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

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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, Malawi, Mozambique, Seychelles, 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

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[1] This is a revised version of a paper that was presented at the WIPO/WTO Regional Colloquium for Teachers of Intellectual Property held at the main Campus of the University of South Africa from 9 to 12 April 2018. However, the views expressed herein are those of the author and cannot be attributed to the organisers of the colloquium.

[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.

which are unable to contain wasteful government expenditure and hold the policy makers to account. Essential medicines are those that are necessary to satisfy the priority health care needs of the population.[7] Their selection is based on "public health relevance, evidence on efficacy and safety, and comparative cost-effectiveness".[8] With specific reference to access to medicines, the most important instruments in the SADC context of access to medicines are the SADC Protocol on Health (hereafter referred to as the Health Protocol),[9] complemented by the Implementation Plan for the SADC Protocol on Health,[10] SADC Pharmaceutical Business Plan[11] and the Draft SADC Strategy for Pooled Procurement of Essential Medicines and Commodities.[12] The above instruments are identified as crucial in the enhancement of regional integration in the context of health and have been developed to underpin the implication of the SADC health programme.[13] The health programme has been developed taking into account global and regional health declarations and targets.[14]

This paper focuses on the pharmaceutical procurement options that are now available for the SADC region to exploit post the adoption of Article 31bis by WTO Members in 2017. In order to give a complete contextualised account of the options, the paper focuses on the historical evolution of Article 31bis, its tenets in the context of access to medicines, the SADC regional integration matrix and how it relates to the options and an evaluation of the options before optimistically concluding that Article 31bis is now the potent arsenal in the SADC access to medicines armoury and must be used without fear of retaliation.

Before talking about the modalities of procuring essential medicines for SADC under Article 31bis, it is essential to give a brief expository account of the events that triggered and led to the adoption of Article 31bis.

2. LEGAL HISTORICAL EVOLUTION OF TRIPS ARTICLE 31bis

The evolution and adoption of Article 31bis is inseparable from the Doha Declaration on TRIPS and Public Health,[15] adopted by the 2001 WTO Ministerial Conference on the 14 November of the same year. Through the Doha Declaration, WTO Members affirmed that there is nothing in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which prevents a WTO Member from taking legislative and other measures to protect public health in order to improve citizens' ability to access affordable medicines.

The Declaration was followed up in August 2003 with further refinement and amendment enabling Members to use compulsory licenses to supply other countries with insufficient or no pharmaceutical manufacturing capacity rather than for the predominant supply of the domestic market.[16] This problem was identified in Paragraph six[17] of the Doha Declaration and a solution thereto was

[7] WHO Expert Committee on the Selection Use of Essential Medicines Meeting, 'The selection and use of essential medicines' (2003) .

[8] PharmacoEconomics & Outcomes, 'WHO releases new edition of Model List of Essential Medicines' (2015) 728 PharmacoEcon Outcomes News PharmacoEconomics & Outcomes News 8.

[9] SADC Protocol on Health (1999) signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004.

[10] SADC Protocol on Health (1999) signed in Maputo, Mozambique on 18 August 1999 and came into force on 14 August 2004. The Implementation Plan provides an overall framework for effecting the provisions of the SADC Protocol on Health <http://www.sadc.int/index.php?cID=1&bID=1283&arHandle=Sidebar&ccm_token=1383736029:41bfb778708ee17dc30b95e83826bc93&btask=passthru&method=signmeup> accessed 6 April 2018.

[11] SADC Pharmaceutical Business Plan 2007–2013, published by the SADC Secretariat on 27 June 2007.

[12] Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013–2017, published by the SADC Secretariat in September 2012.

[13] See executive summary of the SADC Pharmaceutical Business Plan (par 2) 3.

[14] *Ibid* (par 2) 3.

[15] Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), available at <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf > accessed 26 June 2018.

[16] Compulsory licenses fall within what the TRIPS characterises as "other use without the authorisation of the patent holder". Article 31 (f) of TRIPS prescribes that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use".

[17] This is now famously referred to as "the Paragraph six System". See Muhammad Z. Abbas and Shamreeza Riaz, 'WTO "Paragraph 6" system for affordable access to medicines: Relief or regulatory ritualism?' (2018) 21 JWIP 32 for a detailed discussion and critique of the system.

