Domesticating the World Trade Organisation's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities to access essential medicines: any lessons for the SADC from Botswana?

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Abstract

The Southern African Development Community (SADC) has a high disease burden. This is largely attributed to HIV/AIDS, tuberculosis, malaria, and most recently, life-style diseases such as cancer and heart disease. In order for the disease burden to be reduced, access to medicines, which are usually expensive and protected by patent rights, must be improved. Access to medicines, a concept with no clear definition, is generally considered to include various dimensions such as accessibility, affordability, acceptability, and availability. In developed nations, over seventy per cent of drugs are publicly funded or reimbursed. However, in Africa, fifty to ninety per cent of pharmaceutical expenditure is funded out of pocket. This impedes access to medicines because, in the absence of price regulations, drug prices create affordability barriers. One of the most frequently touted solutions to access to medicines is the continuing call to reform intellectual property (IP) laws, especially patent laws, to reduce the effect of monopolistic prices charged by big pharmaceutical companies. It has been suggested that in order for this law-reform project to yield positive results, it must be conducted in compliance with the tenets of the World Trade Organisation's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement by taking advantage of flexibilities which include parallel imports, competition law, compulsory licensing, pre- and post-grant patent opposition, and research exceptions, among others. Botswana, a WTO member, has set the trend for other SADC members by courageously initiating patent law reform in order to improve access to medicines through promulgating the Industrial Property Act of 2010. The Act incorporates most of the TRIPS

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Agreement flexibilities and Botswana's experience may, therefore, offer a useful example for other SADC members. This article provides a critical appraisal of Botswana's recent IP law-reform project directly relevant to access to medicines and identifies thematic lessons from which fellow SADC members may benefit.

INTRODUCTION

The Southern African Development Community (SADC) is constituted by Angola, Botswana, the Democratic Republic of Congo, Lesotho, Swaziland, Namibia, South Africa, Mozambique, Seychelles, Madagascar, Malawi, Mauritius, Tanzania, The Union of Comoros, Zambia, and Zimbabwe. It should be recalled that SADC, which is now a fully-fledged free-trade area, started modestly as the Southern African Development Coordination Conference (SADCC) in Lusaka, Zambia on 1 April 1980. This came after the adoption of the Lusaka Declaration[1] by nine founding member states,[2] namely Angola, Botswana, Lesotho, Malawi, Mozambique, Swaziland, Tanzania, Zambia and Zimbabwe.

Due to positive experiences of close cooperation among the peoples and governments of southern Africa, the SADC was born out of the SADCC. Political independence for many southern African states came against a backdrop of wide-spread poverty, economic backwardness, and the ever-present threat of powerful and hostile white minority-controlled neighbours.[3] The need to work together became apparent to the leaders of the SADCC as a pre-condition for economic survival, economic development, and social advancement. The governments then began to seek areas of mutual interest, first through bilateral cooperation and later through the frontline states grouping.[4]

The Declaration and Treaty of the SADC, which replaced the Coordinating Conference, was signed at the Summit of the Heads of State

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1 The Declaration, which was titled 'Southern Africa: Towards Economic Liberation', was published in 1980, the same time the erstwhile Southern African Coordination Conference (SADCC), predecessor to the current SADC, was formed. For a comprehensive legal historical rendition of the transformation of SADCC to SADC, see generally Patrick Osode, 'The Southern African Development Community in Legal Historical Perspective' (2004) 28 (3) Journal for Juridical Science at 1–9.

2 SADC Secretariat, The Official SADC Trade Industry and Investment Review (1997) 4.

3 Namely South Africa, South West Africa (Namibia) and Rhodesia.

4 The Frontline states became the vehicle through which the region could coordinate its efforts, resources and strategies to support national liberation movements and at the same time resist the aggression of apartheid South Africa.

or Government on 17 July 1992 in Windhoek, Namibia.[5] At the Summit, heads of government of the SADCC agreed to transform the grouping into the SADC, with a thrust towards regional integration in most areas. These included trade, finance, health, shared water sources, and education.[6] Meanwhile, Namibia had joined the regional grouping in 1990, while South Africa joined later in 1994 after the demise of apartheid.

In the short history of the SADC, a series of milestones have been achieved in the context of the SADC Common Agenda.[7] Spurred by the achievement of the milestones, the SADC region adopted an ambitious plan to become a free-trade area by 2008; a customs union by 2010; a common market by 2015; and a monetary union by 2016.[8] Save for the free-trade area target, all the other targets have had to be postponed for various reasons, chief among which include that some SADC members belong to other customs unions, and the difficulty attendant to negotiating a common external tariff.[9]

On health matters specifically, the SADC faces a massive disease burden.[10] The most prevalent diseases are tuberculosis, HIV/AIDS, malaria, and most recently, cancer, and other life-style diseases such as kidney and heart disease.[11] The disease burden is not uniformly spread across

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5 Each SADC member state has a responsibility to coordinate a sector or sectors on behalf of others. Angola coordinates energy, Botswana livestock production and animal disease control, Lesotho environment and land management, Malawi forestry and wildlife, Mauritius tourism, Mozambique transport and communications, Namibia marine fisheries and resources, South Africa finance and investment, Swaziland human resources development, Tanzania industry and trade, Zambia mining and Zimbabwe food, agriculture and natural resources.

6 SADC Secretariat, 'Southern African Development Community: Towards a Common Future' <http://www.sadc.int/about-sadc/overview/history-and-treaty/> accessed 31 November 2014.

7 The SADC Common Agenda is spelt out in Article 5 of the Treaty as amended in 2009 and consists of the policies and strategies of the organisation. See in this specific instance SADC Secretariat, 'SADC Common Agenda' <http://www.sadc.int/about-sadc/overview/sadc-common-agenda/> accessed 31 November 2014.

8 Save for the objective of becoming a free trade area by 2008, which has since been attained, the other three objectives largely remain ambitious projects divorced from the SADC reality on the ground, since their attainment will depend on complete harmonisation across the board, something very difficult in the present SADC context. See further, SADC Secretariat, 'Integration Milestones' <http://www.sadc.int/about-sadc/integration-milestones/> accessed 31 November 2014.

9 Phillimon Mmeso, 'SADC Customs Union, a Mirage' *The Patriot* (Windhoek 17 August 2015) <http://www.thepatriot.co.bw/news/item/1319-sadc-customs-union-a-mirage.html> accessed 26 June 2017.

10 This disease burden, like the situation afflicting other parts of the developing world, is a 'poverty-related' cause, as aptly described by Kristina M Lybecker, 'The Economics of Access to Medicines: Meeting the Challenges of Pharmaceutical Patents, Innovation, and Access for Global Health' (2011) 53 Harvard International L J 25–43 25.

11 According to Rachel Kiddell-Monroe, 'Access to Medicines and Distributive Justice: Breaching Doha's Ethical Threshold' (2015) 14 Developing World Bioethics 59 at 59, it is estimated that by 2030, approximately seventy-five per cent of the world's deaths will be caused by cancer, diabetes, heart and lung disease.

the region because some countries like Swaziland and Lesotho carry the highest HIV/AIDS infections,[12] while Angola, the Democratic Republic of Congo (DRC), Madagascar, Malawi, Mozambique, Tanzania, Zambia, and Zimbabwe still have a high malaria prevalence,[13] which is not easy to justify in a modern society. The SADC members are also in various stages of economic development and more than fifty per cent of the membership qualify as Least Developed Countries (LDCs).[14]

The disease burden situation is made dire by the lack of access to essential medicines, including generic drugs in most SADC member states.[15] The lack of access is also compounded by poverty and weak political (and other) institutions in the region to contain wasteful government expenditure and hold the executive to account. Medicines are central to any public health and medical system, and key to preventing and curing diseases.[16] Having access to essential medicines is, therefore, a fundamental human right of citizens.[17] In 1946, the World Health Organisation (WHO) first recognised the human right to health by declaring that 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic, or social condition.'[18] The highest standard of healthcare[19] implies the ethical responsibility to provide life-saving medicines at costs affordable to developing countries and their poor citizens.[20]

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12 Recent statistics (eg Avert, 'HIV and AIDS in East and Southern Africa (2015)<https://www.avert.org/professionals/hiv-around-world/sub-saharan-africa>) show the following adult HIV prevalence rates for selected SADC countries starting from highest to lowest: Swaziland (28.8%); Lesotho (22.7%); Botswana (22.2%); South Africa (19.2%); Zimbabwe (14.7%) Zambia (12.9%); Malawi (9.1%) and Tanzania (4.7%).

