Patient Rights vs Patent Rights: Access to Medicines Lessons for South Africa Seventeen Years after Doha*

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1 INTRODUCTION

In 2001 in Doha, Qatar, the developing and least-developed country (LDC) members of the World Trade Organisation (WTO) scored a rare victory for access to affordable medicines. The victory was the adoption by the 2001 WTO Ministerial Conference of the now famous Doha Declaration on TRIPS and Public Health on the 14 November of the same year. Through the Declaration, WTO members affirmed that there is nothing in the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) which prevents a WTO member from taking legislative and other measures to protect public health in order to improve citizens' ability to access affordable medicines.

The Declaration was followed up in August 2003 with further refinement and amendment enabling members to use compulsory licenses to supply other countries with limited or no pharmaceutical manufacturing capacity rather than for the predominant supply of the domestic market.[1] In order to actualise the spirit of the August 2003 Decision, an amendment to the TRIPS Agreement was proposed in 2005 and opened for ratification by WTO members.[2] It is important to point out that the proposed amendment explicitly stated that "reservations may

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1 Compulsory licenses (see para 2 3 below) fall within what the TRIPS characterises as "other use without the authorisation of the patent holder". Article 31 (f) of TRIPS prescribes that "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use".

2 See WTO General Council WT/L/641 8 December 2005 decision entitled "Amendment of the TRIPS Agreement" https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (accessed 12-03-2017).

not be entered" in respect of any of its provisions without the consent of the other WTO members.[3] Once fully ratified, the amendment would introduce Article 31 *bis* of the TRIPS Agreement, to override the pre-existing proviso in the TRIPS Agreement that compulsory licenses may only be granted for the predominant supply of the domestic market.[4]

Article 31 *bis* became part of the TRIPS Agreement after acceptance of the Protocol amending the TRIPS Agreement by two thirds of the WTO's members.[5] The amendment took effect on 23 January 2017 and replaced the 2003 waiver for members who have accepted the amendment.[6] For those WTO members who are yet to ratify the amendment, the 2003 Decision (waiver) still applies.

Although South Africa recently accepted and ratified the amendment,[7] many WTO members are yet to signal their acceptance and the period for the acceptance of the Protocol amending the TRIPS Agreement, which was extended for the fifth time to 21 December 2017,[8] has now been extended for the sixth time to 31 December 2019.[9]

Despite having accepted the Protocol amending the TRIPS Agreement, South Africa is yet to domesticate the amendment into its patent law.[10] This lack of domestication occurs against a backdrop of South Africa grappling with a huge disease burden,[11] which may be mitigated by improved access to medicines. The major diseases that are largely responsible for mortality

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3 *Ibid* para 3 of the Protocol amending the TRIPS Agreement.

4 Per Article 31(f) of the TRIPS Agreement.

5 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 12-03-2017).

6 *Ibid*.

7 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 12-03-2017).

8 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 12-03-2017).

9 See https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/78.pdf (accessed 16-01-2018).

10 Section 231 of the Constitution of the Republic of South Africa 1996 sets out the legal framework for the recognition, domestication and application of international agreements in South Africa. Generally, in order for an international agreement to be binding and legally enforceable in South Africa, it must first be domesticated into South African law via the parliamentary process involving the National Assembly and the National Council of Provinces [section 231(4)]. However, this requirement does not apply to agreements of a technical, administrative or executive nature, or agreements which do not require either ratification or accession, entered into by the national executive (section 231(3).

11 According to the *Sunday Times* report of March 12 2017 entitled "How the Grim Reaper cuts down SA Victims" 9, HIV/AIDS is the biggest cause of mortality in all the provinces of the country. However, the major causes of death in South Africa per province are as follows: Eastern Cape (tuberculosis); Free State (pneumonia and other respiratory infections); Gauteng (interpersonal violence); Kwazulu-Natal (stroke and other cerebro-vascular diseases); Limpopo (pneumonia and other respiratory diseases); Mpumalanga (road accidents); Northern Cape (tuberculosis); North West (stroke and other cerebro-vascular diseases) and Western Cape (interpersonal violence).

in South Africa are HIV/AIDS, tuberculosis, pneumonia and other respiratory infections, stroke and other cerebro-vascular diseases.[12]

Additionally, despite showing the right legal[13] and policy[14] intentions, South Africa is yet to take full advantage of the tenets of the Doha Declaration and make maximum use of TRIPS flexibilities[15] to improve access to medicines.[16]

Access to medicines, a concept with no clear definition, is generally considered as a collection of different dimensions[17] such as accessibility,[18] affordability,[19] acceptability,[20] and availability.[21] In developed nations, over 70% of drugs are publicly funded or reimbursed whereas in Africa, 50-90% of pharmaceutical expenditure is funded out of pocket.[22] This is not good news for access to medicines, since drug prices in the absence of price regulations create "affordability barriers".[23]

Access to essential medicines and vaccines depends on specific factors such as rational selection and use, sustainable financing, reliable supply systems and affordable prices.[24]

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12 See generally Pillay-van Wyk *et al* "Rapidly Changing Mortality Profiles in South Africa in its Nine Provinces" 2017 *South African Medical Journal* 168-169.

13 For example, since 1997, the South African Patents Act 57 of 1978 has been amended severally to make it compliant with the TRIPS Agreement.

14 In 2013, South Africa published the draft intellectual property policy and invited public comments on it; the policy made a number of points about intellectual property and public health in a number of instances. The policy was recently replaced by the comprehensive Draft Intellectual Property Policy of the Republic of South Africa Phase I 2017 http://www.dti.gov.za/gazzettes/IP_Policy.pdf (accessed 16-01-2018).

15 TRIPS flexibilities generally refer to the leeway given to WTO Members to take full advantage of the TRIPS Agreement in the local context by passing IP legislation that suits each country's individual needs. For example, a member (like what India has done) may pass legislation that provides for medical patents to show enhanced efficacy as a requirement for patentability, in addition to novelty, inventiveness and utility. Banda "Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region" 2016 *Maryland International Law Journal* 46-52 lists compulsory licensing, transition periods, the LDC exemption and the Paragraph 6 System as some of the important flexibilities. Other important flexibilities include patentable subject matter; patent examinations; pre and post-grant patent opposition,; parallel imports; government use of patents; data protection; regulatory exceptions; research and experimentation exceptions; and the use of competition law.

16 See generally Ndlovu "The WTO TRIPS Agreement and Access to Medicines in South Africa 20 years into Democracy" 2014 *Speculum Juris* 70-100.

17 Tetteh "Providing Affordable Essential medicines to African Households: The Missing Policies and Institutions for Price Containment" 2008 *Social Science and Medicine* 570.

18 Referring to health services coverage.

19 This relates to prices and volumes of consumption.

20 This refers to quality, safety and efficacy.

21 This refers to drug production, procurement and distribution.

22 Tetteh 2008 *Social Science and Medicine* 570.

23 *Ibid*.

24 WHO "Essential Medicines and Health Products Information Portal: A World Health Organization Resource" http://apps.who.int/medicinedocs/en/d/Js6160e/9.html (accessed 19-02-2018).

In the context of this paper, access to medicines also depends on the availability and efficacy of legal instruments at the municipal,[25] regional[26] and international levels.[27]

Not being able to access essential drugs and vaccines limits the enjoyment of the right to health and by extension the right to life on the part of the citizens of developing countries.[28] While the right to health has traditionally been regarded as a civil and political right,[29] it has, nevertheless, been increasingly applied broadly and has been extended in some instances to cases involving access to medicines.[30] The right to health is one among a range of socio economic rights for which states accept an obligation under international law.[31]

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25 In the context of South Africa, the relevant legislations will be the Patents Act 57 of 1978 as amended and the Medicines and Related Substances Control Act 101 of 1965.

26 Good examples in this case would be the Declaration and Treaty of SADC, the SADC Protocol on Health and regional intellectual property instruments such as Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Industrial Property Organization (ARIPO) of 1984.

27 Examples are the Paris Convention, the Patent Cooperation Treaty and the World Trade Organisation Agreement on Trade Related Aspects of Intellectual Property rights (TRIPS).

28 The right to health and the right to life are closely intertwined and are not mutually exclusive. The right to life is encapsulated in article 3 of the Universal Declaration of Human rights and most, if not all constitutions of civilised nations of the world contain the right to life. For example, section 11 of the South African constitution of 1996 provides that everyone has the right to life and the applicability of that provision was tested by country's constitutional court in the landmark case of *S v Makwanyane* 1995 3 SA 360 (SCA) on 6 June 1995. In the case, the majority decision of the court was that the death penalty is inhuman and degrading hence unconstitutional. The Universal Declaration of Human Rights indirectly provides for the right to health in Article 25 in which it is stated among other things, that everyone has the right to a standard of living that is adequate for their wellbeing and that of the family inclusive of medical care. The right to health is also recognised in article 12(1) of the International Covenant on Economic, Social and Cultural Rights while article 16 of the African Charter on Human and Peoples' Rights recognises the right of every individual to enjoy "the best attainable state of physical and mental health". Other international instruments relevant to the right to health are the International Covenant on Civil and Political Rights (article 6), the Convention on the Rights of the Child (article 24), Convention on the Elimination of all forms of Discrimination against Women (article 12) and the Convention on the Elimination of all Forms of Racial Discrimination (art 5). On a related note, see Olowu "Environmental Governance and Accountability of Non-state Actors in Africa: A rights – based Approach" 2007 South *African Yearbook of International Law* 261 279. For a general overview of the right to health and in its democratic context, see Hassim *et al* (eds) *Health and Democracy: A guide to Human Rights, Health Law and policy in post-apartheid South Africa* (2006). For a comprehensive compilation of essential documents, international agreements and treaties pertaining to the right to health, see Bekker (ed) *A Compilation of Essential Documents on the Right to Health* (2000).

29 See for instance article 6 (1) of the International Covenant on Civil and Political Rights which provides that the right to life shall be protected by law and provides further, that no one shall be arbitrarily deprived of his life.

30 Mushayavanhu "The realisation of access to HIV and AIDS – related medicines in Southern African countries: Possibilities and actual realisation of international law obligations" in Viljoen and Precious (eds) *Human Rights under Threat: Four Perspectives on HIV, AIDS and the law in Southern Africa* (2007) 135. For example, in the case of *Odir Miranda v El Salvador* cited by the Mushayavanhu in footnote 26 on page 136, the Inter-American Commission held that El Salvador's refusal to purchase triple therapy HIV medication amounted to a violation of the rights to life and health as provided for in the America Convention.