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 that compulsory licenses may only be granted for the predominant supply of the domestic market.[21]

Article 31bis became part of the TRIPS Agreement after acceptance of the Protocol amending the TRIPS Agreement by two thirds of the WTO's Members.[22] The amendment took effect on 23 January 2017 and replaced the 2003 waiver for Members who have accepted the amendment.[23] For those WTO Members who are yet to accept the amendment, the 2003 Decision (waiver) still applies.

In the SADC, Botswana, Congo, Lesotho, Madagascar, Malawi, Mauritius, Seychelles, South Africa, Tanzania and Zambia have accepted the Protocol Amending the TRIPS Agreement (now Article 31bis). This is good news considering that if ten out of sixteen SADC Member states have signed, this translates to an acceptance figure of more than 60% of the membership. However, mere acceptance is not enough, there is need to domesticate the provisions of Article 31bis into the IP legislations of individual countries in order to take full advantage of the Article. Unless the SADC Member seeking to take advantage of Article 31bis is an LDC, it will be practically impossible to issue a compulsory license to manufacture and export generic drugs in terms of the Article in the absence of domestication. However, such a Member may use the waiver (not Article 31bis) as an importer from another WTO Member that has domesticated Article 31bis. The period for the acceptance of Article 31bis, which period was extended for the fifth time to 21 December 2017,[24] has now been extended for the sixth time to 31 December 2019,[25] and it is hoped that other SADC Members would have accepted it by then.

To fully contextualise this paper, it is important to give a brief exposition of the pharmaceutical procurement options presented by Article 31bis, before looking at how these options are likely to practically apply in the SADC context.

3. OUTLINE OF THE OPTIONS PRESENTED BY ARTICLE 31bis

The salient aspects of Article 31bis, which are relevant to this paper may be summed up as follows:[26]

- Subject to the terms outlined in paragraph 2 of the Annex to the TRIPS Agreement, an exporting Member will be exempt from complying with the provisions of TRIPS Article 31(f) [relating to issuing compulsory licenses for the predominant supply of the domestic market] to the extent necessary to produce

[18] The waivers relate to Members ensuring that products produced under compulsory licenses must be for the predominant supply of the domestic market and the obligation imposed by Article 31(h) of TRIPS on importing Members to pay adequate remuneration to the right holder if a compulsory license is granted.

[19] See WTO General Council WT/L/641 8 December 2005 decision entitled "Amendment of the TRIPS Agreement" <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm > accessed 19 May 2019.

[20] *Ibid* para 3 of the Protocol amending the TRIPS Agreement.

[21] Per Article 31(f) of the TRIPS Agreement.

[22] See WTO "Intellectual Property: Trips and Public Health Amendment of the TRIPS Agreement" <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 19 May 2019.

[23] *Ibid* para 3.

[24] See WTO General Council Decision WT/L/965 of 2 December 2015 <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 19 May 2019.

[25] See<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/78.pdf> accessed on 16 June 2018.

[26] For more details, see the ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT read together with the ANNEX TO THE TRIPS AGREEMENT and the APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT all available at <https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm > accessed 26 July 2018.

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pharmaceutical products and export them to eligible importing Members.

- Where an exporting member grants a compulsory license under the system provided for in Article 31bis and the relevant annexes, adequate remuneration, as specifically mandated by Article 31(h), shall be paid in that member taking into account the economic value of the IP to the importing member. Where a compulsory license is granted for the same products in the eligible importing member, the obligation to pay adequate remuneration shall fall away if such payment has been made in the exporting member.
- In order to harness economies of scale and enhance the purchasing power and facilitate the local production of pharmaceutical products, where a developing or least developed WTO Member is party to an RTA as categorised in Article XXIV of the GATT 1994, the obligation imposed by Article 31(f) shall not apply to the Member to the extent necessary for the exportation of a pharmaceutical product produced or imported under a compulsory licence to fellow developing and least developed Members that share the same health problem in the RTA, provided that at least 50% of Members in the RTA qualify as least developed countries.
- Measures taken in conformity with the provisions of Article 31bis and the accompanying annexes will not be challenged in terms of the dispute settlement procedure provided for in Article XXIII of the GATT 1994, as amounting to either a non-violation complaint or the existence of any other situation.[27]
- It is also important to highlight that Article 31bis and the attendant annexes "are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement[28] other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health..., and to their interpretation".[29]

It is additionally important to emphasise that Article 31bis must be read together with the Annex to the TRIPS Agreement and the Appendix to the Annex to the TRIPS Agreement. The Annex and the Appendix elaborate and explicate Article 31bis. The Annex gives definitions of important terms such as 'pharmaceutical product', 'eligible importing member' and 'exporting member' in addition to outlining the terms for bypassing Article 31(f) of TRIPS in the appropriate context. Very importantly, the Annex lays down the obligations of the importing and exporting members including safeguards against abuse of the system,[30] such as the diversion of pharmaceutical products to other markets.

