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Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region

CHIKOSA BANDA[†]

I. INTRODUCTION: BACKGROUND AND CONTEXT

The advent of the 1994 Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)¹ has given rise to an unprecedented and polarized debate concerning the impact of intellectual property rights (IPRs) on access to essential pharmaceuticals. This debate has focused on the patent system and the role it plays in determining the affordability and accessibility of pharmaceuticals, especially in developing countries. The debate has largely been between those who contend that patents adversely affect access to essential pharmaceuticals and those who claim that patents are necessary and essential for the promotion of biomedical research

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* The Editors and the Maryland Journal of International Law thank the author for his contribution to Volume 31 and note that author is solely responsible for the content and accuracy of references published. 1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement].

and development (R&D).

This article contributes to this debate by outlining the flexibilities the TRIPS Agreement offers to developing and least developed countries (LDCs). It exposes a major weakness of the dominant debates surrounding the issue of intellectual property and access to medicines in the Southern African Development Community (SADC) region and offers a proposal to minimize the international dependence on India's generic medication production. This article argues that the current approaches to the reform of patent law in the SADC are reductive in as far as they assume that the problem of access to pharmaceuticals can be resolved by merely implementing TRIPS flexibilities to facilitate the importation of pharmaceuticals from India, currently the world's largest generic manufacturer for developing countries. It contends that addressing the problem of access to medicines requires more holistic and sustainable solutions, including taking advantage of the decision of the World Trade Organization (WTO) General Council on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (30 August WTO Decision) to stimulate local/regional production of pharmaceuticals.

This paper has six parts. Part I sets out the background and context of this paper. It argues that reforms aimed at taking full advantage of TRIPS flexibilities to import pharmaceutical products represent short- and medium-term solutions to existing access to medicines problems and are unlikely to provide satisfactory and sustainable long-term solutions. Even though Member States predominantly rely on imported generic medicines for their healthcare needs, "there is a need for local production of medicines as reliance on imports may not be sustainable for these countries."²

Part II considers the current situation of innovation and access to medicines in the SADC region. It also outlines the major barriers to innovation and access in the SADC. The section contends that the challenges of pharmaceutical innovation and access in the SADC are multiple and multifaceted, and accordingly, they require regional and even global solutions to surmount. Part III discusses the SADC regional level policy reforms aimed at harnessing economies of scale to stimulate local/regional production of pharmaceuticals. This part argues that the fact that most SADC Member States are LDC is potentially beneficial to the SADC since individual Member states can

2. Nirmalya Syam, *Transition Period for LDCs: Implications for Local Production of Medicines in the East African Community*, RESEARCH PAPERS 59: THE SOUTH CENTRE, 2 (2014).

take advantage of the waivers provided for in the 30 August WTO Decision to produce generic pharmaceuticals for export within the region.

Part IV highlights recent domestic level reforms to incorporate TRIPS flexibilities. The major observation in this section is that most countries in the SADC region have initiated reforms aimed at domesticating TRIPS flexibilities. However, this part notes that the pace at which these reforms are taking place indicates that these countries do not consider these reforms a major priority in their national legal and policy environment. This may pose problems for local/regional production.

Part V outlines the challenges that SADC Members face in implementing TRIPS flexibilities. The major challenge highlighted in this part is the incoherence between national and regional level policies and between national level policies. This part argues that it would be difficult to make progress towards the realization of the right to access pharmaceuticals by addressing these incoherencies. Part VI is the Conclusion.

A. *TRIPS and Access to Pharmaceuticals*

Global efforts to address TRIPS-related public health concerns subsequently led to the adoption of the Declaration on TRIPS and Public Health (the “Doha Declaration”) by a WTO Ministerial Conference held in 2001.³ The Doha Declaration reaffirmed that the TRIPS Agreement should be “interpreted in a manner that is supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.”⁴ It also reaffirmed the right of states to authorize manufacturers to copy patented inventions without the permission of the patent holder during “national emergencies or circumstances of extreme urgency.”⁵ This may include the use of devices such as compulsory licensing. Compulsory licensing refers to the “state-authorized licensing of generic medicines to be produced or bought without the patent owners consent, even though this derogates from the brand-name drug’s market exclusivity.”⁶

3. Doha WTO Ministerial Declaration on the TRIPS and Public Health [WT/MIN(01)/DEC/220 November 2001], https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last accessed Dec. 8, 2016) [hereinafter Doha Declaration].

4. *Id.* para. 4.

5. *Id.*

6. Reed F. Beall, Randal Kuhn, & Amir Attaran, *Compulsory Licensing Often Did Not Produce Lower Prices for Antiretrovirals Compared to International Procurement*, 34

Paragraph 7 of the Declaration exempts LDCs from TRIPS compliance with respect to pharmaceutical products until 1 January 2016.⁷ This period has since been extended to 1 January 2033 by the decision of the Council for TRIPS of 6 November 2015.⁸ Paragraph 6 of the Doha Declaration recognizes the fact that some WTO Members have limited or no pharmaceutical manufacturing capacity. Consequently, they could face difficulties “in making effective use of compulsory licensing under the TRIPS Agreement.”⁹ This is because Article 31 of the TRIPS Agreement severely restricts the freedom of States to use compulsory licenses. The Article provides that a government may only authorize use of the subject matter of a patent without the consent of the right-holder where such use is “predominantly for the supply of the domestic market of the member authorizing such use.”¹⁰ Countries with insufficient or no manufacturing capacity may not take full advantage of compulsory licensing due to their dependence on external manufacturers for their domestic needs. The Ministerial Conference, accordingly, instructed “the Council for TRIPS to find an expeditious solution to this problem.”¹¹

Pursuant to the above instruction, the General Council of the TRIPS subsequently adopted a decision to make it easier for states with insufficient manufacturing capacity to import generic medicine in the event of a public health crisis. The decision, adopted on 30 August 2003, waived the application of Article 31 of the TRIPS Agreement in favor of countries with insufficient or no manufacturing capacity. It made it permissible for Members to grant compulsory licenses for exportation of pharmaceutical products to Members with insufficient or no manufacturing capacity.¹² Paragraph 6 of the decision further

HEALTH AFF. 493 (2015).

7. The paragraph states:

We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement.

Doha Declaration at para. 7. This was formalized by a subsequent decision by the TRIPS Council of 27 June 2002.

8. Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products* (Decision of the Council for TRIPS of 6 November 2015- IP/C/73).

9. See Doha Declaration, *supra* note 3, para. 6.

10. TRIPS Agreement, *supra* note 1 Article 31(h).

11. Doha Declaration, *supra* note 3, para. 6.

12. Paragraph 1(b) of the Decision on the Implementation of Paragraph 6 of the TRIPS

waives the requirements of Article 31(f) of the TRIPS Agreement in order to facilitate the local production of pharmaceuticals by “a party to a regional trade agreement within the meaning of Article XXIV of the GATT” for exportation to members of a regional trade agreement with insufficient or no manufacturing capacity.¹³ In December 2005, the WTO Members adopted a protocol to amend the TRIPS Agreement to formalize the decision of 30 August 2003.¹⁴ The amendment, known as Article 31*bis* of the TRIPS, entered into force on 23 January 2017, upon ratification by two-thirds of the WTO Members.¹⁵

In addition, LDCs are exempt from implementing the general provisions of the TRIPS save for Articles 3, 4, and 5 until 1 July 2021.¹⁶ They are also exempt from implementing, protecting, and enforcing patents on pharmaceuticals until 1 January 2033.¹⁷ The waiver is in line with article 66 of the TRIPS Agreement, which recognizes the “the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base.”¹⁸ The exemption was for an initial period of ten years.¹⁹ This period was made subject to extension upon a duly motivated request by an LDC.²⁰

and Public Health Agreement.

13. *Id.*

14. World Trade Organization General Council Decision of 6 December of 2006, Amendment of the TRIPS Agreement, Decision Of The General Council, WT/L/641 (December 6, 2005), https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm.

15. WTO, WTO IP Rules Amended to Ease Poor Countries Access to Affordable Medicines, 2017 News Items, 23 January 2017, https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm.

16. World Trade Organization–Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66(1) of the TRIPS Agreement for Least Developed Country Members*, DECISION OF THE COUNCIL FOR TRIPS IP/C/64 (June 11, 2013), https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm.

17. World Trade Organization–Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period under Article 66(1) of the TRIPS Agreement for Least Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, Decision of the Council of TRIPS IP/C/73 (November 6, 2016), https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm.

18. Article 66 of the TRIPS Agreement provides as follows:

In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

19. Article 66 of the TRIPS Agreement.

20. *Id.*

Commentators have noted that the above flexibilities, transition periods, and waivers are “the most important policy options available to LDCs to facilitate affordable access.”²¹ In particular, the transition periods are a critical policy instrument for the promotion of local production of pharmaceuticals. This is because the non-recognition and non-enforcement of patents on foreign products potentially ensures that locally produced pharmaceuticals are not excluded from the market due to the existence of patents.²² Moreover, the existing literature suggests that strong patent protection would stifle technological development in LDCs, because it would pose a barrier to learning and copying, which are pre-requisites for technological development.²³

It is against this background that Article 66 of the TRIPS Agreement provides for exemptions that offer LDCs some policy space to facilitate the development of local production capacity. It gives LDCs an opportunity “to do what developed countries themselves had done to build their technological base.”²⁴ This is done through the creation of legal environments that permit the copying and imitation of technologies. The transition periods, as renowned intellectual property researcher Nirmalya Syam notes, have been granted to ensure that LDCs are not hampered by intellectual property rights “from taking suitable measures to develop a sound and viable technological base in different industrial sectors.”²⁵ They are a vital tool for the development of a viable technological base, including pharmaceutical production capacity.²⁶ As a result, LDCs in the SADC region have been presented with an opportunity to take advantage of the transition period and develop viable local production capacity for pharmaceuticals, and do what India has been doing for some time.²⁷

21. Perna Mingma Bomzan, Sanya Reid, & Mirza Alas Protolo, *Submission of the LDC Watch to the United Nations High-Level Panel on Access to Medicines*, LDC WATCH, 2 (2016), <http://www.unsgaccessmeds.org/inbox/2016/2/28/prerna-mingma-bomzan>.