13 See generally SADC, 'SADC Malaria Status by 2012 Report 2012' (2013) 1–31 <https://www.sadc.int/files/6214/1890/8290/000_14_SADC___Malaria_Report_2012.pdf> accessed 26 June 2017.

14 The specific SADC LDCs are Angola, Democratic Republic of Congo, Lesotho, The Union of the Comoros, Malawi, Madagascar, Mozambique, Seychelles, Tanzania and Zambia.

15 This lack of access to essential medicines is real and according to Kiddel-Monroe (n 11), thirty per cent of the global population, which amounts to between 1.3 and 2.1 billion people, still lacks access to essential medicines and those people are largely living in low to middle income countries. This geographical area encapsulates SADC.

16 German Velasquez, 'The Right to Health and Medicines: The Case of Recent Multilateral Negotiations on Public Health, Innovation and Intellectual Property' (2014) 14 Developing World Bioethics 67 at 68.

17 ibid.

18 Peter G Danchin and Diane Hoffmann, 'Access to Essential Medicines in African Countries: An Introduction' (2016) 31 Maryland J of International Law 1 at 1.

19 See Article 12 of the International Covenant on Economic, Cultural and Social Rights on the recognition of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

20 Tom Andreassen, 'Patent Funded Access to Medicines' (2015) 15 Developing World Bioethics 152 at 152.

With specific reference to access to medicines, the most important instruments in the SADC region are the SADC Protocol on Health,[21] complemented by the Implementation Plan for the SADC Protocol on Health,[22] the SADC Pharmaceutical Business Plan,[23] and the SADC Strategy for Pooled Procurement of Essential Medicines and Commodities.[24]

The abovementioned instruments are crucial in the enhancement of regional integration in the context of health and have been developed to underpin the implication of the SADC health programme.[25] The health programme has been developed taking into account the global and regional health declaration and targets.[26]

Currently, all SADC WTO members, including Seychelles, which recently acceded to the WTO,[27] are obliged to incorporate the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS Agreement) in their national legislation.[28] This position is confirmed by the SADC Protocol on Trade, which provides that:

> [m]ember states shall adopt policies and implement measures within the Community for the protection of intellectual property rights, in accordance with the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights.[29]

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

22 The Implementation Plan provides an overall framework for effecting the provisions of the SADC Protocol on Health and is available at <http://www.sadc.int/index.php?cID=1&bID=1283&arHandle=Sidebar&ccm_token=1383736029:41bfb778708ee17dc30b95e83826bc93&btask=passthru&method=signmeup> accessed 6 November 2013.

23 SADC Secretariat, 'SADC Pharmaceutical Business Plan 2007–2013'.

24 SADC Secretariat, 'Draft SADC Strategy for Pooled Procurement of Essential Medicines and Health Commodities 2013—2017'.

25 See executive summary (n 23) para 2 at 3.

26 ibid.

27 Having applied for accession to the WTO on 31 May 1995 (WTO, 'Accession Seychelles' <http://www.wto.org/english/thewto_e/acc_e/a1_seychelles_e.htm> accessed 10 September 2013), and after undergoing protracted accession negotiations, Seychelles became an official member of the WTO on 26 April 2015; following the unanimous ratification the WTO Protocol of Accession of the Republic of Seychelles by the country's National Assembly earlier on 24 March 2015 (see WTO, 'Seychelles to become 161st WTO Member' <https://www.wto.org/english/news_e/news15_e/acc_syc_01apr15_e.htm> accessed 26 June 2017.

28 The TRIPS Agreement requires that all developing countries, other than those designated as LDCs, must have complied with the minimum standards if intellectual property protection by 1 January 2000 [see Arts 65(1) and 65(2) of TRIPS]. LDCs were initially given until 1 January 2005 to comply, but the period was subsequently extended to December 2013, before being recently extended to 1 July 2021 (see WTO, 'The Least Developed get Eight Years More Leeway to Protect Intellectual Property' <http://www.wto.org/english/news_e/news13_e/trip_11jun13_e.htm> accessed 3 October 2013). However, with reference to pharmaceuticals and agricultural products, the due date for compliance by LDCs, which was extended by the Doha Declaration to 2016 [see Art 66 (1) of TRIPS], has not changed.

29 Article 24 of the SADC Protocol on Trade, 1996.

Botswana is a member of the WTO,[30] and by extension, a signatory to the TRIPS Agreement, which allows members to adopt their own intellectual property (IP) legislation, inclusive of patent laws, in such a manner that IP rights do not become barriers to legitimate trade,[31] while at the same time ensuring that 'technology is transferred and disseminated in a manner conducive to social and economic welfare.'[32] It is important here to point out that in the 1980s, patents began to be viewed positively as property rights whose protection was necessary for free trade.[33] Prior to that, patents were viewed as anti-competitive grants of privilege.[34] The elevation of patent rights to the trade sphere gave rise to some of the problems currently experienced in the context of access to medicines.[35]

In order for IP legislation to be conducive to social and economic welfare, the TRIPS Agreement allows members some room to legislate in the context of their socio-economic and other unique characteristics by providing for certain flexibilities.[36] These flexibilities are confirmed by the fact that many industrialised countries developed their intellectual property rights (IPRs) protection on the basis of what may be termed 'their national interest'.[37] Nothing therefore prevents SADC members, and developing countries in general, from coming up with context-specific IP reforms as Botswana has done.

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30 Botswana joined the WTO on 31 May 1995, see WTO, 'Understanding the WTO: The Organisation Members and Observers' <https://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm> accessed 26 June 2017.

31 See preamble to the TRIPS Agreement para 1.

32 Article 7 of the TRIPS Agreement.

33 Stephanie T Rosenberg, 'Asserting the Primacy of Health over Patent Rights: A Comparative Study of the Processes that Led to the Use of Compulsory Licensing in Thailand and Brazil' (2014) 14 Developing World Bioethics 83 at 83.

34 ibid.

35 This is starkly illustrated by the fact that IP negotiations, most of which could easily be concluded at the multilateral level under the auspices of the World Intellectual Property Organisation (WIPO) have now been conveniently shipped away to inappropriate forums such as Economic Partnership Agreements (EPAs). A good example of this phenomenon is illustrated by the Jordan–United States Free Trade Area (Jordan–US FTA), whose principal agreement curtails members' ability to use compulsory licences. For a full analysis of the access to medicines implications of the Jordan–US FTA, see Hamed El-Saidi and Mohamed El-Saidi, 'TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons for the Jordan-United States Free Trade Agreement' (2007) 10 The Journal of World Intellectual Property 438 at 438–475.

36 These flexibilities will allow members to pass IP legislation that does not militate against major social and economic activities of a country, such as its ability to use patented drugs for national emergencies.

37 Sigrid Sterckx, 'Patents and Access to Drugs in Developing Countries: An Ethical Analysis' (2004) 4 Developing World Bioethics 58 at 59.