31 See in this regard Evans "A Human Right to Health?" 2002 *Third World Quarterly* 197.

In this paper, the right to health is considered as one of patient rights, alongside the right to be treated in a humane manner in public and private hospitals. The right of pharmaceutical companies and investors to own, use and license intellectual property to the exclusion of others is considered a patent right. There is an obvious clash between patient and patent rights which may simply be illustrated in the following manner. Lanaszka argues that TRIPS emphasises a property rights approach which favours private "owners" of the inventions,[32] including pharmaceutical companies. This can restrict access on the basis of commercial considerations.[33] This view is supported by Hanefeld, who argues that the restriction of access imposes higher prices for pharmaceuticals and other health care inventions,[34] thus militating against patient rights. This can prevent low-income consumers in developing countries from obtaining life-saving medication and equipment.[35]

The constitutive Act of the African Union[36] recognises the importance of the right to health by providing in Article 3 (n) that one of the African Union's paramount objectives is to work with progressive partners in eradicating preventable diseases and promoting good health in the continent.

The preamble to the TRIPS Agreement makes reference to the protections granted to authors and inventors as "rights" ("recognising that intellectual property are private rights"). General Comment no. 17[37] cites intellectual property rights as different from human rights due to their generally temporary nature which can be revoked, licensed or assigned to someone else.[38] There is a need to strike a balance between the rights of poor people in developing countries to access essential medicines (patient rights) and the rights of pharmaceutical companies to

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32 Lanaszka "The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries" 2003 *International Political Science Review* 181.

33 *Ibid*.

34 Hanefeld "Patent Rights v Patient Rights: Intellectual Property, Pharmaceutical Companies and Access to Treatment for People Living with HIV/AIDS in Sub-Saharan Africa" 2002 *Feminist Review* 84-92.

35 This is in agreement with a similar submission by Rai "The Ends of Intellectual Property: Health as a Case Study" 2007 *Law and Contemporary Problems* 125.

36 Adopted in Lome, Togo on 11 July 2000 and entered into force on 26 May 2001. The full text of the Constitutive Act is available in Heyns and Killander (eds) *Compendium of Key Human Rights Documents of the African Union* (2007) 4 – 12.

37 UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 17: The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary or Artistic Production of Which He or She is the Author (Art. 15, Para. 1 (c) of the Covenant)*, 12 January 2006 E/C.12/GC/17 http://www.unhcr.org/refworld/docid/441543594.html (accessed 19-02-2018).

38 General Comment No. 17 para 2.

continue with medical innovations (patent rights) while gaining market-related returns for their intellectual property.[39]

After giving a full contextual background of the Doha Declaration, compulsory licences, the August 2003 decision, and the amendment to the TRIPS Agreement, we first identify specific provisions of South Africa's patent law that must be amended to make the grant of compulsory licenses less onerous in order to ease the disease burden. Compulsory licenses are the primary focus here because the Doha Declaration was adopted in order to affirm WTO Members' right to invoke compulsory licenses. So important were compulsory licenses that in 2003, a Decision dedicated to them was passed, and such Decision later gave rise to the permanent amendment of TRIPS resulting in the Paragraph 6 system, discussed in detail in paragraph 2 4 below.

Secondly, using a specific drug that has a great potential to reduce South Africa's cancer problem as an example, we suggest practical law reform steps South Africa should pursue in order to realize its citizens' right to health using compulsory licenses. While cognisant of patients' right to health in terms of international and domestic law, we acknowledge the fact that drug patentees have patent rights in their inventions (drugs). In order to balance patient and patent rights, we suggest that a framework for the invocation of compulsory licenses should be developed so that patients enjoy their right to health through accessing affordable medicines while patent rights are respected and patentees remunerated through a compulsory licensing scheme. Finally, we outline very briefly the lessons South Africa can learn from the experiences of fellow African countries and India. In conclusion, we reiterate that the major part of the solution to South Africa's access to medicines problem lies in law reform that is TRIPS-compliant in the South African context post the Doha Declaration on TRIPS and Public Health.

2 CONTEXTUAL BACKGROUND TO THE DOHA DECLARATION

2 1 General background

The Doha Declaration on TRIPS and Public Health may be regarded as an important step towards making the TRIPS Agreement more development friendly.[40] The Declaration was the outcome of a WTO Ministerial meeting which was held in the United Arab Emirates in

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39 Hanefeld 2002 *Feminist Review* 84-92.

40 Elbeshbishi "TRIPS and Public Health: What Should African Countries Do?" 2007 *ATPC Work in Progress no.*49 3.

November 2001.[41] Although the Declaration made specific statements on various issues, the relationship between the TRIPS Agreement and public health was so highly contested that it warranted elucidation in a separate Declaration.[42] The Declaration was initiated by the African Group within the TRIPS Council.[43] The African Group and other third world countries wanted to ensure that the Ministerial Conference in Qatar became an opportunity to demonstrate Members' commitment and contribution to preventing further deaths and saving lives through facilitating easier access to medicines at affordable prices.[44] The gist of the African Group's proposal was that the TRIPS Agreement should not prevent members from taking measures to protect public health.[45] The bulk of the proposal would later be adopted in Doha, Qatar as the Declaration on TRIPS and Public Health.

Specifically, the Doha Declaration states that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health, and in particular, to promote access to medicines for all.[46] The Declaration also explicitly recognises the flexibility within TRIPS to grant compulsory licenses and the rights of members to determine the grounds for the grant of such licenses.[47] The passage of the Declaration was considered a major victory for developing nations.[48] The Declaration also extended the deadline for developing countries to comply with TRIPS provisions relating to pharmaceutical patents until 2016; and for Least-Developed countries (LDCs), the exemption has now been extended to 2033.[49]

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41 Ministerial conference, Fourth Session, Doha 9-14 November 2001, adopted on 14 November 2001.

42 Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2, adopted on 14 November 2001 (the Doha Declaration).

43 Kingah *et al* "How Countries of the Southern African Development Community (SADC) can use the World Trade Organisation and European Community Flexibilities for Better Access to Affordable HIV/AIDS Medicines" 2008 *Monitoring Regional Integration Yearbook* 16. The spokesperson for the African Group at that time was the representative of Zimbabwe, ambassador Boniface Chidyausiku, who was also the chairperson of the TRIPS Council.

44 *Ibid*.

45 *Ibid*.

46 Doha Declaration para 4.

47 Doha Declaration para 5(b).

48 Watson "International Intellectual Property Rights: Do TRIPS Flexibilities Permit Sufficient Access to Affordable HIV/AIDS Medicines in Developing Countries?" 2009 *Boston College International & Comparative Law* 146.

49 On 6 November 2015, the WTO Council for TRIPS decided that Least-developed country (LDC) members of the WTO will be allowed to maintain maximum flexibility in their approach to patenting pharmaceutical products until at least 2033. For specific issues relating to this decision, see WTO "WTO members agree to extend drug patent exemption for poorest members" https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm (accessed 29-03-2016).

In a very important way, the Declaration noted that members will reserve the right to determine what constitutes a national emergency or a case of extreme urgency[50] with the understanding that diseases such as HIV/AIDS, tuberculosis, malaria and other epidemics may come under such a narrow category.[51]

In summary, the Declaration is important in that it gave members the leeway to use TRIPS flexibilities for public health purposes including: giving transition periods for laws to be TRIPS compliant; providing for compulsory licensing; providing for parallel importation and exceptions from patentability; and providing for early working of patents (Bolar exceptions).[52]

However, there was a problem which the Doha Declaration identified and proposed a solution thereto.[53] The problem was caused by the fact that while Article 31(f) of the TRIPS Agreement provides for the possibility of using a patent without the consent of the patent holder, such use must only be for the predominant supply of the domestic market.[54] The implications of this Article for access to medicines were likely to be dire for developing countries with limited or no pharmaceutical manufacturing capacity. Countries that have the capacity to manufacture generic drugs, through the issuance of compulsory licenses, such as India and Brazil, could only do so for the overall predominant supply of their domestic markets. Exports of such generics to countries in dire need would be very much limited.[55]

The above mentioned problem, commonly known as "the paragraph 6 problem", had to be addressed if the ground breaking provisions of the Doha Declaration were to be effective at all. The first step was for members to recognize and acknowledge the fact that contracting parties with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of the compulsory licensing provisions of TRIPS.[56]

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50 For critical perspectives on alternatives to determining and defining national emergency, see generally Manne "Pharmaceutical Patent Protection and TRIPS: The Countries that Cried Wolf and Why Defining 'National Emergency' Will Save them from themselves" 2010 *George Washington International Law Review* 349-379.

51 Doha Declaration para 5 (c).

52 Mabika and Makombe "Claiming our Space: Using the Flexibilities in the TRIPS Agreement to Protect Access to Medicines" 2006 *SEATINI Policy Series* 1.

53 See paragraph 6 of the Declaration.

54 The Council for TRIPS was asked to find an expeditious solution before the end of 2002, but the solution did come later, in fact a year later in the form of the August 2003 Decision.

55 See generally, Scherer and Watal "Post-TRIPS Options for Access to Patented Medicines in Developing Countries" in Maskus (ed) *The WTO Intellectual Property Rights and the Knowledge Economy* (2004) 355-381.

56 Generally provided for in Article 31 of the TRIPS Agreement.

The solution to the problem came in August 2003 in the form of a Decision of the General Council implementing paragraph 6 of the Doha Declaration.[57] The Paragraph 6 Decision addressed the practical legal deficiency identified in paragraph 6 of the Doha Declaration by creating a waiver for Article 31(f) of TRIPS, thus allowing member states to export generic drugs to poorer nations.[58] Canada was the first country to issue a compulsory license[59] under the system, for the production and export of a generic AIDS medicine to Rwanda.[60] The license was issued in October 2007.

2 2 Important provisions of the Doha Declaration

The Doha Declaration, which contains seven paragraphs, was the major WTO Decision to call for an interpretive regime that is sympathetic to access to medicines for developing countries.[61]

The Declaration did recognize the gravity of public health problems affecting developing countries especially problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[62] The Declaration also did acknowledge that the TRIPS Agreement was part of the wider national and international action to address the public health problem.[63] The Declaration also recognized the importance of intellectual property for the development of new medicines but at the same time noted the potential adverse effects of intellectual property (IP) on medicines prices.[64] Therefore, WTO members were equally cognizant of the importance of maintaining the balance of interests in the IP system.[65]

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57 See the 30 August 2003 Decision of the General Council implementing paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1 para 2 http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (accessed 18-09-2013) [hereafter Paragraph 6 Decision]. The 2003 Decision is frequently referred to as the Paragraph 6 Decision because the sixth paragraph of the Doha Declaration specifically identified the manufacturing capabilities issue. The Decision will become a permanent amendment to the TRIPS Agreement once two thirds of the WTO membership sign it, in the meantime, the waiver will apply.