The Appendix deals with how pharmaceutical manufacturing capacity will be assessed and the default position is that all LDCs are deemed to have insufficient or no manufacturing capacity in the pharmaceutical sector.

An expository account of the salient aspects of Article 31bis was necessary in order show that the system will easily be applicable in the SADC RTA context, which is briefly outlined below.

[27] Sub paras (a) –(c) of Article XXIII (1) of the GATT 1994 deal with the "nullification or impairment" of benefits accruing to a WTO Member as a possible trigger of the dispute settlement mechanism of the WTO.

[28] For a full list of these flexibilities, see Lonias Ndlovu, 'Domesticating the World Trade Organisation's Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to access essential medicines: any lessons for the SADC from Botswana?' (2017) 50 Comparative and International Law Journal of Southern Africa 347.

[29] Per para 5 of Article 31*bis*.

[30] For a full discussion of the safeguards, see Antony Taubman, Hannu Wager and Jayashree Watal, *A handbook on the WTO TRIPS agreement* (Cambridge University Press 2012).

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.[31] The SADC membership is composed of at least seven developing and nine least developed Members. Article 31bis was passed with developing and least developed WTO Members in mind, hence it primarily must serve the health interests of countries in this category of economic and other development. The fact that more than 50% of SADC Members are LDCs implies that the region can take advantage of paragraph 3 of Article 31bis and issue compulsory licenses for the export of required drugs within the region.

Additionally, SADC Members share the same or similar disease burden, with HIV/AIDS, tuberculosis and malaria being the most common diseases across the region. Ebola, which recently broke out in the DRC, a SADC Member, can be highly contagious and easily spread and become a common health problem for the region. SADC Members may therefore use the existence of similar health problems to take advantage of the procurement options presented by Article 31bis.

Finally, although there is evidence of modest pharmaceutical manufacturing capacity in the region in countries such as Botswana, Malawi, Mozambique and Zimbabwe,[32] with South Africa having significant capacity, on average, the region has insufficient or no pharmaceutical manufacturing capacity. This presents a window of opportunity for many countries in the region to use Article 31bis as eligible importing members. The presence of some pharmaceutical manufacturing capacity also presents an opportunity for generic drugs to be produced within the region and exported to other areas of need in the region.

The SADC region is therefore a proper candidate for the deployment of Article 31bis because of the nature of the membership configuration, the existence of some pharmaceutical manufacturing capacity and common health problems that make the disease burden intra-regional.

5. AVAILABLE PROCUREMENT OPTIONS IN THE SADC CONTEXT

The options available for SADC Member states to procure essential medicines may be outlined taking into account the following variables. A SADC Member may want to procure a drug to deal with a national emergency, to boost drug stocks and be self-sufficient, to produce a drug locally if pharmaceutical manufacturing capacity exists or to produce or import a drug for the benefit of other neighbouring countries.

Whether or not a generic version of a specified drug will be imported or produced locally will depend on three important factors. Firstly, depending on the patent status of the medicine in the SADC Member in need of it, it may be possible to import the drug from within or outside the region. Secondly, the status of a SADC Member as a developing or least-developed country will determine the utility of Article 31bis. Thirdly and finally, the absence or presence of pharmaceutical manufacturing capacity in a SADC Member will determine the extent to which it can utilise the flexibility introduced by Article 31bis.

Depending on the three factors mentioned immediately above, various options are available for SADC Members to procure essential medicines and ensure access thereto.

[31] Caroline B. Ncube, 'Three Centuries and CountingThe Emergence and Development of Intellectual Property Law in Africa' in Rochelle Dreyfuss, Justine Pila and Caroline B. Ncube (eds), *The Oxford Handbook of Intellectual Property Law* (The Oxford Handbook of Intellectual Property Law, Oxford University Press 2017) p.10.