22. Syam, *supra* note 2, at 2.

23. UNCTAD Secretariat Geneva, *The Least Developed Countries Report 2007: Knowledge, Technological Learning and Innovation for Development*, 103 (2007), http://unctad.org/en/Docs/lc2007_en.pdf.

24. Syam, *supra* note 2.

25. *Id.*

26. Mingma Bomzan et al., *supra* note 21, at 2.

27. See, e.g., William J Bennett, *India Pharmaceutical Patent Law and Its Effects on Novartis AG v Union of India*, 13 WASH. U. GLOBAL L. REV. 535, 535–57 (2014); Sidonie Descheemaker, *India, Pharmacy of the Developing World: IP, Trade and Access to Medicine*, 3 JURA FALCONIS JG, (2013). Prior to 2005, India was able to supply medicines to other developing countries, because it was not granting product patents for pharmaceuticals. This position changed in 2005 when India became fully compliant with the TRIPS Agreement and started granting protection to pharmaceuticals. This means that India will not be able to supply

One would accordingly expect LDCs to take advantage of these transition periods and reform their laws to exclude pharmaceuticals from patent protection. Therefore, it is unsurprising that throughout the past decade there have been intensive discussions regarding how SADC Member States can reform their laws to incorporate flexibilities.²⁸ These discussions have triggered and continue to trigger patent law reform initiatives in the SADC region.²⁹

However, these reforms have predominantly focused on how to take advantage of the flexibilities in order to facilitate the importation of affordable essential medicines from outside the SADC region.³⁰ Much emphasis has been placed on how states can ensure that their legal frameworks facilitate the importation of medicines from countries like India. Little discussion has centered on how to take advantage of paragraph 6 of the 30 August WTO Decision or Article 31 bis (3) to facilitate local or regional production of pharmaceuticals. Consequently, the transition periods do not appear to have triggered much country-level reforms among the SADC LDCs.³¹

Renowned IP and access to medicines advocates K.M. Gopakumar and Sangeeta Shashikant rightly observe that the “use of flexibilities within and outside the TRIPS Agreement has become the

generic medicines that were patented in the post-2005 era, unless compulsory licenses for export are granted.

28. *Breaking IP Barriers: Creating Pathways to Medicine Access* (October 12–13, 2015), http://arasa.info/files/5914/5329/2920/Breaking_IP_Barriers_Meeting_Report.pdf (describing how countries of the SADC can use the WTO and the European Community flexibilities for better access to affordable HIV/AIDS medicines); see also Tenu Avafia, Jonathan Berger, & Trudi Hartzenberg, *Monitoring Regional Integration in Southern Africa Yearbook*, TRADE LAW CENTRE FOR SOUTHERN AFRICA, 270–302, <http://westminsterresearch.wmin.ac.uk/11915/>; Tenu Avafia, Jonathan Berger, & Trudi Hartzenberg, *The Ability of Select Sub-Saharan African Countries to Utilise TRIPS Flexibilities and Competition Law to Ensure a Sustainable Supply of Essential Medicines: A Study of Producing and Importing Countries*, TRALAC WORKING PAPER NO 12 (2006), <http://www.section27.org.za/wp-content/uploads/2010/10/Avafia-Berger-and-Hartzenberg.pdf>; *SADC Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study*, https://www.sadc.int/files/6614/1890/8516/SADC__SADC_POOLED_PROCUREMENT_OF_ESSENTIAL_MEDICINES_AND_MEDICAL_SUPPLI...pdf.

29. Lonias Ndhlovu, *Access to Medicines under the WTO TRIPS Agreement: A Comparative Study of Select SADC Countries* (unpublished LLD Thesis), UNIVERSITY OF SOUTH AFRICA (2014), http://uir.unisa.ac.za/bitstream/handle/10500/14185/thesis_ndlovu_1.pdf?sequence=1.

30. Amal Nagah Elbeshbishi, *TRIPS and Public Health: What Should African Countries Do?*, AFRICAN TRADE POLICY CENTRE (2007), <http://repository.uneca.org/bitstream/handle/10855/13219/bib.%2054458.pdf?sequence=1>

31. Mingma Bomzan et al., *supra* note 21, at 2, 13. The paragraph has been given formal legal force by Article 31bis (3) of the TRIPS Agreement.

dominant approach to addressing concerns over access to patented medical products following the TRIPS patent regime.”³² They note, however, that the strategy of using TRIPS flexibilities to facilitate access to medicines is problematic, because it is based on a number of “unrealistic and flawed assumptions.”³³ One assumption is that all countries have pharmaceutical manufacturing capabilities.³⁴ This assumption is not valid considering that most developing countries are net importers of pharmaceuticals and are unable to use compulsory licensing without relying on other countries.³⁵ While the 30 August WTO Decision allows for compulsory licensing for exportation and importation of pharmaceuticals from producing countries, it has largely been unused, because it is characterized by complex, cumbersome, and tedious procedures and obligations.³⁶

32. K.M. Gopakumar & Sangeeta Shashikant, *Intellectual Property (IP) and Access to Medical Products: A New Paradigm*, (Submission to the United Nations Secretary-General’s High Level Panel on Access to Medicines) (2016), <http://www.unsgaccessmeds.org/inbox/2016/2/28/third-world-networkb>.

33. *Id.* at 1.

34. *Id.*

35. *Id.*

36. Paragraph 2 of the Decision imposes the following obligations on the importing Member:

(a) to notify the TRIPS Council about its intention to import a needed product or needed products. The notification should specify “the name(s) and expected quantities of the product(s) needed;” (b) where a product is protected in its territory, to confirm that “it has granted or it intends to grant a Compulsory License in accordance with Article 31 of the TRIPS and the provisions of this Decision;” (c) to take measures to ensure that the imported product(s) are utilized in line with public health objectives. Accordingly, it is supposed “to take reasonable measures within [its] means, proportionate to its administrative [capacity] and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into [its territory] under the system.” The exporting Member on the other hand is obliged to issue a compulsory license for the export of the needed product. The license should contain a number of the following conditions: (a) the quantities to be manufactured and exported should be restricted to those “necessary to meet the needs of the eligible importing Member;” (b) the licensee must export “the entirety” of what it produces under the license to the Member state that has notified the TRIPS Council of its need; (c) the products must be “clearly identified as being produced under the system.” Identification may take the form of specific marking, special packaging, special coloring, shaping, and labeling (paragraph 2). The Decision acknowledges that the distinct conditions may have an impact on pricing and only requires licensees to distinguish their products to the extent that it is “feasible and does not have a significant impact on price” (Paragraph 2(b) (ii)). The licensee is also obliged to post some information on a website prior to shipment. The post should include the following information (a) the amounts to be shipped to specific destinations and (b) the features that distinguish the licensed products from the originators’ products. The provisions of paragraph 2 have since January 23, 2017, become permanently incorporated into the TRIPS Agreement as paragraph 2 of the

The need to stimulate local production of pharmaceuticals cannot be over-emphasized. This is especially so, given that the patent landscape in India is changing, and India is under increasing pressure to stop making copies of newer medicines.

Another assumption is that there is global support for the use of flexibilities.³⁷ This assumption has limited validity. Currently, developing countries, like India, are under a great deal of domestic and external pressure to avoid utilizing flexibilities and to adopt TRIPS-plus standards, which undermine TRIPS flexibilities.³⁸ As a *Joint Agency Briefing Paper* by HAI-Europe OXFAM observes, a variety of strategies have been used to apply pressure on LMICs to not use TRIPS flexibilities, and/or to introduce additional IP protections, called “TRIPS-plus” provisions. In particular, EU-US trade policy has been used to keep pushing a range of TRIPS-plus IP measures that support the commercial interests of the pharmaceutical industry, while damaging opportunities for innovation and access to medicines in LMIC.³⁹

Obviously, there is less pressure on LDCs, because they are entitled to take advantage of transition periods, and their pharmaceutical industry does not pose a major threat to developed countries. Building up local production capacity within LDCs, by taking advantage of the transition periods, offers a more viable and sustainable solution to the problem of access to medicine that LDC residents currently face.

Annex, to the TRIPS Agreement.

https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm

37. Gopakumar & Shashikant, *supra* note 32.

38. Medecins Sans Frontieres (MSF), *Untangling the Web of Antiretroviral Price Reductions*, 18th ed. (2016), http://www.msf.org/sites/msf.org/files/msf_access_utw.pdf. According to the MSF report, India is under intense pressure, driven by multi-national pharmaceutical companies, to reform its IP policies and laws. It is also under intense pressure to sign Free Trade Agreements (FTAs) that will compel it to adopt TRIPS-plus standards and effectively undermine its ability to utilize TRIPS flexibilities. One such agreement is the EU–India draft FTA. Article 2(1) of the EU–India draft FTA provides that “this chapter shall complement and further specify the rights and obligations between the Parties beyond those under the TRIPS Agreement and other international treaties in the field of intellectual property to which they are parties.” See generally Carlos M Correa, *Negotiation of a Free Trade Agreement European Union–India: Will India Accept TRIPS-Plus Protection?*, OXFAM GERMANY AND THE CHURCH DEVELOPMENT SERVICE (2009), http://www.redge.org.pe/sites/default/files/correa_eu_india_fta.pdf.