58 Para 2 of the Paragraph 6 Decision. The very first country to use the paragraph 6 system was Canada when it sought to supply cheap HIV/AIDS medicines to Rwanda.

59 On compulsory licenses, see para 2 3 below.

60 See Cotter "The Implications of Rwanda's Paragraph 6 Agreement with Canada for other Developing Countries" 2008 Loyola *University Chicago International Law Review* 177-189.

61 Doha Declaration para 1.

62 Doha Declaration para 1. The specific diseases mentioned herein are not a closed list. Except for malaria, the other specified diseases are prevalent in South Africa and therefore directly relevant to the objectives of this paper.

63 *Ibid* para 2.

64 *Ibid* para 3.

65 Kingah *et al* 2008 *Monitoring Regional Integration Yearbook* 17.

The pith and marrow of the Declaration, which has often been cited as one of the most important and potentially revolutionary WTO provisions impacting on access to medicines, is worth citing and is hereby reproduced verbatim:

> "We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, *to promote access to medicines for all*".[66] (Our emphasis.)

The above cited provision was further buttressed by a reaffirmation of WTO Members' right to use, to the full, the provisions of the TRIPS Agreement, which provide flexibility for the purpose of accessing medicines for all.[67]

Paragraph five of the Declaration, which elaborates on the right identified in paragraph four, is also equally important because it gives more detail on what the flexibilities are and how they ought to be interpreted.[68]

Members are urged to apply the customary rules of interpretation of public international law and read each provision of the TRIPS Agreement in light of the object and purpose of the Agreement as expressed in TRIPS objectives and principles.[69]

Very importantly for access to medicines generally and this paper in particular, the Declaration affirms each member's right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[70]

The Declaration gives each WTO member the right to determine what constitutes a national emergency or other circumstances of extreme urgency, and reiterates that public health crises are not limited to those identified in paragraph one.[71] Therefore, the Declaration made it very clear that situations of "national emergency" or of "extreme urgency" are not limited to

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66 Doha Declaration para 4. See on a related note Ferguson "The WTO, Intellectual Property and the Access to Medicines Controversy" 2007 *CRS Report for Congress* 2.

67 Doha Declaration para 4. The specific flexibilities are discussed from para 2 3 below.

68 See generally, para 5 of the Doha Declaration.

69 Doha Declaration para 5 (a). The object and purpose of the TRIPS Agreement are spelt out in "General Provisions and Basic Principles" part 1, Articles 1 – 8 of the TRIPS Agreement.

70 Doha Declaration para 5 (b). Compulsory licenses, which are provided for in Article 31 of TRIPS, will be discussed in detail in para 2.3 below and their use or potential use by SADC member states will be discussed in chapter five below.

71 Doha Declaration para 5 (c). On the subject of interpretive alternatives to "national emergency", see Manne 2010 *George Washington International Law Review* 369 – 378.

short-term crises.[72] Additionally, by giving members the right to determine for themselves what an emergency is, the burden of proof shifts to the complaining party to show that an emergency does not in fact exist.[73] This legal position is different from the one obtaining under the general exceptions of Article XX of the General Agreement on Tariffs and Trade (GATT) 1994 and Article XIV of the General Agreement on Trade in Services (GATS).[74] The reversal of the burden of proof is likely to be favourable to the plight of developing countries and South Africa; they will no longer have the herculean and onerous task of proving that a measure taken in the interest of public health falls within the meaning of emergency or extreme urgency.

What would easily be considered as the strongest point of the Doha Declaration is the acknowledgement that compulsory licensing as provided for in the TRIPS Agreement[75] will not be easy to implement for WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector.[76]

It is important to give an exposition of compulsory licenses early in the paper for proper contextualisation.

2 3 General remarks on compulsory licenses

While TRIPS flexibilities include aspects such as the use of parallel importation, research and early working exceptions, public non-commercial use of patents, the exclusion of new forms of known substances from patentability in some instances, limitations on data protection and exceptions based in competition law, the most important flexibility in the context of the Doha Declaration and this paper is the use of compulsory licenses.[77]

There is no express reference to the term "compulsory licence" in the TRIPS Agreement. Compulsory licences are now considered to fall under the general category of "other use without authorization of the right holder", provided for in Article 31 of TRIPS. However, the Doha Declaration on TRIPS and Public Health and the Ministerial Declaration of 2003 do

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72 Van den Bossche *The Law and Policy of the World Trade Organisation: Text, cases and Materials* (2013) 790.

73 *Ibid*.

74 See further on this point, Correa "The TRIPS Agreement and Developing Countries" in Macrory *et al* (eds) *The World Trade Organisation: Legal, Economic and Political Analysis* (2005) 441.

75 As provided for generally in Article 31 of TRIPS.

76 Doha Declaration paragraph 6.

77 It will be recalled that the whole of Article 31 *bis* is dedicated to the regime for the use of compulsory licenses for domestic use and export.

expressly refer to compulsory licences.[78] The most prominent provisions of the TRIPS Agreement which are relevant to compulsory licences are Articles 7,[79] 8,[80] 31[81] and 40;[82] while Article 5 of the Paris Convention is also very relevant.[83]

A compulsory licence, which may be viewed as some kind of permission from the government, has the effect of extinguishing patent exclusivity and permits the licensee to use the patent without the patentee's consent subject to payment of royalties.[84] At the international law level, it is a requirement that if a compulsory licence is granted, the patent holder must be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.[85] In almost every country that has patent laws, mechanisms to remedy or prevent abuse of patent rights, a good example of which is the ability to issue compulsory licenses, do exist.[86] The issuance of a compulsory licence is subject to a number of other conditions in addition to the remuneration requirement,[87] and additionally, a member state may have its own peculiar conditions prescribed in domestic law.[88]

Among the conditions set out for the granting of compulsory licences in Article 31 of TRIPS, the following are important in the context of the Paragraph 6 Decision, discussed below:[89]

(a) the grantee must first have made efforts, for a reasonable time, to negotiate authorization from the right holder, on "reasonable commercial terms and conditions";[90]

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78 In the Doha Declaration, the concept is mentioned for the first time in paragraph 5(b) while in the 2003 Decision, compulsory licenses are mentioned for the first time in 2 (a) (iii).

79 Objectives.

80 Principles.

81 Other use without authorization of the right holder.

82 Control of anti-competitive practices in contractual licenses.

83 Article 5 A (2) of the Paris Convention succinctly provides that , each country for the Union "shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of exclusive rights conferred by the patent, for example, failure to work".

84 Baker *Processes and Issues for Improving Access to Medicines: Willingness and Ability to Utilise TRIPS Flexibilities in non-producing Countries* (2004) 14.

85 Article 31(h) of TRIPS.

86 Sterckx "Patents and Access to Drugs in Developing Countries: An Ethical Analysis" 2004 *Developing World Bioethics* 61.

87 See for instance TRIPS Article 31 (a) – (l).

88 For example, Section 56 of the South African Patents Act 57 of 1978 lists grounds for compulsory licences including patent abuse generally or in the context of competition law.

89 The following list draws largely from Abbott and Van Puymbroeck "Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision" 2005 *World Bank Working Paper No.* 61 7.

90 Article 31 (b).

(b) Members may dispense with this requirement, however, in the case of a "national emergency or other circumstances of extreme urgency or in cases of public non-commercial use";[91]

(c) the use authorized by the compulsory license must be "predominantly for the supply of the domestic market";[92] and

(d) adequate remuneration must be paid to the right holder.[93]

The requirement that the compulsory licence must be used for the predominant-supply-of-the-domestic-market does not apply if the compulsory licence is granted to remedy anti-competitive practices.[94] Therefore, when an exporting member grants a compulsory licence to remedy an anti-competitive practice it does not act under the 2003 Decision because it does not take advantage of the waiver of Article 31(f) established by the Decision.[95] Instead, it acts under a pre-existing right in the TRIPS Agreement to authorize exports to address anti-competitive practices. In such cases, the importing Member does not need to comply with the notification and other requirements set out in the Decision.

Critiquing the very existence of the above conditions, Reichmann argues that the conditions only magnify the legitimacy of every complying government's right to resort to compulsory licensing whenever its domestic self-interest so requires.[96] Compulsory licences may be granted to third parties for their own use and use by or on behalf of government without the authorization of the right holder.[97] In the context of this paper, compulsory licences may be granted to address public health emergencies by ensuring access to cheaper drugs.[98] It is possible that the granting of one or more of such licences will force prices down, thus furthering consumer welfare.[99] Because compulsory licences must be non-exclusive, this means that licences to use a patent may be given to more than one company.[100]

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91 Article 31(b).
92 Article 31 (f).
93 Article 31 (h).
94 Article 31(k) of TRIPS.
95 Abbott and Puymbroeck above 7.
96 Reichmann J.H Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options (2009) *Pharmaceutical Regulations* 247 – 263.
97 Taubman *et al A Handbook on the WTO TRIPS Agreement* (2012) 109.
98 Correa *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2007) 313.
99 *Ibid*.
100 *Ibid*.

To the extent that compulsory licences would reduce the prices of the patented product and the expected profits of the patent holder, pharmaceutical companies have argued that the granting of such licences would undermine the incentives to engage in future research and development (R&D).[101] This submission is flawed when the results from studies that attempted to examine the effect of compulsory licences on R&D are taken into account.[102] To emphasise the fallacy of the view that compulsory licences have a negative effect on R&D, Tandon notes that generally, firms spend a lot of R&D money on efforts to "invent around" the patents of their competitors.[103] With generalized compulsory licences, these expenditures would be unnecessary and thus increase the welfare benefits.[104] It is also important to record that compulsory licences will ensure that cheaper generic drugs are available and boost the local pharmaceutical manufacturing capacity irrespective of how modest this would be.[105]

It is noteworthy that although the TRIPS Agreement gives several grounds[106] meriting the grant of compulsory licences, when read together with the pertinent provision of the Doha Declaration,[107] there is no limit in any way on the capacity of governments to grant compulsory licences or undertake government use.[108] The absence of restrictions on the purposes for which compulsory licenses may be granted is quite a significant achievement for developing countries and is now considered "as a major policy instrument in attenuating the adverse effects of strong patent protection".[109] The TRIPS Agreement, therefore, gives considerable room to policy makers in the developing countries to come up with their own grounds so that the eleven conditions given by Article 31 do not become restrictions.[110] Therefore, South Africa may include other grounds for compulsory licences and clearly spell out in simple language,

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101 *Ibid*.