[32] Zimbabwe and Mozambique have demonstrated the existence of this capacity in their local contexts as illustrated by Giuliano Russo and Geoffrey Banda, 'Re-Thinking Pharmaceutical Production in Africa; Insights from the Analysis of the Local Manufacturing Dynamics in Mozambique and Zimbabwe' (2015) 50 St Comp Int Dev Studies in Comparative International Development 258.

5.1. Option 1: The Generic Version of the Needed Drug can be Produced within SADC

In accordance with the conventional sanctity of intellectual property rights (IPRs), if a SADC non-LDC Member with pharmaceutical manufacturing capacity is desirous of producing a generic version of a needed drug in its territory and such a drug is protected by a national or regional patent, then such a SADC Member may issue a compulsory licence in terms of its IP laws and regulations, and produce the essential medicine locally. A good example of such a SADC Member will be South Africa, which does have pharmaceutical manufacturing capacity. This type of compulsory license will be the one contemplated by Article 31(f) of TRIPS (predominant supply of the domestic market) accompanied by the payment of adequate remuneration to the patent holder as mandated by Article 31(h) of TRIPS. In this scenario, there is no need to invoke Article 31bis, for it will not be applicable.

Further, as a Member of SADC in which nine out of sixteen Members are LDCs (about 56%), the SADC Member described above may also authorise the manufacture of the needed generic drug to address the health needs of fellow Members sharing the health problem in question. This regional waiver is permitted under paragraph 3 of Article 31bis for countries belonging to RTAs in which more than 50% of the Members are LDCs. The SADC as a regional grouping does meet this prescribed threshold. The generic drug produced under compulsory license by the SADC Member with pharmaceutical manufacturing capacity may then be exported to other Members within the region without restriction. However, in order to export to other SADC Members in terms of the cited paragraph of Article 31bis, the SADC Member must comply with its own IP laws, and where applicable, domesticate Article 31bis so that compulsory licenses go beyond the predominant supply of the domestic market.

Still focusing on this option, SADC LDCs or those other non-LDC Members in which the drug in question is not patent-protected can simply import it from the Member with manufacturing capacity through their usual import procedures. Where a patent exists for the drug in a SADC LDC or any other Member, the drug may only be imported after the importer has issued a compulsory license. However, the importing member will be excused from the obligation to pay adequate remuneration in terms of TRIPS Article 31(h) if the patent holder has already been paid in the SADC Member with manufacturing capacity.

5.2. Option 2: The Generic version of the Needed Drug cannot be Produced within SADC

Assuming that no pharmaceutical capacity exists within the region to produce the generic drug, SADC Members may import the drug from wherever in the world it is readily available. Since patents are territorial or regional, it can happen that medicines patented elsewhere may be available in other countries as generics. A good example of such a source for generics could be India, which did not grant patents on pharmaceuticals until 2005.

Once again, under this option, the first sub-option will be for SADC Members in which the drug is not protected by any national or regional patent to import the drug using normal import procedures. LDCs may simply indicate that that they want to take advantage of the extended transition periods (see option 4 below) and import the drug without restriction. In this case, the LDCs will have to formally indicate their intention to take advantage of the transition period and ensure that safeguards are in place to prevent the diversion of the drug to undeserving non-LDC Members. For those other non-LDC Members, if national or regional patents are an impediment, compulsory licences will have to be issued nationally.

5.3. Option 3: Where no generic version exists

It can happen that a SADC Member is faced with a health problem which can be remedied through a drug for which generic versions do not exist. The first option will be to import the drug from the supplier at exorbitant prices. This option will not be viable for developing and least-developed SADC Members.

However, in terms of the first paragraph of Article 31bis, it is now possible to issue a compulsory license for the

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 other countries outside the region to supply them with cheaper generic versions of the drug. In terms of Article 31bis, the SADC Members may ask other WTO Members (probably developed ones) to issue compulsory licenses for the manufacture and exportation of the drug to the SADC region. The exporting country will have to notify the rest of the WTO membership of its intention to use the system for the benefit of SADC countries as an exporter, while SADC countries will become eligible importing Members. Realistically speaking, the exporter must be enabled by its own domestic legislation to use the procedure outlined herein,[34] and the eligible importing SADC Member must also adhere to its own laws relating to the use of compulsory licences,[35] and if the drug is patent-protected in the SADC Member, then a compulsory license must be issued.