39. *Trading Away Access to Medicines—Revisited: How the European Trade Agenda Continues to Undermine Access to Medicines*, HAI-EUROPE AND OXFAM, 7 (2016), https://www.oxfam.org/sites/www.oxfam.org/files/file_attachments/bp-trading-away-access-medicines-290914-en.pdf.

The critical point is that the overarching assumption behind the dominant approaches to solving access to medicines problems is that addressing patent-related barriers to access using flexibilities to support importation of pharmaceuticals will be a panacea to all problems of access and affordability.⁴⁰ This is problematic considering that obstacles to access to medicines are multiple and multifaceted. Inadequate access to medicine in developing countries cannot just be reduced to patents. It is attributable to many other factors, which have largely been underemphasized in the dominant discourse. These include limited local production capacity, high retail prices, duties, taxes, markups, and other supply chain costs and limited lucrative markets.⁴¹ Limited availability and poor affordability of some medicines has also been attributed to market dominance by a limited number of pharmaceutical companies. For instance, Beran et al. contend, that the limited availability and poor affordability of insulin is attributable to the domination of the market by three companies which account for “90% of the global insulin market in terms of value and volume.”⁴² Apart from stifling competition, the domination of these three companies has also adversely impacted on availability of insulin in many countries.⁴³

Article 31bis of the TRIPS, which has superseded the 30 August Decision, deserves the attention of SADC policy makers, because it has the potential to address both the problems of limited local production and limited lucrative markets.

B. The Shrinking Role of India as the Pharmacy of the Developing World

Patent law reform initiatives in the SADC region have reflected the current overdependence on India as a source of affordable essential generic medicines. This is unsurprising given the importance of India as “the pharmacy of the developing world.”⁴⁴ It is critical to ensure,

40. See, e.g., Amir Attaran, *How Do Patents Affect Access to Essential Medicines in Developing Countries*, 23 HEALTH AFF. 155–66 (2004).

41. Margaret Ewen & David Beran, *Access to Insulin: Current Status and Global Policy Implications, Contribution for the United Nations Secretary-General’s High Level Panel on Access to Medicines* (2016); David Beran, Margaret Ewen, & Richard Laing, *Constraints and Challenges in Access to Insulin: A Global Perspective*, 4 LANCET DIABETES ENDOCRINAL 275–85 (2016), <http://www.unsgaccessmeds.org/inbox/2016/2/25/margaret-ewen-and-david-beran>.

42. Margaret Ewen & Richard Laing, *Constraints and Challenges in Access to Insulin: A Global Perspective*, LANCET DIABETES ENDOCRINAL (2016), <http://www.unsgaccessmeds.org/inbox/2016/2/25/margaret-ewen-and-david-beran>.

43. *Id.*

44. Existing literature reveals that 76 percent of the generic ARVs used in low and

however, that other regions of the world, including the SADC countries, establish their own manufacturing bases. This is for a number of reasons.

First, the policy space available to India to produce and export generic medicines has been largely undermined. Prior to 2005, India was not obliged to provide product patent protection for pharmaceuticals.⁴⁵ However, it is now obliged to comply fully with the TRIPS Agreement.⁴⁶ This makes it difficult for Indian companies to make and export generic versions of post-2005 patented pharmaceuticals to developing countries and LDCs.⁴⁷ Thus, the future access scenario for newer pharmaceuticals looks bleak. Emerging evidence suggests that the cost of treatment is on the increase, because new pharmaceuticals are widely patented in developing countries, including India.⁴⁸ The future looks even more problematic for the SADC region, because most SADC Member States routinely provide patent protection for pharmaceuticals through the African Regional Intellectual Property Organization (ARIPO) system.⁴⁹ This has the potential to inhibit access to new generations of pharmaceuticals, including antiretroviral (ARVs) drugs. The above trend is worrisome given that the number of patients who are resistant to older generations of ARVs and need newer ARVs is on the increase.

Second, India is increasingly being pressured by pharmaceutical corporations and developed countries to reform its laws to provide

middle-income countries originate from India. *See* MSF, *supra* note 37. Ninety-six percent of the HIV medicines donor-funded programs rely on are generics, mostly from India. *See HIV Medicines-Technology and Market Landscape*, UNITAID (March 2014), <http://www.unitaId.eu/images/marketdynamics/publications/HIV-Meds-Landscape-March.pdf>.

45. William Greene, *The Emergence of India's Pharmaceutical Industry and Implications for the U.S. Generic Drug Market*, OFFICE OF ECON. WORKING PAPER, U.S. INTERNATIONAL TRADE COMMISSION NO. 2007-05-A, 1 (2007).

46. *Id.*

47. Wilbert Bannenberg, *Trade, TRIPS and Access to Medicines: Challenges and Opportunities for the SADC Region*, BRIEFING PAPER FOR SADC MEMBER STATES CONSULTATION, BIRCHWOOD, JOHANNESBURG, SOUTH AFRICA, (September 18, 2012), <http://www.sarpam.net/wp-content/uploads//images+docs/3-the-programme/d-trips-trade-access-to-medicines/supporting-documents/Briefing-paper-ENGLISH.pdf>; NEPAD, *Strengthening Pharmaceutical Innovation in Africa Designing Strategies for National Pharmaceutical Innovation: Choices for Decision Makers and Countries* (Final Study Report) 29 (2010).

48. Ellen 't Hoen et al, *Driving a Decade of Change: HIV/AIDS, Patients and Access to Medicines for All*, 14 J. INT'L AIDS SOC. 1-12 (2011), <http://www.jiasociety.org/content/14/1/15>.

49. Sangeeta Shashikant, *The African Regional Intellectual Property Organization (ARIPO) Protocol on Patents: Implications for Access to Medicines*, 56 SOUTH CENTRE-RESEARCH PAPERS, 19 (2014), https://www.southcentre.int/wp-content/uploads/2014/11/RP56_The-ARIPO-Protocol-on-Patents_EN1.pdf.

more protection to patent holders than it is required to do under the TRIPS Agreement.⁵⁰ India is also being pressured to relax its standards in order to extend patent protection to pharmaceutical products that would otherwise not pass the existing criteria for patentability.⁵¹ This effectively constrains its available policy space to use flexibilities in favor of the developing world thus undermining India's role as a supplier of generic pharmaceuticals.⁵²

Third, as a sovereign state, India has its own pharmaceutical R&D priorities, which might not necessarily coincide with the pressing public health needs of the SADC region. Therefore, it would be myopic to place too much reliance on it. As Ellen 't Hoen et al. observe: "Without production sources, the countries that rely on importation will find it hard to source low-cost medicines."⁵³

The importance of developing a regional strategy for addressing the gap that the ongoing Indian law and policy reforms might create for SADC countries cannot be over-emphasized. Such a strategy needs to put strong emphasis on local or regional production of pharmaceuticals. The development of local and regional production capabilities for SADC countries would ultimately help in the development of regional pharmaceutical R&D capabilities for the SADC.

Ironically, most pro-access advocates and SADC policy makers tend to define the problem of access too narrowly by concentrating on the question of affordability and how to facilitate importation of pharmaceuticals from countries like India. This is overly reductive and ultimately unhelpful as a way of finding sustainable solutions to the problem of access. As Reid and Mirza observe:

Developing local or regional pharmaceutical production capacity is a fundamental aspect of access

50. Brook Baker, *Will the Modi Government Succumb to U.S. and Industry Pressure to Modify its Pro-Access Pharmaceutical Patent Policy?* 25 EXPERT OPINION ON THERAPEUTIC PATENTS J. 625–28 (2015), <http://www.tandfonline.com/doi/full/10.1517/13543776.2015.1018890>.

51. Medecins Sans Frontieres (MSF), *A Timeline of U.S. Attacks on India's Patent Law and Generic Competition*, MSF ACCESS CAMPAIGN (2015), https://www.msfaccess.org/sites/default/files/MSF_assets/IP/Docs/IP_factsheet_TimelineUS_PressureIndia_ENG_2014.pdf.

52. MSF, *Decisions Around HIV Treatment in 2015: Seven Ways to Fail, Derail or Prevail*(2015), https://www.msfaccess.org/sites/default/files/HIV_Brief_HIV_Fail_Derail_or_Prevail_ENG_2015.pdf.

53. Ellen 't Hoen et al., *supra* note 48, at. 7

to pharmaceutical products and thus imperative to the fulfillment of the right to health. There is growing concern of the impact of the overwhelming reliance on pharmaceutical imports on affordability, availability and long term sustainability.⁵⁴

C. The Innovation–Access Balance

In order to provide sustainable access to medicine, two broad challenges must be addressed. The first challenge is how to make existing medicines affordable to the poor. The second and more intractable challenge relates to how to devise new ways of stimulating R&D and local production of new medicines for diseases endemic in developing countries.

Access to medicines will only be achieved if medicines are developed and manufactured in the first place, and development requires the creation of a legal framework that is supportive of R&D and local/regional production. Such a legal and policy framework must address both the need to get currently available pharmaceuticals to the developing world and the need to encourage research into future useful products that benefit the poor (as well as local/regional production of the same). This would be in line with the third goal of the UN Strategic Development Goals (SDGs), which contain the following bold commitment:

Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, and provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.

These are the challenges that SADC Member States have recently been attempting to surmount. Thus, the ensuing discussion focuses on the legal and policy reforms that have recently been taking place in the SADC region in order to stimulate local production of

54. Mingma Bomzan et al., *supra* note 21, at 6.

pharmaceuticals.

II. THE SADC REGION AND ACCESS TO PHARMACEUTICAL PRODUCTS: SADC AND ITS DISEASE BURDEN

The SADC was established in 1992 by the Treaty of the Southern African Development Community.⁵⁵ The objective of the treaty was “to promote sustainable and equitable economic growth and socio-economic development that will ensure poverty alleviation, with the ultimate objective of its eradication, enhance the standard and quality of life of the people of Southern Africa and support the socially disadvantaged.”⁵⁶ Regional integration is regarded as a tool for achieving these objectives.