102 See for example a study conducted by Schrener, cited in Correa *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement* (2007) 314, which concluded that for companies subject to compulsory licenses, there was no corresponding decline in R&D but rather a significant rise in such companies' R&D relative to companies of comparable size not subject to such licenses.

103 Tandon "Optimal Patents with Compulsory Licensing" 1982 *Journal of Political Economy* 485.

104 *Ibid*.

105 At least this seems to have been the net result in the Zimbabwean context in 2002, when Varichem, a local pharmaceutical manufacturer, was allowed, through a compulsory license to manufacture varivar, a generic version of a combination of three patented ARV drugs.

106 The major grounds are in case of national emergency or extreme urgency; public non-commercial use; to remedy anti-competitive practices and in case of dependent patents.

107 Specifically paragraph 5 (b) which states very clearly that each member has a right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

108 Correa *supra* 314.

109 Watal *Intellectual Property Rights in the WTO and Developing Countries* (2001) 380 – 381.

110 Watal 381.

peculiar situations, including the inability to access medicines due to exorbitant prices, which may trigger the application for and the granting of a compulsory licence.[111]

Most developing and least developed WTO members lack sufficient pharmaceutical manufacturing capacity to produce generic versions of patented drugs using a compulsory licensing regime. The Council for TRIPS was therefore asked to come up with a solution to the problem posed by Paragraph 6.[112] The solution came in the form of an amendment to the TRIPS Agreement, to be fully passed once ratified by two thirds of the WTO membership.[113] Paragraph 6 is widely considered as a positive development for developing countries, and the successful use of compulsory licenses will hinge on it.

The use of compulsory licenses if further aided by the last paragraph of the Doha Declaration, which deals with two important issues for developing countries – the commitment of developed country members to provide incentives to their enterprises and institutions to encourage technology transfer to LDCs[114] and the exemption of LDCs from protecting pharmaceutical patents until 2016.[115]

Writing in early 2003, Samantha Shoel correctly opined that the Declaration was not legally binding since it was neither an amendment nor a modification.[116] This submission is however no longer legally valid with specific reference to the plight of countries without manufacturing capabilities to use compulsory licensing. This submission is based on the fact that on the 6 December 2005, WTO members agreed to incorporate the 2003 Decision as an amendment and Annex to TRIPS,[117] and on 23 January 2017, this amendment became permanent after five countries, namely, Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Vietnam notified the WTO Secretariat that they had ratified the protocol amending the TRIPS

111 The current circumscribed grounds are encapsulated in section 56 (2) (a) – (e) of the Patents Act, which lists situations in which patent rights will be deemed to be abused.

112 The paragraph 6 phenomenon is discussed fully in 2 4 below.

113 See 2 4 below.

114 The obligation arises pursuant to Article 66 (2) of TRIPS.

115 The 2016 exemption of pharmaceuticals from patentability for LDCs should be read together with the 2021 exemption relating to TRIPS Agreement generally, and the recent extension to 2033 for LDCs. Until January 2033, key provisions of the TRIPS Agreement will not apply to pharmaceutical products in LDCs.

116 Shoel "Why Can't the Poor Access Life-Saving Medicines? An Exploration of Solving the Patent Issue" 2002 *Minnesota Intellectual Property Review* 175.

117 Fergusson "The WTO, Intellectual Property and the Access to Medicines Controversy" 2007 *CRS Report for Congress* 3.

Agreement.[118] The ratification by the five Members actualised the two-thirds threshold that was needed to formally bring the amendment of the TRIPS Agreement into being.

The amendment now formally incorporates Article 31 *bis* of the TRIPS Agreement, the salient features of which are contextually discussed immediately below.

2 4 Important aspects of the August 2003 Decision (now Article 31 *bis* of TRIPS)

The August 2003 Decision was passed in order to remedy the nagging problem in the TRIPS Agreement,[119] which requires that compulsory licenses be used "predominantly" for a member's supply of the domestic market. Because WTO members have now incorporated the 2003 Decision into the TRIPS Agreement permanently, our discussion of the detailed aspects of the Decision are based on the original text that was intended to permanently amend the TRIPS Agreement.[120] The ratification of the amendment[121] took off to a slow start, having been ratified by only 73 members out of a possible 159 in 2013; inclusive of the United States and the European Union.[122] The two-thirds majority threshold was expected to be reached if 106 WTO Members ratified the amendment. African countries in particular, are conspicuous by their reluctance to officially accept the amendment.[123]

The important provisions of the amendment are outlined below. The following brief outline focuses on the five main paragraphs of the Annex to the Protocol amending the TRIPS

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118 See WTO "WTO IP rules amended to ease poor countries' access to affordable medicines" https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm (accessed 29-03-2017).

119 This problem is to be found in Article 31(f) of TRIPS.

120 The permanent amendment was expected to come into force when two-thirds of WTO members ratified it. The ratification was originally expected to occur by the end of 2007, but when it did not materialize, the General Council extended the period up to the end of 2009, and further until 30 November 2011. Because the expected ratification did not materialize in 2011, the period was further extended to happen by 31 December 2013, and in January 2017, the two thirds threshold was reached when more WTO Members came on board.

121 The amendment is captured as Article 31 *bis* of the TRIPS Agreement.

122 See WTO "Members Accepting Amendment of the TRIPS Agreement" http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed 03-10-2013). The EU ratified the amendment as a block (28 countries in all).

123 At the time of writing, only 20 African WTO members had ratified Article 31 *bis* of TRIPS. The names of the relevant countries with dates of accession in brackets are: Benin (23 November 2016); Botswana (18 June 2014); Burkina Faso (17 January 2017); Central African Republic (13 January 2014); Egypt (18 April 2008); Kenya (21 July 2015); Lesotho (4 January 2016); Mali (20 January 2016); Mauritius (16 April 2008); Morocco (2 December 2008); Nigeria (16 January 2017); Rwanda (12 December 2011); Senegal (18 January 2011); Seychelles (8 June 2016); Sierra Leone (21 March 2017); South Africa (23 February 2016); Tanzania (14 March 2016); Togo (13 March 2012); Uganda (12 July 2010); and Zambia (10 August 2009) https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed 19-06-2017).

Agreement[124] together with the attendant conditions spelt out in the Annex to the TRIPS Agreement.

Article 31 *bis* of TRIPS was introduced by the Protocol Amending the TRIPS Agreement.[125] According to Gumbel, the relevant Article was introduced to address the limitations and confusion surrounding TRIPS Article 31(f),[126] which had hitherto allowed compulsory licenses only for the predominant supply of the domestic market.

The Protocol Amending the TRIPS Agreement, which is drafted in preambular language, makes it very clear that once the Protocol enters into force[127] upon being appropriately ratified,[128] the TRIPS shall accordingly be amended by inserting Article 31 *bis* after Article 31 and the Annex to the TRIPS Agreement after Article 73.[129] Very importantly, the Protocol makes it clear that no reservation may be entered against any of its provisions in the absence of the consent of other members of the WTO.[130]

The essence of Article 31 *bis* is captured in the first paragraph of the Annex to the Protocol Amending the TRIPS Agreement,[131] which explicitly suspends the obligations of an exporting member under Article 31(f) of TRIPS for the grant of a compulsory license as long as such a license is necessary for the production of pharmaceutical products for export to eligible importing members according to set conditions.[132] An eligible importing member is defined as any LDC and any other member that has made a notification to the Council for TRIPS of its intention to use the system availed by Article 31 *bis*.[133] An exporting member on the other hand, is a member using the system to produce pharmaceutical products for, and export them to, an eligible importing member.[134]

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124 Full texts of the Protocol Amending the TRIPS Agreement, Annex to the Protocol Amending the TRIPS Agreement and Annex to the TRIPS Agreement are available in Taubman *et al* (2012) 360-366.

125 See *Ibid* 360-361 for a full text of the Protocol Amending the TRIPS Agreement.

126 Gumbel "Is Article 31*bis* Enough? The Need To Promote Economies of Scale In The International Compulsory Licensing System" 2008 *Temple International & Comparative Law Journal* 170.

127 The Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

128 The Initial date for such ratification was 1 December 2007.

129 See para 1 of the Protocol Amending the TRIPS Agreement.

130 Protocol Amending the TRIPS Agreement, para 2. This provision implies that the chances of such a reservation being raised are now very slim, considering that the major players in international economic relations – the United States, the EU, Japan and China have ratified Article 31 *bis*.

131 Article 31 *bis* para 1.

132 The conditions are spelt out in para 2 of the Annex to the TRIPS Agreement.

133 See para (b) of the Annex to the TRIPS Agreement.

134 Annex to the TRIPS Agreement, para (c).

The conditions have been cited as impediments to access to medicines despite the positive aspects of Article 31 *bis*.[135] In order to use the system as an eligible importing member, a notification must be made to the Council for TRIPS covering the following issues: Firstly, the importing member must, in the notification, specify the names and expected quantities of products needed[136] and secondly, confirm that the member has insufficient or no manufacturing capacities in the pharmaceutical sector for the relevant product (s) in question.[137] This last requirement will not apply if the importing member is an LDC.[138] Thirdly, if the product is patented in its territory, and the eligible importing member has granted or intends to grant a compulsory license in accordance with Article 31 of TRIPS and 31 *bis*, this must be confirmed.[139]

The above narrated conditions do not at face value seem to be onerous, however, there are further conditions that a compulsory license issued by an eligible exporting member must comply with.

Firstly, amounts to be manufactured are limited to those required by the importing member that has notified the Council for TRIPS of its need.[140] This reads almost like the old Article 31 of TRIPS, which has similar restrictions albeit in a slightly different context. The second condition applicable to a compulsory license issued by an eligible exporting member is that products produced under such a license shall be clearly identified as such through labelling or marking, special packaging, special colour or shape, as long as the distinction is feasible and does not have a significant impact on price.[141] Thirdly, before the products are shipped to the importing country, the licensee must post on a website (WTO or own website) information relating to quantities being supplied to each destination and distinguishing features of the products.[142]

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135 See for instance Palombi "The Role of Patent Law in Regulating and Restricting Access to Medicines" 2009 *Scripted* 404 wherein he correctly submits that the conditions may amount to "disincentives for the right kind of drugs".

136 Para 2 (a) (i) of the Annex to the TRIPS Agreement. The notification will be made available publicly by the WTO secretariat through a page on the WTO website dedicated to the system.

137 Para 2 (a) (ii) of the Annex to the TRIPS Agreement.

138 *Ibid*.