The TRIPS Agreement provides for exceptions to patentability.[38] These exceptions form the core of what has generally come to be characterised, in access to medicines parlance, as 'TRIPS flexibilities'. The most commonly cited flexibilities, relevant for Botswana in order to improve access to medicines, are: patentable subject matter;[39] patent examinations;[40] pre- and post-grant patent opposition;[41] parallel imports;[42] compulsory licences; and government use of patents,[43] data protection[44] regulatory exceptions,[45] research and experimentation exceptions,[46] and the use of competition law.[47]

The above flexibilities were introduced to enable WTO members to take full advantage of the TRIPS Agreement in the local context by adopting IP legislation that suits each country's individual needs. As early as the year 2000, the United Nations Commission on the Promotion and Protection of Human Rights acknowledged, through a resolution, that there was an apparent conflict between the TRIPS Agreement, on the one hand, and human rights (including the right to health) on the other.[48] This acknowledgement would later be based on the fact that one third of the world population lacks access to essential medicines.[49] The largest portion of this group came from developing countries such as Botswana.

This article gauges the extent of Botswana's incorporation of some of the abovementioned flexibilities and comes to the conclusion that despite some notable criticisms to the contrary, in the SADC region Botswana is a good example of progressive patent law reform practice which other SADC members should look up to. This model lesson is embodied in Botswana's Industrial Property Act of 2010, which incorporates most of the TRIPS flexibilities in the context of the country's prevalent diseases. It

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38 See Arts 30 and 31 of TRIPS. Art 30 provides for exceptions to rights conferred in general terms by providing for limited exceptions when patents may be overridden provided such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking into account interests of third parties. On the other hand, Art 31 provides for 'other use without authorization of the right holder' in the context of issuing compulsory licences and government use orders.

39 Article 27 of TRIPS.

40 These are not expressly provided for by the TRIPS Agreement but are provided for in s 34 of South Africa's Patents Act.

41 Not provided for in both the TRIPS Agreement and the Patents Act. However, the TRIPS may be regarded as indirectly providing for this in Art 27 wherein it clearly delimits what is patentable and what is not. The implication is that Art 27 may be used to prevent the patenting of inventions that do not meet with basic requirements for patentability.

42 Article 6 of TRIPS.

43 Article 31 of TRIPS.

44 Article 39 of TRIPS.

45 Article 30 of TRIPS.

46 Articles 30 and 31 of TRIPS.

47 Article 31(k) of TRIPS.

48 Sterckx (n 37) 59.

49 Hans V Hogerzeil and Zafar Mirza, 'Access to Essential Medicines as Part of the Right to Health' (2011) The World Medicines Situation 1 at 1.

is also important to reiterate and state the axiom that 'one of the important determinants of access to drugs is the working of the patent system.'[50]

In order properly to contextualise this article, a brief discussion of the tenets of patent law is required and, therefore, an account of the basic aspects of patent law is presented immediately below. This is followed by a discussion of how Botswana has domesticated some TRIPS flexibilities into its relevant law. Botswana's domestication of TRIPS flexibilities is not completely flawless. Therefore, a critique of the process followed is necessary and is conducted in the penultimate section of this article. Because this article is about Botswana's domestication of TRIPS flexibilities and what other SADC members can learn from the experience, these lessons are outlined in the penultimate section. In its conclusion, the article reiterates that, while Botswana's experience may be a modest example of laudable domestication, its likely impact on access to medicines is sufficiently significant to warrant characterisation as a positive lesson, from which—in the present context—other SADC members can learn a lot.

A BRIEF PRIMER ON THE LAW OF PATENTS

There is a wide variety of national patent laws unique to each country.[51] In this section of the article, I offer a general outline of patent law rather than discussing patent law in the context of a particular jurisdiction. However, where there are obvious jurisdictional differences, they are briefly highlighted.

A patent can be granted for twenty years to an inventor or the first person to file for a patent.[52] It is granted for products that are new;[53] involve an

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50 Sterckx (n 37) 58.

51 Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines* (OUP 2007) 19.

52 Whether patents should be granted to the first to file, or the first person to invent is one of the raging patent law debates. The United States used to grant patents to the first person to invent [Hestermeyer (n 51) 19]. However, this position has since changed with effect from 16 March 2013 when United States Code Title 35—Patents was amended by the new section 35 USC 102(a)(1) of the same code (United States Patents and Trademark Office <http://www.uspto.gov/patents/law/index.jsp> accessed 5 July 2014). The new law now provides for a 'first-inventor-to file' doctrine implying that the priority date for a patent application will now be the date on which the application for a patent was filed with the relevant office. This position is now similar to the one obtaining in South Africa (see s 31 of the South African Patents Act 57 of 1978).

53 New patents are those that have the attribute of being 'non-obvious' such as was aptly explained in the case of *Roman Roller CC and Another v Speedmark Holdings (Pty) Ltd* 1995 BP 199 (A) 212–221. The issue of obviousness will generally be determined by the Court as held in the cases of *Gentiruco AG v Firestone South Africa (Pty) Ltd* 1971 BP 58 (A) at 92 and *Ensign-Bickford (South Africa) (Pty) Ltd and Others v AECI Explosives and Chemicals Ltd* 1998 BIP 271 (SCA) 281C-D.

inventive step;[54] and are capable of industrial application;[55] by disclosing the invention to the patents office in a way that a person skilled in the art will be able to carry out the invention.[56] For access to medicines, the requirements for patentability are important in preventing a proliferation of evergreen patents that may stifle the growth of the generic drug industry.[57] The importance of novelty as a requirement for patentability can be traced back to 16th century England, as emerges from the leading case of *Darcy v Allen*.[58] In this case, it was held that patent monopolies were only to be granted for products previously unknown in England. It was further held that patent monopolies posed the danger of the patentees demanding unreasonably high prices for the products.[59] After establishing the rudiments of patentability, which continue to inform the intellectual property laws of the world today, the Statute of Monopolies,[60] widely regarded as the first statutory expression of English Patent law, lasted for 200 years.[61]

In South Africa, the term of a patent granted under the current Patents Act, 1978, is twenty years from the date on which the complete specification is lodged at the Patents Office, subject to the payment of the prescribed renewal fees.[62] The term of a patent granted under South Africa's repealed Patents Act, 1952,[63] was sixteen years from the date on which the complete specification was lodged at the Patents Office.[64] However, an extension of that term was possible on application to the Commissioner of Patents[65] on the ground of inadequate remuneration and/or war loss during the normal term.

The typical application for a patent consists of a description of the invention (specification) and the language claiming precisely the technology that was invented and that will be the subject of the patent rights—the

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54 The US Patents Act requires the invention to be non-obvious.

55 The South African Patents Act requires that the invention must be capable of being used or applied in trade, industry and agriculture (s 25 of Act 57 of 1978).

56 See generally s 25 of the South African Patents Act 57 of 1978.

57 Ever greening is the notorious practice of filing applications for minor improvements to existing patents in order to keep competitors at bay, and in the context of medicines, to prevent the development and entry of generic drugs into the market.

58 (1603) 72 Eng. Rep 830; 74 Eng. Rep 1131; 77 Eng. Rep 1260. The products at stake were playing cards.

59 *Darcy v Allen* at 831.

60 English Statute of Monopolies of 1623, 21 Jac. 1 c. 3. The full text of the legislation as originally passed is available at <http://www.ipmall.info/hosted_resources/lipa/patents/English_Statute1623.pdf> accessed 7 March 2013.

61 The Venetian Enactment of 19 March 1474, which appeared years before the English Statute of Monopolies established the foundation for the world's first patent system.

62 Tim D Burrell, *Burrell's South African Patents and Design Law* (3 edn, LexisNexis 1999) 3. This is specifically provided for in s 46 of the Patents Act 57 of 1978.