Good examples of candidate drugs that may be imported under this procurement option, at least in the South African context could be Trastuzumab for cancer, Linezolid for tuberculosis and Entecavir for hepatitis B. In the context of Ebola, the experimental vaccine rVSV-ZEBOV[36] may be imported by the affected SADC Member, such as the DRC, using this procurement option. The importing SADC Member will be expected to take reasonable steps within its means to prevent re-exportation of the imported drug.

5.4. Option 4: The Case of SADC LDCs

This last procurement option may read as repetitive, if not superfluous here in light of the three other options discussed above. However, when one considers the fact that legally, LDCs may avoid applying and enforcing IP rights on pharmaceutical products until 2033,[37] then the unique case of LDCs merits a separate discussion. The other important consideration is that nine of out of sixteen SADC Members (56%) are LDCs, hence this option will only be available for invocation by LDCs, with likely positive access to medicines spinoffs for the rest of the SADC membership as illustrated below.

The table below, adapted from Olasupo Oyodeji Owoeye's initial analysis,[38] outlines TRIPS measures which have been adopted in favour of least developed countries to date.

[33] A good example of this approach is what happened in Rwanda in 2007, as outlined by Béatrice Stirner and Mélanie Bourassa Forcier, 'Twelve years after Canada's access to medicines regime : should South Africa follow the path?' (2015) 132 South African Law Journal 313.

[34] For example the Indian Patents Act, 1970 (incorporating all amendments till 23-06-2017) provides for compulsory licences for manufacture and export of patented pharmaceutical products to any country having insufficient or no pharmaceutical manufacturing capacity in the pharmaceutical sector to address public health problems, provided that a compulsory license has been granted by the importing country or through notification, such a country has allowed the importation of the patented pharmaceutical products from India.

[35] Botswana for example, has domesticated Article 31*bis* in section 32 of the Industrial Property Act No. 8 of 2010.

[36] According to the WTO website <http://www.who.int/news-room/detail/23-12-2016-final-trial-results-confirm-ebola-vaccine-[provides-high-protection-against-disease> accessed 28 June 2018; rVSV-ZEBOV was developed by the Public Health Agency of Canada. The vaccine was licensed to NewLink Genetics, who in turn licensed it to Merck & Co.

[37] Catherine Saez, 'LDC Pharma IP Waiver Until 2033 Approved By WTO TRIPS Council' (2015) Intellectual Property Watch 2015.

[38] Olasupo Ayodeji Owoeye, 'Compulsory patent licensing and local drug manufacturing capacity in Africa' (2014) 92 bwho Bulletin of the World Health Organization 214.

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. Extension of the transitional period under Art. 66.1 of TRIPS for LDCs.	This 2013 decision extends the time for LDCs to implement minimum standards for IP required by TRIPS to 1 July 2021 (with exceptions of Arts. 3, 4, & 5 related to national treatment and most-favoured nation treatment), or until such a date on which they cease to be LDCs, whichever date occurs first.
3. Further extension of transitional period under Art. 66.1 of TRIPS for LDCs.	This 2015 Council for TRIPS decision extends the period during which key provisions of TRIPS will not apply to pharmaceutical products in LDCs until January 2033.[40]

The first measure, which presented an opportunity for LDCs to deal with pharmaceutical products in the context of their national interests, has now been overtaken by events and deserves no commentary beyond this.

The second and third measures, which are still current, have the same implications for the SADC LDC Members. Because both decisions concern the entire TRIPS Agreement, LDCs can choose whether or not to protect pharmaceutical patents and clinical trial data before 2033. The decision also leaves an open option for LDCs to negotiate for further extensions beyond 2033.

Practically speaking, the implication is that a SADC LDC may freely produce generic versions of any patented drugs, both for local needs and export within and outside the region, without any IP restrictions, as if no patent exists for the drug concerned. Imports of any generic medicine into the SADC LDC will also be possible without any IP restriction. The last two measures therefore present an opportunity for SADC Members to take advantage of Article 31bis and produce essential medicines (as generics) for local use or export within the region. This will be done through the instrumentality of LDCs, which can invest in pharmaceutical manufacturing capacity between now and 2033 if not beyond, and replicate India's pharmaceutical manufacturing capacity success story.[41]

A few valedictory practical points must be made with specific regard to the implementation of the LDC transition periods highlighted above.