139 Para 2(a) (iii) of the Annex to the TRIPS Agreement.

140 Para 2(b) (i) of Annex to The TRIPS Agreement.

141 Para 2(b) (ii) of the Annex to the TRIPS Agreement.

142 Para 2(b) (iii) of the Annex to the TRIPS Agreement.

The last general condition relating to the exporting member is that it must notify the Council for TRIPS of the grant of the license including conditions attached to it.[143] The information provided shall include the name and address of the licensee, the product (s) for which the license has been granted, the quantities for which the license has been granted, the countries to which the products are destined and the duration of the license.[144]

Other important considerations which fit very well into the scope of using compulsory licenses in the context of the first paragraph of Article 31 *bis* cover diverse but important issues such as the requirement that importing members establish administrative measures[145] to ensure that there is no trade diversion through re-exportation of products imported through the system.[146] Additionally, members are required to have in place effective legal means to prevent importation into, and sale in, their territories of products of products produced under the system.[147] Further, to aid and abet the transfer of technology in the pharmaceutical manufacturing sector, eligible importing members and exporting members are urged to use the system in such a manner that transfer of technology and capacity building in the pharmaceutical sector is enhanced.[148] Finally, the Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and report annually to the General Council of the WTO.[149]

Having exhaustively dealt with the salient provisions of the first paragraph of Article 31 *bis* and the accompanying conditions, it is now appropriate to move on to the remaining four paragraphs.

A compulsory licenses issued by an exporting member in terms of Article 31 *bis* shall be accompanied by adequate remuneration in terms of Article 31(h) of TRIPS, and such compensation shall be paid in that member taking into account the economic value to the importing member of the authorized use.[150] However, in a context quite relevant to LDCs and the SADC region, if the compulsory license is granted for the same products in the eligible

143 The information will be published on the WTO website.
144 Para 2(b) (iii) of the Annex to the TRIPS Agreement.
145 If an importing member is an LDC or developing member that is unable to establish the relevant administrative structure, then it may be assisted by its developed counterparts, who on request must provide technical and financial assistance.
146 Para 3 of the Annex to the TRIPS Agreement.
147 Para 4 of the Annex to the TRIPS Agreement.
148 Para 6 of the Annex to the TRIPS Agreement.
149 Para 7 of the Annex to the TRIPS Agreement.
150 Article 31 *bis* para 2.

importing member, then the obligation to pay adequate compensation does not arise.[151] However, I submit that the above cited provision is problematic and does not auger well for access to medicines. Firstly, "adequate remuneration" is not defined, neither is "the economic value to the importing member". These issues require further clarification.

The provision of Article 31 *bis* that I consider as very important and likely to solve access issues in the context of LDCs and developing countries in the SADC region is the one dealing with harnessing economies of scale for the purposes of enhancing purchasing power for the facilitation of local production of pharmaceuticals.[152] Very briefly, this paragraph provides that Article 31(f) will not apply if a compulsory license is issued by an a developing or LDC member which 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.[153] The provision of this paragraph must be read together with those in the Annex to the TRIPS Agreement, calling for the facilitation of local production of pharmaceutical products through regional patents.[154] It is recommended that the SADC countries take advantage of this flexibility and consider a regional compulsory license or regional pharmaceutical manufacture of targeted medicines.[155] It is however important to mention that this proposal will not see the light of day if no technical capacity is forthcoming from developed WTO members and other intergovernmental organisations, such as WIPO.[156]

It is important as a valedictory remark to a discussion of Article 31 *bis* to refer to the fact that members shall not challenge any measures taken in conformity with the provisions of the Article and the Annex to the TRIPS in terms of the WTO dispute settlement system.[157] Such a provision will leave members free to apply the pertinent provisions of the Article without the fear of possible litigation.

This Article and the Annex to the TRIPS Agreement is without prejudice to the rights obligations, and flexibilities that members have under the general provisions of TRIPS. It is now therefore appropriate to turn our discussion to compulsory licenses in the context of South Africa.

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151 *Ibid*.
152 Article 31 *bis* para 3.
153 Article 31 *bis* para 3.
154 Para 5 of the Annex to the TRIPS Agreement.
155 See on a closely related general note, Banda 2016 *Maryland Journal of International Law* 59.
156 This issue is specifically acknowledged in para 5 of the Annex to the TRIPS Agreement.
157 Article 31 *bis*, para 4.

3 THE SOUTH AFRICAN IP SITUATION IN THE CONTEXT OF DOHA

3 1 Why are compulsory licenses important for South Africa?

Compulsory licenses are important for South Africa for a number of reasons. They are important in that they ensure that there will be full practical exploitation of the patented invention and that patent rights would not be exercised in such a way as to prejudice the development of industry.[158]

Their main advantage lies in the fact that they can be used to meet the local market demand, to reduce medicine prices and facilitate research and development of new medicines provided the pharmaceutical manufacturing capacity exists.[159]

The primary aim of compulsory licenses would be to level the commercial playing field by curbing excessive pricing by big pharmaceutical companies. Levelling the commercial playing field implies that the dominant business entity selling drugs competes fairly with other existing competitors or potential ones. This has the advantage of bringing prices down, thus improving access to affordable medicines while allowing other players to enter the market and make the environment competitive. Compulsory licensing from several right holders might also allow for the lawful manufacture and sale or rational fixed-dose combination medicines. Compulsory licensing can ensure redundant sources of supply not only to increase competition and lower prices but also to prevent stock-outs. Finally, compulsory licensing can advance the development and use of local pharmaceutical capacity and many argue that this is a lawful purpose.

3 2 South Africa's legal regime for compulsory licenses

South Africa provides for compulsory licensing in its domestic legislation and should take advantage of the use of this TRIPS flexibility in light of the legal clarity brought by the Doha Declaration and Article 31 *bis.*

South Africa does have a comprehensive legal regime regulating the grant and conditions of use of compulsory licenses in a variety of contexts.[160] The most relevant provision which applies directly to access to essential medicines is the one relating to the use of a "compulsory

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158 Burrell *Burrell's South African Patent and Design Law* (1999) 308.

159 Ogendi *Access to Essential Medicine and the Utilisation of Compulsory Licensing and Parallel Importation in Kenya and South Africa* (LLM-dissertation, University of Nairobi, 2013).

160 The specific provisions are sections 55-58 of the Patents Act 57 of 1978 (hereinafter Patents Act).

licence in case of abuse of patent rights".[161] In the international TRIPS context, it is also important to reiterate that South Africa has ratified the amendment to the TRIPS Agreement[162] notwithstanding the fact that no legislation has thus far been passed to domestically effect the amendment.[163]

Section 56 provides for limited grounds[164] upon which licenses may be issued in the event of an abuse of patent rights. The grounds include among the following:

a) Non-working of a patent in the Republic on a commercial scale or to an adequate extent, after the expiry of a period of four years subsequent to the date of the application for the patent or three years subsequent to the date on which that patent was sealed and the Commissioner of Patents is of the opinion that there is no satisfactory reason for such non-working;[165]

b) the demand for the patented article in the Republic is not being met to an adequate extent and on reasonable terms;[166]

c) the refusal of a patentee to grant a license or licenses on reasonable terms prejudices the trade or industry or agriculture of the Republic or the trade of any person or class of persons trading in the Republic, or the establishment of any new trade or industry in the Republic, and the granting of such licenses is in the public interest;[167] and

d) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive

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161 Section 56 of the Patents Act.

162 The date of acceptance of the instrument is indicated on the WTO website as 23 February 2016. See https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (accessed 29-04-2017).

163 In terms of the relevant international law regime, specifically with reference to sections 231 and 232 of the South African Constitution, South African adopts a combination of both the monist and dualist schools of thought when it comes to the relationship between domestic and international law. The implication is that for an international agreement such as Article 31 *bis* to become legally binding on South Africa domestically, it must be enacted into law by national legislation (section 231(4) of the Constitution). For scholarly support of this submission, see generally Ferreira and Ferreira-Snyman, "The Incorporation of Public International Law into Municipal Law and Regional Law against the Background of The Dichotomy between Monism and Dualism" 2014 *Potchefstroom Electronic Law Journal* 1471-1496.

164 The specific grounds are listed in section 56(2).

165 Section 56 (2) (a).

166 Section 56 (2) (c).

167 Section 56 (2) (d).

compared to the price charged for the same product by the patentee or licensee in other countries.[168]

From the above mentioned grounds, the last three seem to be directly applicable to the granting of compulsory licenses to aid access to medicines.

It is possible in terms of the second ground that an important drug may be patented in the Republic but be available to the public in limited quantities which are generally out of reach for the poor.

The third ground may be implicated in situations where the local pharmaceutical industry is hamstrung by the refusal of the patentee to grant licenses on reasonable terms and such refusal then stifles the establishment of pharmaceutical companies that are likely to produce the drug yet the demand for it justifies the granting of licenses.

The last ground would be quite relevant in the context of a big multinational pharmaceutical company, largely pejoratively referred to as "Big Pharma" in access to medicines literature, which holds a patent in an essential drug which is imported but is very expensive locally. With specific reference to this ground, it can be argued on the contrary that the other possible remedy in such a situation would be to make use of the parallel importation provisions in the relevant legislation.[169] However, this ground seems to be the most relevant one which can form the basis for the invocation of compulsory license provisions in the context of access to medicines in South Africa. South Africa's health system relies largely on imported drugs to cure common diseases, and most of these drugs are beyond the reach of the country's sick poor.[170]

The procedure in terms of which an application for a licence can be considered is cumbersome and too legalistic.[171] The application for a compulsory license on the basis of the abuse of rights in a patent must be made by "any interested person",[172] and such "interested person" is not defined. One cannot confidently submit that entities and persons procuring or using medicines would readily be accepted as interested parties. This should be clarified through an amendment. Such an application must be brought by way of notice of motion,

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168 Section 56 (2) (e)

169 Section 45 (2) of the Patents Act deals with the exhaustion of patent rights but does not authorize parallel imports.

170 Section 56 (2) (e) specifically emphasises that fact that the patented product is not accessible in South Africa due to the fact that it is expensive.

171 The cumbersome procedure before the Commissioner of Patents is encapsulated in Regulations 76-105, of the Patent Regulations 1978 as amended.

172 This is provided for in section 56 (1).

supported by evidence on affidavit, and must be served on the patentee and any other person who appears on the register to have an interest in the patent.[173] The patentee or other person is then entitled to oppose the application[174] in the prescribed manner.[175]

The above procedure is cumbersome and should be streamlined to make the applications for compulsory licences quicker, less onerous and cheaper. In practical terms, "quicker" "less onerous" and cheaper means that a new less judicious procedure must be adopted for the grant of compulsory licenses. Presently in South Africa, applications for compulsory licenses mimic a court process before the Commissioner of Patents who hears the dispute just like a normal dispute brought before court, subject to all encumbrances associated with litigation such as legal representation, objections, postponements etc. A quicker and less formal process must therefore be adopted and this will be cheaper because there will be no expenses associated with litigation.