63 Act 37 of 1952.

64 Repealed Patents Act 37 of 1952 s 28.

65 Patents Act 57 of 1978 s 45.

claims.[66] The claims are for the purposes of defining the patentee's rights and not for instructing the public; the latter function falling to the body of the specification.[67] The claim or claims must relate to a single invention, must be clear, and must be fairly based on the matter disclosed in the specification.[68]

Patent offices are, generally, national institutions.[69] They usually examine whether the requirements for patentability under their national laws have been fulfilled;[70] grant the patent if that is the case; and publish the patent application.[71]

Product patents confer the right to prevent third parties who do not have the patentee's consent from making, using, offering for sale, selling, or importing for these purposes, the patented product.[72] Similarly, process patents confer the right to prevent third parties who do not have the patentee's consent from using the process and using, offering for sale, selling, or importing for these purposes a product obtained directly by the patented process.[73] Patent rights shall be enjoyed without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.[74] Anyone engaging in one of the proscribed activities with respect to product and process patents in the manner claimed in the patent faces damages and injunctive relief.[75]

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66 Hennie Klopper and others, *Law of Intellectual Property in South Africa* (LexisNexis 2011) 293.

67 See the following South African cases, *Moroney v West Rand Engineering Works (Pty) Ltd* 1970 BP 452 (T); *Letraset Ltd v Helios Ltd* 1972 BP 243 (A); *Deutsche Gesellschaft Fur Schadlings bekampfung MB v Coopers (South Africa) (Pty) Ltd* 1973 BP 447 (CP) and *Selas Corporation of America v The Electric Furnace Company* 1982 BP 442 (A).

68 Section 32(4) of the South African Patents Act 57 of 1978. In terms of s 10(4) South Africa's repealed patents Act 37 of 1952, in addition to being 'clear', the claims were additionally required to be 'succinct', despite the obvious tautology.

69 There are currently three major regional patent offices that grant patents that are treated like national patents of the member states after they have been granted: The European Patent Office (EPO), the African Regional Industrial Property Organisation (ARIPO), and the *Organisation Africaine de la Propriete Intellectuelle* (OAPI).

70 Not all countries provide for such examination. Some, like South Africa, have registration systems that only examine the formal compliance of the application with the requirements for patentability; with the process of objecting to the patentability of the invention opening after the patent has been published in the Patents Journal. The examination system is common in the US, Germany and the European system.

71 Commonly, the application is usually published a certain time after filing, whether by that time the patent has been granted or not.

72 Hestermeyer (n 51) 19.

73 ibid.

74 Article 27.1 of the TRIPS Agreement.

75 Hestermeyer (n 51) 20.

Process patents[76] may be granted for a patentable process.[77] Such patents similarly confer the right to prevent third parties who do not have the patentee's consent from using the process and using, offering for sale, selling, or importing, for these processes, a product obtained directly by the patented process.[78]

Product patents are more desirable for the patentee than process patents because product patents grant the patentee market exclusivity for the product, whereas the owner of a process patent faces competition from others producing the same product by a different process.[79]

Infringements of product patents[80] are easier to prove than those of process[81] patents because in the case of the former, the patentee can see and point out the infringing product which is produced without prior authorisation.[82] The corollary of the above reasoning is that an inventor of a product will easily identify the same or similar products that has adopted the main integers of the original invention without his or her prior authorisation. The burden is, therefore, on the inventor to prove that the impugned product infringes on his or her existing patent. However, in process patent suits, courts have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process.[83] The burden of proof is reversed in these specific circumstances.[84]

Some countries impose the local-working requirement as a condition for the granting of a patent.[85] This requirement compels the inventor to

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76 Burrell (n 62) 38–39.

77 Previously in the United States of America, there used to exist a misguided notion, fuelled by the dictum in the often cited case of *Cochrane v Deener* 94 US 780, 788, 24 L ed 139 (1877) cited in Burrell (n 62) at 36 and 39, that in order for a process to be patentable, it must act on a substance.

78 Article 27.1 of TRIPS.

79 It is also easier to prove the infringement of a product patent, as anyone selling the product without a licence from the patentee is clearly infringing. Many countries resolve this difficulty for process patent holders by reversing the burden of proof; so that the defendant will have to prove that it is using a different process (see Art 34 of the TRIPS Agreement). However, the strong possibility remains that patentees might be reluctant to commence a lawsuit, because they are uncertain whether the defendant makes use of the patented process.

80 In terms of Art 28.1(a) of TRIPS, where the subject matter of a patent is a product, the patent owner shall have the right to prevent others from the acts of making, using, offering for sale, selling or importing the product.

81 Article 28.1(b) of TRIPS provides that where the subject matter of a patent is a process, the patent owner must be conferred the exclusive rights to prevent others from the act of using the process, and from the acts of: using, offering for sale, selling or importing the product obtained directly by the process.

82 Article 34 of TRIPS read together with Art 28 of same.

83 Article 34.1 of TRIPS.

84 See Articles 1.2 and 1.3 of TRIPS read together with the two antecedent conditions listed in Art 1(a) and (b) of TRIPS.

85 See generally Michael Halewood, 'Mandatory Working and Compulsory Patent Licensing' (1997) 35(2) Osgoodehall Law Journal at 245 and the countries cited at (n 3). The author convincingly argues that such mandatory requirements are TRIPS compliant.

manufacture the product or use the process within the country that grants the patent.[86] As a concept allied to the process of granting patents, the local-working requirement has its origins in French law.[87] The commercial exploitation of certain inventions may be prevented by WTO members in order to: protect public order or morality; protect human, animal or plant life or health; or to avoid serious prejudice to the environment; provided such exclusion is not made solely because the exploitation is prohibited by domestic law.[88]

The General Agreement on Tariffs and Trade of 1947 (now GATT 1994) makes express reference to intellectual property rights by providing that trade restrictions may be imposed if they are necessary to secure compliance with laws and regulations which are not inconsistent with the GATT.[89] Such laws include those relating to the protection of patents, trademarks, copyrights, and deceptive practices.[90] A similar provision, couched in almost identical language, is found in the SADC Protocol on Trade,[91] which provides that members may adopt and enforce measures that are necessary to '*protect intellectual property rights, or to prevent deceptive trade practices.*'[92]

Despite patents allowing the inventor a twenty-year monopoly over an invention, it is possible to use a patent without the authorisation of the right holder.[93] One of the ways through which such use may be made possible is the issuing of compulsory licences.[94] Compulsory licences are very important for access to medicines in the context of Botswana's IP law reform,[95] and may generally be used sparingly and only in situations where there are no other alternative ways of improving access to medicines. Where the patentee wishes to gain commercial advantage by allowing others to use his invention with permission, then voluntary licences may be granted to those who seek them.[96]

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86 See on a related note, Paul Champ and Amir Attaran, 'Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute' (2002) 27 Yale J of International Law 365.

87 Specifically the French Patents Act of 1791 and supplemented by a Regulation dated 25 May 1791, obliging the patentee to work his invention in France within two years of the patent grant, failing which the patent could be revoked.

88 Article 27.2 of TRIPS.

89 Article XXIV(d).

90 ibid.

91 SADC Protocol on Trade <http://www.sadcstan.co.za/Secure/downloads/protocol.pdf> accessed 7 September 2013.

92 ibid at Art 9(d) [emphasis added].

93 See Art 31 of TRIPS.

94 See the conditions for the grant of such licences as categorised in paras (a)–(l) of the TRIPS Agreement. In South Africa, compulsory licences are regulated by the provisions of sections 55 and 56 of the Patents Act 57 of 1978.

95 See the specific discussion of Botswana below.

96 Article 28.2 of TRIPS.

Having discussed the rudiments of patent law in the context of access to medicines generally, it is now appropriate to turn to a discussion of specific aspects of Botswana's IP law reform regime sympathetic to access to medicines.

BOTSWANA'S PATENT LAW LANDSCAPE IN CONTEXT: AN OVERVIEW

Botswana is a member of the WTO which is the multilateral body dealing with international trade and trade-related issues. The WTO sets minimum standards for trade in goods and services, as well as other trade-related issues such as intellectual property rights (IPRs) which are regulated by the TRIPS Agreement of 1994. The TRIPS Agreement has been subject to intense debate and criticism, centred, in the main, on concerns by developing countries that the agreement has failed to promote their efforts to deliver much-needed medical drugs to their citizens.[97]

However, translating the content of international agreements into actual domestic law, practice, and policy is subject to a number of constraints. In the case of TRIPS Agreement's flexibilities, the majority of SADC member states have, due to various constraints, not actually translated these flexibilities into law and practice in order to enhance access to essential medication within their jurisdictions.