The SADC has fifteen Member States, namely: Angola, Botswana, Democratic Republic of the Congo (DRC), Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia, and Zimbabwe.⁵⁷ Eight of these Members States are classified as LDCs. These are Angola, Malawi, Mozambique, Zambia, DRC, Lesotho, Tanzania, and Madagascar.⁵⁸ The defining characteristics of LDCs include poverty, socio-economic inequalities and injustices, low human development, economic vulnerability, limited resilience to natural disasters and limited technological development.⁵⁹ The SADC has a population of approximately 277 million people.⁶⁰

The SADC region is one of the most heavily disease-burdened regions of the world. Its Members continue to bear a disproportionate burden of HIV/AIDS, tuberculosis (TB), and malaria.⁶¹ Non-communicable diseases (NCDs) are also on the increase, especially in

55. The SADC was restructured in 2002 pursuant to major amendments to the 1992 Treaty. The amendments include, a number of provisions relevant to access to medicines. These include Article 5(a) cited in note 36 and Article 5(i) which provides that one of the objectives of the SADC shall be to “combat HIV/AIDS and other deadly or communicable diseases.”

56. *Id.*

57. See Southern African Development Community, *Member States*, <http://www.sadc.int/member-states/>.

58. See United Nations Committee for Development Policy, List of Least Developed Countries, http://www.un.org/en/development/desa/policy/cdp/ldc/ldc_list.pdf.

59. Mingma Bomzan et al., *supra* note 21, at 2.

60. SADC Pharmaceutical Programme, *SADC Pharmaceutical Business Plan*, 5 (2015–2019) [hereinafter SADC PBP (2015–2019)].

61. See SADC, *Communicable Diseases*, <http://www.sadc.int/themes/health/communicable-diseases/>.

the African middle class.⁶²

The SADC's integration agenda primarily focuses on trade, economic growth, and development.⁶³ However, the recognition that Member States cannot address these challenges individually has prompted SADC Members to include health on the SADC integration agenda. Consequently, the integration agenda prioritizes the social and human development aspects of integration. This includes "fostering cooperation in addressing health challenges influenced by the high burden of both communicable diseases, such as HIV/AIDS, TB, and malaria, and NCDs, such as diabetes, hypertension, cancer, and heart problems."⁶⁴ The integration agenda also recognizes the interface and interaction among poverty alleviation, regional integration, economic development, and human rights.⁶⁵

Equitable access to medicines remains illusory for the majority of SADC citizens.⁶⁶ While some SADC Member States have relatively good access to medicines, others do not.⁶⁷ There are also wide disparities in terms of access within specific countries.⁶⁸ There are a number of barriers to the availability of good quality and affordable medicines in the SADC region. These barriers include inadequate national medicine budgets; over-dependence on imported medicines; inadequate R&D; inadequate local production; under-utilization of installed production capacities; poor procurement and supply

62. WHO, *Baseline Assessment of the Pharmaceutical Situation in Southern African Development Community Countries: Fact Book* (2009), http://www.who.int/medicines/areas/coordination/coordination_assessment/en/index3.html.

63. Article 5 of the SADC Treaty; Amos Saurombe, *Regional Integration Agenda for SADC "Caught in the Winds of Change" Problems and Prospects*, 4 J. INT'L COMM. L. & TECH. 100–06 (2009).

64. SADC Pharmaceutical Programme, *SADC Pharmaceutical Business Plan*, 3 (2007–2013), https://www.unido.org/fileadmin/user_media_upgrade/What_we_do/Topics/Business_investment_and_technology_services/CUP/Pharma/Literature/SADC_PHARMACEUTICAL_BUSINESS_PLAN_-APPROVED_PLAN.pdf [hereinafter SADC PBP (2007–2013)].

65. Article 5 of the SADC Treaty.

66. SADC, *Strategy for Pooled Procurement of Essential Medicines and Health Commodities*, 1 (2013–2017), https://www.sadc.int/files/7614/1898/8449/SADC_Strategy_for_Pooled_Procurement_of_Essential_Medicines_and_Health_Commodities.pdf [hereinafter SADC PPEM (2013–2017)].

67. SADC, *Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study*, 10 (2012), https://www.sadc.int/files/6614/1890/8516/SADC_SADC_POOLED_PROCUREMENT_OF_ESSENTIAL_MEDICINES_AND_MEDICAL_SUPPLI...pdf [hereinafter SADC Feasibility Study]; WHO, *Baseline Assessment of the Pharmaceutical Situation in Southern African Development Community Countries: Fact Book*, 1 (2009), http://www.who.int/medicines/areas/coordination/sadc_final.pdf?ua=1

68. *Id.*

management systems; limited supplier base and small quantity requirements⁶⁹; human resource constraints; taxes and tariffs on raw materials and finished products; poor health care infrastructure and systems; small markets; and unaffordable prices.⁷⁰ Outdated IP laws are also implicated, especially in developing member states.⁷¹ All SADC states are Members of the WTO and are obliged to comply with minimum standards of IP protection, including patents.⁷² They are also entitled to take advantage of various flexibilities and waivers available to them under the TRIPS legal framework.

The problem of inadequate access to medicines is also aggravated by the fact that the majority of SADC citizens have no medical insurance. This means that they procure medicines out of pocket.⁷³ Given low earning capacities, medicine is generally out of reach for them.⁷⁴ Therefore, they rely on under-resourced public-sector health service providers for their needs.⁷⁵ Thus, the individual markets of Member States are not attractive to pharmaceutical manufacturers. This has implications for affordability and sustained access.

A. *The SADC Pharmaceutical Market*

The estimated SADC pharmaceutical market is U.S. \$4.1 billion, largely dominated by generic and patented pharmaceuticals from outside Africa.⁷⁶ In terms of HIV/AIDS specific pharmaceuticals, patented pharmaceuticals account for thirty-seven percent while generic pharmaceuticals account for sixty-three percent.⁷⁷

Local manufacturers account for twenty-four percent of the SADC pharmaceutical market.⁷⁸ The SADC pharmaceutical market is largely dominated by South Africa, which has some limited capacity to produce active pharmaceutical ingredients (APIs).⁷⁹ The

69. According to the SADC-PBP (2015-2019), *supra* note 59, these factors effectively undermine the procurement-bargaining power of Member States.

70. SADC PBP (2015–2019), *supra* note 60, at 18.

71. SADC PBP (2007-2013), *supra* note 64, at 9.

72. TRIPS Agreement, *supra* note 1.

73. Insight Actuaries and Consultants *Effective Health Financing Models in SADC: Three Case Studies*, FINMARK TRUST, 4 (2016), <http://www.finmark.org.za/wp-content/uploads/2016/06/regional-sadc-case-studies.pdf>

74. *Id.*

75. *Id.*

76. SADC SPPEM (2013-2017), *supra* note 66, at 11.

77. SADC Feasibility Study, *supra* note 67, at 30.

78. SADC, *Feasibility Study on Regional Manufacturing of Medicines and Health Commodities, Volume 1*, (Final Report) SADC-SHD&SP/CD/C39/2014, 30 (January 2016).

79. International Finance Corporation (IFC), *The Business of Health in Africa*:

pharmaceutical industry outside South Africa primarily focuses on producing “non-complex, high volume, essential products, such as basic analgesics, simple antibiotics, anti-malarial drugs, and vitamins.”⁸⁰

There are a number of factors that undermine local production of pharmaceuticals in the SADC region. These factors include strong competition from Indian manufacturers; lack of local supply of raw materials and overdependence on imported raw materials (from India and China); inadequate incentives (low taxes, preferential treatment, and loans); and lack of policy coherence on tariffs.⁸¹ Additional factors include inadequate usage of existing pharmaceutical production facilities, due to lack of enabling policy environments; inadequate human resource capacity; high operating costs, rendering it more cost effective to import; financial resource constraints; obsolete equipment; inadequate pharmaceutical manufacturing policies/strategies; and absence of and inadequate procurement policies in favor of local manufacturers.⁸² Another factor that undermines local production is limited effective demand for local products in individual SADC LDCs.⁸³ SADC LDCs generally depend on development partners for their pharmaceutical supplies. These development partners either require World Health Organization (WHO) prequalification as condition for procurement or source their products from elsewhere.⁸⁴ This disadvantages some SADC manufacturers who have challenges meeting international quality and other WHO prequalification standards.⁸⁵ As a result, Asian countries have a comparative advantage

Partnering the Private Sector to Improve People’s Lives, International Finance Corporation, World Bank Group, 76 (2007), https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/IFC_HealthinAfrica_Final.pdf

80. *Id.*; see also SADC PBP (2007–2013), *supra* note 64, at 9-10.

81. SADC PBP (2007–2013), *supra* note 63, at 17; EQUINET, *Enhancing Local Medicine Production in East and Southern Africa*, POLICY SERIES NO.39, 2 (2014), http://www.equinet africa.org/sites/default/files/uploads/documents/EQ_GHD_Meds_polbrief39_2014.pdf; Southern and Eastern African Trade, Information and Negotiations Institute (SEATINI) and Centre for Human Rights and Development (CEHURD) *Literature review on bottlenecks to essential medicines production and procurement in East and Southern Africa*, (2013), http://www.equinet africa.org/sites/default/files/uploads/documents/Diss_96_GHD_Litreview_meds_May2013.pdf.

82. SADC Feasibility Study, *supra* note 67, at 16.

83. EQUINET *supra* note 81, at 2, http://www.equinet africa.org/sites/default/files/uploads/documents/EQ_GHD_Meds_polbrief39_2014.pdf.