Grounds for granting compulsory licenses must be expanded. For instance, under the repealed 1952 Patents Act,[176] the listed grounds were:

(a) Where the patent related to food, medicine or surgical or curative devices;[177]

(b) Where the working of a patent without infringement was dependent upon obtaining a licence under an earlier patent;[178]

(c) Where the Patentee had abused or made insufficient use of his patent rights;[179]

The whole section 56 deals with compulsory licences in instances of abuse only despite the fact that the TRIPS Agreement gives WTO members ample legal and policy room to determine their own grounds for issuing compulsory licenses.[180]

The first ground in the repealed Patents Act should be re-enacted in the current patents Act but drafted in such a manner that it is not seen to violate the national treatment principle by

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173 Regulation 96 of the Patent Regulations.
174 Section 56 (3) of the current Patents Act.
175 The "prescribed manner" can be adhered to by following the procedure outlined in Regulations 82-88 of the Patents Regulations.
176 Act 37 of 1952.
177 Section 48 of the repealed Patents Act. This ground has not been re-enacted in the current Patents Act.
178 Section 49 of the repealed Patents Act. This ground is still provided for under section 55 of the current Patents Act.
179 Section 50 of the repealed Patents Act. This ground is replicated in slightly modified language in section 56 (1) of the current Patents Act.
180 See Article 31 of TRIPS read together with para 5 of the Doha Declaration on TRIPS and Public health.

targeting food, medicines or surgical or curative devices when there is a public health or other public interest need. The Act could also be amended to allow compulsory licenses that provide access to essential facilities,[181] to allow production of fixed-dose combination medicines, to create additional sources of supply to prevent stock outs and other supply interruptions, and to promote local production by building pharmaceutical capacity.

3 3 Importance of compulsory licenses: Snippets from pertinent case law

In South Africa the importance of compulsory licenses is illustrated by two cases that were referred to the Competition commission in 2002[182] and 2007 respectively.

In 2002, the Treatment Action Campaign (TAC) lodged complaints against GlaxoSmithKline (GSK) and Boehringer Ingelheim for the excessive prices of zidovudine (AZT) and nevirapine. The Competition Commission found that the prices were excessive and referred the matter to the Competition Tribunal. At this stage of referral, the patentees backed down and agreed to license a generic manufacturer. The prices of the medicines in question dropped. While this case was not brought in terms of section 56 of the Patents Act, had the matter proceeded beyond the Competition Tribunal, a compulsory license was likely to be applied for and issued.

However, despite the above advantages, compulsory licences will be problematic to use in the SADC and South African context because their use will be limited to small quantities of imports to deal with a specific problem. Secondly, due to the lack of pharmaceutical manufacturing capacity, most SADC countries are likely to use the licences as importers, thus retarding the development of domestic manufacturing capacity.[183] The problem of lack of pharmaceutical manufacturing capacity is however insignificant to South Africa, a country with some notable local pharmaceutical manufacturing capacity.

South Africa has therefore not taken advantage of the flexibilities introduced by the Doha Declaration and the subsequent legal intervention introduced post the Declaration due to

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181 In terms of section 1 of the Competition Act 89 of 1998, an "essential facility" means an infrastructure or resource that cannot reasonably be duplicated, and without access to which competitors cannot reasonably provide goods or services to their customers.

182 ***Hazel Tau v GlaxoSmithKline SA (Pty) Ltd*** http://www.section27.org.za/wp-content/uploads/2010/10/TauvGSKevidenceAndLegalSubmissions.pdf (accessed 03-09-2017).

183 ***Hazel Tau v GlaxoSmithKline SA (Pty) Ltd.***

deficiencies in the legal regime outlined above and illustrated by the drug and disease vignette below.

4 DISEASE AND DRUG VIGNETTE: BREAST CANCER AND THE CASE OF TRASTUZUMAB (HERCEPTIN)

4 1 Preliminary remarks

The disease and drug vignette narrated here starkly illustrates South Africa's dire situation with respect to the accessibility and affordability of drugs on the local market. It cannot be overemphasized that South Africa's disease burden is high. If essential drugs are expensive and out of reach of the ordinary patient, this on its own militates against the goal of access to medicines, and violates one of patient rights. If patented drugs are expensive and access to them is further hampered by the fact that the entry of generics is blocked by unreasonable activities of the patentee, this may compel the government to consider using compulsory licenses. The fact that the price is out of reach of the ordinary patient may also necessitate negotiations with the patentee for either a voluntary or compulsory license. The narrative below therefore makes a compelling case for the deployment of compulsory licensing in South Africa in order to undo the negative effects of high prices on essential medicines. The deployment of compulsory licenses will be a classic example of South Africa taking advantage of the flexibility introduced by the Doha Declaration.

4 2 The Cancer drug Trastuzumab

Non-communicable diseases like cancer are a global health crisis that mirrors the HIV/AIDS epidemic.[184] It is estimated that by 2030, 75% of the world's deaths will be attributed to non-communicable diseases, namely, cancer, diabetes, heart and lung disease.[185] For every five deaths globally, three are caused by cancer, lung disease and diabetes; and in 2008, this translated to 36 million deaths per year.[186] In addition to being a global health crisis, non-communicable diseases also reveal a crisis of health inequality in that 80% of the non-communicable disease deaths reported worldwide occur in low and middle income

[184] Kiddell-Monroe "Access to Medicines and Distributive Justice: Breaching Doha's Ethical Threshold" 2014 *Developing World Bioethics* 59.
[185] Kiddell-Monroe 59
[186] Kiddell-Monroe 60.

countries. [187] Cancer has emerged as one of the major causes of morbidity and mortality worldwide, and in 2012, about 14 million new cases were reported.[188]

According to the Cancer Association of South Africa (CANSA) in collaboration with the National Cancer Registry, more than 100 000 South Africans are diagnosed with cancer every year and the cancer survival rate is 6/10.[189] One in four South Africans is affected by cancer, and about 90% of cancers are caused by environmental and life style factors such as smoking, an unhealthy diet and lack of exercise.[190] According to the World Health Organisation (WHO), about one third of cancer related deaths worldwide are due to high body mass index, low fruit and vegetable intake, lack of physical activity, tobacco use, and alcohol use.[191] Cancer is a leading cause of death worldwide, and in 2015, it accounted for 8.8 million deaths.[192]

The most common cancers that account for most cancer-related deaths are: lung, liver, colorectal, stomach and breast cancer.[193]

Among South African women, breast cancer is the major killer cancer.[194] Breast cancer is the number one killer cancer among Indian, coloured and white women while among black women, it comes second to the cancer of the cervix.[195] According to the 2015 WHO Essential Medicines List, the drug Trastuzumab is the best prescription for early stage HER2 positive breast cancer and metastatic HER2 positive breast cancer.[196] When the drug is used in conjunction with chemotherapy, the chances of overall survival and disease-free survival improve significantly.[197]

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187 See WHO "2008-2013 Action Plan for the Global Strategy for the Prevention and Control of Non-communicable Diseases" www.who.int/nmh/publications/ncd_action_plan_en.pdf (accessed 16-07-2017).

188 See generally Stewart and Wild (eds) *World Cancer Report* (2014).

189 See CANSA "South African Cancer Statistics" http://www.cansa.org.za/south-african-cancer-statistics/ (accessed 19-06-2017).

190 "South African Cancer Statistics" http://www.cansa.org.za/south-african-cancer-statistics/ (accessed 19-06-2017).

191 WHO "Cancer Factsheet" http://www.who.int/mediacentre/factsheets/fs297/en/ (accessed 19-06-2017).

192 *Ibid*.

193 *Ibid*.

194 CANSA "Fact Sheet on the Top Ten Cancers per Population Group" http://www.cansa.org.za/files/2017/03/Fact-Sheet-Top-Ten-Cancers-per-Population-Group-in-SA-NCR-2012-web-Feb-2017.pdf (accessed 19-06-2017).

195 *Ibid*.

196 See "WHO Essential Medicines List 2015" http://www.who.int/medicines/publications/essentialmedicines/EML2015_8-May-15.pdf?ua=1 (accessed 19-06-2017).

197 See generally, Perez *et al* "Trastuzumab plus Adjuvant Chemotherapy for Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: Planned Joint Analysis of Overall Survival from NSABP B-31 and NCCTG N9831" 2014 *Journal of Clinical Oncology* 3744-3752.

Manufactured by Roche and marketed as Herceptin, Trastuzumab is an essential medicine used in the treatment of breast cancer, and is available in both the private and public healthcare sectors of South Africa. This drug is however priced out of reach of the average South African. Generally speaking, although the costs of cancer drugs are high, this cost makes a fraction of the total cost of treatment.[198] In 2016, in South Africa, Trastuzumab cost ZAR25 000 per treatment, and if mastectomy were added, the cost ballooned to R500 000.

Currently, the annual cost of the drug is around R550 000 for a 12 month course in the private sector.[199] Although the drug is available at a lower price of around US$ 15 735 (ZAR 211,920) per year in the public sector, there are few public facilities which can access Trastuzumab and the price is still too high. It has been reported in the popular press that negotiations between the South African government and Roche for the reduction of the price of the drug have been ongoing for almost a year and half with no solution in sight.[200] In the negotiations, it was reported that Roche had agreed to offer the drug to South Africa's public sector at an annual treatment price of around R100 000, a price that is at par with low income countries such as India.[201] Roche argued that because Herceptin is an antibody that is a living organism, it is more expensive to make and distribute than regular medicines hence the high price.[202] However, the South African government was adamant that the price could be reduced further.[203] If Roche can sell at such a high price in the private sector and be able to offer such a concessionary price to the public sector (despite it still being high), one cannot escape the conclusion that the price is inflated significantly and smacks of patent abuse.

Roche holds a South African patent in Trastuzumab under the name "Cancer Treatment Combination Therapy Comprising Vinflunine and Trastuzumab".[204] However, this patent has lapsed for want of payment of annual renewal fees,[205] and its status among access to medicines

198 Sartorius and Sartorius "The future cost of cancer in South Africa: An interdisciplinary cost management strategy" 2016 *South African Medical Journal* 949.

199 See Child and Gernon "Women die while waiting for government, pharmaceutical company to agree on price of cancer drug" *The Times* 29 May 2017 http://www.timeslive.co.za/thetimes/2017/05/29/Women-die-while-waiting-for-government-pharmaceutical-company-to-agree-on-price-of-cancer-drug1 (accessed 14-06-17).