In the context of the law of patents, it is important to note that Botswana is also a party to the following international/regional agreements: the Berne Convention;[98] the Harare Protocol (of the African Regional Intellectual Property Organisation (ARIPO));[99] the Lusaka Agreement (of the ARIPO);[100] the Paris Convention;[101] and the Patent Cooperation Treaty.[102]

The current patent law of Botswana is regulated by the Industrial Property Act (the Act),[103] which was assented to by the President on 26 April 2010 and came into operation on 31 August 2012.[104] As a recent piece of legislation, the Act is expected to be very TRIPS-compliant and incorporate most of the relevant flexibilities. This, however, is not necessarily the case as the expository account below shows.

The Act provides for the patentability of *new* inventions involving an *inventive step* and capable of *industrial application.* Further, such inventions

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97 Carlos M Correa, 'Protection and Promotion of Traditional Medicines: Implications for Developing Countries' (2002) <http://apps.who.int/medicinedocs/pdf/s4917e/s4917e.pdf> accessed 14 September 2014 [a study commissioned by the Rockefeller Foundation].

98 Since 15 April 1998.

99 Since 1985.

100 Since 1985.

101 Since 15 April 1998.

102 Since 30 October 2003.

103 Act No 8 of 2010.

104 See Industrial Property Act (Date of Commencement) Order, 2012, (GG) Botswana <http://www.wipo.int/wipolex/en/text.jsp?file_id=277945> accessed 6 November 2013.

may relate to both products and processes.[105] In its interpretation section, the Act differentiates between an 'invention' and a 'patent'. In this regard, it defines an 'invention' as an idea of an inventor which, in practice, may be used as a solution to a specified problem.[106] On the other hand, a 'patent' is simply defined as the document issued to protect the invention under the Act.[107] Patents may be granted for twenty years[108] from the date of filing an application.[109] The Act provides for general exclusions from patentability. These include methods of treatment of the human or animal body, therapeutic equipment, and diagnostics.[110] Also excluded from patentability are inventions the exploitation of which is necessary to protect public order or morality, including the protection of human or animal health, plant life, or to avoid prejudice to the environment.[111] New uses of patents are not specifically excluded in the Act and one may, therefore, conclude that the Act is unfortunately silent on this aspect, with obvious detrimental results for access to medicines for the citizens of Botswana.

From an access to medicines perspective, the delimitation of patentable subject matter and exclusions does not raise any major concern. The law is robust enough in the specific regard to prevent the patenting of undeserving patents, a practice currently bedevilling South Africa through 'ever greening'.[112]

It is noteworthy that the Act provides for pre-grant opposition[113] to patents and the examination of patents for technical quality.[114] Once a patent application has been published in the Patents Journal,[115] members of the public, including those with the technical know-how in the field to which the patent relates, may oppose that grant of the patent on a number of listed grounds.[116]

On a related and positive note for access to medicines, the Registrar of Patents is enjoined to cause a patent to be examined for compliance with the requirements of the Act.[117] If this provision in the Act is read in isolation, one is left with the disappointing impression that the examination contemplated

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105 Section 8(1)–8(2).
106 Section 2 of the Act.
107 ibid.
108 Section 28(1) of the Act.
109 Section 20 of the Act provides that the filing date is the date of application.
110 Section 8(1)(a) of the Act. This is based on Art 27(3) of TRIPS.
111 Section 8(1)(b) of the Act.
112 See for example Phillip de Wet and Sarah Wild, 'New Drug Policy is Patently High Risk' *Mail & Guardian* (Johannesburg 21 October 2014) <http://mg.co.za/article/2014-10-30-new-drug-policy-is-patently-high-risk> accessed 31 October 2014.
113 See section 21 of the Act
114 See section 22 of the Act.
115 Section 21(a) of the Act.
116 Section 21(5)(a)–(c). One of the grounds relevant to access to medicines may be that the invention does not meet the requirements of patentability as specified in the Act.
117 Section 22(1) of the Act.

relates to formal compliance with the Act only. However, a further reading of the Act in the following subsection makes it clear that a formal technical examination, which may be outsourced to persons or institutions (such as universities) appointed by the registrar, is contemplated.[118] The requirement that the Minister may in certain circumstances through Regulations, prescribe the categories of invention in respect of which an examination shall not cover the requirements of novelty and inventive step, is retrogressive. The net effect of this provision is to condone weak patents and introduce ever greening via the back door.[119]

Coming to the TRIPS Agreement flexibilities that may yield positive results for access to medicines, it is emphatically noted that the Industrial Property Act incorporates almost all of the important flexibilities.[120]

On the exhaustion of patent rights and the use of parallel importation, Botswana adopts the international exhaustion of rights regime which allows parallel imports.[121] Very specifically, the pertinent provision regards acts in respect of articles that have been put on the market in Botswana or abroad by the patentee or another person acting with the patentee's consent as exceptions to rights conferred by a patent.[122] This implies that Botswana is permitted by its own law to import cheap medicines from international and regional markets as long as the product has been placed on such markets by the patentee himself or by someone acting on behalf of the patentee with his or her permission. In lay terms, the provision allows for comparative shopping which is likely to yield positive access to medicines for Botswana's poor citizens in need of affordable essential medicines.

Patents may also be used for research purposes[123] by non-right holders as long as the acts performed are for experimental purposes relating to the subject matter of the invention, or are acts performed solely for academic, scientific research, and educational and teaching purposes.[124]

Acts conducted for private non-commercial purposes are also allowed as exceptions to the rights conferred.[125] Private non-commercial players in the context of access to medicines may be civil society organisations, churches, foundations, and donors like the Bill and Melinda Gates Foundation or, in

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118 Section 22(3) of the Act.

119 Section 22(2) provides that the Minister may exempt some inventions from enquiries/examinations relating to novelty and inventive step. This creates the impression (correctly so) that examinations will, under normal circumstances where Ministerial intervention is not contemplated, cover technical issues relating to novelty and inventive step.

120 As will be elaborated upon in ensuing paragraphs, the Act provides for parallel imports, research exceptions to patentability, early working (*bolar* exceptions), private non-commercial use of patents, compulsory licences as some aspects of Art 31*bis* of TRIPS.

121 Section 25 of the Act.

122 Section 25(1)(a) of the Act.

123 Section 25(1)(c).

124 Section 25(1)(j).

125 Section 25(1)(j).

the context of South Africa, non-governmental organisations such as Doctors without Borders (MSF), Section 27, and the Treatment Action Campaign (TAC). The provision for private non-commercial use as an exception to patent rights is a welcome inclusion and a first for the SADC region.

The *bolar* and regulatory exceptions, which ensure that generic versions of the patented product are available on the market immediately, or within a reasonable time after the expiry of the patent,[126] are included in the provision dealing with acts done in respect of the patented invention for purposes of compliance with regulatory marketing approval procedures for pharmaceutical, veterinary, agrochemical, or other products subjected to such procedures.[127] These procedures are correctly characterised as permissible exceptions to patentability.