84. Todd Dickens, *The World Medicines Situation in 2011: Procurement of Medicines*, (WHO-Geneva), <http://apps.who.int/medicinedocs/documents/s18769en/s18769en.pdf>.

85. *Id.* at 23.

over SADC producers due to a number of factors, in particular, human resources, basic costs of production, and experience and economies of scale.⁸⁶ Consequently, it is considered cheaper to source medical products from India than to procure within the region. Therefore, a need exists to create an enabling legal and policy environment for local or regional production of pharmaceuticals products within the region.

Given the limited manufacturing base in the region, SADC LDCs have relied on imports, especially from India, as a source of affordable generic pharmaceuticals for their populations. Eighty-five percent of these HIV/AIDS generics are produced outside the region and fifteen percent are produced in the region.⁸⁷

The burden of procuring and providing medicines has essentially been borne by development partners.⁸⁸ As observed above, the future access scenario looks bleak, given that India can no longer easily make newer versions of generic drugs for export. Therefore, the challenge for SADC countries has been to find a more reliable source of second-line and third-line (or salvage) ARVs.⁸⁹ This concern has resulted in the countries' increasingly inward search on this issue, and they are now actively exploring options for producing generic essential medicines within the SADC region itself.⁹⁰

Given the magnitude of these problems and the recognition that individual countries have serious capacity constraints, SADC Member States have resolved to adopt collective approaches to addressing access to medicine problems.⁹¹ Collective approaches are further seen as a way of enhancing market efficiencies and harnessing economies of scale.⁹²

86. Fei-fei Yue & Ying-ming Yue, *Study of Comparative Advantages of Chinese and Indian Pharmaceutical Industries under Globalization*, 4 *MGNT SCI.* 82 (2010).

87. *Id.*

88. SADC SPPEM (2013–2017), *supra* note 66, at 9.

89. Salvage treatment becomes essential when treatment options become limited due to resistance. According to MSF, the current lowest price of the salvage drug Darunavir + Raltegravir and Eltravirine (DRV+RAL+ETV) is US \$1,859 per person/per year (*Untangling the Web*, 10, 2016).

90. SADC PBP 2015–2019, *supra* note 60.

91. *Id.*

92. SADC, Feasibility Study, *supra* note 67.

III. RECENT LAW AND POLICY REFORMS

A. *Regional Level Reforms*

The desire to find collective solutions to the common problem of inadequate access to medicines has motivated SADC states to develop laws, policies, and programs that seek to address this problem in a collaborative manner. These include two major developments. First, the adoption of the legally enforceable, SADC Protocol on Health in 1999.⁹³ Article 29 of the Protocol obliges state parties to “cooperate and assist one another in the harmonization of procedures of pharmaceuticals, quality assurance and registration, production, procurement, and distribution of affordable essential drugs.”⁹⁴ And second, the adoption of the SADC Pharmaceutical Business Plan (PBP) by SADC Health Ministers in 2006. The PBP was valid from 2007 to 2013.⁹⁵ A new plan has since replaced it and covers the period from 2014 to 2019.⁹⁶ The PBP is designed to operationalize the SADC pharmaceutical program.⁹⁷ Its stated overall objective is to ensure “the availability of essential medicines including African Traditional Medicines to reduce the disease burden in the region.”⁹⁸ At a more specific level, the SADC PBP seeks to “improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines including African Traditional Medicines.”⁹⁹

B. *SADC PBP (2015-2019): Strategic Priority 2*

The SADC has recognized promoting local and regional production capacity of the pharmaceutical industry as one of the key strategic priorities of the PBP. Strategic Priority 2 of the plan focuses on “creating an enabling environment that will maximize the research and production capacity of local and regional pharmaceutical industries in terms of generic essential medicines.”¹⁰⁰ The strategies adopted to achieve this end include promotion of joint ventures and public-private partnerships, and removal of tariff and policy barriers on raw materials.¹⁰¹ The envisaged output of the plan is “50% increase

93. Protocol on Health in the Southern African Development Community (1999).

94. Article 29(a)(b).

95. SADC PBP (2000–2013), *supra* note 66.

96. SADC PBP (2015–2019), *supra* note 60.

97. *Id.* at 9.

98. *Id.* at 4.

99. *Id.*

100. SADC PBP (2015-2019), *supra* note 60, at 19.

101. The rationale behind these initiatives is that they would enhance the viability of the SADC pharmaceutical sector by reducing production costs, harnessing private and public

in local production and availability of essential medicines.”¹⁰²

C. Opportunities to Build a Pharmaceutical Industry in the Region

Prior to 2005, the prospects of building a viable generics industry in SADC were slim because of fierce competition from India and China. These countries have a comparative advantage over SADC countries when it comes to the production of raw materials and finished products. However, as the SADC Feasibility Study observes, the full implementation of the TRIPS Agreement by India presents an opportunity for the SADC pharmaceutical sector.¹⁰³ This is because India cannot easily make generic versions of pharmaceuticals that were patented post-2005.¹⁰⁴ Manufacturers in SADC LDC Members would be entitled to make generics until 2033.¹⁰⁵

The PBP 2015-2019 implicitly recognizes the fact that individual Member States do not have large enough markets to support a viable pharmaceutical industry.¹⁰⁶ It therefore sets out strategies that seek to take advantage of TRIPS flexibilities to improve pharmaceutical manufacturing and distribution capabilities at the regional level. Specifically, the PBP recognizes that the TRIPS Agreement does not oblige LDCs to implement patent and data protection provisions until 2033 or even beyond.¹⁰⁷ According to the PBP, this presents an opportunity for SADC Member States, including LDCs, to take advantage of the transition period and develop their local production capacity.¹⁰⁸ This opportunity was initially recognized in the SADC PBP 2007-2013, which provided as follows: “A second window of opportunity which could be exploited is contained in paragraph 6 of the WTO decision of August 30, 2003, which allows regional blocs with at least half of its membership being LDCs to trade in pharmaceuticals within the bloc without restrictions.”¹⁰⁹

resources, and increasing productivity.

102. *Id.* at 26.

103. SADC, *Pooled Procurement of Essential Medicines and Medical Supplies Situational Analysis and Feasibility Study*, (2012), https://www.sadc.int/files/6614/1890/8516/SADC__SADC_POOLED_PROCUREMENT_OF_ESSENTIAL_MEDICINES_AND_MEDICAL_SUPPLI...pdf

104. SADC Feasibility Study, *supra* note 67, at 30.

105. Decision of the Council for TRIPS of 6 November 2015.

106. SADC PBP (2015–2019) *supra* note 60, at 17.

107. *Id.* at 17, 20.

108. *Id.* at 20.

109. SADC PBP (2007–2013), *supra* note 64, at 12.

Paragraph 6 of the 30 August WTO Decision endeavors to solve the problems of insufficient manufacturing capacity and the absence of lucrative domestic markets by attempting to harness economies of scale using regional trade groupings.¹¹⁰ The paragraph exempts developing countries or LDCs that are members of certain regional trade agreements from some TRIPS obligations.¹¹¹ These include the requirement under Article 31(f) of the TRIPS Agreement that compulsory licensing should be, predominantly, for domestic use.¹¹²

The only countries that can take advantage of this exemption or waiver, however, are those that are members of regional trade agreements, whose membership comprises at least fifty percent LDCs.¹¹³ The scope of the waiver is to enable members to produce or import pharmaceutical products under a compulsory license so those members can export to the markets of other developing or LDC members within the trade block that share the health problem in

110. The paragraph reads as follows:

With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: “where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question”; (SADC is a regional body notified Article XXIV of the GATT).

111. Paragraph 6 (i) of the 30 August Decision. The Paragraph has now become permanently incorporated into the TRIPS by Article 31*bis* (3) which provided as follows:

With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.”

112. *Id.*

113. *Id.*

question.¹¹⁴

The waiver attempts to harness the economies of scale to enhance the existing purchasing power through use of regional trade blocs, and promote and facilitate local production of pharmaceutical products.¹¹⁵

The PBP 2015-2019 recognizes the potential utility of the 30 August WTO Decision as a tool for promoting local/regional production of pharmaceuticals in key Strategic Area 7.¹¹⁶ Paragraph 7(v) of the PBP stipulates that, in order to facilitate trade in pharmaceuticals within the region, SADC members will “utilize the paragraph 6 system or article 31*bis* of the TRIPS Agreement to facilitate local production for export; or importation for re-exportation within SADC as a regional bloc.”¹¹⁷ The difficulty is that SADC LDCs may not have the capacity to reap the full benefits of this waiver because of the absence of lucrative domestic markets, human resource constraints, inadequate technological capacity, poor infrastructure, and inadequate public funding of R&D.¹¹⁸ Some country studies have revealed, however, that various individual SADC countries have some production capacity and could benefit from the economies of scale that Article 31*bis* attempt to harness.¹¹⁹ Article 31 *bis* is flexible enough to allow for the possibility of the manufacture of pharmaceuticals to take place in developing country member states. Therefore, SADC countries can explore the possibilities of harnessing the R&D, as well as production and procurement capabilities of some of its developing member states, including South Africa, to achieve this objective.

Moreover, while individual SADC countries and the region at large may not represent lucrative markets for big pharmaceutical companies, the SADC region may be a large enough market for

114. *Id.*

115. *Id.*

116. SADC PBP (2015–2019), *supra* note 60, at 20.

117. *Id.*

118. LDC Watch, *supra* note 21, at 4.

119. John H Amuasi, *Technology Transfer and Local Manufacturing of Pharmaceuticals: The South African Case, African Dialogue on Technology Transfer for Local Manufacturing Capacity on Drugs and Vaccines Cape Town, South Africa*, ICTSD AND UNCTAD, WITH THE SUPPORT OF THE WHO AND THE EU COMMISSION, 10–11 (December 2009), <http://www.ictsd.org/downloads/2009/12/amuasi-paper-edited.pdf>; United Nations Industrial Development Organization *Pharmaceutical Sector Profile Zimbabwe: Global UNIDO Project: Strengthening the local production of essential generic drugs in least developed and developing countries*, (2011), <http://apps.who.int/medicinedocs/documents/s18701en/s18701en.pdf>; German Technical Cooperation Agency (GTZ), *The Viability of Local Pharmaceutical Production in Tanzania*, 4, 43 (2007), https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Tanzania.pdf.

regional manufacturers. Hence, the Article 31 bis attempts to create viable markets by allowing companies in individual countries to produce for export within the region.