200 Child and Gernon above "Women die while waiting for government, pharmaceutical company to agree on price of cancer drug" *The Times* 29 May 2017 http://www.timeslive.co.za/thetimes/2017/05/29/Women-die-while-waiting-for-government-pharmaceutical-company-to-agree-on-price-of-cancer-drug1 (accessed 14-06-17).

201 *Ibid*.

202 *Ibid*.

203 *Ibid*.

204 South African patent number 2009/08247, with a priority date of 23 November 2009 and granted on 27 October 2010.

205 See Companies and Intellectual Property Commission patent search portal http://patentsearch.cipc.co.za/patents/patentresult.aspx (accessed 14-06-2016).

activists and patent scholars is unclear. It may happen that Roche will apply or has already applied to the relevant Court asking for condonation for late payment of renewal fees.[206] This however is speculative, and the fact of the matter is that the patent has lapsed, unless the contrary is proved.[207]

Between May 2013 and October 2016, Roche applied for further patents which largely amount to inventions around Trastuzumab. It is common practice in big pharmaceutical companies to relentlessly try to obtain extensions of the life-spans of patents[208] through the notorious practice called patent ever greening. The first patent, entitled "Treatment of Her2-Positive Cancer with Paclitaxel and Trastuzumab-Mcc-Dm1", has a priority date of 17 May 2013 and was granted on 30 July 2013. Ironically, in August 2013, the Indian Patents Office in Kolkata refused to grant patents on a version of Roche's drug Trastuzumab, sold as Herceptin.[209] The company was however allowed to retain the patent that will protect the drug from generic competition until 2019.[210]

All other things being equal, it will not be possible to introduce generic equivalents of the relevant drug in South Africa earlier than 2033.[211] It is this drug that is currently the subject of price negotiations between the South African government and Roche. Our prediction is that the negotiations will culminate in a mutually acceptable solution and there will be no need for South Africa to consider negotiations for voluntary or compulsory licenses.

On a worrying note, on 26 and 28 October 2016, Roche applied for two additional patents which implicate Trastuzumab variously. The patent filed on 26 October is for "Targeting Trastuzumab-Resistant Her2+Breast Cancer With A Her3-Targeting Nanoparticle"[212] and the one filed on 28 October is for "Methods of Treating Early Breast Cancer with Trastuzumab-Mcc-Dm1 and Pertuzumab".[213] Both patent applications are complete ones which are however

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206 See section 46 of the Patents Act dealing with the duration of patents subject to payment of renewal fees and the possible extension by not more than six months of the period within which renewal fees may be paid.

207 For example, section 47(1)-(5) of the Patents Act gives the holder of a lapsed patent a chance to apply for its restoration subject to opposition from interested parties.

208 Sterckx "Patents and Access to Drugs in Developing Countries: An Ethical Analysis" 2004 *Developing World Bioethics* 65.

209 Hayden "India spurns cancer patents: Nation seeks to cap high cost of drugs to treat non-infectious Diseases" 2013 *Nature* 266 http://www.nature.com/news/india-spurns-cancer-patents-1.13552 (accessed 19-06-2017).

210 *Ibid*. See further para 5 2 below.

211 See section 46(1) of the Patents Act.

212 Complete South African patent application with patent number 2016/07375.

213 Patent number 2016/07469.

still pending before the Patents Office.[214] For these two recent patent applications, Roche collaborated with private players such as Genentech Inc. and Cedars-Sinai Medical Centre.[215]

The dispute between Roche and the government of South Africa illustrates very starkly a situation in which patent laws militate against access to essential medicines. While it is largely beyond polemics in IP circles that inventors must be rewarded for their innovations, there is a need to strike an equitable balance between patent and patient rights. This balance can be struck properly in the South African context by amending section 56 of the Patents Act in line with the TRIPS Agreement generally and Article 31 *bis* in particular. Once the law has been amended and the grounds for the issuing of compulsory licenses are expanded and clarified, it would be easy to issue compulsory licenses or at least threaten their invocation as some form of leverage in negotiations with the pharmaceutical likes of Roche, GlaxoSmithKline, Bayer and others.

At least in other developing country jurisdictions outlined below, compulsory licenses were effectively used with positive results for access to medicines. South Africa can therefore pluck a leaf from the rest of Africa and India.

5 COMPARATIVE LESSONS FROM OTHER JURISDICTIONS

South Africa can and should learn some useful lessons from Africa and the rest of the developing world on how to effectively take advantage of the Doha Declaration and use compulsory licenses to access essential medicines.

5 1 Lessons from the rest of Africa

In brief, on the African continent, compulsory licences have been used to access lifesaving drugs. In the case of Rwanda, a compulsory license was issued and used in the context contemplated by Article 31 *bis*, wherein the license was issued in Canada for the supply of the domestic market of a third country, namely Rwanda.

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214 See http://patentsearch.cipc.co.za/patents/patentresult.aspx (accessed14-06-2017).

215 See for example PRNEWSWIRE "Roche Diagnostics, Cedars-Sinai Medical Center Enter Strategic Alliance for Center to Operate as a Roche Molecular Center of Excellence: Collaborative relationship designed to help accelerate advancement of new methods in molecular diagnostics testing and personalized predictive treatment", announcing the collaborative relationship between Roche and Cedars-Sinai Medical Center http://www.prnewswire.com/news-releases/roche-diagnostics-cedars-sinai-medical-center-enter-strategic-alliance-for-center-to-operate-as-a-roche-molecular-center-of-excellence-134240268.html (accessed 14-06-2016).

Domestic legislations of most countries in Africa,[216] and in the SADC region,[217] provide for compulsory licences. To date, the following African countries have used compulsory licences to access medicines, particularly in the context of HIV/AIDS: Cameroon (2005), Ghana (2005), Guinea (2005), Eritrea (2005), Mozambique (2004), Swaziland (2004), Zambia (2004) and Zimbabwe (2001).[218] In South Africa, a compulsory licence on the basis of abuse of a patent in the context of competition law was on the verge of being issued in 2003 but the parties negotiated and settled for a voluntary licence, with positive results for access to medicines.[219]

The government of Mozambique in 2004 attempted to locally manufacture the fixed-dose combination of lamivudine, stavudine and nevirapine under a compulsory licence issued to a local pharmaceutical company, Pharco Mozambique. The effort failed because active pharmaceutical ingredients were expensive, thus rendering local production economically unviable.[220] This problem highlights the fact that TRIPS flexibilities on their own cannot resolve the access problem; effective policy instruments and an enabling local environment are prerequisites. It must be reiterated that lack of local manufacturing capacity is not a challenge for South Africa.

Botswana's case is very important in that it has two elements – the legislative intervention in the IP arena generally and the domestication of Article 31 *bis* in particular. South Africa is urged to learn from Botswana[221] and include a ground for the granting of compulsory licenses for export or import based on Article 31 *bis* of TRIPS.[222]

In the specific context of Botswana, once a compulsory license has been granted, "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*

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216 For example, Ghana (section 14 of Patents Act 657 of 2003), Kenya (sections 72 and 80 of Industrial Property Act of 2001, Uganda (section 30 of Patents Act 2002 as amended) and Nigeria (section 11 of the Patents and Designs Act Chapter 344 of 1990.

217 For example, Botswana (sections 34 and 35 of the Industrial Property Act of 2010), Zimbabwe (section 35 of Patents Act (Chapter 26:03) of 1972 as amended) and section 9 of Zambian Patents Act [chapter 400] of 1996.

218 For the specifics, see Love "Recent examples of the use of compulsory licenses on patents" 2007 *Knowledge Ecology International* 15 – 18.

219 *Ibid* 16 – 17.

220 Osewe *et al Improving Access to HIV/AIDS Medicines in Africa: Trade-Related Aspects of Intellectual Property Rights Flexibilities* (2008) 17.

221 Section 31 (3) of Botswana's Industrial Property Act 2010.

222 This Article allows WTO members to use compulsory licenses to manufacture patented products for use by other members. South Africa will qualify as an "importing" or "exporting" member in terms of para 1(b) of the Annex to the TRIPS Agreement. South can make use of the provision if it domesticates the provisions of Article 31 *bis* and the appropriate place to domesticate the provision would be in section 56.

applies" (emphasis added). This is one of several grounds that may be added to expand the grounds outlined in South Africa's section 56 of the Patents Act.

Outside of Africa, South Africa can use the experiences of Argentina, Brazil, India and Thailand to inspire its IP law reform and make effective use of compulsory licenses as prescribed initially by the Doha Declaration, and now by the TRIPS.[223]

5 2 Lessons from a non-African comparable developing jurisdictions

5 2 1 India

South Africa's development trajectory is largely similar to that of India – a fast growing economy with a huge poor population demanding that the government come up with appropriate health policies. The relevant section of India's Patent Law applicable to compulsory licensing is Section 84.[224] The section targets possible abuse of the monopoly granted by a patent, allows for the commercial exploitation of the patented invention in addition to addressing public health concerns.[225] In addition, the grant of a compulsory license under this section cannot be challenged either through an opposition processes or in a court of law.[226] This provision ousting the jurisdiction of the courts to hear such suits is unlikely to be supported in South Africa in light of certain constitutional imperatives.[227]

India is party to the TRIPS Agreement wherein minimum standards for intellectual property regulation are set. It must be underlined and recognized that India has a well-established TRIPS compliant legislative, administrative and judicial framework to safeguard IP rights. Accordingly, India has literally heeded the Doha Declaration on the provision that each member has the right to grant compulsory licenses and also have the freedom to determine the grounds upon which such licenses may be granted.[228] It is also worth highlighting that beyond India's elaborate provision for compulsory licenses, it has also effectively used its legislation to reduce the incidents of patent evergreening[229] by big pharmaceutical companies such as

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223 Such provision is provided for by Article 31 of TRIPS generally and 31 *bis* of same in particular.

224 Chapter XVI of India Patents Act 1970, incorporating all the amendments to the Patents Act 1970 and the Patent Rules 2003 and is updated till 23-06-2017 http://www.ipindia.nic.in/writereaddata/Portal/IPOAct/1_113_1_The_Patents_Act_1970_-_Updated_till_23_June_2017.pdf (accessed 14-07-2017). See additionally, Sampat and Shadlen "Secondary pharmaceutical patenting: A global perspective" 2017 *Research Policy* 693-709.

225 Section 84(1) (c) of the Act provides for compulsory licenses in situations where the patented invention is not available to the public at a reasonably affordable price.

226 Section 92 (1) (3).

227 See specifically section 34 of the Constitution of the Republic of South 1996.

228 India has in fact domesticated Article 31 *bis* in section 92A of its Patent law, which deals with compulsory licenses for export of patented products to countries having insufficient or no manufacturing capacity.