Finally, the Act has very extensive provisions on compulsory licences. Broadly speaking, compulsory licences may be issued for: public interest or for competition;[128] importing patented products in the context of Article 31*bis* of the TRIPS Agreement;[129] to remedy a failure to exploit the patent;[130] and to deal with dependent patents.[131]

Public interest grounds for the issuing of compulsory licences include national security, nutrition, health, development, and other vital sectors of the Botswana national economy.[132] In any of the above instances, the Minister may, without the patentee's consent, but after consulting him or her, authorise a government agency or another person to exploit the patent subject to the payment of adequate remuneration to the patentee.[133] If the compulsory licence is issued in response to anti-competitive practices,[134] the determination/calculation of the remuneration will have to take the economic value of the exploitation of the patent into account.[135] It is also important to take note of the fact that in terms of Botswana's patent law, in cases of national emergency or circumstances of extreme urgency (which are not defined), there is no need for the applicant for a compulsory licence first to have requested a voluntary licence on reasonable terms.[136]

On a further positive note, Botswana has made a modest attempt at domesticating the WTO August 2003 Decision and the waiver thereto, now encapsulated in Article 31*bis* of the TRIPS Agreement, which Botswana has

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126 Amendments to the South African Patents Act of 1978 in 2002 introduced *bolar* provisions.
127 Section 25(f) of the Act.
128 See generally, s 31 of the Act.
129 Section 32 of the Act.
130 Section 33 of the Act.
131 Section 34 of the Act.
132 Section 31(1)(a) of the Act.
133 Section 31(1) of the Act.
134 Section 31(1)(b).
135 Section 31(2) of the Act.
136 Section 31(10) of the Act.

also ratified.[137] To show that the drafters of the patent law were aware of the existence and importance of Article 31*bis*, when compulsory licences are issued in the public interest,[138] the 'exploitation of the patented invention… 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.'[139] Additionally, the government of Botswana may issue a compulsory licence to a third party to import patented products such as *pharmaceutical generic drugs* from any legitimate source without the approval of the patentee, for public interest or in situations of a failure to supply the market.[140] In this context, the importation of the product shall be solely for the public non-commercial use within Botswana, except where paragraph 1 or 3 of Article 31*bis* of the TRIPS Agreement applies.[141] Therefore, the whole of section 32 of the Industrial Property Act of Botswana domesticates the provisions of Article 31*bis* of the TRIPS Agreement. This should be welcomed by access activists and regarded as a valuable lesson for fellow SADC members.

Article 31*bis* was formally built into the TRIPS Agreement after acceptance of the Protocol amending the TRIPS Agreement by two-thirds of the WTO's members.[142] The amendment took effect on 23 January 2017 and replaced the 2003 waiver for members who had accepted the amendment.[143] For those WTO members who are yet to ratify the amendment, the 2003 Decision (waiver) still applies.[144]

Although a limited number of SADC members, including South Africa, have recently accepted and ratified the amendment,[145] others are yet to signal their acceptance. The period for the acceptance of the protocol amending the TRIPS Agreement has, however, been extended by the WTO for the fifth time to 21 December 2017.[146]

Article 31*bis* of the TRIPS Agreement provides for the harnessing of economies of scale for purposes of enhancing the purchasing power for

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137 Botswana ratified the permanent amendment to the TRIPS Agreement on 18 June 2014.

138 Under section 31(1)(a).

139 Section 31(3).

140 Section 32(1)(a)–(b).

141 Article 32(2).

142 See WTO, 'Intellectual Property: Trips and Public Health Amendment of the TRIPS Agreement' <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 12 March 2017.

143 ibid.

144 ibid.

145 South Africa accepted the Protocol amending the TRIPS Agreement on 23 February 2016. For a full list of other WTO members who have thus far accepted the Protocol and the dates of their acceptance, see WTO, 'Intellectual Property: TRIPS and Public Health Amendment of the TRIPS Agreement' <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 12 March 2017.

146 See WTO, 'General Council Decision WT/L/965 of 2 December 2015' <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 12 March 2017.

the facilitation of local production of pharmaceuticals.[147] This provision is important for Botswana and the SADC region in that it will facilitate the regional production of pharmaceuticals for use within the region. Briefly, the relevant paragraph provides that Article 31(f) of the TRIPS Agreement[148] will not apply if a compulsory licence is issued by a developing or LDC member that is party to a regional trade agreement in which at least half of the membership consists of LDCs, in order to export the product to fellow members of the regional group that share the health problem in question.[149] Slightly above fifty per cent of SADC members are LDCs[150] and the region, therefore, qualifies to take advantage of provisions in order to improve access to medicines.

The above provision must obviously be read together with the accompanying Annex to the TRIPS Agreement, calling for the facilitation of local production of pharmaceutical products through regional patents.[151] It is recommended that the SADC members take advantage of this flexibility and consider a regional compulsory licence or regional pharmaceutical manufacture of targeted medicines.[152] It is, however, important to mention that the above proposal will not see the light of day if no technical capacity is forthcoming from developed WTO members and other intergovernmental organisations, such as the World Intellectual Property Organisation (WIPO).[153]

At face value, the above outline shows that Botswana's recent IP law reforms do take into account the tenets of the TRIPS Agreement and should be applauded as a positive intervention. However, there are some grey areas and mistakes that need to be rectified; hence the brief critique immediately below.

DOES BOTSWANA'S DOMESTICATION OF TRIPS FLEXIBILITIES STAND UP TO CRITICAL SCRUTINY?

On a negative note, the major weakness of the Industrial Property Act is the provision dealing with offences and penalties.[154]

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147 Article 31*bis* para 3.

148 It will be recalled that Art 31(f) of TRIPS provides that compulsory licences can only be used to avail products for the predominant supply of the domestic market of the country authorising the licence.

149 Article 31*bis* para 3.

150 Ten of the sixteen SADC member states, namely, The Union of the Comoros, Zambia, Malawi, Angola, Mozambique, Seychelles, Swaziland, Lesotho, Democratic Republic of Congo and Tanzania are classified as LDCs.

151 Paragraph 5 of the Annex to the TRIPS Agreement.

152 See for specific details the SADC Strategy on Pooled Procurement (n 24).

153 This issue is specifically acknowledged in para 5 of the Annex to the TRIPS Agreement.

154 Generally provided for in s 134 of the Act.

The Act proscribes the intentional or wilful performance of any act that constitutes an infringement as defined in the Act.[155] Additionally, any person who 'commits an offence shall be sentenced, on conviction, to a fine of not less than P2 000 but not more than P5 000, or to imprisonment for a term of not less than six months but not more than two years, or to both.'[156] To add to the chilling effect of the provision, if a person commits an offence or unlawful conduct for which no penalty has been specified, that person shall be sentenced to a fine of between P2 000 and P5 000, or to imprisonment for at least six months but not more than two years, or to both.[157]

Criminalising patent infringement, whether wilful or not, does not augur well for access to medicines. The criminalisation will in all likelihood have a chilling effect which will stifle or kill the spirit of research into new drugs based on existing patented ones (generics). The provision criminalising patent infringement is TRIPS-plus, uncommon, and discourages innovation and flexible procurement of drugs due to the fear of criminal sanction. The provision is, however, sanctioned by the TRIPS Agreement in cases of 'wilful infringement on a commercial scale'[158] and, therefore, it may be argued that the criminalisation of patent infringement does have a somewhat textual basis in the TRIPS Agreement. While the Act provides for exceptions to patent rights based on research and regulatory (*bolar*) exceptions as mentioned previously, these provisions will be rendered futile or nugatory by the penalty provisions criminalising patent infringement. If the Botswana parliament is considering amending the Industrial Property Act, section 134 should be amended. Section 134 is bad law from an access to medicines perspective, and fellow SADC members are discouraged from following in Botswana's footsteps in this specific respect.

ARE THERE ANY IMPORTANT THEMATIC LESSONS FOR SADC MEMBERS FROM BOTSWANA?

Fellow SADC members can learn from both the positive and the negative aspects of Botswana's Industrial Property Act and then position themselves accordingly.

On a positive note, Botswana's Industrial Property Act and Regulations[159] domesticate almost all of the important TRIPS Agreement's flexibilities. The specific flexibilities are: compulsory licences; the adoption of an

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155 Section 134(6). This will cover infringing the rights conferred by patents as outlined in section 24 subject to exceptions to the rights conferred as outlined in s 25. Additionally, with reference to other IP forms, the penalty provisions will cover the rights of an owner of a registered design (s 53) and acts that amount to infringement of such rights (s 55); and the rights of owners of registered geographical indications and their infringement [s 111(3)].

