufficient or no pharmaceutical manufacturing capacity in the regional pharmaceutical sector; and
- cannot be replaced by imported quality generics because they do not exist.

In this particular context, SADC Members may rely on

Measure	Purpose
1. LDCs obligations under Art. 70.9 Of TRIPS with respect to pharmaceutical products.[39]	This 8 July 2002 WTO General Council decision exempts WTO LDC Members from the obligation to grant and enforce patents on pharmaceutical products or to protect test data until 1 January 2016.
2.	

exemption to pharmaceutical patents and test data will

BIBLIOGRAPHY

Abbas MZ and Riaz S, 'WTO "Paragraph 6" system for affordable access to medicines: Relief or regulatory ritualism?' (2018) 21 JWIP The Journal of World Intellectual Property 32.

Ferreira G and Ferreira-Snyman AI, 'The Incorporation of Public International Law into Municipal Law and Regional Law against the Background of the Dichotomy between