229 According to Eisenberg "The Problem of New uses" 2005 *Yale Journal of Health Policy Law and Ethics* 717, evergreening is a practice consisting in the extension of the commercial life of a patent through the filing of

Bayer and Roche, thus making the production of affordable generic drugs possible in the country.[230]

Compulsory licensing in India has not been smooth sailing. The United States Representatives (USTR) placed India on its "priority watch" for two years alleging that the country's laws were unfairly favouring local drug makers. India is steadfast in granting licenses under certain conditions, such as public health emergencies, to ensure access to affordable medicines.[231]

The first license was granted in 2012 to allow a local firm, Natco Ltd to sell the generic cancer drug (Naxavar), manufactured by Bayer in Germany at a tenth of the price.[232] However, big International Pharmaceutical companies have pressured India to change its approach. Médecins sans Frontières (MSF) has rightly expressed its worries about the attacks on India's compulsory licensing scheme.[233]

In trying to emphasize on a compromise, the Indian government has been conscious of the need to spur innovation and protect individual rights by retaining the sovereign right to utilise the flexibilities provided in the TRIPS and Doha Declaration. The highest court in India upheld the March 4 2013 decision of the Intellectual Property Appellate Board (IPAB) dismissing the appeal by Bayer against the grant of a compulsory license to Natco for the cancer drug Nexavar.[234] This must be applauded as an approval for a well thought out and articulated process. South Africa or any other country facing similar challenges will in all likelihood be inspired and learn from the decision in the case.

It is thus critical that South Africa looks at India's example in formulating policy and legislation to enable the courts to deal with compulsory licensing disputes which may arise.

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applications for the patenting of new uses of the same product or for marginally improved substances or derivatives. Evergreening is frowned upon because it has anti-competitive effects, delays the entry of generics on the market, and negatively impacts on drug prices.

230 On this point and other related matters, see Ndlovu, "Lessons for the SADC from the Indian case of Novartis AG v Union of India" 2015 *Potchefstroom Electronic Review* 783-815.

231 Baker and Geddes "Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines - Eli Lilly v Canada and the Trans-Pacific Partnership Agreement" 2015 *School of Law Faculty Publications, Paper 15* http://lsr.nellco.org/nusl_faculty/15 (accessed 26-06-2017).

232 See generally http://www.ssrana.in/Intellectual%20Property/Patents/Patents-Compulsory-Licensing-in-India.aspx (accessed 21-05-2017).

233 Tommasini "India: Bayer attempting to block affordable patented drugs" http://www.msf.org/en/article/india-bayer-attempting-block-affordable-patented-drugs (accessed 25-08-2017).

234 Sood "Natco Pharma Ltd. v Bayer Corporation and the Compulsory Licensing Regime in India" 2013 *NUJS Law Review* 99-119.

South Africa needs to contextually adopt the essence of sections 84 and 92 of India's Patent Act.

5 CONCLUSION

It will be recalled that a number of possible solutions to the problem of expensive drugs in poor countries have been proposed by other writers, namely, using parallel imports, the research exception, differential pricing and providing research funding in order to deal with pharmaceutical companies apprehension about the possible loss of profits. One possible radical solution has also been touted, namely, that governments in poor countries should simply overlook existing patent laws and allow generic production of patented drugs. This paper however made a firm case for the use of compulsory licenses as an access to medicines mechanism generally, and in the South African context in particular.

It will be recalled that in 2012, India issued a compulsory licence on a cancer drug sold by the German firm Bayer. In January 2013, India's Ministry of Health recommended compulsory licences for Trastuzumab and two other cancer drugs. In 2012, Indonesia issued compulsory licences for seven drugs while China[235] and the Philippines[236] have amended their laws to make compulsory licences easier to invoke. This should surely inspire South Africa to take bold deliberate steps towards making the regime for compulsory licenses easier and practically possible.[237]

Compulsory licencing as a TRIPS flexibility that was clarified by the Doha Declaration offers unique advantages for WTO members especially the developing ones and LDCs. The main advantage of compulsory licenses is that they can be used to meet the local market demand, to reduce medicine prices and facilitate research and development of new medicines provided the pharmaceutical manufacturing capacity exists.[238]

The above reservations are not that relevant to South Africa, which has some limited manufacturing capacity to produce active pharmaceutical ingredients.[239] What South Africa

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235 Articles 50, 53 and 57 of the amendment to the Patent Law of the People's Republic of China, which was adopted on 27 December 2008 and entered into force on 1 October 2009.

236 Section 93-A of the Republic Act No. 9502 (also known as the "Universally Accessible Cheaper and Quality Medicines Act 2008") and Rule 13 of the Implementing Rules and Regulations of Republic Act No. 9502 provide the legal basis for the grant of a special compulsory licence for the import of patented drugs and medicines, as well as for their manufacture and export.

237 See para 3 3 above.

238 Ogendi *Access to Essential Medicine and the Utilisation of Compulsory Licensing and Parallel Importation in Kenya and South Africa* (LLM-Dissertation, University of Nairobi, 2013).

239 Banda "Intellectual Property and Access to Essential Pharmaceuticals: Recent Law and Policy Reforms in the Southern Africa Development Community Region" 2016 *Maryland Journal of International Law* 59.

needs very urgently is IP law reform, which must be based on the leeway introduced by the Doha Declaration, the 2003 Decision and finally the permanent amendment to TRIPS, which came in the form of Article 31 *bis*, which South Africa has ratified but not domesticated.

Additionally, Article 31(k) of TRIPS expressly relates to licenses granted to remedy anti-competitive practices. This should be reflected in the Patents Act as part of section 56 or as a new provision.[240] There is no reason why the provisions of Article 31(k) should remain in the realm of competition law as if they are not related to IP.[241]

If South Africa's IP law reform could be inspired by the TRIPS Agreement, the Doha Declaration and Article 31 *bis* in light of the situation obtaining in other developing countries, patient and patent rights can harmoniously co-exist for the benefit of access to medicines for the poor. There is really no reason why the IP law reform project should be delayed any longer since the Doha Declaration dismantled the legal impediments and barriers about 17 years ago. While recent government efforts at IP law reform such as the introduction of patent examinations and the adoption of an IP Policy framework are welcome, it is now the appropriate time for South Africa to adopt "radical IP law reform" alongside "radical economic transformation".

However, while law reform based on the tenets of the Doha Declaration and now encapsulated in Article 31 *bis* seems to be a plausible solution, the United States,[242] the European Union, Canada, Switzerland and Japan have constantly tried to undermine the Declaration by attempting to limit its scope.[243] In addition, the proliferation of regional trade agreements[244] and economic partnership agreements between the US/EU and developing countries incorporating IP issues has not helped the situation.[245] These agreements, which are

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240 Examples of anti-competitive practices, characterized as "prohibited practices" in Chapter 2 of the South African Competition Act 89 of 1998 include: restrictive practices, abuse of a dominant position, and various license provisions in the Patents Act.

241 We suggest that section 56 of the Patents Act should make an express reference to Chapter 2 of the Competition Act 89 of 1998 especially the provisions dealing with patent law.

242 Lybecker "The Economics of Access to Medicines: Meeting the Challenges of Pharmaceutical Patents, Innovation, and Access for Global Health" 2011 *Harvard International Law Journal* 28 rightly points out that the United States is "the world's largest and most lucrative pharmaceutical market" with no direct price controls for non-governmental pharmaceutical sales. We submit that the private pharmaceutical sector in the US will in all likelihood lobby the government and put pressure on it to prioritize patents.

243 Sterckx 74.

244 Most of these agreements usually incorporate TRIPS-plus IP provisions as exemplified by the Jordan-US Free Trade Agreement, discussed by EL-Said and El Said "TRIPS-Plus Implications for Access to Medicines in Developing Countries: Lessons from Jordan-United States Free Trade Agreement" 2007 *The Journal of World Intellectual Property* 438-475.

245 Rosenberg "Asserting the Primacy of Health over Patent Rights: A Comparative Study of the Processes that Lead to the Use of Compulsory Licenses in Thailand and Brazil" 2014 *Developing World Bioethics* 83 argues

continuously being negotiated, "threaten to erode or even abandon the Doha Declaration".[246] Other countries have literally traded away TRIPS flexibilities "in exchange for access to US and European markets".[247] On this point, South Africa must be commended for acknowledging the problem and proposing a solution thereto.[248]

It is important for South Africa to reform the cumbersome procedure for granting compulsory licenses under section 56 of the Patents Act. The grounds for the granting of compulsory licenses must be expanded, in line with the Doha Declaration and Article 31 *bis*, which must be urgently domesticated in South Africa's national interest. This national interest includes the right to health, appropriately provided for in the Constitution. The presence of the constitutional provision on the right to health[249] therefore implies that the protection of intellectual property rights on medicines must be subject to considerations of justice and equity in the unique context of South Africa. Patent rights are property rights protected by the Constitution[250] just like the right to health is protected by the Constitution. There surely will be justice and equity in enforcing patent rights as property rights which do not override the right to health. In recognition of this uniqueness, taking on board the requirements of justice and equity, South Africa must selectively learn from the experiences of other jurisdictions discussed here, and patient rights must ultimately trump patent rights. Thailand and Brazil's victories in the compulsory licensing contexts were contingent upon political will, the presence and competence of the generic industry, a strong healthcare infrastructure and close collaboration and trust between key players.[251] The same may be said of the experiences of India and other African countries whose use of compulsory licenses was discussed above. Bar the lack of political will and collaboration between key players, all the other factors are present in abundance in South Africa and should be capitalised upon to spur IP law reform to improve access to medicines and uphold patient rights. Only time, the magician, will tell.

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that many countries have faced such pressure from the US and other developed countries when trying to implement clear compulsory licensing guidelines.

246 Sterckx 74.

247 Rosenberg 2014 *Developing World Bioethics* 84.

248 See DTI *Draft Policy on Intellectual Property (IP) of South Africa: A policy Framework* (2013) published on 4 September 2013 in Government Gazette Notice No: 36816 9, where it is unequivocally recommended that, "South Africa should not enter into bilateral agreements that may negate the gains attained in multilateral agreements such as the TRIPS Agreement on patent flexibilities". The recommendations go further and suggest that South Africa must discourage fellow developing countries from concluding bilateral agreements that undermine TRIPS flexibilities. The 2013 policy has now been replaced by its 2017 counterpart which proposes similar recommendations in para 7.2 under the heading "International IP Cooperation".

249 The right to health is provided for in section 27 of the Constitution of the Republic of South Africa 1996.

250 See section 25 of the Constitution.

251 Rosenberg 2014 *Developing World Bioethics* 91.