156 Section 134 (6) of the Act.

157 Section 134 (7) of the Act.

158 Article 61 of TRIPS.

159 The promulgation of the Industrial Property Act Regulations 2012 was done through Statutory Instrument 70 of 2012.

international exhaustion regime that permits parallel imports; provisions allowing pre- and post-grant patent opposition; patent examinations (both formal and technical); and a list of exclusions from patentability such as diagnostics, therapeutic equipment, and methods of treatment. Botswana took the initiative to evaluate its laws in light of the TRIPS Agreement's flexibilities at a workshop held in Gaborone from 25 to 27 March 2013 and compiled a list of the flexibilities[160] together with an honest evaluation of the country's prospects.

Due to their relevance and practical nature, the recommendations of the workshop are reiterated here as lessons for other SADC countries.

According to the government of Botswana, the new law (encapsulated in the Act and the Regulations) is positive in many respects.[161] The provisions on exclusions from patentability; the patentability criteria; the patent opposition; compulsory licences; the use of competition law; border measures; and the criminalisation of patent infringement, are cited and self-critiqued.[162]

The provisions of Botswana's Industrial Property Act on exclusions from patentability[163] are based on the text of the TRIPS Agreement,[164] which excludes new uses of known substances.[165] However, the Industrial Property Act is not explicit enough to prevent ever greening.[166] The Registrar of Patents will therefore have to develop practical guidelines to ensure that patents are examined when applications for additional patents on the same subject matter are submitted.[167] This will limit ever greening. It has been reported elsewhere that many SADC members provide for exclusions from patentability in their domestic laws. SADC members can, therefore, learn from Botswana's omission by including guidelines that ensure the exclusion of evergreen patents.

The second lesson that SADC members can learn from Botswana's experience and self-evaluation is on the subject of patentability criteria and what amounts to a patent.[168] In its self-evaluation, Botswana observes, quite correctly, that while her laws provide for acceptable patentability criteria,[169]

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160 See Republic of Botswana, 'The Implementation of Trade Related Aspects of Intellectual Property Rights (TRIPS) Flexibilities in the National Intellectual Property Legislation for Strengthening Access to Medicines in Botswana' (2013) *UNDP-SARPAM-Botswana Government Workshop Publication* 10–11.

161 Government of Botswana, 'The Implementation of TRIPS Flexibilities in National IP Legislation for Strengthening access to Medicines in Botswana' (2013) Action Brief 1–32.

162 ibid.

163 See s 9 of the Industrial Property Act.

164 Specifically Arts 27 (2) and 27 (3) of TRIPS.

165 Government of Botswana (n 161) 13.

166 ibid.

167 ibid.

168 For clarity on what amounts to a patent and the applicable patentability criteria, see Arts 1 and 27.1 of the TRIPS Agreement.

169 See s 8 of the Industrial Property Act.

it may not be possible to examine some patents for compliance with the requirements for patentability because of the Ministerial exclusion[170] which has been characterised earlier as militating against access to medicines.[171] Once again, fellow SADC members may learn from Botswana that the exclusion of certain patents from fulfilling technical requirements relating to novelty and an inventive step through a Ministerial decree is undesirable and counterproductive to strict patentability criteria for patent examination. Such an approach does not limit frivolous patents or ever greening and should be avoided.[172]

While SADC members are encouraged to introduce patent examinations into their domestic legal systems, technical and financial capacitation of the Office of the Patent Examiner will be required.[173] This again is an important lesson for fellow SADC members intending to reform their domestic patent laws in that specific regard. South Africa has widely been reported as moving towards the adoption of a substantive patent examination system in the foreseeable future.[174]

While Botswana's Industrial Property Act provides for pre-and post-grant patent opposition,[175] the Regulations do not have provisions detailing the procedure to be adopted when these forms of opposition are to be used.[176] As matters stand, the Act on this aspect (pre and post-grant opposition) is a paper tiger and it will not be possible to enforce it in the absence of guiding Regulations. Pre- and post-grant patent opposition measures should be carried out in a fast, accessible, and cost-efficient manner[177] in order to maximise on the use of the TRIPS Agreement's flexibilities for the benefit of access to medicines. The lesson for fellow SADC members here is that they should not simply incorporate the TRIPS Agreement's flexibilities in their pieces of legislation for incorporation's sake. Rather, the law must be given 'the teeth with which to bite' in a practical context so that statute books are not populated by laws of straw.

Some SADC members, especially LDCs, have passed IP Acts prematurely and the Acts have tied their hands when it comes to accessing cheap generics.[178] This premature promulgation of legislation may be due to the pressure imposed by international organisations like WIPO, trading partners, the donor community, and even ill-informed knee-jerk reactions

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170 Section 22(2) of the Act.
171 See (n 119).
172 Government of Botswana (n 161) 13.
173 Republic of Botswana (n 160) 11.
174 De Wet and Wild (n 112).
175 See generally s 22 of the Act.
176 Government of Botswana (n 161) 13.
177 ibid 14.
178 Good examples of these are Seychelles, Lesotho, Swaziland, Tanzania and Zambia.

to international developments.[179] SADC members should resist these forms of pressure and regulate in the interest of the people rather than other stakeholders such as those mentioned above. This takes us to the next point, which is closely related to this one and is identified by Botswana's self-evaluation report as requiring immediate attention.

The self-evaluation report notes with concern that while one of the major recommendations of the workshop[180] was that the country should not negotiate the TRIPS Agreement's flexibilities away in free trade agreement negotiations, it is somewhat ironic, if not paradoxical, that Botswana was a party to the European Free Trade Area (EFTA) negotiations in her capacity as a member of the Southern African Customs Union (SACU).[181] The Agreement commits SACU members and EFTA countries to continue trade liberalisation, including harmonisation in IP matters.[182] If Botswana were progressively to design its IP laws in terms of the EFTA,[183] then this would reverse the gains made under the Industrial Property Act because EFTA members apply IPR laws with TRIPS-plus commitments.[184] This matter should be brought to the attention of fellow SADC members as a lesson on how not to negotiate in free trade agreements. Unlike Botswana, South Africa has made its position clear and will in future not sign TRIPS-plus free trade agreements.[185] In addition, South Africa has pledged to discourage other African countries from signing TRIPS-plus free trade agreements.[186]

Compulsory licences and government-use orders are well provided for in the Industrial Property Act.[187] This should be lauded as a positive development. The grounds for the granting of compulsory licences are broad enough to include almost all the eventualities, such as public health issues, non-working of patents, anti-competitive behaviour, dependent patents, abuse of patent rights, and situations of national emergency or extreme urgency. Very importantly, the Act makes provision for the

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179 A classic example of this is the fact that many SADC members have rushed to negotiate and sign Economic Partnership Agreements with the United States and the European Communities sometimes to the detriment of their citizens merely because it is the trendy thing to do.

180 See Republic of Botswana (n 160) 4.

181 Government of Botswana (n 161) 19.

182 See specifically Arts 1(c) and 26 of the Free Trade Agreement between the EFTA States and the SACU States, available at <http://www.sacu.int/docs/tradeneg/efta-fta2006.pdf> accessed 29 June 2016.

183 In terms of Art 26 of the Free Trade Agreement, members are expected to commit to a progressive harmonisation of their legal frameworks and review the intellectual property chapter (Art 26) within five years of the agreement coming into force. At the time of writing, no such review had been notified.

184 ibid.

185 See Draft National Intellectual Property Policy 2013: Invitation to the Public to comment on the National Policy on Intellectual Property (GG) 36816 (4 September 2013) 9.

186 ibid.