Some LDCs in the region already have some pharmaceutical manufacturing capacity, albeit limited. As a result they may be potential leaders in manufacturing pharmaceuticals for the SADC region. A recent study on Tanzania, for instance, concluded that there is a case for promoting local production in Tanzania.¹²⁰ This is especially because the public sector, which is mostly supported by donors, represents a relatively significant market and “offers realistic options for a viable business.”¹²¹ The same can be said of other SADC countries.¹²² The study also concludes that a regional approach to pharmaceutical production would make more business sense.¹²³ The only drawback is that most domestic companies do not meet WHO prequalification standards to be eligible for international donor financing.¹²⁴

LDCs within the region could also explore the possibility of collaborating with Indian, Chinese, Brazilian, U.S., and EU manufacturers to open generic plants within their territories, which would service the whole SADC region. Such collaborations are already emerging within the region and in the Common Market for Eastern and Southern Africa (COMESA) area. Mozambique, for instance, has recently started producing generic and older versions of ARVs with assistance from Brazil.¹²⁵

Moreover, utilization of this system would facilitate “the development of a viable technological base, including pharmaceutical production capacity.”¹²⁶ This is because the system endeavors to solve the problem of limited markets for pharmaceuticals within individual countries and attempts to harness economies of scale within regional blocs. The flexibility to produce for export would render the SADC region attractive to generic pharmaceuticals investors and would hence help in the development of a technological base for the region. Therefore, the system provides a window of opportunity for countries

120. *Id.*

121. GTZ, *The Viability of Local Pharmaceutical Production in Tanzania*, 4, 43 (2007), https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Tanzania.pdf.

122. South Africa, Zimbabwe, Zambia and Mozambique.

123. *Id.* at 44.

124. SADC Feasibility Study, *supra* note 67.

125. Bannenberg, *supra* note 47, at 3.

126. Mingma Bomzan et al., *supra* note 21.

within the SADC region to do what India has been doing for some time.

Developed countries also have an obligation to perform in the development of a viable pharmaceutical base for the SADC region. Article 66 of the TRIPS Agreement obliges them to “provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.”¹²⁷ However, there is evidence suggesting that developed countries have not honored their commitment to transfer technology to LDCs.¹²⁸ Nevertheless, this should not be a reason to rule out local production. Rather, it should be a reason to advocate for developed countries to honor their commitments. Given that SADC LDCs have no capacity to make newer pharmaceuticals, including ARVs, they would require a lot of technical and financial support from development partners to develop production capabilities.

Moreover, there is emerging evidence that developing countries have started transferring essential technologies to developing countries and LDCs. Thailand, for example, transferred technology for the formulation of a fixed-dose combination of stavudine, lamivudine, and nevirapine to two companies based in Tanzania and the DRC.¹²⁹ Action Medeor, a German non-governmental organization (NGO), has been involved in an initiative to develop a fixed dose combination formulation of tenofovir, lamivudine, and efavirenz in collaboration with Muhimbili University in Tanzania. The expectation is that the technology would be transferred to local manufacturers at no cost.¹³⁰ Similarly, the Brazilian government was recently involved in a transfer of technology initiative through the Oswaldo Cruz Foundation (FIOCRUZ) to the government of Mozambique, which constructed a new ARV manufacturing plant.¹³¹

Technology transfer by itself, however, would not facilitate technological development in LDCs. Effective use of such technology

127. Doha Declaration, *supra* note 3, para. 7. The Doha Declaration also reaffirms “the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2.”

128. WHO *Pharmaceutical Production and Related Technology Transfer* (2011), http://www.who.int/phi/publications/Local_production_and_access_to_medicines.pdf.

129. *Id.* at 29

130. *Id.*

131. *Id.*

in an LDC context would require building the capacity of pharmaceutical companies in LDCs to assimilate such knowledge and “adopt technical know-how.”¹³² Domestic patent legislation can also facilitate this process by ensuring that patents are not granted unless the inventor describes the invention in such a way that it can be worked by locals. SADC countries may wish to adopt a provision similar to Section 21(10) of the Ugandan Industrial Property Act, 2014, which provides that the registrar may, before granting the patent, require the description in a foreign patent application to be adapted to the ordinary skill in the art of the citizens of Uganda so as to ensure technology dissemination.¹³³

SADC countries would also need to adopt a regional strategy to create a viable market. The recently adopted SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities is, thus, a step in the right direction.¹³⁴ This is because it endeavors to eliminate duplication of efforts and to harness economies of scale.¹³⁵

To conclude, the system represents a significant policy option available to SADC member states to stimulate access to affordable medicine at the regional level. Given that some SADC members are also members of COMESA¹³⁶, Article 31 *bis* presents an amazing potential for smaller SADC states to harness economies of scale. Uganda, a COMESA member, has already amended its law to support the manufacture and export to other countries that share similar health problems.¹³⁷ These would include SADC members who double as COMESA members.¹³⁸ Section 44(e) of the Ugandan Act provides that unauthorized use of a patented invention does not amount to an infringement where the manufacture and export of a patented healthcare invention to another country

132. Syam, *supra* note 2, at 4.

133. Section 21(10).

134. The SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities was adopted in 2013 and will expire in 2017. The stated aim of the strategy is to “facilitate regional cooperation in the procurement of essential medicines and health commodities thus ensuring access to affordable, safe, effective and quality-assured products.” The idea behind the strategy is to promote market efficiencies and bargaining power through regional approaches to procurement. It is hoped that pooled procurement would increase access to essential medicines and the availability of orphan drugs that are characterized by procurement challenges owing to the limited amounts required by individual states.

135. Paragraph 6(i) of the 30 August Decision.

136. These include Malawi, Mauritius, Zambia, Seychelles, Mauritius, Zimbabwe, and Tanzania.

137. Section 44(e) of the Uganda Industrial Property Act.

138. *See supra* note 139.

addresses a health need identified by the other country, where(i) the product is either not patented in the third country; or

(ii) the government of another country has authorized use of the patent without the consent of the patent owner and the production for export of the invention is intended only for the market of the third country.¹³⁹

These provisions position Uganda perfectly to take advantage of the 30 August waiver to export pharmaceuticals to COMESA and some SADC nations.

IV. DOMESTIC LEVEL REFORMS

All SADC states are members of the WTO.¹⁴⁰ They are generally obliged to comply with the TRIPS Agreement.¹⁴¹ However, as stated above, LDCs are exempt from applying some general provisions of the TRIPS until 2021 and pharmaceutical related provisions until 2033.¹⁴² The possibility of utilizing the above transition periods to exclude pharmaceuticals from patentability offers LDCs an opportunity to develop a base for manufacturing generic pharmaceutical products.

The transition period has generally not been utilized, however, by most LDCs within the SADC region. This is in contrast with their East African counterparts, Uganda,¹⁴³ Rwanda,¹⁴⁴ and Burundi,¹⁴⁵ who have recently amended their legislation to take advantage of the transition period and exclude pharmaceuticals from patent protection.¹⁴⁶ Most

139. The Industrial Property Act (2014).

140. For a list of WTO Members *see* https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

141. TRIPS Agreement *supra* note 1, Article 1.

142. The Decision of the Council of the TRIPS of 6 November 2015.

143. Section 8 (3)(f) of the Uganda Industrial Property Act (2014).

144. Article 18 of the Rwanda Intellectual Property Act (2009).

145. Article 17 of the Burundi Industrial Property Act.

146. *See* Article 18 of the Rwandan Industrial Property Act, 2009, Article 17 of the Burundi Industrial Property Act. Section 8(3)(f) of the Ugandan Industrial Property Act, 2014 reads:

The following shall not be regarded as inventions and shall be excluded from patent protection—pharmaceutical products and test data until 1st January 2016 or such other period as may be granted to Uganda or least developed countries by the Council responsible for administering the Agreement on trade related aspects of intellectual property under the World Trade Organization.

Article 102 (15) of the Ugandan Act provides that

the rights accruing from patents for pharmaceutical processes shall not be enforceable until January 1, 2016, or such other period as may be granted to Uganda or least developed countries by the council responsible for administering

SADC LDCs still maintain patent laws that they inherited from their colonial masters.¹⁴⁷ As a recent SADC commissioned study observed, virtually all SADC countries have not taken advantage of the pharmaceutical transition periods and “permit pharmaceutical patenting.”¹⁴⁸ The only exception is Zanzibar, part of Tanzania, which has a separate law to exclude pharmaceuticals from patent protection.¹⁴⁹ Apart from prematurely according patent protection to pharmaceutical products, these laws contain provisions that give more protection to patent owners than required by the TRIPS Agreement.¹⁵⁰ This is problematic given that transition periods were granted “in view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base.”¹⁵¹

A number of reasons may be given as to why this is the case. First, these countries believe that compliance with the TRIPS Agreement can benefit them by creating incentives for innovation. Second, these countries are advised by agencies, such as World Intellectual Property Organization (WIPO) that strong patent regimes stimulate domestic innovation. However, existing studies reveal that protection and enforcement of patents stimulate local innovation “only if accompanied by high levels of economic and infrastructural development, educational attainment and economic freedom.”¹⁵² A study by Margaret Kyle and Yi Qian also concludes that “the existence of IPRs is neither necessary nor sufficient for the launch of

the agreement on trade related aspects of intellectual property under the WTO if alternative processes for making pharmaceutical products that are not subject to exclusive rights are not available and those patents, if enforced, indirectly give rise to market exclusivity of the pharmaceutical products in question.