Unless the SADC Member concerned has a monist legal system,[42] where international law automatically applies domestically as any other law, there will be a need to formally inform other WTO Members that it intends to make use of the transition periods. This can be done through appropriate formal decisions such as a decree, legislative amendment, a ridder or any other intervention citing the specific WTO decision and indicating that the

[39] WTO (2002) 'Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products', GENERAL COUNCIL WT/L/478 12 July 2002, at <https://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm > accessed 29 June 2018.

[40] WTO (2015) 'WTO members agree to extend drug patent exemption for poorest members' at <https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm> accessed 29 June 2018.

[41] It will be recalled that India did not provide for pharmaceutical patents until 2005, when it started making its IP laws TRIPS-compliant.

[42] On the subject of monism and other approaches to the application of international law in municipal law, see generally Gerrit Ferreira and Anél Ferreira-Snyman, 'The Incorporation of Public International Law into Municipal Law and Regional Law against the Background of the Dichotomy between Monism and Dualism' (2014) 17 Potchefstroom Electronic Law Journal 1470.

exemption to pharmaceutical patents and test data will last until 2033 or as long as the country remains an LDC, unless there is a WTO decision to the contrary. Considering that some SADC countries are Members of the African Regional Intellectual Property Organisation (ARIPO), the legislative amendment must refer to the relevant provisions of the Harare Protocol.[43]

6. CONCLUDING REMARKS

It is heartening to report that a number of SADC Members now recognise the importance of article 31bis, and have accepted the protocol amending the TRIPS Agreement, while others, such as Botswana, have gone the extra mile and passed legislation that domesticates Article 31bis.

In a nutshell, this paper showed that Article 31bis is a welcome intervention because for SADC Members, it is now possible to issue compulsory licenses to supply drugs beyond the domestic market; where a SADC Member imports a drug using Article 31bis or the waiver, adequate remuneration may be paid by the exporting country; to harness economies of scale in the SADC pharmaceutical context in which more than 50% of the membership is composed of LDCs, it is now possible to issue a regional compulsory license; measures taken pursuant to Article 31bis or the waiver will not be subject to the WTO dispute settlement system provided for in Article XXIII; SADC Members still reserve their right to invoke other TRIPS flexibilities to access essential medicines and Article 31bis procedures and processes may be used taking into account the terms, conditions and safeguards provided for in the Annex and Appendices to the Article.

This paper further established that it is possible for SADC Members to rely on Article 31bis in the context of the four procurement options, namely, where a generic drug may be produced within the region; where it is not possible to produce the generic drug within the region; where no generic drug exists and where LDCs can take advantage of the unique pharmaceutical patent and test data exemptions extended to them until 2033 and possibly beyond.

The options outlined in this paper are practical and viable because they suit the SADC RTA situation, the common disease burden and the modest pharmaceutical manufacturing capacity. The region must consider investing in pharmaceutical manufacturing capacity to take full advantage of Article 31bis. This can then dovetail into the SADC Strategy on Pooled Procurement, making bulk procurement of pharmaceutical products a reality.

If SADC can seriously consider the options presented here, other African RTAs may learn from it and consider replicating the options in their contexts as well. In the Common Market for East and Southern Africa (COMESA), the East African Community (EAC) and the Economic Community of West African States (ECOWAS), it is possible to rely on paragraph 3 of Article 31bis due to the LDC compositions of the RTAs. 70% of COMESA members are LDCs, while for the EAC and ECOWAS, the figure is 80%. The Southern African Customs Union (SACU), with 40% LDC membership, will not qualify.

Article 31bis therefore, is what the doctor ordered for SADC, taking into account the procurement options presented above.

[43] In terms of section 3(6) of the Harare Protocol, each ARIPO Member state can write to ARIPO and inform it that a patent shall have no effect in its territory for a specific reason, such as the invocation of the relevant TRIPS transitional period for LDCs. In this case, the applicable provision will be section 3 subsection 6 paragraph (a) subparagraph (ii), on the basis that, 'because of the nature of the invention, a patent cannot be registered or granted or has no effect under the national law of that state'.

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