187 See specifically ss 25, 30, 31 and 32 of the Act.

granting of compulsory licences in the context of the WTO August 2003 Decision and the waiver, now captured under Article 31*bis* of the TRIPS Agreement. The expanded grounds for the granting of compulsory licences and the domestication of the provisions of Article 31*bis* of the TRIPS Agreement into the Industrial Property Act provide salutary lessons for SADC members. SADC members are urged to elaborate on and expand the grounds for the granting of compulsory licences. Very importantly, they are urged to domesticate Article 31*bis* of the TRIPS Agreement[188] and accede to it using the formal WTO process.

On another positive note, while Articles 51–60 of the TRIPS Agreement provide for border measures for suspected patent infringement, it is noteworthy that Botswana's Industrial Property Act does not provide for any border measures. In other words, it is silent on the issue. Border measures are prone to abuse by patent holders and not legislating for them is a positive omission. Fellow SADC members must seriously consider a cautious approach to incorporating border measures in their legislation, or not incorporating them at all in order to avoid the seizure of essential generic medicines at ports of entry by right holders or their representatives.

Finally, the TRIPS Agreement provides for the use of competition law by WTO members to remedy anti-competitive practices.[189] South Africa has thus far a chequered history of using the TRIPS Agreement's flexibility appropriately with positive results for access to medicines.[190] While Botswana's Industrial Property Act provides for compulsory licences to combat abuse of patents,[191] the Competition Act,[192] unfortunately, creates a blanket exclusion for the application of any of its provisions to IPR issues. While this exclusion does not in any way imply that anti-competitive conduct in patents will go unpunished,[193] the Competition Act must be the primary piece of legislation that can address such issues. Botswana's position is, therefore, clumsy and anomalous and should be remedied through an appropriate amendment of the relevant law. This issue should, therefore, be characterised as a reverse lesson for SADC on 'how not to legislate in competition matters'.

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188 Angola, the DRC, Mozambique, Malawi, Madagascar, the Union of Comoros, Swaziland and Zimbabwe are yet to ratify the permanent amendment to the TRIPS Agreement in the form of Art 31*bis*.

189 Articles 8.2, 31(k) and 40 of TRIPS.

190 See in this regard Tenu Avafia, Jonathan Berger and 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* (UNDP 2006) 35.

191 Article 31(1)(b) of the Industrial Property Act.

192 Botswana Competition Act of 2009.

193 At least the impugned conduct may be dealt with through s 31(1)(a) and 31(11) of the Industrial Property Act.

All SADC member states save for the Democratic Republic of Congo, Lesotho, Angola, and Mozambique, who have no competition legislation and policies, are encouraged to learn from Botswana's omission and not exclude competition legislation from application in IPR matters.

While the above expository account of Botswana's law has highlighted both positive and negative lessons for other SADC members, Botswana's praiseworthy piece of legislation has never been tested practically in an access to medicines litigation context.[194]

CONCLUSION

Botswana appears to have gone a step further by updating her IP laws and bringing them in line with the recent developments at the WTO level. Such developments include the domestication of some aspects of Article 31*bis* of the TRIPS Agreement and a number of express references to importing generics. This is depicted by the country's honest self-evaluation, which identifies weaknesses in the law and suggests appropriate remedial action. This article does not only commend Botswana's recent IP law reform, but also makes suggestions for improvement, such as the proposal to amend or repeal provisions that criminalise patent infringement.

It is important that both the positive and negative aspects of Botswana's IP law reform agenda are highlighted. Fellow SADC members can learn from the positive provisions by replicating or adapting them to their local situations. On the other hand, SADC members can also learn useful lessons from those few negative aspects of Botswana's IP law reform agenda, and avoid the same pitfalls such as criminalising patent infringement and curtailing the applicability of competition law to IP matters.

This contribution is timely because there is currently a hive of IP law reform activity in the SADC region at the behest of WIPO and international NGOs such as the Southern African Regional Programme for Access to Medicines and Diagnostics (SARPAM). The author was personally involved with the former NGO as a consultant. SARPAM assisted Malawi, Swaziland, Lesotho, Seychelles, Zambia and Zimbabwe to reform their IP laws in order to access essential medicines. These law reform projects will in all likelihood yield positive results for the individual countries if heed is paid to Botswana's experiences and obvious mistakes identified above are avoided.

It is also important to acknowledge that while patents largely remain a barrier to access to medicines in the SADC region, in particular, and the developing world in general, there are other culprits. The culprits,

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[194] The case that comes close but dealt with access to treatment in the context of the constitutional human right to health is that of *Dickson Tapela and Others v Attorney General of Botswana and others,* (case no. MAHGB-000057-14) in which case Sechela J delivered a judgment in favour of the applicants on 22 August 2014 in the High Court in Gaborone. The case had nothing to do with IP issues.

especially in the African context, include corruption, poverty, taxes and tariffs, and pharmaceutical counterfeiting.[195] Each of these elements will inhibit access through financial challenges, higher prices, drug shortages, and wrong or inappropriate pharmaceutical products.[196] On a related note, Banda argues that the current approaches to the problem by SADC members are reductive as 'they assume that the problem of access to pharmaceuticals can be resolved by merely implementing TRIPS flexibilities to facilitate importation of pharmaceuticals from India.'[197] He rightly recommends a more holistic and sustainable approach that takes on board, inter alia, Article 31*bis* of the TRIPS Agreement,[198] as Botswana did in this case.

On a valedictory note, while the ratification and domestication of Article 31*bis* of the TRIPS Agreement by Botswana must be celebrated, it must be stated that other SADC members have since been inspired by Botswana's action and have embarked on far-reaching IP law reforms, some of which domesticate Article 31*bis* of the TRIPS Agreement.[199] The relevant countries are Malawi,[200] Seychelles,[201] Namibia,[202] and Zanzibar,[203] which is part of the United Republic of Tanzania, a SADC member. Some SADC members like Zambia[204] and Zanzibar[205] have even taken advantage of their LDC status by coming up with laws which purport to exclude pharmaceuticals from patentability until they graduate from LDC status.

Although slightly under fifty per cent of SADC members have ratified the permanent amendment to the TRIPS Agreement in the form of Article 31*bis*, not all of them have domesticated the pertinent provision.[206]

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195 Lybecker (n 10) 26.

196 ibid 43.

197 Chikosa Banda, 'Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region' (2016) 31 Maryland J of International Law 44 44–78.

198 ibid.

199 The domestication largely takes the form of incorporation of the pertinent provisions of Article 31*bis* into the respective country's patent law.

200 Malawi has been involved with IP law reforms for quite a while now despite its LDC status and it was recently reported by one of South Africa's premier IP law firms Spoor and Fisher that the country was on the verge of passing a new IP Law which would include utility models (see Spoor and Fisher, 'Malawi: New IP Laws to be Announced' (10 May 2017) <http://www.spoor.com/en/News/malawi-new-IP-laws-to-be-announced/> accessed 29 June 2017).

201 Seychelles Industrial Property Act No 7 of 2014.

202 Industrial Property Act No 1 of 2012.

203 Zanzibar Industrial Property Act of 201).

204 Zambia provides for this in s 16 of its draft law, namely, the Zambian Patents Bill of 2010.

205 In terms of Zanzibar's Industrial Property Act of 2014, s 3(1) exempts 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.'

206 At the time of writing, the SADC members, which had ratified the permanent amendment to the TRIPS Agreement, were Botswana, Lesotho, Mauritius, Seychelles, South Africa, Tanzania and Zambia. See specifically WTO, 'Amendment of the TRIPS Agreement' <https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm> accessed 29 June 2017.

As far as improving access to medicines through the instrumentality of the TRIPS Agreement's flexibilities and the domestication of Article 31*bis* of the TRIPS Agreement are concerned, SADC members did and still do need to learn from Botswana's experience. Botswana was the first SADC member to come up with wholesale IP law reform incorporating the domestication of Article 31*bis* of the TRIPS Agreement. Other SADC members mentioned above have taken their cue from Botswana and leapt aboard the IP Law reform bandwagon.