147. These include Malawi, Zambia, Swaziland, and Lesotho.

148. Sisule Musungu, *Pharmaceutical Patents, TRIPS Flexibilities and Access to Medicines in Southern African Development Community (SADC)*, Report for a SADC member States Consultation (September 18, 2012).

149. Section 3(1) of the Zanzibar Industrial Property Act (2014)

150. For example, The Malawi Patents Act, Section 30 provides for the extension of patent terms beyond the basic term provided for in Section 29. This extension obviously goes beyond the requirements of the TRIPS Agreement. Section 30 exceeds the requirements of TRIPS given that the Agreement does not oblige Members to extend patents beyond their basic term. See Robert Lettington & Chikosa Banda, *A Survey of Policy and Practice on the Use of Access to Medicines Related TRIPS Flexibilities in Malawi*, DFID (2004), http://www.who.int/hiv/amds/countries/mwi_SurveyUseTRIPs.pdf. Additionally, the TRIPS Agreement does not oblige LDCs to provide protection for patents. However, the SADC countries as we have seen above maintain patent protection for pharmaceuticals.

151. TRIPS Agreement *supra* note 1, Article 66(1).

152. Qian Yi, *Do National Patent Laws Stimulate Domestic Innovation in a Global Patenting Environment?*, 89 REV. ECON. & STATS. 436 (2007).

pharmaceuticals at country level.”¹⁵³ On the contrary, it might adversely impact the freedom of manufacturers to make generic versions of essential pharmaceuticals and to broaden their product range.¹⁵⁴ It is difficult to imagine how SADC LDCs can develop a technological base if they prematurely comply with all the provisions of the TRIPS Agreement. The premature implementation of the TRIPS Agreement would stifle the development of useful products in LDCs by preventing “reverse engineering” and by obstructing access to research tools and platform technologies.¹⁵⁵ This would, in turn, hamper the ability of these LDCs to develop technological capacity, including pharmaceutical R&D and production capacity.¹⁵⁶

Nevertheless, most SADC countries have revised or have embarked on the process of revising their IP laws to incorporate or update TRIPS flexibilities. These include Malawi, Seychelles,¹⁵⁷ Namibia,¹⁵⁸ Zanzibar,¹⁵⁹ and Botswana.¹⁶⁰ The progressive country level legal reforms include incorporation of Article 31*bis* of the TRIPS Agreement.¹⁶¹ Some LDCs are developing laws that exclude

153. Margaret Kyle & Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS*, 23 NAT'L BUREAU OF ECON. RESEARCH, WORKING PAPER NO. 20799 (2013).

154. Syam, *supra* note 2, at 6.

155. *Innovation in the Least Developed Countries: Going Beyond Intellectual Property Rights, LDC Report Highlights-Based on the Least Developed Countries Report*, UNCTD, 2 (2007), http://unctad.org/en/docs/ldchr2_en.pdf.

156. *Id.*

157. Seychelles Industrial Property Act (2014).

158. NAMIBIA INDUSTRIAL PROPERTY ACT (2012).

159. ZANZIBAR INDUSTRIAL PROPERTY ACT (2014).

160. BOTSWANA INDUSTRIAL PROPERTY ACT (2010).

161. Section 31(1) of the Botswana Industrial Property Act (2010) authorizes the Minister to issue compulsory licenses in the public interest. Section 31(3) of the Act, however, waives the “domestic market” condition by providing as follows: The exploitation of the patented invention under subsection 1 shall be for the supply of the domestic market in Botswana only, except where paragraph 1 or 3 of Article 31*bis* of the TRIPS Agreement applies. Section 32(2) provides that “the importation of the patented product by a Government agency or any authorized person shall be solely for public non-commercial use within Botswana, except where paragraph 1 or 3 of Article 31*bis* of the TRIPS Agreement is applicable.” Similarly, section 57(1)(e) of the Namibia Industrial Property Act (2012) also domesticates article 31*bis* of the TRIPS Agreement. It provides that where a patent relates to a pharmaceutical product in respect of which Namibia has insufficient or no manufacturing capacity as contemplated in the decision of the General Council of the WTO of August 30, 2003 or in Article 31*bis* of the TRIPS and a License for the importation of the patented product is required” the Minister may issue a “compulsory license to exploit an invention including by importation. Section 14 of the Zanzibar Industrial Property Act (2014) recognizes compulsory licensing for importation pursuant to “the decision of the General Council of the WTO of 30th August 2003.” Section 97(3) of the Act states:

compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing

pharmaceuticals from patentability. Zambia has a draft law which purports to exclude pharmaceuticals from patentability until it graduates from LDC status.¹⁶² Zanzibar has a similar provision in its law.¹⁶³ Consequently, SADC countries are adopting legal provisions aimed at taking advantage of the 30 August waiver to facilitate the importation of drugs from countries that have generic production capacities. The legal provisions are also designed to facilitate the production for export and importation for re-export of medicines within the region.¹⁶⁴ South Africa is in the process of reviewing its patent policy.¹⁶⁵ Failure to accelerate the implementation of TRIPS flexibilities may be symptomatic of the fact that SADC countries do not consider implementing TRIPS flexibilities as a human rights obligation. Conversely, the African Union Resolution 141 on Access to Health and Needed Medicines in Africa calls upon states to take measures to promote, protect, and fulfill access to medicines.¹⁶⁶ Specifically, the Resolution recognizes access to pharmaceuticals as an indispensable element of the right to a highest attainable standard of health.¹⁶⁷ Accordingly, it urges states to promote access to pharmaceuticals by avoiding measures that negatively impact access. These include “implementing intellectual property policies that do not take advantage of all the flexibilities in the . . . TRIPS Agreement that promote access to affordable medicines.”¹⁶⁸ Failure by states to appreciate the human rights basis of their obligations may explain their

capacity in the pharmaceutical sector for the concerned product to address public health problems or needs, provided compulsory license or authorized use of the patent has been granted by such country.

162. Section 16 of the *Zambian Patents Bill (2010)* provides as follows:

Pharmaceutical products and processes shall not be patentable until 1 January 2016 or until the expiry of such later period of extension as may be agreed upon by the World Trade Organization for least developed countries.” Section 68(3) empowers the Registrar promptly to “reject all pharmaceutical and medicines related micro-biological patents until 1 January 2016 or until the expiry of such later period of extension as may be agreed upon by the World Trade Organization for least developed countries.

163. Section 3(1) of the *Zanzibar Industrial Property Act (2014)* excludes pharmaceutical products and processes from patent protection “until January 1, 2016 or the expiry of such later period of extension as agreed upon by the WTO Council for the TRIPS.”

164. In order to take advantage of the 30 August waiver.

165. The Policy partly aims at promoting access to essential medicines. See DEP’T OF TRADE AND INDUSTRY, *DRAFT NATIONAL POLICY ON INTELLECTUAL PROPERTY*, 5 (2013), <http://ip-unit.org/wp-content/uploads/2013/09/DRAFT-IP-POLICY.pdf>.

166. *Resolution on Access to Health and Needed Medicines in Africa, The African Commission on Human and People’s Rights, Meeting of its 44th Ordinary Session held in Abuja Nigeria*, AU RESOLUTION 141, 10–24 (September 2005), <http://www.achpr.org/sessions/44th/resolutions/141/>.

167. Preamble of the resolution.

168. Paragraph 1.

laxity in domesticating TRIPS flexibilities.

V. CHALLENGES

One of the major challenges to implementing TRIPS flexibilities in the SADC region is policy incoherence. A good number of SADC LDCs still provide patent protection for pharmaceuticals despite the fact that they are not obliged to do so under the TRIPS Agreement. This is because LDCs view IP as a vital tool for achieving their developmental objectives.¹⁶⁹ The understanding may be attributable to the technical assistance these countries receive from WIPO and other development partners.¹⁷⁰

While SADC member states are increasingly incorporating TRIPS flexibilities in national legislation, the actual usage of these flexibilities still remains limited.¹⁷¹ This is partly attributed to a number of factors, including inadequate capacity in the region to implement these flexibilities in practice, inadequate awareness of the flexibilities, and pressure from developed countries against the use of flexibilities.¹⁷² The impact of this is that SADC countries cannot take full advantage of Article 31 bis which allows members to produce pharmaceuticals for export to other members. Failure to incorporate or utilize flexibilities also means that members cannot utilize the system provided for under Article 31 bis to import medicine from outside the region for re-exportation to other members within the SADC. In this respect, SADC members appear to be motivated more by the desire to protect their sovereignty than the need to solve common problems. This has accordingly delayed the full implementation of the SADC PBP.

Ten LDCs, five of which are SADC states, are ARIPO members.¹⁷³ ARIPO was created in 1976 by the Agreement on the

169. See submission by Sangeeta Shashikant and Gopakumar Kapoori to the UN Secretary General's High Level Panel on Access to Medicines, March 1, 2016, <http://www.unsgaccessmeds.org/inbox/2016/3/1/third-world-networkc>.

170. See submission by Sangeeta Shashikant and Gopakumar Kapoori to the UN Secretary General's High Level Panel on Access to Medicines, March 1, 2016, <http://www.unsgaccessmeds.org/inbox/2016/3/1/third-world-networkc>.

171. See Sisule Musungu, *Pharmaceutical Patents, TRIPS Flexibilities and Access to Medicines in Southern African Development Community (SADC)*, REPORT FOR A SADC MEMBER STATES CONSULTATION, (September 18, 2012)..

172. See, e.g., UNAIDS, *Intellectual Property and Access to Health Technologies* (2016), http://www.unaids.org/sites/default/files/media_asset/JC2820_en.pdf.

173. Lusaka Agreement on the Creation of the African Regional Organization on Intellectual Property Rights (ARIPO) (1976), http://www.wipo.int/edocs/lexdocs/treaties/en/ap001/trt_ap001_001en.pdf.

Creation of the African Regional Industrial Property Organization adopted at Lusaka, in Zambia.¹⁷⁴ The objectives of ARIPO include promoting the harmonization and development of the industrial property laws among member states. ARIPO also aims at strengthening “cooperation between states in respect of protection and exploitation of patents.”¹⁷⁵ The following SADC countries are members of ARIPO: Botswana, Lesotho, Malawi, Mozambique, Namibia, Swaziland, Tanzania, Zambia, and Zimbabwe.

The ARIPO Secretariat is responsible for granting patents on behalf of member states under the Harare Protocol on Patents and Industrial Designs. The Secretariat undertakes formal and substantive examinations of patent applications to ensure compliance with the prescribed formal requirements and substantive criteria for patentability.¹⁷⁶ When a patent is granted by ARIPO, designated states are supposed to be notified and given a chance to reject the patent.¹⁷⁷ A designated state is given six months to communicate in writing to ARIPO that the granted patent shall have no effect in its territory. The Harare Protocol makes available to states two grounds for rejecting ARIPO granted patents: first, that the invention is not patentable under the provisions of the protocol, and second, that “because of the nature of the invention, a patent cannot be registered or has no effect under the” state’s national law.¹⁷⁸ Failure by the designated state to respond to a notification within six months renders the patent effective in its territory.¹⁷⁹

One major drawback of the Harare Protocol is that it does not recognize LDC transition periods, granted under Article 66 of the TRIPS Agreement and extensions thereof.¹⁸⁰ As a result, it is not uncommon for ARIPO to grant pharmaceutical patents in which LDCs are designated. This is worrisome considering that most members of ARIPO are LDCs and maintain patent laws that do not exclude pharmaceuticals from patentability. In fact, existing studies reveal that rejection of ARIPO patents is uncommon. Most LDCs routinely accept pharmaceutical patents granted by ARIPO partly because of lapses in

174. Agreement on the Creation of the African Regional Industrial Property Organization.

175. See the Preamble to the Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Intellectual Property Organization.

176. Section 3 (2)(a) and section 3(3) of the Harare Protocol.

177. Section 3(6) of the Harare Protocol.

178. Section 3(6) of the Harare Protocol.

179. Section 3(7) of the Harare Protocol.

180. Syam, *supra* note 2, at 8.

the notification and objection systems.¹⁸¹ As Robert Lewis-Lettington and Chikosa Banda have observed, this “means that ARIPO standards are *de facto* emerging as a uniform regional standard that may, in the future, need to be examined in its own right.”¹⁸²

Given the implications of the ARIPO system for the use of transition periods and other flexibilities, it is high time the ARIPO system be thoroughly scrutinized. In this context, commentators have recommended that “the Harare Protocol should exempt the territory of LDCs from the grant of pharmaceutical patents.”¹⁸³ This would not be a farfetched idea. The *Organisation Africaine de la Propriété Intellectuelle* (OAPI), which is ARIPO’s counterpart in francophone Africa, has amended its treaty to provide for the non-applicability of pharmaceutical patents to LDCs. Article 46 of the OAPI agreement provides that

Member States that are LDCs are not obliged to implement the provisions of Annex 1 regarding patents consisting of, or related to, a pharmaceutical product, nor to implement the provisions of Annex VIII regarding confidential information, until 2033 or on the date on which they stop to be classified as an LDC.¹⁸⁴

Incorporating a provision similar to the terms above, into the Harare Protocol, would ensure coherence between regional and the progressive patent law reforms that are taking place in LDCs.

Without addressing the above policy contradictions, it will be difficult for SADC members to make progress in safeguarding access to medicines and stimulating local/regional production of pharmaceuticals.

VI. CONCLUSION

The adoption of the SADC PBP and the increasing incorporation of TRIPS flexibilities in the domestic laws present a vital window of opportunity for member states to take advantage of TRIPS flexibilities

181. Sisule Musungu, *Access to ART and other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislation* (2007), <http://apps.who.int/medicinedocs/documents/s18248en/s18248en.pdf>; Lettington & Banda, *supra* note 150, at 33; Shashikant, *supra* note 49.

182. Lettington & Banda, *supra* note 150, at 33.

183. Shashikant, *supra* note 49, at x.

184. Organisation Africaine de la Propri. . . t. . . Intellectuelle (OAPI), Article 46. (1977), <http://www.oapi.int/index.php/fr/oapi/cadre-juridique/accord-de-bangui>.

and waivers in order to promote local/regional production of pharmaceuticals. A number of challenges and barriers need to be surmounted, however, in order to make local and regional production a reality. First, SADC countries have been over-dependent on India as a source of generic pharmaceuticals and have given inadequate attention to the implication of post-2005 Indian law and policy reforms on future access to medicine. This has obviated the need to develop local and regional production capacity and reform domestic legislation in order to support local production. Second, the SADC PBP is not legally binding. Hence, Members have the option of whether to implement it or not. Third, SADC members have, historically, had limited expertise in IP law. This has undermined progress in law reform.

Recent developments in the SADC region suggest, however, that countries are increasingly becoming aware of the need to find sustainable solutions to the problem of how to access pharmaceutical products. Consequently, they have initiated law patent law reform processes that seek to take full advantage of flexibilities, including the transition periods, in order to stimulate local and regional production of pharmaceuticals.

While this is a welcome development, the pace at which SADC LDCs are reforming their laws is worrisome. This is evidenced by the fact that only one SADC LDC has, to date, enacted a law that takes advantage of the transition periods. As noted above, there are a number of factors behind this, which include inadequate in-country technical and technological capacity, inappropriate TRIPS-related technical assistance programs, and pressure from developed countries.

A number of concrete steps can be taken to accelerate the pace at which SADC countries are adopting flexibilities. First, the SADC should amend its Protocols on Health and Trade¹⁸⁵ in order to incorporate TRIPS-related access to medicines provisions. These provisions should oblige all Member States to domesticate flexibilities and LDCs to take advantage of the TRIPS pharmaceutical waiver. This would pave way for the prioritization of these issues in national legal and policy frameworks. SADC can also take advantage that the majority of its members are LDCs and take advantage of the Article 31 bis to facilitate local/regional production of pharmaceuticals. Incorporating the foregoing provisions into a legally binding protocol would accelerate their adoption by Members. Second, the SADC

185. Southern African Development Community (SADC) Protocol on Trade (1996).

should recognize that access to essential medicines is a human right. Accordingly, individual Members have an obligation to go beyond rhetoric and take concrete steps towards the progressive realization of this right. One strategy towards this would be to popularize the implementation of African Union Resolution 141, which calls upon states to promote, implement, and fulfill access to medicines by adopting TRIPS flexibilities and taking advantage of the TRIPS waivers. Third, there is an urgent need for financial and technical assistance to enable Members to incorporate TRIPS flexibilities. Much of the progress that SADC Members have registered to date has come from the technical support rendered by the Southern African Regional Program on Access to Medicines and Diagnostics (SARPAM). This program has since expired, and it is imperative that new regional vehicles of technical assistance be established to complete the work that SARPAM started. Moreover, Article 67 of the TRIPS Agreement opens up a window of opportunity for SADC Members to request for and receive technical assistance from developed countries. It obliges developed countries to “provide technical and financial cooperation in favor of developing and least-developed country Members.”¹⁸⁶ The cooperation envisaged by this provision includes “assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights.”¹⁸⁷ The TRIPS Agreement, thus, contains inbuilt mechanisms to facilitate the acceleration of the implementation of its provisions, including its flexibilities and waivers. The pace at which reforms will take place will largely depend on the performance of the above obligations by developed and developing states, including LDCs. Given that the implementation of the TRIPS flexibilities is undermined by inadequate expertise, it would be useful to provide post-reform technical support to LDCs. LDCs would require support in order to effectively implement TRIPS flexibilities and waivers in practice.¹⁸⁸

However, it would be difficult to promote the incorporation of TRIPS flexibilities and the adoption of TRIPS waivers unless SADC countries see the direct relevance of the flexibilities to their respective countries. At present, most SADC LDCs do not see the direct implications of failure to incorporate TRIPS flexibilities for access to newer pharmaceuticals. This is because they have no viable technological base and are heavily dependent on India for their pharmaceutical needs. As Médecins Sans Frontières (MSF) observes,

186. TRIPS Agreement *supra* note 1, at Section 67.

187. *Id.*

188. Lettington & Banda, *supra* note 149, at 41.

“extending the period of TRIPS implementation is just one step in addressing the unique challenges of LDCs in Africa but above all there is need to address the underlying issues beyond extensions such as helping LDCs build their technological base.”¹⁸⁹

Consequently, a viable manufacturing base cannot be created without external support. Developed countries have an obligation under Article 66(1) of the TRIPS Agreement to encourage LDCs to create a good and viable technological base. This would be by provision of incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to LDC members. Developed countries must also help SADC generic manufacturers to develop the capacity to produce pharmaceuticals that meet WHO prequalification standards. Given the limited nature of the market in individual states, this would help create a regional and donor market for such pharmaceuticals.

SADC Members need to understand the important role local/regional production of pharmaceuticals can play in addressing the gap left by changes in the Indian IP landscape. They also need to understand the potential utility of flexibilities and waivers as tools for the development of a viable technological base to support generic production. In short, the domestication of TRIPS flexibilities would only be accelerated if LDC members appreciate tangible benefits of doing so.

189. MSF, *supra* note 37, at 16.